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DRAFT EAST AFRICAN STANDARD

Skin powders — Specification — Part 2: Baby powder

EAST AFRICAN COMMUNITY

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standard.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 071, Cosmetics and related products.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

This third edition cancels and replaces the second edition (EAS 425-2:2017), which has been technically revised.

EAS 425 consists of the following parts, under the general title Skin Powder — Specification:

- Part 1: Body and face powder
- Part 2: Baby powder.

Skin powders — Specification — Part 2: Baby powder

1 Scope

This Draft East African Standard specifies the requirements, sampling and test methods for baby powders.

This standard does not apply to medicated powders for which medicinal claims are made.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 346, Labelling of cosmetics — General requirements

EAS 377 (all parts), Cosmetics and cosmetic products

EAS 846, Glossary of terms relating to the cosmetic industry

EAS 847-2, Cosmetics — Analytical methods — Part 2: Determination of moisture content and volatile matter content

EAS 847-16, Cosmetics — Analytical methods — Part 16: Determination of lead, mercury and arsenic content

EAS 847-17, Cosmetics — Analytical methods — Part 17: Determination of pH

EAS 847-23, Cosmetics — Analytical methods — Part 23: Test for absence of grit in powders

EAS 847-24, Cosmetics — Analytical methods — Part 24: Determination of matter insoluble in boiling water

EAS 847-25, Cosmetics — Analytical methods — Part 25: Determination of fineness

EAS 847-26, Cosmetics — Analytical methods — Part 26: Determination of boric acid

ISO 16212, Cosmetics — Microbiology — Enumeration of yeast and mould

ISO 18416, Cosmetics — Microbiology — Detection of Candida albicans

ISO 21149, Cosmetics -- Microbiology -- Enumeration and detection of aerobic mesophilic bacteria

ISO 21150, Cosmetics — Microbiology — Detection of Escherichia coli

ISO 22717 Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa

ISO 22718, Cosmetics — Microbiology — Detection of Staphylococcus aureus

ISO 24153, Random sampling and randomisation procedures

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EAS 846 and the following apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses: — ISO Online browsing platform: available at http://www.iso.org/obp

baby powder

finely powdered, free-flowing absorbent innocuous material such as talc, and may contain a mild perfume and other ingredients consistent with accepted practice in the cosmetic industry

4 Requirements

4.1 General requirements

4.1.1 All ingredients shall comply with EAS 377.

4.1.2 Baby powder shall have no undesirable or harmful effect on the skin when used as intended by the manufacturer.

4.1.3 Baby powder shall be free from colouring matter.

4.2 Specific requirements

Baby powder shall comply with the specific requirements given in Table 1 when tested according to the methods prescribed therein.

S/No.	Characteristic	Requirement	Test method
i	Matter insoluble in boiling water, % m/m, min	90.0	EAS 847-24
ii	Fineness: % m/m, max	Residue on 75-µ sieve: 5	EAS 847-25
		Residue on 150-µ sieve: 0.5	
iii	Boric acid	Absent	EAS 847-26
iv	pH (10 % solution)	5.5 - 9.5	EAS 847-17
v	Freedom from grit	To pass test	EAS 847-23
vi	Moisture content and volatile matter, % m/m, max	2.0	EAS 847-2
vii	Asbestos	Absent	Annex A

Table 1 — Specific requirements for baby powder

4.3 Heavy metal limits

Baby powder shall comply with the limits for heavy metal contaminants in accordance with Table 2.

S/No.	Heavy metal	Limit ^a , mg/kg, Max	Test method		
i)	Lead	10	EAS 847-16		
ii)	Arsenic	2			
iii)	Mercury	2			
^a The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished baby powder shall not exceed 10 mg/kg.					

4.4 Microbiological limits

Baby powder shall comply with the microbiological limits given in Table 3 when tested in accordance with the methods prescribed therein.

Micro-organisms	Limits, max.	Test method
Total viable count, CFU/g, max.	100	ISO 21149
Pseudomonas aeruginosa	Not detected in 1 g of cosmetic product	ISO 22717
Staphylococcus aureus	Not detected in 1 g of cosmetic product	ISO 22718
Candida albicans	Not detected in 1 g of cosmetic product	ISO 18416
Escherichia coli	Not detected in 1 g of cosmetic product	ISO 21150
Total yeast and mould, CFU/g,max.	100	ISO 16212

Table 3 — Microbiological limits for baby powders

5 Packaging

The baby powder shall be packaged in suitable well-sealed containers that shall protect the contents during transportation, handling and storage and shall not cause any contamination or react with the baby powder.

6 Labelling

In additional to the labelling requirements given in EAS 346, the package shall be legibly and indelibly marked with the product name as "Baby powder".

7 Sampling

Sampling shall be carried out in accordance with ISO 24153.

Annex A

(normative)

Determination of asbestos

A.1 Materials

Tremolite and chrysotile.

A.2 Instrument and reagents

The X-ray diffraction analyses is performed with a Rigaku D/max 2550 diffractometer using a graphite diffracted-beam monochromator and Cu Ka radiation at 40 kV and 150 mA. The instrument is configured with a 0.3 mm receiving slit. On the continuous scan, the scanning speed is set at 8 degrees per minute, while when using the step-scan mode the scan counting time is set as 150 seconds. All other reagents are of analytical grade.

