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

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

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| **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** |
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| **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