



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



22 FEB 2018

**FDA ADVISORY**  
No. **2018-051**

**TO: GENERAL CONSUMING PUBLIC**

**SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. B-IN.05.03.1.43.12.17.5965**

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:

	<b>BRAND / PRODUCT NAME</b>	<b>FINDINGS</b>
1.	BEAUTY G Day Cream	Presence of MERCURY
2.	LIXIAO Night Cream	Presence of MERCURY
3.	ROSE Night Cream	Presence of MERCURY
4.	D'SWISS Night Cream	Presence of MERCURY
5.	L'COME Day Cream	Presence of MERCURY
6.	LA WIDYA COLLAGEN Day Cream	Presence of MERCURY
7.	LABITHA Night Cream	Presence of MERCURY
8.	KOREAN WID YA Night Cream	Presence of MERCURY
9.	OZERA Nail Polish Color No. 8	Presence of Rhodamin B (CI 45170, Basic Violet 10)
10.	OZERA Lipstick-29#	Presence of Rhodamin B (CI 45170, Basic Violet 10)
11.	OZERA Lipstick-53#	Presence of Rhodamin B (CI 45170, Basic Violet 10)
12.	OZERA Lipstick-54#	Presence of Rhodamin B (CI 45170, Basic Violet 10)
13.	OZERA Lipstick-57#	Presence of Rhodamin B (CI 45170, Basic Violet 10)
14.	OZERA Lipstick-80#	Presence of Rhodamin B (CI 45170, Basic Violet 10)
15.	OZERA Lipstick-22#	Presence of CI 15585 (Pigment Red 53)
16.	OZERA Lipstick-66#	Presence of CI 15585 (Pigment Red 53)
17.	OZERA Lipstick-131#	Presence of CI 15585 (Pigment Red 53)
18.	OZERA Lipstick-77#	Presence of Rhodamin B (CI 45170, Basic Violet 10) and CI 15585 (Pigment Red 53)
19.	OZERA Lipstick- 82#	Presence of Rhodamin B (CI 45170, Basic Violet 10) and CI 15585 (Pigment Red 53)

*\*Attached is a copy of the Indonesian PMAS Report with Reference No. B-IN.05.03.1.43.12.17.5965*





The aforementioned products have been tested by the National Agency of Drug and Food Control, Indonesia 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).

Products #1 to #8 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 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 are passed on to nursing babies through breast milk which can affect the baby's development.

Products #9 to #19, on the other hand, have been found to contain one or both of the following banned colorants:

1. Color Index (CI) 45170 (synonyms: Rhodamine B, Basic Violet 10), and
2. CI 15585 (synonym: Pigment Red 53).

According to the prevailing cosmetic regulation, these two (2) color ingredients are not allowed to be part of a cosmetic product intended to be distributed in the ASEAN region, including the Philippines because of their potential to cause serious adverse effects including but not limited to cancer.

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 said products:

1. Send an e-mail via [report@fda.gov.ph](mailto:report@fda.gov.ph)
2. Call the Center for Cosmetics Regulation and Research (CCRR) hotline (02) 857-1984
3. Utilize the agency's online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://www.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](http://www.fda.gov.ph). For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto: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



