



T.R.U.E. TEST[®]
**THIN-LAYER RAPID USE
EPICUTANEOUS PATCH TEST**

Now
FDA-approved
for use on patients
as young as
6 years old!

Reference Manual



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Table of Contents

Physician Manual Disclaimer.....	v
T.R.U.E. TEST (Allergen Patch Test) Shipping and Handling.....	vi

Introduction

Contact Dermatitis is Common and Costly.....	1.1
Allergic or Irritant Contact Dermatitis?.....	1.1
Why Patch Test?.....	1.2
T.R.U.E. TEST (Allergen Patch Test) Features and Benefits.....	1.3
T.R.U.E. TEST Case Presentations.....	1.5

T.R.U.E. TEST Quick Reference Guide.....	2.1
--	-----

Clinical Indications and Contraindications

Indications for Use.....	3.1
Contraindications.....	3.2
Precautions.....	3.2
Warnings.....	3.4
Potential Adverse Events.....	3.5

Application of T.R.U.E. TEST

Pretest Considerations.....	4.1
Patient History Including Allergies and Exposures.....	4.2
T.R.U.E. TEST Panel Application.....	4.3

Patient History and Data Forms

Patient Dermatology and Allergy History Form.....	5.1
T.R.U.E. TEST Standard Data Collection Form.....	5.4

Interpretation of T.R.U.E. TEST Results

Interpreting and Recording Reactions to T.R.U.E. TEST Allergens.....	6.1
Differential Diagnosis - Positive Reactions.....	6.3
Diagnostic Path for Positive Reactions.....	6.5
Differential Diagnosis - Negative Reactions.....	6.6
Diagnostic Path for Negative Reactions.....	6.8
Differential Diagnosis - Doubtful or Minimal Reactions.....	6.9
Diagnostic Path for Doubtful or Minimal Reactions.....	6.9
Differential Diagnosis - Irritant Reactions.....	6.10

Allergen Components in T.R.U.E. TEST (Physician Information)

Chart of Common Sources	7.1
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Allergen Information:

Panel 1.3	Panel 2.3	Panel 3.3
1. Nickel Sulfate..... 7.3	13. <i>p</i> -tert-Butylphenol Formaldehyde Resin..... 7.11	25. Diazolidinyl Urea..... 7.19
2. Wool Alcohols..... 7.3	14. Epoxy Resin..... 7.11	26. Quinoline Mix 7.19
3. Neomycin Sulfate..... 7.4	15. Carba Mix..... 7.12	27. Tixocortol-21-Pivalate 7.20
4. Potassium Dichromate..... 7.4	16. Black Rubber Mix 7.13	27. Gold Sodium Thiosulfate..... 7.21
5. Caine Mix... .. 7.5	17. Cl+ Me- Isothiazolinone 7.13	29. Imidazolidinyl Urea..... 7.21
6. Fragrance Mix..... 7.5	18. Quaternium-15 7.14	30. Budesonide..... 7.22
7. Colophony..... 7.7	19. Methylidibromo Glutaronitrile. 7.15	31. Hydrocortisone-17-Butyrate..... 7.22
8. Paraben Mix..... 7.7	20. <i>p</i> -Phenylenediamine 7.15	32. Mercaptobenzothiazole..... 7.23
9. Negative Control..... 7.8	21. Formaldehyde 7.16	33. Bacitracin..... 7.23
10. Balsam of Peru..... 7.9	22. Mercapto Mix..... 7.16	34. Parthenolide..... 7.24
11. Ethylenediamine Dihydrochloride..... 7.10	23. Thimerosal..... 7.17	35. Disperse Blue 106..... 7.24
12. Cobalt Dichloride..... 7.10	24. Thiuram Mix 7.18	36. 2-Bromo-2-Nitropropane-1,3-Diol..... 7.25
Patch composition		7.2

Patch Test Coding and Reimbursement Guide

Coding for Evaluation and Management (E/M) Services.....	8.1
Patch Test Coding	8.2
Patch Test Reimbursement	8.2
Claim Denials and Appeals	8.3

Patient Information about T.R.U.E. TEST and Contact Allergens

Questions and Answers about T.R.U.E. TEST.....	9.1
Reading Labels to Identify Allergens.....	9.3
A Negative Test Result.....	9.4
Allergen Information Sheets.....	9.5

T.R.U.E. TEST Clinical Studies

General Performance and Adverse Events	10.1
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References and Additional Resources

Books and Journal Articles	11.1
Websites	11.4

Physician Manual Disclaimer

The current package insert shipped in each box of T.R.U.E. TEST® (Allergen Patch Test) should be the primary source of information. Please consult this package insert for complete safety and prescribing information.

Some of the information contained in this manual may be outside product labeling and is not intended to advise medical professionals to use T.R.U.E. TEST in a manner inconsistent with product labeling.

This manual is intended only for use as a supplemental and educational resource, with information about the appropriate use, indications and contraindications of T.R.U.E. TEST. The information contained in this manual is not intended to supersede the T.R.U.E. TEST package insert, nor replace current standard guidelines of patient care.

SmartPractice and SmartPractice Denmark assume no liability for the use of this manual.



T.R.U.E. TEST[®] (Allergen Patch Test) Shipping and Handling

For more information about shipping and returns policy see truetest.com.

T.R.U.E. TEST is temperature sensitive and should be stored between 36°F (2°C) and 46°F (8°C). Users are responsible for proper storage and handling.

- T.R.U.E. TEST is shipped in insulated containers with package(s) of gel refrigerant. T.R.U.E. TEST is shipped NEXT DAY DELIVERY within the 48 contiguous United States and the District of Columbia. T.R.U.E. TEST is also shipped 2ND DAY DELIVERY to Alaska and Hawaii.
- A signature is required for T.R.U.E. TEST delivery at the specified address. Signature denotes delivery. Users must coordinate product receipt and appropriate storage.
- As an FDA-regulated biologic, T.R.U.E. TEST is exempt from the Material Safety Data Sheet (SDS) specified by the Occupational Safety and Health Administration (OSHA) and the Department of Transportation (DOT) requirements.
- ➔ • Refrigerate T.R.U.E. TEST promptly after arrival. Do not freeze.
If T.R.U.E. TEST is not refrigerated for 4 hours or more, the product should be discarded.

T.R.U.E. TEST is an FDA-regulated biologic product and cannot be returned unless specifically authorized by SmartPractice.

- If T.R.U.E. TEST arrives with its outer shipping container defective or damaged, users should refuse product delivery. Immediately notify SmartPractice, who will arrange for product replacement.
- If delivered T.R.U.E. TEST product is believed to be defective, users should notify SmartPractice immediately.
- Expired T.R.U.E. TEST product cannot be returned.

T.R.U.E. TEST product stability and expiration:

- T.R.U.E. TEST product will be delivered with an expiration date of 8 months or longer. An expiration date is provided on each T.R.U.E. TEST package.
- The stability of T.R.U.E. TEST allergens is temperature dependent. Users can minimize product deterioration and optimize performance by adhering to recommended temperature limits. When stored between 36°F (2°C) and 46°F (8°C) T.R.U.E. TEST has been shown to maintain its allergen concentration at +20% of batch release levels. When stored at higher temperatures, T.R.U.E. TEST allergens have been shown to deteriorate.
- T.R.U.E. TEST can be allowed to equilibrate for a few minutes at room temperature prior to application. However, no formal studies have been conducted to determine the exact amount of time that T.R.U.E. TEST can remain at room temperature without an adverse effect on allergen concentration.

T.R.U.E. TEST disposal:

- Used T.R.U.E. TEST panels can be handled as medical waste and require no special disposal considerations. Be sure to comply with all federal, state and local regulations when disposing of medical waste.

Please call 1.800.878.3837 if you have additional questions about T.R.U.E. TEST storage, handling, or expiration.

Introduction

Contact Dermatitis is Common and Costly

Allergen exposure is influenced by climate, occupation, cultural habits, and regulations. The prevalence of contact allergy against specific allergens differs among countries as a result of changes and developments in surrounding environments and societies. (Thyssen et al 2007) In the United States, estimates of prevalence range from 5% to 50%, depending on population and defining criteria. According to a 2005 report by The Society for Investigative Dermatology and The American Academy of Dermatology, contact dermatitis is associated with more than 9 million physician office visits and as many as 10% of all dermatology clinic visits. Treating contact dermatitis costs approximately \$1.4 billion annually, with significant losses (~\$500 million) attributed to missed workdays and low productivity. (Bickers et al. 2006) In the UK, occupational contact dermatitis is the most frequently reported occupational skin disease in developed countries and accounts for between 70% and 90% of all reported cases of occupational skin disease. The annual population incidence of occupational contact dermatitis ranges from an estimated 5.7 to 101 cases per 100,000 workers per year. The most reliable studies estimate the incidence to be between 11 and 86 cases per 100 000 workers per year. (Nicholson et al. 2010) Experts believe these numbers may underestimate the impact of contact dermatitis.

Allergic or Irritant Contact Dermatitis?

Although irritant contact dermatitis is thought to be more common, recent studies suggest that allergic contact dermatitis may be responsible for nearly half of dermatitis cases, especially when work related. (Templet et al., 2004; Kucenic and Belsito, 2002) The two major diagnoses of contact dermatitis are irritant (ICD) and allergic (ACD) contact dermatitis. ICD is a non-specific inflammatory dermatosis, primarily caused by the toxicity of chemicals on the skin cells, hence, triggering inflammation by activation of the innate immune system. ACD, however, corresponds to a delayed-type hypersensitivity response and the skin inflammation is mediated by antigen-specific T cells. (Nosbaum et al. 2009)

	Allergic Contact Dermatitis	Irritant Contact Dermatitis
Immune Reaction	T-cell mediated; Localized, but may spread beyond contact site	No immune system involvement; Inflammation at contact site
Most Common Sources	Nickel, fragrance components, rubber processing chemicals, neomycin, preservatives, cobalt and potassium chromate	Detergents, acids, alkalis, oils, solvents, or exposure to abrasive, caustic or wet environments
Onset	Begins within hours or days of exposure	Begins within minutes or hours of exposure
Typical Presenting Symptoms	Pruritis, papules, vesicles, edema, fissures, erythema, and oozing May spread beyond contact site	Skin dryness, fissuring and thickening; edema and erythema Distribution localized to contact site

Allergic contact dermatitis:

In already sensitized individuals, this immunologic response is elicited by contact with a specific allergen or closely related chemical. Symptoms typically manifest 24 to 72 hours after allergen exposure, vary in intensity and often include itching and vesiculation.

More than 3,000 chemicals are reportedly capable of causing allergic contact dermatitis but relatively few allergens account for most cases. These common allergens form the basis of diagnostic patch testing that is used to differentiate allergic from irritant contact dermatitis.

Irritant contact dermatitis:

This non-specific inflammatory condition develops after skin is exposed to substances that are physically, chemically or mechanically traumatizing. Symptoms are usually confined to the area of contact, recur with additional irritant exposure and may be difficult to distinguish from allergic contact dermatitis.



Why Patch Test?

Patch testing is a simple bioassay that helps diagnose and identify causative agent(s) in persistent contact dermatitis. Even experienced dermatologists can miss 20% to 80% of contact allergies when using history alone. (Fischer and Maibach 1990) Patient symptoms, history and physical exam are rarely sufficient. Patch test results can provide crucial information that identifies the offending allergen(s). (Lachapelle and Maibach 2009)

Patient interviews show that patch testing has a positive impact, with a perceived improvement in symptoms. (Paul et al., 1995) Patients learn to identify and avoid allergens, protect their skin from irritants and other allergens, and use therapies appropriately.

**PATCH TESTING CAN HELP
REDUCE THE DURATION OF
PATIENT SYMPTOMS**

Early diagnosis and patient education are associated with improved prognosis, and may be more valuable than job changes. (Cahill et al., 2004; Woo et al., 2003) In a retrospective study of 270 patients with allergic contact dermatitis, patient disease duration after contact allergen testing and treatment was half that of patients treated without testing. (Diepgen 2008; Rajagopalan et al., 1998) Not surprisingly, 84% of patients felt patch testing was worthwhile.

An earlier study reported that symptom duration decreased by half in patients with allergic contact dermatitis who were patch tested.

WITHOUT PATCH TESTING: 265 Days of symptoms (~ 9 months)
WITH PATCH TESTING: 122 Days of symptoms (~ 4 months)
(Lachapelle and Maibach 2009)

Patients can suffer with contact dermatitis for up to 40 years. (Holness and Mace, 2001; Bickers et al. 2006) Unresolved dermatitis costs patients in terms of multiple doctor visits, prescriptions, over-the-counter medicaments, as well as lost time and productivity. The prognosis for these patients with persistent unresolved dermatitis is poor, and most will experience discomfort, embarrassment and other factors that diminish their quality of life. (Holness, 2001; Ayala et al., 2010)

T.R.U.E. TEST® (Allergen Patch Test) Features and Benefits

T.R.U.E. TEST is a ready-to-use patch test for the differential diagnosis of persistent dermatitis. It contains 35 allergens and allergen mixes that are responsible for the majority of cases of allergic contact dermatitis.

T.R.U.E. TEST is convenient to use:

The allergens and allergen mixes require no additional mixing or handling, and are standardized in three ready-to-use T.R.U.E. TEST panels. The use of premeasured allergens minimizes staff preparation time.

T.R.U.E. TEST has a unique design that helps ensure accuracy and reproducibility:

T.R.U.E. TEST allergens and allergen mixes have been incorporated into hypoallergenic, dehydrated, hydrophilic gels attached to a waterproof backing. When applied to the skin, perspiration and transepidermal water loss rehydrate these gels, thereby releasing the allergens onto the skin. The test also contains one uncoated polyester patch as a negative control, which can be used as a baseline for interpreting doubtful or minimal reactions.



T.R.U.E. TEST's Unique Design

LAMINATED FOIL OUTER PACKAGING:

Airtight and opaque, to protect the test from light and moisture

THIN PROTECTIVE PLASTIC COVER:

Protects patches from physical damage during storage and opening of the outer foil.

ADHESIVE TAPE:

Each patch is attached to a pliable, polyester, occlusive and hypoallergenic surgical tape. Reactions to the T.R.U.E. TEST tape or adhesive may occur. T.R.U.E. TEST panel tape and the individual patches are composed of polyester. The adhesive used in the panels is acrylate-based and processed to remove free monomers that may be allergenic.

ALLERGEN-IMPREGNATED VEHICLE:

Each allergen is incorporated into a hydrophilic gel that is dried into a thin film. When applied to the skin, this film becomes hydrated by skin moisture and the allergen is released.

OCCLUSIVE PLASTIC BACKING:

The impermeable, flexible backing assures optimal contact between the skin and the allergen(s) and promotes maximum penetration.

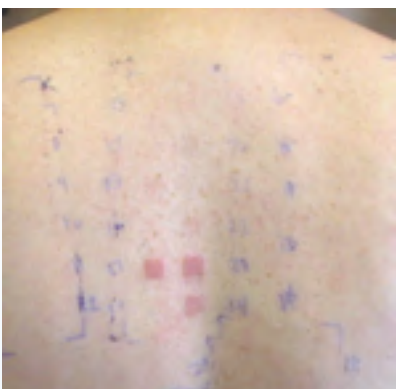
See package insert included with T.R.U.E. TEST for more information.

T.R.U.E. TEST allergens and allergen mixes are formulated for increased stability and distributed homogeneously. This reduces the potential for false-positive and irritant reactions. The allergen dose or concentration has also been optimized to be sufficient for eliciting allergic reactions in weakly sensitized patients, yet low enough to minimize the risk of iatrogenic sensitization. In addition, the panels are wrapped in an airtight foil pouch for protection from light and moisture.

T.R.U.E. TEST can help quickly resolve patient dermatitis:

Nearly one-quarter to two-thirds of patients with ACD will test positive to at least one T.R.U.E. TEST allergen. (Cohen et al., 1997; Marks et al., 1998; Bickers et al. 2006) Some of these reactions will correlate to allergen exposure, while others may suggest allergies to related, cross-reactive substances. Negative results are also common and have diagnostic value in eliminating suspected allergies as well as helping physicians identify other potential allergens or irritants.

T.R.U.E. TEST may also be used to assess the complicating role of contact allergies in recalcitrant cases of atopic dermatitis, seborrheic dermatitis, hypostatic eczema, dyshidrotic eczema, stasis dermatitis, and psoriasis. Consider patch testing as soon as possible for new and referred patients with a prior history of recurring dermatitis, and for established patients returning due to persistent dermatitis.



T.R.U.E TEST Case Presentations

These examples illustrate the importance of patch testing to distinguish allergic versus irritant contact dermatitis. Chemical exposure, history and symptoms often support either diagnosis. Since allergic and irritant contact dermatitis cannot be differentiated easily based on exams or histories alone, patch testing was essential for an accurate diagnosis.

Case History #1:

A radiology technician presented with a 6-month history of pruritic dermatitis on his hands. Although temporarily responsive to corticosteroid therapy, he had developed recurrent lesions that were fissured and erythematous. The patient had a history of childhood atopy, but was otherwise unaware of other allergies.

Exposure history: Working in health care increased the risk of exposure to multiple allergens, especially those related to rubber gloves and other rubber products. The patient acknowledged exposure to a number of potential allergens and irritants, including photographic developing chemicals, soaps and cleansers, sterilizing and disinfecting chemicals, rubber gloves, and metal equipment. At home, he was also exposed to preservatives, fragrances, and other components of topical products used to treat his skin condition.



Patch test results and patient outcome: This patient tested positive to carba mix and thiuram mix, which are substances used in the manufacture of natural and synthetic rubber products. The patient was counseled to avoid direct contact with rubber products, including gloves. The patient's dermatitis resolved when vinyl gloves replaced the rubber gloves at work.

Case History #2:

A 60-year-old homemaker presented with a history of pruritic eruptions. The patient's palms exhibited severe scaling, fissuring and erythema. Fingertip periungual areas were also involved, but not the dorsa of the hands. Patient's skin was otherwise clear, except for localized psoriasis of the left elbow and knee.

The patient's history indicated that her family physician had prescribed a topical corticosteroid cream and advised her to wear rubber gloves and use a moisturizer. When this did not correct the problem, she sought the advice of a dermatologist. The dermatologist prescribed a more potent topical corticosteroid, advised her to avoid wet work, and suggested she wear vinyl gloves because she might be allergic to rubber. When her condition continued to worsen despite these measures, she sought the opinion of a second dermatologist.



Patch test results and patient outcome: The second dermatologist patch tested the patient, which revealed the patient's allergy to quaternium-15, a formaldehyde-releasing preservative found in many different creams and lotions. The patient's moisturizer (advised by her original physician) contained quaternium-15, which was exacerbating her original contact dermatitis symptoms.

After selecting skin care products without quaternium-15, the patient was able to successfully manage her skin's health with this moisturizer, gloves, and the occasional use of a topical corticosteroid. Her psoriasis has remained stable, and without hand involvement.

T.R.U.E. TEST® Quick Reference Guide

See package insert included with T.R.U.E. TEST for more information.

1. Take Patient History and Perform a Physical Exam

- A complete and accurate history is essential. Ask about:
 - Symptoms (duration and distribution)
 - Personal and family history of allergies
 - Exposure to materials or products at work and at home.
- Examine the patient at a level appropriate to case complexity.
- Chronic, persistent dermatitis with characteristics indicative of a contact allergy should be evaluated with patch testing.
- T.R.U.E. TEST (Allergen Patch Test) provides the physician with a ready-to-use test method for identifying the most common contact allergies.



2. Schedule Patient and Provide Pre-Test Instructions

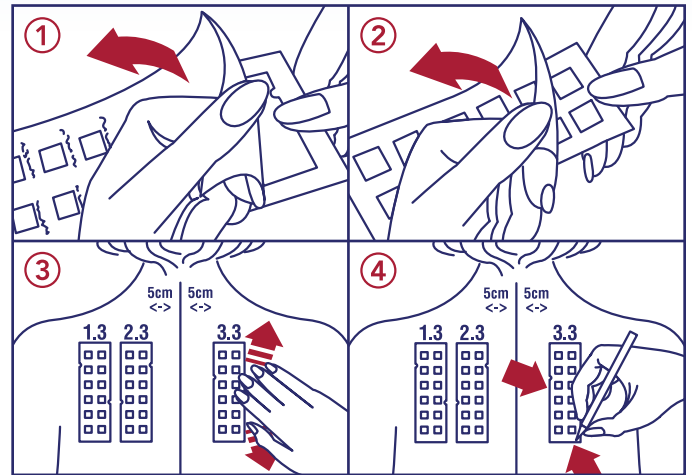
- In patients with severe ongoing dermatitis, defer patch testing until acute symptoms subside to avoid eliciting excited skin syndrome and false positives.
- Two weeks prior to patch testing, patients should stop using oral corticosteroids and avoid the use of topical corticosteroids on the test area.
- Patients should not expose the test area to sun for at least three weeks prior to testing.
- Test area should be clean and free of oils, lotions and ointments. Select an area without scars, active dermatitis, skin eruptions or any other condition that may interfere with test interpretation.
- Coordinate with patient schedules for best compliance.



Counsel patients about the nature, goals and limitations of patch testing.
Provide the patient with the brochure "Make T.R.U.E. TEST your first choice for patch testing"

3. Apply T.R.U.E. TEST Panels

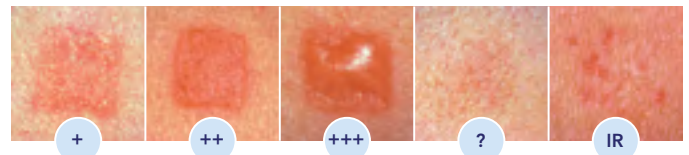
- **STEP 1:** Peel open the package and remove T.R.U.E. TEST Panel 1.3 (Figure 1).
- **STEP 2:** Remove the protective plastic covering from the test surface of the panel (Figure 2). Be careful not to touch the test substances.
- **STEP 3:** Position test Panel 1.3 on the patient's back as shown in Figure 3. Allergen number 1 should be in the upper left corner. Avoid applying the panel on the margin of the scapula or directly over the midline of the spine. Ensure that each patch of the allergen panel is in contact with the skin by smoothing the panel outward from the center to the edge (as illustrated for Panel 3.3 in Figure 3).
- **STEP 4:** With a medical marking pen, indicate on the skin the location of the two notches on the panel (as illustrated for Panel 3.3 in Figure 4).
- **STEP 5:** Repeat the process with test Panel 2.3. Position the test Panel 2.3 beside Panel 1.3, on the left side of the patient's back so that the number 13 allergen is in the upper left corner. Apply test Panel 2.3 five (5) cm from the midline of the spine (Figure 3).
- **STEP 6:** Repeat the process with Panel 3.3 positioning the panel on the right side of the patient's back so that the number 25 allergen is in the upper left corner. Apply test Panel 3.3 five (5) cm from the midline of the spine (Figure 3).
- **STEP 7:** If needed, hypoallergenic surgical tape, appropriate for patch testing, may be used for increased adhesion around the outside edges of the panels.



Instruct patients to keep the panels dry, in place, and protected from direct sunlight for 48 hours.

4. Remove T.R.U.E. TEST at 48 Hours; Interpret Results at 72 and 96 Hours

- Allow transient erythema to subside for 10-15 minutes and document 48-hour readings.
- Recall patient at 72 – 96 hours for additional readings. A second reading is essential to reduce false-positive and false-negative results. Additional readings may be required depending on patient history and results.
- Certain allergens are known late-reactors — readings at 5-7 days may be needed.
- More than one-quarter of patients can test positive to one of the T.R.U.E. TEST allergens. Positive reactions should be confirmed by patient history and symptoms.
- Negative reactions are common. Patients who test negative may be allergic to other substances not included in T.R.U.E. TEST and require additional testing.



- + Weak Positive Reaction:
non-vesicular with erythema, infiltration, possibly papules
- ++ Strong Positive Reaction:
vesicular, erythema, infiltration, papules
- +++ Extreme Positive Reaction:
bullous or ulcerative reaction
- ? Doubtful Reaction:
faint macular erythema only
- IR Irritant Reaction:
Pustules as well as patchy follicular or homogeneous erythema without infiltrations are usually signs of irritation and do not indicate allergy. Itching is a subjective symptom that is expected to accompany a positive reaction.

Interpret reactions using the reading template and International Contact Dermatitis Research Group criteria.

5. Counsel the Patient

- With positive reactions of clinical relevance, counsel patients to avoid each allergen.
- Be sure to provide a copy of “How to Read a Label ” as well as the appropriate patient handouts with information about:
 - where each allergen is found at work and home;
 - tips on how to avoid each allergen;
 - substances (with their chemical names) to avoid; and
 - examples of products that contain the allergen, with potential alternative products.

For valid negative reactions, counsel patients appropriately.

Provide a copy of the patient handout “A Negative Test Result” that discusses the meaning of a negative test and provides tips on better skin care.



6. Coding Procedures and Reimbursement

Follow current coding procedures and guidelines as appropriate for each payer:

- Use 95044 as the CPT® code for patch testing. Enter this code for each of the 35 T.R.U.E. TEST allergens (i.e., 35 times) and the control.
- Use evaluation and management (E/M) codes that match patient status (new, established or consult), history, exam and decision-making criteria. Extensive consultation time may also be reimbursable.
- Support all coding with documentation in the patient’s medical record.
- Utilize computer software, training and outside consultants to improve office coding and reimbursement procedures, such as Ellzey Coding Solutions, Inc. ellzeycodingsolutions.com

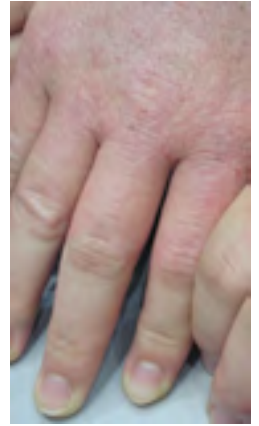


Clinical Indications and Contraindications

Dermatitis that is chronic and persistent should be further evaluated based on the results of a thorough exam and detailed health and occupational history. The initial site of the dermatitis and the pattern of spread are important features. They are often more valuable than the nature of the eruption. Both history and symptom patterns are important to establish risk factors and exposure to allergens and irritants.

Allergic contact dermatitis should be suspected and patch testing considered when:

- Dermatitis does not improve as expected despite treatment;
- Only skin exposed to a possible allergen or irritant is affected;
- Dermatitis appears suddenly, and with no past history;
- Dermatitis has an unusual pattern or distribution;
- There has been contact with a known allergen; or
- Dermatitis persists.



T.R.U.E. TEST® (Allergen Patch Test) provides the physician with an objective method for patch testing to the most common allergens that are responsible for the majority of allergic contact dermatitis cases.

Indications for Use

The primary aim of patch testing with T.R.U.E. TEST is to identify (or exclude) contact allergies to the substances included on test panels.

Conditions where patch testing with T.R.U.E. TEST may be indicated:

- Dermatitis that persists or recurs frequently
- Dermatitis that does not respond to treatment
- Presumed or suspected contact dermatitis
- Dorsal or patchy dermatitis on the hands
- Dermatitis with unusual distribution or eruption patterns
- Dermatitis of indeterminate cause
- Facial dermatitis (excluding classical seborrheic dermatitis)
- Discoid dermatitis on the limbs or trunk
- Leg dermatitis, especially when diffuse or associated with leg ulcers
- Foot dermatitis, alone or with hand dermatitis
- Perianal or perineal dermatitis
- Chronic otitis externa
- Dermatitis or urticarial reactions after ingestion of suspected allergens

See package insert included with T.R.U.E. TEST for more information.

T.R.U.E. TEST may also be used to determine whether there is a contact allergy confounding the treatment of other types of dermatitis (atopic, seborrheic, venous, palmar and plantar hyperkeratotic, vesiculous, or neurodermatitis) or chronic skin disease, such as leg ulcers or psoriasis. T.R.U.E. TEST may also be used for contact allergy testing in patients with a confirmed or suspected type I latex protein allergy, because the product does not contain natural rubber latex.

Contraindications

See package insert included with T.R.U.E. TEST for more information.

Avoid using T.R.U.E. TEST in patients with extensive ongoing outbreaks of contact dermatitis:

In these patients, patch testing can elicit intense reactions at current and previously affected sites, and false positive results could be obtained. Although the amount of each allergen in the T.R.U.E. TEST panels is small, it may be sufficient to exacerbate severe dermatitis reactions in extremely sensitized patients. Do not apply to skin of patients with a history of severe allergic reaction (systemic and/or local) to any of the allergen components or inactive substances of T.R.U.E. TEST.

Do not apply to skin that is injured or inflamed.

Precautions

See package insert included with T.R.U.E. TEST for more information.

T.R.U.E. TEST should only be applied to healthy skin:

Test sites should be free of scars, acne, dermatitis, or other conditions that may interfere with test result interpretation. If excessive body hair occurs at the test site, remove with an electric shaver (do not use razors). Very oily skin may be cleaned with mild soap and water. Avoid using alcohol or other irritating substances on the skin prior to testing. Do not apply T.R.U.E. TEST panels to recently tanned or sun-exposed skin because this may increase the risk of false negatives.

Avoid patient use of topical immunosuppressants and immunomodulators prior to and during testing:

Avoid using test sites to which topical glucocorticoids, antihistamines, immunosuppressants, or immunomodulators are applied. The use of topical steroids or immunosuppressants at or near potential test sites should be avoided from at least one week prior to patch testing through the conclusion of patch testing.

Oral steroids may cause false-negative results of patch testing with T.R.U.E. TEST. The risk of discontinuing or decreasing the dose of oral corticosteroids in order to perform the patch test must be weighed against the benefits of patch testing.

The effect of concomitant systemic antihistamine administration on the performance of patch testing with T.R.U.E. TEST is unknown. Some dermatologists believe systemically administered antihistamines have no effect on patch test results, but there are limited conclusive data. The few published studies of oral antihistamine administration during conventional patch testing indicate that some compounds may increase the risk of false negatives or compromise interpretation of positives. Therefore, due to the risk of suboptimal results, oral antihistamine use before and during T.R.U.E. TEST patch testing is not advised.

The effect of concomitant or prior systemic cyclosporin administration on the performance of patch testing with T.R.U.E. TEST is unknown. When used during conventional patch testing, two published clinical studies suggest that treating patients briefly with oral cyclosporine may help distinguish true-positive reactions from weak or false-positive reactions, and may be helpful in patients with excited skin syndrome.

Topical steroids, antihistamines and other immunosuppressants (e.g., tacrolimus) may be used on non-test areas, but should be avoided on potential patch test areas prior to and during testing.



The safety and efficacy of repetitive testing with T.R.U.E. TEST are unknown.

Sensitization or increased reactivity to one or more of the allergens may occur. If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of conditions that might affect test results.

The safety and efficacy of T.R.U.E. TEST patch testing in children:

During pre-market approval testing of T.R.U.E. TEST, most clinical trial protocols excluded patients under the age of 16, however, recent safety and efficacy studies have been completed and T.R.U.E. TEST has been approved by the FDA for children over 6 years old.

Application of T.R.U.E. TEST in children younger than 6 years of age is considered an off-label use in the United States even when supported by current medical care guidelines.

The safety and efficacy of T.R.U.E. TEST patch testing in women who are pregnant or breast-feeding are unknown:

Animal reproduction studies have not been conducted with T.R.U.E. TEST. It is also not known whether T.R.U.E. TEST can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. T.R.U.E. TEST has been assigned a pregnancy Category C level of fetal risk by the Food and Drug Administration. Therefore, T.R.U.E. TEST should only be applied to pregnant women if clearly needed. It is not known whether any of the allergens in T.R.U.E. TEST are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if T.R.U.E. TEST is administered to a nursing woman.



Keep T.R.U.E. TEST panels dry during testing:

Patients should avoid activities that cause excess perspiration or expose the test area to excess moisture. Showering is not advised. Sponge baths are acceptable provided the patient protects the panels and surrounding skin from excess moisture.



Warnings

See package insert included with T.R.U.E. TEST for more information.

- Acute Allergic Reactions
- Extreme Positive Reactions
- Tape Reactions
- Persistent Reactions
- Repeat Testing
- Sensitization
- Excited Skin Syndrome (Angry Back)
- Irritant Contact Dermatitis
- Late Reactions
- Itching/Burning

Carefully evaluate the use of T.R.U.E. TEST in patients with a known history of severe systemic and/or local reactions to any of the allergen components or inactive substances included in the T.R.U.E. TEST panels before application. If patch testing is performed in these patients, proper medical precautions should be observed.

