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Health Canada Santé Canada

FIRST AID ANTISEPTICS MONOGRAPH

Health Products and Food Branch

FOREWORD

This monograph is intended to replace the existing First aid antiseptics monograph of February 9, 2016. This monograph describes the requirements necessary to receive marketing authorization [i.e. a Drug Identification Number (DIN) or Natural Product Number (NPN)], for topical minor wound cleansers. This monograph does not apply to antiseptic skin cleanser products for personal hand hygiene or to products for professional use. Products which do not meet the criteria outlined in this document can apply for market authorization outside of the monograph stream.

Applicants are reminded that first aid antiseptic skin cleansers, like other non-prescription drugs or natural health products, are subject to the Food and Drug Regulations or the Natural Health Products Regulations administered by the Natural and Non-prescription Health Products Directorate (NNHPD). This includes requirements related to labelling, manufacturing and product specifications. Additional information on labels, outside of those specified in the monograph, such as additional directions for use and/or non-therapeutic claims are acceptable as long as they meet the Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims, the Guidelines for Consumer Advertising of Health products for Nonprescription drugs, Natural Health Products, Vaccines and Medical Devices, and are not false, misleading or counterintuitive to the use of the product.

The development of this monograph is the result of a thorough review of existing regulations, guidance documents, policies and current practices within Health Canada and other leading regulatory agencies.

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 Ingredients

First aid antiseptics are classified as natural health products (NHPs) if they contain one ingredient from Table 1. Combinations are not permitted. Applicants applying for an NPN can access the appropriate forms and guidance at: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html.

First aid antiseptics are classified as non-prescription drugs if they contain one ingredient from Table 2. Combinations are not permitted. Applicants applying for a DIN can access the appropriate forms and guidance at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents.html.

Table 1: NHP medicinal ingredients

Proper name(s)	Common name(s)	Source information Source ingredient(s)	Quantity
Hydrogen peroxide	Hydrogen peroxide	Hydrogen peroxide	3%
• 1-Ethenyl-2-pyrrolidinone homopolymer compound with iodine • 1-Vinyl-2-pyrrolidinone polymers, iodine complex	Povidone-iodine	Povidone-iodine	0.5 – 10%

[1]At least one of the following references was consulted per proper name, common name and source information: USP 38; Gottschalck and McEwen 2006; O'Neil et al. 2001.
[2]At least one of the following references was consulted for the dosage: Khan and Naqvi 2006; Pray 2006; Carruthers-Czyzewski 1996; FDA 1991.

Table 2: Non-prescription drug medicinal ingredients

Medicinal ingredient preferred name[1]	Quantity[1]
Benzalkonium chloride	0.1 – 0.13%
Benzethonium chloride	0.1 – 0.2%

[1]FDA 1991.

Permitted Combinations of Ingredients:

No combinations are permitted.

Route of administration

Topical

Dosage form(s)

The following dosage forms are acceptable when used according to the requirements indicated in this monograph:

Acceptable dosage forms for Non-prescription drugs (NPDs):

Cream; Gel; Lotion; Ointment; Solution; Spray; Swab; Wipe.

Acceptable dosage forms for Natural Health Products (NHPs):

Cream (povidone iodine only); Gel (povidone iodine only); Lotion (povidone iodine only); Ointment (povidone iodine only); Solution; Spray; Swab, medicated; Topical liquid; Wipe, medicated.

Use(s) or Purpose(s)[1]

For all products:

- First aid antiseptic.
- For minor wound cleansing.
- Antiseptic/Medicated/Antibacterial wound cleanser.
- Kills (harmful) bacteria/germs.
- Effective in destroying (harmful) bacteria to provide antiseptic cleansing.
- Helps to prevent/reduce the risk of infection in minor cuts and scratches.

For products containing benzalkonium chloride or benzethonium chloride:

Helps to prevent/reduce the risk of infection in minor burns.

[1]**Note**: At least one of the following references was consulted: Pray 2006; Berardi et al. 2002; Carruthers-Czyzewski 1996; FDA 1991.

Dose(s)

Subpopulation(s)

Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older.

Quantity(ies)

See Tables 1 and 2.

Direction(s) for use

For all products:

- Clean the affected area (FDA 1991).
- Apply a small amount to wound one to three times daily (FDA 1991).
- May be covered with a sterile bandage (FDA 1991).
- Supervise children when they use this product (FDA 1991).

For spray products:

Avoid inhaling or exposing others to spray.

Duration(s) of use

For occasional use.

Risk information

Caution(s) and Warning(s)

For all products:

- **For external use only**.
- **When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water (FDA 1991).
- **Stop use and ask/consult a doctor/physician/health care practitioner/health care provider/health care professional if** symptoms worsen or persist after seven days, or if irritation develops (FDA 2013a, FDA 1991).
- **Keep out of reach of children**. If swallowed, call a poison control center or get medical help right away (FDA 2013a, Zimmerman 1993, FDA 1991).

For products containing povidone-iodine:

- **Ask/consult a doctor/physician/health care practitioner/health care provider/health care professional** prior to use on infants (FDA 2013a).
- **Ask/consult a doctor/physician/health care practitioner/health care provider/health care professional prior to use** if you have a thyroid disease (FDA 2013a).

For products containing benzalkonium chloride or benzethonium chloride:

Ask a doctor or pharmacist before use if you are pregnant or breastfeeding.

Contraindication(s)

For all products:

- **Do not use** in the eyes or over large areas of the body (FDA 1991).
- **Do not use** on deep or puncture wounds, animal bites or serious burns (FDA 1991).

For products containing povidone-iodine:

Do not use if you are pregnant or breastfeeding (FDA 2013a).

For products containing a medicinal ingredient from Table 2:

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

Known Adverse Reaction(s)

For products containing povidone-iodine:

Rare anaphylactic reactions have been known to occur (Gray et al. 2013; Palobart et al. 2009; Yoshida et al. 2008).

Non-medicinal ingredients

Ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database, the *Food and Drug Regulations*, and the current Cosmetic Ingredient Hotlist, when relevant.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations* or *Food and Drug Regulations*.

Specifications

For all products:

This monograph describes those requirements that are specific to this class of non-prescription 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.

For products containing Table 1 NHP medicinal ingredients only:

The finished product must be established in accordance with the requirements described in the NNHPD Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID.

For products containing Table 2 non-prescription drug medicinal ingredients:

Requirements described in the Regulations to the Food and Drugs Act must be met.

DRUG FACTS TABLE:

Drug Facts
Active ingredient (Add dosage unit) **Purpose** Benzethonium chloride OR Benzalkonium chloride XX %……..First Aid Antiseptic
Uses • Helps to prevent/reduce the risk of infection in minor cuts, scratches, and burns • For minor wound cleansing • Antiseptic/Medicated/Antibacterial wound cleanser • Kills (harmful) bacteria/germs • Effective in destroying (harmful) bacteria to provide antiseptic cleansing.
Warnings **For external use only.**
Do not use • in the eyes or over large areas of the body. • on deep or puncture wounds, animal bites or serious burns. • if you are allergic to any ingredients in the product.
Ask a doctor or pharmacist before use if you are pregnant or breastfeeding.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask a doctor if symptoms worsen or persist after seven days, or if irritation develops.
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.
Directions Adults and children 2 years and over: • For occasional use • Clean the affected area • Apply a small amount to wound one to three times daily • May be covered with a sterile bandage • Supervise children when they use this product. *For spray products:* Avoid inhaling or exposing others to spray.
Other information (Add storage information)
Inactive ingredients List all NMIs
Questions? 1-XXX-XXX-XXXX (or other contact information)

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