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Naproxen Suspension 125mg/5mL

Phebra Pty Ltd

Chemwatch Hazard Alert Code: **3**

Chemwatch: **4777-20**
Version No: **2.1.1.1**
Safety Data Sheet according to WHS and ADG requirements

Issue Date: **27/06/2017**
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S.GHS.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	Naproxen Suspension 125mg/5mL
Synonyms	Not Available
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Naproxen is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, for the symptomatic treatment of primary dysmenorrhoea, for the relief of acute and/or chronic pain states in which there is an inflammatory component and as an analgesic in acute migraine attack.

Details of the supplier of the safety data sheet

Registered company name	**Phebra**
Address	19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199|1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	info@phebra.com

Emergency telephone number

Association / Organisation	**Not Available**
Emergency telephone numbers	+61 401 264 004
Other emergency telephone numbers	N/A

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

Poisons Schedule	S4
Classification [1]	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2A, Germ cell mutagenicity Category 2, Reproductive Toxicity Category 1B, Acute Aquatic Hazard Category 2
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI*

Label elements

Hazard pictogram(s)	
SIGNAL WORD	**DANGER**

Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H360	May damage fertility or the unborn child.
H401	Toxic to aquatic life.

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P281	Use personal protective equipment as required.
P273	Avoid release to the environment.

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P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P332+P313	If skin irritation occurs: Get medical advice/attention.

Precautionary statement(s) Storage

P405	Store locked up.

Precautionary statement(s) Disposal

P501	Dispose of contents/container in accordance with local regulations.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
57-50-1	25.5	Sucrose
50-70-4	13	Sorbitol
22204-53-1	2.5	Naproxen
7647-14-5	2	Sodium Chloride
1327-43-1	2	magnesium aluminosilicate
110-17-8	<1	fumaric acid
99-76-3	<1	Methyl Paraben
Not Available	<1	imitation pineapple flavour ,proprietary
Not Available	<1	imitation orange flavour, ,proprietary
Not Available	<1	F.D & C yellow ,proprietary
7732-18-5	>50	water

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	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 Contact	If skin contact occurs: ▸ Immediately remove all contaminated clothing, including footwear. ▸ Flush skin and hair with running water (and soap if available). ▸ Seek medical attention in event of irritation.
Inhalation	▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary.
Ingestion	▸ Immediately give a glass of water. ▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
for non-steroidal anti-inflammatories (NSAIDs)

- Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.
- There are no specific antidotes.
- Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children), and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose).
- Forced diuresis, alkalinisation of urine, hemodialysis, or haemoperfusion may not be useful due to high protein binding.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into

Continued...

account surrounding areas.
Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.
In such an event consider:
- foam.
- dry chemical powder.
- carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.

Advice for firefighters

Fire Fighting	▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves in the event of a fire. ▸ 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	▸ The material is not readily combustible under normal conditions. ▸ However, it will break down under fire conditions and the organic component may burn. ▸ Not considered to be a significant fire risk. ▸ Heat may cause expansion or decomposition with violent rupture of containers. ▸ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). ▸ May emit acrid smoke. Decomposes on heating and produces toxic fumes of: , carbon dioxide (CO_2) , other pyrolysis products typical of burning organic material. May emit corrosive fumes.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	▸ Clean up all spills immediately. ▸ Avoid breathing vapours and contact with skin and eyes. ▸ Control personal contact with the substance, 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	Moderate hazard. ▸ Clear area of personnel and move upwind. ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves. ▸ Prevent, by any means available, spillage from entering drains or water course. ▸ Stop leak if safe to do so. ▸ Contain spill with sand, earth or vermiculite. ▸ Collect recoverable product into labelled containers for recycling.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	▸ Avoid all personal contact, including inhalation. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ Prevent concentration in hollows and sumps. ▸ **DO NOT** enter confined spaces until atmosphere has been checked. ▸ **DO NOT** allow material to contact humans, exposed food or food utensils. ▸ Avoid contact with incompatible materials. ▸ When handling, **DO NOT** eat, drink or smoke. ▸ **DO NOT** allow clothing wet with material to stay in contact with skin
Other information	▸ 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 storage and handling recommendations contained within this SDS.

