**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  Final  Date received by company: dd/mm/yyyy  Sending 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: yyyy  Sex:  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  Unknown  If yes, to which Competent Authority was it reported? :  **e) Corrective actions**  Yes  No *If yes , specify* :    **f) Comments** | |