

# JOHNSON & JOHNSON MEDICAL MICROSIELD PVP

Chemwatch Independent Material Safety Data Sheet

Issue Date: 21-Mar-2011

NC317ECP

CHEMWATCH 6039-23

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## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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### PRODUCT NAME

JOHNSON & JOHNSON MEDICAL MICROSIELD PVP

### SYNONYMS

"Povidone-Iodine Surgical Handwash, Manufacturer's Codes: 61377, 61389"

### PRODUCT USE

Broad spectrum antimicrobial surgical handwash for external use only. Application over large skin areas should be avoided. Use in pregnancy and lactation should be limited.

### 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

North Ryde

NSW, 2113

Australia

Telephone: +61 2 9878 9000

Telephone: 1800 257 210

Emergency Tel: **13 11 26**

Emergency Tel: **+64 3 474 7000 NZ**

Fax: 1800 808 233

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## Section 2 - HAZARDS IDENTIFICATION

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### STATEMENT OF HAZARDOUS NATURE

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

### RISK

Risk Codes

R36

Risk Phrases

- Irritating to eyes.

### SAFETY

Safety Codes

S23

S24

S39

S51

S09

S40

S07

S26

S46

Safety Phrases

- Do not breathe gas/ fumes/ vapour/ spray.
- Avoid contact with skin.
- Wear eye/ face protection.
- Use only in well ventilated areas.
- Keep container in a well ventilated place.
- To clean the floor and all objects contaminated by this material, use water.
- Keep container tightly closed.
- In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
- If swallowed, IMMEDIATELY contact Doctor or Poisons Information Centre (show this container or label).

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## Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
povidone- iodine	25655-41-8	7.5
ammonium nonoxynol sulfate	9051-57-4	0-10
glycerol	56-81-5	0-10
sodium lauryl sulfate	151-21-3	0-10
sodium phosphate, dibasic	7558-79-4	0-10
lauryl pyrrolidone		0-10
hydroxyethylcellulose	9004-62-0	0-10
citric acid monohydrate for pH adjustment		0-10
fragrance		0-10
potassium iodide	7681-11-0	0-10
water	7732-18-5	>20

## Section 4 - FIRST AID MEASURES

### SWALLOWED

- For advice, contact a Poisons Information Centre or a doctor.
- 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.
- If skin or hair contact occurs:
- Flush skin and hair with running water (and soap if available).
  - Seek medical attention in event of irritation.

### INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

### NOTES TO PHYSICIAN

- Treat symptomatically.
- Anaphylaxis is possible for sensitive individuals. Esophageal stricture may persist after recovery from immediate symptoms. Starch (15 g flour in 500ml water) may be used to absorb iodine.

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## Section 5 - FIRE FIGHTING MEASURES

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### EXTINGUISHING MEDIA

- There is no restriction on the type of extinguisher which may be used.

### FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding 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: iodine.

### FIRE INCOMPATIBILITY

- None known.

### HAZCHEM

None

### Personal Protective Equipment

Breathing apparatus.

Gas tight chemical resistant suit.

Limit exposure duration to 1 BA set 30 mins.

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## Section 6 - ACCIDENTAL RELEASE MEASURES

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### MINOR SPILLS

- Clean up all spills immediately.
- Avoid breathing vapours and contact with skin and eyes.
- Control personal contact by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.
- Wipe up.
- Place in a suitable, labelled container for waste disposal.

### MAJOR SPILLS

- 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.

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Section 6 - ACCIDENTAL RELEASE MEASURES

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

## Section 7 - HANDLING AND STORAGE

### PROCEDURE FOR HANDLING

- Avoid mixing with detergents.
- Avoid contact with other chemicals.
- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

### SUITABLE CONTAINER

- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

### STORAGE INCOMPATIBILITY

Avoid contact with reducing agents, alkaloid salts, chloral hydrate, and metallic salts.

### 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 <sup>3</sup>	Notes
Australia Exposure Standards	glycerol (Glycerin mist (a))	10	(see Chapter 14)

The following materials had no OELs on our records

- povidone- iodine: CAS:25655- 41- 8
- ammonium nonoxynol sulfate: CAS:9051- 57- 4 CAS:37226- 45- 2
- sodium lauryl sulfate: CAS:151- 21- 3 CAS:1335- 72- 4 CAS:3088- 31- 1 CAS:9004- 82- 4
- sodium phosphate, dibasic: CAS:7558- 79- 4 CAS:10028- 24- 7
- hydroxyethylcellulose: CAS:9004- 62- 0
- potassium iodide: CAS:7681- 11- 0
- water: CAS:7732- 18- 5

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## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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### MATERIAL DATA

AMMONIUM NONOXYNOL SULFATE:

GLYCEROL:

POTASSIUM IODIDE:

SODIUM LAURYL SULFATE:

SODIUM PHOSPHATE, DIBASIC:

■ 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.

