

2024-02-23



Diaper Rash Products Monograph

Health Products and Food Branch

FOREWORD

This monograph is intended to replace the existing Diaper Rash Products Monograph of December 7, 2018. This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for diaper rash 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. 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 diaper rash 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.

Notes:

- Text in parentheses is additional optional information which can be included on the Product Licence Application form and 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.

MEDICINAL INGREDIENT(S)

Diaper rash products are classified as natural health products (NHPs) if they contain 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>.

Diaper rash products are classified as non-prescription drugs (NPDs) if they contain at least one ingredient from Table 3 at a quantity listed in the table. 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 information ¹				Quantity ²
		Source ingredient(s)	Source material(s)	Part(s)	Preparation	
(2,5-Dioxo-4-	• Allantoin	Allantoin ³	N/A	N/A	N/A	0.5 – 2%

imidazolidinyl)urea	<ul style="list-style-type: none"> • N-(2,5-Dioxo-4-imidazolidinyl)urea • Glyoxyldiureide • 5-Ureidohydantoin 					
Iron oxide (Fe ₂ O ₃), mixture with zinc oxide	Calamine	Calamine ³	N/A	N/A	N/A	1 – 25%
Kaolin	<ul style="list-style-type: none"> • Argilla • Bolus alba • China clay • Hydrated aluminum silicate • Kaolin • Porcelain clay • White bole 	Kaolin ³	N/A	N/A	N/A	4 – 20%
<i>Zea mays</i>	<ul style="list-style-type: none"> • Corn Starch • Starch – Maize • Topical starch • Zea Mays (Corn) Starch • Zea mays starch 	N/A	<i>Zea mays</i> ³	Seed	Dry	10 – 98%
Zinc oxide	<ul style="list-style-type: none"> • C.I. No. 77947 • Zinc oxide 	Zinc oxide ³	N/A	N/A	N/A	1 – 25% (Zinc oxide) 25 – 40% (Zinc oxide ointment)

1. At least one of the following references was consulted per proper name, common name, and source material: RSC 2024; USP-NF 2023; Nikitakis and Lange 2016; Sweetman 2017.
2. At least one of the following references was consulted for the dosage: US FDA 2021; Krinsky 2017; Sweetman 2017; Leung and Foster 2010.
3. Ingredient must be pharmacopoeial grade.

Table 2: Complementary NHP ingredients (safety only)³

Proper name(s) ¹	Common name(s) ¹	Source information ¹			Quantity ²
		Source material	Organism group	Part	
Cod liver oil	<ul style="list-style-type: none"> • Cod liver oil • Lecoris aselli oleum 	N/A	<ul style="list-style-type: none"> • <i>Melanogrammus aeglefinus</i> • <i>Arctogadus glacialis</i> • <i>Gadus</i> 	Liver	5 – 14%

			<ul style="list-style-type: none"> <i>chalcogrammus</i> <i>Gadus macrocephalus</i> <i>Gadus morhua</i> <i>Gadus ogac</i> <i>Pollachius virens</i> 		
<ul style="list-style-type: none"> Anhydrous lanolin Lanolin 	<ul style="list-style-type: none"> Lanolin Wool fat 	<i>Ovis aries</i>	N/A	Wool	15.5%

1. At least one of the following references was consulted per proper name, common name, and source material: RSC 2024; Sweetman 2017; Nikitakis and Lange 2016; USP-NF 2023
2. The following reference was consulted for the dosage: US FDA 2021.
3. Cod liver oil and Lanolin are not permitted as single medicinal ingredients as these ingredients are not sufficient on their own to support the efficacy of the product.
4. The quantities of vitamin A and vitamin D provided by the cod liver oil in the product must not exceed 3000 µg RAE vitamin A (10 000 IU) and 10 µg vitamin D/cholecalciferol (400 IU) per day (US FDA 2021).

Table 3: NPD medicinal ingredients¹

Proper name(s)	Common name(s)	Quantity
<ul style="list-style-type: none"> alpha-(Trimethylsilyl)-omega-methylpoly(oxy(dimethylsilylene)) Dimethicone Dimethyl polysiloxane 	Dimethicone	1 – 30%
Mineral oil	<ul style="list-style-type: none"> Liquid paraffin Mineral oil Paraffin oil Paraffinum liquidum Petrolatum, liquid White mineral oil 	50 – 100%
Petrolatum	<ul style="list-style-type: none"> Petrolatum Petroleum jelly 	30 – 100%
White petrolatum	<ul style="list-style-type: none"> White petrolatum White petroleum jelly 	30 – 100%

