



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2018-148**

18 APR 2018

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Reports on Adulterated Cosmetic Products With the Reference Nos. HSA071413032018 and HSA071513032018

The Food and Drug Administration (FDA) hereby issues this public health warning to inform the public of the ASEAN Post-Marketing Alert System (PMAS) reports on the following cosmetic product/s:

	BRAND / PRODUCT NAME	FINDINGS	Report Reference No.
1.	Wonderglow™ Whitening Specialist Super Ultra Glowing Cream a. Glowing Day Cream b. Glowing Night Cream c. Soap	Glowing Night Cream was verified to contain excessive amount of mercury (7,524 ppm)	HSA071413032018 ¹
2.	Tati Skin Care Therapy 1 Cream	Verified to contain excessive amount of mercury (48,267 ppm)	HSA071513032018 ²
3.	Tati Skin Care Therapy 2 Cream	Verified to contain tretinoin and hydroquinone	

^{1,2} Attached are copies of the Singapore PMAS Reports with Reference Nos. HSA071413032018 and HSA071513032018

The aforementioned products have been tested by the Health Sciences Authority of Singapore as part of its post-marketing surveillance activities and the results of the laboratory analyses show that the products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

Products #1 and #2 have been verified to contain mercury beyond the maximum allowed limit of 1 part per million (ppm). Mercury is a naturally occurring heavy metal which is known to be severely hazardous to health even in small amount. People exposed to mercury exhibits symptoms including but not limited to tremors, numbness and tingling in the hands and feet, gingivitis or inflammation of the gums, pink discolouration of the hands and feet especially in children, irritability, and photophobia or sensitivity to light. Nursing mothers are doubly vulnerable because mercury is passed on to nursing babies through breast milk which can affect the baby's development.



Product #3 has been found to contain hydroquinone and tretinoin, both of which are no longer allowed to be part of a cosmetic product and are classified as drug products in the Philippines because of its multiple serious adverse effects (i.e. sensitivity to light, skin redness and permanent skin discoloration) when used indiscriminately. Additionally, tretinoin may also cause harm to developing fetus. Women planning to get pregnant or are already expecting are strongly advised to avoid using products containing tretinoin.

Because of the hazards posed by the aforementioned cosmetic products, the public is strongly advised to be vigilant and report to FDA, through any of the following channels, any encounter with them:

1. Send an e-mail via report@fda.gov.ph;
2. Call the Center for Cosmetics Regulation and Research (CCRR) hotline (02) 857-1900 local 8113 or 8107; or
3. Utilize the agency's online reporting facility, **eReport**, at ww2.fda.gov.ph/ereport.

Furthermore, the public is also advised to only buy cosmetic products that have been notified with FDA. If unsure of a product's notification status, consumers may verify whether the product is authorized by FDA using the *Search* engine embedded in the FDA website which is accessible at www.fda.gov.ph. For more information and inquiries, please e-mail us at info@fda.gov.ph or call the CCRR hotline mentioned above.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN 20180402084648



ASEAN POST-MARKETING ALERT SYSTEM (Form A)