The safety and efficacy of repetitive testing with T.R.U.E. TEST is unknown. Sensitization or increased reactivity to one or more of the allergens may occur. If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of conditions that might affect test results. In addition, the safety and efficacy of patch testing children using T.R.U.E. TEST in Panels 1.3, 2.3, and 3.3 is not yet established.

Acute Allergic Reactions: Acute allergic reactions, including anaphylaxis, may occur. Appropriate medical treatment must be available in case of an acute allergic reaction, including anaphylaxis, following the application of T.R.U.E. TEST. If a severe allergic reaction occurs, remove the T.R.U.E. TEST panel(s) and initiate treatment. Immediate contact urticaria may present within minutes to an hour after application in patients who are pre-sensitized to some allergens and may be local or generalized. Patients may be advised to remove the panels themselves if they experience systemic symptoms

Itching and burning sensations: Patients should be warned that these reactions are common with patch testing, and may be severe in extremely sensitive patients. Medication may be considered necessary to relieve such symptoms, and on rare occasions it may be necessary to remove T.R.U.E. TEST sooner than 48 hours because of severe itching or burning sensations.

Excited skin syndrome (Angry Back): Excited skin syndrome is a regional state of skin hyper-reactivity caused by the presence of a strong positive reaction which may result in other patch test sites to become reactive. Retesting may be necessary to determine which reactions were falsely positive.

Sensitization: A negative patch test reaction, followed by a positive reaction 10 to 20 days after panel application, may indicate active sensitization. Active sensitization is confirmed upon retesting with a positive reaction occurring at the 72 and/or the 96 hour reading. If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of conditions that might affect test results. The safety and effectiveness of repetitive testing with T.R.U.E. TEST is unknown

Tape Reactions: Reactions to the T.R.U.E. TEST tape or adhesive may occur. T.R.U.E. TEST panel tape and the individual patches are composed of polyester. The adhesive used in the panels is acrylate-based and processed to remove free monomers that may be allergenic.

Irritant Contact Dermatitis: Patients may experience irritant contact dermatitis upon exposure to any of the allergens contained within T.R.U.E. TEST that cause direct damage to the skin at the test site. Recurrence of an irritant response is not limited to exposure to the specific substance, but may follow exposure to any chemical irritants.

Persistent Reactions: Positive reactions may persist from 7 days to months after panel application.

Late Reactions: Late positive reactions may occur 7 to 10 days after application of the panels.

Potential Adverse Events

See package insert included with T.R.U.E. TEST for more information.

Adverse reactions may include:

- Pruritus
- Hyper/hypopigmentation
- Contact urticaria
- Tape irritation
- Erythema
- Scarring
- Delayed reactions
- Burning

Adverse events reported with the use of T.R.U.E. TEST are normally mild and localized to the test site. The most common are **burning, tape irritation, persistent reactions, erythema, and hyper/hypopigmentation**. If these reactions are severe enough, it may be advisable to remove a T.R.U.E. TEST allergen or panel sooner than 48 hours and initiate treatment with a topical (or systemic) corticosteroid.

Tape irritation in T.R.U.E. TEST panels has been reported in 0.8 to 6% of patients in clinical studies. T.R.U.E. TEST adhesive tape is a porous, hypoallergenic surgical tape made of rayon fibers with a polyacrylate adhesive that includes vinyl acetate, 2-ethylhexyl acrylate, hydroxyethyl methacrylate, glycidyl methacrylate.

Hyperpigmentation: It is more likely to occur in patients with extreme positive reactions and is more common in dark-skinned individuals. It may also occur in some patients with irritant reactions. Sunlight or ultraviolet light exposure after patch test removal may also lead to hyperpigmentation of some test sites. Healing usually takes 5 days to 2 weeks but may require additional time to resolve in some patients.

Systemic symptoms such as urticaria (generalized), anaphylaxis, or other type I hypersensitivity reactions have not been reported with the use of T.R.U.E. TEST. However, published case reports have noted that several contact allergens can elicit systemic reactions such as urticaria and respiratory symptoms. As noted above, the use of T.R.U.E. TEST in patients with a known history of severe reactions to any of the allergen components or inactive substances included in the T.R.U.E. TEST should be carefully evaluated and adequate precautions taken before testing.

Panel Adhesion: Problems with panel adhesion were observed during some of the clinical studies. Poor panel adhesion was defined as any panel that fell off prior to the 48 hour removal time, any test panel that was not in good contact with the skin, or if one or more of the patch test allergens were not in good contact with the skin as evidenced at the time of panel removal, 48 hours. If the panel fell off the back prior to the 48-hour removal time frame, the subject was excluded from the efficacy calculations (sensitivity and specificity) but not from the safety analysis. Over all studies, poor panel adhesion occurred 49 times (4.2%).

Postmarketing Experience: The following additional adverse reactions have been identified during post-approval use of T.R.U.E. TEST in adults. Because these reactions are continuously reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to T.R.U.E. TEST exposure.

- Acute allergic reactions
- Excited skin syndrome (Angry back)
- Extreme positive reactions
- Irritant contact dermatitis

Application of T.R.U.E. TEST® (Allergen Patch Test)

Pretest Considerations

Assess all potentially relevant symptoms:

As with other clinical tests, the presence of clinically relevant symptoms and a positive health or occupational history increases the predictive value of patch test results and lowers the possibility of diagnostic errors. Patients should be asked to collect information about potential allergen contact at work and at home.



Counsel patients about the nature, goals and limits of patch testing:

Optimal patch testing requires patient understanding, cooperation and commitment. Be aware of the impact of a patient's educational level and familiarity with medical terms. Also consider potential language barriers and cultural differences when counseling patients.

Explain to patients that patch testing is not like skin prick testing, or other allergy tests. Inform patients that negative as well as positive test results are common, and that both have value in resolving their dermatitis. Provide patients with a copy of "Questions and Answers About T.R.U.E. TEST" (see Patient Information about T.R.U.E. TEST and Contact Allergens section).

Important points to discuss with patients:

- What to expect from the testing process
- Multiple visits are required
- Loose clothing should be worn during the testing
- Test sites may be itchy and uncomfortable
- Oral corticosteroid medications need to be stopped temporarily
- No showering (sponge baths only) because T.R.U.E. TEST must be kept dry
- Vigorous exercise must be avoided and other activities may be limited
- A flare-up of dermatitis elsewhere on their body may occur
- Patients should contact their doctor if reactions become severe

Determine the optimal date to begin testing a patient:

In patients with significant ongoing dermatitis, it is advisable to defer patch testing with T.R.U.E. TEST until symptoms are no longer severe. Patch testing during active outbreaks of dermatitis can result in excited skin syndrome (angry back) and false positive results. Avoid patch testing on patients for three (3) weeks after ultraviolet (UV) treatments, heavy sun, or tanning bed exposure. Avoid using alcohol or other irritating substances on the skin prior to testing.

Discontinue immunomodulator and immunosuppressor therapy if possible. The biologic half-life of these drugs varies, and can range from less than 8 to over 50 hours. Therefore, it can take several days or weeks for their immunosuppressive effects to abate. For optimal test results, the use of topical steroids or immunosuppressants at or near potential test sites should be avoided from at least one week prior to patch testing through the conclusion of patch testing.

Topical therapies may be continued on non-test sites during patch testing. Patients may also continue to use over-the-counter skin and body lotions on non-test sites as they would normally.

Coordinate with patient schedules taking into consideration significant events, holidays, and weekend activities. This approach is more likely to encourage patient participation and a commitment to return for necessary second and third readings. Flexibility and creativity may be key for some patients with scheduling conflicts. For example, family members may be able to document skin reactions using digital photography, if the physician provides guidance and oversight.



Select an appropriate test site:

Verify that an available patch test site on the upper back is free of scars, acne, dermatitis, or other conditions that may interfere with test result interpretation. Avoid application of T.R.U.E. TEST panels to recently tanned or sun-exposed skin because this may increase the risk of false negatives. Avoid excessive sweating during the testing period to maintain sufficient adhesion to the skin. Avoid excessive physical activity to maintain sufficient adhesion and to prevent actual loss of patch test material. Avoid getting the panels and surrounding area wet. If excessive body hair exists at the test site, remove with an electric shaver (do not use razors). Very oily skin may be cleaned with mild soap and water prior to testing.

Limited studies have indicated that skin responsiveness on the upper back may be greater due to an increased density of Langerhans cells and differences in the stratum corneum.

Alternative sites include the upper arm or other areas on the back that are not obstructed by clothing or affected by normal body movements. Regardless, skin at the selected site must be free from topical steroids, active dermatitis, skin damage, and signs of sunburn or significant tanning.

Patient History Including Allergies and Exposures

Detailed health and occupational histories help to identify risk factors (e.g., atopy), and possible sources and exposure routes of allergens and irritants at work and at home (see *Patient History Form, Section 5*).

Using the *Patient Dermatology and Allergy History Form* as a guide, ask for detailed information about:

- Patterns of symptom eruption and distribution
- Family and personal history of allergies
- Pre-existing medical conditions
- Materials, products and pets encountered at home or during recreational activities
- Personal care products used
- Materials and products regularly encountered at work
- History of employment and related materials or products
- Relevant material safety data sheets (SDS), product inserts and labels

Patients with symptoms consistent with allergic contact dermatitis should be advised to collect product content information from work and home to help identify potential allergens. Product content information can be obtained from the SDS, technical specifications, product inserts, and product labels.

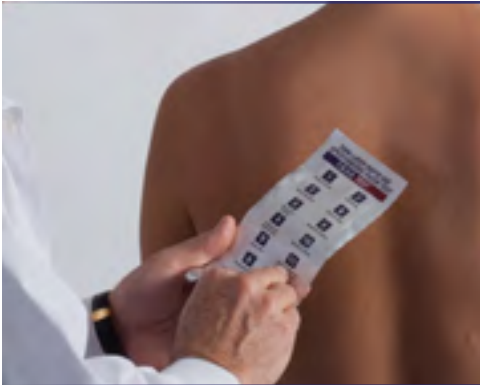
Clarify anatomical and time-dependent relationships between potential allergen exposure and symptom development. Be sure to ask patients about:

- **When** symptoms appear, worsen and improve, e.g. seasonal or time of day;
- **How** long symptoms last, i.e. hours, days or weeks;
- **Where** symptoms occur, e.g. hands, feet or elsewhere;
- **What** activity was performed, e.g. occupation, hobbies sports; and
- **What** products are used daily or for specific activities, and what treatments are currently used.

T.R.U.E. TEST Panel Application

The ready-to-use T.R.U.E. TEST panels should be applied to clean, healthy skin on the patient's upper back or outer surface of the arm. No mixing, measuring or advance preparation is required.

Cleansing of the test area is generally not necessary and should be avoided to minimize skin irritation. For similar reasons, use electric clippers or shavers to remove any unwanted body hair. Avoid using straight-edge razors that can irritate skin.



STEP 1.

Peel open the package and remove T.R.U.E. TEST Panel 1.3.



STEP 2.

Carefully remove the protective cover from the test surface of the panel. Do not touch the test substances.



STEP 3.

Position T.R.U.E. TEST Panel 1.3 on the upper left side of the patient's back so that the No. 1 allergen is in the upper left corner. Avoid applying the panel on the margin of the scapula. From the center of the panel, smooth outward toward the edges, making sure that each allergen contacts the skin firmly and completely.



STEP 4.

With a surgical skin marker, mark the location of the panel's two notches on the skin. (A fluorescent skin marker can also be used to mark the panel notches and detected later using a Wood's lamp.)



STEP 5.

Repeat the process with test Panel 2.3. Position the test panel beside panel 1.3 on the left side of the patient's back so that the number 13 allergen is in the upper left corner. Apply test panel 2.3 five (5) cm from the midline of the spine.



STEP 6.

Repeat the process with T.R.U.E. TEST Panel 3.3. Position this panel on the upper right side of the patient's back so that the No. 25 allergen is in the upper left corner. Apply test Panel 3.3 five (5) cm from the midline of the spine.



STEP 7.

If needed, hypoallergenic surgical tape or patchProtect moisture-resistant patch test cover tape may be used for increased adhesion around the outside edges of the panels.

Study data indicate that T.R.U.E. TEST panels generally adhere well to patient skin. However, in clinical practice, additional circumstances may affect adherence including: 1) excess hair, skin oil or dermatitis at the test site; 2) patient physical activity level; 3) patient perspiration; and 4) climatic extremes, such as high humidity or heat.

If necessary due to patient movements, perspiration or humidity, hypoallergenic tape (e.g., Scanpor®, patchProtect™) may be used to better secure T.R.U.E. TEST panels to skin.

FOR 48 HOURS: Leave T.R.U.E. TEST panels in place, keep dry and protect from direct sun exposure. Following this period, panels should be removed. A preliminary reading may be performed after the skin has been allowed to rest for about 20 minutes.

AT 72-96 HOURS AFTER APPLICATION: Read skin reactions to T.R.U.E. TEST allergens. This minimum time span is necessary for allergic reactions to develop and for irritant reactions to subside.

IMPORTANT TIP:

Additional readings at 5-7 days after test application can be important, because some allergens can elicit late reactions.

T.R.U.E. TEST[®]

**THIN-LAYER RAPID USE
EPICUTANEOUS PATCH TEST**

Patient History and Data Forms

PATIENT DERMATOLOGY & ALLERGY HISTORY FORM

Patient Name: _____ Date: _____

Patient Age: _____ Gender: Male Female

Race: White Hispanic Black/African-American Asian Native American Other _____

Occupation: _____

Current Complaint: _____

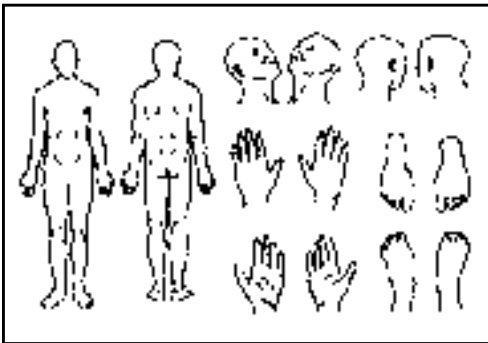
Date of onset and/or duration: _____

Area(s) affected **AT ONSET:** _____

Severity at onset: Mild Moderate Severe

Type and pattern of eruption: _____

Area(s) affected **NOW:** _____



Severity now: Mild Moderate Severe

Current status: Stable Increasing Decreasing

Worsens during: Work week Weekends

Improves during: Weekend Holidays/Vacations

Outbreak frequency: Weekly Monthly Annually Seasonally

Previous Outbreaks: No Yes, on date(s): _____

Previous treatment: Self-treat Physician-treated, on date(s): _____

Existing Conditions

- None
- Alcohol/Drug Abuse _____
- Allergies _____
- Cancer _____
- Cardiovascular Disease _____
- Depression _____
- Diabetes _____
- High Blood Pressure _____
- High Cholesterol _____
- Immune Disorder _____
- Infectious Disease _____
- Other: _____
- Kidney Disease _____
- Liver Disease _____
- Lung/Respiratory Disease _____
- Menopause _____
- Neurological Disorders _____
- Obesity _____
- Pregnancy _____
- Puberty _____
- Skin Disorders _____
- Stroke _____

PATIENT DERMATOLOGY & ALLERGY HISTORY FORM

Current Medications

Indicate start date and dosage

- None
- Antibiotic/Antifungal _____
- Anticoagulants _____
- Antidepressants _____
- Antihistamines _____
- Aspirin _____
- Asthma Medication _____
- Diuretics _____
- Herbs _____
- Hormones _____
- Insulin _____
- Other: _____
- NSAIDs _____
- Oral Contraceptives _____
- Oral Hypoglycemics _____
- Other BP Medication _____
- Rx Pain Meds _____
- Sedatives/Sleep Aids _____
- Statins _____
- Steroids (nasal/topical) _____
- Thyroxin _____
- Vitamins/Minerals _____

Medical Devices

- None
- Include all dental and other surgically inserted devices
- Implants _____
- Braces _____
- Crowns/Bridges _____
- Stents _____
- Fillings _____
- Other: _____

History of Allergic Disorders

- None
- Animals (type): _____
- Asthma
- Childhood Eczema
- Fragrances
- Flowers/Trees/Grasses
- Food Allergy (name): _____
- Hay Fever
- Insects
- Latex (Type I)
- Medicines
- Nickel/Metal
- Rubber
- Suspected Allergy (name): _____
- Urticaria
- Pregnancy
- Other: _____

Previous Drug Reactions

- None
- Yes, name of drug: _____

Family History of Allergies & Asthma

- None
- Asthma Relationship: _____
- Eczema Relationship: _____
- Hay Fever Relationship: _____

Home Environment

Check all that apply

- House
- Constructed after 1980
- Suburban
- Rural
- Duration at residence _____
- Housecleans daily
- Housecleans monthly
- Always participates in housecleaning
- Rarely participates in housecleaning
- Does laundry daily
- Does laundry sometimes
- Equipment/material used: _____
- Apartment/Condo
- Renovated since 1980
- Urban
- Other: _____
- Housecleans weekly
- Housecleans occasionally
- Sometimes participates in housecleaning
- Never participates in housecleaning
- Does laundry weekly
- Never does laundry
- Name of laundry detergent _____

PATIENT DERMATOLOGY & ALLERGY HISTORY FORM

Pets/Animals

- None
- Bird
- Dog
- Livestock (type): _____
- Childhood pet (type): _____
- Recent animal contact: _____
- Symptoms noticed: _____
- Cat
- Rodent
- Other: _____
- Regular pet contact during childhood
- Current pets in house

Sports/Hobbies

- None
- Baseball
- Basketball
- Ceramics
- Football
- Golf
- Home Repairs
- Knitting/Needlework
- Paper Crafts
- Photography
- Piano
- Other instrument: _____
- Running/Hiking
- Sewing
- Tennis/Racquetball
- Woodworking
- Other: _____

Frequency of sport or hobby Daily Weekly Monthly Rarely Once a year

Duration of sport or hobby: _____

Equipment/Material used: _____

Symptoms noticed during sport or hobby: _____

STANDARD DATA COLLECTION FORM

Lot No. _____

Date Applied _____

Date
1st Reading _____

2nd Reading _____

Date
2nd Reading _____

3rd Reading _____

Date
3rd Reading _____

Patient's Name _____

Chart No. _____ Age _____ Sex (M/F) _____ Race _____

Physician's Name _____

Address _____ Phone _____

City _____ State _____ ZIP _____

Allergen No.	CLINICAL RELEVANCE		
	Present	Past	Unknown

PANEL 1.3	
1 = Nickel Sulfate 1st _____ 2nd _____ 3rd _____	7 = Colophony 1st _____ 2nd _____ 3rd _____
2 = Wool Alcohols 1st _____ 2nd _____ 3rd _____	8 = Paraben Mix 1st _____ 2nd _____ 3rd _____
3 = Neomycin Sulfate 1st _____ 2nd _____ 3rd _____	9 = Negative Control 1st _____ 2nd _____ 3rd _____
4 = Potassium Dichromate 1st _____ 2nd _____ 3rd _____	10 = Balsam of Peru 1st _____ 2nd _____ 3rd _____
5 = Caine Mix 1st _____ 2nd _____ 3rd _____	11 = Ethylenediamine Dihydrochloride 1st _____ 2nd _____ 3rd _____
6 = Fragrance Mix 1st _____ 2nd _____ 3rd _____	12 = Cobalt Dichloride 1st _____ 2nd _____ 3rd _____

PANEL 2.3	
13 = p-tert Butylphenol Formaldehyde Resin 1st _____ 2nd _____ 3rd _____	19 = Methylidibromo Glutarosnitrile 1st _____ 2nd _____ 3rd _____
14 = Epoxy Resin 1st _____ 2nd _____ 3rd _____	20 = p-Phenylenediamine 1st _____ 2nd _____ 3rd _____
15 = Carba Mix 1st _____ 2nd _____ 3rd _____	21 = Formaldehyde 1st _____ 2nd _____ 3rd _____
16 = Black Rubber Mix 1st _____ 2nd _____ 3rd _____	22 = Mercapto Mix 1st _____ 2nd _____ 3rd _____
17 = Cl+ Me-Isothiazolinone 1st _____ 2nd _____ 3rd _____	23 = Thimerosal 1st _____ 2nd _____ 3rd _____
18 = Quaternium-15 1st _____ 2nd _____ 3rd _____	24 = Thiuram Mix 1st _____ 2nd _____ 3rd _____

PANEL 3.3	
25 = Diazolidinyl Urea 1st _____ 2nd _____ 3rd _____	31 = Hydrocortisone-17-Butyrate 1st _____ 2nd _____ 3rd _____
26 = Quinoline Mix 1st _____ 2nd _____ 3rd _____	32 = Mercaptobenzothiazole 1st _____ 2nd _____ 3rd _____
27 = Triacetol-21-Pivalate 1st _____ 2nd _____ 3rd _____	33 = Bacitracin 1st _____ 2nd _____ 3rd _____
28 = Gold Sodium Thiosulfate 1st _____ 2nd _____ 3rd _____	34 = Parthenolide 1st _____ 2nd _____ 3rd _____
29 = Imidazolidinyl Urea 1st _____ 2nd _____ 3rd _____	35 = Disperse Blue 106 1st _____ 2nd _____ 3rd _____
30 = Budesonide 1st _____ 2nd _____ 3rd _____	36 = 2-Bromo-2-Nitropropane-1,3-diol 1st _____ 2nd _____ 3rd _____

Description Codes for Patch Test Results:
 Extreme Positive Reaction (+++): spreading, bullous, ulcerative
 Strong Positive Reaction (++) : erythema, edema, papules and vesicles
 Weak Positive Reaction (+): nonvesicular, erythema, infiltration, possibly papules

Doubtful Reaction(?): macular erythema only
 Irritant Reaction (IR)
 Negative Reaction (-)

Interpretation of T.R.U.E. TEST® Results

When applied properly and interpreted correctly, patch testing with T.R.U.E. TEST (Allergen Patch Test) is invaluable in diagnosing allergic contact dermatitis. Under ideal conditions, symptom patterns and sites can help differentiate allergic from irritant reactions.

Distinguishing irritant from allergic contact dermatitis can be most challenging. Both types may exhibit similar characteristics and distributions, especially on the hands. For example, both types of dermatitis can be present and persistent, but irritant reactions are often characterized by discoid hand dermatitis or involvement of interdigital spaces. In some cases, irritant and allergic contact dermatitis may coexist due to increased penetration of allergens or irritants into damaged skin.

In addition to irritant contact dermatitis, other skin conditions and skin tone may complicate interpretation of patch test results. The presence of atopic dermatitis, stasis dermatitis, seborrheic dermatitis, nummular dermatitis, cellulitis, urticaria, mycotic infections, pompholyx, and psoriasis can also impact the differential diagnosis.



Interpreting and Recording Reactions to T.R.U.E. TEST Allergens

STEP 1.

Remove T.R.U.E. TEST Panel 1.3 after 48 hours. This time span is necessary for allergic reactions to develop fully and for irritant reactions to subside. Allow the transient erythema from occlusion to subside for a few minutes and examine the test site for skin reactions.

An identification template is provided for quick identification of causative allergens. Position the identification template so that the notches align with skin markings.

STEP 2.

After 48 hours, interpret any preliminary skin responses to Panel 1.3 allergens. Skin responses are described on the following pages and are interpreted according to criteria established by the International Contact Dermatitis Research Group, as shown below.



+ Weak Positive Reaction: non-vesicular with erythema, infiltration, possibly papules

++ Strong Positive Reaction: vesicular, erythema, infiltration, papules

+++ Extreme Positive Reaction: bullous or ulcerative reaction

? Doubtful Reaction: faint macular erythema only

IR Irritant Reaction: Pustules as well as patchy follicular or homogeneous erythema without infiltrations are usually signs of irritation and do not indicate allergy. Itching is a subjective symptom that is expected to accompany a positive reaction.

STEP 3.

Record interpreted reactions on the *Standard Data Collection Form* (see Section 5).

Interpretations can be annotated as:

- + Weak Positive
- ++ Strong Positive
- +++ Extreme Positive
- ? Doubtful
- IR Irritant

A photograph of a 'STANDARD DATA COLLECTION FORM' used for recording patch test results. The form is divided into several columns and rows, with various fields for patient information, allergen details, and reaction observations.

STEP 4.

Repeat the process with T.R.U.E. TEST Panel 2.3 and 3.3, interpreting and recording visible skin reactions.

AT 72-96 HOURS AFTER APPLICATION:

The patch test reaction on the patient's skin may be evaluated at 48 hours, but an additional reading(s) at 72 and/or 96 hours is necessary. Recall the patient and again interpret skin reactions to T.R.U.E. TEST allergens. Record these second interpretations on the Standard Data Collection Form using the annotations described. **This second reading is essential to help identify and confirm allergic reactions and to allow irritant reactions to diminish.**



Perform additional readings because some allergens that can elicit late reactions should be interpreted 7-10 days after T.R.U.E. TEST application. Advise patients to be aware of potential reactions at these sites (a reading template for at-home use may be helpful). Patients should be advised to report these reactions. Late positive reactions, occurring more than 14 days after application of the panels, may be indicative of active sensitization.

If reactions appear negative – i.e. no visible skin response after multiple readings – the patient may be allergic to substances not included in T.R.U.E. TEST. Consider patch testing with additional substances using Finn Chambers® and additional standardized allergens. Depending on patient history and symptoms, it may be valuable to refer a patient to a contact allergy specialist such as an American Contact Dermatology Society (ACDS) member.

Alternatively, patients with negative test results may be suffering from irritant contact dermatitis or other skin conditions. See the section below entitled "Differential Diagnosis – Negative Reactions" for further information.

Differential Diagnosis – Positive Reactions

Recent studies indicate that between 23% and 62% of patients may test positive to at least one of the 35 allergens and allergen mixes included in T.R.U.E. TEST. (Cohen et al., 1997; Marks et al., 1998; Thyssen et al, 2007) However, not all reactions are considered true positives, or are clinically relevant.

True Positive Reactions:

When performed and read according to international guidelines, true positive reactions are indicative of sensitization, but are not absolute proof. Overall, the percentage of truly positive patients with allergic contact dermatitis has been estimated at 70%. (Nethercott 1994) The frequency of true positive reactions varies by allergen, test conditions and the frequency of testing.

Extreme positive (+++) and strong positive reactions (++) are usually true positive reactions.

Their predictive value increases when the allergy is suspected based on clinical evidence. Therefore, the relevance of positive reactions to current or past eruptions and allergen exposure should be supported by the following:

- Nature and distribution of the skin eruption
- Validity of the relationship between allergen and recent exposure
- Patient's history, especially regarding allergic reactions



+++ Extreme Positive Reaction:

- Coalescing vesicles
- Bullous reaction



++ Strong Positive Reaction:

- Erythema
- Papules
- Infiltration
- Discrete vesicles

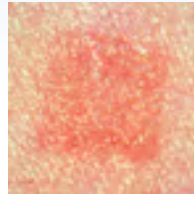
With true positive reactions of past or current relevance, provide the patient with detailed advice on avoiding the discovered allergen, and preventing future exposure (see *Patient Information About T.R.U.E. TEST and Contact Allergen*). Use extreme caution when advising patients about changing jobs or careers; skin condition may not improve in a new work environment. For corresponding physician information about the allergens included in T.R.U.E. TEST see *Allergen Components in T.R.U.E. TEST (Physician Information), Section 7*.

If the relevance of a positive reaction is unknown: First, question the patient in greater detail about possible allergen exposure, allergic history and skin reaction patterns. If this fails to disclose the reaction's significance, the patient should still be advised to avoid the suspected allergen. Reactions that appear positive but cannot be explained may be due to:

- an incomplete medical or occupational history;
- exposure to unsuspected, undetected, unrecognized or ubiquitous allergen(s);
- cross-reactivity to a related allergen; or
- low environmental exposure to an allergen prior to testing.

Weak Positive Reactions:

These reactions must meet the criteria for allergic reactions to be considered valid: papular or vesicular erythema, and infiltration. In contrast, pustules and patchy follicular or homogeneous erythema without infiltration characterize irritant reactions and are not positive reactions.



+ Weak Positive Reaction:

- Erythema
- Infiltration
- Discrete papules

False-Positive Reactions:

If the reaction is a weak positive (+), there is a greater possibility that it is actually a false positive. The frequency of false-positive patch test reactions is estimated at 20% or less, depending on allergen and test conditions. (Nethercott 1994; Le Coz CJ et al. 2009) With experience, physicians can learn to identify false-positive reactions. (Schleichert et al 2010)

Although patch test allergen levels have been carefully calculated to minimize false-positive reactions, some patients may manifest a reaction to what may be a substance well tolerated by others.

False-positive reactions tend to occur more frequently with metals, mixes, and balsam of Peru. They are often due to irritation but may also be caused by the following conditions:

- A strong positive reaction to an adjacent allergen
- Acute dermatitis outbreak at time of testing
- Recent (<3 weeks) contact allergen testing
- Generally irritable skin
- A rare reaction to test tape or patches
- Test materials degraded by poor storage or aging

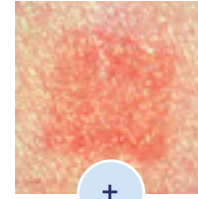
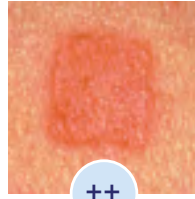
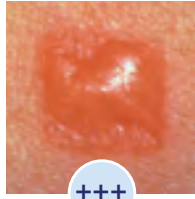
Remember that patient health, skin tone, sweating, and humidity can also affect a reaction's appearance and interpretation. Note that p-phenylenediamine and disperse blue 106 may turn the skin test area black on some patients, but the discoloration does not represent an allergic reaction.

If skin reactions are doubtful: Physicians may consider retesting the patient depending on patient history, symptoms and testing conditions. Retesting may be of greater value when patch test application or care is suspect and reactions are likely to be clinically relevant.

If the reaction has little clinical relevance, interpret weak positive or doubtful reactions with caution. Remember that the safety and efficacy of repetitive testing are unknown, and that the benefit of repeat testing should be weighed against the possible risk of sensitization and false positives.

If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of significant scarring, skin disease, tanning or other conditions that might affect test results.

Diagnostic Path for Positive Reactions



ALL POSITIVE REACTIONS



Is reaction consistent with patient history?



YES

Current or past clinical relevance



TRUE POSITIVE

Discuss avoidance with patient



MAYBE

Unknown clinical relevance



Consider and check for:

- Incomplete history
- Unrecognized allergen exposure
- Ubiquitous allergen
- Cross-reacting allergen
- Latent sensitivity



Re-evaluate or discuss avoidance with patient



DOUBTFUL

For doubtful reactions or potential false positives, consider the possibility of:

- Irritant response
- "Angry Back" or hyperirritable skin
- Acute eruption during testing
- Strong positive at adjacent site
- Previous patch test on same site
- Improper storage and deterioration of T.R.U.E. TEST materials
- Reactions to T.R.U.E. TEST tape or patches (rare)



Consider retesting on different site or after 3 weeks, based on patient history, symptoms and test conditions

Differential Diagnosis – Negative Reactions

Negative reactions to patch testing are common. Between 38% and 77% of patients can test negative to the 35 common allergens and allergen mixes included in T.R.U.E. TEST (Cohen et al., 1997; Marks et al., 1998; Thyssen et al, 2007). Therefore, patients should be informed about the possibility of negative test results during pretest counseling. Physicians should also discuss with patients the value of negative tests, which can be helpful in diagnosing a patient's skin condition.

True Negatives:

When performed and read according to international guidelines, true negative reactions provide important information to help diagnose a patient's condition and guide treatment. True negatives are characterized by no reaction to a test allergen, and the absence of history or symptoms suggesting a contact allergy to that substance.

True negative T.R.U.E. TEST results can add the following clinical value:

- Indications that patients are not allergic to common allergens responsible for most cases of allergic contact dermatitis
- Redirection of the clinical investigation toward other irritants, allergens or underlying conditions (e.g., contact urticaria)
- Reassurance for patients that their skin condition is not caused by common allergens
- Fewer restrictions on patient use of products that contain these common allergens
- Test materials degraded by poor storage or aging

The percentage of patients that are truly negative with no clinical evidence of allergy, i.e., patch test specificity, has been estimated at 80% (Nethercott 1994). However, patch test specificity varies greatly with the type of allergen, test conditions and test frequency.

