

FIRST AID ANTISEPTICS

Date

February 9, 2016

FOREWORD

This monograph describes the requirements necessary to receive marketing authorization (a Natural Product Number (NPN) or a Drug Identification Number (DIN)) 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 should apply outside of the monograph stream.

First aid antiseptics 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_e.html.

First aid antiseptics 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://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index_e.html.

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

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

¹ At least one of the following references was consulted: USP 38; Gottschalck and McEwen 2006; O'Neil *et al.* 2001

² At least one of the following references was consulted: USP 38; O'Neil *et al.* 2001

³ At least one of the following references was consulted: Khan and Naqvi 2006; Pray 2006; Carruthers-Czyzewski 1996; US FDA 1991



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

Medicinal ingredient preferred name⁴	Quantity⁴
Benzalkonium chloride	0.1-0.13%
Benzethonium chloride	0.1-0.2%

Permitted Combinations of Ingredients:

No combinations are permitted.

Route of administration

Topical

Dosage form(s)

Acceptable dosage forms include: Lotion, solution, cream, gel, liquid, ointment, wipes, swabs, sprays.

Use(s) or Purpose(s)⁵

Statement(s) to the effect of:

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:

- First aid to help prevent (reduce the risk of) infection in minor burns.

⁴ US FDA 1991

⁵ At least one of the following references was consulted: Pray 2006; Berardi et al. 2002; Carruthers-Czyzewski 1996; US FDA 1991



Directions for use⁶

Statement(s) to the effect of:

For all products:

- Clean the affected area.
- Apply a small amount to wound one to three times daily.
- May be covered with a sterile bandage.
- Do not use on deep or puncture wounds, animal bites or serious burns.

Duration of use

For occasional use.

Risk information

Caution(s) and Warning(s):

Statement(s) to the effect of:

For all products:

- Keep out of reach of children.⁷
- For external use only. If swallowed, call a Poison Control Center or a health care professional immediately.^{6,8}
- Avoid contact with eyes. If contact occurs, flush thoroughly with water.⁶
- Do not apply over large areas of the body.⁶
- If symptoms worsen or persist after seven days, or if irritation develops, discontinue use and consult a health care practitioner/professional.^{6,7}

For products containing povidone-iodine:

- Consult a health care practitioner/professional before use on infants.⁷
- Consult a health care practitioner/professional before use if you have a thyroid disease.⁷

For products containing benzalkonium chloride or benzethonium chloride:

- If you are pregnant or breastfeeding, consult a health care practitioner/professional prior to use.

⁶ US FDA 1991

⁷ US FDA 2013a

⁸ Zimmerman 1993



Contraindication(s)

For products containing povidone-iodine:

- If you are pregnant or breastfeeding, do not use.⁷

For products containing a medicinal ingredient from Table 2:

- If you are allergic to any of the ingredients, do not use.

Known Adverse Reaction(s)

For products containing povidone-iodine:

- Rare anaphylactic reactions have been known to occur⁹.

Non-medicinal ingredients

Non-medicinal ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID)¹⁰ and must meet the limitations outlined in that database, the *Food and Drug Regulations* (FDR)¹¹, the *Herbs used as Non-medicinal Ingredients in Nonprescription Drugs for Human Use* policy¹², and/or the current Cosmetic Ingredient Hotlist¹³, when relevant.

Specifications

For all products:

This monograph describes 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 ingredients from Table 1: NHP medicinal ingredients and associated doses:

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>.

⁹ Gray et al. 2013; Palobart et al. 2009; Yoshida et al. 2008

¹⁰ Health Canada 2015

¹¹ Government of Canada 2015

¹² Health Canada 1995

¹³ Health Canada 2014a

For products containing ingredients from Table 2: Non-prescription drug medicinal ingredients and associated doses:

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*.

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Appendix 1: Products Facts Table

PRODUCT FACTS TABLE: RECOMMENDED (NOT MANDATORY)¹⁴

Product Facts	
Active ingredient (in each dosage unit)	Purpose
Benzethonium chloride OR Benzalkonium chloride XX %.....	First Aid Antiseptic
Uses	
<ul style="list-style-type: none"> ▪ First aid to help prevent (reduce the risk of) infection in minor cuts, scratches, and burns. ▪ For minor wound cleansing. ▪ Antiseptic/medicated/antibacterial wound cleanser. ▪ Kills harmful bacteria or germs. ▪ Effective in destroying bacteria to provide antiseptic cleansing. 	
Warnings	
<ul style="list-style-type: none"> ▪ For external use only. ▪ If you are pregnant or breastfeeding, consult a health care practitioner prior to use. 	
Do not use:	
<ul style="list-style-type: none"> ▪ if you are allergic to any ingredients in the product. ▪ in the eyes or over large areas of the body. ▪ on deep or puncture wounds, animal bites or serious burns. 	
Stop use and ask a doctor if:	
<ul style="list-style-type: none"> ▪ irritation develops. ▪ condition gets worse or persists after seven days . 	
When using this product:	
<ul style="list-style-type: none"> ▪ If contact with the eyes occurs, rinse with water. 	
Keep out of reach of children	
If swallowed, call a Poison Control Centre or a health care professional immediately.	
Directions	
For occasional use.	
<ul style="list-style-type: none"> ▪ Clean the affected area. ▪ Apply a small amount to wound one to three times daily. ▪ May be covered with a sterile bandage. 	
Inactive ingredients <List all NMIs>	
Questions? Concerns? Call 1-877-XXX-XXXX	

¹⁴ The regulatory amendment for a Fact Table for non-prescription drug products would come into force three years after the day of registration in *Canada Gazette* Part II (June 13, 2017).
<http://gazette.gc.ca/rp-pr/p2/2014/2014-07-02/html/sor-dors158-eng.php>