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<b>Function:</b> Exemptions	<b>Document No:</b> BOMRA/ER/EX/P01/G01
<b>Department:</b> Product Evaluation and Registration	<b>Issue No:</b> 2
	<b>Effective date:</b> 25-03-2020


**Botswana Medicines Regulatory Authority**



**Approved  
By:**


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**Director – Product  
Evaluations and  
Registration**

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**Date of Approval  
(DD/MM//YY)**

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### Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
4	Added contact email addresses of two exemptions officers	2	Pono Pono & Bosele Pebe	06/04/2020
4	Included link to BOMRA bank account details	2	Pono Pono & Bosele Pebe	06/04/2020
4	Added Trading License and Industrial Permit as required attachments for the applicant	2	Pono Pono & Bosele Pebe	06/04/2020
4	Expanded abbreviation of COA to Certificate of Analysis	2	Pono Pono & Bosele Pebe	06/04/2020
4	Added Botswana Bureau Of Standards BOS 844:2020 to the list of preferred standards to use for alcohol based topical hand sanitizers	2	Pono Pono & Bosele Pebe	06/04/2020
All	Issue number to 2 on page headers	2	Pono Pono & Bosele Pebe	06/04/2020

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## 1. Purpose

The intention and purpose of these guidelines is to facilitate access of good quality Topical antiseptics which are not registered in Botswana, and to provide guidance to those submitting applications for Topical antiseptics registration exemption.

It is important to verify the safety (composition and concentrations of ingredients), efficacy of these products and any claims made for these products., an exemption procedure for such products is recommended.

## 2. Scope

This guideline is applicable to applications Antiseptics - Personal Use Products and Professional Healthcare Use Products. Products not covered by this procedure include disinfectants and industrial cleaning solvents.

## 3. Definitions and Abbreviations

### 3.1 Definitions

The following definitions shall apply:

- 3.1.1 Antiseptic: An agent that inhibits or destroys microorganisms on living tissue including skin, oral cavities, and open wounds.
- 3.1.2 Disinfectant: A chemical or physical agent that destroys or removes vegetative forms of harmful microorganisms when applied to a surface.
- 3.1.3 Personal Use Products: products used by an individual in a domestic setting to reduce transient organisms on the skin.
- 3.1.4 Professional Healthcare Use Products: Products for professional healthcare which are indicated for use by individuals to reduce transient and/or resident organisms on the skin in a healthcare setting (such as hospitals, nursing homes, clinics, dental offices). Such products are to be used in accordance with applicable hospital protocols. Professional healthcare use antiseptics include professional hygienic handrubs, professional hygienic handwashes, surgical handrubs, surgical handwashes and patient preoperative skin preparations.

### 3.2 Abbreviations

None


## 4. Guideline

### 4.1 Submission Requirements

Applications should be emailed to **both** [bpebe@bomra.co.bw](mailto:bpebe@bomra.co.bw) and [ppono@bomra.co.bw](mailto:ppono@bomra.co.bw).

The applicants will be required to submit the following:

- 4.1.1 Application for Registration Exemption - Wholesale (Topical Antiseptics), BOMRA/ER/EX/P01/F01


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- 4.1.2 Proof of payment for application for registration exemption (P350 fee). BOMRA bank account details can found on the BOMRA website at <https://www.bomra.co.bw/index.php/bomra-downloads/fees/category/50-bomra-banking-details>
- 4.1.3 Botswana Trading License
- 4.1.4 Industrial License (If manufacturing in Botswana)
- 4.1.5 Evidence of marketing authorization from a Strict Regulatory Agency or other territories.
- 4.1.6 **Composition – name(s) of ingredients and the quantities<sup>1</sup>**
- 4.1.7 **Copy of Certificate of Analysis for the finished product**
- 4.1.8 **Efficacy of the product - In vitro and/or in vivo test results to support the product claims (follow the link at the end of the document for the full guidance document).** Applicable standards for Topical Antiseptics are: In vitro tests- ASTM E 1052-96 and EN 14476; In vivo tests- EN 1499, EN 1500, EN 12791, ASTM E 1115-02, ASTM E 1173-01e1, ASTM E 1174-06, ASTM E 2276-03 and ASTM E 2613-08 or any other recognized international standards. Applicants are also recommended to use any applicable Botswana standards for Topical Antiseptics. For all alcohol based hand sanitizer, standard used should be Botswana Bureau Of Standards “BOS 844:2020”.
- 4.1.9 **Safety – Based on published or unpublished safety data testing local tolerance. Include Safety Data Sheet for each ingredient.**
- 4.1.10 **Labelling** The following information shall appear in legible and indelible labelling on each container or on a label securely attached to each container:
- Manufacturer’s name and physical address
- NOTE** The name, physical address of the distributor/supplier may be added as required.
- Trademark if applicable
  - A statement that the product is an alcohol-based hand sanitizer
  - The type and percentage of alcohol used
  - Net content
  - The batch identification
  - The expiry date or best before date
  - General instructions for use
  - Storage instructions
  - Any applicable warnings

## 4.2 Guidance Documents

Applicants are requested to refer to the following guidance documents on composition, appropriate tests and labelling (claims):

<sup>1</sup> Health Canada Antiseptic Skin Cleansers (Personal Domestic Use): [http://webprod.hc-sc.gc.ca/nhp/nd/bdpsn/atReq.do?atid=antiseptic\\_antiseptique&lang=eng](http://webprod.hc-sc.gc.ca/nhp/nd/bdpsn/atReq.do?atid=antiseptic_antiseptique&lang=eng)

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- a) Health Canada Antiseptic Skin Cleansers (Personal Domestic Use) or alternative references from stringent regulatory authorities.