

JOHNSON & JOHNSON MEDICAL MICROSIELD HANDWASH

Chemwatch Independent Material Safety Data Sheet

Issue Date: 21-Mar-2011

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

JOHNSON & JOHNSON MEDICAL MICROSIELD HANDWASH

SYNONYMS

"Wash Lotion, Manufacturer's Code: 61392, 61413, 61224, 60238"

PRODUCT USE

Liquid hand, face and body washing.

SUPPLIER

Company: Johnson & Johnson Medical Pty Ltd

Address:

PO Box 134

North Ryde

NSW, 2113

Australia

Company: Johnson & Johnson Medical Pty Ltd

Address:

1- 5 Khartoum Road

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Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE

NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to NOHSC Criteria, and ADG Code.

RISK

•None under normal operating conditions.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
sodium lauryl sulfate	151-21-3	0-10
coconut diethanolamide	68603-42-9	0-10
sodium chloride	7647-14-5	0-10
ethylene glycol monostearate	111-60-4	0-10
diazolidinyl urea	78491-02-8	0-10
methyl paraben	99-76-3	0-10
propyl paraben	94-13-3	0-10
citric acid monohydrate for pH adjustment		0-10
fragrance		0-10
water	7732-18-5	>30

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Section 4 - FIRST AID MEASURES

SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

- If this product comes in contact with the eyes:
 - Wash out immediately with fresh running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - Seek medical attention without delay; if pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

- No adverse effects anticipated from normal use.
- Wash affected areas with warm water and soap.
Discontinue use if irritation occurs.
If irritation continues, seek medical attention.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

- Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

FIRE FIGHTING

- Use water delivered as a fine spray to control fire and cool adjacent area.
- Do not approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD

- Non combustible.
- Not considered to be a significant fire risk.
- Expansion or decomposition on heating may lead to violent rupture of containers.
- Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).
- May emit acrid smoke.

Other decomposition products include:
carbon dioxide (CO₂) and nitrogen oxides (NO_x).

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Section 5 - FIRE FIGHTING MEASURES

FIRE INCOMPATIBILITY

- Avoid contamination with strong oxidising agents as ignition may result.

HAZCHEM

None

PERSONAL PROTECTION

Glasses:

Not normally required.

Gloves:

1.NATURAL RUBBER

Respirator:

Type AK- P Filter of sufficient capacity

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Slippery when spilt.
Clean up all spills immediately.
Wipe up.
Place in clean drum then flush area with water.

MAJOR SPILLS

- Slippery when spilt.
Minor hazard.
- Clear area of personnel.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact by using protective equipment as required.
- Prevent spillage from entering drains or water ways.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.
- Wash area and prevent runoff into drains or waterways.
- If contamination of drains or waterways occurs, advise emergency services.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Limit all unnecessary personal contact.
 - Wear protective clothing when risk of exposure occurs.
 - Use in a well-ventilated area.
 - When handling DO NOT eat, drink or smoke.
 - Always wash hands with soap and water after handling.
 - Avoid physical damage to containers.
 - Use good occupational work practice.
 - Observe manufacturer's storing and handling recommendations.
- Avoid production of aerosols.

SUITABLE CONTAINER

- Plastic container.
Polylined drum.

STORAGE INCOMPATIBILITY

- Avoid storage with oxidisers.

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Section 7 - HANDLING AND STORAGE

STORAGE REQUIREMENTS

- Store in original containers.
 - Keep containers securely sealed.
 - Store in a cool, dry, well-ventilated area.
 - Store away from incompatible materials and foodstuff containers.
 - Protect containers against physical damage and check regularly for leaks.
 - Observe manufacturer's storing and handling recommendations.
- Keep cool. Store below 25 deg.C.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA mg/m ³	Notes
Australia Exposure Standards	ethylene glycol monostearate (Stearates (a) (d))	10	(see Chapter 14)

The following materials had no OELs on our records

- sodium lauryl sulfate: CAS:151- 21- 3 CAS:1335- 72- 4 CAS:3088- 31- 1 CAS:9004- 82- 4
- coconut diethanolamide: CAS:68603- 42- 9 CAS:61791- 31- 9
- sodium chloride: CAS:7647- 14- 5
- diazolidinyl urea: CAS:78491- 02- 8
- methyl paraben: CAS:99- 76- 3
- propyl paraben: CAS:94- 13- 3
- water: CAS:7732- 18- 5

MATERIAL DATA

ETHYLENE GLYCOL MONOSTEARATE:

METHYL PARABEN:

PROPYL PARABEN:

SODIUM CHLORIDE:

SODIUM LAURYL SULFATE:

■ Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

ETHYLENE GLYCOL MONOSTEARATE:

METHYL PARABEN:

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

PROPYL PARABEN:

SODIUM CHLORIDE:

SODIUM LAURYL SULFATE:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

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- None assigned. Refer to individual constituents.

COCONUT DIETHANOLAMIDE:

- for diethanolamine:

Odour Threshold: 2.6 ppm

The TLV-TWA is thought to be protective against the significant risk of eye damage and skin irritation.

Odour Safety Factor (OSF)

OSF=1.7 (DIETHANOLAMINE).

ETHYLENE GLYCOL MONOSTEARATE:

■ The stearates have a low order of acute and chronic toxicity. Intratracheal administration of relatively large doses in rats produce varying degrees of pulmonary damage. Acute, gross inhalation exposure has been associated with clinical pneumonitis. A case of "pneumoconiosis with probable heart failure" has been reported in a rubber worker occupationally exposed to zinc stearate dust for 29 years. Several cases of infants developing respiratory distress and in some instances, acute fatal pneumonitis on aspiration of zinc stearate powder, have been reported.

DIAZOLIDINYL UREA:

- Odour Threshold Value for formaldehyde: 0.98 ppm (recognition)

NOTE: Detector tubes for formaldehyde, measuring in excess of 0.2 ppm are available commercially.

Formaldehyde vapour exposure:

Primary irritation is dependent on duration of exposure and individual susceptibility.

The following are typical symptoms encountered at various exposure levels.

0.1 ppm - Lower level of mucous eye, nose and throat irritation

0.8 ppm - Typical threshold of perception

1-2 ppm - Typical threshold of irritation

2-3 ppm - Irritation of eyes, nose and throat

4-5 ppm - Increased irritation, tearing, headache, pungent odour

10-20 ppm - Profuse tearing, severe burning, coughing

50 ppm - Serious bronchial and alveolar damage

100 ppm - Formaldehyde induced chemical pneumonia and death

Despite the intent of the TLV Ceiling recommendation it is believed that 0.3 ppm will not protect that portion of the workforce (up to 20%) reported to be responsive to low ambient concentrations. Because of the dose-related carcinogenic activity for rat and mouse inhalation of formaldehyde, the report of macromolecular adducts in the upper and lower respiratory tracts of nonhuman primates following inhalation of formaldehyde, the human case reports of upper respiratory tract malignant melanoma associated with

formaldehyde inhalation and the suggestive epidemiologic data on human cancer risk, the TLV Committee recommends that workplace formaldehyde air concentrations be reduced to the lowest possible levels that can be achieved using engineering controls.

Odour Safety Factor(OSF)

OSF=0.36 (FORMALDEHYDE).

WATER:

- No exposure limits set by NOHSC or ACGIH.

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PERSONAL PROTECTION

EYE

- No special equipment for minor exposure i.e. when handling small quantities.
- OTHERWISE:
 - Safety glasses with side shields.
 - Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

- No special equipment needed when handling small quantities.
- OTHERWISE: Wear chemical protective gloves, eg. PVC.

OTHER

- No special equipment needed when handling small quantities
- OTHERWISE:
 - Overalls
 - Eyewash unit.

RESPIRATOR

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

- None under normal operating conditions.
- Provide adequate ventilation in warehouse or closed storage areas.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Milky, viscous liquid with a floral fragrance; dispersible in water.

