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## ASSESSING ALLERGENIC INGREDIENTS IN COSMECEUTICALS: A COMPREHENSIVE REVIEW OF ALLERGENS IN THE US MARKET

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### ABSTRACT

Cosmetic allergies a widespread problem, can affect people of all ages and appear in a variety of ways. These allergies are caused by the immune system's sensitivity to normally innocuous compounds, known as allergens, found in common cosmetics such as soaps, lotions, and makeup. In response to allergens, the immune system creates chemical molecules, including antibodies, resulting in a range of symptoms ranging from itchy rashes to life-threatening anaphylactic responses. This study delves into the world of cosmetic allergies, including their origins, symptoms, and frequent allergen classifications. Fragrances, Preservatives, Dyes, and Metals are major offenders, with fragrance-related respiratory problems standing out. Robust testing procedures are required to ensure cosmetic safety, and the USFDA has implemented stringent testing and regulatory systems. Primary goal is to testing processes, focusing on the patch. The purpose of this study is to promote awareness of cosmetic allergies, educate on testing methods, and emphasise the necessity of consumer reporting. Consumers, healthcare providers, and Regulatory organisations must work together to ensure the safety and integrity of cosmetic goods.

**Keywords: Allergens, Cosmetics, USFDA, Regulatory organisations**

## INTRODUCTION:

Cosmetics (such as soaps, facial and eye make-up, perfumes, and so on) might cause an allergic reaction. Many individuals suffer from allergies, and allergies can develop at any age. Allergic reactions are the immune system's reaction to seemingly harmless substances. An allergen can induce the immune system to create chemical molecules like antibodies, resulting in allergy symptoms. Many people are aware that seasonal allergies are triggered by

pollen from flowering plants, as well as food allergies. Cosmetic allergies most commonly manifest as red rashes or itching on the skin; they are also identified as contact dermatitis. Over 4,000 tiny compounds that might cause skin sensitivity have been identified as allergens [1, 2].

Common allergens frequently found in cosmetic products can be categorized into five main groups

**Table 1: Most common allergens are frequently included in cosmetic goods**

S. No.	Category	Example
1	Preservatives	<ul style="list-style-type: none"> <li>➤ Methylisothiazolinone (MIT)</li> <li>➤ Methylchlorisothiazolinone</li> </ul>
2	Fragrances	<ul style="list-style-type: none"> <li>➤ Amyl cinnamal</li> <li>➤ Benzyl benzoate</li> <li>➤ Cinnamyl alcohol</li> <li>➤ Eugenol</li> <li>➤ Farnesol</li> <li>➤ Geraniol</li> </ul>
3	Dyes	<ul style="list-style-type: none"> <li>➤ p-phenylenediamine (PPD)</li> <li>➤ Coal-tar</li> </ul>
4	Natural Rubber	<ul style="list-style-type: none"> <li>➤ Latex</li> </ul>
5	Metals	<ul style="list-style-type: none"> <li>➤ Nickel</li> <li>➤ Gold</li> </ul>

### Symptoms:

The allergic reactions can present a spectrum of symptoms, with common manifestations including hives, itching, rashes, facial swelling, and respiratory distress like wheezing. In severe cases, anaphylaxis, a life-threatening allergic response, may occur, featuring symptoms like loss of consciousness and chest pain. Notably, in accordance with US cosmeceutical regulations, it's important to recognise that fragrance ingredients, which can be inhaled, may also impact the

respiratory system, especially for individuals with conditions like asthma or allergies. This can result in symptoms such as breathlessness, coughing, and chest tightness [1].

### Testing of allergens:

In the US, ensuring safety and allergen content in cosmetics is of paramount importance to protect consumers with sensitivities. Rigorous testing methods and regulations are in place to identify and quantify allergenic ingredients in cosmetic products. These measures play a crucial role

in safeguarding public health and promoting transparency within the cosmetics industry.

This article explores the key testing

procedures and regulatory frameworks that govern allergen detection in cosmetics

across the US market [1].

**Table: 2 Tests for identifying allergens**

Sl. No	Name of the Test	Description
1	Patch Test	A patch test is a type of skin test performed in dermatology to determine whether compounds may cause skin allergies, particularly allergic contact dermatitis.
2	Prick Test	A prick test is a basic medical test that determines whether a person is allergic to cosmetics.
3	Intradermal Test	An intradermal allergy test is a medical procedure that involves injecting a small amount of allergenic chemicals directly beneath the skin's surface to identify allergies.
4	Allergy Blood Test	An allergy blood test, also known as a particular IgE blood test or allergen-specific IgE test, is a medical treatment that detects allergies by testing a person's blood levels of certain antibodies known as immunoglobulin E (IgE).

### Patch Test:

Patch Test is one of the most frequently Used tests for testing of allergens. A patch test is a diagnostic procedure used by dermatologists to detect allergens responsible for skin allergies, particularly allergic contact dermatitis. It involves applying small amounts of potential allergenic substances to adhesive patches, which are then attached to the patient's skin, usually on their upper back. The patches remain in place for 48-72 hours, allowing for the observation of any allergic reactions.

