

Toxicological Assessment of Body Lotion

This safety assessment relates to the formulation described below. If the information below is incorrect, please amend and resubmit for reassessment.

Better Nature International Ltd

Formulation Ref: S012

Final Retailer: N/A

CONSUMER EXPOSURE

| | |
|--|----------------------------------|
| Product Class | Body lotion |
| Physical form | Lotion |
| Amount of product used per application | 7.82g per day [CREMe 2005 study] |
| Part of body exposed to undiluted product | Whole body skin |
| Frequency of exposure to undiluted product | Once a day |
| Time of exposure to undiluted product | Left on |

PRODUCT FORMULATION

The chemical names shown below refer to the raw materials used to formulate this product. The identity of the raw materials is not necessarily based on the International Nomenclature of Cosmetic Ingredients (INCI) and does not represent the INCI listing that must be shown on the product label and is for assessment purposes only. An outline INCI label can be prepared on request.

| Chemical Name | Conc | % Active | Active in Product | CAS No | Einecs No |
|------------------------------------|-------|----------|-------------------|--|-----------------------|
| AQUA | 90.79 | 100 | 90.79 | 7732-18-5 | 231-791-2 |
| MINERAL OIL (PARAFFINUM LIQUIDUM) | 2 | 100 | 2 | 8012-95-1 / 8042-47-5 | 232-384-2 / 232-455-8 |
| CETEARYL ALCOHOL | 2 | 100 | 2 | 67782-27-0 / 8005-44-5 | 287-008-8 |
| GLYCERYL STEARATE | 1.5 | 100 | 1.5 | 123-84-4 / 31588-31-1 | 204-884-4 / 250-705-4 |
| GLYCERIN | 1 | 100 | 1 | 56-81-5 / 8013-25-0 | 200-289-5 |
| STEARIC ACID | 1 | 100 | 1 | 57-11-4 | 200-313-4 |
| SODIUM LAURYL SULFATE | 0.4 | 100 | .4 | 151-21-3 / 68585-47-7 / 68955-19-1 / 73296-89-6 | 205-788-1 / 277-382-3 |
| CARBOMER (BENZENE FREE) | 0.25 | 100 | .25 | 9007-20-9 / 9003-01-4 / 76050-42-5 / 9082-04-8 / 9007-16-3 / 9007-17-4 | POLYMER |
| TRIETHANOLAMINE | 0.25 | 100 | .25 | 102-71-6 | 203-049-8 |
| METHYLPARABEN | 0.2 | 100 | .2 | 99-76-3 | 202-785-7 |
| PERFUME UE00001 WARM VANILLA SUGAR | 0.2 | 100 | .2 | MIXTURE | MIXTURE |
| PROPYLPARABEN | 0.1 | 100 | .1 | 94-13-3 | 202-307-7 |
| DIAZOLIDINYL UREA | 0.25 | 100 | .25 | 78491-02-8 | 278-928-2 |
| DISODIUM EDTA | 0.05 | 100 | .05 | 139-33-3 / 6381-92-6 | 205-358-3 |
| CI 42090 (FD&C BLUE 1) | 0.005 | 100 | .005 | 3844-45-9 | 223-338-8 |
| CI 17200 (D&C RED 33) | 0.005 | 100 | .005 | 3567-88-6 | 222-858-8 |

The following perfume ingredients must, under the 7th amendment to the EU Directive on the Safety of Cosmetics, be declared on the product label

Hydroxyisohexyl 3-cyclohexene carboxaldehyde

Hexyl cinnamal

SAFETY LABELLING

TOXICOLOGICAL & REGULATORY REVIEW

A formula for a body lotion which contains allergens that must be declared on the product label however these are not at levels likely to cause skin sensitization.

If used as directed, use of this product should be uneventful.

Effects of the product as supplied on the skin

The formulation as supplied may cause only minimal skin irritation even if exposure is prolonged and/or repeated.

There are low concentrations of substances present in this product which have allergenic activity. The concentrations present are sufficiently low for the level of use to ensure that people do not become sensitised. However, people who are already sensitised to a substance may react adversely to any product containing that substance even when present at extremely low concentrations.

Exposure to this product is unlikely to result in phototoxic effects.

Unlikely to cause damage to internal organs following absorption through the skin.

Effects of the product as supplied on the eye

Accidental exposure of the eye to the formulation as supplied may result in slight eye irritation.

Effects following ingestion of the product as supplied

The formulation as supplied if swallowed is unlikely to cause harm.