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

State	Liquid	Molecular Weight	Not Applicable
Melting Range (°C)	Not Available	Viscosity	Not Available
Boiling Range (°C)	Not Available	Solubility in water (g/L)	Miscible
Flash Point (°C)	Not Applicable	pH (1% solution)	Not Available
Decomposition Temp (°C)	Not Available	pH (as supplied)	7.0
Autoignition Temp (°C)	Not Available	Vapour Pressure (kPa)	Not Available
Upper Explosive Limit (%)	Not Applicable	Specific Gravity (water=1)	1.015
Lower Explosive Limit (%)	Not Applicable	Relative Vapour Density (air=1)	Not Available
Volatile Component (%vol)	Not Available	Evaporation Rate	Not Available

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Section 10 - STABILITY AND REACTIVITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Ingestion may result in nausea, abdominal irritation, pain and vomiting.

EYE

- The liquid may produce eye discomfort causing smarting, pain and redness.

SKIN

- Not considered an irritant through normal use.

INHALED

- Not normally a hazard due to non-volatile nature of product.

CHRONIC HEALTH EFFECTS

- Principal hazards are accidental eye contact and cleaner overuse. Overuse or obsessive cleaner use may lead to defatting of the skin and may cause irritation, drying, cracking, leading to dermatitis.

TOXICITY AND IRRITATION

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

WATER:

PROPYL PARABEN:

- No significant acute toxicological data identified in literature search.

COCONUT DIETHANOLAMIDE:

SODIUM CHLORIDE:

ETHYLENE GLYCOL MONOSTEARATE:

METHYL PARABEN:

PROPYL PARABEN:

SODIUM LAURYL SULFATE:

- Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

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Section 11 - TOXICOLOGICAL INFORMATION

PROPYL PARABEN:

METHYL PARABEN:

■ For benzoates:

Benzyl alcohol, benzoic acid and its sodium and potassium salt have a common metabolic and excretion pathway. All but benzyl alcohol are considered to be unharmed and of low acute toxicity. They may cause slight irritation by oral, dermal or inhalation exposure except sodium benzoate which doesn't irritate the skin. Studies showed increased mortality, reduced weight gain, liver and kidney effects at higher doses, also, lesions of the brains, thymus and skeletal muscles may occur with benzyl alcohol. However, they do not cause cancer, genetic or reproductive toxicity. Developmental toxicity may occur but only at maternal toxic level.

ETHYLENE GLYCOL MONOSTEARATE:

SODIUM CHLORIDE:

■ The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.

SODIUM CHLORIDE:

COCONUT DIETHANOLAMIDE:

■ The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

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■ Not available. Refer to individual constituents.

SODIUM LAURYL SULFATE:

TOXICITY

Oral (rat) LD50: 1288 mg/kg

IRRITATION

Skin (human): 25 mg/24 hr - Mild

Eye (rabbit): 100 mg/24 hr - Moderate

■ for alkyl sulfates; alkane sulfonates and alpha-olefin sulfonates

Most chemicals of this category are not defined substances, but mixtures of homologues with different alkyl chain lengths. Alpha-olefin sulfonates are mixtures of alkene sulfonate and hydroxyl alkane sulfonates with the sulfonate group in the terminal position and the double bond, or hydroxyl group, located at a position in the vicinity of the sulfonate group.

Common physical and/or biological pathways result in structurally similar breakdown products, and are, together with the surfactant properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health.

Acute toxicity: These substances are well absorbed after ingestion; penetration through the skin is however poor. After absorption, these chemicals are distributed mainly to the liver.

Acute oral LD50 values of alkyl sulfates in rats and/or mice were (in mg/kg):

C10-; 290-580

C10-16-, and C12-; 1000-2000

C12-14, C12-15, C12-16, C12-18 and C16-18-; >2000

C14-18, C16-18-; >5000

The clinical signs observed were non-specific (piloerection, lethargy, decreased motor activity and respiratory rate, diarrhoea). At necropsy the major findings were irritation of the gastrointestinal tract and anemia of inner organs.

Based on limited data, the acute oral LD50 values of alkane sulfonates and alpha-olefin sulfonates of comparable chain lengths are assumed to be in the same range.

The counter ion does not appear to influence the toxicity in a substantial way.

Acute dermal LD50 values of alkyl sulfates in rabbits (mg/ kg):

C12-; 200

C12-13 and C10-16-;>500

Apart from moderate to severe skin irritation, clinical signs included tremor, tonic-clonic convulsions, respiratory failure, and body weight loss in the study with the C12- alkyl sulfate and decreased body weights after administration of the C10-16- alkyl sulfates. No data are available for alkane sulfonates but due to a

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comparable metabolism and effect concentrations in long-term studies effect concentrations are expected to be in the same range as found for alkyl sulfates.

There are no data available for acute inhalation toxicity of alkyl sulfates, alkane sulfonates or alpha-olefin sulfonates.

In skin irritation tests using rabbits (aqueous solutions, OECD TG 404):

C8-14 and C8-16 (30%), C12-14 (90%), C14-18 (60%)- corrosive

Under occlusive conditions:

C12, and C12-14 (25%), C12-15-, C13-15 and C15-16 (5-7%) - moderate to strong irritants

Comparative studies investigating skin effects like transepidermal water loss, epidermal electrical conductance, skin swelling, extraction of amino acids and proteins or development of erythema in human volunteers consistently showed a maximum of effects with C12-alkyl sulfate, sodium; this salt is routinely used as a positive internal control giving borderline irritant reactions in skin irritation studies performed on humans. As the most irritant alkyl sulfate it can be concluded that in humans 20% is the threshold concentration for irritative effects of alkyl sulfates in general. No data were available with regard to the skin irritation potential of alkane sulfonates. Based on the similar chemical structure they are assumed to exhibit similar skin irritation properties as alkyl sulfates or alpha-olefin sulfonates of comparable chain lengths.

In eye irritation tests, using rabbits, C12-containing alkyl sulfates (>10% concentration) were severely irritating and produced irreversible corneal effects. With increasing alkyl chain length, the irritating potential decreases, and C16-18 alkyl sulfate sodium, at a concentration of 25%, was only a mild irritant. Concentrated C14-16- alpha-olefin sulfonates were severely irritating, but caused irreversible effects only if applied as undiluted powder. At concentrations below 10% mild to moderate, reversible effects, were found. No data were available for alkane sulfonates

Alkyl sulfates and C14-18 alpha-olefin sulfonates were not skin sensitizers in animal studies. No reliable data were available for alkane sulfonates. Based on the similar chemical structure, no sensitization is expected.

However anecdotal evidence suggests that sodium lauryl sulfate causes pulmonary sensitization resulting in hyperactive airway dysfunction and pulmonary allergy accompanied by fatigue, malaise and aching. Significant symptoms of exposure can persist for more than two years and can be activated by a variety of non-specific environmental stimuli such as a exhaust, perfumes and passive smoking.

Absorbed sulfonates are quickly distributed through living systems and are readily excreted. Toxic effects may result from the effects of binding to proteins and the ability of sulfonates to translocate potassium and nitrate (NO₃⁻) ions from cellular to interstitial fluids. Airborne sulfonates may be responsible for respiratory allergies and, in some instances, minor dermal allergies. Repeated skin contact with some sulfonated surfactants has produced sensitization dermatitis in predisposed individuals

Repeat dose toxicity: After repeated oral application of alkyl sulfates with chain lengths between C12 and C18, the liver was the only target organ for systemic toxicity. Adverse effects on this organ included an increase in liver weight, enlargement of liver cells, and elevated levels of liver enzymes. The LOAEL for liver toxicity (parenchymal hypertrophy and an increase in comparative liver weight) was 230 mg/kg/day (in a 13 week study with C16-18 alkyl sulfate, sodium). The lowest NOAEL in rats was 55 mg/kg/day (in a 13 week study with C12-alkyl sulfate, sodium).

C14- and C14-16-alpha-olefin sulfonates produced NOAELs of 100 mg/kg/day (in 6 month- and 2 year studies). A reduction in body weight gain was the only adverse effect identified in these studies.

No data were available with regard to the repeated dose toxicity of alkane sulfonates. Based on the similarity of metabolic pathways between alkane sulfonates, alkyl sulfates and alkyl-olefin sulfonates, the repeated dose toxicity of alkane sulfonates is expected to be similar with NOAEL and LOAEL values in the same range as for alkyl sulfates and alpha-olefin sulfonates, i.e. 100 and 200-250 mg/kg/day, respectively, with the liver as potential target organ.

