

Consumer Guide on unwanted reactions to cosmetic products

Manufacturers of cosmetic products want their consumers to enjoy using their products. However companies want to know if someone has a reaction to their product.

This guide helps explain what to do in such an instance and why it is important to inform the cosmetic product manufacturer.

The guidance document has been written by members of the European Personal Care Association, Cosmetics Europe (www.cosmeticseurope.eu). CTPA is a member of Cosmetics Europe.

KEY POINTS

It is very important that you always read and follow the instructions carefully on the packaging, and/or any leaflet, of your cosmetic product before use and follow them closely.

If you believe you have had a reaction to a cosmetic product:

- **Stop using the suspected product(s) and wash off any remaining product that you may have applied.**
 - Unless the reaction clears up quickly, seek medical attention and advice.
 - If at any time you feel your reaction requires urgent medical attention, do not hesitate to contact your doctor or even visit a hospital casualty/emergency department.
 - Although reactions to hair colorants are rare, they can occur and they can develop over time. They may be severe. Such reactions can include redness and swelling of the whole head and face (contact allergy) and must be treated rapidly.
- **A discussion with your healthcare professional should identify the cause of your reaction and help you to avoid such a reaction in the future.**
 - It is important to identify if the reaction is to a specific ingredient, as you could react to the same substance in another product.
- **In all cases, do please contact the company and let them know.**
 - Contact details (post, telephone and /or website are printed on the pack.
 - You will be asked to provide information about yourself, the product and the circumstances. The company may also ask for permission to communicate with your own doctor. All information will be kept confidential in accordance with EU data protection legislation.
 - The company will usually ask you to return the product to identify the exact product.
- **If you have contacted the retailer where you bought the product do also let the company/manufacturer know.**

Contents

Purpose.....	2
Background.....	2
What sort of reactions might occur?.....	3
I've had a reaction; what should I do?.....	3
<i>Healthcare advice</i>	3
<i>Inform the company</i>	4
What happens next?.....	4
<i>Healthcare advice</i>	4
<i>Company obligations</i>	4
I've been offered patch-testing. What is that?.....	5
Should I complain to the retailer?.....	5
Hair colorants.....	5
References.....	6

Purpose

This guide is aimed at consumers who have experienced unwanted symptoms in relation to the use of a cosmetic productⁱ. It provides useful information on what you should do and also tells you what help and advice you can expect from the manufacturer and retailer. In addition, if you have been to your doctor or other healthcare professional, it explains what they should do to report the adverse reaction.

Background

Cosmetic productsⁱ are amongst the safest products available to the consumer. They are regulated by strict European laws (specifically the EU Cosmetic Products Regulation 1223/2009ⁱⁱ) that require cosmetics to be assessed for safety and must be safe for use before they are placed on the market. That assessment must be carried out by a scientific expert, a cosmetic safety assessor, whose qualifications are laid down in the cosmetics laws.

It is though true that almost any substance, natural or man-made, has the potential to produce a reaction in someone, somewhere. Each person is different and we might find we are allergic to substances that others use or consume without any problems. For example, many people can eat peanuts safely while some can react severely to them. Some cosmetic products may simply not suit some people and as a result, there can be adverse reactions, also called 'undesirable effects'. Fortunately these are rare and are usually mild and reversible, meaning they will go away if you stop using the product. However 'serious undesirable effects' may never be excluded in some individuals and, in the case of allergic reaction, the most serious could even require urgent medical intervention.

Unless a company gets feedback from their consumers, or the doctors, it will not learn about undesirable effects caused by their products in certain individuals despite the product having the correct safety assessment. While reactions are understandably of concern for the individuals unfortunate to experience them, we would like to stress that a reaction to a cosmetic product does not necessarily mean that the product itself is unsafe. The company will investigate any reactions to their products to make sure there are no problems with the product

and that they are not unsafe for the general population. The only way for a company to know if its products are causing undesirable effects in certain individuals is for consumers to report them. Therefore, if you believe you have had such a reaction to a cosmetic product, do please contact the company and let them know. Such information helps companies ensure their safety assessments remain relevant and will ultimately help ensure product safety continues to be high.

In addition, the law requires companies to keep records of and review all undesirable effects, while any serious ones must be communicated to the authoritiesⁱⁱⁱ.