<b>ASEAN POST-MARKETING ALERT SYSTEM (Form B)</b> <i>(Use this form for multiple product alerts of same product type with similar issues)</i>		
<b>1. Level of confidentiality (Tick <input checked="" type="checkbox"/>):</b> <input type="checkbox"/> Internal / restricted circulation <input checked="" type="checkbox"/> Public domain, specify website: <a href="http://www.pom.go.id">www.pom.go.id</a>	<b>2. Issue:</b> <input type="checkbox"/> Adulteration <input type="checkbox"/> Counterfeit <input type="checkbox"/> Quality defect <input checked="" type="checkbox"/> Safety aspects <input type="checkbox"/> Others, please specify: <hr/>	<b>3. Action:</b> <input checked="" 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: <hr/>
<b>4. Source / Type:</b>	<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 type="checkbox"/> Others, please specify: <hr/>
<b>Product information (whenever possible, please provide an image of the product)</b>		
<b>5. Product type:</b>	<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: <hr/>
<b>6. Forensic classification in your country:</b>	<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: <hr/>
<b>Reporting country / authority</b>		
<b>7. Name of Country / Issuing authority:</b> Indonesia, National Agency of Drug and Food Control	<b>8. Report reference no.:</b> B-IN.05.03.1.43.12.17.5965	
<b>9. Department / Designation of person issuing the alert:</b> Deputy of Traditional Medicines, Cosmetics and Complementary Product Control	<b>10. Date of report:</b> December, 11 <sup>th</sup> 2017	
<b>Contact person</b>		
<b>11. Name:</b> Mrs. Kenik Sintawati Head of Sub Directorate Traditional Medicine, Food Supplement and Cosmetics Safety Surveillance	<b>12. Department / Designation:</b> Subdirector of Safety Surveillance of Traditional Medicine, Food Supplement and Cosmetic	
<b>13. Email address:</b> surv_otsmkos@yahoo.com	<b>14. Contact no.</b> <b>Telephone no.:</b> +62 21 4244819 <b>Fax no.:</b> +62 21 4244819	



## Annex I

Report reference no.: B-IN.05.03.1.43.12.17.5965

Date of report : December, 11<sup>th</sup>, 2017

No.	Description of Product*				Marketing Authorisation holder / Product licence holder/ Company responsible for placing product in the market	Manufacturer	Investigation i.e.	Action i.e.
	Brand/product name/ Alternative name (e.g. local language)	<ul style="list-style-type: none"> <li>Active ingredients/Generic name/Full formula (for cosmetics, traditional medicines etc.)</li> <li>Strength (if applicable):</li> </ul>	<ul style="list-style-type: none"> <li>Dosage form / Pack size (if applicable)</li> <li>Batch/Lot number</li> </ul>	Intended use as listed on label :				
1.	BEAUTY G Day Cream , NA47150101401	N/A	N/A	N/A	PT. Crystal Beauty, Jakarta-Indonesia	Chiao Tu Cosmetics Co., Ltd. No. 771, Chung Min Road, 824 Yen Chao Hsiang Kaohsiung, Taiwan	Product tested to contain Mercury	Product recalled and press release issued
2.	LIXIAO Night Cream, NA47150103548	N/A	N/A	N/A	PT. Crystal Beauty, Jakarta-Indonesia	Chiao Tu Cosmetics Co., Ltd. No. 771, Chung Min Road, 824 Yen Chao Hsiang Kaohsiung,	Product tested to contain Mercury	Product recalled and press release issued

						Taiwan		
3.	ROSE Night Cream, NA47150101146	N/A	N/A	N/A	PT. Crystal Beauty, Jakarta- Indonesia	Chiao Tu Cosmetics Co., Ltd. No. 771, Chung Min Road, 824 Yen Chao Hsiang Kaohsiung, Taiwan	Product tested to contain Mercury	Product recalled and press release issued
4.	D'SWISS Night Cream, NA47160101201	N/A	N/A	N/A	PT. Sinar Dios Abadi, Jakarta Utara- Indonesia	Bertie Enterprise Corp. No. 186, Chengkong 3rd. Rd Nantao, Taiwan	Product tested to contain Mercury	Product recalled and press release issued
5.	L'COME Day Cream, NA47150104120	N/A	N/A	N/A	PT. Sinar Dios Abadi, Jakarta Utara- Indonesia	Bertie Enterprise Corp. No. 186, Chengkong 3rd. Rd Nantao, Taiwan	Product tested to contain Mercury	Product recalled and press release issued
6.	LA WIDYA COLLAGEN Day Cream, NA47150103942	N/A	N/A	N/A	PT. Sinar Dios Abadi, Jakarta Utara- Indonesia	Bertie Enterprise Corp. No. 186, Chengkong 3rd. Rd Nantao, Taiwan	Product tested to contain Mercury	Product recalled and press release issued
7.	LABITHA Night Cream,	N/A	N/A	N/A	PT. Sinar Dios Abadi, Jakarta	Bertie Enterprise	Product tested to contain	Product recalled

