



11 February 2015

FDA Advisory
No. **2015-006**

**SUBJECT : WARNING AGAINST UNNOTIFIED NAIL
ADHESIVE CONTAINING DIBUTYL PHTHALATE**

The Food and Drug Administration (FDA) Center for Cosmetic Regulation and Research (CCRR) received unnotified samples of Fashion Nail (artificial nail sets with nail adhesive) allegedly containing Dibutyl Phthalate (DBP). The product was tested by the Central Laboratory and was found to contain Dibutyl Phthalate. This substance is a banned ingredient included on the List of Substances which "Must Not Form Part of the Composition of Cosmetic Products" (Annex II Part I Ref. No. 675) of the ASEAN Cosmetic Directive (ACD).



Dibutyl Phthalate has the ability to cause allergic reactions. There were previous cases where allergic response to Dibutyl Phthalate was found to be severe. Allergic reactions can induce a state of hypersensitivity in the immune system. It can cause the immune system to respond to chemical exposures with immunological reactions that are harmful, varying from hives to life threatening responses such as anaphylactic shock, where low blood pressure and breathing difficulties can result in death.




Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



All consumers are advised to buy nail products that have acknowledged notification and distributed by FDA licensed manufacturer/trader/distributor.

All Field Regulatory Officers are hereby ordered to monitor, conduct inventory and seize all cosmetics products that have no FDA Certificate of Product Notification. Likewise, all local government units are requested to ensure that cosmetic products that do not have market authorization are not sold or offered for sale by ambulant and sidewalk vendors. The Bureau of Customs is requested to remain vigilant to prevent the entry of unregistered and toxic health products in the country.

For more information and inquiries please email us at info@fda.gov.ph. To report unnotified cosmetics products kindly email us at report@fda.gov.ph


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