DIAPER RASH PRODUCTS

Date: April 19, 2007

Diaper rash products are classified as natural health products (NHPs) if they contain ingredients from Table 1 only. Applicants applying for a natural product number (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

Diaper rash products are classified as drugs if they contain at least one ingredient at a concentration listed in Table 2 (these ingredients must be declared as medicinal), and make a claim that the product is intended for prevention of diaper rash, protection from wetness that causes diaper rash, protection of chafed skin or temporary relief of minor skin irritation caused by diaper rash. Applicants applying for a drug identification number (DIN) can access the appropriate forms and guidance at:
http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index_e.html

Table 1: NHP medicinal ingredients[1]

Proper name(s)	Common name(s)	Source material(s)	Quantity
Allantoin (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Allantoin** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) **(2,5-Dioxo-4-imidazolidinyl) urea** (USP 30; O'Neil et al. 2001) **Glyoxyldiureide** (Sweetman 2007; Gottschalck and McEwen 2006; O'Neil et al. 2001) **5-Ureidohydantoin** (Sweetman 2007; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Allantoin*** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) CAS No. 000097-59-6 +	**0.5-2%** (FDA 1990)
Calamine (Sweetman 2007; USP	**Calamine** (Sweetman 2007; USP	**Calamine*** (Sweetman 2007; USP	**1-25%** (FDA 1990)

Proper name(s)	Common name(s)	Source material(s)	Quantity
30; Gottschalck and McEwen 2006)	30; Gottschalck and McEwen 2006)	30; Gottschalck and McEwen 2006) CAS No. 008011-96-9 +	
Cod liver oil[1] (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Cod liver oil** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Cod liver (*Gadus morhua* L. (Gadidae) and other species of Gadidae)** (Sweetman 2007; USP 30; O'Neil et al. 2001) CAS No. 008001-69-2 +	**5-14%** (FDA 1990)
Corn starch/Topical starch (NF 25; Sweetman 2007; USP 30; Gottschalck and McEwen 2006)	**Corn starch/Topical starch** (NF 25; Sweetman 2007; USP 30; Gottschalck and McEwen 2006)	**Corn kernel (*Zea mays* L. (Poaceae) kernel)** (USP 30)	**10-98%** (FDA 1990)
Kaolin (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Kaolin** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) **Argilla** (O'Neil et al. 2001) **Bolus alba** (Sweetman 2007; Gottschalck and McEwen 2006; O'Neil et al. 2001) **China clay** (Gottschalck and McEwen 2006; O'Neil et al. 2001) **Hydrated aluminum silicate** (Sweetman 2007; USP 30; O'Neil et al. 2001) **Porcelain clay** (O'Neil et al. 2001) **White bole** (O'Neil et al. 2001)	**Kaolin*** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) CAS No. 001332-58-7 +	**4-20%** (FDA 1990)

Proper name(s)	Common name(s)	Source material(s)	Quantity
Lanolin[1] (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Lanolin** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) **Wool fat** (Sweetman 2007; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Sheep wool (*Ovis aries* L. (Bovidae) wool)** (Sweetman 2007; USP 30; O'Neil et al. 2001) CAS No. 008006-54-0 [+]	**15.5%** (FDA 1990)
Talc (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Talc** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) **Talcum** (Sweetman 2007; O'Neil et al. 2001)	**Talc*** (Sweetman 2007; USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) CAS No. 14807-96-6 [+]	**45-100%** (FDA 1990)
Zinc oxide (USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Zinc oxide** (USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001)	**Zinc oxide*** (USP 30; Gottschalck and McEwen 2006; O'Neil et al. 2001) CAS No. 001314-13-2 [+]	**1-25%**[2] (FDA 1990)

*Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the *Compendium of Monographs* Guidance Document) or requires citation of an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File's registered owner.

[+]The CAS number may be provided as additional information.

[1] See Permitted combinations.

[2] Note that 1-40% zinc oxide is permitted in ointment dosage form, e.g. petrolatum based preparation. See introductory note at the beginning of the monograph for clarification on product classification.

Table 2: Drug medicinal ingredients[1]

Medicinal ingredient preferred name	Quantity
Dimethicone	**1-30%**
Mineral oil	**50-100%**
Petrolatum	**30-100%**
White petrolatum	**30-100%**

[1] See Permitted combinations.

Route(s) of administration: Topical (FDA 1990)

Dosage form(s): Those that are suited to the allowable route of administration, and are established, scientifically recognized dosage forms.

Use(s) or Purpose(s): Statement(s) to the effect of:

For all products:
- Helps prevent diaper rash (FDA 1990).
- Protects chafed skin (or minor skin irritation) due to diaper rash (FDA 1990).
- Helps protect from wetness that causes diaper rash (FDA 1990).
- Temporarily helps relieve minor skin irritation due to diaper rash (FDA 1990).

For products containing calamine, corn starch, kaolin, talc and/or zinc oxide:
Helps treat diaper rash (FDA 1990).

Dose(s):

Subpopulation: Subpopulation does not need to be specified.

Quantity: See Tables 1 and 2 above.

Permitted combinations:
- Cod liver oil and lanolin are not allowed as single medicinal ingredients (FDA 1990).
- Any combination of the ingredients listed in Table 1 and/or 2 is permitted provided each ingredient in the combination is within the specified quantity (FDA 1990).

Directions for use: Statement(s) to the effect of:

For all products:
Apply liberally to a clean and dry diaper area as needed (FDA 1990).

Duration of use: No statement is required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

For all products:
- For external use only.
- Avoid contact with eyes.
- Consult a healthcare practitioner if symptoms worsen or last for more than 7 days (Berardi et al. 2002).

For all powder products:
- Keep out of reach of children (FDA 1990).

- Keep powder away from face to avoid inhalation, which can cause breathing problems (FDA 1990).
- Not intended for use on broken skin (FDA 1990).

Contraindication(s): No reports known.

Known adverse reactions: No reports known.

Non-medicinal ingredients: The *International Nomenclature for Cosmetic Ingredients* (INCI) will be accepted.

For products containing Table 1 medicinal ingredients only:
Ingredients must be chosen from the current NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

Other ingredients currently accepted as cosmetic ingredients will also be considered.

Specifications: This monograph describes those requirements that are specific to this class of 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.

Note that for products containing Table 1 medicinal ingredients only:
Products must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.

For products containing Table 2 drug medicinal ingredients:
Requirements described in the *Regulations to the Food and Drugs Act* must be met.

References:

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Rulemaking for Diaper Rash Drug Products; 1990. [Accessed 2007-03-20]. Available at: http://www.fda.gov/cder/otcmonographs/Skin_Protectant/skin_protectant_diaper_rash_PR_19900620.pdf

Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook, 11th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2006.

NF 25: United States Pharmacopeia and the National Formulary (USP 30/NF 25). Rockville (MD): The United States Pharmacopeial Convention, Inc.; 2007.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 13th edition. Whitehouse Station (NJ): Merck & Co., Inc; 2001.

Sweetman SC, editor. Martindale: The Complete Drug Reference, 35th edition. London (UK): Pharmaceutical Press; 2007.

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