

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



FDA ADVISORY No. **2016-**032 2 n APR 2016

TO

GENERAL CONSUMING PUBLIC, FIELD REGULATORY OPERATIONS OFFICE OF THE FOOD AND DRUG ADMINISTRATION, LAW ENFORCEMENT AGENCIES, LOCAL GOVERNMENT UNITS AND COSMETIC

RETAILERS

SUBJECT

Selected Parabens Declared as Banned Ingredients

that may be Contained in Cosmetic Products

On 25-28 November 2014, it has been adopted during the 21<sup>st</sup> ASEAN Cosmetic Committee (ACC) Meeting and its Related Events in Manila, Philippines that the following ingredients are no longer allowed to be used in the formulation of cosmetic products:

International Nomenclature of Cosmetic Ingredients (INCI)	Other Name
Isopropylparaben	Isopropyl 4-hydroxybenzoate, Sodium salt or Salts of Isopropylparaben
Isobutylparaben	Isobutyl 4-hydroxybenzoate, Sodium salt or Salts of Isobutylparaben
Benzylparaben	Benzyl 4-hydroxybenzoate
Phenylparaben	Phenyl 4-hydroxybenzoate
Pentylparaben	Pentyl 4-hydroxybenzoate

The abovementioned ingredients are commonly used as preservatives in cosmetic products to inhibit or prevent microbial and fungal growth.

In line with the ACC decision, the Food and Drug Administration (FDA) - Center for Cosmetics Regulation and Research (CCRR) issued FDA Circulars 2015-008 and 2015-014 on 14 April 2015 and 14 December 2015 respectively. FDA-CCRR, noting the importance to the cosmetic industry to have ample time to formulate, reformulate, initiate product phaseouts, among others so as not to hamper business operations, has given them until 31 December 2015 to market cosmetic products containing the five (5) identified banned ingredients.



Cosmetic products found to contain any of the five (5) identified banned ingredients pose potential health risk to the consuming public and therefore, shall not be allowed to be placed or to remain in the Philippine market starting 01 January 2016.

The FDA advises the general consuming public against buying and using cosmetic products that contain any of the five (5) identified banned ingredients. The public is encouraged to check if a cosmetic product contains any of the identified banned ingredients before purchasing the product. The full ingredient list of a cosmetic product is found in the "Ingredients" section of the label as shown in Figure 1.

Moreover, the public is also encouraged to check for the following information namely (1) brand and product name, (2) manufacturing/expiry date, (3) net content, (4) batch/ lot number, (5) country of manufacture, (6) instructions for use, (7) special precautions – if applicable, (8) full ingredient list and; (9) name and address of company or person responsible for placing the product in the market.

These information must be displayed prominently on the immediate packaging which refers to the container in direct contact with the product and/or outer packaging of the cosmetic product such as boxes and cartons (refer to Figures 1, 2 and 3).



Figure 1. Sample Ingredient Section of a Cosmetic Product Label

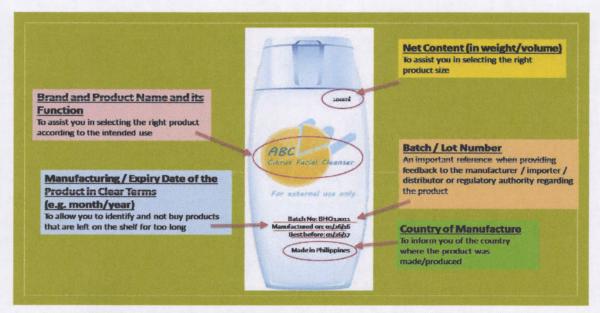


Figure 2. Illustration of a Compliant Cosmetic Product to ASEAN Cosmetic Labeling Requirements (Front)

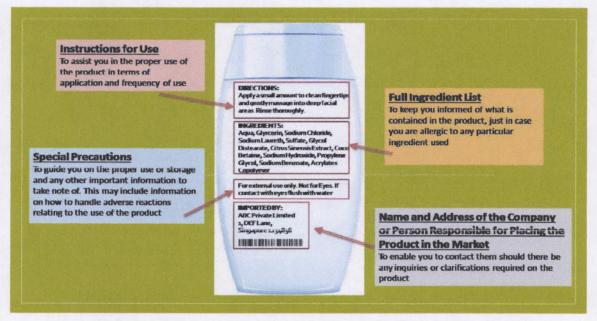


Figure 3. Illustration of a Compliant Cosmetic Product to ASEAN Cosmetic Labeling Requirements (Back)

In cases where the product's shape and/or size does not allow these information to be displayed, consumers are advised to look for other informative materials such as leaflets, pamphlets, hangtags or display panel. However, both the (1) name of the cosmetic product and (2) manufacturer's batch/lot number must always appear on the immediate packaging of the cosmetic product.

The FDA Field Regulatory Operations Office (FROO) is hereby ordered to seize all cosmetic products found in the Philippine market containing any of the five (5) identified banned ingredients listed above.

All local government units and law enforcement agencies are requested to ensure that cosmetic products containing any of the five (5) identified banned ingredients are not sold or made available in their localities or area of jurisdiction.

All cosmetic retailers are warned against selling cosmetic products containing any of the five (5) identified banned ingredients.

The public is enjoined to assist FDA in monitoring the market and to report any suspicious promotional or marketing activities for cosmetic products and their availability in the market through any of the following channels:

1. FDA's e-report (www.fda.gov.ph)
Reports can be sent to FDA via the e-Report section found in the upper right corner of the FDA website. By clicking e-report, another page will appear where you will find the form that must be accomplished (refer to Figures 4 and 5).



Figure 4. e-Report Section of the FDA Website



Figure 5. Filled-up e-Report Form

- 2. Send an email to report@fda.gov.ph
- 3. Contact the FDA CCRR Customer Service Hotline at (02) 857-1984.

For more information and cosmetic-related news, the public may visit the FDA website (www.fda.gov.ph). The FDA website contains the list of all licensed cosmetic companies here in the Philippines as well as the list of all notified cosmetic products so consumers can check whether the cosmetic product they wish to purchase or have already purchased is notified with FDA by making use of the **Search Tab** in the upper right corner of the home page as shown below:



Figure 6. FDA Website Homepage

By Authority of the Secretary of Health

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