Genotoxicity: Alkyl sulfates of different chain lengths and with different counter ions were not mutagenic in standard bacterial and mammalian cell systems both in the absence and in the presence of metabolic activation. There was also no indication for a genotoxic potential of alkyl sulfates in various in vivo studies on mice (micronucleus assay, chromosome aberration test, and dominant lethal assay).

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alpha-Olefin sulfonates were not mutagenic in the Ames test, and did not induce chromosome aberrations in vitro. No genotoxicity data were available for alkane sulfonates. Based on the overall negative results in the genotoxicity assays with alkyl sulfates and alpha-olefin sulfonates, the absence of structural elements indicating mutagenicity, and the overall database on different types of sulfonates, which were all tested negative in mutagenicity assays, a genotoxic potential of alkane sulfonates is not expected.

Carcinogenicity: Alkyl sulfates were not carcinogenic in feeding studies with male and female Wistar rats fed diets with C12-15 alkyl sulfate sodium for two years (corresponding to doses of up to 1125 mg/kg/day). alpha-Olefin sulfonates were not carcinogenic in mice and rats after dermal application, and in rats after oral exposure.

No carcinogenicity studies were available for the alkane sulfonates.

Reproductive toxicity: No indication for adverse effects on reproductive organs was found in various oral studies with different alkyl sulfates. The NOAEL for male fertility was 1000 mg/kg/day for sodium dodecyl sulfate. In a study using alpha-olefin sulfonates in male and female rats, no adverse effects were identified up to 5000 ppm.

Developmental toxicity: In studies with various alkyl sulfates (C12 up to C16-18- alkyl) in rats, rabbits and mice, effects on litter parameters were restricted to doses that caused significant maternal toxicity (anorexia, weight loss, and death).

The principal effects were higher foetal loss and increased incidences of total litter losses. The incidences of malformations and visceral and skeletal anomalies were unaffected apart from a higher incidence of delayed ossification or skeletal variation in mice at > 500 mg/kg bw/day indicative of a delayed development. The lowest reliable NOAEL for maternal toxicity was about 200 mg/kg/day in rats, while the lowest NOAELs in offspring were 250 mg/kg/day in rats and 300 mg/kg/day for mice and rabbits.

For alpha-olefin sulfonates (C14-16-alpha-olefin sulfonate, sodium) the NOAEL was 600 mg/kg/day both for maternal and developmental toxicity.

No data were available for the reproductive and developmental toxicity of alkane sulfonates. Based on the available data, the similar toxicokinetic properties and a comparable metabolism of the alkyl sulfates and alkane sulfonates, alkane sulfonates are not considered to be developmental toxicants.

Although the database for category members with C<12 is limited, the available data are indicating no risk as the substances have comparable toxicokinetic properties and metabolic pathways. In addition, longer-term studies gave no indication for adverse effects on reproductive organs with different alkyl sulfates.

Alkyl sulfates (AS) anionic surfactants are generally classified according to Comité Européen des Agents de Surface et leurs Intermédiaires Organiques (CESIO) as skin irritant (R38), harmful if swallowed (R22) and risk of serious damage to the eyes (R41) but are not included in Annex 1 list of dangerous substances by Council Directive. They are metabolised by the liver and excreted via urine with butyric acid-4-sulfate as its major metabolite. It produces dose dependent toxicity and its irritant effect depends on the length of hydrophobic alkyl chain. It does not cause cancer, reproductive or genetic defect. However, at maternal toxic levels, it may produce foetal defect during organ formation.

NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

Eye (None) None: None rabbit None 250 ugSkin (rabbit):25 mg/24 hr-moderate

Skin (None) None: None rabbit None 50 mg/24Eye (rabbit) 10: mg-

COCONUT DIETHANOLAMIDE:

TOXICITY

Oral (rat) LD50: 2700 mg/kg

Inhalation (Rat) LC50: 88 ppm/h *

■ The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

for diethanolamine (DEA):

DEA has low acute toxicity via the oral and dermal routes of exposure with moderate skin irritation and severe eye irritation. It may damage sperm production, cause anaemia and organ damage especially the kidney and liver. DEA has not been shown to cause genetic defect or cancer; though there is evidence that it may cause cancer in mice. However, it does cause developmental toxicity at maternal toxic levels.

Laboratory testing shows that the fatty acid amide, cocoamide DEA, causes occupational allergic contact dermatitis, and that allergy to this substance is becoming more common.

Alkanolamides are manufactured by condensation of diethanolamine and the methyl ester of long chain fatty

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acids. The alkanolamides are susceptible to the formation of nitrosamines, by either existing contamination or the presence of nitrosating agents. According to the Cosmetic Directive (2000), cocoamide DEA must not be used in products with nitrosating agents, because of the risk of formation of N-nitrosamines. In cosmetics a maximum concentration of 5% fatty acid dialkanolamides is permissible. N-nitrosamines, in animal testing, have been shown to cause cancer. Animal testing has not shown that cocoamide DEA or other FAAs can cause mutations.

For Fatty Nitrogen Derived (FND) Amides)

The chemicals in the Fatty Nitrogen Derived (FND) Amides of surfactants are generally similar to its class in terms of physical and chemical properties, environmental fate and toxicity. It comprises four categories: the substituted amides, fatty acid reaction products with amino compounds, imidazole derivatives and FND amphoteric which represent subcategory I to IV respectively. Its low acute oral toxicity is well established across all subcategories by the available data and show no apparent organ specific toxicity, mutagenic activity, reproductive or developmental defects.

*Ethoquad C/12 SDS

SODIUM CHLORIDE:

TOXICITY

Oral (rat) LD50: 3000 mg/kg

Oral (human) TDL_o: 12357 mg/kg/23d

Intravenous (Mouse) LD50: 645 mg/kg

Oral (Human) TDL_o: 12357 mg/kg

Subcutaneous (Rat) LD: 3500 mg/kg

Intraperitoneal (Mouse) LD50: 2602 mg/kg

Intravenous (Rabbit) LD: 1100 mg/kg

Subcutaneous (Guinea pig) LD: 2160 mg/kg

Intravenous (Guinea pig) LD: 300 mg/kg

Intraperitoneal (Rat) LD50: 2600 mg/kg

Oral (Lowest Toxic Dose) Human: None 8.2 mg/kg

IRRITATION

Skin (rabbit): 500 mg/24h - Mild

Eye (rabbit): 10 mg - Moderate

Eye (rabbit): 100 mg/24h - Moderate

ETHYLENE GLYCOL MONOSTEARATE:

TOXICITY

Oral (rat) LD50: 12100 mg/kg *

Intraperitoneal (mouse) LD50: 200 mg/kg

■ For glycol and diol aliphatic esters: (group C)

According to a classification scheme described by the American Chemistry Council' Aliphatic Esters Panel, Group C substances are comprised of a monocarboxylic acid and a dihydroxy alcohol often referred to "glycol, diol, alkylidene or alkanediyl esters". Esterification of the glycol with fatty acids to form diesters in the 38 to 41 carbon number range, make them relatively non-volatile, high boiling and low water solubility but sufficient polar characteristics to make them useful lubricants and solvents. Metabolism is by hydrolysis and conjugation. Studies show that it has low degree oral and dermal toxicity level in both acute and chronic states. There is no adequate toxicity data till date, but evidence predicts that it does not cause reproductive, developmental or genetic damage.

Non-comedogenic *

[Manufacturer]

IRRITATION

Skin(rabbit): 500 mg/24 hr - Mild

Eye (rabbit): non- irritating *

DIAZOLIDINYL UREA:

TOXICITY

Oral (rat) LD50: 2600 mg/kg

■ Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

For imidazolidinyl urea and diazolidinyl urea:

Imidazolidinyl urea releases formaldehyde into cosmetics at temperatures above 10 °C. A 1974 study found formaldehyde release occurs at the non-physiological conditions of 60 °C and a pH of 6. In water-containing

IRRITATION

Nil Reported

continued...