A.3 Preparation of the 0.5% tremolite and chrysotile standards

In order to determine trace-level tremolite and chrysotile in talc, the asbestos is separated from the impurities.

A.3.1 The tremolite and chrysotile reference standard

The tremolite and chrysotile raw material samples are analyzed by PXRD and the patterns are recorded between 3° and 80°. After the full-range scan, check for contaminants such as mixed calcite and calcium carbonate etc. The limitations of using PXRD as an analytical method include interferences from other crystalline phases and preferred orientations, which can be overcome by proper sample treatment. In order to eliminate the interference of these impurities and prepare the asbestos in a powder form which can be used in homogeneous mixing with talc, the raw materials are processed.

A.3.1.1 Acid treatment

 $3 \mod L^{-1}$ of hydrochloric acid is used in the treatment. Tremolite and chrysotile are treated with acid and then washed with water to remove soluble impurities and excess acid. The 3 mol acid is selected considering its effective of removing impurities and maintaining the intensity of talc.

A.3.1.2 Ashing processing

The powder form of tremolite is obtained after one hour ashing at the temperature of 650 °C and the chrysotile powder form is produced after 1.5 hour ashing at the temperature of 700 °C.

A.3.2 The preparation of talc standard.

Chlorite is a common associated mineral in talc. The diffraction peak of chlorite overlaps with that of talc. Because asbestos is stable at 600 °C while chlorite will be decomposed at this high temperature, talc is ashed for one hour at 600 °C to eliminate the interference of chlorite.

A.3.3 The preparation of the 0.5% tremolite and chrysotile standard

Due to the low content of tremolite and chrysotile asbestos in talc, each standard is prepared separately by accurately weighing 5 mg of tremolite and chrysotile and mixing this well with 995 mg of talc, respectively.

A.3.4 The preparation of talc samples

The talc samples are ground and sieved to reach homogeneity. To avoid the distortion of the PXRD pattern caused by the uniformity of the samples, all of the talc sample particle sizes are controlled under 10 mm. Three testing batches, about 50 mg each, are taken from each type of sample.

A.4 Results and Interpretation

A.4.1 Characteristics diffraction peak

To avoid interference, the characteristic diffraction peak of tremolite is chosen at 2θ degree 10.3°, and the peaks of chrysotile at 2θ degree 12.2° and 24.4° are selected. The scan range is 10 to 11° for tremolite, and 11 to 13° plus 24 to 26° for chrysotile.

A.4.2 The limit of detection (LOD)

Through the continuous reduction of asbestos in the talc, when the signal to noise ratio (SNR) value is 3:1, the content is defined as the LOD. The PXRD results of trace level asbestos in talc show that the LODs of tremolite and chrysotile are all valued as 0.1%.

A.4.3 The standard curve

A series content of 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8% tremolite and chrysotile standards are prepared with purified talc for PXRD analysis, respectively. The results should show that at the characteristics of $2\theta = 10.3^{\circ}$ for tremolite and $2\theta = 12.2^{\circ}$ for chrysotile, the relationship between the content of asbestos and the intensity of the asbestos are linear. The equation obtained from the intensity versus the content of tremolite is Y =245.71X + 537.52 (R² =0.9931) and the linear equation of chrysotile is Y = 129.43X + 449.31 (R² =0.9987). Standard curve results are shown on Table 1.

tremolite			chrysotile		
Concentration(%)	2 θ (°)	Heights (CPS)	Concentration(%)	2 0 (°)	Heights (CPS)
0.3	10.334	616	0.3	12.360	488
0.4	10.348	631	0.4	12.342	502
0.5	10.335	658	0.5	12.377	514
0.6	10.357	684	0.6	12.324	526
0.7	10.303	714	0.7	12.356	539
0.8	1.0362	733	0.8	12.382	554

Table A1 — The PXRD peak intensities of the tremolite and chrysotile asbestos standards

A.5 Sample analysis

Tremolite and chrysotile asbestos samples analysis is carried out by the following steps.

A.5.1 A full range scan is used with the continuous scanning mode. The full PXRD patterns of the samples are recorded between 3° and 60° at the scan speed of 8° per minute.

A.5.2 A partial range scan is performed in the continuous scanning mode and the partial PXRD patterns of the samples are recorded between 9° and 13°,11° to 13° and 22° to 26° with a step size of 0.002[°], respectively. If the characteristic diffraction peaks of tremolite or chrysotile asbestos are present and the SNR is above 10, then asbestos is analysed.

A.5.3 A partial range scan is carried out in the step-scan mode and the partial PXRD patterns of the samples are recorded between 10° and 11°, 11.4° to 12.6°,23.7° to 24.6° with a step size of 0.02° per step and a count time of 150 seconds. If the characteristic diffraction peaks of tremolite or chrysotile asbestos are present and the SNR is above 3, then asbestos is analysed.

Bibliography

- [1] KS 1570-2: 2007, Skin powders Specification Part 2: Baby powder
- [2] EAS 425-2: 2017, Skin powders Specification Part 2: Baby powder
- [3] US 488:2003, Skin powders Specification Part 2: Baby powders

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