AMMONIUM NONOXYNOL SULFATE:

POTASSIUM IODIDE:

POVIDONE-IODINE:

SODIUM LAURYL SULFATE:

SODIUM PHOSPHATE, DIBASIC:

■ 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.

JOHNSON & JOHNSON MEDICAL MICROSIELD PVP:

- None assigned. Refer to individual constituents.

GLYCEROL:

The mist is considered to be a nuisance particulate which appears to have little adverse effect on the lung and does not produce significant organic disease or toxic effects. OSHA concluded that the nuisance particulate limit would protect the worker from kidney damage and perhaps, testicular effects.

WATER:

- No exposure limits set by NOHSC or ACGIH.

### PERSONAL PROTECTION

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### 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.
- Stains may be removed with dilute sodium thiosulfate solution.

### OTHER

- 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

- General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas.
- Avoid production of aerosols.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### APPEARANCE

Dark brown viscous liquid with faint iodine odour; mixes with 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)	5.0
Autoignition Temp (°C)	Not applicable	Vapour Pressure (kPa )	Not available.
Upper Explosive Limit (%)	Not applicable	Specific Gravity (water=1)	1.05
Lower Explosive Limit (%)	Not applicable	Relative Vapour Density (air=1)	Not available.
Volatile Component (%vol)	Not available.	Evaporation Rate	Not available
glycerol log Kow (Sangster 1997):			- 1.76

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## Section 10 - STABILITY AND REACTIVITY

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### CONDITIONS CONTRIBUTING TO INSTABILITY

- Product is considered stable and hazardous polymerisation will not occur.  
*For incompatible materials - refer to Section 7 - Handling and Storage.*

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## Section 11 - TOXICOLOGICAL INFORMATION

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### POTENTIAL HEALTH EFFECTS

#### ACUTE HEALTH EFFECTS

##### SWALLOWED

- Considered an unlikely route of entry in commercial/industrial environments.  
The liquid is discomforting.  
Ingestion may result in nausea, abdominal irritation, pain and vomiting.

##### EYE

- The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

##### SKIN

- Not considered an irritant through normal use.  
The liquid may be slightly discomforting to the skin if exposure is prolonged and is capable of causing transient staining of the skin and skin reactions which may lead to dermatitis from repeated exposures over long periods.  
One patient in 413 patients with contact dermatoses was found to be allergic to povidone-iodine.

##### INHALED

- Not normally a hazard due to non-volatile nature of product.  
Inhalation of aerosols (mists, fumes), generated by the material during the course of normal handling, may be harmful.

#### CHRONIC HEALTH EFFECTS

- There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.  
Chronic use may increase blood iodine levels leading to altered thyroid function.

#### TOXICITY AND IRRITATION

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

##### WATER:

##### HYDROXYETHYLCELLULOSE:

- No significant acute toxicological data identified in literature search.

##### SODIUM LAURYL SULFATE:

##### SODIUM PHOSPHATE, DIBASIC:

##### AMMONIUM NONOXYNOL 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

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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.

SODIUM PHOSPHATE, DIBASIC:

POVIDONE-IODINE:

■ 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.

JOHNSON & JOHNSON MEDICAL MICROSIELD PVP:

■ Not available. Refer to individual constituents.

POVIDONE-IODINE:

TOXICITY

Oral (rat) LD50: >8000 mg/k

Oral (rat) LD50: 5990 mg/kg \* [\* = Manufacturer]

Dermal (human) TDLo: 3400 mg/Kg/24h

IRRITATION

Skin (rabbit): 500 mg Mild

AMMONIUM NONOXYNOL SULFATE:

TOXICITY

Oral (rat) LD50: 8000 mg/kg

IRRITATION

Nil Reported

GLYCEROL:

TOXICITY

Oral (Rat) LD50: 12600 mg/kg

Oral (Guinea pig) LD50: 7750 mg/kg

Oral (Human) TDLo: 1428 mg/kg

Intraperitoneal (Rat) LD50: 4420 mg/kg

Subcutaneous (Rat) LD50: 100 mg/kg

Intravenous (Rat) LD50: 5566 mg/kg

Oral (Mouse) LD50: 4090 mg/kg

Intraperitoneal (Mouse) LD50: 8700 mg/kg

Subcutaneous (Mouse) LD50: 91 mg/kg

Intravenous (Mouse) LD50: 4250 mg/kg

■ For glycerol:

At very high concentration, evidence predicts that glycerol may cause tremor, irritation of the skin, eyes, gastro-intestinal tract and respiratory tract, otherwise it is of low order toxicity. There is no evidence to suggest that it causes cancer, genetic, reproductive or developmental toxicity, however, toxicity is possible in sensitive individuals.