<p><i>Tick ✓</i></p> <p>1. Level of confidentiality:</p> <p><input type="checkbox"/> Internal / Restricted circulation</p> <p><input checked="" type="checkbox"/> On public domain, specify website:</p> <p>_____</p>	<p>2. Issue:</p> <p><input checked="" type="checkbox"/> Adulteration</p> <p><input type="checkbox"/> Counterfeit</p> <p><input type="checkbox"/> Quality defect</p> <p><input type="checkbox"/> Safety aspect</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>	<p>3. Action:</p> <p><input type="checkbox"/> Cancellation of registration</p> <p><input type="checkbox"/> Labelling revision</p> <p><input type="checkbox"/> Recall of product</p> <p><input type="checkbox"/> Suspension of registration</p> <p><input checked="" type="checkbox"/> Withdrawal of product</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>
<p>4. Source / Type of signal:</p>	<p><input type="checkbox"/> Local ADR reports</p> <p><input type="checkbox"/> Scientific literature / local studies</p> <p><input checked="" type="checkbox"/> Post-market sampling and testing activities</p>	<p><input type="checkbox"/> Decision made by other regulatory authorities &/or industry</p> <p><input checked="" type="checkbox"/> Others, please specify:</p> <p>Public feedback</p> <p>_____</p>
<p>Product information (whenever possible, please provide an image of the product)</p>		
<p>5. Product type:</p>	<p><input type="checkbox"/> Biologic</p> <p><input checked="" type="checkbox"/> Cosmetic</p> <p><input type="checkbox"/> Health supplement</p> <p><input type="checkbox"/> Pharmaceutical</p>	<p><input type="checkbox"/> Traditional medicine</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>
<p>6. Forensic classification in your country:</p>	<p><input type="checkbox"/> General sales list / Over-the-counter</p> <p><input type="checkbox"/> Pharmacy only</p>	<p><input type="checkbox"/> Prescription only</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>
<p>7. Brand / Product name (or drug class):</p> <p>Wonderglow™ WHITENING SPECIALIST SUPER ULTRA GLOWING CREAM contains</p> <p>- GLOWING DAY CREAM</p> <p>- GLOWING NIGHT CREAM</p> <p>- Soap</p>		<p>8. Alternative name (e.g. local language):</p> <p>NA</p>
<p>9. Active ingredient / Generic name / Full formula (for cosmetics, traditional medicines etc.):</p> <p>'GLOWING NIGHT CREAM' was tested to contain mercury 7524 ppm (w/w)</p>		
<p>10. Dosage form (if applicable):</p> <p>NA</p>	<p>11. Strength (if applicable):</p> <p>NA</p>	
<p>12. Pack size / Presentation:</p> <p>1 container x 20mg</p>	<p>13. Batch / Lot number:</p> <p>NA</p>	
<p>14. Expiry date (if applicable):</p> <p>NA</p>	<p>15. Date manufactured (if applicable):</p> <p>NA</p>	
<p>16. Intended use as listed on label:</p> <p>Whitening</p>		
<p>17. Countries which the product is exported to:</p> <p>NA</p>		
<p>Company information</p>		
<p>18. Marketing authorisation holder / Product licence holder / Company responsible for placing product in the market:</p> <p>NA</p>		

19. Name & country of manufacturer Wonder Glow Worldwide Email: wonderglowcosmetics@yahoo.com Website: www.wonderglowcosmetics.com & www.wonderglow465.blogspot.com Hp: +60103130800 Mobile: +607721188	
Details / Action(s) taken	
20. Details of Investigations e.g. <ul style="list-style-type: none"> - 'Glowing Night Cream' was tested to contain mercury 7524 ppm (w/w) - Investigation is ongoing. 	
21. Actions / proposed actions to be taken <ul style="list-style-type: none"> - NA 	
Reporting country / authority	
22. Name of country / Issuing authority: Singapore / Health Sciences Authority	23. Report reference no.: HSA071413032018
24. Department / Designation of person issuing the alert: Vigilance and Compliance Branch	25. Date of report: 13 March 2018
Contact person	
26. Name: Dr Wint Maw Thinn	27. Department / Designation: Vigilance and Compliance Branch / Regulatory Specialist
28. Email address: Wint_maw_thinn@hsa.gov.sg	29. Contact no. Telephone no.: 63045463 Fax no.: 64789069

Indicate NA whenever the field is not applicable.

* To provide photograph of product and press statement if any.





SET ASAS 3 DALAM 1 | DIAMOND SERIES |

WONDER GLOW DAY CREAM | 20 GM |

WONDER GLOW NIGHT CREAM | 20 GM |

WONDER BAR SOAP BIRD NEST COLLAGEN | 30 GM |

06/12/2017 09:07



PERTANYAAN / INFORMASI

+6010 313 0800

+607 772 1188

Email : wonderglowcosmetics@yahoo.com

Website : www.wonderglowcosmetics.com
www.wonderglow465.blogspot.com

DISTRIBUTE BY/ DI EDARAN OLEH

WONDER GLOW WORLDWIDE

06/12/2017 09:07



ASEAN POST-MARKETING ALERT SYSTEM (Form A)

