FOREWORD

This monograph describes the requirements necessary to receive marketing authorization (a Natural Product Number (NPN) or a Drug Identification Number (DIN)) for topical antiseptic hand cleansers intended for domestic/personal care use. Domestic/personal care antiseptic products are self-selected by a consumer from a retail outlet for their own personal household use as part of a skin cleansing routine. These types of products are intended to provide a superficial and non-persistent cleaning effect to reduce transient bacterial load on hands.

This monograph does not apply to antiseptic products intended for personal use in a commercial or institutional setting (e.g. workplaces, washrooms in public buildings), or for professional use in food-handling premises or in healthcare settings (e.g. hospitals, nursing homes, clinics, dental offices). The monograph also does not apply to personal use antiseptic products for wound cleansing, or application to sites other than the hands. Products which do not meet the criteria outlined in this document should apply outside of the monograph stream. Applicants/sponsors should consult the Human-Use Antiseptic Drugs guidance document, at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.php, and/or request a pre-submission meeting to discuss appropriate supporting data. For products intended as wound cleansers, applicants should refer to the First Aid Antiseptics monograph.

Domestic/personal care products should be used sparingly and are not a substitute for the use of plain soap and water. Antiseptic skin cleansers should be recommended for use on lightly soiled hands only as a second-line approach or when soap and water are not available.

Antiseptic skin cleansers are classified as natural health products (NHPs) if they contain an ingredient listed in Table 1 and do not contain any ingredient listed in Table 2. Applicants seeking to obtain a NPN can access the appropriate forms and guidance at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index-eng.php.

Antiseptic skin cleansers are classified as non-prescription drugs if they contain an ingredient listed in Table 2. Applicants seeking to obtain a DIN can access the appropriate forms and guidance at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/index-eng.php.

Note: The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Text in parentheses is additional optional information which can be included on the Product Licence Application form and label at the applicant’s discretion.
Medicinal Ingredient(s)

Table 1: NHP medicinal ingredients and associated doses

<table>
<thead>
<tr>
<th>Proper name(s)¹</th>
<th>Common name(s)¹</th>
<th>Source material(s)²</th>
<th>Quantity³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Ethanol</td>
<td>Ethanol</td>
<td>60 - 80%</td>
</tr>
<tr>
<td>Ethyl alcohol</td>
<td>Ethyl alcohol</td>
<td>Ethanol</td>
<td>60 - 80%</td>
</tr>
<tr>
<td>Anhydrous alcohol</td>
<td>Anhydrous alcohol</td>
<td>Ethanol</td>
<td>60 - 80%</td>
</tr>
<tr>
<td>Isopropanol</td>
<td>Isopropanol</td>
<td>Isopropanol</td>
<td>60 - 70%</td>
</tr>
<tr>
<td>Isopropyl alcohol</td>
<td>Isopropyl alcohol</td>
<td>Isopropanol</td>
<td>60 - 70%</td>
</tr>
<tr>
<td>2-propanol</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Non-prescription drug medicinal ingredients and associated doses

<table>
<thead>
<tr>
<th>Medicinal ingredient preferred name</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium chloride</td>
<td>0.1 - 0.15%</td>
</tr>
<tr>
<td>Benzethonium chloride</td>
<td>0.05 - 0.5%</td>
</tr>
<tr>
<td>Chlorhexidine gluconate</td>
<td>2 - 4%</td>
</tr>
<tr>
<td>Chloroxylenol</td>
<td>0.5 - 3%</td>
</tr>
<tr>
<td>Triclosan</td>
<td>0.1 - 1 %</td>
</tr>
</tbody>
</table>

Permitted Combinations of Ingredients

No combinations are permitted.

Route of administration

Topical

Dosage form(s)⁴

Acceptable dosage forms include: Lotion, solution, cream, gel, liquid, wipes, ointment, spray [including non-pressurized sprays, continuous (bag-on-valve) sprays, and aerosol {non-chlorofluorocarbon (CFC)} based sprays].

¹ At least one of the following references was consulted: O’Neil et al. 2001; Gottschalck and McEwen 2006; USP 38
² At least one of the following references was consulted: O’Neil et al. 2001; USP 38
³ At least one of the following references was consulted: WHO 2005; Sweetman 2002; Zimmerman 1993
⁴ Consult Appendix 1 for dosage forms that fall outside of the monograph.
Use(s) or Purpose(s)\textsuperscript{5}

Statement(s) to the effect of:

- Antiseptic cleanser.\textsuperscript{6, 7}
- Medicated cleanser.\textsuperscript{6, 7}
- Antibacterial cleanser.\textsuperscript{6, 7}
- Kills harmful bacteria/germs.\textsuperscript{6, 7}
- Effective in destroying (harmful) bacteria to provide antiseptic cleansing.\textsuperscript{6, 7}
- For personal hand hygiene to help prevent the spread of bacteria.\textsuperscript{7, 8}

Directions for use

Statement(s) to the effect of:

For all products:

- For domestic/personal care use.
- Supervise children when they use this product.\textsuperscript{9}

For products intended as handrubs or wipes:

- Rub thoroughly into hands for at least 30 seconds. Allow to dry.\textsuperscript{9, 10}

For products intended as handwashes:

- Lather in hands with water for at least 30 seconds. Rinse well.\textsuperscript{10}

Duration of use

For occasional use.

