

# Patch Test Reactions Associated With Sunscreen Products and the Importance of Testing to an Expanded Series: Retrospective Analysis of North American Contact Dermatitis Group Data, 2001 to 2010

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**Background:** Both active and inactive ingredients in sunscreen may cause contact dermatitis.

**Objectives:** This study aimed to describe allergens associated with a sunscreen source.

**Methods:** A cross-sectional analysis of patients patch tested by the North American Contact Dermatitis Group between 2001 and 2010 was performed.

**Results:** Of 23,908 patients patch tested, 219 (0.9%) had sunscreen coded as an allergen source. Patients who were male, with occupational dermatitis, or older (older than 40 years) had significantly lower rates of allergic reactions to sunscreens; the most commonly affected areas were the face and exposed sites ( $P < 0.0001$ ). The top 3 most frequent allergens in sunscreens were benzophenone-3 (70.2% for 10% concentration, 64.4% for 3% concentration), DL-alpha-tocopherol (4.8%), and fragrance mix I (4.0%). Less than 40% of positive patch test reactions were detected by the North American Contact Dermatitis Group screening series of 65 to 70 allergens.

**Conclusions:** A supplemental antigen series is important in detecting allergy to sunscreens.

With increasing public awareness of the harmful effects of ultraviolet radiation, the use of sun-protective measures, including sunscreens, has increased.<sup>1,2</sup> Sunscreen agents are also increasingly found in general cosmetics, including makeup, hair products, and moisturizers.<sup>3,4</sup> Lists of active sunscreen ingredients with synonyms and International Nomenclature of Cosmetic Ingredients names are available online.<sup>5</sup> Hence, investigation of contact dermatitis (CD) caused by sunscreens is important, despite the relatively low allergic potential of sunscreen chemicals.<sup>6</sup> Although photoallergy to sunscreen has been well studied and reported,<sup>7-9</sup>

reports of allergic CD caused by sunscreen are limited.<sup>6,10-12</sup> At least 1 study has documented that most individuals who suspect that they are allergic to sunscreen are not.<sup>13</sup> The purpose of this study was to evaluate the prevalence of sunscreens as a source of allergens in patients referred for patch testing in North America. We also evaluated all sources of allergic reactions to benzophenone-3.

## METHODS

### North American Contact Dermatitis Group Database

This study was approved by the Minneapolis Veterans Affairs Medical Center Human Studies Subcommittee. Between January 1,

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2001 and December 31, 2010, the North American Contact Dermatitis Group (NACDG) patch test standard series consisted of 65 to 70 allergens. The NACDG patch testing methods and procedures for determination of allergic reaction relevance and final diagnoses were described previously.<sup>14</sup> Data collected in the database included demographic information (age, sex, race, and occupation), sites of dermatitis (up to 3 sites), diagnoses (up to 3 diagnoses), and patch testing results of specific antigens, which included reactivity strength, clinical relevance (definite, probable, possible, past), occupational relevance (yes, no), and the source of exposure. Clinical relevance was defined as definite (the result of a positive patch test or use test with the suspected object or product was verified to contain the allergen), probable (the allergen could be verified as present in known skin contactants, and clinical presentation was consistent), possible (exposure included products that likely contained the allergen), and past (past exposure included products that likely contained the allergen).<sup>14</sup> Sources of exposure were recorded as triple-digit source codes. Only 1 source was recorded per allergen; therefore, these data included only sunscreen sources that were thought to be the primary source of the allergen. For non-NACDG allergens, clinical relevance, occupational relatedness, and source was also recorded, although the name of the non-NACDG allergen is not collected as part of the database.

Importantly, benzophenone-3 was the only sunscreen filter on the NACDG screening series during the study period. From 2001 to 2008, benzophenone-3 was tested at 3%; from 2009 to 2010, the concentration was increased to 10%. Photopatch testing data were maintained separately from the NACDG screening series data and are not presented here; combining this information is problematic

because of different allergen concentrations, patch test protocol (occlusion of photoallergens for 24 hours, rather than 48 hours), and deidentification of subjects.

## Study Population

The population of interest for this study was composed of patients patch tested by the NACDG between January 1, 2001, and December 31, 2010, who either had (1) sunscreen coded as a source for either an allergen or an irritant reaction or (2) an allergic reaction to benzophenone-3 (3% petrolatum [pet] or 10% pet).

