DUS 2296-1

DRAFT UGANDA STANDARD

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Skin applied mosquito repellents — Specification —Part 1: Lotions, creams, gels and ointments

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Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to co-ordinate the elaboration of standards and is

(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

(c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 301, Chemistry

DUS 2296 consists of the following parts, under the general title Skin applied mosquito repellents — Specification:

- *Part 1: Lotions, creams, gels and ointments*
- *Part 2: Sprays and roll-ons*
- *Part 3: Wipes*
- *Part 4: Bathing soaps*
- *Part 5: Bracelets, wristbands and patches*
- Part 6: Jelly

Skin applied mosquito repellents — Specification — Part 1: Lotions, creams, gels and ointments

1 Scope

This Draft Uganda Standard specifies the requirements, sampling and test methods for skin applied mosquito repellents in form of lotions, creams, gels and ointments

2 Normative references

The following referenced documents 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.

US ISO 18416:2015, Cosmetics — microbiology — detection of candida albicans

US ISO 22717:2015, Cosmetics — microbiology — detection of pseudomonas aeruginosa

US ISO 22718:2015, Cosmetics — microbiology — detection of staphylococcus aureus

US EAS 346, Labelling of cosmetic products — General requirements

US EAS 377 (all parts), Cosmetics and cosmetic products

US EAS 846, Glossary of terms relating to the cosmetic industry

US EAS 847-16, *Cosmetics —Analytical methods —Part 16: Determination of heavy metal content*

US EAS 847-17, *Cosmetics —Analytical methods —Part 17: Physio-chemical test*

US ISO 24153, Random sampling and randomization procedures

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

WDUS 2373-1, Mosquito repellents — Performance test guidelines — Part 1: Skin applied repellents

3 Terms and definitions

For the purposes of this document, the terms and definitions given in US 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

3.1
mosquito
blood-sucking dipterous insect of the family Culicidae. Aedes, Anopheles, Culex, Mansonia, and Stegomyia are genera containing most species involved in the transmission of protozoan and other disease-producing parasites.

3.2
mosquito repellent
substance applied to skin which deters mosquito from approaching or settling.

3.3
natural repellents
repellents that contain, plant-based compounds

3.4
synthetic repellents
conventional repellents containing chemical compounds manufactured to imitate the natural compounds.

3.5
DEET
N,N-Diethyl-meta-toluamide or diethyltoluamide

3.6
IR3535
ethyl butylacetylaminopropionate

3.7
picaridin
1-(1-methylpropoxycarbonyl)-2-(2-hydroxyethyl) piperidine or 2-(2-hydroxyethyl)-1-piperidinecarboxylic acid 1-methylpropyl ester

4 Active ingredients

4.1 Natural repellents

4.1.1 Active ingredients used in natural repellents shall be plant based compounds which are able to deter mosquitoes from approaching or settling. Such shall be essential oils or any other plant extract approved as mosquito repellents.

4.1.2 The manufacturer shall provide adequate data on the repellence of such ingredients.

4.1.3 The manufacturer shall have adequate data justifying the proportion of ingredient(s) used in the product, for which claims are made.

4.1.4 The essential oils used and other plant extracts in natural repellents shall be, but not limited to:

a) cedarwood oil;

b) tea tree oil;

c) geranium oil;

d) rosemary oil;

e) lemongrass oil;

f) citronella oil;

g) eucalyptus oil;

h) cinnamon oil; and

i) neem oil

4.1.5 The proportion of single or blended active ingredient (s) in natural repellent shall be set by the manufacturer in accordance with specific standard and records shall be availed.

4.1.6 Pyrethrum extracts such as pyrethrins shall be considered in natural repellents. The limits of pyrethrins in natural repellents shall not be less than 0.5% w/w, when tested in accordance with annex D.

4.2 Synthetic repellents

4.2.1 Synthetic repellents shall contain synthetic chemical compounds which are able to deter mosquitoes from approaching or settling on the surface.

4.2.2 If a synthetic active ingredient is blended with other active ingredient (s), either natural or synthetic, the proportion shall be set by the manufacturer based on scientific research and records shall be availed.

4.2.3 Synthetic repellents and their active ingredients shall be approved and registered by competent authority before being released to the market.

5 Requirements

5.1 General requirements

5.1.1 The product shall constitute a mosquito repellent that is formulated as lotion, cream, gel or ointment and shall be essentially a product which has active ingredient (s) added to a certain level.

5.1.2 It shall be primarily composed of water, surfactants, fatty alcohol, fragrance, oil and other emollients. All ingredients shall meet the requirements of US EAS 377.

5.1.3 When applied to the skin, the product shall have the benefit of repelling mosquitoes and shall not cause harmful effect to the skin.

5.2 Specific requirements

5.2.1 Active ingredients and their content in synthetic repellents shall meet the requirements prescribed in table 1.

Table 1— Active ingredients content for synthetic repellents in form of lotions, creams, gels and ointments.