Effects of inhaling the product

Inhalation is an unlikely route of exposure

Overall product safety statement

The ingredients are legally permitted as per EU Directive 76/768/EEC and its amendments. They must comply with the relevant purity standards. The product must be manufactured in accordance with EU guidance on Good Manufacturing Practice.

Under normal or reasonably foreseeable conditions of use, product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give users the level of safety they can reasonably expect.

Cosmetic Regulations Product Safety Assessor


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Date: 26 Jan 2011

INGREDIENT TOXICOLOGY REVIEWS

| Chemicals present | Conc | Toxicological Summary | Regulatory control |
|------------------------------------|-------|---|------------------------------|
| AQUA | 90.79 | Cosmetic function : Solvent. Simply water unlikely to cause irritation, allergy or harm. The source of water should be known and either a deionised or high purity grade free from bacteriological contamination should be used in cosmetic products. | Not controlled |
| MINERAL OIL (PARAFFINUM LIQUIDUM) | 2 | Cosmetic Functions : Antistatic / Emollient / Perfuming / Skin Protecting / Solvent. A material with low potential to irritate the skin but prolonged contact may help defat the skin. If ingested small amounts may be accumulated within the body. This material should be restricted to use in skin/hair care formulations. IP346 DMSO Extract should be <3%. For products that may be ingested a food grade mineral oil should be used. The CAS number supplied for this mineral oil is for an oil which falls under the title of 'Other Petroleum Substances' in CONCAWE guidance documents. This would mean that it is not automatically 'highly refined' and that each grade should be treated on a case-by-case basis. The supplier is advised to check that the grade is suitable for use in cosmetic products and if used in a lip product also suitable as a food grade material. Classified as R65 May cause lung damage if swallowed. (Concawe reference). Several ADIs for mineral oil (2002)2 have been set by the JECFA: - For mineral oil with high viscosity: ADI of 0-20 mg/kg body weight (b.w.). - For mineral oil with medium and low viscosity: temporary ADIs: Class I: 0-10 mg/kg b.w. and Class II and III: 0-0.01 mg/kg b.w. A recent scientific opinion from the European Food Safety Authority (EFSA Journal 2009;7(11):1387, 1-39), on high viscosity mineral oil as a food additive established an ADI of 12mg/kg bw/day for high viscosity mineral oils estimating that the potential dietary exposure would be approximately 13mg/kg bw/day for adults and 16mg/kg bw/day for children. The NOAEL for HVMO was considered to be 1200mg/kg bw/day. Toxicological data: Acute toxicity, LD50. Oral. Rat. > 5000 mg/kg; Acute toxicity, LD50. Skin. Rabbit. > 2000 mg/kg; Acute toxicity, LC50. 4 hours. Inhalation. Rat. > 5200 mg/m3; Negative to Modified Ames Test; Does not contain any IARC Group 1, 2(a) or 2(b) Listed Chemicals. Hydrocarbons by IP 346 <1% ingestion may cause: Stomach pain, Diarrhoea. | Controlled |
| CETEARYL ALCOHOL | 2 | Cosmetic Functions : Emollient / Emulsifying / Emulsion Stabilising / Foam Boosting / Opacifying / Surfactant / Viscosity Controlling / Viscosity Increasing Agent-Aqueous & Non-aqueous. Fatty alcohols mix predominantly of cetyl and stearyl alcohols (C16-18) with low potential to irritate the eye and skin. Unlikely to cause adverse effects at typical concentrations used. | Not controlled |
| GLYCERYL STEARATE | 1.5 | Function: emollients, emulsifiers, and stabilizers A monofatty ester of glycerol and the esterification products of glycerine and stearic acid. In acute oral toxicity studies in rats, both ingredients were slightly toxic. Five percent Glyceryl Stearate did not promote the carcinogenicity of DMBA in mouse skin. Primary eye irritation studies, at concentrations up to 100%, were mildly irritating or nonirritating to rabbits. Single and Repeated Insult Patch Tests showed both ingredients to be nonsensitizing and nonirritating. Products containing 2% Glyceryl Stearate were nonphototoxic and nonphotoallergenic. Such esters have a good history of being of low potential to irritate the skin and eye and are considered safe at the present practices of use Reference: International Journal of Toxicology, Vol. 1, No. 4, 169-182 (1982) | |
| GLYCERIN | 1 | Cosmetic Functions : Denaturant / Humectant / Perfuming / Solvent / Fragrance Ingredient / Hair & Skin Conditioning Agent / Oral Care Agent / Skin Protectant / Viscosity Decreasing Agent. In the United States, may be used as an active ingredient in OTC drug products and as a cough remedy. Typical suitable amounts for adults are 10 ml in water 4 times per day. For children 1-4 years 2.5ml diluted in water 3-4 times a day. A polyhydric alcohol with minimal potential to irritate the skin or eyes. If ingested in massive amounts it may induce osmotic effects in the GI tract. Canada, Cosmetic Ingredient Hotlist September 2009 states; Manufacturers of oral and leave-on products containing glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP). | Not controlled |