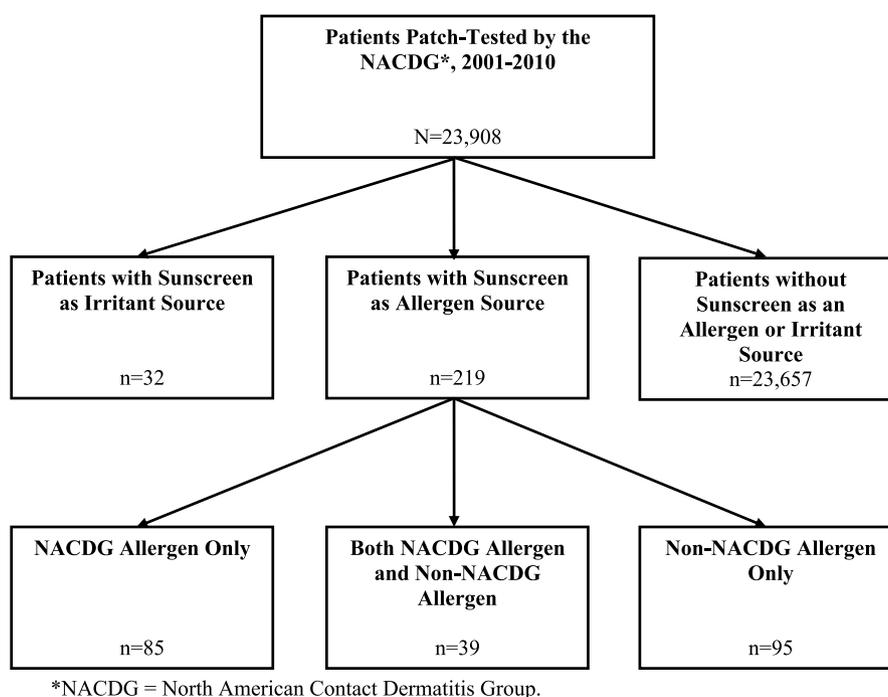
## Data Analysis

At a central location, all data were checked for quality assurance and then manually entered into a computerized database (Access 2007; Microsoft Corp, Redmond, Wash). Data from patients allergic to sunscreens were compared with those who were not, using Pearson  $\chi^2$  test (Fisher exact test, 2 tailed, when appropriate) and calculation of relative risk with confidence intervals using SAS software (version 9.2 Statistical Analysis System; SAS Institute Inc, Cary, NC). A *P* value of less than or equal to 0.05 was considered statistically significant. Given the exploratory nature of this analysis, no statistical adjustments were made for multiple comparisons.

## RESULTS

### Demographics

During the study period, 23,908 patients were patch tested. Two hundred nineteen (0.9%) patients had sunscreen coded as an allergen source, and 32 (0.1%) had sunscreen coded as an irritant



**Figure 1.** Study population subgroups.

source (Fig. 1). Of the 219 patients who had allergic reactions associated with a sunscreen source, 85 (38.9%) had reactions to a NACDG screening allergen only; 95 (43.4%), to a non-NACDG allergen only; and 39, (17.8%) had reactions to both.

As shown in Table 1, characteristics that were statistically significantly lower in sunscreen-allergic patients as compared with nonallergic patients included male sex, occupational dermatitis, and older age. Of the top 12 sites of dermatitis, involvement of the face, most exposed areas, lips, or eyes was statistically significantly higher in patients with sunscreen allergy as compared with those without sunscreen allergy, whereas scattered generalized distribution, or hand or leg involvement was statistically significantly lower. The most frequent final diagnoses in sunscreen allergic patients were allergic CD (59.4%) and photodermatitis (20.1%).

### Patch Test Results

Reaction rates to NACDG screening allergens associated with a sunscreen source are shown in Table 2. The most common allergen (>66%) was benzophenone-3 (3% or 10% concentration). DL-alpha-tocopherol, fragrances (fragrance mix I, *Myroxylon pereirae*), and preservatives (methylchloroisothiazolone/methylisothiazolone, quaternium-15, diazolidinyl urea, paraben mix, methylidibromoglutaronitrile/ phoxyethanol, 1,3-Dimethylol-5,5-dimethyl hydantoin, formaldehyde, and imidazolidinyl urea) were less common ( $\leq 5\%$  each). Almost all reactions were clinically relevant to the patient's current dermatitis (definite, probable, or possible relevance).

