

# Toxicological Assessment of Shower Gel

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: S011

Final Retailer: N/A

## CONSUMER EXPOSURE

Product Class	Shower gel
Physical form	Gel
Amount of product used per application	8g per application [SCCNFP/0321/02]
Part of body exposed to undiluted product	Hands, Hair, general body, possibly eyes
Frequency of exposure to undiluted product	Twice a day
Time of exposure to undiluted product	Washed off immediately
Dilution Factor	Diluted 1 to 200 with water
Part of body exposed to diluted product	Hands, Hair, general body, possibly eyes
Time of exposure to the diluted product	Washed off immediately
Frequency of exposure to the diluted product	Twice a day

## 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	Active in			CAS No	Einecs No
	Conc	% Active	Product		
AQUA	87.2985	100	87.2985	7732-18-5	231-791-2
SODIUM LAURETH SULFATE	6	70	4.2	1335-72-4/3088-31-1/9004-82-4/88585-34-2/88585-34-2 / 68891-38-3 / 81648-58-5 / 98130-61-9	500-223-8 / 1/221-418-0 / 500-234-8
COCAMIDOPROPYL BETAINE	1.5	35	.525	61789-40-0	283-058-8
SODIUM CHLORIDE	3.8	100	3.8	7847-14-5	231-598-3
COCAMIDE DEA	1	82	.82	68603-42-9/ 61791-31-9/ 68155-07-7	271-657-0/ 263-163-9/ 232-483-0
PERFUME UE00002 LAVENDER VANILLA	0.25	100	.25	MIXTURE	MIXTURE
DISODIUM EDTA	0.1	98	.098	139-33-3 / 6381-92-6	205-358-3
CITRIC ACID	0.04	89	.0388	77-92-9 / 5949-29-1	201-069-1
CI 42090 ( FD&C BLUE 1)	0.005	100	.005	3844-45-9	223-339-8
CI 17200 (D&C RED 33)	0.005	100	.005	3567-88-6	222-859-9
METHYLCHLOROISOTHIAZOLINONE	0.001125	100	.001125	28172-55-4	247-500-7
METHYLISOTHIAZOLINONE	0.000375	100	.000375	2682-20-4	220-239-8

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

Linalool

## SAFETY LABELLING

Rinse eyes immediately if product comes into contact with them

---

**TOXICOLOGICAL & REGULATORY REVIEW**

---

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

Cocamide DEA has a limit of a 5% of maximum secondary amine content and this applies to a raw material (REF. Cosmetic Directive 76/768/EEC, Annex III/60). This need to be checked by the supplier.

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 skin irritation especially if exposure is prolonged and/or repeated. However, under normal conditions of use exposure time will be short and the likelihood of causing skin irritation will be very low. 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 on the skin, of the product as diluted for use**

Contact with the dilute solution is unlikely to cause skin irritation even if contact is prolonged and/or repeated.

**Effects of the product as supplied on the eye**

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

**Effects on the eye, of the product as diluted for use**

Accidental exposure of the eye to the diluted product may result in slight eye irritation.

**Effects following ingestion of the product as supplied**

The formulation as supplied if swallowed is likely to cause irritation to the mouth and upper digestive tract.

**Effects on ingestion, of the product as diluted for use**

The diluted product 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.

