First aid antiseptics

First Aid Antiseptics (PDF Version - 381 KB) Foreword This monograph is intended to replace the existing First aid antiseptics monograph of February 24, 2023. 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. Notes: Text in parentheses is additional optional information which can be included on the label at the applicant's discretion. The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant on the label. Date August 28, 2024 Medicinal Ingredient(s) First aid antiseptics are classified as natural health products (NHPs) if they contain only an 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 (NPDs) if they contain an ingredient from Table 2 at a therapeutic quantity. 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. Proper name(s), Common name(s), Source information Table 1: NHP medicinal ingredients Proper name(s) 1 Common name(s) 1 Source information 1 Quantity 2 Source ingredient(s) 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: RSC 2023; USP-NF 2023; Gottschalck and McEwen 2006. 2 Quantity expressed as percentage weight by volume (% w/v). At least one of the following references was consulted for the dosage: US FDA 2023; Khan and Naqvi 2006; Pray 2006; Carruthers-Czyzewski 1996. Table 2: NPD medicinal ingredients Medicinal ingredient preferred name 1 Quantity 1 Benzalkonium chloride 0.1 - 0.13% Benzethonium chloride 0.1 - 0.2% 1 US FDA 2023. Permitted combinations No combinations are permitted. Route of administration Topical Dosage form(s) Acceptable dosage forms for NHPs Cream (povidone iodine only); Gel (povidone iodine only); Liquid; Lotion (povidone iodine only); Ointment (povidone iodine only); Solution; Spray; Swab; Topical liquid; Wipe. Acceptable dosage forms for NPDs Cream; Gel; Lotion; Ointment; Solution; Spray; Swab; Wipe. Use(s) or Purpose(s) 1 All products First aid antiseptic. For minor wound cleansing. Antiseptic/Medicated/Antibacterial wound cleanser. Kills (harmful) bacteria/germs (on minor wounds). Effective in destroying (harmful) bacteria to provide antiseptic cleansing (of minor wounds). Helps to prevent/reduce the risk of infection in minor cuts and scratches. 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: US FDA 2023; Pray 2006; Berardi et al. 2002; Carruthers-Czyzewski 1996. 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 All products Clean the affected area (US FDA 2023). Apply a small amount to wound 1 to 3 times daily (US FDA 2023). May be covered with a light sterile bandage (US FDA 2023). Supervise children when they use this product (US FDA 1994). Spray products Avoid inhaling or exposing others to spray. Duration(s) of use For occasional use. Risk information Caution(s) and Warning(s) All

products For external use only (US FDA 2023). When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water (US FDA 1994). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or persist after 7 days, or if irritation develops (US FDA 2023). Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away (US FDA 2013; US FDA 1994; Zimmerman 1993). Products containing povidone-iodine Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a thyroid disease (US FDA 2013). Products containing benzalkonium chloride or benzethonium chloride Ask a doctor or pharmacist before use if you are pregnant or breastfeeding. Contraindication(s) All products Do not use in the eyes or over large areas of the body (US FDA 2023). Do not use on deep or puncture wounds, animal bites or serious burns (US FDA 2023). Products containing povidone-iodine Do not use if you are pregnant or breastfeeding (US FDA 2013). 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) 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 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 a Table 1 NHP medicinal ingredient 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 a Table 2 NPD medicinal ingredient Requirements described in the Regulations to the Food and Drugs Act must be met. For products containing a Table 1 NHP medicinal ingredient Example of Product Facts Consult the Guidance Document, Labelling of Natural Health Products for more details. For products containing a Table 2 NPD medicinal ingredient Drug Facts Table References cited Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Carruthers-Czyzewski P, editor. Nonprescription Drug Reference for Health Professionals. 1st edition. Ottawa (ON): Canadian Pharmaceutical Association; 1996. Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook. 11th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2006. Gray Pe, Katelaris CH, Lipson D. Recurrent anaphylaxis caused by topical povidone-iodine (Betadine). Journal of paediatrics and child health 2013;49(6):506-507. Khan MN and AH Naqvi. Antiseptics, iodine, povidone iodine and traumatic wound cleansing. Journal of tissue viability 2006;16(4):6-10. 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Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record. Federal Register, Volume 78, Number 242, December 17, 2013. [Accessed 2024 January 28]. Available from: https://www.federalregister.gov/documents/2013/12/17/2013-29814/safety-and-effectiveness-of-consumer-antiseptics-topical-antimicrobial-drug-products-for US FDA 1994: United States Food and Drug Administration. 21 CFR Parts 333 and 369. Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products. Federal Register, Volume 56, Number 140, July 22, 1991. [Accessed 2024 January 28]. Available from: https://www.federalregister.gov/documents/1994/06/17/94-14503/topical-antimicrobial-drug-products-for-over-the-counter-human-use-tentative-final-monograph-for USP-NF 2023: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2023. Yoshida K, Sakurai Y, Kawahara S, Takeda T, Ishikawa T, Murakami T, Yoshioka A. Anaphylaxis to polyvinylpyrrolidone in povidone-iodine for impetigo contagiosum in a boy with atopic dermatitis. International archives of allergy and immunology 2008;146:169-173. Zimmerman DR. Zimmerman's Complete Guide to Nonprescription Drugs. Detroit (MI): Gale Research Inc.; 1993. References reviewed Arai K, Yamazaki