### Benzophenone-3 Sources

The sources of benzophenone-3 allergy are summarized in Table 3. Sunscreens, personal care products, moisturizers, cosmetics, and lipsticks were the most common culprits.

## DISCUSSION

This study explored the prevalence of sunscreens as a source of allergic reactions and irritant dermatitis in North America and identified several key findings. First, the rate of allergic reactions to sunscreens was low (0.9%). Second, almost two thirds (61.2%) of sunscreen allergic patients had at least 1 non-NACDG allergen responsible for a reaction to sunscreen, highlighting the importance of additional allergen series to supplement NACDG screening series for patients with suspected sunscreen allergy. Third, of NACDG allergens, benzophenone-3, the only active sunscreen ingredient included in the NACDG standard series, was the most common responsible allergen in sunscreens. Furthermore, patch testing to benzophenone-3 at 10% concentration yielded a 6.3% higher detection rate than benzophenone-3 3%, although this was not statistically significant ( $P = 0.5251$ , data not shown). Last, our study showed that the top allergens among inactive ingredients in sunscreens were DL-alpha-tocopherol, fragrances, and preservatives.

### Demographics

Male sex, older age, and occupational dermatitis were less likely to be associated with sunscreen allergy. The differences in sex and

age distribution could be explained by differences in behavior. Young males typically limit sunscreen usage to extended activities under the sun, whereas young females often use sunscreen for a wider variety of occasions in their daily lives.<sup>15</sup> Johnson and Lookingbill<sup>16</sup> reported that Pennsylvania Caucasian subjects younger than 30 years were more likely to use sunscreens. A survey done in northeastern England by Ling et al<sup>17</sup> further supports these observations; these researchers found a higher level of female sunscreen usage from ages 25 to 74 years and a downward trend for sunscreen usage as age increased. In addition to age and sex differences, the occupational results are not surprising. Sunscreen is not often provided by employers in North America; it is also likely that most of the employed workers in this study cohort worked indoors. As might be expected, sunscreen allergy was most commonly associated with dermatitis on exposed areas such as the face. These findings are consistent with previous reports.<sup>9,18,19</sup>

## Allergens

Benzophenone-3 (oxybenzone) was the most common allergen in the NACDG screening series associated with a sunscreen source, with positive patch test reactions in approximately two thirds of the sunscreen-allergic patients. It was the only active sunscreen chemical in the NACDG standard series. Previous studies have not evaluated benzophenone-3 allergy rates specifically from sunscreen use but rather overall prevalence rates. In a study involving 182 of patients tested over 6 years at the Mayo Clinic, 1.7% of all patch tested patients had a positive reaction to benzophenone-3 (3% concentration).<sup>20</sup> Benzophenone-3 is also one of the most common photoallergens.<sup>21</sup> Bryden et al photopatch tested 1155 patients in the United Kingdom and reported that 21% of the patients showed positive photoallergic patch test reactions to benzophenone-3 (10% concentration).<sup>9</sup> In their report, benzophenone-3 was the top allergen in patients suspected of having sunscreen allergy.<sup>9</sup> Other European and Australian studies also have reported benzophenone-3 as one of the top sunscreen allergens in photopatch testing.<sup>8,22-24</sup>

DL-alpha-tocopherol (Vitamin E) was the most frequent inactive ingredient allergen associated with a sunscreen source. This is unexpected because it is not a common allergen overall, with a positive reaction rate of 0.7% in the most recent NACDG report.<sup>14</sup> However, DL-alpha-tocopherol is frequently found in sunscreens and other products that contain sunscreen components. In a review of over-the-counter products, Scheman et al<sup>25</sup> found that 82.6% of sunscreen products contain DL-alpha-tocopherol. The popularity of DL-alpha-tocopherol may be due to its antioxidant properties, added to reduce photoaging<sup>26</sup> and decrease UV-induced damage.<sup>27</sup> It may also help stabilize UV filters.

