Sigma Pharmaceuticals Ledermix Refill No. 2

Sigma Pharmaceuticals

Chemwatch Hazard Alert Code: **3**

Chemwatch: **6081-81**
Version No: **2.1.1.1**
Safety Data Sheet according to WHS and ADG requirements

Issue Date: **01/01/2013**
Print Date: **19/01/2017**
S.GHS.AUS.EN

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

Product Identifier

Product name	Sigma Pharmaceuticals Ledermix Refill No. 2
Synonyms	Not Available
Other means of identification	Not Available

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

Relevant identified uses	A dental restorative agent for the rapid relief of pain associated with acute pulpal and periodontal inflammations.

Details of the supplier of the safety data sheet

Registered company name	Sigma Pharmaceuticals
Address	96 Merrindale Drive South Croydon VIC 3136 Australia
Telephone	+61 3 9839 2800
Fax	+61 3 9839 2801
Website	www.sigmaco.com.au
Email	Not Available

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability	0		
Toxicity	0		
Body Contact	1		
Reactivity	1		
Chronic	3		

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	S4
Classification [1]	Skin Sensitizer Category 1, Carcinogenicity Category 2, Reproductive Toxicity Category 1B
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI*

Label elements

GHS label elements	
SIGNAL WORD	DANGER

Hazard statement(s)

H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.

Precautionary statement(s) Prevention

Continued...

P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
P261	Avoid breathing mist/vapours/spray.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/attention.
P363	Wash contaminated clothing before reuse.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash 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
64-73-3	0-10	demeclocycline hydrochloride
76-25-5	0-10	triamcinolone acetonide
		excipients, as
25322-68-3	NotSpec.	polyethylene glycol
1314-13-2	NotSpec.	zinc oxide
102-71-6	NotSpec.	triethanolamine
10043-52-4	NotSpec.	calcium chloride

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▸ Immediately hold eyelids apart and flush the eye continuously with 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. ▸ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▸ Transport to hospital or doctor without delay. ▸ 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	▸ 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.

Indication of any immediate medical attention and special treatment needed

The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is called for. Where possible the dose should be withdrawn or reduced. Acute renal insufficiency should be treated with intravenous hydrocortisone sodium succinate with infusions of 0.9% dextrose. *MARTINDALE, The Extra Pharmacopoeia, 29th Ed.*

Patients or individuals exposed regularly in an occupational setting, should be evaluated periodically for evidence of HPA axis suppression. The evaluation may be performed by using the ACTH stimulation, A.M. plasma cortisol and urinary free cortisol tests. If HPA axis suppression is confirmed the individual should be removed from exposure. Recovery of the HPA axis function is generally prompt upon exposure cessation. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

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

Continued...

- Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▸ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

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.
Fire/Explosion Hazard	▸ Non combustible. ▸ Not considered a significant fire risk, however containers may burn. Decomposition may produce toxic fumes of: , carbon dioxide (CO2) carbon monoxide (CO) , hydrogen chloride , phosgene , nitrogen oxides (NOx) , other pyrolysis products typical of burning organic material. May emit poisonous fumes. 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 contact with skin and eyes. ▸ Wear impervious gloves and safety goggles. ▸ Trowel up/scrape up.
Major Spills	Minor hazard. ▸ Clear area of personnel. ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Control personal contact with the substance, by using protective equipment as required.

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.
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. |Store below 30 degC.

Conditions for safe storage, including any incompatibilities

Suitable container	▸ Polyethylene or polypropylene container. ▸ Packing as recommended by manufacturer. ▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	▸ Avoid reaction with oxidising 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	zinc oxide	Zinc oxide (dust) / Zinc oxide (fume)	10 mg/m3 / 5 mg/m3	10 mg/m3	Not Available	Not Available

Continued...