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cosmetics like shampoos, formaldehyde release increases with a rise in pH and temperature of the solution as well as a longer storage period

Acute toxicity: The prevalence of positive reactions to imidazolidinyl urea was 1.9 percent and 3.2 percent in patients with contact dermatitis in two independent studies. Concomitant positive reactions have also been reported for imidazolidinyl urea and formaldehyde as well as imidazolidinyl urea and N-(3-chloroallyl)hexaminium chloride (Quaternium-15) ./

A British study conducted between 1982-1993 showed that the frequency of preservative allergy to imidazolidinyl urea in 5,167 patients with contact dermatitis was 0.99%. Furthermore, the face and the hands were the sites of allergy for 69% and 19% of patients, respectively. Curiously imidazolidinyl urea did not induce contact sensitivity in several reports. In a study, 200 subjects were given repeated insult patch tests with a 10% aqueous solution of imidazolidinyl urea three times per week for five weeks. These subjects were challenged for 24 hours after treatment and no evidence of primary irritation or sensitization occurred. Imidazolidinyl urea sensitised 60-70% of female Dunkin Hartley guinea pigs in a dose-dependent manner. The animals were patch tested with 1, 5, and 10% imidazolidinyl urea in petrolatum and read after 48 hours. Imidazolidinyl urea was found to be a sensitizer after topical applications of 25 μ l of 10, 25, or 50 percent to CBA/Ca mice daily for three days induced significant radiolabelled thymidine incorporation into local lymph nodes four days after the last treatment with imidazolidinyl urea

Skin irritation: Imidazolidinyl urea was non-irritating after an application of 0.1 ml of a solution containing 5, 10, or 20 percent of this compound in the right eye of albino rabbits. In another study, imidazolidinyl urea did not produce any irritation after application to the shaved backs of albino rabbits at concentrations of 0, 1, 2.5, and 5 percent

Imidazolidinyl urea was described as not phototoxic in female Hartley guinea pigs after intradermal injections of 1-5% doses into the shaved backs and subsequent irradiation with FL20E and FL20BLB light for 30 minutes. The animals were again injected and irradiated 24 and 48 hours after the initial injection with no reaction

Subchronic Toxicity: Imidazolidinyl urea was applied in powder form at concentrations of 20, 45, 90, and 200 mg/kg/day to the shaved backs of five male and female albino rabbits for 6 hr/day, 5 d/wk, for three weeks. The only treatment-related effects reported were a slight to mild inflammatory and focal ulcerative effect. Seven male and female rats that were fed 6, 28, 130, or 600 mg/kg of imidazolidinyl urea daily for 90 days showed no differences in the haematology, urinalysis, and pathology profiles when compared to controls. However, imidazolidinyl urea induced a decrease in weight gain in males fed diets over 28 mg/kg/day

Reproductive and/or Developmental Effects: Imidazolidinyl urea induced a slight increase in the number of resorptions and/or foetal deaths in utero on day 17 in female albino mice that were orally intubated with 30, 95, and 300 mg/kg from day 6 to 15 of gestation. However, no different abnormalities in soft or skeletal tissue with respect to controls were found. This compound was found to be slightly foetotoxic but not teratogenic in mice

Genetic toxicity: Imidazolidinyl urea was mutagenic in *Salmonella typhimurium* strains TA98 and TA100 at concentrations up to 1,500 μ g/plate in the presence or absence of rodent liver S-9 fraction

Diazolidinyl urea was mutagenic in *Salmonella typhimurium* strains TA98, TA100, and TA102 with and without metabolic activation. This compound induced micronuclei in Chinese hamster V79 cells with and without metabolic activation. Diazolidinyl urea also inhibited the formation of microtubuli at 3 mmol/l. In contrast, the Cosmetic Ingredients Review Expert Panel (1990) found that diazolidinyl urea was not mutagenic in *S. typhimurium* and that this compound did not induce micronuclei

Cytotoxicity: Imidazolidinyl urea induced a significant dose- and time-dependent decrease in cell viability of HL60 cells after 3, 6, or 24 hours of incubation at a concentration range of 0.01-1%. Apoptotic markers of cell death, DNA subdiploid content, internucleosomal DNA fragmentation, and caspase activation were observed in HL60 cells treated with low concentrations of imidazolidinyl urea (0.01% and 0.1%). However, at higher concentrations (0.5-1%), the mechanism of cell death was necrosis.

Imidazolidinyl urea was not cytotoxic to normal human fibroblasts after incubation with 1- 30% solutions for up to 30 minutes.

Formaldehyde generators (releasers) are often used as preservatives and generated following hydrolysis. According to Annex VI, the maximum authorised concentration of free formaldehyde is 0.2% and must be labelled with the warning sign "contains formaldehyde" where the concentration exceeds 0.05%. The use of formaldehyde-releasing preservatives ensures that the level of free formaldehyde in the products is always low but sufficient to inhibit microbial growth, though it may disrupt metabolism to cause death of the organism. However there is a concern that it can produce carcinogenic amines (nitrosamines) when used in formulations containing amines.

METHYL PARABEN:

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TOXICITY

Oral (mouse) LD50: 2100 mg/kg

IRRITATION

Nil Reported [Manufacturer]

SENSITISER

coconut diethanolamide	Australia Final Report on Hazard Classification of Common Skin Sensitisers	Recommended for Hazard Classification (R43)	No
diazolidinyl urea	Australia Final Report on Hazard Classification of Common Skin Sensitisers	Recommended for Hazard Classification (R43)	Yes

Section 12 - ECOLOGICAL INFORMATION

ETHYLENE GLYCOL MONOSTEARATE:

METHYL PARABEN:

PROPYL PARABEN:

SODIUM LAURYL SULFATE:

- Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

- Toxic to aquatic organisms.

METHYL PARABEN:

PROPYL PARABEN:

ETHYLENE GLYCOL MONOSTEARATE:

- May cause long-term adverse effects in the aquatic environment.

PROPYL PARABEN:

METHYL PARABEN:

- For benzoates:

The ultimate environmental characteristics for benzoates may be determined by the properties of ions. The description below assumes these to be non-toxic.

Environmental Exposure and Fate

Distribution modelling using Mackay Level III (the EPA default: equal releases (10,000 kg/hr) and equal distribution to all compartments was used) indicates water (34.8-50%) and soil (48.4-64.2%) to be the main compartment for benzyl alcohol, benzoic acid, sodium and potassium benzoates. None are expected to volatilise to the atmosphere (< 1.51%), nor to adsorb to sediment (< 0.09 %).

However physical chemical properties and use patterns indicate water to be the main compartment for these substances.

Based on structure and organic chemistry rules (e.g. bonding in organic molecules, activation energy, reactivity, transformations, addition, substitution, elimination) no hydrolysis is expected at pH ranges of 4 - 11.

The calculated photodegradation for benzyl alcohol and the benzoates are 50% after 1.3 to 3 days, and the measured photodegradation for benzoic acid is 90% after 140 minutes.

Biodegradation and Bioaccumulation:

This family of substances is readily biodegradable (> 90% after 28 days) both aerobically and anaerobically (Benzoic acid is used as positive control in OECD Guideline for ready biodegradability testing).

From the results of numerous removal experiments the main elimination pathway for the chemicals is biotic mineralisation. The octanol/water partition coefficient of all compounds indicates a low potential for bioaccumulation. This is also supported by the rapid biotransformation and/or excretion of these compounds in urine in mammals.

Ecotoxicity:

From the data (fish, daphnia, algae, bacteria) it is obvious that neutralisation of the pH greatly reduces (up to one order of magnitude) the acute toxicity of benzoic acid. This is also supported by the lower toxicity observed with sodium benzoate. Under environmental relevant conditions therefore the acute toxicity of benzoic acid, sodium benzoate and potassium benzoate for all four trophic levels is > 100 mg/l. Under

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environmental relevant conditions the acute toxicity of benzyl alcohol for fish, daphnia and bacteria is > 100 mg/l. For algae, an EC 50 3 hrs of 95 mg/l is reported. Under environmental relevant conditions, benzoic acid and its salts have very low acute toxicity, whereas benzyl alcohol has low to moderate acute toxicity.

COCONUT DIETHANOLAMIDE:

SODIUM CHLORIDE:

ETHYLENE GLYCOL MONOSTEARATE:

DIAZOLIDINYL UREA:

METHYL PARABEN:

PROPYL PARABEN:

SODIUM LAURYL SULFATE:

■ DO NOT discharge into sewer or waterways.