\textsuperscript{5} Consult Appendix 2 for uses or purposes that fall outside of the monograph.
\textsuperscript{6} Berardi \textit{et al.} 2002
\textsuperscript{7} Ascenzi 1996
\textsuperscript{8} Trampuz and Widmer 2004
\textsuperscript{9} US FDA 2013a
\textsuperscript{10} Health Canada 2009
Risk information

Caution(s) and Warning(s)

Statement(s) to the effect of:

For all products:

- Keep out of reach of children.\(^{10}\)
- For external use only. If accidental ingestion occurs, call a Poison Control Center immediately.\(^{11}\)
- Avoid contact with the eyes. If contact occurs, flush eyes with water.\(^{11}\)
- If irritation develops, discontinue use and consult a health care practitioner.\(^{6,12}\)

For products containing ethanol or isopropanol:

- Flammable. Keep away from open flame and sources of heat.\(^{7}\)

Contraindication(s)

For products containing a medicinal ingredient from Table 2:

- Do not use if you are allergic to any of the ingredients.

Known Adverse Reaction(s)

No statement is required.

Non-medicinal ingredients

Non-medicinal ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID)\(^{13}\) and must meet the limitations outlined in that database, the Food and Drug Regulations (FDR)\(^{14}\), the Herbs used as Non-medicinal Ingredients in Non-prescription Drugs for Human Use\(^{15}\) policy, and/or the current Cosmetic Ingredient Hotlist\(^{16}\), when relevant.

\(^{10}\) Health Canada 2009
\(^{11}\) Zimmerman 1993
\(^{12}\) US FDA 1994
\(^{13}\) Health Canada 2015
\(^{14}\) Government of Canada 2015
\(^{15}\) Health Canada 1995
\(^{16}\) Health Canada 2014a
Specifications

For all products:

This monograph describes requirements that are specific to this class of drugs and to NHPs. Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the monograph.

All personal hand use products are expected to demonstrate in vivo and in vitro efficacy against bacteria at a minimum. Such data is maintained on file with the applicant/sponsor unless filing outside of the monograph. See the Human-Use Antiseptic Drugs guidance document for recommended test methods [Section 5 - Tables 1 and 2]. Claims for fungi, mycobacteria and/or viruses require additional supporting data outside of the monograph.

For products containing ingredients listed in Table 1 NHP medicinal ingredients:

The finished product must be established in accordance with the requirements described in the NNHPD Quality of Natural Health Products Guide available at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php.

For products containing ingredients from Table 2 drug medicinal ingredients:

Health Canada’s Guidance Document: Labelling of Pharmaceutical Drugs for Human Use should be consulted for applicable labelling requirements.

Products must comply with the requirements in the Food and Drugs Act and associated Regulations. It is also noted that all products are subject to Part C, Division 2 of the Food and Drug Regulations.

When applicable, the medicinal ingredient(s) should comply with the specifications outlined in the associated monograph from the standards listed on Schedule B to the Food and Drugs Act.

Where no Schedule B monograph exists for the finished product’s dosage form, specifications should be similar to those of a comparable compendial dosage form demonstrating the product’s identity, potency, purity and quality.

Products that contain medicinal ingredients not included in Table 2 may be considered New Drugs as per section C.08.001 of the Food and Drug Regulations.
References cited


References reviewed


References reviewed


Appendix 1: Dosage forms that fall outside the scope of this monograph

The following dosage forms for antiseptic products are associated with indications of use that fall outside the scope of this monograph:

- Sponge
- Shampoo
- Bar soaps
- Swabs

These, as well as all other dosage forms not identified as acceptable in the ‘Dosage form(s)’ section of this document, require assessment outside of the monograph stream.
Appendix 2: Uses or purposes that fall outside the scope of this monograph

The following indications for antiseptic products would require a review outside of the monograph. Applicants/sponsors should consult the Human-Use Antiseptic Drugs guidance document and/or request a pre-submission meeting to discuss appropriate supporting data. These include, but are not limited to:

- For use on any body part other than hands.
- Antiseptic for use on large areas of the body (e.g. pre-operative showering or bathing).
- For use at the pre-injection or catheter insertion site.
- For use during or after skin piercing (e.g. ear piercing, tattoo).
- For wound cleansing.
- For use in a commercial or institutional setting.
- For professional food handler or healthcare use.
- Anti-viral.
- Anti-mycobacterial.
- Antifungal.
- Log or % reduction claims (e.g. Kills 99.99% of bacteria).
- Efficacy against/highlighting of any specific organisms.
- Persistence claims.
- Sterile.
- Any claim that implies that the product provides an instantaneous/immediate effect.