Undesirable Effect Report Form for Cosmetic Products

Please complete all relevant sections of this form in confidence and return to Cosmetics Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77.

Telephone 353-1-6764971, e-mail cosmetics@hpra.ie

A privacy notice in relation to the personal data collected on this form is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) under ‘Report an Issue’ and ‘Medicine Quality Issue/Defect’.

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| Reporter name:         Address:      E-mail:      Telephone number:      If you are not the consumer, state profession:       |
| If reporter is not consumer, insert consumer initials:       | Sex: [ ]  M [ ]  F | Age:       |
| Suspected product(s) *(include full name and brand)*:       |
| Batch number and expiry date if present on pack:       | Product reference number/shade/colour (if applicable):       |
| Dates/duration of use:       |
| Address on pack (EU address):       |
| Is the product for professional use only? [ ]  Yes [ ]  No *(should be stated on the pack)* |
| Precautions stated on the pack:       |
| Name and address of retailer of the product:       |
| Details of reaction: *(brief description of the reaction including location of the reaction, location of application of the product)*       |
| Time to first signs of reaction: *(seconds/days)*      | Date of occurrence of reaction*:*       | Duration of reaction:       |
| Treatment given/action taken:       |
| Use of product discontinued: [ ]  Yes [ ]  NoImprovement on discontinuation: [ ]  Yes [ ]  NoSubsequently reapplied: [ ]  Yes [ ]  NoIf yes, outcome:       |
| Details of other cosmetics used at the same time:       |
| Description of allergies (past and present, if applicable):       |
| If a patch test was performed prior to use of the cosmetic product, describe the type of test used and the results of the patch test:       |
| Description of any other underlying disease, conditions or medication (if applicable):       |
| Was a healthcare professional consulted?[ ]  Yes [ ]  No |
| Contact details of the healthcare professional *(note the healthcare professional may be contacted in the case of a serious undesirable effect):*       |
| *Include healthcare professional report and photos of the product if possible.* |

Signature: Date:

Thank you for taking the time to complete this form.