



LOUIS SANTIER

COSMETIC PRODUCT ADVERSE REACTION
REPORT FORM

Applicant details:

First and last name*

Telephone*

E-mail address:

Details of the product suspected of an adverse reaction:

Full product name*

Lot number*

Shelf life*

Details of the person who has suffered the adverse reaction:

First and last name*

Age*

Occupation if it is linked to the use of this cosmetic product*

Residence or correspondence address*

Telephone*

E-mail address:

Does the person who has suffered the adverse reaction have an allergic disposition?

Description of the adverse reaction:

Date of start of use of the cosmetic product*

Date of end of use of the cosmetic product*

Date when the symptoms occurred*

Was the product used for the first time?*

Frequency of cosmetic product use*

times

(per day / week / month / year)

Place of application*:

face

scalp

body

other

Did the adverse reaction occur in the place of the cosmetics application?*

yes

no

Description of the symptoms

Other cosmetics / medicines used at the same time (please specify):

Medical information / medical history relevant in this case:

Allergies diseases (please specify)*:

yes

no

Skin diseases (please specify)*:

yes

no

Description of treatment following alleged cosmetic reaction:

Has the cosmetic product use been ceased (date)?*

Has any medical consultation taken place (date and place of consultation, prescribed medicines)?*

Has a pharmacological treatment been administered (which)?*

Date and signature of the applicant

*mandatory fields

To be filled by the Manufacturer:**Identification code of the report:**

Date the Responsible Person received the report

Person receiving the report

Date of receipt of the report

Signature of the person receiving the report

Pursuant to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, hereinafter: GDPR) we would like to inform you that the Controller of personal data provided by you in the form above is Protigon with its seat in Jarocin, 6 Dnieprowa Street, email: support@24customercare.com.

The personal data provided will be processed by Protigon for the sole purpose of:

(a) monitoring the safety of cosmetic products, including reporting serious adverse reactions to the competent authorities in the scope of:

- health data which will be processed pursuant to Article 9(2)(i) of the GDPR, i.e. where processing is necessary for reasons of public interest in the area of public health in the form of ensuring high standards of quality and safety of health care,
- other personal data which will be processed pursuant to Article 6(1)(c) of the GDPR, i.e. where processing is necessary for compliance with a legal obligation to which the Controller is subject pursuant to the provisions resulting from Article 23 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products,

(b) the establishment, exercise or defense of any claims between you and the Controller, for health data pursuant to Article 9(2)(f) of the GDPR, and for other data pursuant to Article 6(1)(f) of the GDPR, i.e. on the basis of a legitimate interest pursued by the Controller, which is the opportunity to exercise or defend claims.

The recipients of the personal data shall be employees and associates Protigon, entities acting on behalf of and for Protigon, including entities providing support for the assessment of adverse reactions, and national and foreign entities and bodies authorized to process such data under the provisions of law, in particular, the Chief Health Inspector and other bodies of the Member States of the European Union in which the Controller distributes cosmetic products. Your data will be processed for no longer than is required by the provisions on the cosmetic product safety oversight or the provisions on the limitation period for claims. Personal data will be processed for a period of 2 years, i.e. until the limitation period for claims has expired. The provision of personal data is voluntary, but necessary for a legitimate investigation into the safety assessment of cosmetic products and reporting serious adverse reactions to cosmetic products. You have at all times the right to access the content of the data, the right to rectify it, the right to delete the data (only for the processing of data for the legitimate interests of the Controller – the basis for processing Article 6(1)(f) and Article 9(1)(f) of the GDPR), the right to restrict processing, the right of objection (only if the data are processed in the legitimate interests of the controller – the basis for processing Article 6(1)(f) and Article 9(1)(f) of the GDPR). The right of objection and the right to delete data are not applicable to the extent that the Controller processes the data pursuant to Article 6(1)(c) and Article 9(2)(i) of the GDPR and where necessary for the establishment, exercise or defense of any claims Protigon. Please send the statements regarding the exercise of the rights to the e-mail address: support@24customercare.com. If, despite our support, you believe that your personal data is being processed in violation of applicable law, you have the right to lodge a complaint before the supervisory authority (i.e. the President of the Data Protection Office). The personal data you provide will not be the subject of any profiling or automated decision-making activities, nor will it be transferred to third countries.