| STEARIC ACID | 1 | Cosmetic Functions: Cleaning / Emulsifying / Emulsion stabilising / Masking / Refatting / Surfactant. This fatty acid has a low potential to irritate the skin. When added as super fatting agent to soap reduces the skin and eye irritancy potential. Animal studies indicate that these fatty acids are not eye irritants, skin sensitizers or photosensitizers. Formulations containing stearic, myristic and oleic acids up to 13% were not primary or cumulative skin irritants nor sensitizers. Little acute toxicity observed with Oleic, Lauric, Palmitic, Myristic, or Stearic Acid when feeding to rats at 15 to 19g/kg. Feeding of oleic acid in a chronic study resulted in normal growth and health except the reproductive capacity of female rat was impaired. (CIR Compendium 2009) | |
| SODIUM LAURYL SULFATE | .4 | As supplied irritating to skin and eyes. When mixed with other surface active molecules the intrinsic potential to irritate the skin or eyes is markedly reduced. Use at up to 12% active in a rinse off product is unlikely to cause skin irritancy. Sodium lauryl sulfate has been reviewed by the CIR expert panel (JACT 2(7):127-181, 1993 confirmed 06/02; IJT 24(S1):89-96, 2005) and shown to be safe for use up to 25% in products intended for rinse off application. The panel also concluded it was suitable for leave-on cosmetic products intended for continuous contact up to a maximum of 1%. | |
| CARBOMER (BENZENE FREE) | .25 | Cosmetic Functions : Emulsion Stabilising / Gel Forming / Viscosity Controlling / Viscosity Increasing Agent-Aqueous. A polymeric thickening agent also used as film formers and binding agents. Polyacrylic acids have a low potential to cause irritation or allergy. The Cosmetic Ingredients Review Panel reaffirmed its conclusion that carbomers showed low potential for skin irritation and sensitization at concentrations up to 100%. It also referenced that Carbomers have low toxicity if ingested. Some grades of Carbomer contain benzene as a result of the manufacturing process. The EU Cosmetics Directive prohibits the use of benzene except for traces that are technically unavoidable or cannot be reasonably removed in Good Manufacturing Practice and provided such traces cannot cause harm to human health. As there are benzene-free grades that are available, the grade used must not contain benzene in order to comply with the EU Cosmetic Product Directive. This particular grade is of a benzene-free grade and considered as a suitable and acceptable purity for use in cosmetic products. Carbomers are considered as a safe cosmetic ingredient in present practices of use. | Not controlled |
| TRIETHANOLAMINE | .25 | Cosmetic Functions : Buffering / Emulsifying / Masking / Surfactant. A base soluble in water and organic solvents. In free base form irritant to skin and eye, when ionised has lower potential to cause irritation. Used in cosmetics to neutralise polymers or to form soaps. Mild skin and eye irritants leading to restriction in prolonged contact with skin at higher concentrations but little skin sensitisation in clinical testing at the typical low concentrations. Nonmutagenic in the Ames test and no carcinogenic activity in dermal data. Do not use with nitrosating systems such as bronopol. Minimum purity: 99 per cent. Maximum secondary amine content: 0.5 per cent (applies to raw materials) Maximum nitrosamine content: 50 µg/kg (applies to raw materials). Keep in nitrite free containers. Maximum of 2.5% in leave-on products. No limit in rinse-off products. CIR concludes safe for use in rinse-off products; but up to 5% in leave-on cosmetic products; and should not be used in products containing N-nitrosating agents. | Controlled |
| METHYLPARABEN | .2 | Methylparaben is one of a family of para-hydroxybenzoate commonly Parabens). They are antimicrobial preservatives particularly effective against yeast and molds. Methylparaben has a low acute oral toxicity (LD ₅₀ oral mouse >8000mg/kg). Widely used in cosmetic products, pharmaceuticals, foods and in beverages. Permitted in cosmetic products in EU and USA at 0.4% (as the acid single paraben) or at 0.8% (as mixture of parabens). Concern with their safe use followed observation of different degrees of estrogenic activity with the individual parabens in <i>in vitro</i> tests (cited in Gandy, R et al, Crit. Rev. Toxicol, 2005, 35(5), 435-58, Darbra, P D et al, 2004). However, evaluation of their toxicological effects by