

2018-12-07



# Diaper Rash Products Monograph

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Health Products and Food Branch

## FOREWORD

This monograph is intended to replace the existing Diaper Rash Products Monograph of May 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 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. 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 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.

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)

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 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) <sup>1</sup>	Common name(s) <sup>1</sup>	Source material(s) <sup>1</sup>				Quantity <sup>2</sup>
		Proper name(s)	Common name(s)	Part(s)	Preparation(s)	
(2,5-Dioxo-4-imidazolidinyl)urea	<ul style="list-style-type: none"> <li>Allantoin</li> <li>N-(2,5-Dioxo-4-imidazolidinyl) urea</li> <li>Glyoxyldiureide</li> <li>5-Ureidohydantoin</li> </ul>	N/A	Allantoin <sup>3</sup>	N/A	N/A	0.5 – 2%
Iron oxide (Fe <sub>2</sub> O <sub>3</sub> ), mixture with zinc oxide	Calamine	N/A	Calamine <sup>3</sup>	N/A	N/A	1 – 25%
Kaolin	<ul style="list-style-type: none"> <li>Argilla</li> <li>Bolus alba</li> <li>China clay</li> <li>Hydrated aluminum silicate</li> <li>Kaolin</li> <li>Porcelain clay</li> <li>White bole</li> </ul>	N/A	Kaolin <sup>3</sup>	N/A	N/A	4 – 20%
Talc	<ul style="list-style-type: none"> <li>Talc</li> <li>Talcum</li> </ul>	N/A	Talc <sup>3</sup>	N/A	N/A	45 – 100%
<i>Zea mays</i>	<ul style="list-style-type: none"> <li>Corn Starch</li> <li>Starch – Maize</li> <li>Topical starch</li> <li>Zea Mays (Corn) Starch</li> <li>Zea mays starch</li> </ul>	<i>Zea mays</i> <sup>3</sup>	S/O	Seed	Dried	10 – 98%
Zinc oxide	<ul style="list-style-type: none"> <li>C.I. No. 77947</li> <li>Zinc oxide</li> </ul>	N/A	Zinc oxide <sup>3</sup>	N/A	N/A	1 – 25% (Zinc oxide)  1 – 40% (Zinc oxide)



## **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 all products:

- Helps prevent diaper rash (FDA 2003).
- Protects chafed skin due to diaper rash (FDA 2003).
- Helps protect from wetness that causes diaper rash (FDA 2003).

For Allantoin, Calamine, Kaolin, Zinc oxide, Dimethicone, Mineral oil, Petrolatum, White petrolatum:

- Temporarily protects and helps relieve minor skin irritation due to diaper rash (FDA 2003).

For products containing Calamine, Kaolin and/or Zinc oxide:

- Helps treat/ heal diaper rash (FDA 2003).

## **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 (FDA 2003).

### **Directions for use:**

#### **For all products:**

- Apply liberally to a clean and dry diaper area as needed (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 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 (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 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)**

<b>Drug Facts</b>	
<b>Active ingredient (w/w)</b> Dimethicone XX % .....	<b>Purpose</b> Diaper rash treatment
<b>Uses</b> <ul style="list-style-type: none"> <li>• Helps prevent diaper rash</li> <li>• Protects chafed skin due to diaper rash</li> <li>• Helps protect from wetness that causes diaper rash</li> <li>• Temporarily protects and helps relieve minor skin irritation due to diaper rash</li> </ul>	
<b>Warnings</b> <b>For external use only.</b>	
<b>When using this product</b> avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
<b>Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if</b> symptoms worsen or last for more than 7 days.	
<b>Keep out of reach of children.</b> If swallowed, call a poison control centre or get medical help right away.	
<b>Directions</b> Adults, children, and infants: Apply liberally to a clean and dry diaper area as needed.	
<b>Other information</b> [If no other information, delete this section]	
<b>Inactive ingredients</b> List NMI's	
<b>Questions?</b> 1-XXX-XXX-XXXX (or other contact information)	

<b>Drug Facts</b>	
<b>Active ingredient (w/w)</b> Mineral oil XX % .....	<b>Purpose</b> Diaper rash treatment
<b>Uses</b> <ul style="list-style-type: none"> <li>• Helps prevent diaper rash</li> <li>• Protects chafed skin due to diaper rash</li> <li>• Helps protect from wetness that causes diaper rash</li> <li>• Temporarily protects and helps relieve minor skin irritation due to diaper rash</li> </ul>	
<b>Warnings</b> <b>For external use only.</b>	
<b>When using this product</b> avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
<b>Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if</b> symptoms worsen or last for more than 7 days.	
<b>Keep out of reach of children.</b> If swallowed, call a poison control centre or get medical help right away.	
<b>Directions</b> Adults, children, and infants: Apply liberally to a clean and dry diaper area as needed.	
<b>Other information</b> [If no other information, delete this section]	
<b>Inactive ingredients</b> List NMIs	
<b>Questions?</b> 1-XXX-XXX-XXXX (or other contact information)	



<b>Drug Facts</b>	
<b>Active ingredient (w/w)</b> Petrolatum XX % .....	<b>Purpose</b> Diaper rash treatment
<b>Uses</b> <ul style="list-style-type: none"> <li>• Helps prevent diaper rash</li> <li>• Protects chafed skin due to diaper rash</li> <li>• Helps protect from wetness that causes diaper rash</li> <li>• Temporarily protects and helps relieve minor skin irritation due to diaper rash</li> </ul>	
<b>Warnings</b> <b>For external use only.</b>	
<b>When using this product</b> avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
<b>Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if</b> symptoms worsen or last for more than 7 days.	
<b>Keep out of reach of children.</b> If swallowed, call a poison control centre or get medical help right away.	
<b>Directions</b> Adults, children, and infants: Apply liberally to a clean and dry diaper area as needed.	
<b>Other information</b> [If no other information, delete this section]	
<b>Inactive ingredients</b> List NMIs	
<b>Questions?</b> 1-XXX-XXX-XXXX (or other contact information)	

<b>Drug Facts</b>	
<b>Active ingredient (w/w)</b> White petrolatum XX % .....	<b>Purpose</b> Diaper rash treatment
<b>Uses</b> <ul style="list-style-type: none"> <li>• Helps prevent diaper rash</li> <li>• Protects chafed skin due to diaper rash</li> <li>• Helps protect from wetness that causes diaper rash</li> <li>• Temporarily protects and helps relieve minor skin irritation due to diaper rash</li> </ul>	
<b>Warnings</b> <b>For external use only.</b>	
<b>When using this product</b> avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
<b>Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if</b> symptoms worsen or last for more than 7 days.	
<b>Keep out of reach of children.</b> If swallowed, call a poison control centre or get medical help right away.	
<b>Directions</b> Adults, children, and infants: Apply liberally to a clean and dry diaper area as needed.	
<b>Other information</b> [If no other information, delete this section]	
<b>Inactive ingredients</b> List NMIs	
<b>Questions?</b> 1-XXX-XXX-XXXX (or other contact information)	

## REFERENCES

FDA 2003: USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 347. Skin protectant products for Over-the-Counter Human Use, Final Monograph; 2003. [Accessed 2018-09-28]. Available at: <https://www.gpo.gov/fdsys/pkg/FR-2003-06-04/pdf/03-13751.pdf>

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