Adverse reactions are complex, various factors can trigger them and they may vary from one person to another. Having information reported to the companies is important in helping to understand such reactions.

What sort of reactions might occur?

Most of the time, when a reaction occurs, it involves skin manifestations such as, for instance, itchiness, redness or a rash and sometimes swelling. Most reactions of this kind are mild and will clear up on their own after the product has stopped being used.

It is possible that some people may develop an allergy to a product or one of its ingredients. It is important to note that some substances may require several exposures over time (months or years) to trigger an allergy. So you may have used the same product for a long time before developing a reaction to it.

In the case of product getting in the eye or a reaction involving the eye, there can be stinging and watering of the eye, blurring of vision and the eyelids can be shut tight. In such a case, it is advised to immediately and thoroughly rinse the affected eye.

Reactions to oral care products can include gum dryness, redness and/or swelling as well as general discomfort in the mouth.

Reactions can sometimes be more severe, for example reactions to some hair colorants, and should be seen by a doctor. If at any time you feel your reaction requires urgent medical attention, do not hesitate to contact your doctor or even visit a hospital casualty/emergency department.

In all cases, unless the reaction clears up quickly, it is usually better to seek medical attention and advice.

I've had a reaction; what should I do?

The first thing to do is stop using the suspected product(s) and wash off any remaining product that you may have applied. In the case of product entering the eye, the eyes should be thoroughly rinsed with water, even if this may be difficult.

Healthcare advice

If the reaction is severe, do visit a healthcare professional: your doctor or a pharmacist, or in the case of a reaction to a toothpaste or mouthwash, you might want to visit your dentist.

Please **remember to take the product with you** as it will provide helpful information and accurate identification of the actual product used.

In case of reactions to hair colorants do **not colour your hair** again, but seek advice from the manufacturer and/or a healthcare professional. This will also be mentioned in the safety instructions for use.

Healthcare professionals will ask you about the product(s) you have used and will try to establish the cause of your reaction. Based on the reported timings (the term 'chronology' may be used), the symptoms (visible and felt) and the outcome of any reapplication, the health professional will evaluate the nature of the adverse reaction and the role of the product(s). In order to ensure the reaction can be investigated fully, it is important to have as much information as possible. Dated photographs might be useful.

A detailed discussion with your healthcare professionals should identify the cause of your reaction, or if other causes than the product are possible, and help you to avoid such a reaction in the future.

If the reaction is severe or increasing in severity, or if at any time you feel your reaction requires urgent medical attention, do not hesitate to contact your doctor or even visit a hospital casualty/emergency department. Some rare but severe allergic reactions may require a rapid treatment.

Inform the company

In all cases, if you have a reaction **do contact the company** that supplied or made the product. The name and address or a telephone number is printed on the pack. You can also consult their website which may have dedicated information for customer comments.

By telling the companies you are providing the industry with invaluable information to help ensure cosmetic products continue to be safe to use for the general population. Companies will monitor any trends in reported reactions and if on the very rare occasion a problem is identified with a cosmetic product, appropriate action will be taken by the company.

What happens next?

Healthcare advice

If you are seen by a doctor or pharmacist, follow their instructions. If the problem persists, do return for further advice. The doctor or pharmacist may wish to report some incidents to the authorities. We would always encourage the healthcare professional to inform the manufacturer of a reaction to a known cosmetic product. As mentioned, in order to ensure the reaction is analysed and reported appropriately, it is also recommended to contact the manufacturer in all cases, even if it has already been reported to the healthcare provider.

Doctors who treat serious cases of reactions to cosmetic products should be encouraged to report these cases to the authorities. This guide advises doctors always to contact the manufacturer if a patient presents with a reaction to a cosmetic product.

Company obligations

Once you have contacted the manufacturer, that company will record and investigate the adverse reaction. This is required by the legislation. In order to do this, you will be asked to provide information about yourself, the product and the circumstances of the reaction. Those details may be asked over the telephone or you may be asked to complete a form and return it to the company. Those details will be kept confidential in accordance with EU data protection legislation.

The company will usually ask you to return the product. This is normal and will enable the company to identify the specific product batch to make sure the complaint can be investigated fully.

If you have sought medical attention, the company may ask for permission to communicate with your own doctor. This is to help the company to better understand the potential causes and the exact type of the reaction and, if appropriate, to decide what to do to minimise the risk of it happening to someone else. Companies will never contact your doctor directly without your written permission.

