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Formulated powder hair dyes, aryl diamine based — Specifications

EAST AFRICAN COMMUNITY

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PUBLIC REVIEW

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PUBLIC REVIEW

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.

In order to achieve this objective, the Community established an East African Standards Committee mandated to develop and issue East African Standards.

The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. 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 procedures of the Community.

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.

Formulated powder hair dyes, aryl diamine based — Specification

1 Scope

This Draft East African Standard specifies the requirements for formulated powder hair dyes, aryl diamine based. The hair dyes shall be in black or other colours as ready for use or in powder form. This standard only covers permanent powder hair dyes based on aryl di-amines which act as primary intermediates in dyes. It does not apply to vegetable-based hair dyes, metallic-based hair dyes and liquid hair dye

2 Normative references

DEAS 346 Labelling of cosmetics — General requirements

DEAS 377-2, Cosmetics — List of substances which must not form part of the composition of any cosmetic product.

DEAS 377-3, Cosmetics — List of substances which cosmetics must not contain except subject to the restrictions and conditions laid down.

3 Requirements

3.1 General requirements

3.1.1 All ingredients used in the manufacture of powder hair dye shall conform to *DEAS 377-2* and *DEAS 377-3* in addition to the requirements therein

3.1.2 The powder hair dye shall be fine and free flowing.

3.1.3 The powder hair dye shall contain an aryl diamine as the active ingredient and a solid peroxide as the oxidizing agent. It may, in addition, contain one or more other substances in accordance with *EAS 377....*:

4.1.4 The dye shall be dermatologically safe and shall not cause irritation of the scalp.

4.1.5 The dye shall have no undesirable effect on the hair.

4.2 Specific requirements

The hair dye shall comply with the requirements given in Table 1 when tested in accordance with the methods prescribed therein.

Table 1 — Requirements for powder hair dyes

Characteristic	Requirements		Method of test (Ref. to Annex)
	Type 1 (Black)	Type 2 (Other colours)	
pH of 5 % (m/m) solution in water	7 — 10	7 — 10	A
Aryl diamine content %, calculated as free base	10 — 30	5 — 10	B

The products shall comply with the requirements for contaminants in accordance with Table 2.

Table 2: Requirements for contaminants

S/N	Characteristic	Requirement	Method of test
1	Lead, ppm, max	20	Annex C
2	Arsenic, ppm, max	2	Annex D
3	Mercury, ppm, max	2	Annex E
NOTE The total amount of heavy metals as lead, mercury and arsenic, in combination, in the finished product should not exceed 20 ppm.			

5 Dye ready for use

5.1 Preparation

The dye ready for use shall be prepared by mixing the powder dye with the diluent as recommended by the manufacturer in the leaflet describing instructions for use.

5.2 Requirements

The aryl amine content in dye ready for use shall be as given in Table 2. The procedure for calculation is given in 5.3. The lower limit of dye is prescribed to check the effectiveness of the dye while the upper limit is prescribed to ensure that the concentration of aryl amine remains within safe limits.

Table 2 — Requirements for dye, ready for use (5.2)

Characteristic	Requirement		Method of test
	Type 1	Type 2	
Aryl di-amine in the solution after recommended dilution, calculated as free base.	1.5—3.0	0.75—1.5	The procedure for calculation is as given in 5.3.

5.3 The procedure for calculation of active content in solution after recommended dilution with the diluent is as follows:

where,

X = Aryl amine content in powder hair dye, and

Y = Number of parts of diluent mixed with 1 part of dye.

6 Packaging

The product shall be packed in suitable well-sealed containers that shall protect the contents and shall not cause any contamination or react with the product.

7 Labelling

The containers shall be securely closed and in addition to the labelling requirements of DEAS 346. The labelling shall be in either English, Kiswahili or French or in combination as agreed between the manufacturer and supplier. The following information shall be indelibly and legibly marked on the container:

- a) product name;
- b) net contents;
- c) Manufacturer's name, physical address, and trade mark (if any) and name and physical address of the distributor/supplier if any
- d) batch number in code or otherwise;
- e) the date of manufacture in the form "mm/yyyy",
- f) best before date in the form "mm/yyyy"; and
- g) Country of origin
- h) instructions for use;
- i) all ingredients shall be declared in descending order of predominance. The INCI label names shall be used.