S/N	Characteristic	Requirements	Test methods
i	DEET, % w/w.	4 – 50	Annex A
ii	Picaridin, % w/w.	5 – 20	CIPAC 740
iii	IR3535, % w/w.	7.5 – 20.07	CIPAC 667

5.2.2 The product shall comply with the specific requirements given in table 2 when tested in accordance to the methods described therein.

Table 2— Specific requirements for skin applied mosquito repellents in form of lotions, creams, gel and ointments

S/N	Characteristic	Requirements	Test methods
i	Thermal stability	To pass test	US EAS 847-18
ii	pH	3.5 – 8.5	US EAS 847-17
iii	Total fatty substance content, % m/m, min	5	Annex C
iv	Total residues, % m/m, max	40	Annex B

5.3 Heavy metal requirements

The product shall comply with the heavy metal requirements given in Table 3 when tested in accordance with the test methods specified therein.

Table 3— Heavy metal requirements for skin applied mosquito repellent in form of lotions, creams, gel and ointments

S/N	Heavy metals.	Limit, mg/kg, max	Test method
i	Lead,	10	US EAS 847-16
ii	Arsenic,	2	
iii	Mercury,	2	

5.3.1 The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished product shall not exceed 10 mg/kg

5.4 Microbiological requirements

The product shall comply with the microbiology limits specified in table 4 when tested in accordance to the methods described therein

Table 4— Microbiology limits for skin applied mosquito repellent in form of lotions, creams, gel and ointments

S/N	Characteristic.	Requirements	Test methods
i	Total viable count, cfu/g, max	1000	US ISO 21149
ii	Staphylococcus aureus (per g)	Not detected	US ISO 22718
iii	Pseudomonas aeruginosa (per g)	Not detected	US ISO 22717
iv	Candida albicans (per g)	Not detected	US ISO 18416

5.5 Biological efficacy

When tested in accordance with **DUS 2373-1**, the product shall repel 100% of the mosquitoes from approaching or climbing on that surface, within protection time indicated by the manufacturer.

6 Packaging

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

7 Labelling

7.1 In addition to the labelling requirements given in US EAS 346, the package shall be legibly and indelibly marked with the following information:

a) name of the product; as “skin applied mosquito repellent”

b) form of product as “lotion”, “cream”, “gel” or “ointment”

c) instructions for use;

d) active ingredient (s) content

e) protection time.

f) age group and/or health condition for which use is prohibited

g) storage conditions

h) precaution/warning

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8 Sampling

Random samples of the product shall be drawn for test in accordance with US ISO 24153 from the market, factory or anywhere else.

Annex A
(normative)

Determination of DEET content

A.1 General

The sample is dissolved in carbon disulfide and the difference in absorbance at 14.18 µm and at 14.48 µm is determined. The quantity of meta-isomer is obtained from this value by means of a calibration curve prepared by the use of a reference standard

A.2 Apparatus

A.2.1 Double-beam infrared spectrophotometer. Perkin-Elmer model 21 or equivalent

A.2.2 Two equivalent infrared absorption cells, with sodium chloride windows and a path length of approximately 0.4 mm.

A.3 Preparation of calibration curve

A.3.1 Weigh (to the nearest 0.1 mg) into four volumetric flasks sufficient amounts of the reference DEET standard of known purity to give concentrations of approximately 20, 40, 60 and 80 g/L when dissolved in carbon disulfide.

A.3.2 Fill the reference cell with carbon disulfide and the sample cell with each of the standard solutions in turn, and record the spectra. The spectrum may be scanned rapidly, except for the region 12 – 15 µm, where a normal speed should be used. Carry out a blank measurement with carbon disulfide to correct for any inequality in the paired cells and to determine whether a cell correction is required.

A.3.3 Measure the absorbance at 14.18 µm and at 14.48 µm and calculate the difference between these values, ΔA, for each of the solutions. Plot the values of ΔA against the concentration (g/L) of the meta-isomer.

A.3.4 If a cell correction is required, the value of ΔA is determined from the formula:

$\Delta A = [A14.18 – A14.48]_{ref.} - [A14.48]_{blank}$

Where ref. = determination with reference standard

blank = determination on CS2 blank

A.4 Procedure

Weigh (to the nearest 0.1 mg) about 0.5 g of the sample, transfer quantitatively to a 10 mL volumetric flask, and make up to the mark with carbon disulfide. Measure the infrared absorption at 14.18 µm and 14.48 µm using the same conditions as described in clauseA.3. Determine the concentration of meta-isomer by comparing this value with the calibration curve. A standard sample should be run each day to check the calibration of the instrument.

A.5 Calculation

DEET content (g/kg) = $(C_1 \; x \; P)/C_2$

where,

C_1 = concentration (g/L) of standard DEET found from calibration curve

C_2 = concentration (g/L) of sample taken

P = purity (g/kg) of the reference standard

Annex B
(normative)

Determination of residue

B.1 Procedure

B.1.1 Weigh accurately about 5 g of the material in a weighed, clean and dry squat form weighing bottle and dry to constant mass at 105ºC± 1ºC. Cool in desiccators and weigh.

