**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)

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| --- | --- |
| **1) Case report** | **2) Company** |
| **Company report number**:**Competent Authority code number**:  Type of the report: [ ]  Initial [ ]  Follow-up [ ]  FinalDate received by company: dd/mm/yyyySending date to Competent Authority: dd/mm/yyyy  | **[ ]  Distributor** **[ ]  Responsible person**Company name:      Address and local contact details:  |
| **3) Seriousness criteria** |
| **[ ]  Temporary or permanent functional incapacity** [ ]  **Congenital anomalies** **[ ]  Disability** **[ ]  Immediate vital risk** **[ ]  Hospitalization** **[ ]  Death**  |
| **4) Primary reporter** | **5) End user** |
| [ ]  Consumer [ ]  Health professional [ ]  Other (*specify*):      Has the reported information been confirmed by a medical professional :  [ ]  Yes  [ ]  No | Code:    Age (at time of SUE):       Date of birth: yyyySex: [ ]  Female [ ]  Male [ ]  Unknown Country of residence:       |
| **6) Suspected product**  | **7) Description of serious undesirable effect (SUE)**  |
| **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*  |  **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 [ ]  UnknownIf yes, to which Competent Authority was it reported? :      **e) Corrective actions** [ ]  Yes [ ]  No *If yes , specify* :      **f) Comments** |