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.

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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 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 sensitisation is expected.

However anecdotal evidence suggests that sodium lauryl sulfate causes pulmonary sensitisation 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 (NO<sub>3</sub><sup>-</sup>) 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

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sulfonated surfactants has produced sensitisation 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). 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

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## Section 11 - TOXICOLOGICAL INFORMATION

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

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

SODIUM PHOSPHATE, DIBASIC:

TOXICITY

Oral (rat) LD50: 17000 mg/kg

Intravenous (Rabbit) LD: 1075 mg/kg

■ The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

IRRITATION

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

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

POTASSIUM IODIDE:

TOXICITY

Oral (mouse) LDLo: 1862 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.

Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.

Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema.

Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.

IRRITATION

Nil Reported

## Section 12 - ECOLOGICAL INFORMATION

POTASSIUM IODIDE:

POVIDONE-IODINE:

■ Iodine is an important element in studies of environmental protection and human health, global-scale hydrologic processes and nuclear nonproliferation. Biogeochemical cycling of iodine is complex, because iodine occurs in multiple oxidation states and as inorganic and organic species that may be hydrophilic, atmophilic, and biophilic. Experiments illustrate complex behavior with various processes occurring, including iodate reduction, irreversible retention or mass loss of iodide, and rate-limited and nonlinear sorption. There was an appreciable iodate reduction to iodide, presumably mediated by the structural Fe(II) in some clay minerals; therefore, careful attention must be given to potential interconversion among species when interpreting the biogeochemical behavior of iodine in the environment.

Iodine (I<sub>2</sub>) is electrochemically reduced to ionic iodide by natural processes but humic acid appears to promote the reaction. The different oxidation species of iodine have markedly different sorption properties. Hence, changes in iodine redox states can greatly affect the mobility of iodine in the environment. A major microbial role has been suggested in the past to account for at least some of these redox changes. Both soluble ferrous iron and sulfide, as well as iron monosulfide (FeS) were shown to abiologically reduce iodate to iodide. These results indicate that ferric iron and/or sulfate reducing bacteria are capable of mediating both direct, enzymatic, as well as abiotic reduction of iodate in natural anaerobic environments.

Environmental and geological evidence indicates that iodine can become associated with natural organic matter

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(NOM) in soils and sediments. Previous studies have shown that iodine (including 129I) can be strongly retained in organic-rich surface soils and sediment and that soluble iodine may be associated with dissolved humic material. Iodine and iodate undergo an abiotic pseudo first-order reaction with peat leading to either reduction of iodate or iodine to iodide or incorporation of the iodine atoms into the organic matrix. Iodine appears to be incorporated in sphagnum peat by aromatic substitution for hydrogen on phenolic constituents of the peat.

AMMONIUM NONOXYNOL SULFATE:

GLYCEROL:

SODIUM LAURYL SULFATE:

SODIUM PHOSPHATE, DIBASIC:

POTASSIUM IODIDE:

POVIDONE-IODINE:

■ DO NOT discharge into sewer or waterways.

POVIDONE-IODINE:

AMMONIUM NONOXYNOL SULFATE:

■ 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.

In air ammonia is persistent whilst, in water, it biodegrades rapidly to nitrate, producing a high oxygen demand. Ammonia is strongly adsorbed to soil. Ammonia is non-persistent in water (half-life 2 days) and is moderately toxic to fish under normal temperature and pH conditions. Ammonia is harmful to aquatic life at low concentrations but does not concentrate in the food chain. Ammonium ions may be toxic to fish at 0.3 mg/l

Drinking Water Standards:

0.5 mg/l (UK max.)

1.5 mg/l (WHO Levels)

Soil Guidelines: none available.

Air Quality Standards: none available.

for alkylphenols and their ethoxylates, or propoxylates:

Environmental fate: Alkylphenols are ubiquitous in the environment after the introduction, generally as wastes, of their alkoxyated forms (ethoxylates and propoxylates, for example); these are extensively used throughout industry and in the home.