Fragrances are common ingredients in personal care products including sunscreens. Scheman et al<sup>25</sup> found that 82.6% of the over-the-counter sunscreens contain fragrances and *Fisher's Contact Dermatitis* lists 14 sunscreens that contain balsam of Peru.<sup>28</sup> *M. pereirae* and fragrance mix I were the second and third most common inactive ingredient allergens in sunscreen allergic patients.

**TABLE 1. Demographics of Patients With Sunscreen as Sources of Allergic Reaction\***

| Demographics          | Patients With Allergy<br>to Sunscreen, n (%) | Patients With No Allergy<br>to Sunscreen, n (%) | RR (95% CI)                    |
|-----------------------|--|---|--------------------------------|
|                       | n = 219                                      | n = 23,689                                      | P                              |
| Men†                  | 35 (16.0)                                    | 8256 (34.9)                                     | 0.46 (0.34–0.62)<br><0.0001    |
| White                 | 185 (84.5)                                   | 20745 (87.6)                                    | 0.96 (0.91–1.02)<br>0.1671     |
| Occupational‡         | 3 (1.4)                                      | 3030 (12.8)                                     | 0.11 (0.03–0.33)<br><0.0001    |
| Atopy‡                | 79 (36.1)                                    | 4802 (20.3)                                     | 0.87 (0.73–1.04)<br>0.1177     |
| Atopic eczema†        | 41 (18.7)                                    | 6746 (28.5)                                     | 0.92 (0.70–1.22)<br>0.5701     |
| Hay fever             | 52 (23.7)                                    | 3415 (14.4)                                     | 0.83 (0.66–1.06)<br>0.1222     |
| Asthma                | 27 (12.3)                                    | 9784 (41.3)                                     | 0.86 (0.60–1.22)<br>0.3811     |
| Age >40 y†            | 121 (55.3)                                   | 15907 (67.1)                                    | 0.82 (0.73–0.93)<br>0.0002     |
| Top 12 Sites§         |  |   |                                |
| Face†                 | 80 (36.5)                                    | 4855 (20.5)                                     | 1.78 (1.49–2.13)<br><0.0001    |
| Most exposed areas    | 48 (21.9)                                    | 325 (1.4)                                       | 15.98 (12.17–20.98)<br><0.0001 |
| Arm                   | 35 (16.0)                                    | 3701 (15.6)                                     | 1.02 (0.75–1.39)<br>0.8844     |
| Scattered generalized | 30 (13.7)                                    | 5182 (21.9)                                     | 0.63 (0.45–0.87)<br>0.0035     |
| Hand†                 | 26 (11.9)                                    | 6654 (28.1)                                     | 0.42 (0.29–0.61)<br><0.0001    |
| Neck                  | 26 (11.9)                                    | 1989 (8.4)                                      | 1.41 (0.98–2.03)<br>0.0653     |
| Eyelids               | 22 (10.0)                                    | 2223 (9.4)                                      | 1.07 (0.72–1.59)<br>0.7383     |
| Trunk                 | 22 (10.0)                                    | 2805 (11.8)                                     | 0.85 (0.57–1.26)<br>0.4128     |
| Lips                  | 14 (6.4)                                     | 877 (3.7)                                       | 1.73 (1.04–2.88)<br>0.0364     |
| Leg†                  | 12 (5.5)                                     | 2637 (11.1)                                     | 0.49 (0.28–0.85)<br>0.0080     |
| Eyes                  | 6 (2.7)                                      | 210 (0.9)                                       | 3.09 (1.39–6.88)<br>0.0039     |
| Scalp                 | 5 (2.3)                                      | 1110 (4.7)                                      | 0.49 (0.20–1.16)<br>0.0933     |

\*Includes allergy to both NACDG and non-NACDG allergens.

†Male, Occupational, Age, Hand, Leg, Face, Atopic Dermatitis index.

‡Atopic dermatitis, asthma, or hay fever.

§Up to 3 anatomical sites were coded, thus total of more than 219.

CI, confidence interval; RR, risk ratio.

