

9) Relevant underlying conditions

- Yes No *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 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 (please state number of attachments, if any):