In some patients, T.R.U.E. TEST reactions are negative or doubtful, but their symptoms and history strongly suggest a contact allergy. Physicians should also consider other possibilities, including other potential allergens or conditions such as atopic dermatitis or irritant dermatitis.

Remember that even when individual allergens and mixes are considered, T.R.U.E. TEST only includes 58 of 3700 known allergens. Therefore, consideration should be given to patch testing patients with additional allergens using Finn Chambers. As needed, refer patients to a specialist with training and experience in contact allergy testing (e.g., members of the ACDS).

When discussing negative T.R.U.E. TEST results, provide patients a copy of "A Negative Test Result" (Section 9) and advise them that:

- their skin condition is not caused by common allergens, which reduces restrictions on their use of consumer, commercial and health care products;
- negative results are common and occur in more than 25% of patients who undergo patch testing;
- negative results can still help diagnose their condition and refine their treatment;
- reactions can still occur to other allergens, possibly requiring additional testing;
- skin may still be irritated by substances and environments at home or at work, requiring alternative products or avoidance strategies;
- skin must be cared for properly, taking into consideration alternative skin care products; and
- to contact a physician if they suspect product-related reactions again.

False Negatives:

Not all negative reactions are true negatives. Based on generalized estimates (*Nethercott 1994*), false-negative results may occur in 30% of patch-tested patients. To minimize the risk of false negatives, T.R.U.E. TEST uses standardized amounts of allergens and allergen mixes and controls the composition, concentration and associated vehicles. Consistent with this, studies have shown that T.R.U.E. TEST results are very reproducible, with discordant reactions observed in less than 5% of patients (*Ale & Maibach 2004; Lachappelle and Maibach 2009*).

False-negative reactions to T.R.U.E. TEST may occur for several reasons:

- A second and later readings were not performed
- Test panel was removed too soon, i.e., before 48 hours
- Use of topical corticosteroids on the test site
- Use of oral corticosteroids (equivalent to 15 mg of prednisolone)
- Insufficient contact between the allergen patch and skin
- Effect of UV light (photosensitization or tanned skin)
- Absence of adjuvant factors involved in eruptions
- Allergen concentration is too low for a reaction

The duration of patch test exposure and reaction development can be critical: Because some positive allergic reactions only appear after the third day, it is essential to perform additional readings at later time points. In patients who sweat heavily or wet T.R.U.E. TEST panels while bathing, skin contact with test panels may be reduced, influencing the validity of test results.

Physicians may consider retesting the patient depending on patient history, symptoms and testing conditions. Retesting may be of greater value when patch test application or care is suspect and reactions are likely to be clinically relevant.

If the reaction has little clinical relevance, interpret doubtful reactions with caution. Remember that the safety and efficacy of repetitive testing are unknown, and that the benefit of repeat testing should be weighed against the possible risk of sensitization.

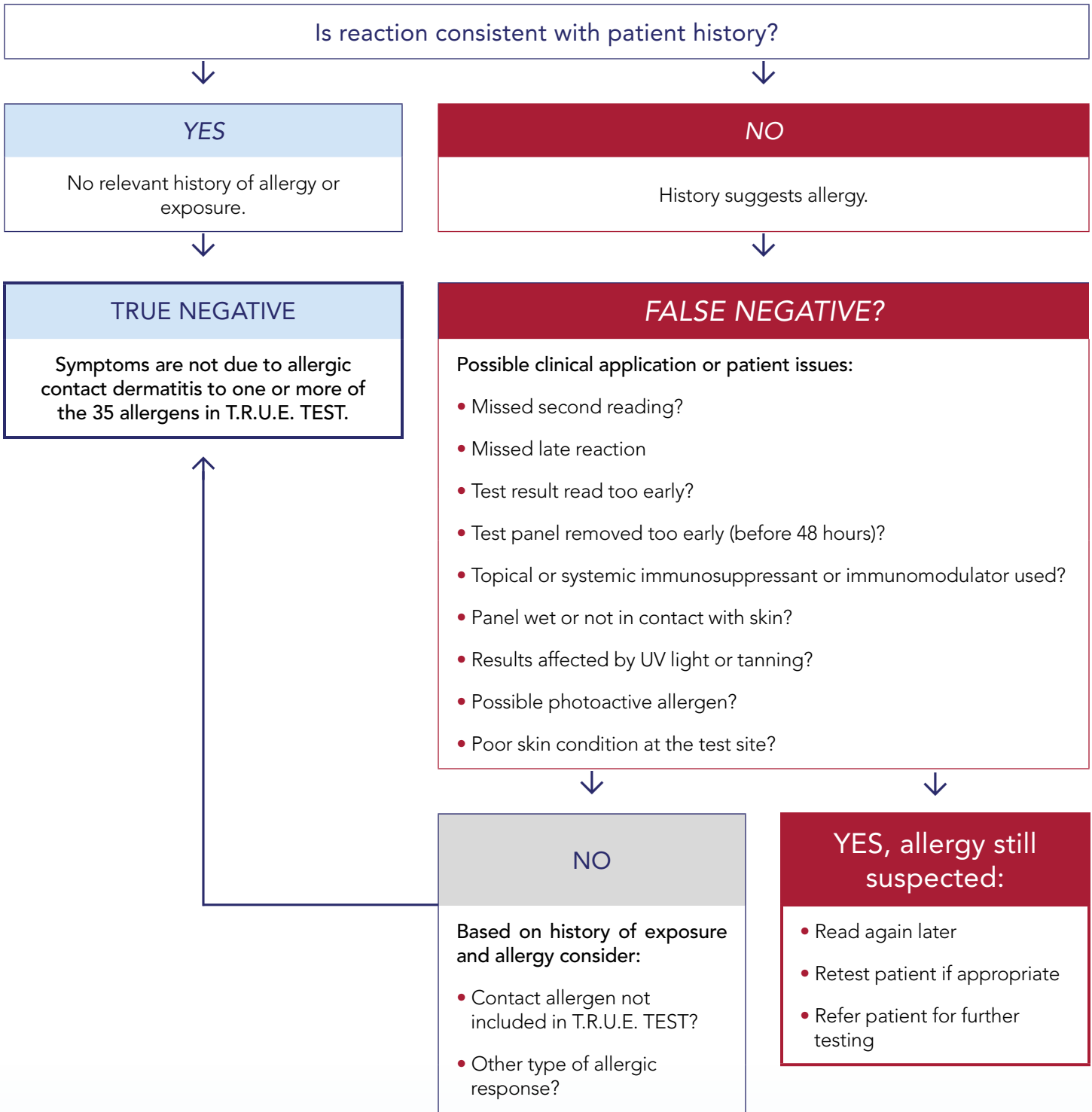
If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of significant scarring, skin disease, tanning or other conditions that might affect test results.

Skin condition and immune responsiveness are important factors: Both are adversely influenced by UV light exposure (e.g., tanning and photosensitization). Some pharmacologic agents can have immunosuppressive activity and results should be interpreted carefully in patients taking these medications. Patients must also stop using topical corticosteroids on test sites, and avoid using oral corticosteroids for at least 2 weeks prior to testing.

Occasionally, the concentration of the allergen used is too low to elicit a detectable skin response. This may be especially true for some weakly sensitized patients in whom the focal allergen application in patch tests may be below their symptom elicitation threshold. In real life, patients often react to allergen exposure occurring over large areas of skin or through broken skin.

Diagnostic Path for Negative Reactions

NEGATIVE REACTIONS



Differential Diagnosis – Doubtful or Minimal Reactions

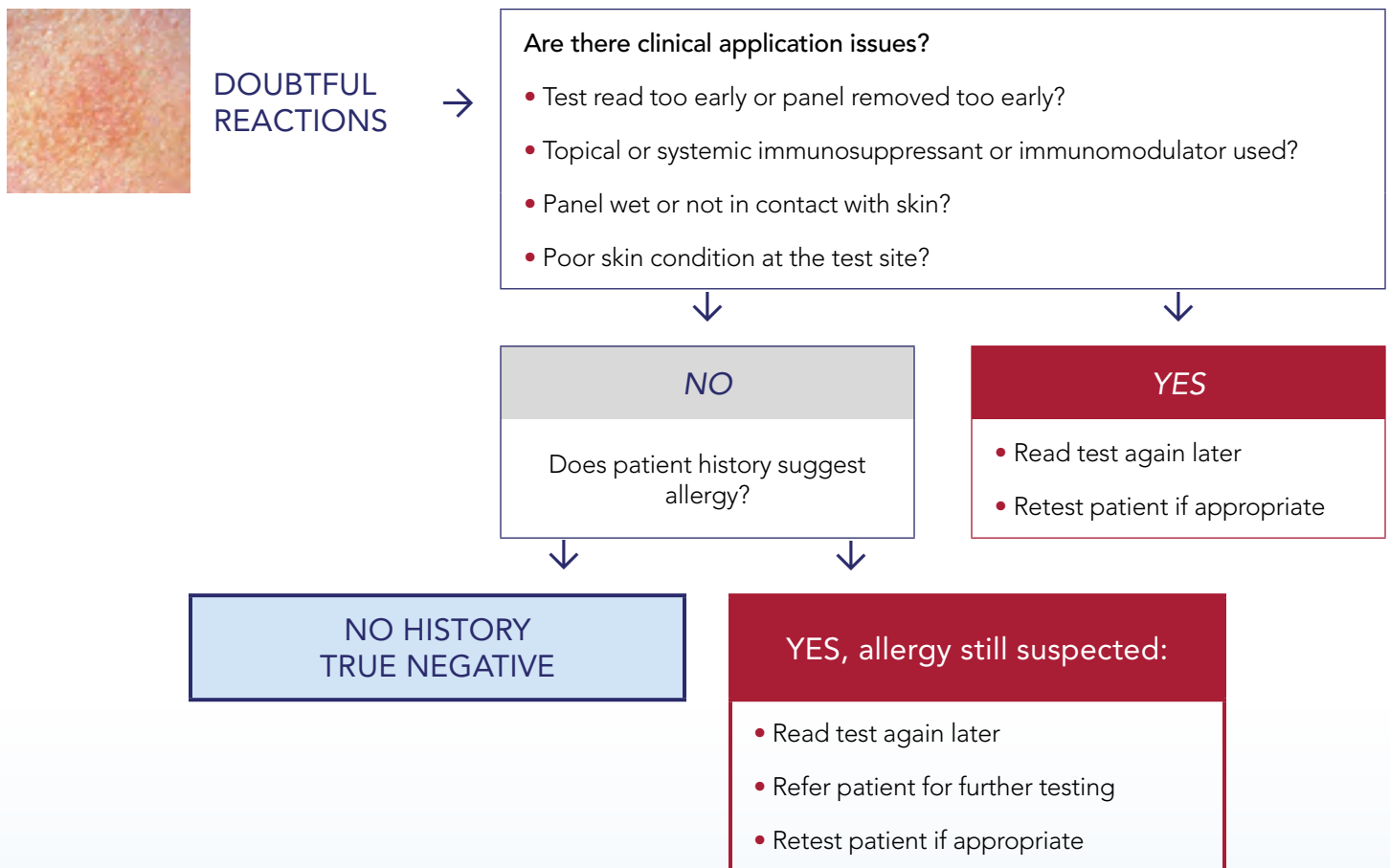
Doubtful or minimal reactions are often characterized as faintly macular, with homogenous erythema and no infiltration. To assess whether patch test conditions or technique influenced the results, consider:

- The timing or number of readings (too early and without another reading?)
- Loss of skin contact
- Possible interference by immunosuppressive agents
- Potentially hyperirritable skin

When unsupported by patient symptoms or history, most doubtful reactions should be regarded as negative. However, physicians may consider retesting the patient depending on patient history, symptoms and testing conditions. Retesting may be of greater value when patch test application or care is suspect and reactions could be clinically relevant. Remember that the safety and efficacy of repetitive testing are unknown, and that the benefit of repeat testing should be weighed against the possible risk of sensitization and false positives.

If patients undergo a second series of patch tests immediately, select a new test site for T.R.U.E. TEST application. Alternatively, the same site may be retested after a 3-week clearing period, provided the site remains free of significant scarring, skin disease, tanning or other conditions that might affect test results.

Diagnostic Path for Doubtful or Minimal Reactions





Differential Diagnosis – Irritant Reactions

Strong irritant reactions are not expected with the concentration of allergens used in T.R.U.E. TEST. Mild irritant reactions can be difficult to distinguish from doubtful or weak positive reactions. Remember that patient health, sweating, and humidity can also affect reaction strength and appearance.

As described in the table below, irritant reactions are characterized by pustules and erythema that is patchy, follicular or homogeneous with no infiltration. In contrast, true positive reactions are characterized by reactions that are papular, vesicular and erythematous with infiltration.



Differentiating Allergic and Irritant Reactions:

Characteristic	Allergic reactions	Irritant reactions
Timing	Tend to persist or increase from day 2 to day 4; may only appear after day 2	Tend to be maximal on day 2 and fade on removal of patch
Outline	Tend to spread	Often sharply delineated
Lesion	Usually erythematous, palpable and eczematous; infiltration or edema present; may be papular, vesicular or coalescing into bullous reactions	May show discrete, patchy or homogenous erythema without infiltration; may be petechial, follicular or pustular
Skin Reaction		

Allergen Components in T.R.U.E. TEST® (Physician Information)

Common Sources

	Personal Care Products	Clothing & Jewelry	Drugs & Medical Products	Rubber Products	Cleaning Products	Industry & Product Manufacture
T.R.U.E. TEST PANEL 1.3 ALLERGENS						
1. Nickel sulfate		✓				✓
2. Wool alcohols	✓	✓	✓		✓	✓
3. Neomycin sulfate			✓			✓
4. Potassium dichromate		✓	✓			✓
5. Caine mix			✓			✓
6. Fragrance mix	✓		✓		✓	✓
7. Colophony	✓		✓		✓	✓
8. Paraben mix	✓		✓			✓
9. Negative control						✓
10. Balsam of Peru	✓		✓		✓	✓
11. Ethylenediamine dihydrochloride			✓			✓
12. Cobalt dichloride		✓				✓

T.R.U.E. TEST PANEL 2.3 ALLERGENS						
13. <i>p</i> -tert-Butylphenol formaldehyde resin	✓	✓			✓	✓
14. Epoxy resin		✓	✓		✓	✓
15. Carba mix	✓	✓		✓		✓
16. Black rubber mix		✓		✓		✓
17. Cl+Me-Isothiazolinone	✓		✓		✓	✓
18. Quaternium-15	✓		✓		✓	✓
19. Methyl dibromo glutaronitrile	✓				✓	✓
20. <i>p</i> -Phenylenediamine	✓	✓		✓		✓
21. Formaldehyde	✓	✓			✓	✓
22. Mercapto mix		✓	✓	✓		✓
23. Thimerosal	✓	✓	✓			✓
24. Thiuram mix		✓	✓	✓		✓

Common Sources

	Personal Care Products	Clothing & Jewelry	Drugs & Medical Products	Rubber Products	Cleaning Products	Industry & Product Manufacture
T.R.U.E. TEST PANEL 3.3 ALLERGENS						
25. Diazolidinyl urea	✓		✓		✓	✓
26. Quinoline mix	✓		✓		✓	✓
27. Tixocortol-21-pivalate	✓		✓			✓
28. Gold sodium thiosulfate		✓	✓			✓
29. Imidazolidinyl urea	✓		✓		✓	✓
30. Budesonide	✓		✓			✓
31. Hydrocortisone-17-butyrate			✓			✓
32. Mercaptobenzothiazole		✓	✓	✓		✓
33. Bacitracin			✓			✓
34. Parthenolide	✓					✓
35. Disperse blue 106		✓				✓
36. 2-Bromo-2-nitropropane-1,3-diol	✓		✓			✓

For additional information about the allergens on T.R.U.E. TEST panels, refer to *Patient Information (Section 9)*.

Chemical identification numbers have been included to help identify specific chemicals such as:

- CAS (Chemical Abstracts Service) Registry Number;
- EINECS (European Inventory of Existing Commercial Substances); and
- EPA (Environmental Protection Agency) Pesticide Chemical Code for substances regulated by the EPA.

Patch Composition

Tape Composition: Rayon Fibers

Patch Composition: Polyester

Adhesive Composition: Acrylate-based

Panel 1.3

1. Nickel Sulfate

Dose: 200 mcg/cm² **Vehicle:** hydroxypropyl cellulose

Allergen patch components: Nickel, 36 mcg

Synonyms or components:

Nickel sulfate:

- Nickel (Ni)
- Nickel alloys
- Nickel catalyst
- Elemental nickel
- Nickel soluble salts
- Carbonyl nickel powder
- Nickel-plating

Chemical Identification: CAS Registry Nos. 7440-02-0, 7786-81-4; EINECS Nos. 231-111-4, 232-104-9

Other substances to which the patient may react:

- Possible coexisting allergies to chromate and cobalt with occupational exposure.

Potential Allergen Sources:

- Nickel and nickel-plated objects; tools; metal machine parts and equipment;
- Nickel catalysts, powders and pigments;
- Metalworking fluids and oils;
- Costume jewelry; keys, coins and utensils;
- Metal clothing fasteners;
- Foods such as legumes, nuts, grains, fish, chocolate, and potatoes.

2. Wool Alcohols (Lanolin)

Dose: 1000 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Cholesterol, lanosterol, agnosterol (and dihydro derivatives); straight- and branched-chain aliphatic alcohols; 810 mcg total (the active allergenic component has not been identified)

Synonyms or components:

Wool alcohols (or lanolin):

- Adeps Lanae
- Degras
- Fats, lanolin
- Wool wax or wool wax, lanolin
- Anhydrous lanolin
- Fats and glyceridic oils, wool
- Wool grease, fat or fatty acid

Chemical Identification: CAS Registry Nos. 8006-54-0, 8020-84-6; EINECS 232-348-6, 232-418-6; EPA Pesticide Chemical Code 031601

Potential Allergen Sources:

- Personal care products such as cosmetics and cleansers;
- Pet care products;
- Metalworking fluids.

3. Neomycin Sulfate

Dose: 600 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Neomycin sulfate, USP, 486 mcg

Synonyms and components:

Neomycin sulfate:

- Neomycin B sulfate

Chemical Identification: CAS Registry Nos. 1405-10-3; EINECS 215-773-1; EPA Pesticide Chemical Code 006313

Other substances to which the patient may react:

- Topical antibiotic creams,
- Injectable antibiotics: kanamycin, mycifradin, sisomycin, paromomycin, streptomycin, butirosin, spectinomycin, fradiomycin

Potential Allergen Sources:

- Topical antibiotics, with or without anti-inflammatories or anti-pruritics

4. Potassium Dichromate (Chromium)

Dose: 54 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Chromium, 15.7 mcg

Synonyms and/or components:

Potassium dichromate:

- Chromic acid salts
- Chromium and chromium salts
- Chromium compounds
- Chromium metal or chrome
- Dipotassium dichromate (or bichromate)

Chemical Identification: *Potassium dichromate* - CAS Registry Nos. RN: 7778-50-9; EINECS 231-906-6; EPA Pesticide Chemical Code 068302

Chromium - CAS Registry Nos. 7440-47-3; EINECS 231-157-5

Potential Allergen Sources:

- Industrial, construction and home repair products such as cement, concrete; wood preservatives;
- Leather and hide glues;
- Metal working, welding and plating with chrome alloys; cutting oils, corrosion inhibitors, drilling muds;
- Green dyes and metallic pigments; inks and paints
- Chromic surgical gut sutures, orthopedic and dental implants or prosthesis.

5. Caine Mix

Dose: 630 mcg/cm²

Vehicle: Povidone

Allergen patch components: Benzocaine, USP, 378 mcg;
Tetracaine HCl, USP, 66 mcg;
Dibucaine HCl, USP, 66 mcg

Synonyms and/or components:

Benzocaine:

- Benzoic acid, 4-amino-, ethyl ester
- 4-Carboethoxyaniline
- 4-(Ethoxycarbonyl)aniline
- Ethyl 4-aminobenzoate
- Ethyl PABA

Tetracaine:

- Benzoic acid, 4-(butylamino)-, 2-(dimethylamino)ethyl ester
- *p*-Butylaminobenzoyl-2-dimethylaminoethanol
- Dimethylaminoethyl *p*-butyl-aminobenzoate

Dibucaine:

- alpha-Butyloxycinchoninic acid diethylethylenediamide
- 2-Butoxy-N-(2-(diethylamino)ethyl)-cinchoninamide
- 2-Butoxyquinoline-4-carboxylic acid diethylaminoethylamide
- Cinchocaine

Chemical Identification: *Benzocaine* - CAS Registry Nos. 94-09-7; EINECS 202-303-5; EPA Pesticide Chemical Code 097001

Dibucaine - CAS Registry Nos. 85-79-0; EINECS 201-632-1

Tetracaine - CAS Registry Nos. 94-24-6; EINECS 202-316-6

Potential Allergen Sources:

- Topical anesthetics (over-the-counter and prescription)
- Topical antiseptic preparations (over-the-counter and prescription)

6. Fragrance Mix

Dose: 500 mcg/cm²

Vehicle: Povidone

Allergen patch components: Geraniol, 81 mcg;
Cinnamaldehyde, 41 mcg;
Hydroxycitronellal, 63 mcg;
Cinnamyl alcohol, 63 mcg;
Eugenol, 41 mcg;
Isoeugenol, 17 mcg;
 α -Amylcinnamaldehyde, 17 mcg;
Oak moss, 81 mcg

Synonyms and/or components:

Geraniol:

- Geraniol alcohol
- Geranyl alcohol
- trans-3,7-Dimethyl-2,6-octadien-1-ol

Cinnamaldehyde:

- Cassia aldehyde
- Cinnamal
- Cinnamic aldehyde
- 3-Phenyl-2-propenal
- 3-Phenylacrolein

Hydroxycitronellal:

- Citronellal hydrate
- Lilyl aldehyde
- Oxydihydrocitronellal
- 7-Hydroxy-3,7-dimethyloctanol
- Muguet synthetic

Cinnamyl alcohol:

- Cinnamic alcohol
- 3-Phenylallyl alcohol
- 3-Phenyl-2-propenol

Eugenol:

- Allylguaiacol
- 4-Hydroxy-3-methoxyallylbenzene
- 2-Methoxy-4-(2-propenyl)phenol
- 4-Allylcatechol 2-methyl ether
- 2-Methoxy-4-allylpheno

Isoeugenol:

- 2-Methoxy-4-(1-propenyl)phenol
- 4-Propenylguaiacol
- 4-Hydroxy-3-methoxypropenylbenzene

α -Amylcinnamaldehyde:

- Amyl cinnamal
- 2-Benzylideneheptanal
- 2-(Phenylmethylene)heptanal
- α -Amyl- β -phenylacrolein
- Jasmine aldehyde
- 2-Pentylcinnamaldehyde

Chemical Identification: *Geraniol* - CAS Registry # 106-24-1; EINECS 203-377-1; EPA Pesticide Chemical Code 597501
Cinnamaldehyde - CAS Registry # 104-55-2, EINECS 203-213-9; EPA Pesticide Chemical Code 040506
Hydroxycitronellal - CAS Registry # 107-75-5; EINECS 203-518-7
Cinnamyl alcohol - CAS Registry # 104-54-1; EINECS 203-212-3
Eugenol - CAS Registry # 97-53-0; EINECS 202-589-1; EPA Pesticide Chemical Code 102701
Isoeugenol - CAS Registry # 97-54-1; EINECS 202-590-7
 α -Amylcinnamaldehyde - CAS Registry # 122-40-7; EINECS 204-541-5 and 215-565-0

Other substances to which the patient may react:

- Colophony
- Citral
- Farnesol
- Lyral
- Propolis balsam
- Balsam of Peru and its components (cinnamic acid, methyl cinnamate, cinnamein, vanillin, and cinnamyl cinnamate)

Potential Allergen Sources:

- Perfumes and colognes; cosmetics; personal care, hygiene, oral hygiene and hair care products;
- Over-the-counter and prescription medicines;
- Pet care products; insecticides and pesticides;
- Household cleaners, air fresheners and deodorizers; paper products;
- Some foods and flavorings; botanical (herbal) products;
- Metal working fluids and industrial cleaners, deodorizers and masking fragrances;
- Candles, incense and essential oils.

7. Colophony

Dose: 1200 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Colophony, 972 mcg

Synonyms and/or components:

Colophony:

- Abietic acid
- Colophonium
- Tall oil
- Wood or pine rosin
- Abietic alcohol, abietyl alcohol, or methyl abietate alcohol
- Disproportionated rosin
- Rosin, gum rosin, or rosin gum

Chemical Identification: CAS Registry Nos. 8050-09-7, EINECS 232-475-7, EPA Pesticide Chemical Code 067205

Other substances to which the patient may react:

- Wood tars
- Rosin esters
- Fragrances, essential oils and some spices

Potential Allergen Sources:

- Wood products, sawdust, wood fillers; glues and adhesives;
- Coatings, polishes, and waxes; waxed thread;
- Industrial lubricants and cutting fluids; soldering products;
- Instrument rosin;
- Topical salves.

8. Paraben Mix

Dose: 1000 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Methyl p-hydroxybenzoate, 162 mcg;
Ethyl p-hydroxybenzoate, 162 mcg;
Propyl p-hydroxybenzoate, 162 mcg;
Butyl p-hydroxybenzoate, 162 mcg;
Benzyl p-hydroxybenzoate, 162 mcg;

Synonyms and/or components:

Methyl p-hydroxybenzoate:

- Benzoic acid, 4-hydroxy-, methyl ester
- Methyl parahydroxybenzoate
- Methylparaben
- 4-Hydroxybenzoic acid methyl ester
- p-Methoxycarbonylphenol

Ethyl p-hydroxybenzoate:

- Benzoic acid, 4-hydroxy-, ethyl ester
- Ethylparaben
- 4-Hydroxybenzoic acid ethyl ester
- p-Carboxyphenol
- Ethyl p-oxybenzoate

Propyl p-hydroxybenzoate:

- Benzoic acid, 4-hydroxy-, propyl ester
- Propylparaben
- 4-Hydroxybenzoic acid propyl ester

Butyl p-hydroxybenzoate:

- Benzoic acid, 4-hydroxy-, butyl ester
- 4-Hydroxybenzoic acid butyl ester
- Butylparaben

Benzyl p-hydroxybenzoate:

- Benzylparaben
- *p*-Hydroxybenzoic acid benzyl ester
- Benzoic acid, 4-hydroxy-, phenylmethyl ester
- Phenylmethyl 4-hydroxybenzoate

Chemical Identification: *Methyl p-hydroxybenzoate*- CAS Registry Nos. 99-76-3, EINECS 202-785-7, EPA Pesticide Chemical Code 061201

Ethyl p-hydroxybenzoate- CAS Registry Nos. 120-47-8, EINECS 204-399-4, EPA Pesticide Chemical Code 061202

Propyl p-hydroxybenzoate- CAS Registry Nos. 94-13-3, EINECS 202-307-7, EPA Pesticide Chemical Code 061203

Butyl p-hydroxybenzoate- CAS Registry Nos. 94-26-8, EINECS 202-318-7, EPA Pesticide Chemical Code 061205

Benzyl p-hydroxybenzoate- CAS Registry Nos. 94-18-8, EINECS 202-311-9

Potential Allergen Sources:

- Products for personal care, hygiene, oral hygiene and hair care;
- Most cosmetics;
- Pet care and grooming products;
- Analgesic medications for skin; and hemorrhoid preparations.

9. Negative Control

The negative control is an uncoated polyester patch with no allergen or vehicle. It is used to differentiate negative reactions and help interpret doubtful or minimal reactions to the allergen-containing patches.

10. Balsam of Peru

Dose: 800 mcg/cm²

Vehicle: Povidone

Allergen patch components: Balsam of Peru, 648 mcg total

Synonyms, components, or chemically related allergens:

Balsam of Peru:

- Balsam of Tolu
- Cinnamein
- Peruvian balsam
- Myroxylon pereirae oleoresin
- Balsam Peru oil or extract
- Balsam fir oleoresin or oil
- Hyperabsolute balsam, Peru

Balsam of Peru components:

- Cinnamic or cinnamyl acid; 3-phenyl-2-propenoic acid; 3-phenylacrylic acid
- Cinnamal or cinnamic aldehyde; cassia aldehyde; 3-phenyl-2-propenal
- Cinnamic or cinnamyl alcohol; 3-phenyl-2-propenol; 3-phenylallyl alcohol
- Methyl cinnamate or cinnamylate; cinnamic acid methyl ester; methyl 3-phenylpropenoate
- Benzyl cinnamate or cinnamein; cinnamic acid benzyl ester; phenylmethyl 3-phenyl-2-propenoate
- Vanillin or vanillic aldehyde; vanillaldehyde; 4-hydroxy-3-methoxybenzaldehyde; 2-methoxy-4-formylphenol
- Eugenol or allylguaiacol; 2-methoxy-4-(2-propenyl)phenol; 2-methoxy-4-allylphenol
- Cinnamyl cinnamate or styracin; 3-phenylallyl cinnamate; 3-phenyl-2-propenyl 3-phenyl-2-propenoate

Chemical Identification: Peruvian balsam CAS Registry Nos. 8007-00-9, EINECS 232-352-8

Other substances to which the patient may react:

- Colophony
- Propolis balsam
- Gum benzoin
- Fragrance mix components - eugenol, isoeugenol, cinnamaldehydes, cinnamyl alcohol

Potential Allergen Sources:

- Perfumes and colognes; cosmetics; personal care, hygiene, oral hygiene and hair care products;
- Over-the-counter and prescription medicines;
- Pet care products; pesticides;
- Household cleaners, air fresheners and deodorizers; paper products;
- Some foods and flavorings; botanical (herbal) products;
- Metal working fluids and industrial cleaners, deodorizers and masking fragrances;
- Candles, incense and essential oils.

11. Ethylenediamine Dihydrochloride

Dose: 50 mcg/cm²

Vehicle: Methyl-cellulose

Allergen patch components: Ethylenediamine, 18 mcg

Synonyms and/or components:

Ethylenediamine dihydrochloride

- Chlor-ethamine
- 1,2-Diaminoethane dihydrochloride
- Dimethylenediamine dihydrochloride
- Ethylenediamine (EDA)
- Ethylenediammonium chloride

Chemical Identification: CAS Registry No. 333-18-6, EINECS 206-369-6

Other substances to which the patient may react:

- Diethylenetriamine (DETA)
- Disalicylalpropylenediimine
- Epoxy amines
- Triethylenetetramine (TETA)
- Rarely, orally administered piperazine-related antihistamines

Potential Allergen Sources:

- Used in the industrial manufacturing of chelating agents, corrosion inhibitors, fuel additives, epoxy curing agents, pharmaceuticals, carbamate-based chemicals, bleach activators, retention and processing aids, plastic lubricants, urethane foam catalysts, printing ink binders, and textile dye-assist compounds.

12. Cobalt Dichloride

Dose: 20 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Cobalt, 4 mcg

Synonyms and/or components:

Cobalt dichloride or cobalt:

- Cobalt metal, metal powder, dust or fume

Chemical Identification: CAS Registry No. 7440-48-4, EINECS 231-158-0

Other substances to which the patient may react (based on cosensitization):

- Chromate
- Nickel

Potential Allergen Sources:

- Cement and bricks;
- Cobalt and cobalt alloys; cobalt catalysts; cobalt fumes, powders and pigments;
- Metalworking fluids and oils;
- Metal tools, jewelry and utensils (as with nickel);
- Paints, inks, glazes and finishes.

Panel 2.3

13. *p*-tert-Butylphenol Formaldehyde Resin

Dose: 45 mg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: *p*-tert-Butylphenol formaldehyde resin, 36 mg

Synonyms and/or components:

p-tert-Butylphenol formaldehyde (PTBP):

- Paraformaldehyde, formaldehyde, *p*-tert-butylphenol polymer
- 4-(1,1-Dimethylethyl)phenol, formaldehyde polymer
- Formaldehyde, *p*-tert-butylphenol polymer
- *p*-tert-Butylphenol formaldehyde resin (PTBP FR)

Chemical Identification: CAS Registry No. 25085-50-1

Potential Allergen Sources:

- Adhesives and glues in leather and rubber shoe manufacturing and repair; neoprene adhesives; glues for furniture and auto upholstery;
- Construction materials such as laminated wood products;
- Manufacture of fiberglass and mineral fiber insulation; modifiers in resin manufacturing;
- Photosensitive coatings.