I've been offered patch-testing. What is that?

In some specific instances, your doctor or the company may suggest you visit a dermatologist or allergologist for further investigation. If an allergic reaction is expected or cannot be excluded, a patch test may be advised where the product and ingredients are applied to the skin under controlled conditions. It will involve several separate visits where the doctor will carry out a series of patch tests to try to identify what substance in the product caused your reaction. This is important for you to identify the specific ingredient(s), since you could react to the same substance in another product.

If the cause of your allergic reaction is identified, you can minimise the risk of a repeat reaction by avoiding other consumer products containing the same ingredient. In Europe, all cosmetics have the list of their ingredients appearing on the packaging to help consumers avoid products containing a substance to which they are allergic. The name might sometimes be complex but once you know what to look for, you can avoid it in any other cosmetic you might want to try. Ingredients are named using the International Nomenclature of Cosmetic Ingredients, known as INCI. This means that in whatever European country you buy your cosmetic product (and in many places around the world), the ingredient names will be the same.

Should I complain to the retailer?

You can of course contact the retailer where you bought your product. However, since retailers usually do not have the detailed product knowledge of the manufacturer, in most cases they will contact the manufacturer to let them know of the adverse reaction.

If you have contacted the retailer about another company's branded cosmetic product, do also let the manufacturer know about the contact you have made with the retailer.

However, if the product in question is actually one of the retailer's own brand of cosmetic products, then the retailer is classed as the 'manufacturer' and will follow the same procedures as the manufacturer explained above.

Hair colorants

Many millions of hair colorants are used in Europe each year in perfect safety. However, because some people have the potential to develop allergies to ingredients of hair colorants, there are very clear warnings and instructions provided for use. Manufacturers go beyond the legally required allergy warnings that must be labelled on-pack and it is very important that you always carefully read the instructions on the packaging and the leaflet of your product before use and follow them fully.^{iv}

Some hair colorants require you to carry out an Allergy Alert Test a full 48 hours each time before you intend to dye your hair. The aim is to identify people at risk before they colour their hair and so avoid a bad reaction.

You do not need to purchase a second product for the Allergy Alert Test. You should use a little of the one you intend to use to colour your hair, as instructed. Replace the tops afterwards and the remaining product will be fine for you to use 48 hours later, if you have not reacted to the Allergy Alert Test.

If you react to the test, if you have a rash on your face, if your scalp is sensitive, irritated or injured or if you had a reaction to a hair coloration or to a 'black henna' temporary tattoo before, this is a clear indication that you are at risk of reacting to the hair colorant and so should **not** go ahead and dye your hair. Do not change to another brand or colorant; many hair colorant products use the same ingredients and you could react to the new brand or shade as well as to a hair colorant you tolerated well in the past. Please do not think that as you have bought

the product, you might as well use it rather than waste money. Contact the manufacturer for a refund. They would rather do that than risk you having a nasty reaction.

Although reactions to hair colorations are rare, they can occur, they can develop over time and they may be severe. Such reactions can include redness and swelling of the whole head and face (contact allergy) and must be treated rapidly. In isolated cases severe **immediate** reactions in relation to the use of hair colorations may occur, similar to reactions to bee stings or peanuts. They may be associated with breathing difficulties or circulation problems. In such a situation - independent of the cause of the reaction - emergency treatment is always needed.

References

ⁱ The definition of a cosmetic product is provided in the EU Cosmetic Products Regulation (1223/2009):

‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours

The Regulation also gives an indicative list of what is classified as a cosmetic product:

The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product. Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoos), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

ⁱⁱ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

ⁱⁱⁱ National Authorities Contact Points for Serious Undesirable Effects to Cosmetics:
<http://ec.europa.eu/DocsRoom/documents/13251/attachments/9/translations>

^{iv} Safe use of hair colouring products
<http://www.colourwell-colourwise.eu/>
<http://www.thefactsabout.co.uk/hair-colorants-and-haircare/content/28>

Further information:

- Facts about cosmetics safety:
<http://www.thefactsabout.co.uk/confidence-in-cosmetics/content/128>
- Cosmetics Europe Guidelines on Roles and Responsibilities along the supply chain of cosmetics:
<https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=89&catid=46>