1. See Permitted combinations.

ROUTE(S) OF ADMINISTRATION

Topical

DOSAGE FORM(S)*Acceptable dosage forms for NHPs:*

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- Cream; Gel; Lotion; Oil; Ointment; Paste; Powder; Salve; Solution; Topical liquid; Wipe, medicated

Acceptable dosage forms for NPDs:

- Cream; Gel; Lotion; Oil; Ointment; Paste; Solution; Wipe

USE(S) OR PURPOSE(S)

Self-Care Framework Category I Uses or Purposes:

For products with an ingredient from Table 1 or 3:

- Helps prevent diaper rash (US FDA 2021).
- Protects chafed skin/minor skin irritation due to diaper rash (US FDA 2021).
- Helps protect from wetness that causes diaper rash (US FDA 2021).
- Temporarily helps relieve minor skin irritation due to diaper rash (US FDA 2021).
- Helps treat/ heal diaper rash (US FDA 2021).

DOSE(S)

Subpopulation(s):

Infants 0 to 1 years, Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older.

Quantity:

See Tables 1, 2, and 3 above.

Permitted combinations:

- Any combination of the ingredients listed in Tables 1, 2 and/or 3 is permitted provided each ingredient in the combination is within the specified quantity (US FDA 2021).

Directions for use:

For all products:

- Apply liberally to a clean and dry diaper area as needed (US FDA 2021).

Duration(s) of use:

No statement is required.

RISK INFORMATION

Caution(s) and warning(s):

For all products:

- **For external use only** (US FDA 2021).
- **When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water (US FDA 2021).
- **Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if** symptoms worsen, last for more than 7 days or re-occur within a few days (US FDA 2021).
- **Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

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 all powder products:

- **Do not use** on broken skin (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*, and the current [Cosmetic Ingredient Hotlist](#), when relevant.

STORAGE CONDITION(S)

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

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must comply with the requirements outlined in the [NHPID](#).

For products containing Table 3 NPD medicinal ingredients:

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

For products containing Table 1 and 2 NHP medicinal ingredients only:

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredients (w/w)	
Allantoin	XX %
Zinc oxide	XX %
Lanolin (<i>Ovis aries</i> – wool)	XX %
Uses	
• Helps prevent and treat diaper rash • Protects minor skin irritation due to diaper rash • Helps protect from wetness that causes diaper rash • Temporarily helps relieve minor skin irritation due to diaper rash.	
Warning	
For external use only	
Do not use on broken skin ¹ .	
When using this product • avoid contact with eyes. If contact occurs, rinse thoroughly with water • keep powder away from face to avoid inhalation, which can cause breathing problems ¹ .	
Stop use and ask a health care practitioner if symptoms worsen, last for more than 7 days or reoccur within a few days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions	
Adults, adolescents, children and infants: •Apply liberally to a clean and dry diaper area as needed.	
Other information	
(Add storage information)	
Non-medicinal ingredients	
List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

¹For powder products

For products containing Table 3 NPD medicinal ingredients:

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

Drug Facts	
Active ingredient (w/w) Dimethicone XX %	Purpose Diaper rash treatment
Uses • Helps prevent diaper rash • Protects chafed skin due to diaper rash • Helps protect from wetness that causes diaper rash • Temporarily helps relieve minor skin irritation due to diaper rash • Helps treat diaper rash	
Warnings For external use only.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen, last for more than 7 days or re-occur within a few days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults, children, and infants: Apply liberally to a clean and dry diaper 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 Diaper rash treatment
Uses • Helps prevent diaper rash • Protects chafed skin due to diaper rash • Helps protect from wetness that causes diaper rash • Temporarily helps relieve minor skin irritation due to diaper rash • Helps treat diaper rash	
Warnings For external use only.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen, last for more than 7 days or re-occur within a few days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults, children, and infants: Apply liberally to a clean and dry diaper 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 %	Diaper rash treatment
Uses • Helps prevent diaper rash • Protects chafed skin due to diaper rash • Helps protect from wetness that causes diaper rash • Temporarily helps relieve minor skin irritation due to diaper rash • Helps treat diaper rash	
Warnings For external use only.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen, last for more than 7 days or re-occur within a few days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults, children, and infants: Apply liberally to a clean and dry diaper 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 %	Diaper rash treatment
Uses	
• Helps prevent diaper rash • Protects chafed skin due to diaper rash • Helps protect from wetness that causes diaper rash • Temporarily helps relieve minor skin irritation due to diaper rash • Helps treat diaper rash	
Warnings	
For external use only.	
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a doctor if symptoms worsen, last for more than 7 days or re-occur within a few days.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions	
Adults, children, and infants: Apply liberally to a clean and dry diaper 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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