

99118045261000

Reports of serious undesirable effects (SAEs) of cosmetic products Receipt

Heruntergeladen am 02.07.2025

<https://fimportal.de/xzufi-services/102889186/B100019>

| Modul | Sachverhalt |
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| Leistungsschlüssel | 99118045261000 |
| Leistungsbezeichnung I | Reports of serious undesirable effects (SAEs) of cosmetic products Receipt |
| Leistungsbezeichnung II | Report undesirable effects and damage to health with cosmetics |
| Typisierung | 1 - Bund: Regelung und Vollzug |
| Quellredaktion | Bund |
| Freigabestatus Katalog | fachlich freigegeben (gold) |
| Freigabestatus Bibliothek | unbestimmter Freigabestatus |
| Begriffe im Kontext | |
| Leistungstyp | Leistungsobjekt mit Verrichtung |
| Leistungsgruppierung | |
| Verrichtungskennung | Entgegennahme (261) |
| SDG-Informationsbereich | nicht SDG-relevant |

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| Lagen Portalverbund | Verbraucherschutz (1150300), Statistische Erhebungen und Meldepflichten (2090200), Verbraucherschutz (2140100) |
| Einheitlicher Ansprechpartner | Nein |
| Fachlich freigegeben am | 05.06.2025 |
| Fachlich freigegeben durch | Federal Ministry of Justice and Consumer Protection |
| Handlungsgrundlage | https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32009R1223 |
| Teaser | If you use cosmetics and adverse effects occur, you can report this. As a manufacturing or trading company, you must report effects with serious health consequences to the authorities. |
| Volltext | <p>If you use cosmetic products, so-called undesirable effects may occur in rare cases, for example allergic reactions, skin irritation or other intolerances:</p> <ul style="list-style-type: none"> • burning scalp • itching • redness • skin rash • Swelling of body parts <p>Every time an adverse reaction is reported, consumers can be better protected in future, for example through</p> <ul style="list-style-type: none"> • targeted controls • product warnings • product recalls • Adjustment of the formulation • Adaptation of labeling <p>Notification as a consumer:</p> <p>If you as a consumer notice such a negative effect on your health after using cosmetic products, you can inform the Federal Office of Consumer Protection and Food Safety (BVL).</p> <p>Alternatively, you can also contact the following bodies</p> |

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directly:

- the manufacturing or importing company indicated on the packaging
- the retail store where you purchased the product
- the competent authorities, usually the food inspectorate in your district or city

The following persons can pass on information about the undesirable effects:

- yourself or a person you authorize, for example relatives or a legal representative if you are under 16 years of age, you must be represented in any case
- medical professionals such as a doctor, pharmacist, nurse or nurse practitioner
- Employees of hairdressing salons, beauty and massage studios, for example

Notification as a company:

If you, as a company that manufactures, imports or trades cosmetics, become aware of adverse effects, you must

- check whether it is a serious undesirable effect (SUE) according to the criteria of the EU Cosmetics Regulation. As a rule, SUEs require a medical assessment and usually also treatment. This includes, for example a sick note because the hands are swollen hospitalization for further examination an anaphylactic, i.e. allergic shock
- if it is an SUE, it is your duty to inform the competent authority.

Erforderliche Unterlagen

For consumers:

- If you submit a notification, it should include the following information: Your initials (names) Your year of birth Your symptoms the time of onset the nature of the consequences the name of the cosmetic product concerned

For companies:

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| | <ul style="list-style-type: none"> • Notification form A |
| Voraussetzungen | |
| Kosten | There are no costs for you. |
| Verfahrensablauf | <p>As a consumer, you can report your notification in different ways:</p> <ul style="list-style-type: none"> • Inform the BVL directly online, by post or e-mail Online procedure: The online form guides you step by step through the information required by the authority. E-mail or post: Download the checklist from the BVL website and fill it out directly. You can remain anonymous when reporting, but one person should be identifiable for queries, for example: doctor, hairdresser, relative Send the completed checklist to the BVL by e-mail or print it out and send it by post. The notification can also be sent informally by e-mail or post, but should then contain various required information (see online form or checklist). Once you have informed the BVL, the information will be forwarded to the competent authority. • informal notification in writing to the manufacturer or importer, which you will find on the packaging, the retailer or the competent authority. If the manufacturer, importer or retailer classifies the case as a serious undesirable effect, they must forward the report to the competent authority. • Information to the competent authority If the information is sent informally by e-mail or post, it should contain various necessary information (see online form or checklist). Companies and authorities consult with each other in order to classify the undesirable effects and coordinate measures. <p>As a manufacturer, importer or trading company based in Germany, you can send your notification of serious adverse effects to the competent authority by e-mail or post using notification form A:</p> <ul style="list-style-type: none"> • Download the notification form A from the BVL website. • You can fill in the form directly or print it out. • Send the completed form by e-mail or by post to the |

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| | <p>supervisory authority responsible for you.</p> <p>As a manufacturer, importer or trading company based abroad, you can submit your notification of serious undesirable effects to the BVL using the online procedure, by e-mail or by post:</p> <ul style="list-style-type: none"> • Online procedure: Only companies based abroad can use the online form. It guides you step by step through the necessary information and provides an upload for the notification form A, which is also available in English. You do not need a user account to use the online procedure or to report from abroad. • E-mail or post: Download the notification form A. You can fill in the form directly or print it out. Send the completed form to the BVL by e-mail or post. |
| Bearbeitungsdauer | 20 Werktag(e) |
| Frist | Retailers, manufacturers or importers must immediately report serious adverse effects of cosmetics to the competent monitoring authority, at the latest within 20 days of becoming aware of them. |
| weiterführende Informationen | <p>https://www.bvl.bund.de/DE/Arbeitsbereiche/03_Verbraucherprodukte/03_AntragstellerUnternehmen/02_Kosmetik/02_SUE/bgs_fuerAntragsteller_kosmetik_SUE_node.html</p> <p>https://www.bvl.bund.de/DE/Arbeitsbereiche/03_Verbraucherprodukte/02_Verbraucher/07_FAQ/04_FAQ_UnerwunschteWirkungen/bgs_kosmetik_FAQ_node.html</p> <p>https://www.bvl.bund.de/SharedDocs/Flyer/nach_TheMen/21_Flyer_Kosmetik_Unerwunschte_Wirkungen.html</p> <p>https://www.bvl.bund.de/SharedDocs/Downloads/03_Verbraucherprodukte/Kosmetik/SUE_Leitlinien_de.pdf</p> <p>https://www.bvl.bund.de/DE/Arbeitsbereiche/03_Verbraucherprodukte/03_AntragstellerUnternehmen/02_Kosmetik/08_Adressen/Adressen_Behoerden/kosmetik_adressen_Behoerden_node.html</p> |
| Hinweise | |
| Rechtsbehelf | You cannot lodge an appeal. |
| Kurztext | <ul style="list-style-type: none"> • may occur when using cosmetics: adverse effects, for |

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example skin rash or itching Serious adverse effects that require, for example, sick leave or hospitalization

- Consumers should definitely report any adverse effects to inform the manufacturing company, the importing company - see packaging - or the retailer or make a report to the responsible local authorities or to the Federal Office of Consumer Protection and Food Safety (BVL)
- Notification can be made informally or via third parties such as doctors' surgeries, pharmacies or hairdressing salons
- without reporting undesirable effects, authorities or companies will not become aware of these cases
- Manufacturers, importers and distributors must check notifications are obliged to report serious adverse effects to the competent authority
- for companies, there is a mandatory notification form A for serious adverse reactions
- competent authorities coordinate measures if necessary, for example product controls or product recalls

Ansprechpunkt

Zuständige Stelle

Formulare

Ursprungsportal

Reports of serious undesirable effects (SAEs) of cosmetic products Receipt, Meldungen ernster unerwünschter Wirkungen (SUE) kosmetischer Mittel Entgegennahme