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Conditions for safe storage, including any incompatibilities

Suitable container	▸ Packaging as recommended by manufacturer. ▸ Check that containers are clearly labelled. ▸ Tamper-proof containers. ▸ Polyethylene or polypropylene containers. ▸ Metal drum with sealed plastic liner. ▸ Glass container is suitable for laboratory quantities
Storage incompatibility	▸ Avoid reaction with oxidising agents, bases and strong reducing agents.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	Sucrose	Sucrose	10 mg/m3	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Sorbitol	Hexanehexol, 1,2,3,4,5,6-; (Mannitol)	120 mg/m3	1,400 mg/m3	2,700 mg/m3
Sodium Chloride	Chloride; (Chloride(1-); Chloride ions)	0.5 ppm	2 ppm	20 ppm

Ingredient	Original IDLH	Revised IDLH
Sucrose	Not Available	Not Available
Sorbitol	Not Available	Not Available
Naproxen	Not Available	Not Available
Sodium Chloride	Not Available	Not Available
magnesium aluminosilicate	Not Available	Not Available
fumaric acid	Not Available	Not Available
Methyl Paraben	Not Available	Not Available
imitation pineapple flavour ,proprietary	Not Available	Not Available
imitation orange flavour, ,proprietary	Not Available	Not Available
F.D & C yellow ,proprietary	Not Available	Not Available
water	Not Available	Not Available

Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.
Personal protection	
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: ▸ Chemical goggles. ▸ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. ▸ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses 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.
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended.

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	Suitability and durability of glove type is dependent on usage. ▸ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▸ Double gloving should be considered. ▸ PVC gloves. ▸ Change gloves frequently and when contaminated, punctured or torn. ▸ Wash hands immediately after removing gloves. ▸ Protective shoe covers. [AS/NZS 2210] ▸ Head covering.
Body protection	See Other protection below
Other protection	▸ For quantities up to 500 grams a laboratory coat may be suitable. ▸ For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. ▸ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. ▸ For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. ▸ Eye wash unit. ▸ Ensure there is ready access to an emergency shower. ▸ For Emergencies: Vinyl suit
Thermal hazards	Not Available

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:
"Forsberg Clothing Performance Index".
The effect(s) of the following substance(s) are taken into account in the ***computer-generated*** selection:
Naproxen Suspension 125mg/5mL

Material	CPI
BUTYL	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NITRILE	C
PVA	C
VITON	C

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion
C: Poor to Dangerous Choice for other than short term immersion
NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Light orange opaque suspension with an orange odour and uniformly distributed particles which readily resuspend on shaking.

Physical state	Liquid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available
pH (as supplied)	2.2-3.7	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	500
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	Not Available	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Not Available	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Available	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	Not Available	**Volatile Component (%vol)**	Not Available
Vapour pressure (kPa)	Not Available	**Gas group**	Not Available
Solubility in water (g/L)	Immiscible	**pH as a solution (1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

SECTION 10 STABILITY AND REACTIVITY

Continued...

Reactivity	See section 7
Chemical stability	▸ Unstable in the presence of incompatible materials. ▸ Product is considered stable. ▸ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Not normally a hazard due to non-volatile nature of product
Ingestion	Side-effects associated with naproxen include gastro-intestinal disturbance (such as bleeding or peptic ulcer), headache, dizziness, nervousness, vomiting, cramps, skin rash, itch, ringing in the ears, oedema, depression, drowsiness, sleeplessness and blurred vision and other eye reactions. Meningitis and skin effects such as rash, blisters, hives, hair loss, erythema multiforme and Stevens-Johnson syndrome. Aspirin-sensitive asthmatic patients developed reactions (runny nose, chest tightness, wheezing and difficulty breathing) after taking Naproxen in doses of 40-80mg. Naproxen and naproxen sodium are sensitive to sunlight and can produce an inflammatory side effect with sunlight. Swallowing 50 grams of sorbitol has a laxative effect, with vomiting and diarrhoea. Swallowing may also cause hives. Swallowing 20 grams per day has led to severe diarrhoea and weight loss. Sorbitol may also worsen irritable bowel syndrome and similar gastrointestinal conditions. Even swallowing a small amount may result in severe abdominal pain. Extremely large doses of sucrose, given by mouth, may cause gastro-intestinal disturbance. It is estimated that 450 grams of candy would produce symptoms of acute gastroenteritis in a 10-kilogram child. However, this would almost certainly cause vomiting, so gastroenteritis is unlikely. The material has **NOT** been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.
Skin Contact	There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.
Eye	There is some evidence to suggest that this material can cause eye irritation and damage in some persons.
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. Abnormalities of liver-function tests, impairment of renal function, agranulocytosis and thrombocytopenia may be longer term manifestations of Naproxen exposure. Haemolytic and aplastic anaemia, neutropenia and decreases in haemoglobin and haematocrit may also occur. Animal testing showed that sorbitol caused thickening of bone and excretion of citrate. Sorbitol was not shown to cause birth defects. Otherwise, sorbitol was not shown to cause toxic effects at concentrations up to 15%. Sucrose reportedly causes skin disease in bakers, candy makers and related occupations. High uncontrolled glucose levels in pregnant women are related with an increased rate of miscarriage and an early increase in death rate and illness in newborns. Sucrose given into a vein at a concentration of 50% to reduce intracranial pressure or as a diuretic carries a grave risk of kidney damage. Poisoning in animals has caused diarrhoea, prostration, bluing of the extremities, seizures, stupors and death due to failure of breathing. Widespread pathological changes have included shrinkage, swelling and cell death of the kidney tubule lining, inflammation of small arteries, inflammation of the liver and heart muscle, congestive inflammation of the brain and some kidney enlargement. In a sugar refinery, lung function tests were reduced in workers exposed to sugar dust. A proportion of workers complained of cough and/or phlegm, but this finding was not significant. Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhoea or constipation, perforations causing serious infection, and blood in the vomit or stools.