14 Epoxy Resin

Dose: 50 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Diglycidylether of bisphenol A, 32 mcg

Synonyms and/or components:

Epoxy resin or diglycidylether of bisphenol A:

- Bisphenol A diglycidyl ether
- Diglycidyl bisphenol A
- Diphenylol propane diglycidyl ether
- Diomethane diglycidyl ether
- 2,2-Bis(4-glycidioxyphenyl)propane
- 4,4'-Isopropylidenediphenol diglycidyl ether
- 4,4'-Dihydroxydiphenyldimethylmethane diglycidyl ether

Chemical Identification: CAS Registry No. 1675-54-3, EINECS 216-823-5

Other substances to which the patient may react:

- Tosylamide epoxy resin
- Bisphenol A-glycidyl methacrylate (or Bis-GMA)
- Epoxy resins with diglycidyl ethers of bisphenol F

Potential Allergen Sources:

- Two-component paints, protective coatings and adhesives;
- Manufacturing of epoxy composite products including lightweight equipment, tennis racquets, skis, and circuit boards;
- Electron microscopy embedding media;
- Dental bonding agents and dental restorative materials.

15. Carba Mix

Dose: 250 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Diphenylguanidine, 67 mcg;
Zincdibutyldithiocarbamate, 67 mcg;
Zincdiethyldithiocarbamate, 67 mcg

Synonyms and/or components:

Diphenylguanidine:

- N,N'-Diphenylguanidine
- 1,3-Diphenylguanidine

Zincdibutyldithiocarbamate:

- Bis(N,N-dibutyldithiocarbamato)zinc
- Carbamic acid, dibutyldithio-, zinc complex
- Zinc bis(dibutyldithiocarbamate)

Zincdiethyldithiocarbamate:

- Diethyldithiocarbamic acid zinc salt
- Zinc bis(diethyldithiocarbamate)
- Zinc diethylcarbomodithioate

Chemical Identification: *Diphenylguanidine* - CAS Registry Nos. 102-06-7, EINECS 203-002-1

Zincdibutyldithiocarbamate - CAS Registry Nos. 136-23-2, EINECS 205-232-8

Zincdiethyldithiocarbamate - CAS Registry Nos. 14324-55-1

Other substances to which the patient may react:

Thiuram-based rubber additives that have the potential for cross-reactivity and cosensitization -

- Tetramethylthiuram monosulfide
- Tetramethylthiuram disulfide
- Dipentamethylenethiuram disulfide
- Disulfiram

Potential Allergen Sources:

Used in fungicides, pesticides and the manufacturing of natural rubber, butyl rubber, nitrile or neoprene for:

- Industrial and safety products such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation, and sheeting;
- Office products such as rubber bands, erasers, mats, and utility gloves;
- Health care equipment such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons, and tubing;
- Sports equipment and household products such as wetsuits, shoes, boots, masks, racquet and club handles.

16 Black Rubber Mix

Dose: 75 mcg/cm²

Vehicle: Povidone

Allergen patch components: N-Isopropyl-N'-phenyl paraphenylenediamine, 10.2 mcg;
N-Cyclohexyl-N'-phenyl paraphenylenediamine, 25.5 mcg;
N, N'-Diphenyl paraphenylenediamine, 25.5 mcg

Synonyms and/or components:

N-Isopropyl-N'-phenyl-paraphenylenediamine:

- N-Phenyl-N'-isopropyl-p-phenylenediamine

N-Cyclohexyl-N'-phenyl-paraphenylenediamine:

- N-Cyclohexyl-N'-phenyl-1,4-benzenediamine

N,N'-Diphenyl-paraphenylenediamine:

- Diphenyl-p-phenylenediamine
- p-Phenylaminodiphenylamine
- p-Bis(phenylamino)benzene
- 1,4-Dianilinobenzene
- 4,4'-Diphenyl-p-phenylenediamine

Chemical Identification: *N-Isopropyl-N'-phenyl-paraphenylenediamine* – CAS Registry Nos: 3085-82-3, EINECS 221-404-5;
N-Cyclohexyl-N'-phenyl-paraphenylenediamine – CAS Registry RN: 101-87-1, EINECS 202-984-9
N,N'-Diphenyl-paraphenylenediamine – CAS Registry Nos. 74-31-7, EINECS 200-806-4

Potential Allergen Sources:

Antidegradant used in the manufacture of black rubber for:

- Industrial products such as tires, belts, masks, aprons, gaskets, flanges, stoppers, shoes and boots, sheeting and flooring
- Black rubber components on health care and laboratory equipment
- Office products made with black rubber components such as feet and wheels on equipment
- Household products and sports equipment made with black rubber such as masks and goggles, shoes, tires, boots, masks, racquet and club handles

17. Cl+ Me-Isothiazolinone (MCI/MI)

Dose: 4 mcg/cm²

Vehicle: Povidone

Allergen patch components: 5-Chloro-2-methyl-4-isothiazolin-3-one (MCI), 2.4 mcg;
2-Methyl-4-isothiazolin-3-one (MI), 0.8 mcg

Synonyms and/or components:

5-Chloro-2-methyl-4-isothiazolin-3-one:

- Methylchloroisothiazolinone (MCI)
- Kathon
- 5-Chloro-2-methyl-2H-isothiazol-3-one

2-Methyl-4-isothiazolin-3-one: • *Methylisothiazolinone (MI)*

- 2-Methyl-3(2H)-isothiazolone
- 2-Methyl-2H-isothiazol-3-one

Chemical Identification: *5-Chloro-2-methyl-4-isothiazolin-3-one* – CAS Registry Nos. 26172-55-4, EINECS 247-500-7
2-Methyl-4-isothiazolin-3-one – CAS Registry Nos. 2682-20-4, EINECS 220-239-6,
EPA Pesticide Chemical Code 107104

Other substances to which the patient may react:

- Other chlorinated isothiazolinones

Potential Allergen Sources:

Biocide and preservative used in industrial and consumer products including:

- Cleaning and laundry products, skin cleansers and shampoos, hair coloring products, hand and body lotions, cosmetics;
- Latex paints, adhesives and glues;
- Industrial metal working fluids.

18. Quaternium-15

Dose: 100 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Quaternium-15, 81 mcg

Synonyms and/or components:

Quaternium-15:

- Hexamethylenetetramine chloroallyl chloride
- Chloroallyl methenamine chloride
- N-(3-Chloroallyl)hexaminium chloride
- 3,5,7-Triaza-1-azoniaadamantane, 1-(3-chloroallyl)-, chloride

Chemical Identification: CAS Registry Nos. 4080-31-3, EINECS 223-805-0, EPA Pesticide Chemical Code 017901

Other formaldehyde-releasing substances to which the patient may react:

- Formaldehyde or formalin; formic aldehyde; oxymethylene
- Bronopol or 2-bromo-2-nitropropane-1,3-diol
- Diazolidinyl urea or N,N'-bis(hydroxymethyl) urea; 1-(1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)-1,3-bis(hydroxymethyl)urea
- DMDM Hydantoin or 1,3-cimethylol-5,5-dimethylhydantoin;
1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione
- Imidazolidinyl urea or imidurea; N,N"-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)urea
- Tris nitro or trimethylolnitromethane; nitroisobutylglycerol; 2-nitro-2-(hydroxymethyl)-1,3-propanediol, tris(hydroxymethyl)nitromethane

Potential Allergen Sources:

- Personal care products (cosmetics, hair and hygiene products),
- Household cleaning agents and latex paints
- Industrial polishes, waxes, inks, paints and metal working fluids.

19. Methyl dibromo Glutaronitrile (MDBGN)

Dose: 5 mcg/cm²

Vehicle: Povidone

Allergen patch components: Methyl dibromo Glutaronitrile, 4 mcg

Synonyms and/or components:

Methyl dibromo Glutaronitrile (MDBGN):

- Methyl dibromoglutaronitrile
- Bromothalonil
- Metacide 38
- 2-Bromo-2-(bromomethyl)pentanedinitrile

Chemical Identification: CAS Registry Nos. 35691-65-7; EINECS 252-681-0

Other substances to which the patient may react:

Cross-reactivity is not a major concern for Methyl dibromo Glutaronitrile (MDBGN).

Potential Allergen Sources:

Used as a preservative to prevent chemical change or microbial action:

- Cosmetic and personal care products such as body creams, facial and hand lotions, sun screens, baby lotions, shower gels, ultrasonic gel, toilet paper, shampoos, and massage oils;
- Industrial products such as cutting oils, drilling oils, glues, and coolants.

20. *p*-Phenylenediamine

Dose: 90 mcg/cm²

Vehicle: Povidone

Allergen patch components: *p*-Phenylenediamine, 73 mcg

Synonyms and/or components:

p-Phenylenediamine:

- Paraphenylenediamine (PPD)
- 4-Phenylenediamine
- Phenylenediamine
- *p*-Diaminobenzene
- 4-Aminoaniline
- 1,4-Benzenediamine
- 1,4-Diaminobenzene

Chemical Identification: CAS Registry Nos. 106-50-3, EINECS 203-404-7

Other substances to which the patient may react:

- Textile dyes such as aniline yellow (*p*-aminoazobenzene; *p*-dimethylaminoazobenzene) or disperse orange (1-amino-2-methylantraquinone);
- Hair dyes *p*-toluenediamine and *p*-toluenediamine sulfate;
- 4,4'-Methylenedianiline in some rubbers, plastics and epoxy resins;
- Other aminobenzene-related compounds.

Potential Allergen Sources:

- Permanent and semipermanent coloring products for hair and facial hair;
- Temporary, paint-on and black henna tattoos;
- Textile and fur dyes;
- Photodeveloping agents and printing inks;
- Black rubber products.

21. Formaldehyde

Dose: 180 mcg/cm²

Vehicle: Povidone

Allergen patch components: Formaldehyde, 146 mcg

Synonyms and/or components:

Formaldehyde:

- Formalin
- Methaldehyde
- Methylene oxide
- Oxymethylene
- Formic aldehyde
- Methyl aldehyde
- N-methylol

Chemical Identification: CAS Registry Nos. 50-00-0, EINECS 200-001-8, EPA Pesticide Chemical Code 043001

Other formaldehyde-releasing substances to which the patient may react:

- Bronopol or 2-bromo-2-nitropropane-1,3-diol
- Diazolidinyl urea or N,N'-bis(hydroxymethyl) urea; 1-(1,3-Bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)-1,3-bis(hydroxymethyl)urea
- DMDM Hydantoin or 1,3-cimethylol-5,5-dimethylhydantoin; 1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione
- Imidazolidinyl urea or imidurea; N,N"-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)urea
- Tris nitro or trimethylolnitromethane; nitroisobutylglycerol; 2-nitro-2-(hydroxymethyl)-1,3-propanediol, tris(hydroxymethyl)nitromethane

Potential Allergen Sources:

- Pressed wood construction materials (particleboard, fiberboard, plywood), and urea-formaldehyde resins and foams;
- Durable press fabrics;
- Personal care products (cosmetics, hair and hygiene products);
- Metal working fluids, glues, cleaning agents, latex paints, polishes, waxes, inks;
- Embalming and preserving fluids.

22. Mercapto Mix

Dose: 75 mcg/cm²

Vehicle: Povidone

Allergen patch components: N-Cyclohexylbenzothiazyl-sulfenamide, 20.3 mcg;
Dibenzothiazyl disulfide, 20.3 mcg;
Morpholinylmercaptobenzothiazole, 20.3 mcg

Synonyms and/or components:

N-Cyclohexylbenzothiazyl-sulfenamide:

- Cyclohexyl benzothiazolesulfenamide
- Benzothiazyl-2-cyclohexylsulfenamide
- 2-(Cyclohexylaminothio)benzothiazole

Dibenzothiazyl disulfide:

- 2,2'-Dithiobis(benzothiazole)
- 2,2'-Bis(benzothiazolyl) disulfide
- 2-Mercaptobenzothiazole disulfide
- Dibenzothiazolyl disulfide
- 2,2'-Dibenzothiazyl disulfide

Morpholinylmercaptobenzothiazole:

- 2-Benzothiazolyl morpholino disulfide
- 2-Morpholinodithiobenzothiazole
- Benzothiazole 2-(4-morpholinyl)
- 4-Morpholinyl 2-benzothiazyl disulfide
- Benzothiazole, 2-(4-morpholinyl)dithio

Chemical Identification: *N-Cyclohexylbenzothiazyl-sulfenamide* – CAS Registry Nos. 95-33-0, EINECS 202-411-2

Dibenzothiazyl disulfide – CAS Registry Nos. 120-78-5, EINECS 204-424-9, EPA Pesticide Chemical Code 009202

Morpholinylmercaptobenzothiazole – CAS Registry Nos. 95-32-9, EINECS 202-410-7

Other substances to which the patient may react:

- Due to cosensitization, commonly used rubber additives such as thioureas.

Potential Allergen Sources:

Used in the manufacturing of natural rubber, butyl rubber, nitrile or neoprene for:

- Industrial and safety products such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation, and sheeting;
- Office products such as rubber bands, erasers, mats, and utility gloves;
- Health care equipment such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons, and tubing;
- Sports equipment and household products such as gloves, swimwear, toys, wetsuits, footwear, masks, racquet and club handles.

23. Thimerosal

Dose: 7 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Thimerosal, 6 mcg

Synonyms and/or components:

Thimerosal:

- Mercuriothiolate
- Merthiolate
- Sodium ethylmercurithiosalicylate
- Mercury, ((o-carboxyphenyl)thio)ethyl-, sodium salt
- Sodium 2-(ethylmercurithio)benzoate
- Mercury, ethyl(2-mercaptobenzoato-S)-, sodium salt

Chemical Identification: CAS Registry Nos. 54-64-8, EINECS 200-210-4, EPA Pesticide Chemical Code 078901

Other substances to which the patient may react:

- Other mercurial compounds
- Thiosalicylic acid derivatives such as piroxicam (Feldene®)

Potential Allergen Sources:

Infrequently used as a preservative in:

- Some vaccines and ophthalmic, otic and nasal preparations;
- Some fluorescent dyes in metal and forensic industries;
- Some thiosalicylic acid-based nonsteroidal anti-inflammatories

24. Thiuram Mix

Dose: 27 mcg/cm²

Vehicle: Povidone

Allergen patch components: Tetramethylthiuram monosulfide, 5.5 mcg;
Tetramethylthiuram disulfide, 5.5 mcg;
Disulfiram, USP, 5.5 mcg;
Dipentamethylenethiuram disulfide, 5.5 mcg

Synonyms and/or components:

Tetramethylthiuram monosulfide:

- Tetramethylthiuram sulfide
- Sulfide, bis(dimethylthiocarbamoyl)
- Tetramethyldithiocarbamic acid anhydrosulfide
- Bis(dimethylthiocarbamoyl) sulfide

Tetramethylthiuram disulfide:

- Bis(dimethyl thiocarbamoyl)disulfide
- Tetramethylthiocarbamoyl disulphide
- Thiram
- N,N'-(Dithiodicarbonothioyl)bis(N-methylmethanamine)
- Tetramethylthioperoxydicarbonic diamide

Disulfiram:

- Bis(N,N-diethylthiocarbamoyl) disulfide
- Tetraethylthiuram disulfide
- Tetraethylthioperoxydicarbonic diamide
- 1,1'-Dithiobis(N,N-diethylthioformamide)

Dipentamethylenethiuram disulfide:

- Bis(pentamethylene)thiuram disulfide
- 1,1'-(Dithiodicarbonothioyl)bispiperidine
- Disulfide, bis(1-piperidinylothioxomethyl)

Chemical Identification: *Tetramethylthiuram monosulfide* - CAS RN: 97-74-5, EINECS 202-605-7;

Tetremethylthiuram disulfide - CAS Registry Nos. 137-26-8, EINECS 205-286-2, EPA Pesticide Chemical Code 079801;

Disulfiram - CAS Registry Nos. 97-77-8, EINECS 202-607-8;

Dipentamethylenethiuram disulfide - CAS Registry Nos. 94-37-1, EINECS 202-328-1

Other substances to which the patient may react:

- Carbamates (carba mix), due to either cross-reactivity or cosensitization;
- Other rubber additives due to cosensitization.

Potential Allergen Sources:

Used in fungicides, pesticides, seed protectants, animal repellants, Antabuse® and the manufacturing of natural rubber, butyl rubber, nitrile or neoprene for:

- Industrial and safety products such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation, and sheeting;
- Office products such as rubber bands, erasers, mats, and utility gloves;
- Health care equipment such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons, and tubing;
- Sports equipment and household products such as toys, gloves, swimwear, wetsuits, shoes, boots, masks, racquet and club handles.

Panel 3.3

25. Diazolidinyl Urea (Germall® II)

Dose: 550 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Diazolidinyl urea, 446 mcg

Synonyms or components:

Diazolidinyl urea:

- Germall 11
- Imidazolidinyl urea 11
- N-(1,3-Bis(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)-N,N'-bis(hydroxymethyl)urea
- N-(Hydroxymethyl)-N-(1,3-dihydroxymethyl-2,5-dioxo-4-imidazolidinyl)-N'-(hydroxymethyl) urea
- N-(Hydroxymethyl)-N-(1,3-dihydroxymethyl-2,5-dioxo-4-imidazolidinyl)-N'-(hydroxymethyl)urea

Chemical Identification: CAS Registry Nos. 78491-02-8, EINECS Nos. 278-928-2

Other substances to which the patient may react:

- Imidazolidinyl urea
- Bronopol
- Dimethyl dimethyl hydantion
- Formaldehyde
- Quaternium 15

Potential Allergen Sources:

- Products for personal care, hygiene, and hair care;
- Cosmetics;
- Cleaning agents;
- Liquid soaps;
- Pet shampoos.

26. Quinoline Mix

Dose: 190 mcg/cm² **Vehicle:** Povidone

Allergen patch components: Quinoline mix, 154 mcg

Synonyms or components:

Quinoline mix:

- 1-Azanaphthalene
- 2,3-Benzopyridine
- Benzopyridine
- Chinoline
- 1-Benzazine
- Benzo(b)pyridine
- Chinoleine
- Leucol

Quinoline Mix components:

- Clioquinol
- Clorquinaldol

Chemical Identification: CAS Registry Nos. 91-22-5, EINECS Nos. 202-051-6,
Other Registry Nos. 20214-07-7, FEMA No. 3470

Other substances to which the patient may react:

- Vioform
- Diodoquin
- Quinoloar

Potential Allergen Sources:

- Paste bandages;
- Prescription and nonprescription preparations such as topical antibiotics and antifungal creams, lotions, ointments;
- Animal food;
- Bacteriostatic and fungistatic cream (eg. Sterosan Cream).

27. Tixocortol-21-Pivalate

Dose: 3 mcg/cm²

Vehicle: Povidone

Allergen patch components: Tixocortol-21-Pivalate, 2 mcg

Synonyms or components:

Tixocortol-21-Pivalate:

- Tixocortol pivalate [USAN]
- 11beta,17-Dihydroxy-21-mercaptopregn-4-ene-3,20-dione 21-pivalate Pivalone
- Pregn-4-ene-3,20-dione, 21-((2,2-dimethyl-1-oxopropyl)thio)-11,17-dihydroxy-, (11beta)-)

Chemical Identification: CAS Registry Nos. 55560-96-8, EINECS Nos. 259-706-4

Other substances to which the patient may react:

- Cloprednol
- Hydrocortisone
- Hydrocortisone acetate
- Prednisolone
- Fludrocortisone acetate
- Hydrocortisone 17-butyrate

Potential Allergen Sources:

- Anti-inflammatory agents/ prescription and nonprescription
- Nasal suspensions for rhinitis
- Lozenges for pharyngitis
- Rectal suspension for ulcerative colitis

28. Gold Sodium Thiosulfate

Dose: 75 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Gold Sodium Thiosulfate, 23 mcg

Synonyms or components:

Gold Sodium Thiosulfate:

- Auricidine
- Aurolin
- Auropin
- Aurothion
- Natrium-bis (thiosulfato) aurat (I)
- Sanochrysin
- Sodium aurothiosulfate
- Thiochrysin
- Aurocidin
- Auropex
- Aurosan
- Crisalbine
- Novacrysin
- Sodium aurothiosulphate dihydrate
- Solfocrisol

Chemical Identification: CAS Registry Nos. 10210-36-3, EINECS Nos. 233-563-8

Potential Allergen Sources:

- Gold in jewelry;
- Occupational exposure to gold;
- Previous rheumatoid arthritis treatment;
- Dental restorations;
- Gold-plated intracoronary stents.

29. Imidazolidinyl Urea (Germall® 115)

Dose: 600 mcg/cm²

Vehicle: Povidone

Allergen patch components: Imidazolidinyl urea, 486 mcg

Synonyms or components:

Imidazolidinyl urea (Germall® 115):

- Imidazolidinyl urea
- Imidurea
- Urea, N,N"-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidin-yl) urea
- N,N"-Methylenebis(N'-(1-(hydroxymethyl)-2,5-dioxo-4-imidazolidin-yl)-

Chemical Identification: CAS Registry Nos. 39236-46-9, EINECS Nos. 254-372-6,

Other Registry Nos. 82852-50-4

Other substances to which the patient may react:

- Diazolidinyl urea
- Formaldehyde
- Bronopol
- Quaternium 15
- Dimethyl dimethyl hydantion

Potential Allergen Sources:

- Products for personal care, hygiene, and hair care
- Cosmetics
- Cleaning agents
- Liquid soaps
- Moisturizers

30. Budesonide

Dose: 1 mcg/cm²

Vehicle: Povidone

Allergen patch components: 81 mcg

Synonyms or components:

Budesonide:

- (11-beta,16-alpha)-16,17-(Butylidenebis(oxy))-11,21-dihydroxypregna-1,4-diene-3,20-dione
- (RS)-11beta,16alpha,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde
- 16-alpha,17-alpha-Butylidenedioxy-11-beta,21-dihydroxy-1,4-pregnadiene-3,20-dione
- Bidien
- Rhinocort
- Entocort
- Budeson
- Spirocort

Chemical Identification: CAS Registry Nos. 51333-22-3, EINECS Nos. 257-139-7

Other substances to which the patient may react:

- Amcinonide
- Hydrocortisone-17-butyrate
- Hydrocortisone-17-aceponate
- Hydrocortisone buteprate
- Methylprednisolone aceponate
- Prednicarbate
- Triamcinoline
- Tixocortol Pivalate

Potential Allergen Sources:

- Anti-Inflammatory agents;
- Ear, Nose, and eye drops;
- Rectal suspension (colitis treatments).
- Creams, lotions, ointments, and powders;
- Inhalation drugs, tablets, and injectables;

31. Hydrocortisone-17-Butyrate

Dose: 20 mcg/cm²

Vehicle: Povidone

Allergen patch components: Hydrocortisone-17-Butyrate, 16 mcg

Synonyms or components:

Hydrocortisone-17-Butyrate:

- Alfason
- Hycortate
- Lacoidon
- Bucort
- Locoid
- Hydrocortisone butyrate
- Cortisol 17-butyrate
- Laticort
- Lacoid

Chemical Identification: CAS Registry Nos. 50-23-7, EINECS Nos. 200-020-1

Other substances to which the patient may react:

- Alclomehtasone dipropionate
- Methylprednisolone aceponate
- Hydrocortisone acetate
- Prednicarbate
- Budesonide
- Tixocortol Pivalate

Potential Allergen Sources:

- Topical over-the-counter (OTC) and prescription pharmaceuticals

32. Mercaptobenzothiazole

Dose: 75 mcg/cm²

Vehicle: Povidone

Allergen patch components: Mercaptobenzothiazole, 61 mcg

Synonyms and/or components:

Mercaptobenzothiazole (MBT):

- 2-Mercaptobenzothiazole
- 2-Benzothiazolinethione
- 2-Benzothiazolethiol
- Benzothiazole-2-thione
- 2-Benzothiazolyl mercaptan

Chemical Identification: CAS Registry Nos. 149-30-4; EINECS 205-736-8

Other substances to which the patient may react:

- Due to cosensitization, rubber additives such as dibutyl thiourea or diphenyl thiourea, often used in rubber products with MBT.

Potential Allergen Sources:

Used in the manufacturing of natural rubber, butyl rubber, nitrile or neoprene for:

- Industrial and safety products such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation, and sheeting;
- Office products such as rubber bands, erasers, mats, and utility gloves;
- Health care equipment such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons, and tubing;
- Sports equipment and household products such as utility gloves, swimwear, toys, wetsuits, shoes, boots, masks, racquet and club handles.

33. Bacitracin

Dose: 600 mcg/cm²

Vehicle: Hydroxypropyl cellulose

Allergen patch components: Bacitracin, 486 mcg

Synonyms and/or components:

Bacitracin:

- 22601-59-8
- Bacitracin A
- C15482
- CHEMBL1200558

Chemical Identification: CAS Registry Nos. 1405-87-4; EINECS 215-786-2

Other substances to which the patient may react:

- Neomycin
- Polymixin

Potential Allergen Sources:

Used as an antibiotic for postoperative and wound care. It is often a first-line topical remedy for many cutaneous injuries and dermatoses, as well as eye and ear disorders.

34. Parthenolide

Dose: 3 mcg/cm²

Vehicle: Povidone

Allergen patch components: Parthenolide, 2 mcg

Synonyms and/or components:

Parthenolide:

- 4,5-alpha-Epoxy-6-beta-hydroxygermacra-1(10), 11(13)-dien-12-oic acid gamma-lactone
- NSC 157035
- (-)-Parthenolide
- Parthenolide

Chemical Identification: CAS Registry Nos. 20554-84-1

Potential Allergen Sources:

Parthenolide occurs naturally in thousands of plants including daisies, feverfew, and magnolia.

35. Disperse Blue 106

Dose: 50 mcg/cm²

Vehicle: Povidone

Allergen patch components: Disperse Blue 106, 41 mcg

Synonyms and/or components:

- Eythanol, 2-(ethyl(3-methyl-4-((5-nitro-2-thiazolyl)azo)phenyl)amino)-

Chemical Identification: CAS Registry Nos. 12223-01-7; EINECS 271-183-4

Other substances to which the patient may react:

- Due to a close structural similarity Disperse Blue 124.
- Some patients with disperse dye allergy also react to para-phenylenediamine.

Potential Allergen Sources:

Used as a textile dye found in fabrics colored dark blue, brown, black, purple, and some greens:

- Acetate and polyester fabrics and liners
- Bedding, clothing, nylon stockings, swimming suits, tights (Spandex & Lycra), Velour
- Children's diapers

36. 2-Bromo-2-Nitropropane-1,3-Diol

Dose: 250 mcg/cm²

Vehicle: Povidone

Allergen patch components: 2-Bromo-2-nitropropane-1, 3-diol, 203 mcg

Synonyms and/or components:

2-Bromo-2-nitropropane-1, 3-diol:

- 3-propanediol
- Bronopol
- Onyxide 500
- 2-Bromo-2-nitro-1

Chemical Identification: CAS Registry Nos. 52-51-7; EINECS 200-143-0

Other substances to which the patient may react:

- Related preservatives formaldehyde, quaternium-15, diazolidinyl urea, DMDM hydantoin, imidazolidinyl urea, and tris nitromethane.

Potential Allergen Sources:

Used as a preservative to prevent chemical change or microbial action:

- Cosmetic and personal care products
- Topical medications

Patch Test Coding and Reimbursement Guide

Accurate coding and documentation are essential for appropriate reimbursement for medical services, including dermatology. Coding is intended to transform a physician's verbal descriptions of diseases and procedures into standardized numeric designations, facilitating patient care documentation and billing.



Currently, the three major coding systems include the American Medical Association's Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). These systems are used by both government and private health care payers for health care reimbursement. They can change frequently and vary by geographic location and payer. Always refer to current versions of these coding guides.

In addition to understanding these coding systems used in health care, physicians and staff should know the policies and procedures for their primary payers or contracted health plans. This includes information about patient coverage, anticipated and contracted reimbursement rates, definition of complete claims, claims appeal processes, as well as appropriate contact numbers, email and addresses.

Disclaimer: The brief information included here about coding and reimbursement is for educational purposes only. It should not replace current Medicare or specific payer policies, state or federal regulations, medico-legal practice guidelines, or consultation with coding experts or attorneys. Users should always consult payers for final guidance and about changes in coding and reimbursement practices. SmartPractice® and SmartPractice Denmark® assume no liability from the use of this manual.

Coding for Evaluation and Management (E/M) Services

A generalized summary of evaluation and management (E/M) service coding is shown below. For complete information about these procedures, refer to current versions of the American Academy of Dermatology Coding and Documentation Manual and the American Medical Association's CPT and ICD-9-CM guidance manuals.

CPT code	History ¹	Physical exam ²	Medical decision process	Time ³ (minutes)
New Patients (i.e., no professional services within previous 3 years)*				
99201	Problem-focused	Problem-focused	Straight forward	10
99202	Expanded problem-focused	Expanded problem-focused	Straight forward	20
99203	Detailed	Detailed	Low complexity	30
99204 [†]	Comprehensive	Comprehensive	Moderate complexity	45
99205 [†]	Comprehensive	Comprehensive	High complexity	60
Established Patients				
99211	Minimal	Minimal	Minimal	5
99212	Problem-focused	Problem-focused	Straight forward	10
99213	Expanded problem-focused	Expanded problem-focused	Low complexity	15
99214	Detailed	Detailed	Moderate complexity	25
99215 [†]	Comprehensive	Comprehensive	High complexity	40

Note: If more than one service or procedure is performed on the same day as an E/M use modifier "25."

* Although dermatologists may receive patients by referral, these are usually coded as new patients not consultations. Consultation codes are used when advice is formally requested by another physician currently providing care for that patient, and influences that patient care. Strict criteria, including extensive documentation, must now be met for billing consultation services.

¹ Per Medicare, "history" is often defined based on the chief complaint, history of present illness, a review of systems, and any relevant history (e.g., past, family or social).

² Per Medicare, 1) a "problem-focused" exam means the affected body area or organ system; 2) an "expanded problem focused" exam means the affected body area or organ system and other related systems; 3) a "detailed" exam means a more extensive exam of the affected body area or organ system and other related organ systems and 4) a "comprehensive" exam means an extensive exam of 12 organ systems or complete exam of a single organ system.

³ Per Medicare, the length of time spent with a patient does not primarily control the level of service billed, unless it constitutes more than 50% of the face-to-face time such as when providing counselling or coordinating care.

[†] Dermatologists, physician's assistants, and nurse practitioners should not use 99204, 99205, or 99215, as these codes require extensive documentation for levels of care rarely performed and/or medically necessary

Patch Test Coding

For complete information about coding procedures, physicians are referred to current versions of the *American Academy of Dermatology Coding and Documentation Manual* and the *American Medical Association's CPT and ICD-9-CM* guidance manuals.

- For each patch test(s), use **CPT code 95044** (or 95052 for photo patch tests). According to Medicare guidelines, the number of tests (i.e., allergen patches) must be specified. For T.R.U.E. TEST® panels 1.3 and 2.3, and 3.3, the total number of patches is 36. This number (36) is the multiplier used for the 95044 reimbursement fee.
Note: Patch test CPT code (95044) does not include a professional or E/M service component.
- Medicare and third party payers can have different patch testing policies, including different maximum allowable tests (i.e., 95044) per beneficiary per year. Carefully review any limitations in payer policies that may impact office procedures and patient care.
- The level of **E/M service** reported should be based on *current history, exam and decision-making criteria*, and not solely on time spent with the patient. Support E/M service reporting with clear documentation in the medical record.
- Depending on patient care provided, it may be appropriate to bill for a separately identifiable E/M service that occurs on the same day as patch testing. If this is the case, it should be reported using **modifier 25**, recognized by most payers.
- The **ICD-9-CM codes** for diagnoses of allergic contact dermatitis vary (e.g., 692.0 for detergent-based to 692.9 for an unspecified cause). Use appropriate ICD-9-CM codes (including V codes) to identify diagnoses, symptoms, other conditions, problems and complaints.

Patch Test Reimbursement

Accurate coding and documentation are essential for reimbursement for medical services. Coding is intended to transform a physician's verbal descriptions of diseases and procedures into standardized numeric designations, facilitating patient care documentation, and billing.

Currently, the three major coding systems include:

- The American Medical Association's Current Procedural Terminology (CPT)
- The Healthcare Common Procedure Coding System (HCPCS)
- The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

These systems are used by both government and private health care payers for health care reimbursement. They can change frequently and vary by geographic location and payer. Always refer to current versions of these coding guides.

