Skin applied mosquito repellents—
Specification —

Part 5:

Bracelets, wristbands and patches
In order to match with technological development and to keep continuous progress in industries, standards are subject to periodic review. Users shall ascertain that they are in possession of the latest edition.
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DRS 392-5: 2018

Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettement as Rwanda Standards.

DRS 392-5 was prepared by Technical Committee RSB/TC 015, Pharmaceutical Products.

DRS 392 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

Committee membership

The following organizations were represented on the Technical Committee on Pharmaceutical Products (RSB/TC 015) in the preparation of this standard.

National Industrial Research and Development Agency (NIRDA)
National Pharmacy Council (NPC)
University of Rwanda/College of Sciences and Technology (UR/CST)
Pharmacie NOVA
Rwanda Development Board (RDB)
AGROPY LTD
IKIREZI NATURAL PRODUCTS
HORIZON/SOPYRWA
Rwanda Social Security Board (RSSB)
Pharmavie

University of Rwanda/College of Medicine and Health Sciences (UR/CMHS)

Rwanda Biomedical Center/ Malaria and Other Parasitic Diseases Division (RBC/MOPDD)

Society for Family Health (SFH) – Rwanda

Rwanda Biomedical Center/Medical Procurement and Production Division (RBC/MPPD)

INES – RUHANGERI

Rwanda Standards Board (RSB) – Secretariat
Introduction

Mosquito repellents are an effective complement to bed nets in the prevention of mosquito borne diseases, especially malaria.

Insecticides are used either for killing or controlling harmful insects. The insecticides which are applied for repelling insects are termed as "Repellents". Mosquito is one of the most harmful insects for mankind. To destroy them, many preparations are available on the market in various recipes like pest killer spray, soap, oil, powder, repellent etc. Out of these, mosquito repellent is the most popular as it has germicidal and disinfectant properties and is able to repel mosquitoes and is convenient to use.

The mosquito repellent is used for warding off mosquitoes which are the most harmful insects. Nowadays, mosquito repellents are used for controlling mosquitoes and are becoming most preferably than other mosquito destroyers gradually. With the rise in the standard of living, increasing urbanization and population, the demand of mosquito repellent mat is constantly increasing particularly in tropical places. It is a convenient method for protection against mosquitoes, so it has a tremendous market potential. Thus, there is a very good scope for development of such units in the country.

Skin applied mosquito repellents possess the potential to target residual transmission. Entomological evidence has shown that repellents provide personal protection against malaria. Product examples that are commonly used include lotions, gels, creams, ointments among others. However, many more types of skin applied repellent products are now developed in various forms such as sprays and roll-ons, wipes, soaps and bracelets, wristbands and patches.
Skin applied mosquito repellents — Specification — Part 5: Bracelets, wristbands and patches

1 Scope

This Draft Rwanda Standard prescribes the requirements, sampling and test methods for skin applied mosquito repellents formulated and/or prepared as bracelets, wristbands and patches and meant to be applied directly to skin.

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.

- RS 191, Refined pyrethrum concentrate — Specification
- RS ISO 24153, Random sampling and randomization procedures
- CIPAC 760, Determination of picaridin
- CIPAC 667, Determination of ethyl butylacetamidopropionate
- RS ISO 22198, Textiles — Fabrics — Determination of width and length
- RS ISO 2589, Leather — Physical and mechanical tests — Determination of thickness
- DRS 394-1, Mosquito repellents — Performance Test Guidelines — Part 1: Skin applied repellents

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

- bracelet
  ornamental band, hoop, or chain worn on the wrist or arm.

- wristband
  small bracelet or band worn around the wrist for identity purposes or to soak up sweat when playing sport.
3.3

patch

A piece of cloth or other material used to mend or strengthen a torn or weak point.

3.4

mosquito

Any of numerous arthropod animals of the class mosquito, having an adult stage characterized by three pairs of legs and a body segmented into head, thorax, and abdomen and usually having one or two pairs of wings.

3.5

mosquito repellent

Substance applied to skin, clothing, or other surfaces which discourages mosquito (and arthropods in general) from landing or climbing on that surface.

3.6

natural repellents/biopesticides

Repellents that contain natural, plant-based active ingredients

3.7

synthetic repellents

Conventional repellents containing synthetic chemical active ingredients and carrier synthetic chemical compounds as approved by a competent authority.

