



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



29 MAY 2018

FDA ADVISORY
No. **2018-178**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. HSA0716525042018

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.	Balleza Skincare Night Cream	Verified to be adulterated with toxic levels of Mercury (Hg)
2.	Balleza Skincare Treatment	Hydroquinone detected
3.	Brilliant Skin Essentials Rejuvenating Cream Exfoliant Cream	Hydroquinone and tretinoin detected
4.	Brilliant Skin Essentials Whitening Cream 10g	Hydroquinone and tretinoin detected
5.	Brilliant Skin Essentials Whitening Facial Toner 60mL	Hydroquinone detected
6.	Droplets of Nature Rejuvenating Cream Lift & Correct 10g	Hydroquinone and tretinoin detected
7.	Droplets of Nature Rejuvenating Toner Lift & Correct 60mL	Hydroquinone detected
8.	Professional Skin Care Formula by Dr. Alvin Rejuvenating Cream	Hydroquinone and tretinoin detected
9.	Speaks G Skin Essential Brightening Rejuvenating Cream 10g	Hydroquinone and tretinoin detected

**Attached is a copy of the PMAS Report from Singapore with Reference No. HSA0716525042018*

The aforementioned products have been tested by the Health Sciences Authority (HSA) 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).

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 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.

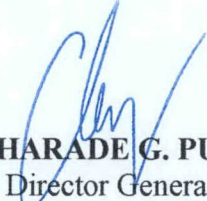
Products #2 to #9 have been found to contain hydroquinone and/or tretinoin, both of which are no longer allowed to be part of a cosmetic and are classified as drug products in the Philippines because of its multiple serious adverse effects (i.e. sensitivity to light, skin redness and permanent skin discoloration) 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 through the *Search* engine embedded in the FDA website accessible at ww2.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 20180508100725



ASEAN POST-MARKETING ALERT SYSTEM (Form B) <i>(Use this form for multiple product alerts of same product type with similar issues)</i>		
Tick <input checked="" type="checkbox"/> 1. Level of confidentiality: <input type="checkbox"/> Internal / Restricted circulation <input checked="" type="checkbox"/> On public domain, specify website: www.hsa.gov.sg	2. Issue: <input checked="" type="checkbox"/> Adulteration <input type="checkbox"/> Counterfeit <input type="checkbox"/> Quality defect <input type="checkbox"/> Safety aspect <input type="checkbox"/> Others, please specify:	3. Action: <input type="checkbox"/> Cancellation of registration <input type="checkbox"/> Labelling revision <input checked="" type="checkbox"/> Recall of product <input type="checkbox"/> Suspension of registration <input type="checkbox"/> Withdrawal of product <input type="checkbox"/> Others, please specify:
4. Source / Type of signal:	<input type="checkbox"/> Local ADR reports <input type="checkbox"/> Scientific literature / local studies <input checked="" type="checkbox"/> Post-market sampling and testing activities	<input type="checkbox"/> Decision made by other regulatory authorities &/or industry <input checked="" type="checkbox"/> Others, please specify: PMAS
Product information (whenever possible, please provide an image of the product)		
5. Product type:	<input type="checkbox"/> Biologic <input checked="" type="checkbox"/> Cosmetic <input type="checkbox"/> Health supplement <input type="checkbox"/> Pharmaceutical	<input type="checkbox"/> Traditional medicine <input type="checkbox"/> Others, please specify:
6. Forensic classification in your country:	<input checked="" type="checkbox"/> General sales list / Over-the-counter <input type="checkbox"/> Pharmacy only	<input type="checkbox"/> Prescription only <input type="checkbox"/> Others, please specify:
Reporting country / authority		
7. Name of country / Issuing authority: Singapore / Health Sciences Authority		8. Report reference no.: HSA0716525042018
9. Department / Designation of person issuing the alert: Vigilance and Compliance Branch		10. Date of report 25 April 2018
Contact person		
11. Name: Choong Chih Tzer		12. Department / Designation: Vigilance and Compliance Branch
13. Email address: Choong_chih_tzer@hsa.gov.sg		14. Contact no. Telephone no.: 68663548 Fax no.: 64789069

