

<b>Report Form for Product Complaints and suspected Adverse Effects / Reactions</b> 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.:					
<b>Reporter / Customer information:</b>					
<b>Reporter name (mandatory):</b>					
Customer name / contact					
Customer number					
Order- / Delivery-note number					
Customer address:(street, ZIP, town, country)					
Customer phone / fax / e-mail:					
<b>Product information:</b>					
<b>Product name (mandatory)</b> size / amount/ article no:					
<b>Batch-no. or Serial-no. (mandatory in case of product complaint)</b> / Expiry date:					
<b>Description of the complaint / adverse effect / drug reaction (mandatory):</b>				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					
<b>Patient information in case of suspected adverse effect (AE) / drug reaction (ADR):</b>					
<b>Gender (mandatory):</b>		<input type="checkbox"/> male <input type="checkbox"/> female    divers		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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<b>Suspected adverse effect (AE) / drug reaction (ADR) information:</b>		
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
<b>Following action was taken:</b> <input type="checkbox"/> surgical intervention <input type="checkbox"/> hospitalisation <input type="checkbox"/> prolongation of hospitalisation <input type="checkbox"/> none of them	<b>Final outcome of the AE /ADR:</b> <input type="checkbox"/> unknown <input type="checkbox"/> recovered <input type="checkbox"/> not yet recovered <input type="checkbox"/> irreversible damage <input type="checkbox"/> death (date):	<b>Reaction relation to product:</b> <input type="checkbox"/> definitely <input type="checkbox"/> probable <input type="checkbox"/> possible <input type="checkbox"/> unlikely <input type="checkbox"/> not assessable
<b>Further information relevant for case evaluation:</b>		
e.g. underlying diseases (e.g. allergy, skin diseases), pregnancy, concomitant medication, laboratory data, test results (if applicable, use attachment)		
Who was informed : <input type="checkbox"/> manufacturer / <input type="checkbox"/> MAH / <input type="checkbox"/> local authority / <input type="checkbox"/> others:		
<b>Received by schülke / contractual partner (name, date, signature) (mandatory):</b>		
<b>Transfer to:</b>	<input type="checkbox"/> E-mail: <a href="mailto:complaints@schuelke.com">complaints@schuelke.com</a>	<input type="checkbox"/> Fax: +49 (0) 40 52100511