Rinse eyes immediately if product comes into contact with them

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**

**Intertek**

*A T Grotkiewicz*

A T Grotkiewicz MSc, EurChem, CChem, CSci, MRSC

Centre Court, Meridian Business Park, Leicester. LE19 1WD

**Date:** 01 Feb 2011

---

INGREDIENT TOXICOLOGY REVIEWS

Chemicals present	Conc	Toxicological Summary	Regulatory control	
AQUA	87.2985	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	
SODIUM LAURETH SULFATE	4.2	Cosmetic Functions : Cleansing / Emulsifying / Foaming / Surfactant. As supplied the product is significantly irritating to the skin and eyes. The neat product is classified as R41. Risk of serious damage to eyes and R38, Irritating to skin. When diluted for use the irritancy potential will be reduced especially in the presence of other surfactant molecules which reduce the critical micellar concentration of the surfactant mix. Used mainly in rinse-off products at typical concentrations 10-20%.		
COCAMIDOPROPYL BETAINE	.525	Cosmetic Functions : Antistatic / Cleansing / Foam Boosting / Hair Conditioning / Surfactant / Viscosity Controlling. Irritating to the skin and eye but with potential to reduce the irritancy of surfactant mixtures by reducing the critical micellar concentration. The undiluted material may cause gastrointestinal irritation if swallowed. The level of free amine needs to be kept as low as possible to reduce the risks of sensitisation. Oral LD50 (mice) 4.91 g/kg and 7.45 ml/kg (rat). A 28 day study induced lesions in non-glandular portion of the stomach at high doses. Ref Suppliers data The CIR Expert panel conclude that CAPB is safe to use in rinse-off products but should not exceed 3.0 % in products that are intended to remain in contact with the skin for prolonged periods.		
SODIUM CHLORIDE	3.8	Cosmetic Functions : Bulking / Masking / Oral Care / Viscosity controlling / Viscosity Increasing Agent-Aqueous / Flavouring Agent. Commonly used as a viscosity controller at up to 8%. Unlikely to alter the toxic properties of the formulation although the change in viscosity may alter the bioavailability of components.	Not controlled	
COCAMIDE DEA	.82	Cosmetic Functions : Emulsifying / Emulsion Stabilising / Foam Boosting / Surfactant / Viscosity Controlling / Viscosity Increasing Agent-Aqueous. Classified as Risk of serious damage to eyes. Prolonged skin contact to the undiluted may cause defatting. Will interact with other surfactants to reduce overall irritancy. Not reported to be a skin sensitizer. Ingestion of the undiluted material may induce gastric irritation. LD50 >2000mg/kg (OECD401). Non Irritant at 5% (eyes rabbit) (OECD 405)At in use levels of up to 5% unlikely to have any adverse effect on skin or eyes or if swallowed. Maximum secondary amine content: 0.5% in the finished cosmetic product. Other limitations and requirements; - Do not use with nitrosating systems - Maximum secondary amine content: 5% (applies to raw materials) - Maximum nitrosamine content: 50 microgram/kg - Keep in nitrite-free containers	Controlled	Do not use with nitrosating systems (Bronopol) III/1, 60-Must not contain > 5% DEA
PERFUME UE00002 LAVENDER VANILLA	.25	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 6.36% 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	
DISODIUM EDTA	.098	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.		
CITRIC ACID	.0396	Cosmetic Functions : Buffering / Chelating / Fragrance Ingredient / Masking / pH Adjuster. An organic acid irritating to the eye in undiluted form. A common constituent of foods. At typical levels in cosmetics unlikely to cause adverse effects.  Canadian Holist states AHA's-Permitted at total concentrations equal to or less than 10%, with a pH equal to or greater than 3.5. All leave-on skin products containing AHAs at concentrations equal to or greater than 3% shall carry cautionary statements like "Avoid contact with the eyes" and for certain products "It is recommended that prior to exposure to the sun, users cover areas where AHAs have been applied with sunscreen". "Contact of the product with the skin must be of limited frequency and duration." Preparations intended to be diluted in bath water may contain levels of citric acid exceeding 10%.	Not controlled	
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	IV/1-Controlled E1 133
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	IV/1 & III/2, 58 Controlled for Non-oxidising colouring agents for hair dyeing
METHYLCHLOROISOTHIAZOLINONE	.001125	An effective preservative at 7.5ppm. Normally used in combination with methylisothiazolinone in a 3:1 mixture. May induce sensitisation at 15ppm. Unlikely to cause sensitisation if used at up to 7.5ppm in rinse off products only. Not permitted or suitable for use in skin application products when used independently. Listed in Annex III of the Biocides Directive 1048/2005 therefore this preservative is no longer a permitted biocide/preservative in the EU for use in toys, detergents and other general products. Alternative restrictions may be available for use in Cosmetics.	Not permitted	Not permitted
METHYLISOTHIAZOLINONE	.000375	An effective preservative. The Cosmetic Regulations 2005 amendment states the max allowed concentration of methylisothiazolinone when used by itself is 0.01% in both leave-on and rinse-off products. The CIR expert panel concluded in a tentative report in April 2008 that this preservative when used alone was safe for use up to 100ppm, 0.01% in all cosmetic products. The use of this preservative in leave-on cosmetic product is relatively new with little data on market exposure and its use should be monitored carefully and any adverse reactions fed back to the manufacturer or supplier. According to manufacturers data (Rohm Haas) No evidence of sensitization in subjects when tested up to and including 600 ppm (0.06%) active ingredient. Threshold for irritation and sensitization is at or above 1000 ppm active ingredient. No evidence of phototoxicity when tested at 200 ppm a.i. No evidence of photoallergy when tested at 200 ppm a.i. Acute Oral Toxicity, rat LD50 = 2634 mg/kg (m), 1091 mg/kg (f) Acute Dermal Toxicity, rat LD50 >5000 mg/kg (m & f combined). Skin and eye Irritation, rabbit Non-irritating when tested at maximum use concentration of 100 ppm a.i.. A recent publication in Contact Dermatitis has reported cases of allergic contact dermatitis from the use of intimate hygiene wipes causes anal lesions and facial dermatitis from a make up remover. (Contact dermatitis 63, 98, 2010).	Approved preservative	VI/1,39