Annex I

Report reference no.:

HSA0716525042018

Date of report:

25 April 2018



No	Description of product *				Marketing authorisation holder / Product licence holder / Company responsible for placing product in the market	Manufacturer	Investigations i.e.	Actions i.e.
	Brand / Product name / Alternative name (e.g. local language)	<ul style="list-style-type: none"> Active Ingredients / Generic name / Full formula (for cosmetics, traditional medicines etc.) Strength (if applicable): 	<ul style="list-style-type: none"> Dosage form / Pack size (if applicable) Batch / Lot number Date of Expiry or Manufacture (if applicable) 	Intended use as listed on label:				
1	Balleza SKINCARE NIGHT CREAM	Not Stated	Batch No: BSC 010217 Mfg Date: Feb 2017 Exp Date: Feb 2019	Night Cream	Queens Beauty SG Pte Ltd	Sofieya Secret Resources Malaysia	Verified to be adulterated with toxic levels of mercury	Class II Retail Level All Batch
2	Balleza SKINCARE TREATMENT	Not Stated	Batch No: BSC 010217 Mfg Date: Feb 2017 Exp Date: Feb 2019	Treatment Cream	Queens Beauty SG Pte Ltd	Sofieya Secret Resources Malaysia	Hydroquinone Detected	Class II Retail Level All Batch
3	Brilliant Skin Essentials Rejuvenating Cream Exfoliant Cream	Water Cetearyl Alcohol Propylene Glycol Retinol Mineral Oil Microcrystalline Wax Alpha-Arbutin Niacinamide Lactic acid Glycerine Sodium Citrate Sodium Laureth Sulfate Allantoin	10g / Container	Exfoliant Cream	Jaz En Joy Beauty	Philippines	Hydroquinone and Tretinoin Detected	Class II Retail Level All Batch
4	Brilliant Skin Essentials Whitening Cream 10g	Kojic Acid Dipalmitate Hydrolyzed Collagen Papaya Extract Mulberry Extract	10g/ Container	Whitening Cream	Jaz En Joy Beauty	Philippines	Hydroquinone and Tretinoin Detected	Class II Retail Level All Batch

		Alpha Arbutin Retinyl Palmitate Citric Acid Alpha Tocopherol (Vitamin E) Niacinamide (Vitamin B3) Grapeseed Oil Phenylethyl Resorcinol Claire Blanch						
5	Brilliant Skin Essentials Whitening facial toner 60ml	Aqua Ascorbic Acid Tocopherol Licorice Bearberry Extract Mulberry Extract Carica Papaya Extract Retinyl Palmitate Niacinamide (Vitamin B3)	60ml/ Bottle Batch No: RC1006600128 Exp Date: 08 MAR 2019	Facial Toner	Jaz En Joy Beauty	Philippines	Hydroquinone Detected	Class II Retail Level All Batch
6	droplets of Nature. REJUVENATING CREAM Lift & Correct 10g	Aqua Cetyl Alcohol Cetearyl Alcohol Ceteareth 20 Glycerin Cera Alba (Bees Wax) Glyceryl Stearate/Peg-100 Stearate Squalene Caprylic/Capric Triglycerides Lactic acid Citric Acid Sodium Lactate Helianthus Annus (Sunflower) seed Oil Niacinamide (Vitamin B3) Tocopherol (Vitamin E) Aloe Bardanesis Leaf Extract Pentylene Glycol Arbutin Retinyl Palmitate Bengkoang Extract Glycolic Acid Kojic Acid Dipalmitate Bearberry Extract Phenoxyethanol	10g/ Container Batch No: 2RJJS Mfg Date: 1117 Exp Date: 1119	Cream	Jaz En Joy Beauty	Philippines	Hydroquinone and Tretinoin Detected	Class II Retail Level All Batch
7	droplets of Nature. REJUVENATING TONER Lift & Correct 60mL	Aqua Ethyl Alcohol Glycerin Propylene Glycol	60ml/ Bottle Batch No: 4RJJS Mfg Date: 1117 Exp Date: 1119	Toner	Jaz En Joy Beauty	Philippines	Hydroquinone Detected	Class II Retail Level All Batch



