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Health Canada Santé Canada

Medicated Skin Care Products Monograph

Health Products and Food Branch

Canada

FOREWORD

This monograph is intended to replace the existing Medicated skin care products of April 3, 2007. This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for medicated skin care products. The monograph identifies the permitted medicinal and non-medicinal ingredients, concentrations, indications, directions and conditions of use for these products to be market authorized without the submission to Health Canada of additional evidence. It also may contain the test methods recommended to be used to comply with the requirements of this monograph. 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 medicated skin care products, 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 INGREDIENT(S)

Medicated skin care products are classified as natural health products (NHPs) if they contain only ingredients from Tables 1 and 2. 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.

Medicated skin care products are classified as non-prescription drugs if they contain at least one ingredient from Table 3 at a quantity listed. 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)[1]	Common name(s)[1]	Source material(s)[1]				Quantity[2]
		Proper name(s)	Common name(s)	Part(s)	Preparation(s)	
Acetic acid, zinc salt	• Zinc acetate • Acetic acid, zinc salt, dihydrate	N/A	• Zinc acetate[3] • Zinc acetate, dihydrate[3]	N/A	N/A	0.1 – 2%
Adeps solidus	• Hard fat • Hard fat triglyceride esters	Adeps solidus[3]	N/A	N/A	N/A	50 – 100%
Aluminum hydroxide	• Aluminum hydroxide • Aluminum hydrate	N/A	Aluminum hydroxide[3]	N/A	N/A	0.15 – 5%
Avena sativa	• Colloidal oatmeal • Oatmeal colloidal	*Avena sativa*	N/A	Seed	Dried	1 – 100%
• Carbamide • Carbonyldiamide	• Urea • Carbamide	N/A	Urea[3]	N/A	N/A	10%
Carbonic acid sodium salt (1:1)	• Sodium bicarbonate • Baking soda • Carbonic acid monosodium salt • Sodium hydrogen carbonate	N/A	Sodium bicarbonate[3]	N/A	N/A	1 – 100%
Carbonic acid, zinc salt (1:1)	Zinc carbonate	N/A	Zinc carbonate[3]	N/A	N/A	0.2 – 2%
(2,5-Dioxo-4-imidazolidinyl)urea	• Allantoin • N-(2,5-Dioxo-4-	N/A	Allantoin[3]	N/A	N/A	0.5 – 2%

	imidazolidinyl) urea • Glyoxyldiureide • 5-Ureidohydantoin					
Iron oxide (Fe_2O_3), mixture with zinc oxide	Calamine	N/A	Calamine[3]	N/A	N/A	1 – 25%
Kaolin	• Argilla • Bolus alba • China clay • Hydrated aluminum silicate • Kaolin • Porcelain clay • White bole	N/A	Kaolin[3]	N/A	N/A	4 – 20%
• DL-Lactic acid • 2-Hydroxy-2-methylacetic acid	• DL-Lactic acid • Lactic acid	N/A	Lactic acid[3]	N/A	N/A	2 – 5%
• Lanolin • Anhydrous Lanolin	• Lanolin • Wool fat	*Ovis aries*	N/A	Wool	N/A	12.5 – 50%
Olea europaea	• Olive oil • Olea europaea (olive) fruit oil • Olea europaea fruit oil	*Olea europaea*	N/A	Fruit flesh	Fresh	≤ 100%
1,2,3-Propanetriol	• Glycerine • Glycerin • Glycerol	N/A	Glycerol[3]	N/A	N/A	20 – 45%
Prunus dulcis	• Almond oil • Prunus amygdalus dulcis (sweet almond) oil	*Prunus dulcis*	N/A	Seed	Fresh	≤ 100%
Theobroma cacao	• Cocoa butter • Cocao butter • Theobroma oil	*Theobroma cacao*	N/A	Seed	Fresh	50 – 100%
Zea mays	• Corn Starch • Starch – Maize • Topical starch • Zea Mays (Corn) Starch • Zea mays starch	*Zea mays*[3]	N/A	Seed	Dried	10 – 98%
Zinc oxide	• C.I. No. 77947	N/A	Zinc oxide[3]	N/A	N/A	1 – 25%

	• Zinc oxide					(Zinc oxide) 1 – 40% (Zinc oxide ointment)

1. At least one of the following references was consulted per proper name, common name, and source material: USP 41; Nikitakis and Lange 2016; Sweetman 2017; O'Neil et al. 2018; NF 36.
2. At least one of the following references was consulted for the dosage: FDA 2003; Leung and Foster 2010; Krinsky 2017; Sweetman 2017.
3. Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Quality of Natural Health Products Guide).