	NA47160100888				Utara-Indonesia	Corp. No. 186, Chengkong 3rd. Rd Nantao, Taiwan	Mercury	and press release issued
8.	KOREAN WID YA Night Cream, NA26160102781	N/A	N/A	N/A	PT. Billindo Kristal Jaya, Jakarta-Indonesia	HongikSkin/ LK Cosmetics, Seoul, South Korea	Product tested to contain Mercury	Product recalled and press release issued
9.	OZERA Nail Polish Color No. 8 NA11151501122	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain Rhodamin B (CI 45170, Basic Violet 10)	Product recalled and press release issued
10.	OZERA Lipstick-29#, NA11161301172	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain Rhodamin B (CI 45170, Basic Violet 10)	Product recalled and press release issued
11.	OZERA Lipstick-53#, NA11161301141	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain Rhodamin B (CI 45170, Basic Violet 10)	Product recalled and press release issued
12.	OZERA Lipstick-54#, NA11161301176	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain Rhodamin B (CI 45170, Basic Violet 10)	Product recalled and press release issued
13.	OZERA Lipstick-57#, NA11161301140	N/A	N/A	N/A	PT. Adi Parama Wardhana,	Made in China	Product tested to contain Rhodamin B	Product recalled and press



					Jakarta-Indonesia		(CI 45170, Basic Violet 10)	release issued
14.	OZERA Lipstick-80#, NA11161301139	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain Rhodamin B (CI 45170, Basic Violet 10)	Product recalled and press release issued
15.	OZERA Lipstick-22#, NA11161301174	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain CI 15585 (Pigment Red 53)	Product recalled and press release issued
16.	OZERA Lipstick-66#, NA11161301137	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain CI 15585 (Pigment Red 53)	Product recalled and press release issued
17.	OZERA Lipstick-131#, NA11161301173	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain CI 15585 (Pigment Red 53)	Product recalled and press release issued
18.	OZERA Lipstick-77#, NA11161301175	N/A	N/A	N/A	PT. Adi Parama Wardhana, Jakarta-Indonesia	Made in China	Product tested to contain Rhodamin B (CI 45170, Basic Violet 10) and CI 15585 (Pigment Red 53)	Product recalled and press release issued
19.	OZERA Lipstick-	N/A	N/A	N/A	PT. Adi	Made in China	Product tested	Product

	82#, NA11161301138				Parama Wardhana, Jakarta- Indonesia		to contain Rhodamin B (CI 45170, Basic Violet 10) and CI 15585 (Pigment Red 53)	recalled and press release issued
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1. BEAUTY G Day Cream, NA47150101401



2. LIXIAO Night Cream, NA47150103548



3. ROSE Night Cream, NA47150101146



4. D'SWISS Night Cream, NA47160101201



5. L'COME Day Cream, NA47150104120



6. LA WIDYA COLLAGEN Day Cream, NA47150103942



7. LABITHA Night Cream, NA47160100888



8. KOREAN WID YA Night Cream, NA26160102781



9. OZERA Nail Polish Color No. 8 , NA111515051122



10. OZERA Lipstick-29#, NA11161301172



11. OZERA Lipstick-53#, NA11161301141



12. OZERA Lipstick-54#, NA11161301176





13. OZERA Lipstick-57#, NA11161301140



14. OZERA Lipstick-80#, NA11161301139



15. OZERA Lipstick-22#, NA11161301174



16. OZERA Lipstick-66#, NA11161301137



17. OZERA Lipstick-131#, NA11161301173



18. OZERA Lipstick-77#, NA11161301175



19. OZERA Lipstick-82#, NA11161301138