3.8

DEET

N,N-Diethyl-meta-toluamide or diethyltoluamide

3.9

IR3535

Ethyl butylacetylaminopropionate

3.10

Picaridin
4 Requirements

4.1 General

4.1.1 The product shall constitute a mosquito repellent that is formulated in the form of wristbands, bracelets or patches, impregnated with active ingredient(s) at a certain level that purport to repel mosquitoes.

4.1.2 The product shall be a pack of bands primarily composed of 100% microfiber with no harmful chemicals used.

4.1.3 Each band shall have an effective fragrance for repelling mosquitoes.

4.2 Active ingredients

4.2.1 Natural repellents

4.2.1.1 Active ingredients used in natural repellents shall be natural plant based ingredients such as essential oils or any other plant extract approved as mosquito repellents.

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

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

4.2.1.5 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; and
   h) Cinnamon oil.
   i) Neem oil
4.1.2.6 The proportion of single or blended active ingredient(s) in natural repellent shall be set by the manufacturer in accordance with specific standard of the essential oil used and records shall be availed.

4.1.2.7 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 % and the extract used shall meet the requirements of RS 191.

4.2 Synthetic repellents

4.2.2.1 Synthetic repellents shall contain synthetic chemical compounds which are able to discourage mosquitoes and send them flying or crawling away.

4.2.2.2 If the synthetic chemical 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.

4.2.2.3 The active ingredient content shall be declared and the average content measured shall meet the requirements as specified in table 1.

Table 1 — Synthetic active ingredient

<table>
<thead>
<tr>
<th>S/N</th>
<th>Ingredients</th>
<th>Limits (% w/w)</th>
<th>Test methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>i.</td>
<td>DEET, % w/w</td>
<td>4 – 50</td>
<td>Annex A</td>
</tr>
<tr>
<td>ii.</td>
<td>Picardin, % w/w</td>
<td>5 – 20</td>
<td>CIPAC 740</td>
</tr>
<tr>
<td>iii.</td>
<td>IR3535, % w/w</td>
<td>7.5 – 20.07</td>
<td>CIPAC 667</td>
</tr>
</tbody>
</table>

4.3 Specific requirements

The product shall comply with the specific requirements given in table 2.

Table 2 — Specific requirements — Physical properties

<table>
<thead>
<tr>
<th>S/N</th>
<th>Parameters</th>
<th>Requirements</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>i.</td>
<td>Length (mm)</td>
<td>150 – 250</td>
<td>RS ISO 22198</td>
</tr>
<tr>
<td>ii.</td>
<td>Width (mm)</td>
<td>12 – 25</td>
<td></td>
</tr>
<tr>
<td>iii.</td>
<td>Thickness (mm)</td>
<td>2 – 4</td>
<td>RS ISO 2589</td>
</tr>
<tr>
<td>iv.</td>
<td>Circumference (mm)</td>
<td>X – Small</td>
<td>165.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Small</td>
<td>177.8</td>
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<tr>
<td></td>
<td></td>
<td>Medium</td>
<td>190.5</td>
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<tr>
<td></td>
<td></td>
<td>Large</td>
<td>203.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>X – Large</td>
<td>215.9</td>
</tr>
</tbody>
</table>

4.4 Biological efficacy

When tested in accordance with DRS 394-1, the product shall have repelled 100 % of the mosquitoes from landing or climbing on that surface, within protection time indicated by the manufacturer.
5 Packaging and labelling

5.1 Packaging
The product shall be packaged in a suitable, well-closed container, to protect the integrity of the product during handling, transportation, storage and sale.

5.2 Labelling
The package shall be labeled legibly and indelibly with the following information:

   a) name of the product;
   b) manufacturer's name and physical address;

NOTE The name, physical address of the distributor/supplier and trade mark may be added as required.
   c) active ingredient content,
   d) batch or code number;
   e) net weight;
   f) country of origin;
   g) instructions for use;
   h) date of manufacture and best before date;
   i) safety precaution;
   j) special population whose exposure is prohibited (out of reach of children and pregnant women); and
   k) storage conditions.

6 Sampling
Random samples of the product shall be drawn for test in accordance with RS 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:

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

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 14.46 µm using the same conditions as described in section 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) = \[ \frac{C_1 \times P}{C_2} \]

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.
Bibliography


