| **Report Form for Product Complaints and suspected Adverse Effects / Reactions** Schülke & Mayr GmbH, Robert-Koch-Str. 2, 22851 Norderstedt, Germany | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Medicinal Product | Medical Device | | Cosmetic Product | | | Biocide | Technical Product | | Others |
| Initial  Follow-up information to case No.: | | | | | | | | | |
| **Reporter / Customer information:** | | | | | | | | | |
| ***Reporter name (mandatory):*** | | | |  | | | | | |
| Customer name / number / contact | | | |  | | | | | |
| Customer address:  (street, ZIP code, town, country) | | | |  | | | | | |
| Customer phone / fax / e-mail: | | | |  | | | | | |
| **Product information:** | | | | | | | | | |
| ***Product name (mandatory)*** / size / amount: | | | |  | | | | | |
| ***Batch-no. or Serial-no.*** ***(mandatory in case of product complaint)*** / Expiry date: | | | |  | | | | | |
| ***Description of the complaint / adverse effect / drug reaction (mandatory:)*** Date of onset / occurrence: | | | | | | | | | |
| Product applied / used from – till: | | | |  | | | | | |
| Another product used previously / before?  (If yes, which product?) | | | |  | | | | | |
| Product / Sample | | will be returned  is available  is not (anymore) available | | | | | | | |
|  | | | | | | | | | |
| **Patient information in case of suspected adverse effect (AE) / drug reaction (ADR):** | | | | | | | | | |
| ***Gender (mandatory):*** | | male  female | | | Initials: | | |  | |
| Age / Date of birth: | |  | | | Weight / Height: | | | kg       cm | |
| Reason for use: | |  | | | Route of application: | | |  | |
| Further persons affected? | | yes  no | | | If yes, how many? | | |  | |
|  | | | | | | | | | |
| **Suspected adverse effect (AE) / drug reaction (ADR) information:** | | | | | | | | | |
| Contact details of involved physician / pharmacist (name / address / e-mail / phone / fax): | | | | | | | | | |

|  |  |  |
| --- | --- | --- |
| Progress of adverse effect / drug reaction and therapy: (if applicable, use attachment) Life threatening?  yes  no | | |
| **Following action was taken:**  surgical intervention   hospitalisation  prolongation of hospitalisation  none of them | **Final outcome of the AE /ADR:**  unknown  recovered   not yet recovered   irreversible damage   death (date): | **Reaction relation to product:**  definitely  probable  possible  unlikely  not assessable |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Further information relevant for case evaluation:** | | | | | |
| e.g. underlying diseases (e.g. allergy, skin diseases), pregnancy, concomitant medication, laboratory data, test results (if applicable, use attachment) | | | | | |
| Epikutan-Test:  negative  positive\*) | | Positive with Code : | | | |
| Who was informed :  manufacturer /  MAH /  local authority /  others: | | | | | |
| **Received by schülke / contractual partner (name, date, signature) *(mandatory)*:** | | |  | | |
| **Transfer to:** | **E-mail:** bezpieczenstwo.sm@schuelke.com | | | **Phone:** +48 661 333 385 | **Fax:** +48 22 1160701 |
| **\*) Please attach / send test result** | | | | | |

*Please be advised that the information provided in the application by Ms / Mrs and personal data will be processed and administered in accordance with the Act of 29 August 1997. On the Protection of Personal Data (Dz. U. of 2002. No. 101, item. 926, as . d.) by Schulke Poland Sp. z o.o., Al. Jerozolimskie 132 , 02-305 Warsaw, with a view to filing adverse reaction. Please also note that yours data will NOT be passed on to others and that you have the right to access their data, the right to correct them right to object to their processing in the above order,   
as well as the right to request to stop processing and deletion of your personal data . Giving the above data is voluntary.*