SUE FORM A: NOTIFICATION OF SUE BY RESPONSIBLE PERSON OR DISTRIBUTOR TO COMPETENT AUTHORITY

(according to Article 23 of Regulation (EC) No 1223/2009 on cosmetic products)

1) Case report

Company report number:

Competent Authority code number:

Type of the report:

☐ Initial ☐ Follow-up ☐ Final

Date received by company: dd/mm/yyyy

Sending date to Competent Authority: dd/mm/yyyy

2) Company

☐ **Distributor** ☐ **Responsible person**

Company name:

Address and local contact details:

3) Seriousness criteria

☐ **Temporary or permanent functional incapacity**
☐ **Disability**
☐ **Hospitalization**
☐ **Congenital anomalies**
☐ **Immediate vital risk**
☐ **Death**

4) Primary reporter

☐ Consumer

☐ Health professional

☐ Other (*specify*):

Has the reported information been confirmed by a medical professional : ☐ Yes ☐ No

5) End user

Code:

Age (at time of SUE): Date of birth: yyyy

Sex: ☐ Female ☐ Male ☐ Unknown

Country of residence:

6) Suspected product

a) Full name of suspected product

……

Company:

Category of product:

Batch number:

Notification number:

b) Use of product

Date of first ever use: dd/mm/yyyy

Frequency of use: times per (day/week/month/year)

Professional use: ☐ Yes ☐ No

Application site(s):

Product use stopped :

☐ Yes ☐ No ☐ N/A ☐ Unknown

Date of stopping the product use: dd/mm/yyyy

c) Re-exposure to the suspected product

☐ Positive ☐ Negative ☐ Not performed ☐ Unknown

d) Other suspected cosmetic products used concomitantly:

……

……

Complementary information can be attached to the document /related in the narrative

7) Description of serious undesirable effect (SUE)

a) Type of effect

-Country of occurrence:

-Date of onset: dd/mm/yyyy

-Time from the beginning of use to onset of first symptoms:
(minutes/ hours/days/months)

-Time from last use to onset of first symptoms:
(minutes/ hours/days/months)

-Reported signs/ symptoms:

-Reported diagnosis (if any):

b) Location of SUE

☐ Skin, area(s) concerned :
☐ Scalp ☐ Hair ☐ Eyes ☐ Teeth ☐ Nails
☐ Lips
☐ Mucosae, specify:
☐ Others, specify:

☐ SUE in area of product application

☐ SUE out of area of product application

8) Outcome of SUE(s)

☐ Recovered *If recovered, specify the time for recovering:*

☐ Improving ☐ Aftereffects (sequalae) ☐ Ongoing ☐ Unknown

☐ Other:

9) Relevant underlying conditions

☐ Yes ☐ No ☐ Unknown *If yes, specify* :
☐ Relevant treatment(s):
☐ Additional concurrent use of other products (drugs, food supplements, ...):

10) Relevant medical information / history

☐ Allergic diseases, specify: *If tests previously performed, specify the type and results*:

☐ Cutaneous diseases, specify:
☐ Other relevant underlying disease(s):
☐ Skin specificities including phototype:

☐ Others (*example: specific climatic conditions or specific exposure):*

11) Case management

a) Treatment(s) of SUE

Drug prescription: Name of product (INN)	Dose	Duration

b) Other measure(s):

Duration / complementary details:

c) Seriousness of undesirable effect

c-1) Functional incapacity *(if applicable)*
Description:

☐ If temporary, specify the duration:
☐ Expert evaluation available ☐ Medical certificate available
☐ Corrective treatment of the functional incapacity:

c-2) Disability *(if applicable)*, specify the %:
Description:

☐ Expert evaluation available ☐ Medical certificate available

c-3) Hospitalization *(if applicable):*

Duration of hospitalization: Hospital name and address:
Corrective treatment received during the hospitalization:

Drug prescription: Name of product (INN)	Dose	Duration

Treatment /measure taken after hospitalization:

c-4) Congenital anomalies *(if applicable)* :

☐ Detected during pregnancy ☐ Expert evaluation available
☐ Detected after delivery

c-5) Immediate vital risk *(if applicable):*
Treatment and specific measures:

c-6) Death *(if applicable):*
Date: dd/mm/yyyy Diagnosis: ☐ Medical certificate available

12) Complementary investigations

☐ Yes ☐ No *If yes , specify* :

☐ **Allergic testing :**

☐ Skin test(s) performed with the suspected cosmetic product(s) :

Product(s) tested	Method(s) used	Readings on	Results

☐ Skin test(s) performed with the substances (*if available, attach the complete results to this form)*

☐ Other results of allergic testing: ……..

☐ Other additional investigation(s) (*specify, including results):*

13) Summary from Responsible Person or Distributor

a) Narrative

b) Follow-up

Specify Competent Authority case identification number (if available):

c) Causality assessment

☐ Very likely ☐ Likely ☐ Not clearly attributable ☐ Unlikely ☐ Excluded ☐ Unassessable

d) Management

Has this SUE already been submitted to a Competent Authority?: ☐ Yes ☐ No ☐ Unknown
If yes, to which Competent Authority was it reported? :

e) Corrective actions

☐ Yes ☐ No *If yes , specify* :

f) Comments