

Korea Food & Drug Administration Notification No. 2008-270

In amending criteria and test methods for functional cosmetics (Korea Food & Drug Administration Notification No. 2008-59, 2008. 8. 26), we hereby, according to the Administrative Procedures Act, Article 46, notify the purpose and reason of the amendment to collect public opinions.

December 8th, 2008

Commissioner, Korea Food & Drug Administration

Preliminary Administrative Notice of Partial Amendment in Criteria and Test Methods for Functional Cosmetics

1. Reason for Amendment

To minimize confusion of regulation application due to change of content in the Criteria and Test Methods for Functional Cosmetics in accordance with the change of the notification title "Criteria and Test Methods for Cosmetics" (Korea Food & Drug Administration Notification No. 2007-45, 2007. 6. 26) and to improve civil expediency through addition of new standards and partial amendment of test items and criteria.

2. Summary of Content

- A. Amendment of cited notification title in the Criteria and Test Methods for Functional Cosmetics in accordance with the change in notification title of

Criteria and Test Methods for Cosmetics (Korea Food & Drug Administration Notification No. 2007-45, 2007. 6.26)

B. Partial amendment of criteria and test methods for 3 products including Retinol Cream (Amendment Section 2)

C. Addition of Standards for Arbutine•Adenosine Lotion, Arbutine•Adenosine Cream, and Arbutine•Adenosine Solution (Amendment Section 4, Established)

3. Submission of Opinion

Any group or individual who has opinions regarding the Partial Amendment Notification of Criteria and Test Methods for Functional 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 28, 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

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According to Cosmetic Act, Article 4, Paragraph 1, and Cosmetic Act Enforcement Ordinance, Article 6, Paragraph 1, Criteria and Test Methods for Functional Cosmetics (Korea Food & Drug Administration Notification No. 2008-59, 2008. 8. 26) shall be amended as the following:

2008. . .

Commissioner, Korea Food & Drug Administration

Partial Amendment in Criteria and Test Methods for Functional Cosmetics

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

General Provision No.2 shall be deleted; No.1 shall be No.2; No.1 shall be established as the following.

1. This standard specification aims to determine the domain in which submission of documents regarding criteria and test methods can be exempted when one submits documents to receive inspection for functional cosmetics according to □Cosmetic Act□Article 4, Paragraph 1, and □Cosmetic Act Enforcement Ordinance Article□Article 6, paragraph 1.

In General Provision No.2 (previously No.1), "shall be referred to as "Criteria and Test Methods for Functional Cosmetics" and shall be abbreviated as □Test Methods□." shall be amended as "shall be referred to as□Criteria and Test Methods for Functional Cosmetics□"; "in English abbreviation" shall be amended as "and in short form,".

In General Provision No.3, "Test Methods" shall be "Standard Specifications"; "suitability of functional cosmetics is its" shall be "inspection of functional cosmetics is"; "Provisions for inspecting functional cosmetics and such" shall be "□Provisions for inspecting functional cosmetics and such (Korea Food & Drug Administration

Notification); "shall be decided in accordance with the provisions for specifications of cosmetic ingredient, criteria, and test methods, or Korea Food & Drug Administration Notification." shall be "Provisions of □Criteria and Test Methods for Cosmetics□(Korea Food & Drug Administration Notification) shall be applied.".

General Provision No.4 shall be deleted.

General Provision No.5 shall be No.4, and the provisory clause of No.4 (previously No.5) shall be of the following:

However, the additives should not affect the safety of the corresponding agent and should not change the functionality or affect the test.

General Provision No.6 shall be No.5, and No.5 (previously No.6) shall be of the following: Besides the test methods provided in this standard specifications, if other test methods that have high accuracy and precision and whose results are reliable exist, those test methods may be used.

From General Provision No.7 through No. 10 shall be General Provision No.6 through No.9 respectively.

In Section 1, Arbutine Lotion and Arbutine Cream Content, "In asterisk 5- criteria and test methods for cosmetics provisions for specifications of cosmetic ingredients, criteria, and test methods and such (Korea Food & Drug Administration Notification)" shall be "In□criteria and test methods for cosmetics□(Korea Food & Drug Administration Notification)".

In Section 2, retinol lotion, retinol cream, retinyl palmitate lotion, retinyl palmitate cream, and adenosine cream contents, "asterisk 5- criteria and test methods for cosmetics from provisions for specifications of cosmetic ingredient, criteria, and test methods (Korea Food & Drug Administration Notification)" shall be "in□criteria and

test methods for cosmetics (Korea Food & Drug Administration Notification)";
"10mL of this solution" from Quantitative Analysis of Retinol Cream shall be "5mL of this solution".

