

05 July 2013

**FDA Advisory**  
No. **2013-017**

**SUBJECT: FDA RECALLS KANEBO SKIN WHITENING PRODUCTS**  
**CONTAINING 4HPB (4-(4-hydroxyphenyl)-2-butanol) OR**  
**RHODODENOL**

In response to the skin whitening products that were voluntarily recalled by Kanebo Cosmetics Inc., Lissage Ltd. and E'quipe, Ltd. in Japan and from all over Asia, including Taiwan, Hong Kong, South Korea, Thailand, Singapore, Malaysia, Indonesia, Myanmar, the Philippines, and Vietnam on July 4, 2013, the Philippine FDA hereby recalls all products that were issued FDA market authorization and to ban other products manufactured by Kanebo that contain 4HPB [4-(4-hydroxyphenyl)-2-butanol] or Rhododenol, a substance contained in the skin whitening or brightening products that was developed by Kanebo and have been reported or implicated to cause white blotches and uneven coloring of the skin.

The recalled Kanebo products with the different variance are as follows:

1. Kanebo BLANCHIR SUPERIOR:
  - White Deep Clear Conditioner (all 7 items)
  - White Deep Milky Conditioner (all 3 items)
  - White Deep Night Conditioner (all 4 items)
  - White Deep Mask
  - White Deep UV Day Protector
2. SUISAI:
  - Whitening Essence
3. TWANY:
  - Esthetude White Lotion (all 6 items)
  - Esthetude White UV Protect Serum
  - Esthetude White Clear Tight Mask
  - Century The Lotion (all 2 items)
4. IMPRESS:
  - IC White Lotion (all 2 items)
  - IC White Emulsion (all 2 items)
  - IC White Fit Mask 3D
  - Granmula Lotion
5. AQUALEAF
  - MCT Whitening Essence



6. LISSAGE brands

- White Skin Maintainer (all 8 items)
- White Whitening Repair Cream
- White Trial Set (all 4 items)
- Beauté Circu Lead a

7. E'quipe brands RMK:

- Skintuner Brightening (both 2 items)
- Intensive Brightening Essence

8. SUQQU:

- Whitening Repair Essence
- Whitening Lotion
- Whitening Barrier Emulsion

The active ingredient known as 4HPB or Rhododenol is derived from a substance found in barks of the white birch tree. Kanebo Cosmetics discovered that the compound confers strong whitening effects by suppressing the production of melanin, the pigment that gives the skin color, in several stages.

Melanin provides some protection against skin damage from the sun, and the melanocytes increase melanin production in response to sun exposure. Dark-skinned people have more melanin in their skin than light-skinned people have. Melanin comes in two types, eumelanin, a brown-to-black type, and pheomelanin, a yellow-to-reddish-brown type. Eumelanin is thought to be the main cause of dark spots, dullness, and other types of pigmentation. Rhododenol inhibits eumelanin synthesis by preferentially lowering the amount and activity of the enzyme tyrosinase. Tyrosinase is a key factor in melanin synthesis. When activated, it binds with the amino acid tyrosine and gradually changes it to melanin. 4HPB or Rhododenol, however, inhibits the activation of melanin production by binding with tyrosinase before the tyrosinase has the chance to bind with tyrosine. This action is called "competitive inhibition." Rhododenol also reduces the amount of tyrosinase by accelerating its degradation.

Rhododenol has now been linked or associated with the white blotches on the skin after using the Kanebo whitening products, which prompted Kanebo Cosmetics Inc., Lissage Ltd. and E'quipe, Ltd. in Japan to voluntarily recall some of their products.

The public is hereby advised not to buy Kanebo cosmetic products containing 4HPB or Rhododenol. The cosmetic inspectors are hereby order to inventory and seal recalled or banned Kanebo cosmetic products in the market. To report or to seek more clarification regarding this matter, please inform FDA using the eReport platform of the Official website (<http://www.fda.gov.ph>) or directly email [report@fda.gov.ph](mailto:report@fda.gov.ph).



**KENNETH Y. HARTIGAN-GO, MD**  
Acting Director General