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| Initial Report  Tracking N°  Information date : | Country :  Name of local office : | Local case N°  File N° |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **INFORMATION ABOUT THE REPORTER** | | | | |
| Consumer  Distributor/Subsidiary  Competent Authorities  Health Professionnal  Other (precise) | | | | |
| **Name** | **Address** | **Phone N°** | **E-mail** | **Country** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **INFORMATION ABOUT THE PATIENT** | | | | |
| Same as reporter | | | | |
| **Initiales of the patient** | **Age** | Men  Women | Pregnant  No  Yes, week of pregnancy | |
| **Relevant medical history / simultaneous diseases** *(e.g. herpes, immunological disease, cutaneous infection, surgical or dental intervention… Non exhaustive list)* | | | Allergies  No  Yes | If yes, please specify |
| **Simultaneous drugs.** If yes, please specify the indication for which the drug(s) is/are prescribed | | | Skin type:  Sensitive?  No  Yes | |
| **Sun / extreme cold exposure**?  No  Yes | | | | |
| **Change in the habits (washing liquid, household products, other cosmetic products, perfume…) ?** | | | | |

| **INFORMATION ABOUT THE EVENT** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Product(s) / Commercial name** | **Batch N°** | **Application site(s)** | **Date of first use (dd-mm-yyyy)** | **Use frequency (x/day, x/week, x/month)** | **Date of last use (dd-mm-yyyy)** | | **Other products used on the affected area** |
|  |  |  |  |  |  | |  |
| **Description of the undesirable event(s)** | | | **Affected area(s)** | **Date of beginning (dd-mm-yyyy)** | **Date of end (dd-mm-yyyy)** | **Reuse of suspected product(s)** | |
|  | | |  |  |  | yes (same undesirable effect after reuse)  yes (no undesirable effect after reuse)  no (no reuse)  unknown information | |
| **Consequence of the undesirable effect:**  consultation with a health professionnal (specify)  work stopping (specify)  urgent medical intervention (specify)  hospitalization (specify)  sequelae, infirmity or disability (specify)  other (specify) | | | | | | | |

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| **COMMENTARIES** |
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Signature of the reporter Date of the report