After the test period, the patches are removed, and the dermatologist examines the skin for signs of irritation or allergic responses. Patch tests are crucial for accurately identifying substances causing skin allergies, aiding dermatologists and patients in recognizing allergens to avoid and creating effective treatment plans. They are especially valuable when there is suspicion of contact allergies, as they can pinpoint specific triggers that might not be easily identifiable through other diagnostic methods [1].



**Figure 1: Example for Patch Test**

**RESULTS AND DISCUSSION:****How to report a cosmetic related problem:**

If you have a problem with a cosmetic product, we should stop using it immediately and we have to consult a healthcare physician. Then, notify the FDA about the problem. If we experience a response to a cosmetic product, such as a rash or hair loss, or if we observe something unusual about the product, such as an unpleasant odour or colour change, we should notify the FDA. Cosmetic products are different from medicines, and they have their own rules from the FDA. These can include things like tattoos, lotions, makeup, deodorants, and more.

To report a problem, we can call the FDA, fill out a form online, or send a paper form to them. The law doesn't require cosmetic businesses to disclose issues to the FDA, so your disclosure is critical to keeping cosmetics safe. When we will contact the FDA, we have to provide information about ourself, the product, and what went wrong. The FDA will keep our information private and use our report to see if others had similar issues. They'll also check if there's a broader problem with the product that could affect public health. While they may not act on every report, they do look into all of them to make sure people are safe [3].

**Table 3: Procedure for reporting cosmetic related problem [3]**

<b>How to Report an Issue</b>	<p>You may report an issue with a cosmetic to the FDA in two ways:</p> <ol style="list-style-type: none"> <li>1) <b>Contact MedWatch, the FDA's safety information and adverse event reporting programme.</b> <ul style="list-style-type: none"> <li>• Call 1-800-FDA-1088.</li> <li>• To file a voluntary report online, visit <a href="http://www.fda.gov/medwatch">http://www.fda.gov/medwatch</a>.</li> </ul> </li> <li>2) <b>Find a Customer Complaint Coordinator in your region. Find one at <a href="http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators">http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators</a>.</b></li> </ol>
<b>Who Needs to Report a Problem</b>	Consumers and healthcare practitioners can report problems.
<b>What information should you include in your report</b>	<p>When contacting FDA, please include the following information in your report if known:</p> <ol style="list-style-type: none"> <li>1) <b>Information on the affected person:</b> <ul style="list-style-type: none"> <li>• Name, address, phone number, and email address</li> <li>• Age, gender, and ethnicity.</li> </ul> </li> <li>2) <b>Product Details:</b> <ul style="list-style-type: none"> <li>• Product name and manufacturer</li> <li>• Product codes or identifying markings on label or container</li> <li>• Purchase date and location.</li> </ul> </li> <li>3) <b>Problem Description:</b> <ul style="list-style-type: none"> <li>• Describe the response or problem</li> <li>• Include any medical therapy offered.</li> </ul> </li> </ol>
<b>What will the FDA do with your report?</b>	<p>Upon receipt of the report:</p> <ul style="list-style-type: none"> <li>• The FDA guarantees confidentiality for all reports.</li> <li>• The FDA will add the information to its database to identify similar issues reported by others.</li> <li>• The FDA evaluates reports to identify potential public health concerns.</li> <li>• The FDA may or may not take action on every report received; however, the agency does review all reports to determine if action is warranted to safeguard public health.</li> </ul>

### **Adverse Event Reporting System for cosmetics in US:**

In the US, the adverse event reporting system (CAERS) database at the Centre for Food Safety and Applied Nutrition is likely a storage place for information with respect to problems with food, dietary supplements, and cosmetics. When someone has a bad reaction to something they ate or put on their skin, they can report it to the FDA, and this information goes into the CAERS Database. This helps the FDA keep an eye on the safety of these products.

The database contains different kinds of information. It has details about the people who had the problem, like their age and where they live, and each report gets a special ID number. It also has information about the product that caused the issue and what kind of symptoms people had because of it [4].

This database is crucial for the FDA to watch over the safety of these products. It lets them see if there are patterns or common issues with certain foods, supplements, and cosmetics. By studying this data, they can take action to keep people safe. So, the CAERS Database is a vital tool in making sure the things we eat and put on our bodies are safe for everyone [3].

### **SUMMARY AND CONCLUSION:**

Allergies can arise from various cosmetic products and affect individuals of all ages. They result from the immune system's

response to typically harmless substances called allergens, leading to symptoms ranging from mild rashes to severe anaphylactic reactions. Common allergen categories include fragrances, preservatives, dyes, and metals, with fragrance-related respiratory effects being particularly important for individuals with conditions like asthma. There are various allergen testing methods, including patch tests, prick tests, intradermal tests, and allergy blood tests. Among these, the patch test stands out as a valuable tool for accurately identifying skin allergens. In US the center for food safety and applied nutrition's Adverse Event Reporting System (CAERS) database plays a pivotal role in tracking adverse events associated with food, dietary supplements, and cosmetics, enhancing consumer safety and product integrity. Finally, cosmetic allergies present a significant concern necessitating vigilance, effective reporting, and collaborative efforts between consumers and healthcare providers.

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