Preservatives are common culprits causing allergy in personal care products including sunscreens. Diazolidinyl urea is a formaldehyde releasing preservative that ranked as the fifth most common allergen in sunscreen-allergic patients in our study. Although in general, diazolidinyl urea is a less common cause of

allergy than other preservatives such as quaternium-15,<sup>14</sup> it is more commonly used in sunscreens (11.6% of sunscreens contain diazolidinyl urea vs 5.8% containing quaternium-15).<sup>25</sup> Methylchloroisothiazolinone/methylisothiazolinone is a preservative mixture and was the sixth most frequent allergen source in

**TABLE 2. Reaction Rates of NACDG Standard Allergens Associated With a Sunscreen Source**

| Allergen   | Allergic Reactions, n (%)* | Clinical Relevance |           |           |         |
|--|----------------------------|--------------------|-----------|-----------|---------|
|  |                            | Definite           | Probable  | Possible  | Past    |
| Benzophenone-3 (10% or 3% pet)                           | 82/124 (66.1)              | 18 (22.0)          | 38 (46.3) | 24 (29.3) | 2 (2.4) |
| Benzophenone-3 10% pet                                   | 26/37 (70.2)               | 5 (19.2)           | 11 (42.3) | 9 (34.6)  | 1 (3.8) |
| Benzophenone-3 3% pet                                    | 56/87 (64.4)               | 13 (23.2)          | 27 (48.2) | 15 (26.8) | 1 (1.8) |
| DL-alpha-tocopherol 100%                                 | 6/124 (4.8)                | 1 (16.7)           | 4 (66.7)  | 1 (16.7)  | 0 (0.0) |
| Fragrance mix I 8% pet                                   | 5/124 (4.0)                | 1 (20.0)           | 0 (0.0)   | 4 (80.0)  | 0 (0.0) |
| <i>M. pereirae</i> 25% pet                               | 5/124 (4.0)                | 0 (0.0)            | 0 (0.0)   | 5 (100.0) | 0 (0.0) |
| Methylchloroisothiazolone/methylisothiazolone 100 ppm aq | 3/87 (3.4)                 | 1 (33.3)           | 1 (33.3)  | 1 (33.3)  | 0 (0.0) |
| Diazolidinyl urea 1% pet                                 | 4/123 (3.3)                | 0 (0.0)            | 1 (25.0)  | 3 (75.0)  | 0 (0.0) |
| Quaternium-15 2% pet                                     | 4/124 (3.2)                | 3 (75.0)           | 0 (0.0)   | 1 (25.0)  | 0 (0.0) |
| Paraben mix 12% pet                                      | 3/124 (2.4)                | 1 (33.3)           | 2 (66.7)  | 0 (0.0)   | 0 (0.0) |
| Diazolidinyl urea 1% aq                                  | 3/124 (2.4)                | 1 (33.3)           | 1 (33.3)  | 1 (33.3)  | 0 (0.0) |
| Methylchloroglutaronitrile/phenoxyethanol, 2.0% pet      | 3/124 (2.4)                | 0 (0.0)            | 1 (33.3)  | 2 (66.7)  | 0 (0.0) |
| Propylene glycol, 30.0% aq                               | 2/123 (1.6)                | 0 (0.0)            | 0 (0.0)   | 2 (100.0) | 0 (0.0) |
| Formaldehyde 1% aq                                       | 2/124 (1.6)                | 0 (0.0)            | 1 (50.0)  | 1 (50.0)  | 0 (0.0) |
| DMDM hydantoin 1% pet                                    | 2/124 (1.6)                | 1 (50)             | 0 (0.0)   | 1 (50.0)  | 0 (0.0) |
| Benzocaine 5% pet  | 1/87 (1.1)                 | 0 (0.0)            | 1 (100.0) | 0 (0.0)   | 0 (0.0) |
| Carba mix 3% pet   | 1/123 (0.8)                | 0 (0.0)            | 0 (0.0)   | 1 (100.0) | 0 (0.0) |
| Nickel sulfate 2.5% pet                                  | 1/123 (0.8)                | 0 (0.0)            | 0 (0.0)   | 1 (100.0) | 0 (0.0) |
| Imidazolidinyl urea 2% aq                                | 1/124 (0.8)                | 1 (100.0)          | 0 (0.0)   | 0 (0.0)   | 0 (0.0) |
| Lanolin alcohol 30% pet                                  | 1/124 (0.8)                | 0 (0.0)            | 1 (100.0) | 0 (0.0)   | 0 (0.0) |