In addition to understanding these coding systems, physicians and staff should know the policies and procedures for their primary payers or contracted health plans. This includes information about patient coverage, anticipated and contracted reimbursement rates, definition of complete claims, claims appeal processes, as well as appropriate contact numbers, email and addresses.

On national average, U.S. Medicare reimbursement (2015) is approximately \$5.73 per CPT 95044. Below is an example of what a typical physician administered, T.R.U.E. TEST reimbursement may look like for a new patient.

New Patient E/M Fee CPT code 99203 (20 min)	\$108.00
Patch Test Allergens \$5.73 x 36 CPT Code 95044	\$206.28
Panel Removal and First Reading E/M Fee (48 hrs.) CPT code 99212 (10 min.)	\$43.68
Second Reading E/M Fee (72 hrs.) CPT code 99212 (10 min.)	\$43.68
Final E/M and Patient Counseling CPT code 99214 (25 min.)	\$107.76
Final Reimbursement with 2 Readings	\$509.40
Final Reimbursement with 1 Reading	\$465.72

Claim Denials and Appeals

Claim or coverage denials are best avoided by being as proactive as possible. Understanding the coverage limitations of various health care plans and obtaining preauthorization is likely to reduce unwanted and unexpected denials.

However, claim denials do occur and the American Medical Association has reported that a significant proportion of physician revenue can be associated with underpaid or denied claims.

Moreover, the majority of claim denial or underpayment can arise from errors attributable to health care providers and payers. Therefore, it is important that physicians and staff learn to analyze rejected claims, manage claim denials effectively, and implement appeal strategies.



Tips for improving claims management overall:

- Understand the claims appeal process applicable to your local, regional and national payers.
- Review claims before submission. Use a reference sheet to crosscheck for common coding errors and proper payer procedures.
- Regularly evaluate payers' explanation of benefits (EOB) for potential errors or underpayments.
- Record claim follow-up including a summary of payer information, source(s) and reasons for denial, as well as any actions taken.
- Using standardized professional claims appeal letters may facilitate the process, and payers may be more likely to respond quickly. Clearly state the rationale for the appeal, date of service, patient information, and appropriate documentation for all patient care provided.
- For payers unfamiliar with T.R.U.E. TEST, it may be helpful to note that it is the only allergen patch test approved by the FDA for marketing and sale in the United States.

T.R.U.E. TEST[®]

**THIN-LAYER RAPID USE
EPICUTANEOUS PATCH TEST**

Patient Information
about T.R.U.E. TEST[®]
& Contact Allergens

Information for Patients

PATIENT NAME: _____

Patch testing will begin at: _____ (Time) on _____ (Day/Date)

Return for **reading #1** at: _____ (Time) on _____ (Day/Date)

Return for **reading #2** at: _____ (Time) on _____ (Day/Date)

Return for reading #3 at: _____ (Time) on _____ (Day/Date)

Final results and counseling at: _____ (Time) on _____ (Day/Date)

Pre-test Instructions (if you have any questions, ask your doctor): _____

- | | |
|---|---|
| <input type="checkbox"/> Wear comfortable clothing | <input type="checkbox"/> Avoid using alcohol or other irritating substances |
| <input type="checkbox"/> No oral corticosteroids for 2 weeks prior to testing | <input type="checkbox"/> Shave off excessive back hair with an electric razor |
| <input type="checkbox"/> No skin lotions or medicines on test areas | <input type="checkbox"/> Other: _____ |

Questions and Answers about T.R.U.E. TEST® (Allergen Patch Test)



What is allergic contact dermatitis?

This is a skin reaction that occurs when you touch or contact substances that you are allergic to. Your skin can be itchy, cracked, red, sore, and even bleed. The substances that cause this reaction can be an ingredient in your makeup, aftershave, shampoo, jewelry, medication, and clothing. You may also find these substances at work in your cleaning supplies, paper and ink, medicines, disinfectants, construction materials and rubber products.

What is T.R.U.E. TEST?

T.R.U.E. TEST is a reliable, easy-to-use patch test. It is designed to help your doctor find out whether you are allergic to the substances included on the test panels (shown in the table below). The test panels contain 35 different substances known to cause allergic contact dermatitis. T.R.U.E. TEST also includes a negative control that can help your doctor interpret your skin reactions.

Panel 1.3	Panel 2.3	Panel 3.3
1. Nickel sulfate	13. <i>p</i> -tert-Butylphenol formaldehyde resin	25. Diazolidinyl Urea
2. Wool alcohols	14. Epoxy resin	26. Quinoline Mix
3. Neomycin sulfate	15. Carba mix	27. Tixocortol-21-Pivalate
4. Potassium dichromate	16. Black rubber mix	28. Gold Sodium Thiosulfate
5. Caine mix	17. Cl+Me- Isothiazolinone	29. Imidazolidinyl Urea
6. Fragrance mix	18. Quaternium-15	30. Budesonide
7. Colophony	19. Methylidibromo Glutaronitrile	31. Hydrocortisone-17-Butyrate
8. Paraben mix	20. <i>p</i> -Phenylenediamine	32. Mercaptobenzothiazole
9. Negative control	21. Formaldehyde	33. Bacitracin
10. Balsam of Peru	22. Mercapto mix	34. Parthenolide
11. Ethylenediamine dihydrochloride	23. Thimerosal	35. Disperse Blue 106
12. Cobalt dichloride	24. Thiuram mix	36. 2-Bromo-2-nitropropane-1,3-diol

How long will I have to wear T.R.U.E. TEST?

You must wear the panels (on your back or an alternative site) for about 2 days. Do not remove the panels unless your doctor tells you to do so. You must return to have the panels removed. At this time, your doctor will take the first skin reading.

What activities should I avoid while wearing T.R.U.E. TEST?

You must be careful to keep the T.R.U.E. TEST panels or the surrounding skin dry. Moisture can cause the panels to loosen, wash away the test substances or marking ink. To avoid this:

- **Do not wet T.R.U.E. TEST panels or the surrounding skin while bathing.** Take sponge baths for the first 48 hours. Do not shower until the patches are removed.
- Avoid getting T.R.U.E. TEST panels or the surrounding skin wet while exercising or participating in activities that may cause you to sweat, such as vigorous exercise or sunbathing.

If an area of the test panel does become loose, use hypoallergenic adhesive tape to reattach it to your skin in exactly the same position as before. Apply tape only around the outside edge of the panels.

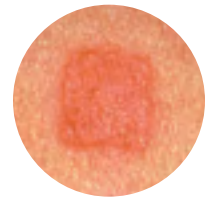
What should I do if my skin itches or burns while wearing T.R.U.E. TEST?

Itching and burning sensations are common side effects. Try not to scratch the patch test area. Scratching can irritate your skin, and may make the itching worse. It also can affect your doctor's ability to interpret your skin's reaction. If the itching or burning becomes severe, you should contact your doctor immediately.

What reactions will alert my doctor?

At each skin reading, your doctor will carefully examine the test area for signs of an allergic reaction. It may look like a small skin rash with swelling, redness and tiny blisters.

It is very important that you keep all appointments. Your doctor needs to see your skin and check for signs of an allergic reaction in the test area.



A positive test

When will my T.R.U.E. TEST results be known?

Some reactions to the substances in T.R.U.E. TEST appear within a few days, while others can take as long as 10 days to appear. Your doctor will determine how long it will take to complete your test based on your history and symptoms. Your doctor will discuss your results with you during your last appointment.

If I am allergic to a substance in T.R.U.E. TEST, what should I do? If you test positive, your doctor will explain which substance you are allergic to and talk to you about how to avoid contact. Your doctor will provide information about:

- 1) Where the substance can be found at work and at home;
- 2) What products are likely to contain this substance;
- 3) Steps you can take to avoid this substance; and
- 4) Alternative products you can use that don't contain this substance.

What does a negative test result mean?

Negative results are very common. If you test negative, you will not have to avoid products that contain the 35 common allergens and allergen mixes included in T.R.U.E. TEST. However, you still can have other allergies. Although the 35 allergens and allergen mixes in T.R.U.E. TEST are the most common, there are many more substances that could be causing your symptoms. Some patients need additional tests to determine if they are allergic to less common allergens.

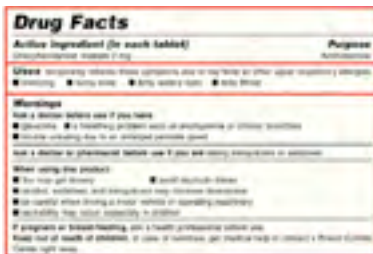
Your doctor may decide that your symptoms are due to an irritant reaction, and talk with you about how to better care for your skin and avoid irritating substances. If your doctor believes your skin's reaction is due to some other condition, you may be referred to a specialist for further testing and treatment.

Reading Labels to Identify Allergens



Product labels are meant to tell you how to use a product wisely and safely, and often include content information. Cosmetics, over-the-counter medicines, prescription drugs, and pesticides are required by law to identify ingredients. Knowing where to look and how to read this information can help you avoid contact with substances that may cause your skin to react.

Beware of products labeled as hypoallergenic, natural or organic. These labels do not mean that the product does not contain allergens. To the Food and Drug Administration (FDA) and most dermatologists, these terms are only marketing hype.



Where should you look on medicines for ingredients?

Over-the-counter medicines and sunscreens must list *active* and *inactive* ingredients in a “DRUG FACTS” label, like the one shown. Be sure to check both ingredient lists to make sure that your allergen(s) is not listed.

Prescription drugs must also list active and inactive ingredients. You can find this information in the package insert, and on patient information supplied with the drug. Your pharmacist can also help you identify the drug’s active and inactive ingredients.

Where should you look on cosmetics for ingredient information?

Cosmetics are products that cleanse, beautify or alter your appearance, such as makeup, body lotions and hand cleansers. By law, they must have ingredient information listed on the label. Ingredients are often listed in descending order, so that the first chemical in the list is present in the greatest amount. But if ingredient concentrations are less than 1%, these ingredients may be listed in any order.

Does a product SDS contain ingredient information?

Yes. At work, material safety data sheets (SDS) contain information about ingredients, properties and hazards of products in the workplace. By law, SDS must list any hazardous ingredient whose concentration is greater than 1%. Ideally, SDS would list all product ingredients with chemical names. But because the laws vary by state, SDS information can be incomplete and sometimes confusing. If you have questions or concerns about a product or chemical at work, talk to your employer or contact the product manufacturer.

Where else can you look for ingredient information on products?

If a product contains a pesticide, it must identify active and inactive (or inert) ingredients on the label. Therefore, products used in lawn and garden care, or to control insects will have this information on the label. Products that contain disinfectants or antibacterial agents – such as most dishwashing soaps and hand soaps – must also list this information.

For more information about product labels, you can visit the web sites of the Occupational Safety and Health Administration (osha.gov), FDA (fda.gov/opacom/morecons.html) and Environmental Protection Agency (epa.gov/epahome/topics.html). The United States National Library of Medicine also has web sites with product content information at Haz-Map: Occupational Exposure to Hazardous Agents (hazmap.nlm.nih.gov) and the Household Product Database (householdproducts.nlm.nih.gov). Learning to read labels may seem challenging, but it can help you safely use household and work products, as well as avoid products that contain your allergen.

A Negative Test Result

Your T.R.U.E. TEST results suggest that you are not allergic to 35 of the most common contact allergens and allergen mixes. A negative test result is very common: as many as 6 out of every 10 patch-tested people test negative. Your negative result will help your doctor treat your skin condition correctly so that it can begin to heal.

Could you be allergic to other substances not included in T.R.U.E. TEST?

Yes. You were tested to 36 patches that include 34 mixes that can cause allergic contact dermatitis in most people. But there are several thousand known allergens, and you may be allergic to one not included in T.R.U.E. TEST. Based on your symptoms, health history and occupation, your doctor may decide to patch test you with other allergens.

Could your T.R.U.E. TEST results be wrong?

The accuracy of patch test results varies by allergen, and with the intensity of your skin's reaction. Strong T.R.U.E. TEST reactions are easiest to identify and the most accurate. Weak and questionable T.R.U.E. TEST reactions are harder to identify, less accurate and easier to miss.

Some T.R.U.E. TEST reactions may need more time to develop. If you notice skin reactions at the test site after your doctor has removed T.R.U.E. TEST and finished the readings, contact your doctor promptly.

Test results can also be affected by your health, personal habits, and medications. Talk to your doctor if you have recently taken steroids or used any topical medications on your back. Also tell your doctor if the T.R.U.E. TEST panels became loose or wet during the test period.

What else could be causing your skin rash, redness or cracking?

Other conditions can cause skin reactions including abnormal immune reactions, and harsh skin care. Of these, two common conditions include atopic dermatitis and irritant contact dermatitis.

Atopic dermatitis, or "eczema," is rash or skin reaction to substances normally considered harmless such as dust. You may be more likely to have atopic dermatitis if you have a personal or family history of other allergies. Your doctor may perform additional tests to diagnose this condition.

Irritant contact dermatitis is a rash or skin reaction to a harsh, irritating substance that has damaged your skin. Common irritating substances include detergents, solvents, acids, alkalis, and machine oils. Harsh, wet, hot, or cold environments can also irritate skin.

What can you do to prevent skin reactions and keep your skin healthy?

- Use mild soaps and cleansers for regular skin hygiene. Using alcohol hand rubs with emollients can also reduce the impact of repeated, harsh hand washing.
- Apply moisturizing lotions and creams regularly to help replace and retain skin moisture. Sunscreens can also help prevent skin damage from UV radiation.
- Avoid products that damage your skin, such as acids, alkalis, and solvents that strip skin oils and water.
- Use topical steroids with care. Frequent and long-term use can lead to thin, fragile skin, as well as a contact allergy.
- Reduce direct skin contact with known allergens and substances that you have reacted to previously. Protect your skin by wearing gloves and protective clothing.
- If you develop new skin reactions, see your doctor. Prompt medical attention and an accurate diagnosis are the excellent tools for taking care of your skin.



Your T.R.U.E. TEST results indicate that you have a contact allergy to nickel. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Nickel is one of the most common metals in the modern environment, both at work and at home and reportedly causes more dermatitis than all other metals combined. It is used in metal alloys, nickel plating, metal and chemical manufacturing, and the production of batteries and coins. Nickel is often used to coat other metals to give them a shiny metallic finish. Nickel is found on the surface of common metallic and metal-plated items such as metal jewelry, watchbands, keys, tools, equipment, scissors, kitchen utensils, coins, and clothing fasteners such as buttons, zippers and snaps. It is occasionally found in eye cosmetics. While nickel is found in stainless steel, allergic reactions to products made with stainless steel (for example, dental and surgical instruments) are rare because typically only minimal amounts of nickel are released.

WHERE IS NICKEL FOUND?

At work, you may find nickel in or around:

- Metal alloys
- Copper-nickel tubing for salt water
- Machine parts
- Chemical catalysts
- Aluminum electrical joint compounds
- Equipment
- Orthodontic and dental appliances
- Welding and cutting
- Nickel plating
- Metal-working fluids and oils
- Batteries
- Dyes
- Insecticides

At home, you may find nickel in or around:

- Jewelry
- Scissors
- Metal utensils
- Magnets
- Chrome and brass
- Metallic powders
- Some white or 14-kt gold jewelry
- Watchbands
- Pigments
- Hair ornaments
- Eyeglasses
- Keys
- Batteries
- Hand tools
- Buttons and snaps
- Zippers
- Eyeshadow
- Coins
- Some bronze objects
- Some objects with white or 14-kt gold
- Knitting needles

Dietary exposure to nickel can provoke dermatitis in sensitized individuals. Foods reported to be high in nickel include legumes, whole grain flour, oats, soybeans, shellfish, fish, asparagus, beans, mushrooms, onions, corn, spinach, tomatoes, peas, pears, all types of nuts, raisins, rhubarb, tea, cocoa, baking powder, cabbage, sprouts, all canned foods or foods cooked in nickel utensils, licorice, chocolate and potatoes. A recent study reported that nickel was also found in several complementary and alternative remedies (CAR), including preparations advertised to treat asthma, acne, atopic eczema, seborrhea and psoriasis. Herbal remedies, herbal teas and some over-the-counter multivitamins have also been listed as sources of potential nickel exposure. Food containing nickel is seldom a problem, but if you are severely allergic to nickel discuss whether you need to avoid foods rich in nickel with your doctor.

HOW CAN YOU AVOID NICKEL?

- Minimize skin contact with nickel. Aluminum, yellow gold, silver and platinum are usually safe alternative metals.
- Avoid wearing jewelry that may contain nickel.
- Wear clothing with nonmetallic zippers and fasteners.
- Use scissors, kitchen utensils, combs and other metal items with plastic or wood handles.
- Only wear earrings guaranteed to be free of nickel.
- Select a watch with a stainless steel back.
- Coat metallic items that are difficult to avoid contact with such as door keys and doorknobs with several layers polyurethane lacquer.
- Wear protective clothing to perform wet work, because moisture increases the penetration of nickel into the skin.
- Only use products that do not list nickel or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- If you think that you contact nickel at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.
- Inform your healthcare providers that you are allergic to nickel.
- Wear protective gloves made of cotton when handling coins, tools or other metal items. Gloves made of disposable rubber or vinyl can also be worn when handling metal objects.
- Jewelry and other metal objects can easily be tested for the presence of nickel using a spot test called Reveal & Conceal Nickel Spot test available on myskinallergy.com
- Tell your physician, pharmacist, dentist, beautician and hairdresser that you are allergic to nickel.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Nickel sulfate (NiSO₄) or nickel soluble salts; nickel (Ni); carbonyl nickel powder; nickel alloys; nickel-plating; elemental nickel; nickel catalyst

You also may react to other metal substances that often are present together with nickel:

- Palladium
- Chrome (or chromate)
- Cobalt

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **nickel** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to wool alcohols. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Wool alcohols are natural products obtained from the fleece of sheep and are commonly used in cosmetics, toiletries and medicines.

WHERE ARE WOOL ALCOHOLS (OR LANOLIN) FOUND?

At work, you may find wool alcohols (or lanolin) in:

- Manufacture and use of personal care products such as hand lotions and cosmetics
- Manufacture and use of pet care or veterinary products
- Metal-working fluids including lubricants, cutting fluids and corrosion inhibitors
- Polishes and waxes
- Printing inks
- Impregnating agents for textile, leather goods and furs
- Insulation for wiring

At home, you may find wool alcohols (or lanolin) in:

- Cosmetics such as foundations, powders, blush, mascaras, eye shadows, eyeliners, eye pencils
- Skin care products such as balms, creams, ointments, lotions and moisturizers
- Personal hygiene items such as soaps, cleansers and shampoos
- Lipsticks and lip balms
- Facial masks
- Sunscreens
- Over-the-counter and prescription treatments for skin rashes or dermatitis
- Pet shampoos, conditioners and grooming aids
- Hair removers and shaving products
- Nail enamel remover
- Baby oils
- Diaper lotions
- Hair sprays
- Hemorrhoid preparations
- Household polishes and waxes
- Shoe polishes

HOW CAN YOU AVOID WOOL ALCOHOLS OR LANOLIN?

- Do not use products with wool alcohols or lanolin on your skin, hair or body. Only use products that do not list wool alcohols, lanolin, or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, talk to your pharmacist or doctor.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to wool alcohols or lanolin. Ask for preparations that do not contain wool alcohols (lanolin) or related substances.
- If you must use or contact wool alcohols or lanolin when caring for children or pets, wear protective gloves and clothing. Utility gloves made of natural or synthetic rubber or vinyl are good for working with wool alcohols (or lanolin).
- If you think that you contact wool alcohols or lanolin at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Wool alcohols (lanolin) or anhydrous lanolin
- Wool Fat or Grease
- Wool Wax
- Wool Grease Fatty Acid
- Wool Fats and Glyceridic Oils
- Fats
- Lanolin
- Adeps Lanae
- Degras

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **wool alcohols** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to neomycin. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Neomycin is a topical antibiotic that may be found in both prescription medicines and over-the-counter first-aid preparations.

WHERE IS NEOMYCIN FOUND?

At work, you may find neomycin in prescription or over-the-counter topical medicines (skin, eyes, ears) used on humans and animals.

- Veterinary medicines for skin, eyes and ears
- Topical antibiotics for skin, eyes and ears

At home, you may find neomycin in first-aid medicines and topical preparations used to treat skin, eye and ear infections. Neomycin may be used with other antibiotics and agents that reduce itching and swelling.

- Antibiotic creams, lotions and ointments
- Eye medications
- Petcare and veterinary products
- Ear medications

You may need to avoid other related antibiotics. Some people with neomycin contact allergies will also react to framycetin, bacitracin, or gentamicin, which are also topical medicines used to treat skin, ear and eye infections.

Some people may have reactions to a few antibiotics that are usually given by injection, such as kanamycin. Talk to your doctor if you have questions or have ever reacted to these antibiotics.

HOW CAN YOU AVOID NEOMYCIN?

- Check all topical antibiotic preparations (prescription and over-the-counter) for neomycin. Do not use products with neomycin or related chemicals on the label, package insert or ingredient list. If no information is available, talk to your pharmacist or contact the manufacturer.
- Tell your physician, pharmacist, dentist and veterinarian that you are allergic to neomycin. Ask for preparations that do not contain neomycin or related substances.
- If you must use or contact neomycin when caring for children or pets, wear protective gloves. Utility gloves made of natural or synthetic rubber or vinyl are good for working with most neomycin preparations.
- If you think that you contact neomycin at work, ask your employer for Material Safety Data Sheets (MSDS) or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Neomycin sulfate or neomycin B sulfate

You also may react to other topical antibiotics related to neomycin or that are used with neomycin:

- Framycetin
- Gentamycin
- Bacitracin – many people with neomycin allergies are also allergic to bacitracin

You also may react to neomycin-related injectable antibiotics:

- Kanamycin
- Mycifradin
- Sisomycin
- Paromomycin
- Streptomycin
- Butirosin
- Spectinomycin
- Fradiomycin

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **neomycin** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to potassium dichromate. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Potassium dichromate is a chromium salt or chromate and is a common metal in the earth's crust. Chromium and chromates occur naturally in our environment, including in soil and water. They are also common ingredients in products made of chrome, stainless steel, cement and leather.

WHERE IS POTASSIUM DICHROMATE (OR CHROMIUM) FOUND?

At work, you may find chromates or chromium in:

- Construction materials such as cement, mortar, concrete, bricks, plaster, drywall
- Leather tanning and product manufacturing
- Primers and chromate-based pigments in paints
- Cutting oils, corrosion inhibitors, oils, fuels and drilling muds
- Liners in high temperature industrial furnaces
- Pyrotechnics
- Printing inks
- Manufacturing, plating and metal working with chrome alloys and stainless steel
- Orthopedic and dental implants, dental prostheses
- Wood preservative manufacturing
- Green dyes used in felt and textiles
- Chrome alloy welding fumes
- Chromic surgical gut sutures

At home, you may find chromates or chromium in:

- Orthopedic and dental implants, dental prostheses
- Leather products including shoes, boots, gloves
- Pigments in inks and paints
- Construction materials such as cement, mortar, concrete, bricks, plaster, drywall
- Green dyes used in felt and textiles
- Make up
- Foods and vitamin supplements
- Pressure-treated wood
- Household repair materials

HOW CAN YOU AVOID POTASSIUM DICHROMATES (OR CHROMIUM)?

- Allergic skin reactions to chromates (or chromium) can become severe and chronic. Therefore, it's important to avoid touching chromates or inhaling chrome alloy fumes or getting them on your clothing.
- Only use products that do not list chromates (or chromium) or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Avoid tanned leather products unless vegetable tannins have been used. Use instead vegetable tanned leather shoes or plastic shoes. For those with shoe dermatitis from chromate and leather, wearing heavy socks and reducing perspiration and moisture may help to reduce dermatitis.
- Do not handle burnt matches or ash. Use a lighter instead.
- In the workplace, avoid wet cement and mortar. Even the dust or fumes from chromate-containing products should be avoided. Chromate-reduced cement added ferrous sulfate is an alternative. Change oils and cutting fluids used in machine work often.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to chromates (or chromium). Ask for preparations that do not contain chromates or related substances.
- Wear protective gloves and clothing. Heavy-duty and utility gloves of natural or synthetic rubber or vinyl may provide adequate protection for working with products that contain chromates (or chromium). Heavy-duty fabric or canvas gloves may be substituted for leather gloves.
- If you think that you contact chromates (or chromium) at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Potassium dichromate or dipotassium dichromate (or bichromate)
- Chromium compounds
- Chromium and chromium salts
- Chromium metal or chrome
- Chromic acid salts

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **potassium dichromate** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to caine mix. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Caine mix contains the following three allergens:

- Benzocaine, SP
- Tetracaine hydrochloride, USP
- Dibucaine hydrochloride, USP

These substances are local anesthetics used in topical over-the-counter and prescription products to numb or soothe the skin.

WHERE IS CAINE MIX FOUND?

At work, you may find caine mix or one of its components in:

- Manufacture of medicines containing benzocaine, tetracaine or dibucaine
- First-aid analgesics and antiseptics with benzocaine, tetracaine or dibucaine

At home, you may find caine mix or one of its components in:

- Over-the-counter first-aid treatments for the pain and itching of injured skin
- Prescription therapies for ear and eye inflammation
- Sprays and lozenges for coughs and sore throats
- Hemorrhoid treatments

Benzocaine and related anesthetics are also found in some products used to treat athlete's foot, calluses, warts and corns.

You also may react to sunscreens and creams containing para-aminobenzoic acid (PABA) and to permanent hair dyes.

HOW CAN YOU AVOID CAINE MIX OR ONE OF ITS COMPONENTS?

- Check all topical skin, eye and ear preparations (prescription and over-the-counter) for caine mix or one of its components. Only use products that do not list benzocaine, tetracaine or dibucaine on the label, ingredient list or package insert. If no information is available, talk to your pharmacist or contact the product manufacturer.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to caine mix. Ask for preparations that do not contain caine mix or its components.
- If you must use products that contain caine mix on pets or children, wear protective gloves. Utility gloves made of natural or synthetic rubber or vinyl are good for working with most preparations that contain caine mix or its components.
- If you think that you contact caine mix or its components at work, ask your employer for Material Safety Data Sheet (MSDS), package insert or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients or package insert:

- Benzocaine or 4-carbethoxyaniline; ethyl PABA; benzoic acid, 4-amino-, ethyl ester; ethyl 4-aminobenzoate
- Tetracaine or dimethylaminoethyl p-butyl-aminobenzoate; benzoic acid, 4-(butylamino)-, 2-(dimethylamino)ethyl ester
- Dibucaine or cinchocaine; butyloxycinchoninic acid diethylethylenediamide; 2-butoxyquinoline-4-carboxylic acid diethylaminoethylamide

Benzoic Acid Derivatives:

- Metabutethamine
- Procaine
- Proparacaine
- Benoxinate hydrochloride
- Butamben picrate
- Cocaine hydrochloride
- Butacaine
- Amylocaine
- Benzamine
- Naepaine
- Cyclomethycaine
- Orthocaine
- Meprylcaine hydrochloride
- Propoxycaine
- Metabutozycaine risocaine
- Piperocaine hydrochloride
- Chloroprocaine hydrochloride
- Hexylcaine hydrochloride
- Meta-aminobenzoic acid esters
- Proparacaine hydrochloride

Other Agents:

- Procainamide – anti-arrhythmic
- PABA esters – sunscreens
- Hydrochlorothiazide – diuretic
- Aniline dyes
- Sulfonamides – antibiotics
- Sulfonylureas – antidiabetic agent
- para-aminobenzoic acid (p-amino-benzoic acid) (PABA) – sunscreens
- Paraphenylenediamine (p-phenylenediamine) hair and fur dyes
- Para-aminosalicylic acid (p-amino-salicylic acid) (PAS) – antimicrobial agent

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **caine mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to fragrance mix. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Fragrance mix contains the following eight substances:

- Geraniol
- Hydroxycitronellal
- a-Amylcinnamaldehyde
- Eugenol
- Cinnamaldehyde
- Cinnamyl alcohol
- Isoeugenol
- Oak moss

Fragrances can be found in most products. They are used to add flavor or scent to a product or may mask a product's unpleasant smell. They may come from natural (animals or plants) or synthetic sources.

Contact allergy to fragrances is common.

WHERE IS FRAGRANCE MIX OR ONE OF ITS COMPONENTS FOUND?

At work, you may find fragrance mix or one of its components in the manufacture or use of:

- Herbal and botanical products
- Metal-working fluids
- Pesticides and insect repellents
- Cleaning and degreasing products
- Scented candles and incense
- Scented tobaccos
- Some foods, beverages and oils that contain citrus, clove and cinnamon
- Dental medicaments and cements
- Essential oils and aromatherapy
- Polishes and waxes
- Perfumes and colognes
- Paper products
- Air fresheners and deodorizers

At home, you may find fragrance mix or one of its components in:

- Perfumes and colognes
- Scented candles
- Facial tissue and toilet paper
- Pet care and grooming products
- Household cleaners, waxes and polishes
- Car care products, cleaners, waxes and polishes
- Soaps, cleansers, deodorants, toothpastes and hygiene products
- Cosmetics such as foundations and powders, blush, mascaras, eye shadows, eyeliners and pencils
- Some foods, beverages and oils that contain citrus, clove and cinnamon
- Air fresheners and deodorizers
- Pesticides and insect repellents
- Aromatherapy products, incense
- Lipsticks and lip balms
- Nail care products such as polish and remover
- Detergents, fabric softeners and stain removers
- Shampoos, conditioners, hair coloring and haircare products
- Skin ointments, creams, lotions, moisturizers, medications and tanning products
- Shaving products

Fragrances are used to flavor foods and tooth pastes. They are also found in dental materials, topical medicaments and medical pastes and gels such as EKG gels. Sometimes perfumes are added to ventilation systems in buildings and airplanes. Some industrial products such as metal-working fluids, may also contain fragrances.

Fragrances also occur naturally in some foods and spices.

HOW CAN YOU AVOID FRAGRANCE MIX OR ONE OF ITS COMPONENTS?

- Fragrances are found in most personal care and household products and many industrial products. Only use "fragrance-free" products. Avoid products labeled "unscented" because they may still contain a masking fragrance.
- Look for products that do not list "fragrance" or one of the fragrance mix components on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.

Avoid balms, propolis and tea-tree oil.

- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to fragrance mix. Ask for preparations that do not contain fragrances.
- If you must use products that contain fragrances on pets or children, wear protective gloves. Utility or disposable gloves made of natural or synthetic rubber or vinyl are good for working with most products that contain fragrance mix or one of its components.

If you are severely allergic, a diet free of cinnamon, cloves, vanilla and citrus should be considered. Avoid peel from citrus fruits.

- If you think that you contact fragrance mix or one of its components at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Geraniol or geraniol alcohol or geranyl alcohol
- Cinnamaldehyde or cinnamic aldehyde, cinnamal, cassia aldehyde, 3-phenylacrolein
- Hydroxycitronellal or citronelal hydrate, lilyl aldehyde, muguet synthetic, oxydihydrocitronellal
- Cinnamyl alcohol or cinnamic alcohol, 3-phenylallyl alcohol
- Eugenol or allylguaiacol, 2-methoxy-4-allylphenol, 4-hydroxy-3-methoxyallylbenzene
- Isoeugenol or 4-propenylguaiacol, 2-methoxy-4-(1-propenyl)phenol, 4-hydroxy-3-methoxypropenylbenzene
- Amylcinnamaldehyde or amyl cinnamal, jasmine aldehyde, --amyl-, -phenyl acrolein, 2-benzylidene heptanol
- Oak moss or oakmoss, oakmoss oil or extract, oakmoss absolute resin, oakmoss concrete

Other names for fragrances:

- Aroma chemicals
- Essential oils of plants and animals
- Perfumes
- Colognes
- Masking or unscented perfumes
- Toilet water

You also may react to fragrance mix-related substances such as:

- Balsam of Peru and its components (cinnamic acid, methyl cinnamate, cinnamein, vanillin & cinnamyl cinnamate)
- Citral, lylal, colophony, farnesol, propolis balsam
- Cassia oil
- Citronella candles
- Cinnamon
- Cloves
- Narcissus oil
- Sandalwood oil

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **fragrance mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to colophony. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Colophony comes from the sap of coniferous trees such as pines, junipers, firs and cedars. Colophony (or rosin) is found in personal care and beauty products, topical medications, surface coatings, lubricants, adhesives and sealants, as well as in the rosin for string instruments and dancers' shoes.