<p><i>Tick ✓</i></p> <p>1. Level of confidentiality:</p> <p><input type="checkbox"/> Internal / Restricted circulation</p> <p><input checked="" type="checkbox"/> On public domain, specify website:</p> <p>_____</p>	<p>2. Issue:</p> <p><input checked="" type="checkbox"/> Adulteration</p> <p><input type="checkbox"/> Counterfeit</p> <p><input type="checkbox"/> Quality defect</p> <p><input type="checkbox"/> Safety aspect</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>	<p>3. Action:</p> <p><input type="checkbox"/> Cancellation of registration</p> <p><input type="checkbox"/> Labelling revision</p> <p><input type="checkbox"/> Recall of product</p> <p><input type="checkbox"/> Suspension of registration</p> <p><input checked="" type="checkbox"/> Withdrawal of product</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>
<p>4. Source / Type of signal:</p>	<p><input type="checkbox"/> Local ADR reports</p> <p><input type="checkbox"/> Scientific literature / local studies</p> <p><input type="checkbox"/> Post-market sampling and testing activities</p>	<p><input type="checkbox"/> Decision made by other regulatory authorities &/or industry</p> <p><input checked="" type="checkbox"/> Others, please specify:</p> <p>Public feedback</p> <p>_____</p>
Product information (whenever possible, please provide an image of the product)		
<p>5. Product type:</p>	<p><input type="checkbox"/> Biologic</p> <p><input checked="" type="checkbox"/> Cosmetic</p> <p><input type="checkbox"/> Health supplement</p> <p><input type="checkbox"/> Pharmaceutical</p>	<p><input type="checkbox"/> Traditional medicine</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>
<p>6. Forensic classification in your country:</p>	<p><input type="checkbox"/> General sales list / Over-the-counter</p> <p><input type="checkbox"/> Pharmacy only</p>	<p><input type="checkbox"/> Prescription only</p> <p><input type="checkbox"/> Others, please specify:</p> <p>_____</p>
<p>7. Brand / Product name (or drug class):</p> <p>Tati skin care Therapy 1 cream and</p> <p>Tati skin care Therapy 2 cream</p>	<p>8. Alternative name (e.g. local language):</p> <p>Tati skincare</p>	
<p>9. Active ingredient / Generic name / Full formula (for cosmetics, traditional medicines etc.):</p> <p>Tati skin care Therapy 1 cream - Mercury 48267 ppm(w/w)</p> <p>Tati skin care Therapy 2 cream - Tretinoin and Hydroquinone</p>		
<p>10. Dosage form (if applicable):</p> <p>NA</p>	<p>11. Strength (if applicable):</p> <p>NA</p>	
<p>12. Pack size / Presentation:</p> <p>1 container x 5g or 1 container x 10g</p>	<p>13. Batch / Lot number:</p> <p>NA</p>	
<p>14. Expiry date (if applicable):</p> <p>NA</p>	<p>15. Date manufactured (if applicable):</p> <p>NA</p>	
<p>16. Intended use as listed on label:</p> <p>Whitening</p>		
<p>17. Countries which the product is exported to:</p> <p>NA</p>		
Company information		
<p>18. Marketing authorisation holder / Product licence holder / Company responsible for placing product in the market:</p> <p>Tati_skincare NOT 170505953K / NOT 170505954K</p>		
<p>19. Name & country of manufacturer</p> <p>www.tatiskincare.com</p>		
Details / Action(s) taken		

20. Details of investigations e.g.	
<ul style="list-style-type: none"> - Tati skin care therapy cream 1 found to contain Mercury - Tati skin care therapy cream 2 found to contain Tretinoin and Hydroquinone - Investigation is ongoing. 	
21. Actions / proposed actions to be taken	
<ul style="list-style-type: none"> - NA 	
Reporting country / authority	
22. Name of country / Issuing authority: Singapore / Health Sciences Authority	23. Report reference no.: HSA071513032018
24. Department / Designation of person issuing the alert: Vigilance and Compliance Branch	25. Date of report: 13 March 2018
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Indicate NA whenever the field is not applicable.

* To provide photograph of product and press statement if any.

Picture(s) of product, if any