SODIUM LAURYL SULFATE:

■ for alkyl sulfates; alkane sulfonates and alpha-olefin sulfonates:

Environmental fate:

The close structural similarities result in physico-chemical properties and environmental fate characteristic which follow a regular pattern.

The most important common structural feature of the category members is the presence of a predominantly linear aliphatic hydrocarbon chain with a polar sulfate or sulfonate group, neutralised with a counter ion (i.e., Na⁺, K⁺, NH₄⁺, or an alkanolamine cation).

The hydrophobic hydrocarbon chain (with a length typically between C8 and C18) and the polar sulfate or sulfonate groups confer surfactant properties and enable the commercial use of these substances as anionic surfactants

The structural similarities result in the same mode of ecotoxic action. Within each subcategory the most important parameter influencing ecotoxicity is the varying length of the alkyl chain. Although the counter ion may also influence the physico-chemical behaviour of these chemicals, the chemical reactivity and classification for the purpose of this assessment is not expected to be affected by the difference in counter ion.

As ionic substances, all members of this category have extremely low vapor pressures. Calculated values are in the ranges 10⁻¹¹ to 10⁻¹⁵ hPa (C8-18 alkyl sulfates), 4.3.10⁻¹¹ to 9.10⁻¹⁵ hPa (C8-18 alkane sulfonates), 2.1.10⁻¹³ to 6.9.10⁻¹⁵ hPa (C14-18 alkene sulfonates) and 3.3.10⁻¹⁷ to 5.8.10⁻¹⁹ hPa (C14-18 hydroxy alkane sulfonates). Therefore, they decompose before reaching their theoretical boiling points.

Measured water solubilities are available only for alkyl sulfates; they are in the range 196 000 mg/l (C12) to 300 mg/l (C16) and by factors of 50 to 300 higher than calculated values (C12: 617 mg/l, C16: 5 mg/l).

As surfactants have a tendency to concentrate at hydrophilic/hydrophobic boundaries rather than to equilibrate between phases log K_{ow} is not a good descriptor of surfactant hydrophobicity and only of limited predictive value for the partitioning of these compounds in the environment.

All calculated physico-chemical properties of surfactants should be treated with caution, because the estimation models do not take into account surfactant properties. In addition, the results are doubtful for ionic substances.

Deduced from physico-chemical and surfactancy properties the target compartment for the substances of this category is the hydrosphere. Based on the ionic structure partitioning into the atmosphere can be excluded.

In water, the compounds are stable to hydrolysis under environmental conditions.

Taking into account the low BCF factors (<73) that were determined for (up to) C16-alkyl sulfates, any significant bioaccumulation is not expected.

Soil sorption increases with chain length. Strong sorption on soils would be expected for chain length C14 upwards. Sediment concentrations were between 0.0035 and 0.021 mg/kg dw indicating that accumulation in sediments is low. Under certain conditions of reduced moisture in soil, i.e. in arid or semi-arid regions, accumulation in soil cannot be excluded.

The substances of this category are readily biodegradable. Significant biodegradation of alkyl sulfates in the raw sewage, i.e. in the sewer system before reaching the (waste-water treatment plant (WWTPs) is very likely. The substances of this category are quantitatively removed in WWTPs, mainly by biodegradation. Because of the anaerobic degradation of alkyl sulfates in sewage sludge, exposure of agricultural soils due to application of sludge as fertiliser is not expected. However, for alkane sulfonates and alpha-olefin sulfonates this exposure pathway cannot be excluded due to their recalcitrant or limited anaerobic degradability.

For alkyl sulfates: The biological degradation of AS is initiated by a hydrolytic cleavage of the sulfate

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ester bond catalysed by alkylsulfatases. The cleavage leaves inorganic sulfate and fatty alcohol which undergo oxidation by dehydrogenases to produce fatty acids via fatty aldehydes. The fatty acids are degraded by beta-oxidation and finally totally mineralised or incorporated into biomass. The biodegradation pathway for secondary AS differs from that of the primary AS by the formation of a ketone instead of an aldehyde. The biological degradation of AS is initiated by a hydrolytic cleavage of the sulfate ester bond catalysed by alkylsulfatases. The cleavage leaves inorganic sulfate and fatty alcohol which undergo oxidation by dehydrogenases to produce fatty acids via fatty aldehydes. The fatty acids are degraded by beta-oxidation and finally totally mineralised or incorporated into biomass. The biodegradation pathway for secondary AS differs from that of the primary AS by the formation of a ketone instead of an aldehyde. Biodegradation under anoxic conditions is anticipated to follow the same pathway as for the aerobic degradation.

Primary and secondary AS generally undergo complete primary biodegradation within a few days followed by a rapid ultimate biodegradation. Branched AS are also degraded quite rapidly, but multiple branchings of the alkyl chain considerably reduce the rate and extent of primary biodegradation. There are numerous studies confirming the aerobic biodegradability of AS, and linear primary AS exceeds all other anionic surfactants in the rate of primary and ultimate biodegradation. Also secondary AS are normally readily biodegradable as, e.g., the oxygen uptake from biodegradation of a linear secondary C10-13 AS corresponded to 77% ThOD in 22 days. Some highly branched AS being poorly primary biodegradable may also resist ultimate biodegradation. Both linear and 2-alkyl-branched primary AS are degraded to a high extent under anaerobic conditions.

AS are generally considered to have a low potential for bioconcentration in aquatic organisms

For alkane sulfonates: Alkane sulfonate anionics (SAS) undergo rapid primary biodegradation with Methylene Blue Active Substance (MBAS) removal higher than 90% within a few days. Removal of 96% were seen in the OECD screening test for primary biodegradation. In activated sludge simulation tests, 96% of C10-18 SAS was removed, while the parent C13-18 SAS was removed by 83-96%.

Alkyl sulfonates are not degraded under anoxic conditions

For alpha-olefin sulfonates: alpha-Olefine sulfonates (AOS) AOS undergo rapid primary biodegradability with methylene blue active substances (MBAS) removal between 95 and 100% in 2 to 8 days in river water and inoculated media. The ultimate biodegradability of AOS exceeds the pass requirements in OECD 301 tests for ready biodegradability. report 85% DOC removal in the modified OECD screening test, 85% ThOD in the closed bottle test, and 65-80% ThCO₂ in the Sturm test. In activated sludge simulation tests, AOS was removed by 100% MBAS and 88% DOC. The alkene sulfonates and hydroxyalkane sulfonates in commercial AOS are both ultimately biodegraded as approximately 84% ThCO₂ was obtained during degradation of C14, C16, and C18 within 27 days, whereas the corresponding 3-hydroxyalkane sulfonates were degraded by approximately 86% under the same conditions.

AOS are not readily degradable under anaerobic conditions Reports indicate a range of 31% to 43% MBAS removal under anoxic conditions indicating primary biodegradation

Ecotoxicity:

The aquatic toxicity is influenced by a number of parameters, the length of the alkyl chain being most important. The pH and temperature of water bodies can affect the EC/LC₅₀ values for compounds that contain ammonium ions.

The most sensitive trophic level in tests on the toxicity of alkyl sulfates were invertebrates, followed by fish. Algae proved to be less sensitive. The key study for the aquatic hazard assessment is a chronic test on *Ceriodaphnia dubia*, which covers a range of the alkyl chain length from C12 to C18. A parabolic response was observed with the C14 chain length being the most toxic (NOEC = 0.045 mg/l).

For alkyl sulfates: Fish LC₅₀ (96 h): fathead minnow - fry 10.2 mg/l; juvenile 17 mg/l; adult 22.5 mg/l; rainbow trout 4.6 mg/l (static)

The aquatic toxicity of AS seems to increase with increasing alkyl chain length. This has been shown for daphnids and for some fish species. An overall comparison of the acute toxicity between the primary and secondary AS shows only minor differences in the toxicity, although only a few studies for comparison are available.

The available data describing the toxicity of AS towards algae indicate that the lowest EC₅₀ values range between 1 and 10 mg/l for C12 AS

The toxicity of AS towards invertebrates has mainly been examined in tests with *Daphnia magna*. The acute toxicity of AS to *Daphnia magna* increased with increasing alkyl chain length. It has been shown that during degradation of C12 AS, the toxicity first increased to a maximum after 30 hours and then fell to almost a negligible value. The increase in toxicity was explained by the formation of the more toxic dodecanoic acid which is rapidly transformed to other and less toxic metabolites.