	TOXICITY	IRRITATION
Naproxen Suspension 125mg/5mL	Not Available	Not Available
Sucrose	Oral (rat) LD50: 29700 mg/kg[2]	Not Available
Sorbitol	Oral (rat) LD50: 15900 mg/kg[2]	Not Available
Naproxen	Oral (rat) LD50: 248 mg/kg[2]	Not Available
Sodium Chloride	Dermal (rabbit) LD50: >10000 mg/kg[1] Oral (rat) LD50: 3000 mg/kg[2]	Eye (rabbit): 10 mg - moderate Eye (rabbit):100 mg/24h - moderate Skin (rabbit): 500 mg/24h - mild
magnesium aluminosilicate	Oral (rat) LD50: >2000 mg/kg[1]	Not Available
fumaric acid	Dermal (rabbit) LD50: 20000 mg/kg[2]	Eye (rabbit): 100 mg/24h-moderate

Continued...

	Oral (rat) LD50: 6800 mg/kg[2]	Skin (rabbit): 500 mg/24h - mild
Methyl Paraben	**TOXICITY**	**IRRITATION**
	Oral (rat) LD50: 2100 mg/kg[2]	Not Available
water	**TOXICITY**	**IRRITATION**
	Not Available	Not Available

Legend:	*1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*

SUCROSE	Oral (Human) TDLo: 9.6E-5 mg/kg
SODIUM CHLORIDE	The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
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 unharmful 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.
Naproxen Suspension 125mg/5mL & WATER	No significant acute toxicological data identified in literature search.
Naproxen Suspension 125mg/5mL & SODIUM CHLORIDE & METHYL PARABEN	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. 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. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.
SODIUM CHLORIDE & FUMARIC ACID	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.

Acute Toxicity	⊘	**Carcinogenicity**	⊘
Skin Irritation/Corrosion	✔	**Reproductivity**	✔
Serious Eye Damage/Irritation	✔	**STOT - Single Exposure**	⊘
Respiratory or Skin sensitisation	⊘	**STOT - Repeated Exposure**	⊘
Mutagenicity	✔	**Aspiration Hazard**	⊘

Legend: ✘ *– Data available but does not fill the criteria for classification*
✔ *– Data available to make classification*
⊘ *– Data Not Available to make classification*

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Naproxen Suspension 125mg/5mL	**ENDPOINT**	**TEST DURATION (HR)**	**SPECIES**	**VALUE**	**SOURCE**
	Not Available	Not Available	Not Available	Not Available	Not Available
Sucrose	**ENDPOINT**	**TEST DURATION (HR)**	**SPECIES**	**VALUE**	**SOURCE**
	Not Available	Not Available	Not Available	Not Available	Not Available
Sorbitol	**ENDPOINT**	**TEST DURATION (HR)**	**SPECIES**	**VALUE**	**SOURCE**
	Not Available	Not Available	Not Available	Not Available	Not Available
Naproxen	**ENDPOINT**	**TEST DURATION (HR)**	**SPECIES**	**VALUE**	**SOURCE**
	Not Available	Not Available	Not Available	Not Available	Not Available
Sodium Chloride	**ENDPOINT**	**TEST DURATION (HR)**	**SPECIES**	**VALUE**	**SOURCE**
	LC50	96	Fish	1000mg/L	4
	EC50	48	Crustacea	402.6mg/L	4
	EC50	96	Algae or other aquatic plants	2430mg/L	4
	NOEC	6	Fish	0.001mg/L	4