Alkylphenol ethoxylates are widely used surfactants in domestic and industrial products, which are commonly found in wastewater discharges and in sewage treatment plant (STP) effluent's. Degradation of APEs in wastewater treatment plants or in the environment generates more persistent shorter-chain APEs and alkylphenols (APs) such as nonylphenol (NP), octylphenol (OP) and AP mono- to triethoxylates (NPE1, NPE2 and

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NPE3). There is concern that APE metabolites (NP, OP, NPE1-3) can mimic natural hormones and that the levels present in the environment may be sufficient to disrupt endocrine function in wildlife and humans. The physicochemical properties of the APE metabolites (NP, NPE1-4, OP, OPE1-4), in particular the high Kow values, indicate that they will partition effectively into sediments following discharge from STPs. The aqueous solubility data for the APE metabolites indicate that the concentration in water combined with the high partition coefficients will provide a significant reservoir (load) in various environmental compartments. Data from studies conducted in many regions across the world have shown significant levels in samples of every environmental compartment examined. In the US, levels of NP in air ranged from 0.01 to 81 ng/m<sup>3</sup>, with seasonal trends observed. Concentrations of APE metabolites in treated wastewater effluents in the US ranged from < 0.1 to 369 ug/l, in Spain they were between 6 and 343 ug/l and concentrations up to 330 ug/l were found in the UK. Levels in sediments reflected the high partition coefficients with concentrations reported ranging from < 0.1 to 13,700 ug/kg for sediments in the US. Fish in the UK were found to contain up to 0.8 ug/kg NP in muscle tissue. APEs degraded faster in the water column than in sediment. Aerobic conditions facilitate easier further biotransformation of APE metabolites than anaerobic conditions.

Nonylphenols are susceptible to photochemical degradation. Using natural, filtered, lake water it was found that nonylphenol had a half-life of approximately 10-15 h under continuous, noon, summer sun in the surface water layer, with a rate approximately 1.5 times slower at depths 20-25 cm. Photolysis was much slower with ethoxylated nonylphenol, and so it is unlikely to be a significant event in removal of the ethoxylates.

Air: Alkylphenols released to the atmosphere will exist in the vapour phase and is thought to be degraded by reaction with photochemically produced hydroxyl radicals, with a calculated half-life, for nonylphenol, of 0.3 days.

Water: Abiotic degradation of alkylphenol is negligible. Biodegradation does not readily take place. The half-life in surface water may be around 30 days.

Degradation: Alkylphenol ethoxylates (APES) may abiotically degrade into the equivalent alkylphenol. During degradation ethylene oxide units are cleaved off the ethylene oxide chain until only short-chain alkylphenol ethoxylates remain, typically mono- and diethylene oxides. Oxidation of these oligomers creates the corresponding carboxylic acids. This leaves several degradation products: short-chain ethoxylates, their carboxylic acids, and alkylphenols.

Biodegradation: Alkylphenols are not readily biodegradable. Several mechanisms of microbial aromatic ring degradation have been reported, the most common being formation of catechol from phenol, followed by ring scission between or adjacent to the two hydroxyl groups.

The full breakdown pathway for APES has not yet been determined, and all studies have so far focused on identification of intermediates in bacterial culture media, rather than studying cell-free systems or purified enzymes. It is, however, likely that microbial metabolism usually starts by an attack on the ethoxylate chain, rather than on the ring or the hydrophobic chain. The ethoxylate groups are progressively removed, either by ether cleavage, or by terminal alcohol oxidation followed by cleavage of the resulting carboxylic acid.

Biodegradation of APES produces less biodegradable products: alkylphenol mono- and di-ethoxylates, alkylphenoxy acetic and alkylphenoxy polyethoxy acetic acids, and alkylphenols. These metabolites frequently persist through sewage treatment and in rivers. Anaerobic conditions generally lead to the accumulation of alkylphenols. The rate of biodegradation seems to decrease with increasing length of the ethylene oxide chain.

Bioaccumulation: Metabolites of APES accumulate in organisms, with bioconcentration factors varying from ten to several thousand, depending on species, metabolite and organ.

The metabolites of APES are generally more toxic than the original compounds. APES have LC50s above about 1.5 mg/l, whereas alkylphenols, such as nonylphenol, have LC50s are generally around 0.1 mg/l.