NOTE INCI stands for International Nomenclature Cosmetic Ingredient.

Intended effect, i.e. 'PERMANENT HAIR DYE'

NOTE This information may be supplied in an enclosed leaflet if the package is too small.

7.2 In addition to the above, the following information shall also be given in the leaflet:

- (i) Procedure for conducting preliminary test for sensitivity (patch test).
- (ii) Instructions for use.

8 Caution/warning

8.1 The following warnings shall be printed on the label if the package is for general use:

- (i) 'Can cause an allergic reaction'.

(ii) 'Do not use to dye eyelashes or eyebrows'.

8.2 The following warnings shall be printed on the label if the package is for professional use:

(i) 'For professional use only'.

(ii) 'Can cause an allergic reaction'.

(iii) 'Wear suitable gloves'.

9 Patch test

Each package shall contain instructions in shall be in either English, Kiswahili or French or in combination as agreed between the manufacturer and supplier. for carrying out a preliminary test by the intended user to avoid skin irritation, as follows:

'Para-phenylenediamine containing preparations may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. For carrying out the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol.

Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After 48, h wash the area gently with soap and water. If no irritation or inflammation is apparent, it shall be assumed that no hyper sensitivity to the dye exists. The test shall, however, be carried out before each and every application. This preparation shall on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result'.

10 Sampling

Sampling shall be done in accordance with EAS 381. Representative unopened samples shall be drawn for test from the market or anywhere else following the procedure of random selection. The samples shall be declared as complying with to the specification if they comply with all the specified requirements.

Annex A (normative)

Determination of pH

A.1 Apparatus

Any pH meter equipped with a glass electrode.

A.2 Procedure

Prepare 5 per cent solution (m/m) of the powder dye in water. Determine its pH at 25 ± 2 °C using the pH meter. Give the results, correct to an integer.

Annex B (normative)

Determination of dye content

B.1 Principle

This method estimates the para-phenylenediamine as diacetyl derivative of para-phenylenediamine.

B.2 Apparatus

B.2.1 G4 Sintered Glass Crucibles.

B.2.2 Continuous Extraction Apparatus as illustrated in Figure 1.

B.3 Reagents

B.3.1 Chloroform

B.3.2 Acetic Anhydride

B.4 Procedure

B.4.1 Weigh accurately 1 g to 2 g of the sample into the inner tube of the continuous extractor previously charged with chloroform. Add about 60 mL of chloroform, and completely extract the dye. About 5 h of extractions is sufficient. (See Figure 1).

B.4.2 Remove the flask and transfer the filtrate to a 250-mL beaker. Rinse with a few small portions of chloroform. Evaporate the chloroform to about 25 mL and add 1 mL of acetic anhydride slowly, with stirring. Let it stand for 1 hour and filter on a weighed G4 sintered glass crucible. Wash the beaker and the precipitate with three or more 5 mL portions of chloroform. Carefully remove the last traces of the precipitate from the beaker. Dry the crucible to constant mass at 120 °C and weigh the precipitate.

