Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.

Section A – About the Adverse Event

1. What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect (including new or worsening symptoms)
- ☐ Used a product incorrectly which could have led to a problem
- ☐ Noticed a problem with the quality of the product
- ☐ Had problems after switching from one product maker to another maker

2. Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm
- ☐ Disability or health problem
- ☐ Other serious/important medical incident
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death (include date) (e.g., 01-Jan-1900):

3. Date the Event occurred *(e.g., 01-Jan-1900)*

4. Date of this Report *(01-JAN-1900)*

4. Tell us what happened, how it happened or why it happened. *(Include as many details as possible. Regulatory Matters may reach out to you for any additional documents if necessary)*

5. Relevant Tests/Laboratory Results	Date *(e.g., 01-Jan-1900)*

Relevant Tests/Laboratory Results	Date *(e.g., 01-Jan-1900)*

Additional Comments

Section B – Product Availability

1. Do you still have the product in case we need to evaluate it? *(Do not send the product to Regulatory Matters. We will contact you directly if we need it.)*

☐ Yes ☐ No

2. Do you have a picture of the product? *(check yes if you are including a picture)* ☐ Yes

Section C – About the cosmetic or make-up products

1. Name(s) of the product as it appears on the box, bottle, or package *(Include as many names as you see)*

2. Check if therapy is on-going ☐

3. Name(s) of the company that makes (or compounds) the product

4. Expiration date *(e.g., 01-Jan-1900)*

5. Lot number

6. Quantity *(for example, 1 teaspoon)*

7. Frequency *(for example, twice daily or at bedtime)*

8. How was it used (for example, on the skin)?

9a. Date the person first started using the product *(e.g., 01-Jan-1900)*

9b. Date the person stopped using the product *(e.g., 01-Jan-1900)*

10. Give best estimate of duration | Unit

11. Why was the person using the product?

12. Did the problem stop after the person reduced the dose or stopped taking or using the product?

☐ Yes ☐ No

13. Did the problem return if the person started taking or using the product again?

☐ Yes ☐ No ☐ Didn't restart

Section D – About the Person Who Had the Problem

1. Person's Initials:

2a. Sex: Enter the patient's sex at birth *(the sex that a person has or was assigned to at birth)*.

☐ Male ☐ Female ☐ Undifferentiated ☐ Decline to answer

2b. Gender: Enter the patient's current gender *(how the patient thinks of themself)*.

☐ Cisgender man/boy *(gender corresponds with birth sex)*
☐ Cisgender woman/girl *(gender corresponds with birth sex)*
☐ Transgender man/trans man/ female-to-male (FTM)
☐ Transgender woman/trans woman/ male-to-female (MTF)
☐ Other gender category; please specify:
☐ Decline to answer

3. Age *(specify unit of time for age)*

☐ Year(s) ☐ Week(s) ☐ Month(s) ☐ Day(s)

4. Date of Birth *(e.g., 01-Jan-1900)*

5. Weight *(Specify lbs or kg)*

☐ lb ☐ Kg

6. Ethnicity *(Choose only one)*

☐ Hispanic/Latino ☐ Not Hispanic/Latino

7. Race *(Choose all that apply)*

☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

8. List known medical conditions. *(Such as irritant (or) allergic contact dermatitis, acne, rosacea, eczema, or others)*

9. Please list all allergies *(such as to drugs, foods, pollen or others)*

10. List any other important information about the person *(such as tobacco product use, pregnancy, alcohol use, etc.)*

11. List all current prescription medications and medical devices being used.

12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information.

1. Last name

2. First name

3. Number/Street

4. City and State/Province

5. ZIP or Postal code

6. Country

7. Telephone number

8. Email address

9. Today's date *(e.g., 01-Jan-1900)*

10. Did you report this problem to the company that makes the product (the manufacturer/compounder)?

☐ Yes ☐ No

11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

Send This Report by Email

Keep the product in case the Regulatory Matters wants to contact you for more information. Please do not send products to the Regulatory Matters.

Email this form to adverse.events@regulatorymatters.co

Thank you for helping us protect the public health.