Oestrogenic activity: The role of alkyl chain length and branching, substituent position, number of alkylated groups, and the requirement of a phenolic ring structure was assessed in fish. The results showed that most alkylphenols were oestrogenic, although with 3-300 thousand times lower potency than the endogenous estrogen 17beta-estradiol. Mono-substituted tertiary alkylphenols with moderate (C4-C5) and long alkyl chain length (C8-C9) in the para position exhibited the highest oestrogenic potency. Substitution with multiple alkyl groups, presence of substituents in the ortho- and meta-position and lack of a hydroxyl group on the benzene ring reduced the oestrogenic activity, although several oestrogenic alkylated non-phenolics were identified.

Human exposure: Alkylphenols were first found to be oestrogenic (oestrogen-mimicking) in the 1930s, but more recent research has highlighted the implications of these effects. The growth of cultured human breast cancer cells is affected by nonylphenol at concentrations as low as 1 uM (220 ug/l) or concentrations of octylphenol as low as 0.1 uM (20 ug/l). Oestrogenic effects have also been shown on rainbow trout hepatocytes, chicken embryo fibroblasts and a mouse oestrogen receptor.

The insecticide chlordecone (Kepone) shows similar behaviour to alkylphenols, accumulating in liver and adipose tissue, and eliciting oestrogenic activity. Workers exposed to this insecticide can suffer

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reproductive effects such as low sperm counts and sterility. In addition, the oestrogenic effects of chlordecone on MCF7 cells occur at similar concentrations to those of alkylphenols, suggesting that alkylphenols will be a similar health hazard if target cells are exposed to  $\mu\text{M}$  levels of these compounds. By comparing environmental concentrations, bioconcentration factors and in vitro oestrogenic effect levels, current environmental levels of alkylphenolic compounds are probably high enough to affect the hormonal control systems of some organisms. It is also possible that human health could be being affected.

## GLYCEROL:

■ For glycerol

log Kow : -2.66- -2.47

BOD 5: 0.617-0.87,31-51%

COD : 1.16,82-95%

ThOD : 1.217-1.56

Completely biodegradable.

Environmental fate:

Based on the relevant physical-chemical properties and the fact that glycerol is readily biodegradable, glycerol will partition primarily to water.

Biodegradability: Glycerol is considered to be readily biodegradable in the aquatic environment. Pre-adapted microorganisms can degrade glycerol rapidly under both aerobic and anaerobic conditions.

Bioaccumulation: Based on Log Kow -1.76, glycerol will have a low bioaccumulation potential and is not expected to bioaccumulate.

Photodegradation: The calculated half-life for the photo-oxidation (reaction with hydroxyl radicals) of glycerol in air is 6.8 hours (EPIWIN vs 3.04).

Stability in Water: Glycerol does not contain functional groups that are expected to react with water.

Transport between Environmental Compartments: From the EQC model (Mackay level III), it can be deduced that 100% of glycerol will end up in the water phase. Negligible amounts will be distributed towards soil, air and sediment

Ecotoxicity:

Fish LC50: >5000 mg/l

Algae IC50: >2900 mg/l

Bacteria EC50: .10000 mg/l (*Pseudomonas putida*)

The weight of evidence indicates that glycerol is of low toxicity to aquatic organisms and this conclusion is supported by QSAR predictions. The lowest LC50 for fish is a 24-h LC50 of >5000 mg/l for *Carassius auratus* (Goldfish) and for aquatic invertebrates, a 24 h EC50 of >10000 mg/l for *Daphnia magna* is the lowest EC50.

Several tests on algae are available, which suggest very low toxicity to a range of species, however their validity is uncertain. A QSAR prediction for the 96h EC50 to algae was 78000 mg/l. No toxicity towards the microorganism *Pseudomonas putida* was observed at 10000 mg/l after exposure for 16 hours. No long-term aquatic toxicity data is available. Screening studies are available on frog and carp embryos which indicate some effects on growth and hatching rates respectively at very high concentrations of glycerol, >7000 mg/l.

However, their ecological relevance is not clear.

## SODIUM LAURYL SULFATE:

■ Toxic to aquatic organisms.

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.

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<sup>+</sup>, K<sup>+</sup>, NH<sub>4</sub><sup>+</sup>, 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

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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 Kow 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 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

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ready biodegradability. report 85% DOC removal in the modified OECD screening test, 85% ThOD in the closed bottle test, and 65-80% ThCO<sub>2</sub> 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% ThCO<sub>2</sub> 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.

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*

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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).