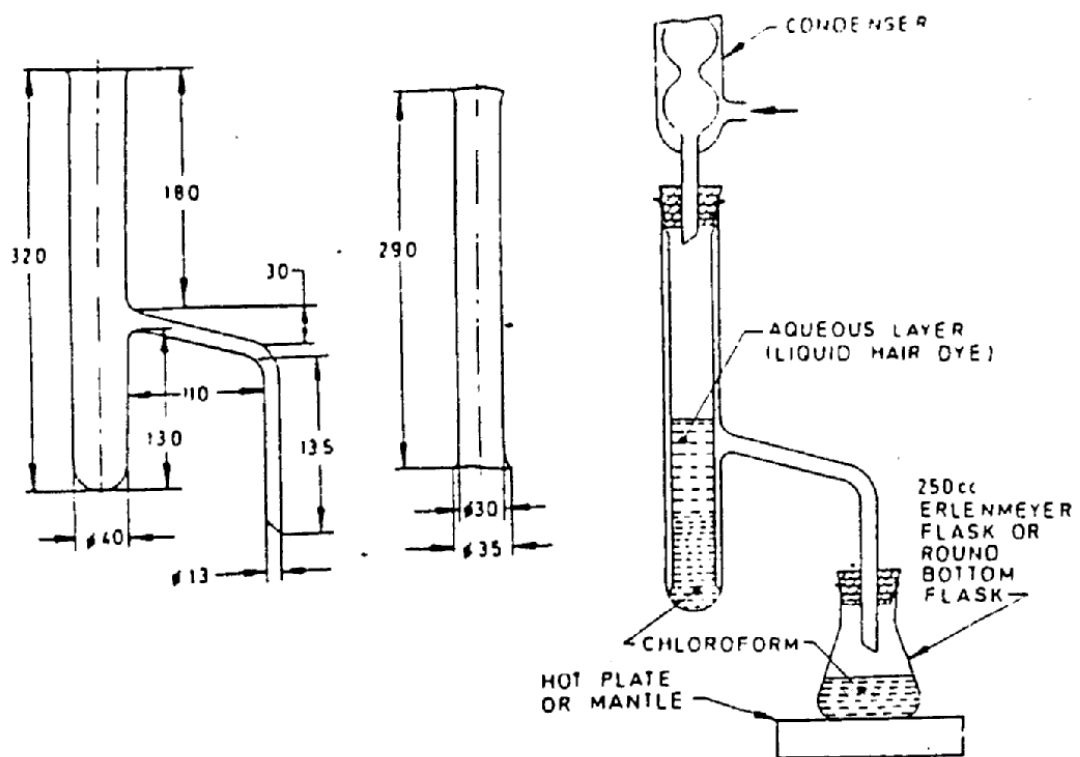
B.5 Calculation

$$\text{P-phenylenediamine, per cent by mass} = \frac{M_1 \times 0.5626 \times 100}{M_2}$$

where,

M_1 = mass in g of the precipitate, and

M_2 = mass in g, of the sample taken for extraction.



All dimensions in millimetres

Figure 1 — Continuous extraction apparatus

Annex C (normative)

Test for lead using atomic absorption spectrophotometer (AAS)

C.1 Outline of the method

The sample is passed through wet digestion using pressure decomposition. The amount of lead is then determined using AAS.

C.2 Reagents

C.2.1 The reagents used shall be of analytical-reagent grade. Water must be distilled or deionized.

C.3 Procedure

C.3.1 Weigh accurately 0.4 g of the sample and put this into a 50 mL decomposition pressure tube. Add 7.0 mL of concentrated nitric acid. Add 2.0 mL of water. Close the pressure vessel, and apply between 15 – 20 N/m² of pressure. Digest for about 2 h. Transfer to a 20 mL volumetric flask and make to the mark.

C.3.2 Prepare the standard solutions for lead. Aspirate into the flame each of the standard solutions in ascending order of concentration. Take the absorbance reading for each concentration using the AAS. Plot a calibration graph of the concentration of lead in the standard solutions against the corresponding values of absorbances.

C.3.3 Aspirate into the flame the sample solution. Take the absorbance reading from the AAS and give it a value X. From the graph, use the value of absorbance X to read the corresponding value of concentration. Let this value of concentration be C.

C.4 Calculation

$$\text{Amount of lead} = \frac{C \times D}{M}$$

where,

C = Concentration of the sample solution,

M = Mass of the sample in grams, and

D = Dilution factor.

Annex D (normative)

Test for arsenic using atomic absorption spectrophotometer (AAS)

D.1 Outline of the method

The sample is passed through wet digestion using pressure decomposition. The sample is further prepared using vapour generation method. The amount of arsenic is then determined using AAS.

D.2 Reagents

The reagents used should be of analytical-reagent grade. Water shall be distilled or de-ionized.