WHERE IS COLOPHONY FOUND?

At work, you may find colophony in:

- Wood and sawdust
- Coated papers
- Cutting fluids
- Paints and stains
- Asphalt products
- Greases and oils
- Polyethylene
- Waterproofings
- Linoleum
- Wood fillers
- Printing inks
- Lacquers and varnishes
- Polishes and waxes
- Corrosion inhibitors
- Solvents
- Neoprene rubber
- Soldering materials
- Drive belts

At home, you may find colophony in:

- Instrument rosin
- Waxed threads
- Furniture polishes and waxes
- Yellow laundry bar soap
- Match tips
- Creams
- Cosmetics
- Concealers
- Eyeliners
- Lipsticks
- Diapers, feminine napkins
- Wax depilatories
- Pine-oil cleaners
- Glues, adhesives, tapes, stamps
- Fireworks
- Color pencils
- Foundations
- Sunscreens
- Mascaras

Other possible sources include dental-impression materials, ostomy appliances, wound dressings and salicylic acid plasters. Some veterinary medications such as topical salves, hoof ointments and softeners and first-aid ointments, may contain colophony.

Sometimes allergy to colophony may be a marker for allergy to perfumes, flavors and spices. Colophony is present in wood, sawdust and gum from coniferous trees.

HOW CAN YOU AVOID COLOPHONY?*

- Only use products that do not list colophony or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Avoid contact with sawdust and sap from pine trees and other coniferous trees.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to colophony. Ask for preparations that do not contain colophony or related substances.
- Wear protective gloves. Heavy-duty gloves made of vinyl or synthetic rubber are good for temporary work with veterinary medications, pine-oil cleaners, varnishes, or paints. Use cotton gloves to protect your hands from paper products that contain or are coated with colophony.
- If you think that you contact colophony at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a product without colophony or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Colophony
- Abietic alcohol, abietyl alcohol or methyl abietate alcohol
- Disproportionated rosin
- Colophonium
- Rosin, gum rosin or rosin gum
- Wood or pine rosin
- Tall oil
- Abietic acid
- Resina terebinthinae
- Rosin solder flux fume

Colophony-related substances that you may also react to:

- Wood tars
- Fragrances, essential oils and some spices
- Rosin esters
- Spices (nutmeg, paprika, mace, cloves)
- Pine and other evergreen trees

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **colophony** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to paraben mix. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Paraben mix contains the following five substances:

- Methyl p-hydroxybenzoate
- Ethyl p-hydroxybenzoate
- Propyl p-hydroxybenzoate
- Butyl p-hydroxybenzoate
- Benzyl p-hydroxybenzoate

Parabens are used as preservatives in many over-the-counter medications, cosmetics, and personal care and hygiene products.

WHERE IS PARABEN MIX OR ONE OF ITS COMPONENTS FOUND?

At work, you may find paraben mix or one of its components in the manufacture or use of:

- Metal-working oils and fluids
- Cosmetics
- Personal care and hygiene products
- Hair care products
- Agriculture-food production and processing
- Veterinary medications and pet care products
- Antiseptic topical medications

At home, you may find paraben mix or one of its components in:

- Lipsticks and lip balms
- Pet care and grooming products
- Soaps, cleansers and hygiene products
- Topical medications for skin pain or infections or hemorrhoid treatments
- Skin ointments, creams, lotions, sunscreens and moisturizers
- Shaving products
- Preservatives used in some foods
- Shampoo, conditioner, hair coloring and hair care products
- Cosmetics such as foundations and powders, blush, mascaras, eye shadows, eyeliners and pencils, lipsticks, quick-dry nail products, bronzers, makeup removers

Parabens are found in many dermatological creams, ear and nose drops, rectal and vaginal medications, bandages and local anesthetics.

HOW CAN YOU AVOID PARABEN MIX AND ITS COMPONENTS?

- Use products that do not list paraben mix or related chemicals on the label, ingredients list, product insert or Material Safety Data Sheet (MSDS). If no information is available, talk to your pharmacist or contact the product manufacturer.
- Some patients who are allergic to paraben mix can wear cosmetics that contain parabens without reacting, but you should stop using a product if skin symptoms develop. Eating foods containing paraben preservatives is rarely a problem.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to paraben mix or one of its components. Ask for preparations that do not contain paraben mix or related substances.
- If you must use products that contain parabens on pets or children, wear protective gloves. Utility or disposable gloves made of natural or synthetic rubber or vinyl are good for working with products that contain paraben mix or one of its components.
- If you think that you contact paraben mix or one of its components at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Methyl p-hydroxybenzoate or methylparaben; 4-hydroxybenzoic acid methyl ester; methyl parahydroxybenzoate; p-methoxycarbonylphenol
- Ethyl p-hydroxybenzoate or ethylparaben; 4-hydroxybenzoic acid ethyl ester; ethyl p-oxybenzoate; p-carbethoxyphenol
- Propyl p-hydroxybenzoate or propylparaben; 4-hydroxybenzoic acid propyl ester
- Butyl p-hydroxybenzoate or butylparaben; 4-hydroxybenzoic acid butyl ester
- Benzyl p-hydroxybenzoate or benzylparaben; phenylmethyl 4-hydroxybenzoate; p-hydroxybenzoic acid benzyl ester

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **paraben mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

NEGATIVE CONTROL

The negative control is an uncoated patch that contains neither allergen nor vehicle. The patch is made of polyester like the rest of the T.R.U.E. TEST[®] panel. The tape contains rayon fibers and the adhesive is acrylate-based. The negative control can help doctors interpret doubtful reactions to the other patches that contain allergens.

It is very unlikely that patients would react to the negative control. If a reaction is observed at this patch site, it may mean that a patient is allergic to the polyester patch material used in T.R.U.E. TEST. It also may mean that a patient has extremely sensitive skin, making it difficult to interpret patch test or skin test reactions in general.

Your T.R.U.E. TEST results indicate that you have a contact allergy to balsam of Peru. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Balsam of Peru is a fragrant resinous liquid harvested from trees grown in Central America. Not commonly used today, balsam of Peru may still be found as a fragrance, flavor, or antibacterial ingredient. Balsam of Peru contains a mixture of many substances related to cinnamon, vanilla and clove fragrances, and flavorings.

A positive patch test to balsam of Peru often indicates fragrance allergy.

WHERE IS BALSAM OF PERU FOUND?

At work, you may find balsam of Peru or one of its components used to add flavor or fragrance in the manufacture of:

- Herbal and botanical products
- Cleaning products
- Dental medicaments and cements
- Pesticides
- Scented candles
- Perfumes and colognes
- Scented tobaccos
- Some foods and spices
- Essential oils & aromatherapy products
- Air fresheners and deodorizers

At home, you may find balsam of Peru or one of its components in:

- Perfumes and colognes
- Cosmetics
- Insect repellents
- Medicinal creams and ointments
- Oral and lip medications
- Tomatoes, citrus
- Chocolates
- Chewing gums
- Flavored tobaccos
- Scented candles
- Baby powders
- Sunscreens, suntan lotions
- Hair conditioners and shampoos
- Medicated lozenges
- Pesticides
- Air fresheners and deodorizers
- Colas, sodas and flavored beverages
- Wines, liquors and aperitifs
- Cinnamon, vanilla and other spices
- Essential oils & aromatherapy products

Balsam of Peru may be found in veterinary preparations.

HOW CAN YOU AVOID BALSAM OF PERU?

- Only use products that do not list balsam of Peru or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS).
- Choose fragrance-free personal care products and cosmetics. Avoid “unscented” products because they contain a masking fragrance related to balsam of Peru.
- **Be especially careful with diaper products and hemorrhoid treatments.**
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to balsam of Peru. Ask for preparations that do not contain balsam of Peru or related substances.
- If your symptoms are severe, your doctor may recommend a special diet to reduce your exposure to foods that may contain balsam of Peru in flavors and spices.
- Wear protective gloves. Gloves made of natural or synthetic rubber or vinyl are good for working with products that contain balsam of Peru – provided the gloves have no added flavors.

- If you think that you contact balsam of Peru at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Balsam of Peru or Myroxylon pereirae oleoresin; Peruvian balsam; balsam Peru oil or extract; balsam fir oleoresin or oil; hyperabsolute balsam, Peru; cinnamein, balsam of Tolu, China oil, black balsam, Surinam balsam, Indian balsam, Honduras balsam

Balsam of Peru may contain:

- Cinnamic or cinnamyl alcohol; 3-phenyl-2-propenoic acid; 3-phenylacrylic acid
- Cinnamal or cinnamic aldehyde; cinnamaldehyde; 3-phenyl-2-propenal
- Methyl cinnamate or methyl cinnamylate; cinnamic acid methyl ester; methyl 3-phenylpropenoate
- Benzyl cinnamate or cinnamein; cinnamic acid benzyl ester; phenylmethyl 3-phenyl-2-propenoate
- Vanillin or vanillic aldehyde; vanillaldehyde; 2-methoxy-4-(2-propenyl)phenol; 2-methoxy-4-allylphenol
- Eugenol or allylguaiacol; 2-methoxy-4-(2-propenyl)phenol; 2-methoxy-4-allylphenol
- Cinnamyl cinnamate or styracin; 3-phenylallyl cinnamate
- Benzoic alcohol
- Benzyl benzoate and other benzoates
- Benzyl acetate
- Benzoic acid
- Benzaldehyde
- Benzyl salicylate
- Cinnamic aldehyde
- Citrus peel
- Coniferyl alcohols
- Coumarin
- Farnesol
- Isoeugenol
- Nerolidol
- Resinous substances
- Tea Tree Oil

You also may react to substances related to balsam of Peru such as:

- Fragrance mix components
- Propolis balsam
- Balsam of Copaiba
- Essence of orange peel
- Turpentine
- Beeswax
- Diethylstilbestrol
- Spices (e.g. Jamaican pepper, cinnamon, cloves, nutmeg, paprika, curry, vanilla)
- Gum benzoin
- Colophony
- Tincture of krameria
- Balsam of Tolu
- Storax (Styrax)
- Wood tars
- Coumarin

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **balsam of Peru** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to ethylenediamine dihydrochloride. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Ethylenediamine is a substance that is used to manufacture various drugs and industrial compounds. Ethylenediamine dihydrochloride is a colorless liquid that is used as a preservative, emulsifier and stabilizer in certain medical creams, cosmetics and a variety of other products.

WHERE IS ETHYLENEDIAMINE FOUND?

At work, you may find ethylenediamine used in the manufacture of:

- Bleach activators
- Drugs and polyamines
- Lubricants and waxes
- Metal-binding agents known as chelators
- Curing agents in epoxy resins and coatings
- Surfactants, emulsifiers and dispersants
- Binders for printing inks
- Urethane foam catalysts
- Textile dye-assist compounds
- Carbamates for fungicides and rubber additives
- Fuel additives and corrosion inhibitors

At home, you are unlikely to encounter ethylenediamine even though it has been used as a starting material to produce many drugs, laundry additives, fungicides and cured epoxy products.

Some antihistamines used in the treatment of asthma, hay fever, motion sickness and hives may cross react with ethylenediamine dihydrochloride. You may have a general skin reaction to these antihistamine drugs as well as to aminophylline drugs used for asthma, which may contain ethylenediamine dihydrochloride as an impurity.

Rarely, a few individuals with ethylenediamine allergies may develop skin reactions to some piperazine-related drugs, including some antihistamines. Talk to your doctor if you have any reactions to these medications.

You may be exposed to ethylenediamine dihydrochloride through industrial products such as solvents, textile resins, inhibitors, antifreezes, epoxy hardeners and coolant oils.

Water-based industrial products may contain ethylenediamine dihydrochloride as a fungicide. It is also a component of some dyes, insecticides and synthetic waxes.

HOW CAN YOU AVOID ETHYLENEDIAMINE?

- Avoid direct skin contact with chelators and the substances used to manufacture carbamates, epoxy resin curing agents, fuel additives and the other industrial products listed above.
- Do not use products that list ethylenediamine or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist, dentist and veterinarian that you are allergic to ethylenediamine. Ask for preparations that do not contain ethylenediamine or related substances.
- Wear protective gloves. Heavy-duty gloves made of natural or synthetic rubber or vinyl may be good for working with many potential sources of ethylenediamine.
- If you think that you contact ethylenediamine at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert:

- Ethylenediamine dihydrochloride or 1,2-ethanediamine dihydrochloride, chlorethamine, dimethylenediamine dihydrochloride, ethylenediammonium chloride and 1,2-diaminoethane dihydrochloride

Ethylenediamine dihydrochloride-related substances that you may also react to:

- Diethylenetriamine (DETA)
- Triethylenetetramine (TETA)
- Dipropylenetriamine (DPTA)
- Tetraethylenepentamine (TEPA)
- Aminophylline
- Piperazine

Other related substances to which you may react:

- Aminophylline
- Buclizine
- Chlorcyclizine
- Cyclizine
- Hydroxyzine hydrochloride
- Epoxy resin catalysts (ethylenediamine and chemically related amines such as diethylenediamine, dipropylenetriamine, triethylenetetramine, tetraethylenetetramine, trimethylhexamethylenediamine)
- Meclizine
- Piperazine-based antihistamines
- Promethazine hydrochloride (HCl)
- Tripelennamine

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **ethylenediamine dihydrochloride** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to cobalt dichloride. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Cobalt is a silvery metal with many properties similar to those of iron and nickel. Cobalt is used with other metals to make metal alloys.

WHERE IS COBALT FOUND?

At work, you may find cobalt in:

- Bricks and cement
- Metal carbide manufacturing, etching, grinding, welding & metal working materials
- Cobalt-based pigments, additives and drying agents in paints
- Catalyst/promoter in resins and plastics
- Printing inks
- Cobalt-based pigments and glazes during pottery manufacture and finishing
- Orthopedic and dental implants, dental prosthesis

Major industrial use of cobalt is in alloys or as a binder of tungsten in hard metals. Cobalt is present in magnets, welding rods (also in the smoke) and welding stainless steel. Industrial exposure to cobalt can include glass, lubricating oils and animal feeds. Cobalt is used in the rubber tire industry as an oxidizing agent in automobile exhaust control and as a catalyst or accelerator for the production of terephthalate, polyester and acrylate plastics.

At home, you may find cobalt in:

- Cobalt-based pigments, additives & drying agents in ceramic paints and glazes
- Some spray paints and enamels, wood stains, paints and finishes
- Bricks and cements
- Etching and grinding metal carbides
- Metal tools, utensils & objects such as keys, magnets, clothing fasteners & jewelry
- Orthopedic and dental implants, dental prostheses
- Vitamin B12 supplements

Cobalt is also used as pigment in light brown hair dyes and makeup. It is sometimes used in blue tattoos and may be found in solid soaps.

HOW CAN YOU AVOID COBALT?

- Only use products that do not list cobalt or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Because cobalt and nickel can be found in many of the same metal products, allergies to both metals can develop. To prevent this, consider wearing jewelry made of sterling silver or other precious metals, rather than costume jewelry. Coat or cover the handles of frequently handled metal objects likely to contain cobalt.
- Metallic items that are difficult to avoid such as keys may be coated with several layers of clear nail polish or polyurethane lacquer. Larger objects can be covered with plastic, for example, the tools used by hairdressers and textile workers. If possible, select scissors and tools with handles of plastic, wood, or high-quality stainless steel.

- Reactions to metal instruments used by dentists and physicians are unlikely because skin contact is too brief. Reactions to metal dental appliances and orthopedic implants are rare.
- At work, avoid exposure to metallic dust and cobalt etching; metal salts for electroplating; wet cement and wet alkaline clay containing cobalt, paints, lacquers, varnishes, printing inks; and animal feed enriched with cobalt salts. If possible, avoid wet work since moisture increases the penetration of cobalt into the skin.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to cobalt. Ask for products that do not contain cobalt or related substances.
- If you must contact products that contain cobalt, wear protective gloves. Heavy-duty gloves made of natural or synthetic rubber or vinyl can provide sufficient protection when working with liquids or wet cement and clay. Fabric or leather gloves can protect your hands from cobalt while working with dry metal, ceramics, or cement products.
- If you think that you contact cobalt at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.
- Jewelry and other metal objects can easily be tested for the presence of cobalt using a spot test called Reveal & Conceal Cobalt Spot Test available on myskinallergy.com

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Cobalt or cobalt dust and fume; cobalt metal and metal powder
- Cobalt-related substances that you may also react to:
 - Nickel
 - Chromate

Synonyms for cobalt:

- Cobalt blue
- Cobaltous chloride
- Cobalt dichloride
- Cobalt chloride
- Cobaltous chloride hexahydrate
- Cobalt (II) chloride hexahydrate

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN COBALT?*

- Metal costume jewelry, piercings and hair ornaments
- Cobalt-based pigments in paints, enamels, inks and glazes
- Metal fasteners including buttons, zippers, snaps, hooks, rivets, buckles, pins
- Metal tools, equipment, utensils and keys

WHAT PRODUCTS MAY NOT CONTAIN COBALT?*

- Stainless steel, plastic, gold (18k) or silver jewelry or decorative items
- Stainless steel tools and utensils or those with plastic-coated handles
- Titanium or stainless steel orthodontic materials and ceramic brackets
- Organic nonmetallic pigments for paints, enamels, inks, and glazes

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **cobalt dichloride** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to *p*-tert-butylphenol formaldehyde resin. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

This substance is most commonly found in glues; surface coatings; and adhesives used in shoes, upholstery, leather, and hobbies.

WHERE IS P-TERT-BUTYLPHENOL FORMALDEHYDE RESIN FOUND?

At work, you may find *p*-tert-butylphenol formaldehyde resin in and around:

- Manufacture and use of polychloroprene adhesives
- Manufacture and repair of shoes, especially shoes and components made of rubber
- Adhesives used on electrocardiograph monitoring electrodes
- Production of fiberglass and mineral fiber insulation
- Manufacture of construction materials such as laminated wood and plywood products
- Surface coatings, varnishes and inks
- Duplicating paper

It is also used in the automotive industry as a sealant and brake lining for cars.

At home, you may find *p*-tert-butylphenol formaldehyde resin in:

- Glued rubber and leather goods such as shoes, handbags, watchbands, hats and belts. When shoes get wet, the allergen in these glues may be dissolved and can come in contact with the skin.
- Glues for fabric and upholstered furniture

It may be included in cosmetics (e.g., deodorants, lip liner) and plastic mail adhesives.

HOW CAN YOU AVOID P-TERT-BUTYLPHENOL FORMALDEHYDE RESIN?

- Only use products that do not list *p*-tert-butylphenol formaldehyde resin or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Avoid the use of waterproof glues in leather and rubber shoes. If you must wear leather or rubber shoes, change socks frequently to prevent exposure through sweat. You may have to replace shoes that become soaked by water if you develop a rash on your feet. Do not have components of shoes reglued by a shoe repair person.
- Avoid direct skin contact with glued wood or laminated wood products as well as with fiberglass and mineral fiber materials.
- It may be necessary to avoid duplicating paper and glued fabric materials.
- If you must work with materials that may contain *p*-tert-butylphenol formaldehyde resin, wear protective gloves. Heavy-duty chemically resistant gloves may be good for working with adhesives that contain this resin. When working with finished wood and dry products, use fabric or leather gloves to protect your hands from contacting the resin.
- Tell your physician and pharmacist that you are allergic to *p*-tert-butylphenol formaldehyde resin. Ask for products that do not contain *p*-tert-butylphenol formaldehyde resin or related substances.
- If you think that you contact *p*-tert-butylphenol formaldehyde resin at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- *p*-tert-butylphenol formaldehyde (PTBP) or paraformaldehyde
- formaldehyde, *p*-tert-butylphenol polymer
- *p*-tert-butylphenol formaldehyde resin (PTBP FR)
- formaldehyde, *p*-tert-butylphenol polymer
- 4-(1,1-cimethylethyl)phenol, formaldehyde polymer

Related substances to which you may react:

- Neoprene adhesives

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN P-TERT-BUTYLPHENOL FORMALDEHYDE RESIN?*

- Leather and rubber adhesives in the shoe and upholstery industries

WHAT PRODUCTS MAY NOT CONTAIN P-TERT-BUTYLPHENOL FORMALDEHYDE RESIN?*

- Shoes and products made of vinyl, plastic, silicone, polyurethane, polyethylene, or acrylates
- Scanpor[®] surgical paper tape

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain ***p*-tert-butylphenol formaldehyde resin** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to epoxy resin. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Epoxy resins are found in two-component adhesives, coatings, paints and composite materials with a curing agent. These epoxy resins are commonly found in industry and at home.

WHERE IS EPOXY RESIN FOUND?

At work, you may find epoxy resin in and around:

- Production of molds, dies and models
- Two-component paints and adhesives
- Electron microscopy embedding media
- Art and sculpture materials
- Manufacture of epoxy composite products such as tennis racquets, skis and circuit boards
- Lightweight equipment and rotor production
- Flooring, floor sealers and coatings
- Protective finishes, coverings and coatings
- Dental restoratives and epoxies

The most common epoxy exposure is from 2-component adhesive. Epoxy resin is also found in adhesive tapes, surface coatings, paints, putties and inks. It may be found in encapsulation of electrical parts and in some dental bonding agents.

Epoxy can be added to other plastic materials (e.g. some vinyl plastic products such as eyeglass frames, vinyl gloves, handbags and plastic necklaces).

In industry, epoxy resin is used for product finishes and repairs such as floor, wall, road and bridge coatings; appliance finishes; automotive primers; and flame-retardants. Skin reactions may occur from exposure to varnishes, laminates, paints, tool handlers, die-castings, or model-making as well as to materials used by artists and sculptors.

Note: Only resin and hardener, the two components of uncured epoxy, are allergenic. Cured (hardened plastic) is seldom a problem.

At home, you may find epoxy resin in and around:

- Two-component paints, glues and adhesives
- Model and mold construction
- Flooring, floor sealers and coatings
- Protective finishes, coverings and surface coatings
- Art and sculpture materials
- Fiberglass repair

HOW CAN YOU AVOID EPOXY RESIN?

- Do not touch or handle uncured epoxy resin and avoid breathing fumes. Only use products that do not list epoxy resin or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist and dentist that you are allergic to epoxy resin. Ask for products that do not contain epoxy resin or related substances.
- If you must work with epoxy resin, use Silvershield[®]/4H[®] glove protective gloves that are chemically resistant. For hobby and detail work, use tools rather than bare hands when working with epoxy resin.
- If you think that you contact epoxy resin at work, ask your employer for a MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing chemically resistant protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Epoxy resin or diglycidyl ether of bisphenol A
- Diglycidyl bisphenol a
- Diomethane diglycidyl ether
- Diglycidyl diphenylpropane ether
- 2,2-bis(4-glycidyloxyphenyl)propane
- Araldite[®]
- 4,4'-Isopropylidenediphenol diglycidyl ether
- DGEBA epoxy resin
- Epichlorohydrin
- 4,4'-Isopropylidenediphenol-epichlorohydrin

You also may react to substances related to bisphenol A based epoxy resins such as:

- Bisphenol A-glycidyl methacrylate
- Epoxy resins with diglycidyl ethers of bisphenol F
- Tosylamide epoxy resin

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **epoxy resin** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to carba mix. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Carba mix contains the following three allergens:

- Diphenylguanidine
- Zinc dibutyldithiocarbamate
- Zinc diethyldithiocarbamate

These chemicals are used as fungicides and pesticides and also in the manufacture of many rubber products. You are most likely to contact these substances when using, wearing or handling rubber products at work or at home.

WHERE IS CARBA MIX OR ONE OF ITS COMPONENTS FOUND?

At work, you may find carba mix or one of its components in the manufacturing or use of:

- Industrial and safety products made with natural rubber, butyl rubber, nitrile or neoprene such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation and sheeting
- Office products made with natural rubber, nitrile, or neoprene such as rubber bands, erasers, mats and utility gloves
- Health care equipment made with natural rubber, butyl rubber, nitrile or neoprene such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons and tubing
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as wetsuits, shoes, boots, masks, and racquet and club handles
- Chemicals used as fungicides or to prevent mildew or mold

At home, you may find carba mix or one of its components in:

- Household products made with natural rubber, butyl rubber, nitrile or neoprene such as rubber bands, ear and headphones, masks, condoms and diaphragms, goggles, shoes, utility gloves, swimwear, toys, hoses, tubing and elastic
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as shoes, wetsuits, boots, masks, and racquet and club handles
- Fungicides and pesticides used in the garden

Carba mix chemicals also can be found in some soaps, shampoos, disinfectants and adhesives as well as in anti-rust products.

HOW CAN YOU AVOID CARBA MIX OR ONE OF ITS COMPONENTS?

- Avoid direct skin contact with rubber products in your car, at work and at home. Use rubber-free alternatives made of vinyl, plastic, leather, wood, or fabric.

Some surgical gloves are labeled “hypoallergenic and rubber free” and are made of synthetic materials free of latex and all rubber accelerators. Examples are some gloves made of a synthetic co-polymer of styrene and butadiene, polyvinyl (PVC) or nitrile. Articles made with PVC, polyvinyl acetate or silicone are also suitable alternatives.

- Use fabric or plastic films to handle rubber products and to avoid direct skin contact.

Avoid rubber insoles, rubber boots and rubber shoes such as sneakers and tennis shoes. Wear solid leather shoes with no inner or outer soles, such as moccasins. If in doubt, wear new shoes for a few days and watch for a rash. Try insoles free of carba mix chemicals to see if insoles makes dress shoes wearable for you.

Beware of socks and stockings worn with shoes containing carba mix chemicals. The carba mix chemicals can contaminate the shoes and do not wash out.

- Only use products that do not list carba mix, one of its components, or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS).
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to carba mix, which is often used in rubber products. Ask for rubber products that do not contain carba mix or related substances.
- Wear protective gloves and clothing made of leather, fabric, plastic or rubber that is free of carba mix and related substances.
- Use heavy duty nonrubber gloves (SmartPractice[®] Heavy Duty vinyl or Silvershield[®]/4H[®] gloves) when working with chemicals that might contain carba mix or one of its components.
- If you think that you contact carba mix or one of its components at work, ask your employer for MSDS or manufacturer information on the product(s). Wear protective clothing when handling items such as rubber hoses, seals, and cables. Talk to your employer about using a different product.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with carba mix or the following names in the list of ingredients, MSDS, or package insert.

- Diphenylguanidine or 1,3-Diphenylguanidine; N,N'-Diphenylguanidine
- Zinc dibutyldithiocarbamate or bis(N,N-dibutyldithiocarbamato)zinc; carbamic acid dibutyldithio-, zinc complex; zinc bis(dibutyldithiocarbamate)
- Zinc diethyldithiocarbamate or diethyldithiocarbamic acid zinc salt; zinc bis(diethyldithiocarbamate); zinc diethylcarbomodithioate

You also may react to the following substances because they are similar to carbamates:

- Tetramethylthiuram monosulfide
- Tetramethylthiuram disulfide
- Dipentamethylenethiuram disulfide
- Disulfiram
- Manganese salts of diethyl- or dibutyl-dithiocarbamates

If your skin is regularly exposed to rubber, you may develop reactions to other substances used in the manufacture of rubber such as mercaptobenzothiazoles, mercapto mix, and thioureas.

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN CARBA MIX OR RELATED SUBSTANCES?*

- Gloves, condoms, bottle nipples and other products made of natural rubber, butyl rubber, nitrile or neoprene
- Antabuse[®] (medication for alcoholism)

WHAT PRODUCTS MAY NOT CONTAIN CARBA MIX OR RELATED SUBSTANCES?*

- Products made entirely of vinyl, plastic, silicone, polyurethane, polyethylene, or acrylates
- Gloves made of vinyl, polyurethane, polyethylene, or special thermoplastic elastomers
- Nitrile or neoprene gloves manufactured without carbamates or thiurams
- Fungicides without carbamates

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **carba mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to black rubber mix chemicals. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Black rubber mix contains the following three substances:

- N-isopropyl-N'-phenyl paraphenylenediamine
- N-cyclohexyl-N'-phenyl paraphenylenediamine
- N, N'-diphenyl paraphenylenediamine

These allergens are rubber additives known as antioxidants. Because they discolor the rubber, these additives primarily are used to produce black rubber.

WHERE IS BLACK RUBBER MIX OR ONE OF ITS COMPONENTS FOUND?

At work, you may find black rubber mix or one of its components in the manufacture of:

- Black rubber products such as tires, belts, masks, hoses, cables, aprons, gloves, gaskets, flanges, stoppers, shoes and boots, sheeting and flooring
- Black rubber components on health care and laboratory equipment
- Office products made with black rubber components such as feet and wheels on equipment

At home, you may find black rubber mix or one of its components in:

The black rubber mix ingredients are less common in products for home use, but they may be found in certain types of rubber articles.

- Household products made with black rubber such as masks and goggles, shoes and tires, watchbands, underwear elastic, stockings, dental tips
- Sports equipment made with black rubber such as boots, masks, squash balls, and racquet and club handles

The black rubber mix ingredients are seldom used in the manufacture of rubber gloves for domestic or hospital use.

Hair dyes and textile dyes may cross react with the black rubber mix chemicals.

HOW CAN YOU AVOID BLACK RUBBER MIX OR ONE OF ITS COMPONENTS?

- Avoid skin contact with black and dark gray rubber. If an object looks like it is made of rubber and it is black, it probably will be a problem. Avoid black rubber sports equipment. Carry gloves in your car in case of a tire change. Use caution when handling other parts that may contain rubber.
- Workers with this allergy may experience a problem handling rubber hoses, seals and cables. If you suspect that you are being exposed to this allergen at work, consult your employer regarding Material Safety Data Sheet (MSDS). Talk to your employer about using a different product or about wearing protective gloves and clothing.
- Only use products that do not list black rubber mix or one of its components or related chemicals on the label, ingredient list or MSDS. If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to black rubber mix or one of its components.
- If you must handle black rubber products, wear protective gloves. Utility or disposable gloves made of fabric, natural or synthetic rubber or vinyl are good for protecting you from black rubber mix or one of its components.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with black rubber mix or the following names in the list of ingredients, MSDS or package insert.

- N-Isopropyl-N'-phenyl-paraphenylenediamine or N-phenyl-N'-isopropyl-p-phenylenediamine
- N-Cyclohexyl-N'-phenyl-paraphenylenediamine or N-cyclohexyl-N'-phenyl-1,4-benzenediamine
- N,N'-Diphenyl-paraphenylenediamine or diphenyl-p-phenylenediamine; 1,4-dianilinobenzene; p-phenylaminodiphenylamine; p-bis(phenylamino)benzene; 4,4'-diphenyl-p-phenylenediamine

Common trade names:

- N-Phenyl-N-cyclohexyl-p-phenylene-diamine (CPPD) Phenylcyclohexyl PPD Flexzone™ GH
- Isopropyl-N-phenyl-p-phenylenediamine (IPPD)
- Akrochem® Antioxidant ANTO "H"[™] IP
- Isopropyl 0 PPD
- Flexzone 3-C IPPD
- Permanex™ PD1
- Santoflex®
- N,N -Diphenyl-p-phenylenediamine (DPPD) Diphenyl® PPD

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN BLACK RUBBER MIX OR ONE OF ITS COMPONENTS?*

Products made with black rubber such as tires and wheels, industrial belts, masks and goggles, boots and shoes, sports equipment, plugs and stoppers.

WHAT PRODUCTS DO NOT CONTAIN BLACK RUBBER MIX OR ONE OF ITS COMPONENTS?*

Products made entirely of vinyl (PVC), plastic, silicone, polyurethane, polyethylene, or acrylates.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **black rubber mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to Cl+Me– Isothiazolinone (also known as MCI/MI) or one of its components. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Cl+Me–Isothiazolinone contains methylchloroisothiazolinone (MCI) and methylisothiazolinone (MI).

These substances are used as preservatives and biocides in many personal care, household and industrial products.

WHERE IS CL+ ME– ISOTHIAZOLINONE OR ONE OF ITS COMPONENTS FOUND?

