Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 June 2013

FDA Circular
No. 2013-015
Center for Cosmetic Regulation and Research

SUBJECT: DEREGULATION OF BULK INDUSTRIAL CHEMICALS USED AS RAW MATERIALS IN COSMETIC PRODUCTS AND HOUSEHOLD PRODUCTS CONSIDERED AS URBAN HAZARDOUS SUBSTANCES

A cosmetic product is intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly of cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting them, and Household/Urban Hazardous Substance (HHUS) product falling under the definition of household/urban hazardous substances is any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizers, agricultural pesticides, and agricultural insecticides, and other economic poisons, radioactive substances, or substances intended for use as fuels, coolants, refrigerants and the like, require FDA approval and market authorization by virtue of Republic Act (RA) No. 9711 or the FDA Act of 2009.

Several government agencies are mandated by law to regulate the manufacture, importation, export, distribution, storage, transport, sale and use of industrial chemicals and hazardous waste materials, namely DENR Environmental Management Bureau by virtue of RA No. 6969 of 1990, An Act To Control Toxic Substance and Hazardous and Nuclear Wastes, Providing Penalties For Violations Thereof, and for Other Purposes; Department of Labor and Employment (DOLE) by virtue of Presidential Decree No. 442, Book 4, Title I, Chapter II; the Philippine National Police (PNP) Fire and Explosives Division by virtue of Executive Order No. 522, Presidential Decree No. 1866 on Codifying the Laws on Illegal/Unlawful Possession, Manufacture, Dealing in, Acquisition or Disposition, of Firearms, Ammunition or Explosives or Instruments Used in the Manufacture of Firearms, Ammunition or Explosives, and Imposing Stiffer

Penalties for Certain Violations Thereof and for Relevant Purposes, RA No. 8294, otherwise known as An Act Amending the Provisions of Presidential Decree No. 1866 and PNP SOP NP No. 4; the Philippine Drug Enforcement Agency (PDEA) by virtue of RA 9165 of 2002, An Act Instituting the Comprehensive Dangerous Drugs Act of 2002, Repealing RA No. 6425, otherwise known as the Dangerous Drugs Act of 1972, as amended, providing funds therefore, and for other purposes and Board Regulation No. 3-2003, Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other lawful Acts in Connection With Any Dangerous Drugs, Controlled Precursors and Essential Chemicals and Other Similar or Analogous Substances.

In view of the above, all industrial chemicals, whether local or imprted, in raw and in bulk forms, for industrial use and intended for further processing as ingredients to manufacture or produce cosmetic products or preparation of HUHS falling within the definition of HUHS except for Household/Urban Pesticides shall no longer be regulated by this Office.

All establishments with existing FDA License to Operate (LTO) as Raw Material Manufacturer, Trader or Distributor, or both, for Cosmetics and HUHS and all market authorization holders of valid Certificate of Product Registrations (CPR), are hereby advised not to renew the said FDA authorizations. However, any establishments packaging and labeling industrial chemical into consumer products must secure proper authorization from the FDA.

For the guidance of all concerned. This Circular shall take effect immediately upon approval.

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Acting Director General