		Squalene Sodium Lactate Lactic acid Niacinamide (Vitamin B3) Arbutin Bengkoang Extract Bearberry Extract Aloe Bardanesis Leaf Extract Retinyl Palmitate Kojic Acid Dipalmitate Phenoxyethanol						
8	Professional Skin Care Formula by Dr. Alvin Rejuvenating Cream	Water Cetearyl Alcohol Propylene Glycol Mineral Oil Microcrystalline Wax Paraffin Ethylhexyl methoxycinnamate Alpha Arbutin Rumex Occidentalis Extract Glycerin Ascorbic acid Vigna Aconitifolia Seed Extract Sodium Citrate Sodium Lauryl Sulfate Lactic Acid Methy Paraben Propyl Paraben Allantoin BHT	Exp Date: 06-2019	Cream	MyieSkin Shop	Not Stated	Hydroquinone and Tretinoin Detected	Class II Retail Level All Batch
9	Speaks G Skin Essential Brightening Rejuvenating Cream 10g	Water Cera Alba (Beeswax) Caprylic/Capric Triglyceride Cetearyl Alcohol (and) Cetereath 20 Lactic Acid Niacinamide Bengkoang Extract Glyceryl Stearate (and) PEG 100 Glycrrhiza Glabra (Licorice) Root Extract Butylene Glycol Allantoin Arbutin Citrus Aurantium Dulcis (Orange) Peel Oil	10g/Container Batch No: SG000004 Mfg Date: SEP 2017 Exp Date: SEP 2019	Face Cream	MyieSkin Shop	Not Stated	Hydroquinone and Tretinoin Detected	Class II Retail Level All Batch

		Phenoxyethanol VitisVinifera (Grapeseed) Oil lycerin Citric Acid Tocopherol Triethanolamine (99%) Retinyl Palmitate Helianthus Annus (Sunflower) Seed Oil Bisabolol Carbomer Disodium EDTA						
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* To provide photograph of product.

	Product	Undeclared Ingredients
1	Balleza SKINCARE NIGHT CREAM 	Mercury
2	Balleza SKINCARE TREATMENT 	Hydroquinone

3	<p>Brilliant Skin Essentials Rejuvenating Cream Exfoliant Cream</p> 	<p>Hydroquinone and Tretinoin</p>
4	<p>Brilliant Skin Essentials Whitening Cream 10g</p> 	<p>Hydroquinone and Tretinoin</p>

5	<p>Brilliant Skin Essentials Whitening facial toner 60ml</p> 	<p>Hydroquinone</p>
6	<p>droplets of Nature. REJUVENATING CREAM Lift & Correct 10g 2RJJS</p> 	<p>Hydroquinone and Tretinoin</p>

7	<p>droplets of Nature. REJUVENATING TONER Lift & Correct 60mL 4RJJS</p> 	<p>Hydroquinone</p>

8	<p>Professional Skin Care Formula by Dr. Alvin Rejuvenating Cream</p>  <p>The images show the product packaging and the cream itself. The top row shows two jars of 'Professional Skin Care Formula by Dr. Alvin Rejuvenating Cream'. The bottom row shows two close-ups of the cream, which is a light yellow color. One close-up shows the expiration date 'EXP:06-2019' on the jar lid.</p>	<p>Hydroquinone and Tretinoin</p>
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9 | Speaks G Skin Essential Brightening Rejuvenating Cream 10g



Hydroquinone and
Tretinoin