Studies showed that the 24 h-LC₅₀ values for killifish in distilled water decreased by a factor of about 10 when the alkyl chain was increased by two carbon atoms. C16 was 10 times more toxic than C14, which was about 10 times more toxic than C12 AS.

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The toxicity of AS to fish has been demonstrated to increase with increasing alkyl chain length as also seen in studies with *Daphnia magna*. The acute toxicity on *Daphnia magna* has been determined for chain length C8-C14. Results were comparable to alkyl sulfates in the range between C8 and C10, while C12 and C14 are significantly less toxic. Chronic data obtained for C12 alkane sulfonate sodium and C12-alkyl sulfate sodium with the rotifer *Brachionus calyciflorus* similarly show that alkane sulfonates might be less toxic than alkyl sulfates. C16 and C18 alkane sulfonates are assumed to exhibit the same toxicity than alkyl sulfates of comparable chain lengths. No data are available concerning the toxicity of alkane sulfonates on fish and algae. However, a similar toxicity might be assumed because of structural and physico-chemical similarities between the three subcategories

Whereas most correlations between AS structure and toxicity show an increasing toxicity with increasing alkyl chain length, the budding in *Hydra attenuata* was apparently more affected by C10 AS than by C12, C14, and C16 AS. The authors suggested that the decrease in toxicity with increasing alkyl chain length was attributable to reduced solubility in water

Tests on the toxicity to microorganisms were only conducted with alkyl sulfates as test substances. A test on the inhibition of respiration of activated sludge resulted in an 3 h-EC50 of 135 mg/l (nominally). The lowest effect value for protozoa was obtained from a test on *Uronema parduczi* using C12-alkyl sulfate sodium - 20 h-EC5 was 0.75 mg/l.

Experimental test results on benthic organisms in a water-sediment system are not available. However, due to sediment-water partitioning coefficients $K_d < 350$, no significant risk for organisms in this compartment is to be expected.

Data indicate that toxic effects on soil organisms might only be expected at high concentrations for alkyl sulfates. Toxicity of alkane sulfonates and alpha-olefin sulfonates can not be assessed because test results for terrestrial organisms are not available.

For alpha-olefin sulfonates, reliable short-term tests on fish, invertebrates and algae are available. The results indicate that toxicity is increasing as the alkyl chain length increases. The lowest available effect value is the 96 h-LC50 = 0.5 mg/l, determined in tests on *Oryzias latipes*, *Rasbora heteromorpha* and *Salmo trutta*

Algae show toxic effects to growth when exposed 10-100 mg/l for C14-18 AOS.

EC50 values for *Daphnia magna* have been determined within the range 5-50 mg/l for C14-18 AOS . Another study with *Daphnia magna*, showed EC50 values of 16.6 mg/l for C14-16 AOS and 7.7 mg/l for C16-18 AOS.

Studies performed with fish show that the higher homologues of AOS are more toxic than the lower ones. This has been illustrated for different fish species (LC50 (96 h) range 0.5-5.3 mg/l)

For alkane sulfonates: The toxicity of various SAS homologues was determined in tests with *Chlamydomonas variabilis*. After 24 hours of exposure at 20 C, there was a tendency to an increased toxicity with increasing chain length. The EC50 values were 125 mg/l for C10.3, 74.9 mg/l for C11.2, 32.4 mg/l for C14, 15.8 mg/l for C15, 9.42 mg/l for C16, 3.93 mg/l for C17, 3.71 mg/l for C18.9, and 8.47 mg/l for C20.7.

SIDS Initial Assessment Profile

Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, Environment Project, 615, 2001. Torben Madsen et al: Miljoministeriet (Danish Environmental Protection Agency).

COCONUT DIETHANOLAMIDE:

■ Harmful to aquatic organisms.

for diethanolamine (DEA):

log Kow : -1.43

Koc : 4

Half-life (hr) air : 4

Henry's atm m³ /mol: 5.35E-14

BOD 5: 0.03-0.1,0.9%

BOD 28: 57 mg/gm

COD : 1590 mg/gm

TPC 470 mg/gm

ThOD : 2.13

BCF : <1

Based on its physicochemical properties and biodegradation characteristics , DEA is not expected to pose a high risk to drinking water, and its potential for bioconcentration in aquatic organisms is low. DEA is categorized as "practically nontoxic" on an acute basis to freshwater invertebrates, estuarine/marine invertebrates, and freshwater plants

Environmental fate:

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In soil and water, DEA is expected to biodegrade fairly rapidly following acclimation (half-life on the order of days to weeks). In soil, DEA should leach. In the atmosphere, DEA is expected to exist almost entirely in the vapor phase. Reaction with photochemically generated hydroxyl radicals is expected to be the dominant removal mechanism (half-life, four hours). This compound may also be removed from the atmosphere in precipitation. The Henry's Law constant for DEA is $3.87 \times 10^{-11} \text{ atm} \cdot \text{m}^3/\text{mol}$ which suggests that DEA is essentially nonvolatile from water. The half-life for DEA vapour reacting with photochemically generated hydroxyl radicals in the atmosphere has been estimated to be four hours based on an estimated reaction rate constant of $8.9 \times 10^{-11} \text{ cm}^3/\text{molecules}/\text{sec}$ at 25°C and an average ambient hydroxyl concentration of $5 \times 10^5 \text{ molecules}/\text{cm}^3$.

DEA, in the presence of nitrites, can form N-nitrosodiethanolamine (NDELA). In air, NDELA is expected to exist solely as a vapor based on a vapor pressure of $2.78 \times 10^{-4} \text{ mmHg}$ at 25°C . Vapor-phase NDELA will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals with an estimated half-life of 13 hours. NDELA is stable to direct photolysis. In soil, an estimated K_{oc} of 4.8 suggests that this compound is expected to have very high mobility; it is expected to biodegrade slowly in soil. In summary, it appears that DEA is relatively short lived and that it does not present a high risk to contaminate drinking waters. NDELA, a potential formation product, is persistent to biotic and abiotic processes, and mobile. The amounts formed are uncertain (it is only indicated that the half-life is in the order of days to weeks). The water quality criteria (WQC) for nitrosamines is 0.0008 ug/L (U.S. Clean Water Act)

DEA's potential for bioconcentration in aquatic organisms is low

At very low concentrations (about 10 ppm) diethanolamine can be degraded in biological wastewater treatment plants.

Ecotoxicity:

Fish LC50 (96 h): Fathead minnow 100 mg/l; (48 h): Bluegill sunfish 1850 mg/l

Daphnia magna LC50 (48 h): 109 mg/l

DEA is categorized as ranging from moderately toxic to practically nontoxic to freshwater invertebrates based on EC50 values ranging from 2.15 to 306 mg/L.

DEA is categorized as "practically nontoxic" to estuarine/ marine invertebrates. EC50 values for estuarine/ marine invertebrates (shrimps and mollusks) exposed to DEA ranged from >100 to 2,800 mg/L.

DEA is categorised as practically nontoxic to freshwater plants on an acute basis based on EC50 values ranging from 103 to 523 mg/L.

Fatty acid amides (FAA) are nonionics used in hair shampoo, liquid soaps, shaving creams and other personal care products. FAA consist of a fatty acid, usually derived from coconut oil, which is linked to an amide group by a C-N bond. The amide may be typically either be monoethanolamide (MEA), diethanolamide (DEA), or monoisopropanolamide (MIPA).

Most fatty acid amides (FAA), such as the widely used cocodiethanolamide (cocoamide DEA) and cocomonethanolamide (cocoamide MEA), are ultimately degraded in the OECD tests for ready biodegradability under aerobic conditions. The available data describing the aerobic biodegradability of the ethoxylated FAA are contradictory. Certain data indicates that these surfactants do not pass the criteria for ready biodegradability, whereas the opposite is the case for data obtained from Akzo Nobel

The anaerobic biodegradability of FAA has been examined for cocoamide MEA by using the ECETOC screening test. Ultimate anaerobic biodegradability of cocoamide MEA reached 79% of the theoretical gas production, ThGP, during incubation of diluted digested sludge for 42 days at 35°C . By use of the ISO 11734 screening test, which corresponds to the ECETOC method, the ultimate anaerobic biodegradability of cocoamide MEA attained 81% during 56 days

No experimental data describing the bioaccumulation potential of fatty acid amides were found in the literature

The aquatic toxicity of FAA has been determined for species representing the three trophic levels algae, invertebrates, and fish. Cocoamide DEA appears to be more toxic to aquatic organism than cocoamide MEA.