expert panels (namely, SCCP/01706, CIR, 2006) found their effect to be generally minimal compared to endogenous estrogenic activities in the human body. Some of the evidence for their unlikely adverse effects were as follows: they are hydrolyzed before they have the opportunity to accumulate inside the skin; penetration into the skin's stratum corneum depends on their ester chain length; margin of safety (MOS) of 6000 and 3000 for the single and mixture parabens respectively in adults and 1890 and 940 for infants. Furthermore, about 20 years of clinical patch testing had not indicated an increase in the overall dermatitis patients. The conclusion is that they are practically not irritating, nor sensitising and not carcinogenic to normal skin at concentrations used in cosmetic products. *FDA believes that at the present time there is no reason for consumers to be concerned about the use of cosmetics containing parabens* (FDA, 2009). Similarly the European Food Services Authority (EFSA) adopted the acceptable daily index ADI) of 0 - 10 mg/kg body weight for the sum of Methyl- and Ethylparabens and their salts in food. Evaluation of new data on these preservatives continues and any updated information will be reflected in future toxicological assessments. | Approved preservative |
| PERFUME UE00001 WARM VANILLA SUGAR | .2 | As supplied classified as R43, May cause sensitisation by skin contact. The perfume should comply to IFRA Code of Practice and standards. When used at not more than 11.11% in a leave-on product the concentration of each allergen will be at least 10 times lower than that shown not to induce allergy in human volunteers. | Not controlled |
| PROPYLPARABEN | .1 | A preservative with a good history of safe use. Inevitably with a preservative used as widely as this, some people have been shown to be sensitive to this substance but the incidence of reaction is very low. A useful preservative in combination with other preservatives. | Approved preservative |
| DIAZOLIDINYL UREA | .25 | Approved preservative for use in all product types. Diazolidinyl urea is a formaldehyde releaser which contributes to the skin sensitivity of this preservative. Maximum allowable concentration is 0.5%. Diazolidinyl urea is a heterocyclic urea. Data from CIR Compendium 2009, slightly toxic to rats in acute oral studies but was relatively non-toxic in subchronic studies, not an ocular or skin irritant in rabbits. In three studies using a maximization procedure, Diazolidinyl Urea was a mild sensitizer in guinea pigs, but was not a sensitizer in a fourth study in which non-maximization procedure was used. Non-mutagenic when tested in the Ames test, or in the micronucleus assay. Mild cumulative skin irritant in humans when tested at 0.4%. Non sensitizing (RIPT study) on non-patient volunteers. Fifty-seven of 2385 patients had allergic reactions to 1.0 percent Diazolidinyl Urea. It was not a photosensitizer at 0.25 percent. The CIR panel concluded that this preservative is safe for use not exceeding 0.5%. | Approved preservative |
| DISODIUM EDTA | .05 | Cosmetic Functions : Chelating / Viscosity Controlling. EDTA is used as a chelating agent in cosmetic formulations. The CIR expert panel concluded that a maximum safe concentration of EDTA and its salts is 25% for inhalation of aerosol products so no concerns over adverse effects from typical concentrations. The ability of these complexes to aid penetration of certain compounds, particularly calcium based compounds, must also be taken into account when used with other chemicals that are considered safe because they are not significantly absorbed. Unlikely to add to the toxicity of rinse off products. | |
| CI 42090 (FD&C BLUE 1) | .005 | A dye thoroughly tested for use as a food additive (an FDA colour) and cosmetic dye. Unlikely to cause adverse effects when used in cosmetics. Permitted in US for use in all cosmetic products including those used near the eye. Unlikely to cause adverse effects at the typical concentrations used in cosmetics. Widely used and well accepted in cosmetic products. Canada cosmetic use; coal tar dye permitted in the area of the eye. The Cosmetics Directive 2009/36/EC has amended the use of this colour to be used in non oxidative hair dyes at a maximum concentration of 0.5%. This does not effect its use in other permitted cosmetic product types. Approved colour for use in finger paints EN71:7 | Approved colour all products |
| CI 17200 (D&C RED 33) | .005 | A monoazo dye thoroughly tested for use as a food additive (an FDA colour) and cosmetic dye. Unlikely to cause adverse effects when used in cosmetics. Permitted in US for use in all cosmetic products including those used near the eye. Permitted in US in all cosmetic products 74.2333 Lip products (3% max) | Approved colour all products |