

# DRAFT UGANDA STANDARD

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## Skin applied mosquito repellents — Specification — Part 4: Bathing soaps



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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 coordinate 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

WDUS 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 4: Bathing soaps

## 1 Scope

This Draft Uganda Standard specifies the requirements, sampling and methods of test for skin applied mosquito repellents in form of bathing soaps meant to be applied directly to the skin.

## 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.

ISO 862, Surface active agents — Vocabulary

US EAS 877, Bathing bar — Specification

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

CIPAC 740, Determination of picaridin

CIPAC 667, Determination of ethyl butylacetamidopropionate

US ISO 685, Analysis of Soaps — Determination of total alkali content and total fatty matter content

US ISO 456, Surface-active agents — Determination of free caustic alkali

US EAS 814, Determination of biodegradability of surfactants — Test method

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

US ISO 24153, Random sampling and randomization procedures

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 862, Surface active agents — Vocabulary 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

#### **bathing soap**

soap product in the form of a bar or cake containing fatty acids and/or synthetic surface active agents as active ingredients and which is used for bathing purposes.

### 3.2

#### **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.

### 3.3

#### **mosquito repellent**

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

### 3.4

#### **natural repellents**

repellents that contain, plant-based compounds

### 3.5

#### **synthetic repellents**

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

### 3.6

#### **DEET**

N,N-Diethyl-meta-toluamide or diethyltoluamide

### 3.7

#### **IR3535**

ethyl butylacetylaminopropionate

### 3.8

#### **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 and other plant extracts used 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 B.

## **4.2 Synthetic repellents**

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

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

## **5 Requirements**

### **5.1 General requirements**

**5.1.1** The product shall constitute a mosquito repellent that is formulated as bathing soap and shall be essentially a product which has active ingredient (s) added to a certain level.

**5.1.2** The product shall be in the form of cake or bar. The colour of the cake or bar shall generally be uniform.

**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

**5.1.4** The product shall not have an unpleasant odor

**5.1.5** The product shall be firm and smooth in texture

**5.1.6** All ingredients shall conform to the requirements of US EAS 377 and shall be declared on the label following descending order in terms of quantity.

### **5.2 Specific requirements**

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

**Table 1— Active ingredients content for synthetic repellents in form of bathing soaps.**

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 requirement 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 bathing soaps.**

S/N	Parameter	Requirements	Test methods
i	Total fatty matter, % by mass, min	50	US ISO 685
ii	Total alkalinity (as NaOH) % by mass, max.	1.0	
iii	Free caustic alkali (as NaOH), % by mass, max.	0.05	US ISO 456
iv	Lather, mL, min	200	US EAS 877
v	Mush (loss in mass due mashing on a wet surface), g/30 cm <sup>2</sup> , max.	10	
vi	Rosins, as % of total fatty matter, max	2	
vii	Freedom from grittiness	To pass the test	
viii	Biodegradability test	To pass test	US EAS 814

### 5.3 Biological efficacy

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

## 6 Packaging

The product shall be packaged in a suitable, well-closed container, to protect the integrity of the product.

## 7 Labelling

The container shall be labelled legibly and indelibly with the following information:

- a) name of the product; as “mosquito repellent”
- b) name and physical address of manufacturer;
- c) active ingredient content;
- d) form of repellent as “bathing soap”
- e) batch or code number;



- f) net weight in grams;
- g) country of origin;
- h) instructions for use;
- i) date of manufacture
- j) expiry date;
- k) safety precautions;
- l) special population whose exposure is prohibited (out of reach of children and pregnant women); and
- m) storage conditions.

## **8 Sampling**

Sampling shall be done in accordance with US ISO 24153.

## 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  $\mu\text{m}$  and at 14.48  $\mu\text{m}$  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  $\mu\text{m}$ , 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  $\mu\text{m}$  and at 14.48  $\mu\text{m}$  and calculate the difference between these values,  $\Delta A$ , for each of the solutions. Plot the values of  $\Delta A$  against the concentration (g/L) of the meta-isomer.

**A.3.4** If a cell correction is required, the value of  $\Delta A$  is determined from the formula:

$$\Delta A = [A_{14.18} - A_{14.48}]_{\text{ref.}} - [A_{14.48}]_{\text{blank}}$$

Where ref. = determination with reference standard

blank = determination on CS<sub>2</sub> 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  $\mu\text{m}$  and 14.48  $\mu\text{m}$  using the same conditions as described in clause A.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) =  $(C_1 \times P)/C_2$

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

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## Annex B (normative)

### Determination of total pyrethrins

#### B.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).

#### B.2 Reagents

B.2.1 World pyrethrum standard, 50 %

B.2.2 Acetonitrile, HPLC grade

B.2.3 Water, HPLC grade

#### B.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 5 $\mu$  Reverse Phase (or equivalent)}.

#### B.4 Operating conditions

B.4.1 Flow rate: 1.5 ml/min

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

B.4.3 Elution: Isocratic

B.4.4 Oven temperature: 40 °C

B.4.5 Wavelength: 240 nm

B.4.6 Injection Volume: 15  $\mu$ l

B.4.7 Stop time: 22 min

B.4.8 Post time: 1 min

#### B.5 Preparation of the standard

Weigh 20 mg of the pyrethrum standard to the nearest 0.0001g 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.

## B.6 Sample preparation

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

## B.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%.

## B.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 %)) ÷ (Average standard area X Weight of sample.)*

## Bibliography

- [1] DRS 392-4: 2018, Skin applied mosquito repellents — Specification — Part 4: Bathing Soaps
- [2] RS 191: 2019, Refined pyrethrum concentrate — Specification

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