An exceptionally high toxicity of cocoamide MEA was reported for two tests with the green alga *Scenedesmus subspicatus* as the 96 h-EC50 were 1.0 and 1.1 mg/l. More recent tests with a pure cocoamide ME - purity about 95.5% C12-18 gave EC50 values of 16.6 mg/l for *Scenedesmus subspicatus* and 17.8 mg/l for *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*). The latter data indicate that the toxicity of cocoamide MEA to algae are not markedly higher than the toxicity to daphnids and fish, and EC50 values above 10 mg/l are probably more representative for the toxicity towards algae. The ethoxylated FAA show the same level of

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aquatic toxicity as the non-ethoxylated FAA

Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, Environment Project, 615, 2001. Miljøministeriet (Danish Environmental Protection Agency).

For Fatty Nitrogen-Derived Amides (FND Amides)

Environmental fate:

As expected for molecules of this size, model predictions for the chemicals with definable structures indicate they are nonvolatile. Predicted or measured Kow values are of limited practical use for the FND Amides. An inherent property of surfactants is that they tend to accumulate at the interface between hydrophobic and hydrophilic phases rather than equilibrate between the two phases. Therefore, the accurate measurement of the Kow of any surfactant is notoriously difficult. The measured values for water solubility of the FND Amides indicate that they are insoluble. The model predictions, however, range from insoluble to moderately soluble. The physical/chemical properties of surfactants often make water solubility data of little practical value in the determination of environmental fate and effects.

Due to the low volatility of the FND Amides atmospheric photodegradation estimates are of no practical use. However, photodegradation was predicted that could be modeled. These predictions indicate that these chemicals would be expected to degrade relatively rapidly upon exposure to light (t_{1/2} values ranging from approximately 2.2 to 9.5 hours).

Due to the surfactant properties and solubility of the FND Amides, hydrolytic stability is of minimal value for determining environmental fate or effects.

Biodegradability: There are adequate measured data across Subcategories I, II and IV to allow the conclusion that these chemicals are readily or inherently biodegradable. Further, the model predictions provide reasonably close estimates to these measured values. Minimal degradability of the one chemical, [CAS RN 68122-86-1], from Subcategory III indicates these chemicals are slowly degraded. The slower degradation of these materials is likely the result of limited water solubility and behavior of the chemicals in aqueous solution. Longer single alkyl group substitutions and/or multiple long-chain alkyl substituents result in slower "inherent" biodegradability.

Ecotoxicity:

The reliable data for acute toxicity to fish and daphnid indicate that the FND Amides like surfactants in general, may adversely affect aquatic organisms (LC₅₀ and EC₅₀ values ranging from 0.2 to 59 mg/l). Many of the ECOSAR model estimates for the acute toxicity endpoints indicate the chemicals are "not toxic at solubility".¹ However, for surfactants such as the FND Amides the acute aquatic toxicity generally is considered to be related to the effects of the surfactant properties on the organism and not to direct chemical toxicity.

For surfactants:

Environmental fate:

Octanol/water partition coefficients cannot easily be determined for surfactants because one part of the molecule is hydrophilic and the other part is hydrophobic. Consequently they tend to accumulate at the interface and are not extracted into one or other of the liquid phases. As a result surfactants are expected to transfer slowly, for example, from water into the flesh of fish. During this process, readily biodegradable surfactants are expected to be metabolised rapidly during the process of bioaccumulation. This was emphasised by the OECD Expert Group stating that chemicals are not to be considered to show bioaccumulation potential if they are readily biodegradable.

Several anionic and nonionic surfactants have been investigated to evaluate their potential to bioconcentrate in fish. BCF values (BCF - bioconcentration factor) ranging from 1 to 350 were found. These are absolute maximum values, resulting from the radiolabelling technique used. In all these studies, substantial oxidative metabolism was found resulting in the highest radioactivity in the gall bladder. This indicates liver transformation of the parent compound and biliary excretion of the metabolised compounds, so that "real" bioconcentration is overstated. After correction it can be expected that "real" parent BCF values are one order of magnitude less than those indicated above, i.e. "real" BCF is <100. Therefore the usual data used for classification by EU directives to determine whether a substance is "Dangerous to the Environment" has little bearing on whether the use of the surfactant is environmentally acceptable.

Ecotoxicity:

Surfactant should be considered to be toxic (EC₅₀ and LC₅₀ values of < 10 mg/L) to aquatic species under conditions that allow contact of the chemicals with the organisms. The water solubility of the chemicals does not impact the toxicity except as it relates to the ability to conduct tests appropriately to obtain exposure of the test species. The acute aquatic toxicity generally is considered to be related to the effects of the surfactant properties on the organism and not to direct chemical toxicity.

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SODIUM CHLORIDE:

■ Although inorganic chloride ions are not normally considered toxic they can exist in effluents at acutely toxic levels (chloride >3000 mg/l). The resulting salinity can exceed the tolerances of most freshwater organisms.

Inorganic chlorine eventually finds its way into the aqueous compartment and as such is bioavailable. Incidental exposure to inorganic chloride may occur in occupational settings where chemicals management policies are improperly applied. The toxicity of chloride salts depends on the counter-ion (cation) present; that of chloride itself is unknown. Chloride toxicity has not been observed in humans except in the special case of impaired sodium chloride metabolism, e.g. in congestive heart failure. Healthy individuals can tolerate the intake of large quantities of chloride provided that there is a concomitant intake of fresh water.

Although excessive intake of drinking-water containing sodium chloride at concentrations above 2.5 g/litre has been reported to produce hypertension, this effect is believed to be related to the sodium ion concentration.

Chloride concentrations in excess of about 250 mg/litre can give rise to detectable taste in water, but the threshold depends upon the associated cations. Consumers can, however, become accustomed to concentrations in excess of 250 mg/litre. No health-based guideline value is proposed for chloride in drinking-water.

In humans, 88% of chloride is extracellular and contributes to the osmotic activity of body fluids. The electrolyte balance in the body is maintained by adjusting total dietary intake and by excretion via the kidneys and gastrointestinal tract. Chloride is almost completely absorbed in normal individuals, mostly from the proximal half of the small intestine. Normal fluid loss amounts to about 1.5-2 liters/day, together with about 4 g of chloride per day. Most (90 - 95%) is excreted in the urine, with minor amounts in faeces (4-8%) and sweat (2%).

Chloride increases the electrical conductivity of water and thus increases its corrosivity. In metal pipes, chloride reacts with metal ions to form soluble salts thus increasing levels of metals in drinking-water. In lead pipes, a protective oxide layer is built up, but chloride enhances galvanic corrosion. It can also increase the rate of pitting corrosion of metal pipes.

TLm 96 > 1000 ppm

ETHYLENE GLYCOL MONOSTEARATE:

■ For glycol and diol aliphatic esters:

Environmental fate:

Solubility: In general, the glycol monoesters with shorter carbon-number fatty acids (C6-C7) were predicted to be more water-soluble and less lipophilic than the corresponding glycol monoesters containing long-chain fatty acids such as stearic and oleic acids. The glycol diesters were predicted to be more lipophilic and less water-soluble than the corresponding glycol monoesters [e.g., ethylene glycol distearate (CAS 627-83-8) versus its monostearate (CAS 111-60-4); 2,2-dimethyl-1,3-propanediol dioleate (CAS 42222-50-4) versus its monooleate (CAS 67989-24-6)]. In addition, the glycol diesters have higher boiling points than the corresponding monoesters.