M, Maeda T, Okura T, Tsuboi R. Influence of various treatments including povidone-iodine and healing stimulatory reagents in a rabbit ear wound model. International Wound Journal 2013;10(5):542-548. Ascenzi JM. Handbook of Disinfectants and Antiseptics. New York (NY): Marcel Dekker; 1996. Atiyeh BS, Dibo SA, Hayek SN. Wound cleansing, topical antiseptics and wound healing. International wound journal 2009;6(6):420-430. AHFS 2014: American Hospital Formulary Service®. McEvoy GK (ed). AHFS Drug Information 2014®. [Internet] Published by Authority of the Board of the American Society of Health-System Pharmacists®, Bethesda, Maryland. [Accessed 2014 April 10]. Available from http://online.statref.com Aiello AE, Larson EL, Levy SB. Consumer Antibacterial Soaps: Effective or Just Risky? Clinical Infectious Diseases. 2007;45(Supplement 2):S137-S147. CDC 2005: Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002; Volume 51(No. RR-16). Geronemus RG, Mertz PM, Eaglstein WH. Wound healing. The effects of topical antimicrobial agents. Archives of dermatology 1979;115(11):1311-1314. Gilmore OJ, Reid C, Strokon A. A study of the effect of povidone-iodine on wound healing. Postgraduate medical journal 1977;53(617):122-125. Goldenheim PD. An appraisal of povidone-iodine and wound healing. Postgraduate medical journal 1993;69(Suppl 3):S97-S105. Gravett A, Sterner S, Clinton JE, Ruiz E. A trial of povidone-iodine in the prevention of infection in sutured lacerations. Annals of emergency medicine 1987;16(2):167-171. Guideline for Hand Hygiene in Health-Care Settings. Morbidity and Mortality Weekly Report. Volume 51, Number RR-16, October 25, 2002. Juhasz I. Experiences with the use of povidone-iodine-containing local therapeutics in dermatological surgery and in the treatment of burns: testing for allergic sensitization in postsurgery patients. Dermatology 2002;204(Suppl 1):52-58. Kramer SA. Effect of povidone-iodine on wound healing: a review. Journal of vascular nursing 1999;17(1):17-23. Nili F, Hantoushzadeh S, Alimohamadi A, Shariat M, Rezaeizadeh G. Iodine-containing disinfectants in preparation for caesarean section: impact on thyroid profile in cord blood. Postgraduate medical journal 2015 -133540. doi: 10.1136. Epub ahead of print. Norman D. The use of povidone-iodine in superficial partial-thickness burns. British journal of nursing 2003;12(6 Suppl):S30-S36. Peter FW, Li-Peuser H, Vogt PM, Muehlberger T, Homann HH, Steinau HU. The effect of wound ointments on tissue microcirculation and leucocyte behaviour. Clinical and experimental dermatology 2002;7(1):51-55. Roberts AH, Roberts FE, Hall RI, Thomas IH. A prospective trial of prophylactic povidone iodine in lacerations of the hand. Journal of hand surgery 1985;10(3):370-374. Sweetman SC, editor. Martindale: The Complete Drug Reference. 33rd edition. London (GB): Pharmaceutical Press; 2002. Trampuz AT and Widmer AF. Hand hygiene: a frequently missed lifesaving opportunity during patient care. Mayo Clinic proceedings 2004;79:109-116. WHO 2005: WHO guidelines on hand hygiene in health care. Geneva (Switzerland): World Health Organization Press; 2005. Zahidi A, Draoui M, Mestassi M. Iodine status and the use of iodized antiseptics in the mother-newborn pair. Therapie 1999;54(5)545-548. Zhen ZJ, Lai ECH, Lee QH, Chen HW, Lau WY, Wang FJ. Conventional wound management versus a closed suction irrigation method for infected laparotomy wound - A comparative study. International Journal of Surgery 2011;9:378-381. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Proper name(s)1Common name(s)1Source information1Quantity2Source ingredient(s) Hydrogen peroxideHydrogen peroxideHydrogen peroxide3%1-Ethenyl-2-pyrrolidinone homopolymer compound with iodine1-Vinyl-2-pyrrolidinone polymers, iodine complexPovidone-iodinePovidone-iodine0.5 - 10%