Table 2: Complementary NHP ingredients (safety only)[3]

Proper name(s)[1]	Common name(s)[1]	Source material(s)[1]			Quantity[2]
		Proper name(s)	Organism group(s)	Part(s)	
Cod liver oil	• Cod liver oil • Lecoris aselli oleum	N/A	Gadidae	Liver	5 – 14%

1. At least one of the following references was consulted per proper name, common name, and source material: USP 41; Nikitakis and Lange 2016; Sweetman 2017; O'Neil et al. 2018.
2. The following reference was consulted for the dosage: FDA 2003.
3. Cod liver oil is not permitted as a single medicinal ingredient as this ingredient is not sufficient on its own to support the efficacy of the product.

Table 3: Non-prescription drug medicinal ingredients[1]

Proper name(s)	Common name(s)	Source material(s)	Quantity
		Common name(s)	
• alpha-(Trimethylsilyl)-omega-methylpoly(oxy(dimethylsilylene)) • Dimethicone • Dimethyl polysiloxane	Dimethicone	Dimethicone	1 − 30%
Mineral oil	• Liquid paraffin • Mineral oil • Paraffin oil • Paraffinum liquidum • Petrolatum, liquid • White mineral oil	Mineral oil	50 − 100%
Petrolatum	• Petrolatum • Petroleum jelly	Petrolatum	30 − 100%

White petrolatum	• White petrolatum • White petroleum jelly	White petrolatum	30 − 100%

1. See Permitted combinations.

ROUTE(S) OF ADMINISTRATION

Topical

DOSAGE FORM(S)

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

USE(S) OR PURPOSE(S)

Self-Care Framework Category I Uses or Purposes:

For products containing allantoin, almond oil, cocoa butter, cod liver oil, corn starch, dimethicone, glycerine, hard fat, lactic acid, lanolin, mineral oil, olive oil, petrolatum, white petrolatum, or urea, the following statement may be made:

- Temporarily protects and helps relieve minor skin irritation and itching (Krinsky 2017, FDA 2003).

For products containing allantoin, cocoa butter, cod liver oil, hard fat, lanolin, mineral oil, petrolatum and/or white petrolatum, the following statement may be made:

- Temporarily protects and helps relieve minor skin irritation and itching due to minor cuts, scrapes and burns (FDA 2003).

For products containing aluminum hydroxide, calamine, kaolin, zinc acetate, zinc carbonate and/or zinc oxide, the following statement may be made:

- Temporarily dries the oozing and weeping and helps relieve minor skin irritation and itching due to poison ivy/oak/sumac (FDA 2003).

For products containing colloidal oatmeal, the following statement may be made:

- Temporarily protects and helps relieve minor skin irritation and itching due to rashes, eczema, poison ivy/oak/sumac, and insect bites (FDA 2003).

For products containing sodium bicarbonate, the following statement may be made:

- Temporarily protects and helps relieve minor skin irritation and itching due to poison ivy/oak/sumac, and insect bites (FDA 2003).

For products containing colloidal oatmeal and mineral oil in combination, the following statement may be made:

- Temporarily protects and helps relieve minor skin irritation and itching due to (rashes)(and/ or)(eczema).

Note: Product labels must contain at least one of the above health claims. Claims that are non-therapeutic in nature such as “relieves dry skin” or “protects against and alleviates chapping,

cracking and roughness due to dryness" are acceptable as additional information, provided that the claims are true and verifiable.

DOSE(S)

Subpopulation(s):
Infants 6 to 12 months, Children 1 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older

Quantity:
See Tables 1, 2, and 3 above.

Permitted combinations:

- Any two or more of the following ingredients may be combined, provided each ingredient in the combination is within the concentration specified above: mineral oil, petrolatum, and white petrolatum (FDA 2003).
- Any two or more of the NHP ingredients may be combined, provided each ingredient in the combination is within the concentration specified above.

Directions for use:

For all products, excluding colloidal oatmeal products, that are used as a soak in a bath, as a compress, or as a wet dressing, and sodium bicarbonate products used as a paste, a soak in a bath, a compress, or wet dressing:

- Apply to affected area as needed (FDA 2003).

For colloidal oatmeal products used as a soak in a bath:

1. Using warm water turned on at full force, slowly sprinkle (*applicant to insert quantity to be used*) under running water (FDA 2003). (Applicant must provide adequate directions to allow consumers to obtain a solution containing: For tub bath/infant bath: a minimum of 0.007% colloidal oatmeal or 0.003% colloidal oatmeal when in combination with mineral oil. For foot bath: a minimum of 0.25% colloidal oatmeal.)
2. Stir thoroughly to prevent clumping and settling (FDA 2003).
3. Soak affected area for 15 to 30 minutes as needed or as directed by a health care practitioner (FDA 2003).
4. Pat dry (do not rub) to keep a thin layer on the skin (FDA 2003).

For colloidal oatmeal products used as a compress or wet dressing:

1. Using warm water turned on at full force, slowly sprinkle (*applicant to insert quantity to be used*) under running water (FDA 2003). (Applicant must provide adequate directions to allow consumers to obtain a solution containing a minimum of 0.25% colloidal oatmeal.)
2. Stir thoroughly to prevent clumping and settling (FDA 2003).
3. Soak a clean, soft cloth in the mixture (FDA 2003).
4. Apply cloth loosely to affected area for 15 to 30 minutes (FDA 2003).
5. Repeat as needed or as directed by a health care practitioner (FDA 2003).
6. Discard mixture after each use (FDA 2003).

