Partial Amendment of Criteria and Test Methods for Cosmetics

2008. 12. 10.

Korea Food & Drug Administration

Korea Food & Drug Administration Notification No. 2008-271

In amending criteria and test methods for cosmetics (Korea Food & Drug Administration Notification No. 2007-45, 2007. 6. 29), we hereby, according to the Administrative Procedures Act, Article 46, notify the purpose and reason of the amendment to collect public opinions.

December 10th, 2008

Commissioner, Korea Food & Drug Administration

Preliminary Administrative Notice of Partial Amendment in Criteria and Test

Methods for Cosmetics

1. Reason for Amendment

To minimize confusion of regulation application due to change of content in the Criteria and Test Methods for Cosmetics in accordance with the amendment of the Cosmetic Act Enforcement Ordinance (2008.9.11).

2. Summary of Content

Amendment of terminologies of cosmetic types and amendment of criteria and test methods in Criteria and Test Methods for Cosmetics due to change in cosmetic types in accordance with the Asterisk 2. Amendment of Precautions in Using Different Types of Cosmetics (2008.9.11) in Cosmetic Act Enforcement Ordinance.

3. Submission of Opinion

Any group or individual who has opinions regarding the Partial Amendment Notification of Criteria and Test Methods for Cosmetics may submit a written opinion that includes the following information to the commissioner of Korea Food & Drug Administration (cc: the chief of Drug Safety Policy; address: 38-29 2nd floor, Nokbun-dong, Eunpyung-gu, Seoul; phone: 02-3156-8010) by December 30, 2008.

- A. Opinions regarding preliminary notice (whether you agree or disagree and why)
- B. Name (If group, title of the group and name of the representative), address, and phone number
- C. Other Comments

Korea Food & Drug Administration Notification No. 2008 -

Criteria and Test Methods for Cosmetics (Korea Food & Drug Administration Notification No. 2007-45, 2007. 6. 29) in accordance with Cosmetic Act, Article 9 shall be amended as the following:

2008. . .

Commissioner, Korea Food & Drug Administration

Partial Amendment in Criteria and Test Methods for Cosmetics

Part of the Criteria and Test Methods for Cosmetics shall be amended as the following:

I. In General Cosmetics, 1. Criteria, 1) Content, D), "Korea Food & Drug Administration Notification No.2003-19 Mass (Volume) Deviation Criteria and Test Methods for Medicines" shall be "General Test Methods not Specified in Korea Pharmacopeia (Korea Food & Drug Administration Notification)"; in 2) pH, "make-up products" shall be "toning cosmetic products" and "facewashing cosmetics" shall be "bodywash and bathing products for children"; in 3) Lead and 4) Arsenic, "make-up products" shall be "toning cosmetic products"; in 5) Mercury, the provisory clause shall be deleted.

I. In General Cosmetics, 2. Test Methods, 1) Content, D), "Korea Food & Drug Administration Notification No.2003-19 Mass (Volume) Deviation Criteria and Test Methods for Medicines" shall be "General Test Methods not Specified in Korea Pharmacopeia (Korea Food & Drug Administration Notification)".

- II. Permanent Wave and Hair Straightener Products, 9, D shall be amended as the following:
 - D. The second agent: conforms to 1. Cold double bath permanent wave products whose main ingredient is thioglycolic acid or its salts B. Criteria and Test Methods of the second agent.
- III. shall be established as the following:

III. Others

- 1. For aerosol products, inject the product into the separator funnel and keep for more than 1 hour while opening the funnel cap occasionally. Take the separated solution from the funnel and use it as sample.
- 2. When it is hard to collect the sample by volume accurately due to viscosity of the sample, the sample may be collected by weight. In this case, 1g shall be considered as 1mL.
- 3. Reagent, Test Solution and Standard Solution
 - 1) Standard Iron Solution: accurately weigh 0.7021g of ferrous ammonium sulphate and add 50mL of water to dissolve. Add 20mL of sulphuric acid to the solution and heat. Drop 0.6% potassium permanganate solution until bright red colour remains and discharge coldness followed by adding water to make 1L. Put 10mL of this solution into a 100mL-volumetric flask and add water to make 100mL. 1mL of this solution contains 0.01mg of iron (Fe).
 - 2) For other reagents, test solutions, and standard solutions, use those of reagent, test solution, and standard solution for volumetric analysis of general test methods for criteria of cosmetic ingredients.

ADDENDUM

This notice shall be effective immediately.