RISK INFORMATION

Caution(s) and Warning(s) All products For external use only (US FDA 2023).When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water (US FDA 1994).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or persist after 7 days, or if irritation develops (US FDA 2023).Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away (US FDA 2013; US FDA 1994; Zimmerman 1993). Products containing povidone-iodine Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a thyroid disease (US FDA 2013). Products containing benzalkonium chloride or benzethonium chloride Ask a doctor or pharmacist before use if you are pregnant or breastfeeding.

Contraindication(s) All products Do not use in the eyes or over large areas of the body (US FDA 2023).Do not use on deep or puncture wounds, animal bites or serious burns (US FDA 2023). Products containing povidone-iodine Do not use if you are pregnant or breastfeeding (US FDA 2013). 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) 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 currentNatural Health Products Ingredients Database(NHPID) and must meet the limitations outlined in that database, theFood and Drug Regulations, and the currentCosmetic Ingredient Hotlist, when relevant. Storage conditions Must be established in accordance with the requirements described in theNatural Health Products RegulationsorFood and Drug Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products RegulationsorFood and Drug Regulations.

SPECIFICATIONS

Notes: Text in parentheses is additional optional information which can be included on the label at the applicant's discretion.The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant on the label. Date August 28, 2024

REFERENCES

2Quantity expressed as percentage weight by volume (% w/v). At least one of the following references was consulted for the dosage: US FDA 2023; Khan and Naqvi 2006; Pray 2006; Carruthers-Czyzewski 1996. Table 2: NPD medicinal ingredientsMedicinal ingredient preferred name1Quantity1Benzalkonium chloride0.1 - 0.13%Benzethonium chloride0.1 - 0.2% 1US FDA 2023. Permitted combinations No combinations are permitted. Route of administration Topical

Proper name(s)1	Common name(s)1	Source information1	Quantity2
Source ingredient(s)			
Hydrogen peroxide	Hydrogen peroxide	Hydrogen peroxide	3%
1-Ethenyl-2-pyrrolidinone homopolymer compound with iodine	Povidone-iodine	1-Vinyl-2-pyrrolidinone polymers, iodine complex	0.5 - 10%

Medicinal ingredient preferred name1	Quantity1

Benzalkonium chloride	0.1 - 0.13%
Benzethonium chloride	0.1 - 0.2%