

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR No. 2017-015 12 7 DEC 2017

TO:

ALL HOUSEHOLD/URBAN PESTICIDE (HUP)
MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER

CONCERNED PARTIES

SUBJECT: Adoption of the ASEAN Cosmetic Directive (ACD) Annexes II and

VI as Standards for Household/Urban Pesticides (HUP)

WHEREAS the 1987 Constitution of the Republic of the Philippines provided that "the State shall protect and promote the right to health of the people and instill health consciousness among them."

WHEREAS Republic Act (RA) No. 3720, as amended by RA No. 9711, otherwise known as "Food and Drug Administration Act of 2009" created the Food and Drug Administration (FDA) under the Department of Health (DOH) and mandated the agency to ensure the safety, quality and efficacy of health products under its jurisdiction including household/urban pesticide (HUP) products.

WHEREAS Section 4 (m) of the same gave to the FDA the function, power and duty "to develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products."

WHEREAS Section 11 (a) of the same and Administrative Order (AO) No. 2014-0038 dated 27 October 2014 "Rules and Regulations Governing Household / Urban Pesticides Licensing of Establishments and Operators, Registration of their Products and for Other Purposes" prohibits the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any adulterated Household/Urban Pesticide (HUP) products.

WHEREAS the ASEAN Cosmetic Directive (ACD), its annexes and appendices have been adopted and implemented through the issuance of Administrative Order (AO) No. 2005-0015 "Adoption of the Association of Southeast Asian Nation (ASEAN) Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents" and AO No. 2005-0025 "Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents," respectively to enhance cooperation amongst the ten (10) ASEAN Member States (AMS) in ensuring the quality and safety of cosmetic products marketed in the ASEAN region and to eliminate barriers to its trade.

WHEREAS the ASEAN Cosmetic Directive (ACD) Annex II "List of Substances Which Must Not Form Part of the Composition of Cosmetic Products" lists down substances that are considered







unsafe/hazardous for consumer consumption and must not be allowed to be part of a cosmetic product.

WHEREAS the ACD Annex VI "List of Preservatives Which Cosmetic Products May Contain" provides the list of preservatives allowed to be used in cosmetic products and lay down the maximum authorized concentration of these substances.

WHEREAS the decision to include the ingredients and their restrictions, if any, in the aforementioned ACD annexes are made after careful evaluation of their toxicological data and in consideration of the aggregate exposures of consumers to the restricted ingredients.

WHEREAS cosmetics and HUPs are both consumer products and, as such, contributes to the overall aggregate exposure of consumers.

NOW THEREFORE, the FDA, in its authority to regulate HUP products and to develop and issue the necessary standards to effectively carry out its mandate, adopts the aforementioned ASEAN Cosmetic Directive (ACD) Annexes and any of their future updates as part of the HUP standards. All HUP products made available in the market shall conform to the maximum authorized concentrations laid down in the adopted ACD annexes. In cases wherein ACD Annex VI has made a distinction between leave-on and rinse-off products, the HUP product shall be classified accordingly and the respective concentration shall apply.

This circular shall take effect fifteen (15) days following its publication in a newspapers of general circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register.

Director General

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