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magnesium aluminosilicate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
fumaric acid	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	EC50	48	Crustacea	212mg/L	4
	EC50	72	Algae or other aquatic plants	=41mg/L	1
	EC10	72	Algae or other aquatic plants	=32mg/L	1
Methyl Paraben	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	EC50	48	Crustacea	41.1mg/L	4
	NOEC	504	Crustacea	0.2mg/L	2
water	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

Legend:	*Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

Environmental Fate: Naproxen and naproxen sodium, a drug widely used for treating pain and swelling, were found to be sensitive to sunlight resulting to the formation of several photoproducts. Study shows that naproxen can be rapidly mineralized in soil depending on the temperature and moisture content of the soil. Further, the study demonstrates that naproxen can be removed primarily by microbial degradation. In the absence of preferential flow or runoff, the chemical pose little risk in contaminating adjacent water or crops.
Ecotoxicity: Toxicity studies show that photoproducts of naproxen were found to be more toxic than the parent compound. Long term exposure to naproxen and naproxen sodium showed higher toxicity than the acute tests.
Rotifer LC50 (24h): B. calyciflorus 62.48 mg/l (Naproxen); 56.64 mg/l (Naproxen sodium); 4.51 mg/l (photodegradate 4)
Crustancean LC50 (24h): T.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Sucrose	LOW	LOW
Sorbitol	LOW	LOW
Naproxen	HIGH	HIGH
Sodium Chloride	LOW	LOW
fumaric acid	LOW	LOW
Methyl Paraben	LOW	LOW
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
Sucrose	LOW (LogKOW = -3.7)
Sorbitol	LOW (LogKOW = -3.0108)
Naproxen	LOW (LogKOW = 2.4187)
Sodium Chloride	LOW (LogKOW = 0.5392)
fumaric acid	LOW (LogKOW = 0.46)
Methyl Paraben	LOW (LogKOW = 1.96)
water	LOW (LogKOW = -1.38)

Mobility in soil

Ingredient	Mobility
Sucrose	LOW (KOC = 10)
Sorbitol	LOW (KOC = 10)
Naproxen	LOW (KOC = 349.3)
Sodium Chloride	LOW (KOC = 14.3)
fumaric acid	LOW (KOC = 6.314)
Methyl Paraben	LOW (KOC = 125.6)
water	LOW (KOC = 14.3)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

Continued...

	A Hierarchy of Controls seems to be common - the user should investigate: ▸ Reduction ▸ Reuse ▸ Recycling ▸ Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. ▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains. ▸ It may be necessary to collect all wash water for treatment before disposal. ▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▸ Where in doubt contact the responsible authority. ▸ Recycle wherever possible. ▸ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▸ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). ▸ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

SUCROSE(57-50-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards | Australia Inventory of Chemical Substances (AICS)

SORBITOL(50-70-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

NAPROXEN(22204-53-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

SODIUM CHLORIDE(7647-14-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

MAGNESIUM ALUMINOSILICATE(1327-43-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

FUMARIC ACID(110-17-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists | Australia Inventory of Chemical Substances (AICS)

METHYL PARABEN(99-76-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

WATER(7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (Naproxen; Sucrose; magnesium aluminosilicate; Methyl Paraben; fumaric acid; water; Sorbitol; Sodium Chloride)
China - IECSC	N (Naproxen)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Naproxen; Sucrose; Methyl Paraben)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	N (Naproxen)
USA - TSCA	N (Naproxen)
Legend:	*Y = All ingredients are on the inventory* *N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

Continued...

SECTION 16 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
Sorbitol	50-70-4, 98201-93-5, 15060-73-8, 3959-53-3, 63800-20-4, 69-65-8, 75398-79-7, 8013-15-8, 8014-89-9, 8036-93-9, 8042-39-5, 8045-74-7, 8046-05-7, 36134-87-9
Naproxen	22204-53-1, 23979-41-1
Sodium Chloride	7647-14-5, 14762-51-7, 16887-00-6
magnesium aluminosilicate	1327-43-1, 12511-31-8, 71205-22-6

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.

The 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.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit。
IDLH: Immediately Dangerous to Life or Health Concentrations
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index