B.1.2 Calculation

Residue percent by mass = 100 (M_1/M_2)

where,

M_1 = mass in g of the residue; and

M_2 = mass in g the material taken for test

Annex C
(normative)

Determination of total fatty substance content

C.1 Outline of the method

The emulsion is broken with dilute mineral acid and the fatty matter is extracted with petroleum ether. It is weighed after removal of the solvent.

C.2 Reagents

C.2.1 Dilute hydrochloric acid 1:1 (v/v)

C.2.2 Petroleum, B.P. 40 °C to 60 °C

C.2.3 Methyl orange indicator solution—Dissolve 0.1 g of methyl orange in 100 mL of water.

C.2.4 Sodium sulphate, desiccated

C.3 Procedure

C.3.1 Weigh accurately about 2 g of the material into a conical flask; add 25 ml of dilute hydrochloric acid, fit a reflux condenser into the flask and boil the contents until the solution is perfectly clear.

C.3.2 Pour the contents of the flask into a 300 ml separation funnel and allow it to cool to 20 °C and rinse the conical flask with 50ml of petroleum ether in portions of 10 ml.

C.3.3 Pour the ether rinsings into the separation funnel shake the separation funnel well and leave until the layers separate.

C.3.4 Separate out the aqueous phase and shake it out with 50mL portions of ether twice. Combine all the ether extracts and wash them with water until free of acid (when tested with methyl orange indicator solution).

C.3.5 Filter the ether extracts through a filter paper containing sodium sulphate into a conical flask which has been previously dried at a temperature of 60 °C± 2 °C and then weighed.

C.3.6 Wash the sodium sulphate on the filter with ether and combine the washings with the filtrate. Distil off the ether and dry the material remaining in the flask at a temperature of 60 °C± 2 °C to constant mass.

C.4 Calculation

The total fatty substance shall be calculated as follows:

Total fatty substance, percent by mass = $\frac{M_1}{M_2}\ 100$

where,

M_1 is the mass, in grams, of the residue, and

M_2 is the mass, in grams, of the material taken for the test.

Annex D
(normative)

Determination of total pyrethrins

D.1 General

The active ingredients in pyrethrum extract may be determined using a HPLC system first by injecting a solution of the analyte into the chromatograph, followed by the separation and comparison of peaks areas of the analytes in the sample with that of an external standard containing a known amount of the analytes. The peaks are eluted in the following order: Cinerin II, Pyrethrin II, Jasmolin II (total Pyrethrins II) and Cinerin I, Pyrethrin I, Jasmolin I (total Pyrethrins I).

D.2 Reagents

D.2.1 World pyrethrum standard, 50 %

D.2.2 Acetonitrile, HPLC grade

D.2.3 Water, HPLC grade

D.3 Apparatus

A liquid chromatography System equipped with an auto-sampler, a Variable Wavelength Detector (or equivalent) and a Column {Phenomenex, 250 x 4.6 mm Luna Phenyl-Hexyl 5µ Reverse Phase (or equivalent)}.

D.4 Operating conditions

D.4.1 Flow rate: 1.5 ml/min

D.4.2 Composition: 40:60 (%, v/v water/acetonitrile)

D.4.3 Elution: Isocratic

D.4.4 Oven temperature: 40 ºC

D.4.5 Wavelength: 240 nm

D.4.6 Injection Volume: 15 µl

D.4.7 Stop time: 22 min

D.4.8 Post time: 1 min

D.5 Preparation of the standard

Weigh 20 mg of the pyrethrum standard to the nearest 0.0001 g in a 100 mL volumetric flask and dilute to volume with Acetonitrile and label it. Transfer a small portion to a sample vial and label it accordingly.

D.6 Sample preparation

In a 100 ml volumetric flask, weigh 20 mg to the nearest 0.0001 g of the sample to be analyzed and dilute to volume with Acetonitrile. Sample this solution using a vial and label it accordingly.

D.7 Procedure

After the chromatograph is stable, make a minimum of three injections for the standard solution as well as for the analyte and average the area counts. The relative Standard Deviation between injections should be within 2 %.

D.8 Calculation of the % total pyrethrins (active ingredient)

The % Total Pyrethrins is calculated as follow:

$\%\ active\ ingredients$ = $(Average\ sample\ area\ X\ weight\ of\ standard\ X\ Purity\ of\ the\ standard\ (in\ \%)) \div (Average\ standard\ area\ X\ Weight\ of\ sample.)$

Bibliography

[1] Product Performance Test Guidelines. OPPTS 810.3700: Insect Repellents to be applied to human Skin

[2] RS 392-1: 2018, Skin applied mosquito repellents — Specification — Part 1: Lotions, creams, gels and ointments

[3] US EAS 786:2013, Skin care creams, lotions and gels — Specification

[4] RS 191: 2019, Refined pyrethrum concentrate — Specification

Certification marking

Products that conform to Uganda standards may be marked with Uganda National Bureau of Standards (UNBS) Certification Mark shown in the figure below.

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