### SODIUM PHOSPHATE, DIBASIC:

■ The principal problems of phosphate contamination of the environment relates to eutrophication processes in lakes and ponds. Phosphorus is an essential plant nutrient and is usually the limiting nutrient for blue-green algae. A lake undergoing eutrophication shows a rapid growth of algae in surface waters. Planktonic algae cause turbidity and flotation films. Shore algae cause ugly muddying, films and damage to reeds. Decay of these algae causes oxygen depletion in the deep water and shallow water near the shore. The process is self-perpetuating because anoxic conditions at the sediment/water interface causes the release of more adsorbed phosphates from the sediment. The growth of algae produces undesirable effects on the treatment of water for drinking purposes, on fisheries, and on the use of lakes for recreational purposes.

### HYDROXYETHYLCELLULOSE:

■ Cellulosic products, including cellulose ethers, generally have a low biodegradation rate and are generally of low toxicity to fish.

Sugar-based compounds (saccharides), including polysaccharides are generally easily decomposed by biodegradation. Not all polysaccharides decompose with equal rapidity, and polysaccharides are also synthesised by microorganisms during, for example, the compost maturation phases. Water-insoluble species such as cellulose take longer to decompose and those with a significant degree of branching also take longer.

### POTASSIUM IODIDE:

Fish LC50(48 h): 0.09-0.48 mg/L

Invertebrate LC50 (48 h): 0.8 mg/L

Nitrif. inhib.: inhib at 0.05mg/L

### Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
glycerol	LOW		LOW	HIGH
sodium lauryl sulfate	HIGH		LOW	LOW
hydroxyethylcellulose	LOW		LOW	HIGH
potassium iodide	HIGH		LOW	HIGH

## 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.
- Iodine is reduced to iodide by addition of thiosulfate. The remaining solution is then suitable for disposal to the sewer. Seek approval from

continued...

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Section 13 - DISPOSAL CONSIDERATIONS

local authorities.

## 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

**povidone-iodine (CAS: 25655-41-8) is found on the following regulatory lists;**

"Australia Inventory of Chemical Substances (AICS)"

**ammonium nonoxynol sulfate (CAS: 9051-57-4,37226-45-2) is found on the following regulatory lists;**

"Australia Inventory of Chemical Substances (AICS)"

**glycerol (CAS: 56-81-5) is found on the following regulatory lists;**

"Australia Exposure Standards", "Australia High Volume Industrial Chemical List (HVICL)", "Australia Inventory of Chemical Substances (AICS)", "Australia Therapeutic Goods Administration (TGA) Substances that may be used as active ingredients in Listed medicines", "CODEX General Standard for Food Additives (GSFA) - Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP", "GESAMP/EHS Composite List - GESAMP Hazard Profiles", "IMO IBC Code Chapter 18: List of products to which the Code does not apply", "IMO MARPOL 73/78 (Annex II) - List of Other Liquid Substances", "International Council of Chemical Associations (ICCA) - High Production Volume List", "International Fragrance Association (IFRA) Survey: Transparency List", "OECD Representative List of High Production Volume (HPV) Chemicals"

**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"

**sodium phosphate, dibasic (CAS: 7558-79-4,10028-24-7) 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"

**hydroxyethylcellulose (CAS: 9004-62-0) is found on the following regulatory lists;**

"Australia Inventory of Chemical Substances (AICS)"

**potassium iodide (CAS: 7681-11-0) 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"

**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 PVP (CW: 6039-23)**

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## Section 16 - OTHER INFORMATION

### INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
ammonium nonoxynol sulfate	9051- 57- 4, 37226- 45- 2
sodium lauryl sulfate	151- 21- 3, 1335- 72- 4, 3088- 31- 1, 9004- 82- 4
sodium phosphate, dibasic	7558- 79- 4, 10028- 24- 7

### REPRODUCTIVE HEALTH GUIDELINES

Ingredient	ORG	UF	Endpoint	CR	Adeq TLV
potassium iodide	1.0 mg/m3	NA	NA	NA	Yes

■ These exposure guidelines have been derived from a screening level of risk assessment and should not be construed as unequivocally safe limits. ORGS represent an 8-hour time-weighted average unless specified otherwise.

CR = Cancer Risk/10000; UF = Uncertainty factor:

TLV believed to be adequate to protect reproductive health:

LOD: Limit of detection

Toxic endpoints have also been identified as:

D = Developmental; R = Reproductive; TC = Transplacental carcinogen

Jankovic J., Drake F.: A Screening Method for Occupational Reproductive

American Industrial Hygiene Association Journal 57: 641-649 (1996).

■ 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](http://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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Section 16 - OTHER INFORMATION

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*This is the end of the MSDS.*