In Section 3, Ethylhexyl Methoxycinnamate, "96.0% or higher" shall be "95.0%";
in Quantitative Analysis of Phenylbenzimidazole Sulfonic Acid, "dissolve in methanol to make 250mL" shall be "dissolve in 10mL of 1N sodium hydroxide and add methanol to make 250mL" and "by making it 250mL by dissolving it in methanol" shall be "by performing the same procedure as with the sample".

Section 4 shall be established as the following:

Section 4

Functional cosmetics that help skin whitening and wrinkle improvement

Arbutine·Adenosine Lotion

This functional cosmetic contains arbutine ($C_{12}H_{16}O_7$: 272.25) which takes up more than 90.0% of indicated amount when quantifying and adenosine ($C_{10}H_{13}N_5O_4$: 267.24).

Law . This functional cosmetic is a product whose main ingredients (functional ingredients) are arbutine and adenosine. This product may be added with additives such as stabilizer, wetting agent, emulsifier, moisturizer, pH conditioner, colorant, and flavouring agent to increase stability and value. However, when additives whose ingredients are recognized as functional ingredients, they should not contain more contents than what is recognized as functional ingredients.

The holding time of major peak obtained from a sample of the quantitative analysis of confirmation test is the same as the holding time obtained from a standard solution.

pH standard ± 1.0 (2 $\rightarrow$ 30), (provided, that pH value ranges from 3.0 to 9.0)
methanol 0.2 V/V % or less (only test products whose ethanol content is over 4%)

CONTENTS- Suitable when testing according to the clause "Criteria of Content and Test Methods for General Cosmetics" in Criteria and Test Methods for Cosmetics (Korea Food & Drug Administration Notification).

QUANTITATIVE ANALYSIS- From the functional cosmetic, accurately weigh 20mg of arbutine and 0.4mg of adenosine. Add mobile phase to disperse them and make exactly 50mL. Filter if necessary. This solution shall be the sample solution. Separately, accurately weigh approximately 20mg of arbutine standard and add mobile phase to dissolve to make 50mL. This shall be the standard arbutine solution. Also, accurately weigh approximately 20mg of adenosine standard and add mobile phase to make 100mL. Again, take exactly 4mL of this solution and add mobile phase to make 100mL. This shall be the standard adenosine solution. Take 10 μ L each from the sample solution and the standard solution and test according to the liquid chromatography in the following operation parameter. Calculate each of the peak area, AT, and AS of the sample and standard solutions.

Amount of Arbutine (C₁₂H₁₆O₇) (mg)

$$= \text{Amount of Arbutine Standard (mg)} \times A_T/A_S$$

Amount of Adenosine (C₁₀H₁₃N₅O₄) (mg)

$$= \text{Amount of Adenosine Standard (mg)} \times A_T/A_S \times 1/50$$

<Operation parameter>

Detector: UV spectrophotometer (wavelength: 260nm)

Column: fill a stainless steel tube whose inner diameter and length are 4.6mm and 15cm respectively with 5 μ octadecyl silanized (ODS) silica gel for liquid chromatography.

Mobile phase: ethanol•10mM potassium dihydrogen phosphate mixture (10:90)

Flow rate: 1.0mL/min.

Arbutine·Adenosine Cream

This functional cosmetic contains arbutine ($C_{12}H_{16}O_7$: 272.25) which takes up more than 90.0% of indicated amount when quantifying and adenosine ($C_{10}H_{13}N_5O_4$: 267.24).

Law. This functional cosmetic is a product whose main ingredients (functional ingredients) are arbutine and adenosine. This product may be added with additives such as stabilizer, wetting agent, emulsifier, moisturizer, pH conditioner, colorant, and flavouring agent to increase stability and value. However, when additives whose ingredients are recognized as functional ingredients, they should not contain more contents than what is recognized as functional ingredients.

The holding time of major peak obtained from a sample of the quantitative analysis of confirmation test is the same as the holding time obtained from a standard solution.

pH standard ± 1.0 (2 $\rightarrow$ 30), (provided, that pH value ranges from 3.0 to 9.0)

Mercury 1 ppm or less (1 g)

CONTENTS- Suitable when testing according to the clause "Criteria of Content and

Test Methods for General Cosmetics" in Criteria and Test Methods for Cosmetics (Korea Food & Drug Administration Notification).