For sodium bicarbonate products used as a paste:

1. Add water to form a paste (FDA 2003).

2. Apply to affected area as needed or as directed by a health care practitioner (FDA 2003).

For sodium bicarbonate products used as a soak in a bath:

1. Dissolve 250 to 500 mL (1 to 2 cups) in a tub of warm water (FDA 2003).
2. Soak for 10 to 30 minutes as needed or as directed by a health care practitioner (FDA 2003).
3. Pat dry (do not rub) to keep a thin layer on the skin (FDA 2003).

For sodium bicarbonate products used as a compress or wet dressing:

1. Add to water to make a mixture in a container (FDA 2003).
2. Soak a clean, soft cloth in the mixture (FDA 2003).
3. Apply cloth loosely to affected area for 15 to 30 minutes (FDA 2003).
4. Repeat as needed or as directed by a health care practitioner (FDA 2003).
5. Discard mixture after each use (FDA 2003).

Duration(s) of use:
No statement is required.

RISK INFORMATION

Caution(s) and warning(s):

For all products:

- **For external use only** (FDA 2003).
- **When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water. (FDA 2003).
- **Stop use and ask/consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if** symptoms worsen or last for more than 7 days (FDA 2003).
- **Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

For products containing colloidal oatmeal or sodium bicarbonate (when labelled for use as a soak, compress or wet dressing):

- **When using this product** in some skin conditions, soaking too long may over-dry the skin (FDA 2003).

For all products containing lactic acid at concentrations ranging from 3-10%:

- This product contains lactic acid [an alpha-hydroxy acid (AHA)] which may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Limit sun exposure and apply a sunburn protectant while using this product and for a week afterwards.

For all powder products:

- **When using this product** keep powder away from face to avoid inhalation, which can cause breathing problems (FDA 2003).

Contraindication(s):
For products containing zinc acetate or sodium bicarbonate:

- **Do not use** on children less than 2 years of age, unless directed by a doctor/ physician/

health care practitioner/ health care provider/ health care professional (FDA 2003).

For all powder products:

- **Do not use** on broken skin (FDA 2003).

For products marketed to temporarily protect minor cuts, scrapes and/or burns:

- **Do not use** on deep or puncture wounds, animal bites or serious burns (FDA 2003).

Known adverse reaction(s):
No statement required.

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 (FDR), and the current Cosmetic Ingredient Hotlist, when relevant.

STORAGE CONDITION(S)

No statement required.

SPECIFICATIONS

This monograph describes those requirements that are specific to this class of non-prescription drugs and to natural health products (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 and 2 NHP medicinal ingredients only:
The finished product specifications 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 3 non-prescription drug medicinal ingredients:
Requirements described in the Regulations to the Food and Drugs Act must be met.

DRUG FACTS TABLES (Format Optional for Self-Care Category I)

Drug Facts	
Active ingredient (w/w) Dimethicone XX % ……	**Purpose** Protects skin
Uses • Temporarily protects and helps relieve minor skin irritation and itching	
Warnings **For external use only**	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask/consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if symptoms worsen or last for more than 7 days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children 6 months and older: Apply to affected area as needed.	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts	
Active ingredient (w/w) Mineral oil XX % ……	**Purpose** Protects skin
Uses • Temporarily protects and helps relieve minor skin irritation and itching (due to minor cuts, scrapes and burns)	
Warnings **For external use only**	
Do not use on deep or puncture wounds, animal bites or serious burns.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask/consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if symptoms worsen or last for more than 7 days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children 6 months and older: Apply to affected area as needed.	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

Drug Facts
Active ingredient (w/w) **Purpose** Petrolatum XX % …… Protects skin
Uses • Temporarily protects and helps relieve minor skin irritation and itching (due to minor cuts, scrapes and burns)
Warnings **For external use only**
Do not use on deep or puncture wounds, animal bites or serious burns.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask/consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if symptoms worsen or last for more than 7 days.
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.
Directions Adults and children 6 months and older: Apply to affected area as needed.
Other information [If no other information, delete this section]
Inactive ingredients List NMIs
Questions? 1-XXX-XXX-XXXX (or other contact information)

Drug Facts
Active ingredient (w/w) **Purpose** White Petrolatum XX % …… Protects skin
Uses • Temporarily protects and helps relieve minor skin irritation and itching (due to minor cuts, scrapes and burns)
Warnings **For external use only**
Do not use on deep or puncture wounds, animal bites or serious burns.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask/consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if symptoms worsen or last for more than 7 days.
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.
Directions Adults and children 6 months and older: Apply to affected area as needed.
Other information [If no other information, delete this section]
Inactive ingredients List NMIs

Questions? 1-XXX-XXX-XXXX (or other contact information)

REFERENCES

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