\*Denominator is number of patients with at least 1 NACDG allergy from a sunscreen source tested to allergen. aq, aqueous; DMDM, 1,3-Dimethylol-5,5-dimethyl.

the present study. Interestingly, previous reports indicated that this mix was highly allergenic.<sup>29,30</sup> However, MI is becoming increasingly used by manufacturers as a single agent preservative. Recent reports suggest that testing the methylchloroisothiazolinone/methylisothiazolinone mixture may miss a significant number of clinically relevant allergies to MI alone.<sup>29,31</sup>

### Detection Rate

The present study found that 61.2% (134/219) of the patients had at least 1 allergen with a sunscreen source that would have been missed by the NACDG standard series; 43.4% (95/219) of the patients only reacted to a non-NACDG sunscreen allergen.

Hence, it is essential to patch test with supplemental allergens in patients with clinical suspicion of sunscreen CD. Because the NACDG screening series contains only 1 active sunscreen chemical, it would be desirable to include supplementary sunscreen allergens from specialized series, when appropriate. Lists of suggested sunscreen allergens have been previously published.<sup>32</sup>

### Allergen Source

Notably, our study showed that benzophenone-3, an active sunscreen ingredient, is present as well in a wide range of other cosmetics and skin care products and that these products may be significant benzophenone-3 allergen sources (Table 3). Although it is intuitive

**TABLE 3. Sources of Benzophenone-3 Allergy**

| Allergen            | Sources   | Frequency, n (%) |
|---------------------|---|------------------|
|                     |   | n = 173*         |
| Benzophenone-3 (3%) | Sunscreens                                      | 86 (49.7)        |
|                     | Personal care products, not otherwise specified | 28 (16.2)        |
|                     | Moisturizers, lotions, creams                   | 10 (5.8)         |
|                     | Cosmetics                                       | 10 (5.8)         |
|                     | Lipsticks                                       | 5 (2.9)          |
|                     | Makeup  | 2 (1.2)          |
|                     | Shampoos  | 1 (0.6)          |
|                     | Solvents, oils, lubricants, fuels               | 1 (0.6)          |
|                     | Unknown   | 30 (17.3)        |

\*Total number of benzophenone-3 sources.



**Figure 2.** Patient with strong vesicular patch test reaction to benzophenone-3, which was clinically relevant as an ingredient in her waterless hand cleanser and several body fragrance sprays.

that active sunscreen agents would be desirable to the consumer in moisturizers, foundations, and lip products, many consumers and physicians are not aware of the presence of active sunscreen agents in other items such as shampoo, nail polish, fragrance sprays, and waterless hand cleansers (Fig. 2). In the later group of products, sunscreens function to prevent ultraviolet degradation of formulation ingredients rather than protect human skin from sun-related damage.

### Limitations

This study has several limitations. First, in such a cross-sectional study, causal relationships cannot be determined. Second, these results are from a tertiary referral population, and therefore, they may not be characteristic of the general population. Third, because the names of non-NACDG screening allergens are not recorded in the database, information regarding these allergens is not available. Fourth, only 1 allergen source is coded for each allergen; therefore, these data reflect underreporting of sunscreen sources (eg, if an allergen could be found in multiple sources, then a more general source category such as “personal care products” would likely be coded). Fifth, relevance for common (eg, fragrance) and other allergens (eg, alpha-tocopherol) require detailed study. Finally, photoallergy and photopatch test results are not included in these data.

### SUMMARY

This large epidemiologic evaluation of consecutively patch tested patients in North America found that 0.9% of the patients had an allergic reaction to a chemical associated with a sunscreen source. As expected, benzophenone-3 was the most common responsible sunscreen allergen in NACDG screening series. However, evaluation of common inactive ingredient allergens found that DL-alpha-tocopherol, fragrance mix I, *M. pereirae*, and diazolidinyl urea were common culprits. Almost two thirds of patients had at least 1 sunscreen-related reaction to a non-NACDG allergen, highlighting the importance of utilizing additional allergen series to test patients with clinical suspicion of sunscreen-induced CD.

Investigation of the sources of common sunscreen ingredients showed that, in addition to sunscreen products, many other consumer products also contribute to sunscreen associated CD.

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