At work, you may find Cl+ Me– Isothiazolinone or one its components in:

- Industrial metal working, lubricating and cutting fluids
- Latex emulsions and paints
- Manufacture of cleaning, personal hygiene, cosmetic, skin care and hair care products
- Air conditioning and cooling liquids
- Adhesives and glues
- Cleaning products, hand soaps and cleansers
- Slime control in paper mills

At home, you may find Cl+ Me– Isothiazolinone or one its components in:

- Cosmetics such as foundations and powders, blush, mascaras, eye shadows, eyeliners and pencils
- Cleaning products, waxes, polishes and paints
- Skin care products such as creams, lotions, moisturizers and tanning products
- Hair care products such as conditioners, shampoos and coloring agents
- Laundry products such as detergents, and fabric softeners
- Personal hygiene items such as soaps, cleaners, bubble baths and wipes

HOW CAN YOU AVOID CL+ ME– ISOTHIAZOLINONE?

- This substance is very common in personal care, cosmetic and household products. Only use products that do not list Cl+ Me– Isothiazolinone (MCI/MI) or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If there no information is available, find an alternate product or contact the product manufacturer.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to Cl+ Me– Isothiazolinone (MCI/MI). Ask for preparations that do not contain this substances.
- If you must use products that contain Cl+ Me– Isothiazolinone (MCI/MI) on pets or children, wear protective gloves. Utility gloves made of natural or synthetic rubber or vinyl are good for working with products that may contain Cl+ Me– Isothiazolinone (MCI/MI).
- If you think that you contact Cl+Me– Isothiazolinone at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing heavy-duty protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Methylchloroisothiazolinone (MCI)
- 5-chloro-2-methyl-4-isothiazolin-3-one
- Kathon
- 5-chloro-2-methyl-2H-isothiazol-3-one
- Methylisothiazolinone (MI)
- 2-methyl-4-isothiazolin-3-one
- 2-methyl-3(2H)-isothiazolone
- 2-methyl-2H-isothiazol-3-one

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **Cl+Me–isothiazolinone** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to quaternium-15. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Quaternium-15 is commonly used in personal care products such as cosmetics, soaps and shampoos. It belongs to a group of preservatives known as formaldehyde-releasing agents.

WHERE IS QUATERNIUM-15 FOUND?

At work, you may find quaternium-15 or formaldehyde-releasing agents in:

- Urea-formaldehyde foam insulation
- Electrode attachment gels used in healthcare
- Embalming and preserving fluids
- Pressed wood such as particleboard, medium density fiberboard, plywood, and oriented strandboard
- Urea-formaldehyde resins
- Metal-working fluids and coolants
- Glues, inks, toners and paints
- Cleaning products, waxes and polishes

At home, you may find quaternium-15 or formaldehyde-releasing agents in:

- Cosmetics such as foundations and powders, blush, mascaras, eye shadows, eyeliners and pencils
- Durable press (wrinkle-resistant) fabrics
- Cleaning products, waxes, polishes and paints
- Tobacco and cigarette smoke
- Skin care products such as creams, lotions and moisturizers
- Personal hygiene items such as soaps, cleansers and shampoos
- Smoke from wood, coal, kerosene or charcoal fires

HOW CAN YOU AVOID QUATERNIUM-15?

- Do not use products with quaternium-15 on your face, hair or body. Only use products that do not list quaternium-15 on the label, ingredient list or Material Safety Data Sheet (MSDS). It may be wise to avoid products that contain other formaldehyde-releasing agents.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to quaternium-15. Ask for preparations that do not contain quaternium-15 or other formaldehyde-releasing agents.
- If you must use products with quaternium-15 at work on your children or pets, wear protective gloves. Heavy-duty gloves made of natural or synthetic rubber or vinyl are good for working with products that contain quaternium-15.
- If you think that you contact quaternium-15 at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Products that include other quaternium substances are safe to use, but avoid products with the following names in the list of ingredients, MSDS or package insert.

- Quaternium-15 or chloroallyl methenamine chloride
- Hexamethylenetetramine chloroallyl chloride
- 3,5,7-triaza-1-azoniaadamantane, 1-(3-chloroallyl)-, chloride; N-(3-chloroallyl) hexaminium chloride

You also may react to other formaldehyde-releasing agents such as:

- Formaldehyde or formalin; formic aldehyde; oxymethylene
- Bronopol or 2-bromo-2-nitropropane-1,3-diol
- Diazolidinyl urea or N,N'-bis(hydroxymethyl) urea; 1-(1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl)-1,3-bis(hydroxymethyl)urea
- DMDM hydantoin or 1,3-cimethylol-5,5-dimethylhydantoin; 1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione
- Imidazolidinyl urea or imidurea; or N,N"-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)urea
- Tris nitro or trimethylolnitromethane; 2-nitro-2-(hydroxymethyl)-1,3-propanediol; tris(hydroxymethyl)nitromethane; nitroisobutylglycerol

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **quaternium-15** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to methyldibromo glutaronitrile (MDBGN). This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Methyldibromo glutaronitrile, also referred to as dibromodicyanobutane, is a component of the preservative of Euxyl K400. Euxyl K400 also contains phenoxyethanol (PE). Because of its sensitizing potential, it has been banned for use in leave-on products in Europe. The European Cosmetic Directive prohibits the use of methyldibromo glutaronitrile. Therefore, it should not be found in cosmetic products sold in European Union states. You are most likely to contact methyldibromo glutaronitrile when using cosmetic and personal care products such as body creams, facial and hand lotions, sunscreens, baby lotions, shower gels, ultrasonic gels, toilet papers, shampoos and massage oils. It is also found in cutting oils, drilling oils, glues and coolants.

WHERE IS METHYLDIBROMO GLUTARONITRILE FOUND?

At work, you may find methyldibromo glutaronitrile in:

- Cutting oils and drilling oils
- Coolants
- Glues and adhesives

At home, you may find methyldibromo glutaronitrile in:

- Skin care products such as body creams, facial/hand lotions, sunscreens, massage oils and baby lotions
- Personal hygiene products such as moist toilet paper, shampoos, conditioners and shower gels
- Medical products such as ultrasonic gels

HOW CAN YOU AVOID METHYLDIBROMO GLUTARONITRILE?

- Avoid direct skin contact with products that contain methyldibromo glutaronitrile. Be sure to read ingredients in all personal care products before you use them.
- Only use products that do not list methyldibromo glutaronitrile or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to methyldibromo glutaronitrile. Ask for products that do not contain methyldibromo glutaronitrile or related substances.
- Use heavy-duty utility gloves when working with chemicals that might contain methyldibromo glutaronitrile.
- If you think that you contact methyldibromo glutaronitrile at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing different protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- 1,2-Dibromo-2,4-dicyanobutan
- 2-Bromo-2-(bromomethyl) glutaronitrile
- 2-Bromo-2-(bromomethyl) pentanedinitrile
- Glutaronitrile, 2-bromo-2-(bromomethyl)-
- Methyldibromo glutaronitrile
- Pentanedinitrile, 2-bromo-2-(bromomethyl)-
- MDBGN

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **methyldibromo glutaronitrile** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to p-phenylenediamine. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

p-phenylenediamine is a dark dye used in almost all permanent hair dyes and in some semipermanent hair colorings such as henna.

WHERE IS P-PHENYLENEDIAMINE FOUND?

At work, you may find p-phenylenediamine in:

- Dyes and coloring agents for textiles, furs and other products
- Permanent and some semipermanent hair dyes
- Photographic developers
- Temporary, paint-on and black henna tattoos
- Black rubber products and equipment parts
- Printing inks

At home, you may find p-phenylenediamine in:

- Permanent and some semipermanent hair coloring products
- Photographic developers
- Textile and fur dyes
- Temporary, paint-on and black henna tattoos
- Coloring agents for facial hair
- Printing inks

HOW CAN YOU AVOID P-PHENYLENEDIAMINE?

- Only use products that do not list p-phenylenediamine or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, talk to your pharmacist or doctor.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to p-phenylenediamine. Ask for preparations that do not contain p-phenylenediamine or related substances. Be sure to test hair coloring products before use according to the manufacturer's directions.
- You also may react to some textile dyes related to p-phenylenediamine. Talk to your doctor about avoiding clothing, fabric and furs in certain colors.
- If you must use products containing p-phenylenediamine on others, wear protective gloves. Utility and disposable gloves made of natural or synthetic rubber or vinyl may provide sufficient protection to work with p-phenylenediamine depending on the product.
- If you think that you contact p-phenylenediamine at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- p-phenylenediamine or paraphenylenediamine
- 4-phenylenediamine
- phenylenediamine
- p-diaminobenzene
- 4-aminoaniline
- 1,4-benzenediamine
- 1,4-diaminobenzene

You also may react to p-phenylenediamine-related substances in textiles, hair colorings and other products:

- Aniline yellow dyes such as p-aminoazobenzene or p-dimethylaminoazobenzene
- 4,4'-Methylenedianiline in some rubbers, plastics and epoxy resins
- Other aminobenzene-related compounds
- Disperse Orange dye 1-amino-2-methylantraquinone
- Hair dye p-toluenediamine

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **p-phenylenediamine** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to formaldehyde. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Formaldehyde is used as a preservative and disinfectant in many industrial and household products. It is also used to finish durable press fabrics. Formaldehyde-releasing agents can be a common source of formaldehyde at home and at work.

WHERE IS FORMALDEHYDE FOUND?

At work, you may find formaldehyde and formaldehyde-releasing agents in:

- Urea-formaldehyde foam insulation and resins
- Finish treatments on some textiles and fabrics
- Embalming and preserving fluids
- Pressed wood such as particleboard, medium density fiberboard, plywood, and oriented strandboard
- Photographic developer chemicals
- Industrial metal working fluids and coolants
- Glues, inks, toners and paints
- Cleaning agents, waxes and polishes

At home, you may find formaldehyde and formaldehyde-releasing agents in:

- Cosmetics such as foundations and powders, blush, mascaras, eye shadows, eyeliners and pencils
- Durable press (wrinkle-resistant) fabrics
- Cleaning products, waxes, polishes and paints
- Tobacco and cigarette smoke
- Skin care products such as creams, lotions and moisturizers
- Personal hygiene items such as soaps, cleansers and shampoos
- Smoke from wood, coal, kerosene, or charcoal fires

HOW CAN YOU AVOID FORMALDEHYDE?

- Wash new clothing and bedding several times in hot water before use. Avoid permanent press and wrinkle-resistant clothing.
- Only use products that do not list formaldehyde or formaldehyde-releasing agents on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to formaldehyde. Ask for preparations that do not contain formaldehyde or formaldehyde-releasing agents.
- Wear protective gloves. Heavy-duty chemically resistant gloves made of natural or synthetic rubber may be good for working with formaldehyde. Use fabric or leather gloves to protect your hands from wood products that may contain formaldehyde.
- If you think that you contact formaldehyde at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Formaldehyde or formalin; formic aldehyde; methaldehyde; methyl aldehyde; methylene oxide; N-methylol; oxymethylene

You also may react to formaldehyde-releasing preservatives such as:

- Bronopol, also known as 2-bromo-2-nitropropane-1,3-diol
- Diazolidinyl urea, also known as N,N'-bis(hydroxymethyl) urea and 1-(1,3-Bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl)-1,3-bis(hydroxymethyl) urea
- DMDM hydantoin, also known as 1,3-cimethylol-5,5-dimethylhydantoin and 1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione
- Imidazolidinyl urea, also known as imidurea and N,N'-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)urea
- Tris nitro, also known as trimethylolnitromethane, nitroisobutylglycerol and 2-nitro-2-(hydroxymethyl)-1,3-propanediol, tris(hydroxymethyl)nitromethane
- Quaternium15, also known as chloroallyl methenamine chloride, N-(3-chloroallyl)hexaminium chloride and hexamethylenetetramine chloroallyl chloride

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **formaldehyde** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to mercapto mix. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Mercapto mix contains the following three substances:

- N-Cyclohexylbenzothiazyl-sulfenamide
- Dibenzothiazyl disulfide
- Morpholinylmercaptobenzothiazole

You may contact these substances when using, wearing or handling rubber-based products at work or at home. Work shoes and athletic shoes are often made with rubber components that contain mercapto mix or related substances.

WHERE IS MERCAPTO MIX OR ONE OF ITS COMPONENTS FOUND?

At work, you may find mercapto mix or one of its components in:

- Industrial and safety products made with natural rubber, butyl rubber, nitrile or neoprene such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation and sheeting
- Office products made with natural rubber, nitrile or neoprene such as rubber bands, erasers, mats and utility gloves
- Health care equipment made with natural rubber, butyl rubber, nitrile or neoprene such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons and tubing
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as wetsuits, shoes, boots, masks, and racquet and club handles

At home, you may find mercapto mix or one of its components in:

- Household products made with natural rubber, butyl rubber, nitrile or neoprene such as rubber bands, ear- and headphones, masks, condoms and diaphragms, goggles, shoes, utility gloves, swimwear, toys, hoses, tubing and elastic
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as shoes, wetsuits, boots, masks, and racquet and club handles

HOW CAN YOU AVOID MERCAPTO MIX OR ONE OF ITS COMPONENTS?

- Avoid direct skin contact with rubber products in your car, at work and at home. Use rubber-free alternatives made of vinyl, plastic, leather, wood or fabric. Avoid rubber boots, shoes and insoles.
- Use fabric or plastic films to handle rubber products and to avoid direct skin contact.
- Only use products that do not list mercapto mix, one of its components, or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS).
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to mercapto mix, which is often used in rubber products. Ask for products that do not contain mercapto mix or related substances.
- Wear protective gloves and clothing made of leather, fabric, plastic or rubber that is free of mercapto mix and related substances.
- Use heavy-duty nonrubber gloves (SmartPractice[®] Heavy Duty vinyl or Silvershield[®]/4H[®] gloves) when working with chemicals that might contain mercapto mix or one of its components.
- If you think that you contact mercapto mix or a related substance at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing different protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- N-Cyclohexylbenzothiazyl-sulfenamide or cyclohexyl benzothiazolesulfenamide; 2-(cyclohexylaminothio)benzothiazole; benzothiazyl-2-cyclohexylsulfenamide
- Dibenzothiazyl disulfide or 2,2'-cithiobis(benzothiazole); dibenzothiazolyl disulfide; 2,2'-bis(benzothiazolyl) disulfide; 2,2'-dibenzothiazyl disulfide; 2-mercaptobenzothiazole disulfide
- Morpholinylmercaptobenzothiazole or 2-benzothiazolyl morpholino disulfide; 2-morpholinodithiobenzothiazole; benzothiazole 2-(4-morpholinyl); 4-morpholinyl 2-benzothiazyl disulfide; benzothiazole, 2-(4-morpholinylidithio)

Because mercapto mix is used in certain types of rubber products, you may also react to other substances used in the manufacture of rubber such as thioureas. If your skin is regularly exposed to rubber, you could develop reactions to other substances in rubber such as thiurams, carbamates and mercapto mixes.

WHAT PRODUCTS MAY NOT CONTAIN MERCAPTO MIX SUBSTANCES?*

- Products made entirely of vinyl, plastic, silicone, polyurethane, polyethylene, or acrylates

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **mercapto mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to thimerosal. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Thimerosal was commonly used as an antiseptic (such as Merthiolate or Mercurochrome[®]) and preservative in many medicines and vaccines. Over the past few decades, thimerosal has been replaced with other preservatives. Now, thimerosal is rarely included in antiseptics or medications, including merthiolate.

A contact allergy to thimerosal should not affect your ability to be vaccinated because most modern vaccines do not contain thimerosal. Vaccines given to children under the age of 6 are made without thimerosal. A few adult vaccines are still manufactured with thimerosal as a preservative, but thimerosal-free alternatives can usually be found if needed.

WHERE IS THIMEROSAL FOUND?

At work, you may find thimerosal in:

- Fluorescent dyes in metal working industries and forensic laboratories
- Vaccine and pharmaceutical manufacturing

At home, you may find thimerosal in:

- Vaccines and antitoxins
- In some nose, eye and ear medications (prescription and over-the-counter)
- Antiseptic sprays

HOW CAN YOU AVOID THIMEROSAL?

- Only use products that do not list thimerosal or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist, dentist and veterinarian that you are allergic to thimerosal. Ask for vaccines and medicines that do not contain thimerosal.
- If you think that you contact thimerosal at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing protective gloves and clothing to reduce skin contact.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert.

- Thimerosal or mercuriothiolate
- Merthiolate
- Sodium ethylmercurithiosalicylate
- Sodium 2-(ethylmercurithio)benzoate
- Mercury, ethyl(2-mercaptobenzoato-s)-, sodium salt
- Mercury, ((o-carboxyphenyl)thio)ethyl-, sodium salt

WHAT ARE SOME SIMILAR PRODUCTS THAT DO NOT CONTAIN THIMEROSAL OR A RELATED SUBSTANCE?*

- Most vaccines recommended for children under 6 years of age: measles, mumps, rubella (German measles), polio, pertussis (whooping cough), diphtheria, tetanus, Haemophilus influenzae type b (Hib), hepatitis B, varicella (chickenpox) and pneumococcal disease
- Some influenza (flu) vaccines
- Most types of adult vaccines are available in a thimerosal-free formulation

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **thimerosal** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to thiuram mix. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Thiuram mix contains the following four substances:

- Tetramethylthiuram monosulfide
- Disulfiram (tetraethylthiuram disulfide)
- Tetramethylthiuram disulfide
- Dipentamethylenethiuram disulfide

These substances are used as fungicides and pesticides and in the manufacture of many rubber products. You are most likely to contact this substance when using, wearing or handling natural or synthetic rubber products at work or at home.

WHERE IS THIURAM MIX OR ONE OF ITS COMPONENTS FOUND?

At work, you may find thiuram mix or one of its components in:

- Industrial and safety products made with natural rubber, butyl rubber, nitrile or neoprene such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation and sheeting
- Office products made with natural rubber, nitrile or neoprene such as rubber bands, erasers, mats and utility gloves
- Health care equipment made with natural rubber, butyl rubber, nitrile or neoprene such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons and tubing
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as wetsuits, shoes, boots, masks, and racquet and club handles
- Chemicals used to prevent mildew or mold
- Agricultural chemicals used as fungicides, seed protectants and pesticides

At home, you may find thiuram mix or one of its components in:

- Household products made with natural rubber, butyl rubber, nitrile or neoprene such as rubber bands, ear- and headphones, masks, condoms and diaphragms, goggles, shoes, utility gloves, swimwear, toys, hoses, tubing and elastic
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as shoes, wetsuits, boots, masks, and racquet and club handles
- Chemicals for the garden such as fungicides, pesticides and animal repellents

HOW CAN YOU AVOID THIURAM MIX OR ONE OF ITS COMPONENTS?

- Avoid direct skin contact with rubber products in your car, at work and at home. Use rubber-free alternatives made of vinyl, plastic, leather, wood, or fabric.
- Use fabric or plastic films to handle rubber products and to avoid direct skin contact.
- Only use products that do not list thiuram mix, one of its components, or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS).
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to thiuram mix, which is often used in rubber products. Ask for rubber products that do not contain thiuram mix or related substances.
- Wear protective gloves (fabric or leather) when handling dry rubber goods at work and at home.
- Use heavy duty nonrubber gloves (SmartPractice[®] Heavy Duty vinyl or Silvershield[®]/4H[®] gloves) when working with chemicals that might contain thiuram mix or one of its components.
- If you think that you contact thiuram mix or one of its components at work, ask your employer for MSDS or manufacturer information on the product(s). Wear protective clothing when handling items such as rubber hoses, seals, and cables. Talk to your employer about using a different product.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with thiurams or the following names in the list of ingredients, MSDS, or package insert.

- Tetramethylthiurammonosulfide or bis(dimethylthiocarbamoyl) sulfide; tetramethylthiuram sulfide; tetramethyldithiocarbamic acid anhydrosulfide; sulfide, bis(dimethylthiocarbamoyl)
- Tetramethylthiuramdisulfide or thiram; bis(dimethyl thiocarbamoyl)disulfide; tetramethylthioperoxydicarbonic diamide; N,N'-(dithiodicarbonothioyl)bis(N-methylmethanamine); tetramethylthiocarbamoyldisulphide
- Disulfiram or 1,1'-dithiobis(N,N-diethylthioformamide); bis(N,N-diethylthiocarbamoyl) disulfide; tetraethylthiuram disulfide; tetraethylthioperoxydicarbonic diamide
- Dipentamethylenethiuramdisulfide or disulfide, bis(1-piperidinythioxomethyl); bis(pentamethylene)thiuram disulfide; 1,1'-(dithiodicarbonothioyl)bis(piperidine)

If your skin is regularly exposed to rubber, you may develop reactions to other substances commonly used in the manufacture of rubber such as mercapto-benzothiazoles, mercapto mix and thioureas.

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN THIURAM MIX OR RELATED SUBSTANCES?*

- Antabuse[®] medication for alcoholism
- Gloves, condoms, bottle nipples and other products made of natural rubber, butyl rubber, nitrile, or neoprene

WHAT PRODUCTS MAY NOT CONTAIN THIURAM MIX OR RELATED SUBSTANCES?*

- Products made entirely of vinyl, plastic, silicone, polyurethane, polyethylene or acrylates

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **thiuram mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to diazolidinyl urea (Germall® II). This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Diazolidinyl urea is used as a preservative in a variety of applications, most notably in personal care products and cosmetics. It is effective against a broad spectrum of bacteria, fungi and yeast.

WHERE IS DIAZOLIDINYL UREA FOUND?

At work, you may find diazolidinyl urea in or around:

- Cleansers
- Liquid soaps
- Cleaning agents
- Moisturizers
- As a preservative in multiple products
- Pet shampoos

If you suspect you are being exposed to this allergen at work, contact your employer regarding Material Safety Data Sheets (MSDS).

At home, you may find diazolidinyl urea in or around:

- Cosmetics
- Shampoos/conditioners
- Skin care products
- Haircare products
- Lotions
- Creams
- Moisturizers
- Liquid or powder foundations
- Concealers
- Bronzers/Self-tanners
- Makeup removers
- Sunscreens
- Eye shadow
- Mascaras
- Liquid soaps
- Bubble baths
- Baby wipes
- Over-the-counter and prescription topical medicines
- Detergents
- Dishwashing liquids
- Cleaning agents

HOW CAN YOU AVOID DIAZOLIDINYL UREA?

- Check all skin care products, toiletries, soaps and detergents (prescription and over-the-counter) for diazolidinyl urea or related ingredients. Do not use products that list these substances on the label or package insert. If no information is available, ask your pharmacist or the manufacturer.
- Inform your healthcare providers that you are allergic to diazolidinyl urea and ask that they use products that are free from this allergen.
- Avoid cosmetics and other personal care products with diazolidinyl urea or its synonyms, particularly in stay-on products (rinse-off products may involve less risk).
- Check each new purchase; products once tolerated may cause reactions due to changes in formulations involving a different preservative.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS, or package insert:

- Diazolidinyl urea
- N,N'-Bis(hydroxymethyl) urea
- N-(1,3-Bis(hydroxymethyl)-2, 5-dioxo-4-imidazolidinyl)-
- Diazolidinylurea;
- Urea, N-(1,3-bis(hydroxymethyl)-2, 5-dioxo-4-imidazolidinyl-N,N'-bis(hydroxymethyl)-
- 1-(1,3-Bis(hydroxymethyl)-2, 5-dioxoimidazolidin-4-yl)-1, 3-bis(hydroxymethyl) urea
- Germall II
- Tetramethylolhydantoin urea

Because diazolidinyl urea is a formaldehyde releaser, you may also react to other formaldehyde-releasing substances such as imidazolidinyl urea, formaldehyde, Bronopol, quaternium 15 and dimethyl hydantoin.

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **diazolidinyl urea** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to quinoline mix. This contact allergy may cause your skin to react when it is exposed to the mix ingredients, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

The ingredients of the Quinoline Mix are a group of synthetic antibacterial agents that may be used in combination with corticosteroids to treat skin infections.

Quinoline mix contains the following two allergens:

- Clioquinol (CAS # 130-26-7)
- Chlorquinaldol (CAS # 72-80-0)

WHERE IS QUINOLINE MIX FOUND?

You may find the ingredients of the Quinoline Mix in both prescription and in nonprescription topical medicines.

HOW CAN YOU AVOID QUINOLINE MIX?

- Check all skin antibacterial agents for quinoline mix ingredients.
- Inform your healthcare providers that you are allergic to quinoline mix and ask that they use products that are free from the ingredients of this mix.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- Clioquinol
- 5-Chloro-7-iodo-8-hydroxyquinoline
- 5-Chloro-7-iodo-8-quinolinol
- 5-Chloro-8-hydroxy-7-iodoquinoline
- 7-Iodo-5-chloro-8-hydroxyquinoline
- 7-Iodo-5-chloroxine
- Chinoform
- Vioform
- Chlorquinaldol
- 5,7-Dichloro-2-methyl-8-hydroxyquinoline
- 5,7-Dichloro-2-methyl-8-quinolinol
- 5,7-Dichloro-8-hydroxyquinaldine
- 5,7-Dichloro-8-quinaldinol

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **quinoline mix** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to tixocortol-21-pivalate. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Tixocortol-21-pivalate is a widely used topical anti-inflammatory corticosteroid used in both prescription and nonprescription topical ointments, creams, tablets, or injections.

WHERE IS TIXOCORTOL-21-PIVALATE FOUND?

At work, you may find tixocortol-21-pivalate in or around:

- Medicaments
- Creams, lotions, ointments and powders

At home, you may find tixocortol-21-pivalate in or around:

- Anti-inflammatory agents found in both prescription and nonprescription medications
- Creams, lotions, ointments and powders for eczema and other local inflammations
- Ear, nose and eye drops
- Rectal suspensions

HOW CAN YOU AVOID TIXOCORTOL-21-PIVALATE?

- Check all topical anti-inflammatory preparations (prescription and over-the-counter) for tixocortol-21-pivalate and related corticosteroids. Do not use products that list these substances on the label or package insert. If no information is available, ask your pharmacist.
- Inform your healthcare providers that you are allergic to tixocortol-21-pivalate and ask that they use products that are free from this allergen.
- Avoid preparations that contain tixocortol-21-pivalate and cross-reacting corticosteroids.
- Avoid nasal sprays that contain tixocortol-21-pivalate and related corticosteroids.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- Tixocortol-21-pivalate
- Tixocortol pivalate
- 11beta,17-dihydroxy-21-mercaptopregn-4-ene-3,20-dione 21-pivalate
- Pivalone
- Pregn-4-ene-3,20-dione, 21-((2,2-dimethyl-1-oxopropyl)thio)-11, 17-dihydroxy-, (11beta)-

You also may react to products such as:

- Amcinonide
- Budesonide
- Cloprednol
- Desonide
- Fludrocortisone acetate
- Fluocinolone acetonide
- Fluocinonide
- Flurandrenolide
- Halcinonide
- Hydrocortisone
- Hydrocortisone-17-butyrate
- Hydrocortisone acetate
- Hydrocortisone butyrate
- Hydrocortisone probutate (hydrocortisone buteprate)
- Hydrocortisone valerate
- Methylprednisolone
- Micronized fluocinonide
- Prednicarbate
- Prednisolone
- Prednisolone acetate
- Steroid: group b
- Steroid: group d2
- Triamcinolone

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **tixocortol-21-pivalate** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to gold sodium thiosulfate. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Gold sodium thiosulfate is a fairly common sensitizer with elicitation of symptoms linked to gold in jewelry, occupational exposure to gold, dental restorations, gold-plated intracoronary stents and previous rheumatoid arthritis treatment.

WHERE IS GOLD SODIUM THIOSULFATE OR GOLD FOUND?

At work, you may find gold sodium thiosulfate or gold in or around:

- Electronics
- Gold-plating processes
- Medical and dental devices or implants

At home, you may find gold sodium thiosulfate or gold in or around:

- Gold or gold-plated jewelry
- Rheumatoid arthritis treatment
- Dental restorations
- Gold-plated intracoronary stents

HOW CAN YOU AVOID GOLD SODIUM THIOSULFATE OR GOLD?

- Check all gold-appearing jewelry for a stamp that indicates the purity (1-999 or .1-.999) or the karat (10K, 14K, 18K, 22K, or 24K). Also avoid all gold-plated jewelry.
- Inform your healthcare providers, including dental providers, that you are allergic to gold sodium thiosulfate. Ask that they use products free from this allergen. Gold filling does NOT need to be removed unless significant oral disease is present and associated with a positive patch test.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- Gold sodium thiosulfate
- Thiosulfuric acid, gold(1+) sodium salt (2:1:3)
- Gold sodium thiosulfate
- Gold trisodium bis(thiosulphate)
- Thiosulfuric acid (H₂S₂O₃), gold(1+) sodium salt (2:1:3)

Your T.R.U.E. TEST results indicate that you have a contact allergy to imidazolidinyl urea (Germall[®] 115). This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Imidazolidinyl urea is used as a preservative in a variety of applications, most notably in personal care products and cosmetics. It is effective against a broad spectrum of bacteria, fungi and yeast.

WHERE IS IMIDAZOLIDINYL UREA FOUND?

At work, you may find imidazolidinyl urea in or around:

- Cleansers
- Liquid soaps
- Cleaning agents
- Moisturizers
- As a preservative in multiple products
- Burn remedies
- Shampoos
- Moisturizing lotions and creams
- Sunscreens
- Petcare products

If you suspect you are being exposed to this allergen at work, contact your employer regarding Material Safety Data Sheets (MSDS).

At home, you may find imidazolidinyl urea in or around:

- Foundations, powders, concealers
- Eye makeup (liners, shadows, mascara)
- Facial makeup (blushes)
- Bronzes and tanning creams
- Makeup removers
- Cuticle removers
- Burn remedies
- Shampoos
- Moisturizing lotions and creams
- Body powders
- Sunscreens
- Cleansers and other skin care products
- Prescription topical medications
- After shave

HOW CAN YOU AVOID IMIDAZOLIDINYL UREA?

- Check all skin care products, toiletries, soaps and detergents (prescription and over-the-counter) for imidazolidinyl urea or related ingredients. Do not use products that list these substances on the label or package insert. If no information is available, ask your pharmacist or the manufacturer.
- Inform your healthcare providers that you are allergic to imidazolidinyl urea and ask that they use products that are free from this allergen.
- Avoid cosmetics and other personal care products with imidazolidinyl urea or its synonyms, particularly in stay-on products.
- Check each new purchase; products once tolerated may cause reactions due to changes in formulations involving a different preservative.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- Imidazolidinyl urea
- Imidurea
- Urea, N,N"-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl urea
- N,N"-Methylenebis(N'-(1-(hydroxymethyl)-2,5-dioxo-4-imidazolidin-yl)-

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

Because imidazolidinyl urea is a formaldehyde releaser, you also may react to other formaldehyde-releasing substances such as diazolidinyl urea, formaldehyde, Bronopol, quaternium-15 and dimethyl hydantoin.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **imidazolidinyl urea (Germall[®] 115)** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to budesonide. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Budesonide is a potent corticosteroid and anti-inflammatory agent that is most commonly used topically to treat skin disease. Budesonide may be found in medications used to treat asthma, noninfectious rhinitis (including hay fever and other allergies), and nasal polyposis.

WHERE IS BUDESONIDE FOUND?

At work, you may find budesonide in or around:

- Anti-inflammatory agents found in topical medications
- Creams, lotions, ointments and powders
- Inhalation drugs, tablets and injectables
- Rectal suspensions for treatment of colitis and related diseases

At home, you may find budesonide in or around:

- Anti-inflammatory agents found in medications prescribed topically for eczema and other local inflammations
- Creams, lotions, ointments and powders
- Ear, nose and eye drops for rhinitis, otitis and conjunctivitis
- Inhalation drugs, tablets and injectables for rhinitis, asthma and other allergy-related lung diseases
- Rectal suspensions for treatment of colitis and related diseases

HOW CAN YOU AVOID BUDESONIDE?

