

Report Form for Product Complaints and suspected Adverse Effects / Reactions Schülke & Mayr GmbH, Robert-Koch-Str. 2, 22851 Norderstedt, Germany					
Medicinal Product <input type="checkbox"/>	Medical Device <input type="checkbox"/>	Cosmetic Product <input type="checkbox"/>	Biocide <input type="checkbox"/>	Technical Product <input type="checkbox"/>	Others <input type="checkbox"/>
<input type="checkbox"/> Initial <input type="checkbox"/> Follow-up information to case No.:					
Reporter / Customer information:					
Reporter name (mandatory):					
Customer name / contact					
Customer number					
Order- / Delivery-note number					
Customer address:(street, ZIP, 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	<input type="checkbox"/> will be returned		<input type="checkbox"/> is available		<input type="checkbox"/> is not (anymore) available
Patient information in case of suspected adverse effect (AE) / drug reaction (ADR):					
Gender (mandatory):	<input type="checkbox"/> male <input type="checkbox"/> female		Initials:		
Age / Date of birth:			Weight / Height:		kg cm
Reason for use:			Route of application:		
Further persons affected?	<input type="checkbox"/> yes <input type="checkbox"/> no		If yes, how many?		

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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? <input type="checkbox"/> yes <input type="checkbox"/> no
Following action was taken: <input type="checkbox"/> surgical intervention <input type="checkbox"/> hospitalisation <input type="checkbox"/> prolongation of hospitalisation <input type="checkbox"/> none of them	Final outcome of the AE /ADR: <input type="checkbox"/> unknown <input type="checkbox"/> recovered <input type="checkbox"/> not yet recovered <input type="checkbox"/> irreversible damage <input type="checkbox"/> death (date):	Reaction relation to product: <input type="checkbox"/> definitely <input type="checkbox"/> probable <input type="checkbox"/> possible <input type="checkbox"/> unlikely <input type="checkbox"/> 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: <input type="checkbox"/> negative <input type="checkbox"/> positive*)	Positive with Code :	
Who was informed : <input type="checkbox"/> manufacturer / <input type="checkbox"/> MAH / <input type="checkbox"/> local authority / <input type="checkbox"/> others:		
Received by schülke / contractual partner (name, date, signature) (mandatory):		
Transfer to:	<input type="checkbox"/> E-mail: complaints@schuelke.com	<input type="checkbox"/> Fax: +49 (0) 40 52100511

*) Please attach / send test result