Polyethylene glycol (or polyoxyethylene) esters, that contain more than one repeating ethylene glycol unit, generally showed greater water solubility than the corresponding monoethylene glycol esters, owing to the increased polarity of multiple ether linkages; this was consistent with what would be expected. The greater degree of ether linkage was also consistent with the lower lipophilicity (log P) values predicted by EPIWIN. The distribution between the environmental compartments for glycol esters appears to be influenced by lipophilicity or water solubility. For lipophilic glycol esters with calculated log Kow >7, the EQC (Level III) model predicted a greater chemical distribution in the sediment and soil compartment. Conversely, for glycol esters with greater water solubility characteristics [e.g., heptanoic acid, ester with 2,2,4-trimethyl-1,3-pentanediol (CAS 71839-38-8); triethylene glycol, diheptanoate (CAS 7434-40-4); heptanoic acid, oxybis(2,1-ethanedioxy-2,1-ethanedioyl) ester (CAS 70729-68-9)], the EQC Level III model predicted greater distribution in the water compartment, in comparison to other very water-insoluble glycol esters.

Biodegradability: It is expected that the glycol esters would be rapidly and extensively biodegraded in the environment. The extent of biodegradation has been reported to range from 65% to 98% in 28 days for four glycol esters. These results indicate that the glycol esters are rapidly and extensively biodegraded. The tested substances covered the C15-C23 carbon range for the glycol esters. Glycol esters above C30 appear to be mainly comprised of the glycol diesters such as the dioleates and distearates, and several are simply to be diester homologs of the corresponding monooleate or monostearate esters. These diesters are expected to be microbially metabolized in the environment to the corresponding monoesters, some of which have been reported to be extensively biodegraded. For example, the glycol monooleate ester, 9-octadecenoic acid (Z)-, ester with

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2,2-dimethyl-1,3-propanediol (CAS 67989-24-6) has been demonstrated to be readily biodegradable in the OECD 301B modified Sturm test. Since 9-octadecenoic acid (Z)-, 2,2-dimethyl-1,3-propanediyl (di)ester (CAS 4222-50-4) is the corresponding diester derivative of the above glycol monooleate (i.e., CAS 67989-24-6), it is not unexpected that the dioleate would be extensively biodegraded as well. This is based on the premise that the dioleate would be expected to be microbially metabolized (hydrolyzed) to the monooleate, which has already been found to be readily biodegradable.

Biodegradation or enzymatic (microbial) breakdown of the glycol esters would be expected to ultimately lead to the free glycol such as propylene glycol, ethylene glycol, polyethylene glycol and to the corresponding free fatty acids, including stearic acid and oleic acid. There are adequate biodegradability data in the scientific literature to support the premise that these constituent components, namely, the free glycols and the free fatty acids, would be expected to be rapidly and extensively biodegraded in aerobic systems (e.g., sewage, activated sludge, wastewater) in the environment

Ecotoxicity:

The available data for the tested glycol esters indicate that acute aquatic toxicity would not be expected at the water solubility limit or water saturation levels (WSL) of the tested glycol ester materials. While the higher molecular weight glycol esters (>C38, MW ~600) have not been evaluated, they are probably expected to have low degrees of aquatic toxicity due to their very low water solubility.

It is of interest to note that ethylene glycol and propylene glycol are not acutely toxic to aquatic organisms. In addition, free fatty acids (e.g., stearic and oleic acids) that may be generated from enzymatic metabolism of the glycol esters are expected to have low degrees of aquatic toxicity.

DIAZOLIDINYL UREA:

■ For imidazolidinyl urea and diazolidinyl urea:

Diazolidinylurea is not readily biodegradable as only 24% ThCO₂ was attained in a standard laboratory test, OECD 301B (CETOX 2000). According to a QSAR estimation (EPIWIN 1994) the logK_{ow} of diazolidinyl urea is -7.49 which implies that the potential bioaccumulation in aquatic organisms is expected to be low.

The toxicity of diazolidinylurea has been examined in test with fish (species not indicated) and *Daphnia magna* where LC₅₀ and EC₅₀ (48-h) were determined to > 100 mg/l and 35 mg/l, respectively (CETOX 2000).

For formaldehyde:

Environmental fate:

Formaldehyde is ubiquitous in the environment as a contaminant of smoke and as photochemical smog. In the atmosphere, formaldehyde both photolyses and reacts with reactive free radicals (primarily hydroxyl radicals); half-lives in the sunlit tropospheres are 1.25 to 6 hours for photolysis, and 7.13-71.3 hours for reaction with hydroxyl radicals.

Reaction with nitrate radicals, insignificant during the day, may be an important removal process at night. Due to its solubility, formaldehyde will efficiently transfer to rain and surface water; one model predicts dry deposition and wet removal half-lives of 19 and 50 hours, respectively.

In water, formaldehyde will biodegrade to low concentrations within days; adsorption to sediment and volatilisation are not expected to be significant routes.

In soil, aqueous solutions of formaldehyde leach through the soil; at high concentrations adsorption to clay minerals may occur. Although biodegradable under both aerobic and anaerobic conditions the fate of formaldehyde in soil is unclear.

It does not bioconcentrate in the food chain.

Concentrated solutions containing formaldehyde are unstable, both oxidising slowly to form formic acid and polymerising. In the presence of air and moisture, polymerisation takes place readily in concentrated solutions at room temperature to form paraformaldehyde, a solid mixture of linear polyoxymethylene glycols containing 90-99% formaldehyde.

Drinking Water Standards:

hydrocarbon total: 10 ug/l (UK max.)

pesticide: 0.1 ug/l (UK max.)

formaldehyde: 900 ug/l (WHO guideline)

Air Quality Standards:

<0.1 mg/m³ as a 30 min. average, indoor air, non-industrial buildings (WHO guideline).

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Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
sodium lauryl sulfate	HIGH		LOW	LOW
sodium chloride	LOW		LOW	HIGH
methyl paraben	LOW		LOW	MED
propyl paraben	LOW		LOW	MED

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Bury residue in an authorised landfill.
- Recycle containers if possible, or dispose of in an authorised landfill.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None (ADG7)

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADG7, UN, IATA, IMDG

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE None

REGULATIONS

Regulations for ingredients

sodium lauryl sulfate (CAS: 151-21-3,1335-72-4,3088-31-1,9004-82-4) is found on the following regulatory lists;

"Australia Hazardous Substances", "Australia Inventory of Chemical Substances (AICS)", "Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6", "FEMA Generally Recognized as Safe (GRAS) Flavoring Substances 24 - Primary Names and Synonyms", "International Fragrance Association (IFRA) Survey: Transparency List", "OECD Representative List of High Production Volume (HPV) Chemicals"

coconut diethanolamide (CAS: 68603-42-9,61791-31-9) is found on the following regulatory lists;

"Australia Final Report on Hazard Classification of Common Skin Sensitisers", "Australia Inventory of Chemical Substances (AICS)", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD Representative List of High Production Volume (HPV) Chemicals"

sodium chloride (CAS: 7647-14-5) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "Australia Therapeutic Goods Administration (TGA) Substances that may be used as active ingredients in Listed medicines", "International Fragrance Association (IFRA) Survey: Transparency List", "OECD Representative List of High Production Volume (HPV) Chemicals"

ethylene glycol monostearate (CAS: 111-60-4) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "OECD Representative List of High Production Volume (HPV) Chemicals"

diazolidinyl urea (CAS: 78491-02-8) is found on the following regulatory lists;

"Australia Final Report on Hazard Classification of Common Skin Sensitisers", "Australia Hazardous Substances", "Australia Inventory of Chemical Substances (AICS)"

methyl paraben (CAS: 99-76-3) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "International Council of Chemical Associations (ICCA) - High Production Volume List", "International Fragrance Association (IFRA) Survey: Transparency List"

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propyl paraben (CAS: 94-13-3) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "International Fragrance Association (IFRA) Survey: Transparency List"

water (CAS: 7732-18-5) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "IMO IBC Code Chapter 18: List of products to which the Code does not apply", "International Fragrance Association (IFRA) Survey: Transparency List", "OECD Representative List of High Production Volume (HPV) Chemicals"

No data for Johnson & Johnson Medical Microshield Handwash (CW: 4706-25)

Section 16 - OTHER INFORMATION

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
sodium lauryl sulfate	151- 21- 3, 1335- 72- 4, 3088- 31- 1, 9004- 82- 4
coconut diethanolamide	68603- 42- 9, 61791- 31- 9

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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This is the end of the MSDS.