- Check all topical anti-inflammatory preparations (prescription and over-the-counter) for budesonide and related corticosteroids. Do not use products that list these substances on the label or package insert. If no information is available, ask your pharmacist.
- Inform your healthcare providers that you are allergic to budesonide and ask that they use products that are free from this allergen.
- Avoid preparations that contain budesonide and cross-reacting corticosteroids.
- Avoid nasal sprays that contain budesonide and related corticosteroids.
- When purchasing products that may come in contact with your skin, check the list of ingredients for the names in the following lists. If in doubt, contact your pharmacist or physician.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients:

- (11-beta,16-alpha)-16,17-(Butylidenebis(oxy))-11, 21-dihydroxypregna-1,4-diene-3,20-dione
- (RS)-11beta,16alpha,17,21-Tetrahydroxypregna-1, 4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde
- 16-alpha,17-alpha-butylidenedioxy-11-beta, 21-dihydroxy-1,4-pregnadiene-3,20-dione
- Bidien
- Budeson
- Cortivent
- Entocort
- Micronyl
- Preferid
- Pulmicort
- Respules
- Rhinocort
- Rhinocort alpha
- Rhinocort aqua
- Spirocort

Avoid medication such as:

- Amcinonide
- Fluclozide
- Fluocinolone acetonide
- Halcinonide
- Pulmicort[®]
- Rhinocort[®]
- Triamcinolone
- Triamcinolone diacetate
- Desonide
- Flunisolide
- Fluocinonide
- Procinonide
- Rhinocort Aqua[®]
- Symbicort[®]
- Triamcinolone acetonide

You also may react to other medications such as:

- Hydrocortisone-17-butyrate
- Hydrocortisone buteprate
- Prednicarbate
- Hydrocortisone-17-aceponate
- Methylprednisolone aceponate

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **budesonide** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to hydrocortisone-17-butyrate. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Hydrocortisone-17-butyrate is a mid-potent (Group D2) corticosteroid used in both prescription and nonprescription topical ointments, creams, tablets, or injection, to treat inflammatory skin diseases and psoriasis. Corticosteroid contact allergy may be difficult to diagnose. Failure to improve when treated with corticosteroids can be a symptom of contact allergy.

WHERE IS HYDROCORTISONE-17-BUTYRATE FOUND?

At work, you may find hydrocortisone-17-butyrate in or around:

- Medicaments
- Creams, lotions, ointments and powders

At home, you may find hydrocortisone-17-butyrate in or around:

- Anti-inflammatory agents found in both prescription and nonprescription medications
- Creams, lotions, ointments and powders for eczema and other local inflammations
- Ear, nose and eye drops
- Rectal suspensions

HOW CAN YOU AVOID HYDROCORTISONE-17-BUTYRATE?

- Check all topical anti-inflammatory preparations (prescription and over-the-counter) for hydrocortisone-17-butyrate and related corticosteroids. Do not use products that list these substances on the label or package insert. If no information is available, ask your pharmacist.
- Inform your healthcare providers that you are allergic to hydrocortisone-17-butyrate and ask that they use products that are free from this allergen.
- Avoid preparations that contain hydrocortisone-17-butyrate and cross-reacting corticosteroids.
- Avoid nasal sprays that contain hydrocortisone-17-butyrate and related corticosteroids.
- Be aware that if others such as a spouse or children use topical skin care products that contain this chemical, skin-to-skin transfer may occur to you.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- h.17b
- Laticort
- Iocoid
- hb(sub17)
- Alfason
- Cortisol 17-butyrate
- Plancol
- Hydrocortisone 17-butyrate
- Hydrocortisone butyrate

You also may react to products such as:

- Amcinonide
- Budesonide
- Cloprednol
- Cortifoam cortisol
- Cortril
- Desonide
- Efcortin
- Efcortelin
- Elcorbin
- Fludrocortisone acetate
- Fluocinolone acetonide
- Fluocinonide
- Flurandrenolide
- Halcinonide
- Hydrocortisone
- Hydrocortisone 17-butyrate
- Hydrocortisone acetate
- Hydrocortisone butyrate
- Hydrocortisone valerate
- Hydroxycorticosterone
- Incortin-H Kendall's compound F
- Methylprednisolone
- Micronized fluocinonide
- Prednicarbate
- Prednisolone
- Prednisolone acetate
- Proctoscort
- Rectoid
- Steroid: group b
- Steroid: group d2
- Triamcinolone

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **hydrocortisone-17-butyrate** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to mercaptobenzothiazole (MBT). This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

You are most likely to contact mercaptobenzothiazole when using, wearing or handling natural or synthetic rubber products at work or at home. Work shoes and athletic shoes are often made with rubber components that contain mercaptobenzothiazole or related substances.

WHERE IS MERCAPTOBENZOTHIAZOLE FOUND?

At work, you may find mercaptobenzothiazole in:

- Industrial and safety products made with natural rubber, butyl rubber, nitrile or neoprene such as boots, shoes, adhesives, plugs, goggles, mats, headphones, masks, respirators, aprons, gloves, cords, tubing, insulation and sheeting
- Office products made with natural rubber, nitrile or neoprene such as rubber bands, erasers, mats and utility gloves
- Health care equipment made with natural rubber, butyl rubber, nitrile or neoprene such as medical and utility gloves, masks, bed sheeting, dental dams, anesthesia equipment, aprons and tubing
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as wetsuits, shoes, boots, masks, and racquet and club handles

At home, you may find mercaptobenzothiazole in:

- Household products made with natural rubber, butyl rubber, nitrile or neoprene such as rubber bands, ear- and headphones, masks, condoms and diaphragms, goggles, shoes, utility gloves, swimwear, toys, hoses, tubing and elastic
- Sports equipment made with natural rubber, butyl rubber, nitrile or neoprene such as shoes, wetsuits, boots, masks, and racquet and club handles

HOW CAN YOU AVOID MERCAPTOBENZOTHIAZOLE?

- Avoid direct skin contact with rubber products in your car, at work and at home. Use rubber-free alternatives made of vinyl, plastic, leather, wood or fabric. Avoid rubber boots, shoes and insoles.
- Use fabric or plastic films to handle rubber products and to avoid direct skin contact.
- Only use products that do not list mercaptobenzothiazole or related chemicals on the label, ingredient list or Material Safety Data Sheet (MSDS). If no information is available, contact the product manufacturer.
- Tell your physician, pharmacist, dentist, veterinarian, beautician and hairdresser that you are allergic to mercaptobenzothiazole, which is often used in rubber products. Ask for products that do not contain mercaptobenzothiazole or related substances.
- Wear protective gloves and clothing made of leather, fabric or rubber that is free of mercaptobenzothiazole.
- Use heavy duty nonrubber gloves (SmartPractice[®] Heavy Duty vinyl or Silvershield[®]/4H[®] gloves) when working with chemicals that might contain mercaptobenzothiazole.
- If you think that you contact mercaptobenzothiazole at work, ask your employer for MSDS or manufacturer information on the product(s). Talk to your employer about using a different product or about wearing different protective gloves and clothing.

WHAT SHOULD YOU LOOK FOR AND AVOID?*

Avoid products with the following names in the list of ingredients, MSDS or package insert.

- Mercaptobenzothiazole (MBT) or 2-mercaptobenzothiazole; 2-benzothiazolinethione; 2-benzothiazolethiol; benzothiazole-2-thione; 2-benzothiazolyl mercaptan

Because mercaptobenzothiazole is used in certain types of rubber products, you may also react to other substances used in the manufacture of rubber such as thioureas. If your skin is regularly exposed to rubber, you may develop reactions to other substances in rubber such as thiram, carbamates and mercapto mixes.

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN MERCAPTOBENZOTHIAZOLE?*

- Natural rubber, butyl rubber, nitrile or neoprene rubber products

WHAT PRODUCTS MAY NOT CONTAIN MERCAPTOBENZOTHIAZOLE?*

Products made entirely of vinyl, plastic, silicone, polyurethane, polyethylene or acrylates

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **mercaptobenzothiazole** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to bacitracin. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Bacitracin is a common antibiotic used for postoperative and general wound care, often a first-line topical remedy for virtually all skin injuries and dermatoses as well as for some ear and eye disorders.

WHERE IS BACITRACIN FOUND?

At Work, you may find bacitracin in or around:

- Topical antibiotics
- Animal feeds

If you suspect you are being exposed to this allergen at work, contact your employer regarding Material Safety Data Sheets (MSDS).

At Home, you may find bacitracin in:

- Prescription and in over-the-counter preparations such as topical antibiotic creams, lotions, ointments
- Paste bandages sold in pharmacies for the treatment of wound infections, infected eczema and mycotic skin infections
- Ophthalmic and otic products

HOW CAN YOU AVOID BACITRACIN?

- Check all skin antibacterial agents for bacitracin ingredients.
- Inform your healthcare providers that you are allergic to bacitracin and ask that they use products that are free from this allergen. Bacitracin preparations are sometimes used topically in surgical wounds. When a topical antibiotic is required, request a suitable safe alternative.
- Use only products that do not list bacitracin (or synonyms), especially antibiotic preparations.
- Patients who are allergic to bacitracin should also avoid neomycin. Co-reactivity can occur when used simultaneously with neomycin and should be avoided
- Cross-reactions can occur when used simultaneously with polymixin, because both substances are derived from *Bacillus subtilis*.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- Bacitracin
- Bacitracin A
- Mycitracin
- Bacitracin zinc salt
- ChEMBL1200558
- C15428

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN BACITRACIN*?

- Double antibiotic ointment
- Bactine Antiseptic
- Neosporin[®] First-aid Antibiotic Ointment
- Triple antibiotic ointment
- Eye drops

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **bacitracin** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to parthenolide. This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Parthenolide is a sesquiterpene lactone (SQL), which occurs naturally in the flowers and fruit of the plant, feverfew (*Tanacetum parthenium*). It is well known in natural medicine for its relief of migraines and blood clots. It also acts as an anti-inflammatory for the relief of arthritis and as a digestive aid. Parthenolide has shown anti-tumor and anticancer properties as well as Ultra Violet B and oxidative stress protection in a variety of cell lines, with low toxicity to healthy cells. Parthenolide is proposed for use in lieu of SQL mix as a good indicator of SQL allergy.

WHERE IS PARTHENOLIDE FOUND?

At work, you may find parthenolide in or around:

- Plants, gardens
- Floral shops
- Greenhouses

If you suspect you are being exposed to this allergen at work, contact your employer regarding Material Safety Data Sheets (MSDS).

At home, you may find parthenolide in:

- Tablets or tinctures
- Herbal teas containing sesquiterpenes
- Natural supplements
- Plants

HOW CAN YOU AVOID PARTHENOLIDE?

- Check all skin antibacterial agents for parthenolide-related ingredients.
- Inform your healthcare providers that you are allergic to parthenolide and ask that they use products that are free from this allergen.
- Use only ingredients that do not list parthenolide (or synonyms), especially antibiotic preparations.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- Feverfew
- *Tanacetum parthenium*
- *Chrysanthemum parthenium*
- 2,3,6,7,7a,8,10a,10b-octahydro-1a,5-dimethyl-8-methyleneoxireno(9,10)cyclodeca(1,2-b)furan-9(1aH)-one
- 4Xi-germacra-1(10),11(13)-dien-12-oic acid, 4,5-epoxy-6.alpha-hydroxy-, gamma-lactone
- Oxireno(9,10)cyclodeca(1,2-B)furan-9(1ah)-one, 2,3,6,7,7A,8,10A,10B-octahydro-1A,5-dimethyl-8-methylene-
- Parthenolide

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN PARTHENOLIDE*?

Parthenolide can be found in:

- Plants
- Herbal Teas
- Tablets
- Tinctures
- Natural remedies and supplements

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **parthenolide** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to disperse blue 106. This contact allergy may cause your skin to react when it is exposed to this substance and related dyes, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Disperse blue 106 is a dark blue textile dye found in fabrics colored dark blue, brown, black, purple and some greens. It is frequently found in 100% acetate and 100% polyester fabrics. Some patients with disperse dye allergy also react to para-phenylenediamine.

WHERE IS DISPERSE BLUE 106 FOUND?

At work, you may find disperse blue 106 in or around:

- Fabrics and clothing
- Textiles
- Uniforms

If you suspect you are being exposed to this allergen at work, contact your employer regarding Material Safety Data Sheets (MSDS). If you must work with products you know contain disperse dyes, wear protective gloves. Utility or disposable gloves made of natural or synthetic rubber or vinyl are best.

At home, you may find disperse blue 106 in:

- Acetate and polyester fabrics/liners
- Dyed fabrics such as bedding, clothing, nylon stockings, swimming suits, tights, velour
- Children's diapers

HOW CAN YOU AVOID DISPERSE BLUE 106?

- Inform your healthcare providers and your hairdresser that you are allergic to disperse blue 106 and ask that they use products that are free from this allergen.
- Avoid polyester and acetate fabrics and nylon that could be dyed with disperse blue 106.
- Dyes are water soluble, so wash clothing before you wear it the first time to remove excess dye.

Avoidance of textile dyes is difficult because there is no product labeling of the dyes used in the U.S. Furthermore, the correlation between positive patch tests to disperse dyes and presence of those dyes in the garments suspected as causing skin problems is poor.

WHAT SHOULD YOU LOOK FOR AND AVOID?

- Avoid garments made from pure polyester and acetate blends dyed blue or dark colors such as black, brown, green, violet and purple.
- Wear loose fitting clothes if possible.
- Avoid nylon stockings, especially dark colors.
- Levi's[®] 501 blue jeans seldom cause dermatitis in dye-sensitive individuals.
- Wear undyed natural-based fabrics such as silk, cotton, and wool. Clothing should be true white (not off-white) synthetic fabrics.

Note: Another dye, disperse blue 124, is structurally similar to disperse blue 106 and also should be avoided.

When purchasing products that may come in contact with your skin, check the list of ingredients for the above names. If in doubt, contact your pharmacist or physician.

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **disperse blue 106** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

Your T.R.U.E. TEST results indicate that you have a contact allergy to 2-bromo-2-nitropropane-1,3-diol (Bronopol). This contact allergy may cause your skin to react when it is exposed to this substance, although it may take several days for the symptoms to appear. Typical symptoms include redness, swelling, itching and fluid-filled blisters.

Bronopol is an antimicrobial agent commonly used as a preservative in many types of cosmetics, personal care products and topical medications. It is used as an anti-infective, antimicrobial, fungicide, germicide, bactericide, slimicide and wood preservative. Bronopol is a formaldehyde-releasing preservative (FRP), which is used in place of formaldehyde for people who are sensitive to it.

WHERE IS BRONOPOL™ FOUND?

At work, you may find Bronopol in or around:

- Process and metal-working fluids
- Fuel/oil storage tanks
- Agriculture chemicals
- Pesticides
- Cooling lubricants
- Water-based paints, inks, adhesives and glues
- Paper mills and products
- Orthopedic casts
- Biocides
- Cleaning agents
- Root canal disinfectants
- Maintenance, sampling, or other procedures related to manufacturing

If you suspect you are being exposed to this allergen at work, contact your employer regarding Material Safety Data Sheets (MSDS).

At home, you may find Bronopol in:

- Finger paints
- Washing detergents
- Blushers
- Creams
- Foundations
- Hair dressings
- Mascara
- Topical antibiotic/antifungal creams /ointments
- Kitty litter
- Toiletries and cleansers
- Cleansing lotions
- Eyebrow pencils
- Hair conditioners
- Humidifiers
- Mouthwash
- Shampoos

HOW CAN YOU AVOID BRONOPOL™?

- Check all skin antibacterial agents for Bronopol ingredients.
- Inform your healthcare providers that you are allergic to Bronopol and ask that they use products that are free from this allergen.
- Do not use products that list Bronopol (or synonyms) especially antibiotic preparations.
- Avoid contact with oxidizing materials, bases (can generate formaldehyde), amines, or strong acids.

WHAT SHOULD YOU LOOK FOR AND AVOID?

Avoid products with the following names in the list of ingredients:

- CAS No. 52-51-7
- Bronopol
- 2-Bromo-2-nitropropane-1,3-diol
- 2-Bromo-2-nitro-1,3-propanediol

Note: This substance may release formaldehyde and cross-reacts with other FRPs. Therefore, if you are allergic to formaldehyde, your doctor may advise you to avoid contact with Bronopol, even if you did not have a positive patch test to Bronopol itself.

When purchasing products that may come in contact with your skin, check the list of ingredients for any of the names above. If in doubt, contact your pharmacist or physician.

WHAT ARE SOME PRODUCTS THAT MAY CONTAIN BRONOPOL™*?

- BNPD
- BIOBAN™ Bronopol PC Preservative
- BIOBAN BP-Plus Preservative
- BIOBAN BP-M Antimicrobial
- ROCIMA™ 614

*These lists are brief and provide just a few examples. Read product labels carefully and talk to your doctor if you have any questions. Product formulations may change from time to time without notice. Talk to your doctor for specific instructions. For additional information about products that might contain **2-bromo-2-nitropropane-1,3-diol (Bronopol)** or a related substance, go to the Household Products Database online (householdproducts.nlm.nih.gov) at the United States National Library of Medicine.

T.R.U.E. TEST® Clinical Studies

In the United States and worldwide, more than 25 clinical studies involving over 4,500 patients have been conducted to evaluate the consistency, reproducibility, optimal dose, performance, safety, efficacy, and clinical relevance of T.R.U.E. TEST (Allergen Patch Test). T.R.U.E. TEST has been shown consistently to provide a safe, effective, clinically relevant method of diagnosing allergic contact dermatitis.

General Performance and Adverse Events

Nine (9) studies were conducted in North America and Europe to evaluate the effectiveness, frequency of patch reactions, and/or sensitivity and specificity, and/or agreement with a reference allergen (when used) of T.R.U.E. TEST used to diagnosis allergic reactions to one or more substances in the panels in adults. Subjects ranged in age from 18 through 86 years. Subjects with suspected allergic contact dermatitis, based on history or clinical signs, were tested in all studies (see package insert).



Clinical study #1:

This study evaluated the efficacy of T.R.U.E. TEST Panel 1.1. A total of 127 subjects with suspected contact dermatitis were recruited. T.R.U.E. TEST Panel 1.1, containing 12 allergens (no negative control was on the original Panel 1) was applied to the subject's back and remained there for 48 hours. The results were evaluated after 48 and 72 to 96 hours. Forty-five (45) subjects showed a total of 65 reactions to 11 of the 12 allergens in Panel 1.1. There were positive test reactions to all allergens except potassium dichromate.

Clinical study #2:

This study evaluated the efficacy of T.R.U.E. TEST Panel 2.1. A total of 121 subjects with suspected contact dermatitis were recruited. T.R.U.E. TEST Panel 2.1, containing 11 allergens and a negative control, was applied to the subject's back and remained there for 48 hours. The results were evaluated after 72 to 96 hours. Thirty-two (32) subjects showed a total of 46 positive test reactions. There were positive responses to all of the allergens except quinoline mix and paraben mix.

Clinical study #3:

This study evaluated the efficacy of T.R.U.E. TEST Panels 1.1 and 2.1 in a North American patient population referred for patch testing. One hundred nineteen (119) subjects were enrolled. T.R.U.E. TEST Panels 1.1 and 2.1, containing 23 allergens and a negative control, were applied to the subject's back and remained there for 48 hours. The results were evaluated at 72 to 96 hours after application. Results show that 66 subjects had a total of 123 positive test reactions. There were positive test responses to all of the allergens.

Clinical study #4:

This study was an open, multicenter, study that evaluated the efficacy of T.R.U.E. TEST and obtained information on late reactions and persistent local responses at a Day 21 safety visit (see Table 2). A total number of 50 prospectively identified subjects with suspected contact dermatitis were recruited. The most common dermatitis site was the hand, and the most common dermatitis type was allergic. T.R.U.E. TEST Panels 1.1 and 2.1 (24 allergens or allergen mixes, no negative control) were applied to the subject's back and remained there for 48 hours. The results were evaluated after 72 to 96, 120, or 168 hours. Thirty-two (32) subjects showed a total of 66 reactions to 21 of the 24 allergens included in T.R.U.E. TEST. The following allergens gave no reactions: caine mix, epoxy resin, quinoline mix, and black rubber mix.

Clinical study #5:

This single-site study evaluated the sensitivity and specificity of T.R.U.E. TEST Panel 3 allergens diazolidinyl urea (DU) (Germall® II) and imidazolidinyl urea (IMID) (Germall® 115) for diagnosing allergic contact dermatitis in a North American patient population. Comparison of allergen reactivity between allergens in T.R.U.E. TEST and allergens in petrolatum were made. One hundred thirty (130) subjects were enrolled and included 100 consecutive subjects (subjects with a clinical history consistent with allergic contact dermatitis without a previous positive patch test reaction) and sensitive subjects with a previous positive patch test reaction to petrolatum-based DU (15 subjects) and IMID (15 subjects) allergens in the past 5 years and a clinical history of allergic contact dermatitis. T.R.U.E. TEST Panel 3 allergens DU and IMID were applied to the subject's back and remained there for 48 hours. Patch test reactions were evaluated at 72 to 96 hours and again 7 days after application using the study endpoints, including measurements of positive reaction frequency, specificity, sensitivity, and agreement estimate for each allergen.

Clinical study #6:

This study evaluated the sensitivity and specificity of T.R.U.E. TEST Panel 3 allergens tixocortol-21-pivalate (TIX) and budesonide (BUD) for diagnosing allergic contact dermatitis in a North American patient population. Comparison of allergen reactivity between allergens in T.R.U.E. TEST and allergens in petrolatum were made. One hundred twenty-eight (128) subjects were enrolled and included 100 consecutive subjects (subjects with a clinical history consistent with allergic contact dermatitis without a previous positive patch test reaction) and sensitive subjects with a previous positive patch test reaction to petrolatum-based TIX (9 subjects) and BUD (19 subjects) allergens in the past 5 years and clinical history of allergic contact dermatitis. T.R.U.E. TEST Panel 3 allergens TIX and BUD were applied to the subject's back and remained there for 48 hours. Patch test reactions were evaluated 72 to 96 hours and again 7 days after application for 94 subjects. Six (6) subjects were withdrawn at Visit 2 due to poor tape adhesion prior to Visit 2. Patch test reactions were evaluated using the study endpoints, including measurements of positive reaction frequency, specificity, sensitivity, and agreement estimate.

Clinical study #7:

This study evaluated the sensitivity and specificity of T.R.U.E. TEST Panel 3.1 allergens tixocortol-21-pivalate (TIX), Hydrocortisone-17-butyrate (H-17-B), and budesonide (BUD) for diagnosing allergic contact dermatitis in a European patient population. Comparison of allergen reactivity between allergens in T.R.U.E. TEST and allergens in petrolatum were made. The enrolled study population included 200 consecutive subjects (subjects with a clinical history consistent with allergic contact dermatitis without a previous positive patch test reaction). T.R.U.E. TEST allergens TIX, H-17-B, BUD, and the corresponding petrolatum reference allergens were applied to the subject's back and remained there for 48 hours. Patch test reactions were evaluated at 72 to 96 hours and again 7 days after application. Of the 200 consecutive subjects evaluated, 1 subject was withdrawn due to poor tape adhesion prior to Visit 2 and 1 subject was excluded due to no follow-up visits. Therefore, 198 subjects were included in the evaluation of TIX and BUD. In addition, 3 subjects were withdrawn due to the H-17-B reference allergen patch not being applied at the initial visit. Therefore, 195 subjects were included in the evaluation for H-17-B. Patch test reactions were evaluated using the study endpoints, including measurements of positive reaction frequency, specificity, sensitivity, and agreement estimate.

Clinical study #8:

This was an open-label, prospective, multi-center (5 site) study that evaluated the sensitivity and specificity of gold sodium thiosulphate (GST), Hydrocortisone-17-butyrate (H-17-B), bacitracin, parthenolide, methyl dibromo glutaronitrile (MDBGN), disperse blue 106 (DB106), and 2-bromo-2-nitropropane-1,3-diol (bronopol) in adult subjects with suspected contact dermatitis and in adult subjects with a known or suspected sensitization to at least 1 of the 7 allergens. Of the 235 enrolled subjects, 110 were consecutive subjects (subjects with a clinical history consistent with allergic contact dermatitis without a previous positive patch test reaction) and 125 were sensitive subjects (subjects with a previous positive patch test reaction to at least 1 of the 7 allergens). The frequencies of all patch test reactions for each allergen were tabulated at 72 to 96 hours.

The agreement between the T.R.U.E. TEST allergens and their corresponding reference allergens was generally high among subjects who were sensitive to each allergen. With the exception of MDBGN, subjects who had sensitivities to each individual allergen had similar reactions to both the T.R.U.E. TEST allergens and the corresponding reference allergens with percent agreements ranging from 75.0% (for bacitracin) to 94.4% (for parthenolide). The results for MDBGN in this study may be unreliable due to the presence of phenoxyethanol (PE) in the reference allergen. Specifically, PE is a recognized irritant.

Clinical study #9:

This in-use study evaluated the relationship between reactions caused by a natural sensitizer, such as nickel-containing costume jewelry, and T.R.U.E. TEST. Forty-nine (49) subjects with history of cutaneous reactions to jewelry were tested with T.R.U.E. TEST Panel 1.1. A medallion containing approximately 20% nickel served as a positive control. Reactions were evaluated 72 to 96 hours after application. In comparing the in-use test results, 35% of the T.R.U.E. TEST nickel patch positive results would have been considered false positives and 5.3% would have been considered false negatives. However, the results from this study may be unreliable. The metal composition of jewelry can vary greatly from manufacturer to manufacturer and thereby alter the bioavailability of the nickel ions. A different medallion could have produced either a greater or lesser correlation with the T.R.U.E. TEST nickel patch. The comparatively large number of additional nickel positive results obtained with T.R.U.E. TEST may be true positives unresponsive to the particular medallion used in this study, although false-positive reactions cannot be ruled out.

Post-marketing study:

A survey conducted from January 1995 through the end of December 1995 supports the results of the above clinical trials. This survey evaluated a total of 1,772 data collection forms completed by physicians using T.R.U.E. TEST in 1995.

According to survey results, allergens with the highest reaction rate frequency included nickel (17.6%), Quaternium-15 (Q-15) (11.0%), thimerosal (9.1%), and formaldehyde (9.0%). When clinical relevance was addressed (in 27% of surveys), test results corresponded to the patient's contact history in 75.9% of these cases. The survey also reaffirmed the observed minimal adverse events and irritation. Tape irritation and adhesion problems were reported infrequently (2.5% and 4.6%, respectively). The number of adverse events reported was also very small and centered around the typical symptoms of an allergic reaction.

A Phase 4 postmarketing open-label, non-randomized, non-blinded prospective study evaluated nine subjects who had previous positive patch test results for Q-15. The subjects were exposed to the T.R.U.E. TEST Q-15 patch at a concentration of 100 mcg/cm² and daily applications of a topical product containing Q-15 after the completion of the patch test. Reactions were evaluated 72 to 96 hours after application. T.R.U.E. TEST detected Q-15 sensitivity in 87.50% (7/8) of the Q-15 allergic subjects while the topically applied lotion elicited a positive response in 50% (4/8) of the study population. One subject tested negative to both methods of Q-15 and was removed from the endpoint analysis.

Published studies in adult patients:

Krob et al. (*Journal of the American Academy of Dermatology* 2004) published a meta-analysis of previously published T.R.U.E. TEST clinical data. Consistent with earlier results, nickel (14.7%) was reportedly the most prevalent allergen, followed by thimerosal (5.0%), cobalt (4.8%), fragrance mix (3.4%) and balsam of Peru (3.0%). Although there were differences in prevalence, T.R.U.E. TEST results are in general agreement with other patch test methods and with data from the North American Contact Dermatitis Group.

Over 3,700 allergens have been identified to date as associated with allergic contact dermatitis. With only 23 allergens currently included in the panels licensed for sale in the United States, Krob et al. suspected that without supplemental allergens, T.R.U.E. TEST may miss other highly relevant allergens.

Sherertz et al. (*Journal of the American Academy of Dermatology* 2001) reported that T.R.U.E. TEST might miss some positive reactions to fragrance mix, thiuram mix and carba mix. In a study of 318 patients evaluated simultaneously with T.R.U.E. TEST and allergens in Finn Chambers[®], multiple discordant reactions were noted. The limited results of this study suggested that some negative reactions to fragrance mix, thiuram mix and carba mix might be false.



Children and Adolescents 6 through 17 Years of Age

Two studies were conducted in the US to evaluate the diagnostic performance of T.R.U.E. TEST in children and adolescents 6 through 17 years of age. Subjects had three T.R.U.E. TEST panels applied to their back or upper arm for 48 hours. Reactions at the patch test sites were evaluated at days 3 and/or 4, 7 and 21 after patch test application [see Interpretation Instructions (2.4)].

Pediatric Study #1

In an open-label, prospective, single-center study conducted in the US, 102 children and adolescents 6 through 17 years of age with suspected allergic contact dermatitis were enrolled to evaluate the diagnostic performance of a previously approved version of T.R.U.E. TEST (Panels 1.1, 2.1, 3.1). This version included a negative control and 28 allergens and allergen mixes, 4 (on Panel 1.1) of which were reformulated and are not included on Panel 1.3. The per-protocol analysis set included 100 subjects.

Pediatric Study #2

In an open-label, prospective, multi-center study conducted in the US, 116 children and adolescents 6 through 17 years of age with suspected allergic contact dermatitis were enrolled. Although the three T.R.U.E. TEST panels administered to subjects in this study included all 35 allergens and allergen mixes, the primary analysis of diagnostic performance was limited to the 4 reformulations and the 7 new allergens and allergen mixes.

Published studies in pediatric patients:

Since the premarket approval testing of T.R.U.E. TEST, which excluded patients younger than 16 years of age, some studies have reported on its use in pediatric patients ranging from 6 months to 14 years of age. Postmarketing surveys have shown that physicians in the United States occasionally patch test children using T.R.U.E. TEST. Of 3,200 reports filed in a two-year period, 19 were for patients under the age of 13, and 74 were for patients between the ages of 13 and 19.

Jacobs et al. (*Dermatitis 2011*) evaluated the efficacy and safety of TRUE Test panels 1.1, 2.1, and 3.1 in children and adolescents (mean age 11.6 years) suspected of having allergic contact dermatitis (ACD). Positive reactions noted in more than 10% of the children were to nickel sulfate (29.7%), p-tert-butylphenol formaldehyde resin (16.8%), wool alcohols (15.8%), fragrance mix (12.9%), and cobalt dichloride (12.9%). Of the 101 subjects, 77 (76.2%) tested positive to one or more of the 28 allergens.

Johnke et al. (*Contact Dermatitis 2004*) reported on the use of T.R.U.E. TEST patches in infants up to 18 months of age. Of the 543 infants tested, 8.6% had positive nickel reactions. However, of these, only one was considered clinically relevant. These investigators also cautioned that the adult level of nickel allergen in T.R.U.E. TEST (0.2 mg) may elicit more transient false-positive reactions in infants.

Mortz et al. (*Acta Derm Venereol 2002*) used T.R.U.E. TEST panels on 1,146 schoolchildren in the 8th grade. Tests adhered well in 93% of patients, and reactions to the tape were seen in only 2% of those tested. In this pediatric population, 15% tested positive to one or more of the T.R.U.E. TEST allergens. However, more of these schoolchildren had a history of atopy or hand dermatitis.

Bruckner et al. (*Pediatrics 2000*) patch tested 85 children from 6 months to 5 years of age using T.R.U.E. TEST. They reported the overall prevalence of contact allergies in these children at 24.5%. Irritant reactions to the tape were reported in 7.4% of the tested children, and 6% removed the patches early due to discomfort.

Romaguera and Vilaplana (*Contact Dermatitis 1998*) patch tested 141 children with T.R.U.E. TEST. Of these, 45% were determined to have allergic contact dermatitis, most commonly to nickel, cobalt, mercurials, fragrance and rubber-based chemicals.

Note: This information is not intended to advise medical professionals to use T.R.U.E. TEST in a manner inconsistent with product labeling. Application of T.R.U.E. TEST in children is considered an off-label use even when supported by current medical care guidelines.

Please consult the T.R.U.E. TEST package insert for complete safety, clinical test data and prescribing information.



References and Additional Resources

Note: Current full prescribing information (package insert) is included in each box of T.R.U.E. TEST® (Allergen Patch Test) manufactured by SmartPractice Denmark.

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Haz-Map: Occupational Exposure to Hazardous Agents (Specialized Information Services, National Library of Medicine): hazmap.nlm.nih.gov

Contact Dermatitis Institute: contactdermatitisinstitute.com

T.R.U.E. TEST® (Allergen Patch Test): truetest.com

Finn Chambers®: finnchambers.com

ACDS/CAMP: Contact Allergen Management Program (hosted by the American Contact Dermatitis Society): contactderm.org

DermIS: An online database of dermatologic diseases and images: dermis.net

American Academy of Dermatology (AAD): aad.org

American Academy of Allergy, Asthma and Immunology (AAAAI): aaaai.org

Occupational Safety and Health Administration (OSHA): osha.gov

Food and Drug Administration (FDA): fda.gov

Environmental Protection Agency: nrdc.org

Dermatitis Academy: dermatitisacademy.com