D.3 Procedure

D.3.1 Weigh accurately 0.4 g of the sample and put this into a 50 mL decomposition pressure tube. Add 7.0 mL of concentrated nitric acid. Add 2.0 mL of water. Close the pressure vessel, and apply between 15 – 20 N/m² of pressure. Digest for about 2 h. Transfer to a 20 mL volumetric flask and make to the mark. Further, prepare the sample using the vapour generation method. In this method, arsenic compounds are reduced to the trivalent state and AsH₃ is generated using the varian vapour generation kit.

D.3.2 Prepare the standard solutions for arsenic. Aspirate into the flame each of the standard solutions in ascending order of concentration. Take the absorbance reading for each concentration using the AAS. Plot a calibration graph of the concentration of arsenic in the standard solutions against the corresponding values of absorbances.

D.3.3 Aspirate into the flame the sample solution. Take the absorbance reading from the AAS and give it a value *X*. From the graph, use the value of absorbance *X* to read the corresponding value of concentration. Let this value of concentration be *C*.

D.4 Calculation

$$\text{Amount of arsenic} = \frac{C \times D}{M}$$

where,

C = Concentration of the sample solution,

M = Mass of the sample in grams, and

D = Dilution factor.

Annex E (normative)

Test for mercury using atomic absorption spectrophotometer (AAS)

E.1 Outline of the method

The sample is passed through wet digestion using pressure decomposition. The sample is further prepared using vapour generation method. The amount of mercury is then determined using AAS.

E.2 Reagents

The reagents used shall be of analytical-reagent grade. Water must be distilled or de-ionized.

E.3 Procedure

E.3.1 Weigh accurately 0.4 g of the sample and put this into a 50 mL decomposition pressure tube. Add 7.0 mL of concentrated Nitric acid. Add 2.0 mL of water. Close the pressure vessel, and apply between 15 — 20 N/m² of pressure. Digest for about 2 h. Transfer to a 20 mL volumetric flask and make to the mark. Further prepare the sample using the vapour generation method.

E.3.2 Prepare the standard solutions for mercury. Aspirate into the flame each of the standard solutions in ascending order of concentration. Take the absorbance reading for each concentration using the AAS. Plot a calibration graph of the concentration of mercury in the standard solutions against the corresponding values of absorbances.

E.3.3 Aspirate into the flame the sample solution. Take the absorbance reading from the AAS and give it a value *X*. From the graph, use the value of absorbance *X* to read the corresponding value of concentration. Let this value of concentration be *C*.

E.4 Calculation

$$\text{Amount of Mercury} = \frac{C \times D}{M}$$

where,

C = Concentration of the sample solution,

M = Mass of the sample in grams, and

D = Dilution factor.

Annex F

(normative)

Dye identification and dyeing test

F.1 Identification by Thin Layer Chromatography (TLC) method

To about 1 g of the product add 5 mL of mixture of Ethanol and Strong Ammonia Solution (95:5). After shaking, use the centrifuged supernatant as the test solution. Separately, to mixture of Ethanol and Strong Ammonia Solution (95:5) add 2.5 g of p-Phenylenediamine Sulfate, 0.05 g of o-Aminophenol, 0.30 g of m-

Aminophenol, 0.05 g of p-Aminophenol and 0.40 g of m-Phenylenediamine Sulfate to make 50 mL of the standard solution on a thin layer. Perform the test by Thin-layer chromatography with Diethylether as developer. When spraying p-Dimethylaminobenzaldehyde TS on the thin layer, the spot colors and R_f values obtained from the test solution and the standard solution are equal.

F.2 Dyeing test

To 3 g of this product add 30 mL of water to make tint mixture. Soak white test wool cloth in the tint mixture and leave it for 20 minutes at 30 °C. When water-washed and dried at 80 °C, the test cloth shall display the colour of the dye.

F.3 Reagent and Test solution

- To 3 g of p-Dimethylaminobenzaldehyde add 60 mL of Methanol, and add 20 mL of Hydrochronic Acid.
- White Test Wool Cloth.

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