



FDA ADVISORY
No. **2018-232**

27 JUL 2018

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. (12)/MOH/DPS/PMAS/072018

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

	BRAND / PRODUCT NAME	FINDINGS
1.	Tati 5 in 1 Skincare New & Improved Glow of Lasting Beauty – Ultra Night Cream	Presence of MERCURY
2.	Tati 5 in 1 Skincare New & Improved Glow of Lasting Beauty – Ultra Treatment Cream	Presence of HYDROQUINONE and TRETINOIN
3.	GP Cream Night Cream	Presence of HYDROQUINONE and TRETINOIN

**Attached is a copy of the Brunei Darussalam PMAS Report with Reference No. (12)/MOH/DPS/PMAS/072018*

The aforementioned products have been tested by the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam as part of their post-marketing surveillance activities and results of the laboratory analyses show that these products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

Product #1 has 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 hands and feet, gingivitis or inflammation of the gums, pink discoloration of the hands and feet especially in children, irritability, and photophobia or sensitivity to light. Nursing mothers are doubly vulnerable because mercury are passed on to nursing babies through breast milk which can affect the baby's development.

Products #2 and #3, on the other hand, have 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.

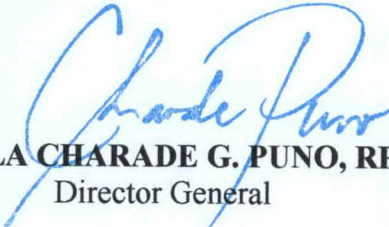


Because of the hazards posed by the aforementioned products, the public is strongly advised to be vigilant and report to FDA through any of the following channels any encounter with these products:

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 8107 or 8113**
3. Utilize the agency's online reporting facility, **eReport**, at www2.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 through the *Search* engine embedded in the FDA website 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.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN 20180723103013



ASEAN POST-MARKETING ALERT SYSTEM (Form B)

(Use this form for multiple product alerts of same product type with similar issues)

<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>www.moh.gov.bn</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 type="checkbox"/> Others, please specify:</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>
Reporting country / authority		
<p>7. Name of country / Issuing authority:</p> <p>Brunei Darussalam, Ministry of Health</p>	<p>8. Report reference no.:</p> <p>(12)/MOH/DPS/PMAS/072018</p>	
<p>9. Department / Designation of person issuing the alert:</p> <p>Department of Pharmaceutical Services</p>	<p>10. Date of report:</p> <p>18 July 2018</p>	
Contact person		
<p>11. Name:</p> <p>Ms Norhasidah Abd Rahman</p>	<p>12. Department / Designation:</p> <p>Pharmacy Enforcement Section Department of Pharmaceutical Services</p>	
<p>13. Email address:</p> <p>norhasidah.rahman@moh.gov.bn</p>	<p>14. Contact no.</p> <p>Telephone no.: +673 2393298 EXT 209 Fax no.: +673 2393291</p>	

* To provide photograph of product.

Annex I

Report reference no.: (12)/MOH/DPS/PMAS/072018

Date of report: 18 July 2018

No	Description of product*				Marketing authorisation holder/ Product licence holder/ Company responsible for placing product in the market	Manufacturer • Name • Country	Investigations i.e. • Type of quality defect i.e. microbial contamination, heavy toxic metals, dissolution test • Type and amount of adulterant • Details of ADR	Actions i.e. • Level of recall e.g. hospital, retail, consumers • Type of recall e.g. batch specific • Date of withdrawal of recall etc
	Brand/ Product name/ Alternative name (e.g. local language)	• Active ingredients/ Generic name/ Full formula (for cosmetics, traditional medicines etc.) • Strength (if applicable)	• Dosage form/ Pack size (if applicable) • Batch/ Lot number • Date of Expiry or Manufacture (if applicable)	• Intended use as listed on label:				
1.	Tati 5 in 1 Skincare New & Improved Glow of Lasting Beauty – Ultra Night Cream	Not Stated	Dosage Form : Not Stated Pack Size : 5G Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• It rejuvenated and revitalizes the skin from within leaving is soft supple and young-looking.	Not Stated	Made in Malaysia	Product tested and found to contain MERCURY	The product is banned from the market
2.	Tati 5 in 1 Skincare New & Improved Glow of Lasting Beauty – Ultra Treatment Cream	Not Stated	Dosage Form : Not Stated Pack Size : 5G Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• Lighten your face as natural. • Reduce black or dark spots and reduce the wrinkles, lightening skin, revitalizing and pore reducer with arbutin extracts as the melanin growth effectively.	Not Stated	Made in Malaysia	Product tested and found to contain HYDROQUINONE & TRETINOIN	The product is banned from the market
3.	GP Cream Night Cream	Not Stated	Dosage Form : Not Stated Pack Size : Not Stated Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• Not Stated	Not Stated	Not Stated	Product tested and found to contain HYDROQUINONE & TRETINOIN	The product is banned from the market

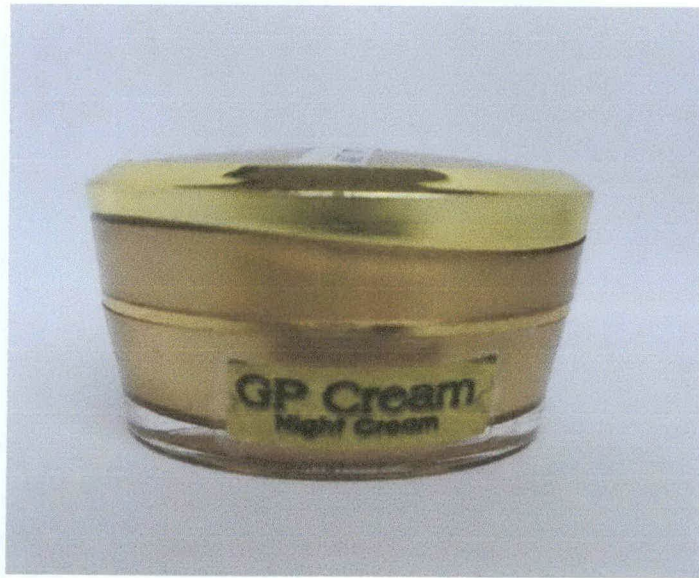
Picture of Product



Tati 5 in 1 Skincare New & Improved Glow of Lasting Beauty – Ultra Night Cream



Tati 5 in 1 Skincare New & Improved Glow of Lasting Beauty – Ultra Treatment Cream



GP Cream Night Cream