QUANTITATIVE ANALYSIS- From the functional cosmetic, accurately weigh 20mg of arbutine and 0.4mg of adenosine. Add mobile phase to disperse them and make exactly 50mL. Filter if necessary. This solution shall be the sample solution. Separately, accurately weigh approximately 20mg of arbutine standard and add mobile phase to dissolve to make 50mL. This shall be the standard arbutine solution. Also, accurately weigh approximately 20mg of adenosine standard and add mobile phase to make 100mL. Again, take exactly 4mL of this solution and add mobile phase to make 100mL. This shall be the standard adenosine solution. Take 10 μ L each from the sample solution and the standard solution and test according to the liquid chromatography in the following operation parameter. Calculate each of the peak area, AT, and AS of the sample and standard solutions.

Amount of Arbutine (C₁₂H₁₆O₇) (mg)

$$= \text{Amount of Arbutine Standard (mg)} \times A_T/A_S$$

Amount of Adenosine (C₁₀H₁₃N₅O₄) (mg)

$$= \text{Amount of Adenosine Standard (mg)} \times A_T/A_S \times 1/50$$

<Operation parameter>

Detector: UV spectrophotometer (wavelength: 260nm)

Column: fill a stainless steel tube whose inner diameter and length are 4.6mm and 15cm respectively with 5 μ octadecyl silanized (ODS) silica gel for liquid chromatography.

Mobile phase: ethanol•10mM potassium dihydrogen phosphate mixture (10:90)

Flow rate: 1.0mL/min.

Arbutine·Adenosine Solution

This functional cosmetic contains arbutine ($C_{12}H_{16}O_7$: 272.25) which takes up more than 90.0% of indicated amount when quantifying and adenosine ($C_{10}H_{13}N_5O_4$: 267.24).

Law . This functional cosmetic is a product whose main ingredients (functional ingredients) are arbutine and adenosine. This product may be added with additives such as stabilizer, wetting agent, emulsifier, moisturizer, pH conditioner, colorant, and flavouring agent to increase stability and value. However, when additives whose ingredients are recognized as functional ingredients, they should not contain more contents than what is recognized as functional ingredients.

The holding time of major peak obtained from a sample of the quantitative analysis of confirmation test is the same as the holding time obtained from a standard solution.

pH standard ± 1.0 (2 $\rightarrow$ 30), (provided, that pH value ranges from 3.0 to 9.0)

Methanol 0.2 V/V % or less (only test products whose ethanol content is over 4%)

CONTENTS- Suitable when testing according to the clause "Criteria of Content and Test Methods for General Cosmetics" in Criteria and Test Methods for Cosmetics (Korea Food & Drug Administration Notification).

QUANTITATIVE ANALYSIS- From the functional cosmetic, accurately weigh 20mg of arbutine and 0.4mg of adenosine. Add mobile phase to disperse them and make exactly 50mL. Filter if necessary. This solution shall be the sample solution.

Separately, accurately weigh approximately 20mg of arbutine standard and add mobile phase to dissolve to make 50mL. This shall be the standard arbutine solution. Also, accurately weigh approximately 20mg of adenosine standard and add mobile phase to make 100mL. Again, take exactly 4mL of this solution and add mobile phase to make 100mL. This shall be the standard adenosine solution. Take 10 μ L each from the sample solution and the standard solution and test according to the liquid chromatography in the following operation parameter. Calculate each of the peak area, AT, and AS of the sample and standard solutions.

Amount of Arbutine (C₁₂H₁₆O₇) (mg)

$$= \text{Amount of Arbutine Standard (mg)} \times A_T/A_S$$

Amount of Adenosine (C₁₀H₁₃N₅O₄) (mg)

$$= \text{Amount of Adenosine Standard (mg)} \times A_T/A_S \times 1/50$$

<Operation parameter>

Detector: UV spectrophotometer (wavelength: 260nm)

Column: fill a stainless steel tube whose inner diameter and length are 4.6mm and 15cm respectively with 5 μ octadecyl silanized (ODS) silica gel for liquid chromatography.

Mobile phase: ethanol•10mM potassium dihydrogen phosphate mixture (10:90)

Flow rate: 1.0mL/min.

ADDENDA

Article 1 (Effective Date) This notice shall be effective immediately.

Article 2 (Interim Measures)