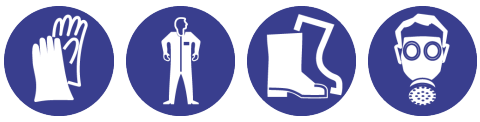
Australia Exposure Standards	triethanolamine	Triethanolamine	5 mg/m3	Not Available	Not Available	Sen

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
polyethylene glycol	Polyethylene glycol	30 mg/m3	1,300 mg/m3	7,700 mg/m3
zinc oxide	Zinc oxide	10 mg/m3	15 mg/m3	2,500 mg/m3
triethanolamine	Triethanolamine; (Trihydroxytriethylamine)	15 mg/m3	240 mg/m3	1,500 mg/m3
calcium chloride	Calcium chloride	12 mg/m3	130 mg/m3	790 mg/m3

Ingredient	Original IDLH	Revised IDLH
demeclocycline hydrochloride	Not Available	Not Available
triamcinolone acetonide	Not Available	Not Available
polyethylene glycol	Not Available	Not Available
zinc oxide	2,500 mg/m3	500 mg/m3
triethanolamine	Not Available	Not Available
calcium chloride	Not Available	Not Available

Exposure controls

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.
Personal protection	
Eye and face protection	▸ Safety glasses with side shields. ▸ Chemical goggles. ▸ 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.
Skin protection	See Hand protection below
Hands/feet protection	▸ Wear chemical protective gloves, e.g. PVC. ▸ Wear safety footwear or safety gumboots, e.g. Rubber **NOTE:** ▸ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▸ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.
Body protection	See Other protection below
Other protection	▸ Overalls. ▸ P.V.C. apron. ▸ Barrier cream.
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:
Sigma Pharmaceuticals Ledermix Refill No. 2

Material	CPI
BUTYL	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
PVA	C
PVC	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

Respiratory protection

Type AK-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.
Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	AK-AUS P2	-	AK-PAPR-AUS / Class 1 P2
up to 50 x ES	-	AK-AUS / Class 1 P2	-
up to 100 x ES	-	AK-2 P2	AK-PAPR-2 P2 ^

^ - Full-face
A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Continued...

"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.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Greyish yellow smooth paste; mixes with water.

Physical state	Non Slump Paste	**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 Applicable
pH (as supplied)	Not Available	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	Not Applicable	**Taste**	Not Available
Evaporation rate	Fast	**Explosive properties**	Not Available
Flammability	Not Applicable	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Applicable	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	Not Applicable	**Volatile Component (%vol)**	Not Available
Vapour pressure (kPa)	Not Available	**Gas group**	Not Available
Solubility in water (g/L)	Miscible	**pH as a solution (1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	Product is considered stable and 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	Not normally a hazard due to non-volatile nature of product The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	Considered an unlikely route of entry in commercial/industrial environments Ingestion may result in nausea, abdominal irritation, pain and diarrhoea
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. When applied to the eye, corticosteroids may produce ulceration of the cornea, raised eye pressure and reduced vision; internal administration can cause cataracts.
Chronic	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Repeated or prolonged exposures to tetracyclines can cause sore throat, hoarseness, a black hairy tongue, bulky loose stools, fat in the faeces, inflammation of the mouth cavity, difficulty swallowing, damage to the anogenital area and ulcers of the oesophagus. Deposits in the eye may cause abnormal pigmentation of the conjunctivae. Chronic exposure to glucocorticoids can lead to changes in hormone production, a characteristic "moon face" appearance and a "lemon with matchsticks" fat distribution (central obesity with wasting of limbs), susceptibility to infections, osteoporosis, cataracts, glaucoma, mental disturbance, high blood sugar and sugar in the urine. There may be muscular weakness and fatigue, acne, period disturbances in women and peptic ulcers.

Sigma Pharmaceuticals Ledermix Refill No. 2	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
demeclocycline hydrochloride	**TOXICITY**	**IRRITATION**
	Oral (rat) LD50: 2372 mg/kg[2]	Not Available

Continued...

triamcinolone acetonide	TOXICITY	IRRITATION
	Oral (rat) LD50: 1451 mg/kg[2]	Not Available
polyethylene glycol	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >20440 mg/kg[2]	Eye (rabbit): 500mg/24h - mild.
	Oral (rat) LD50: 600 mg/kg[2]	Skin (rabbit): 500mg/24h - mild.
zinc oxide	TOXICITY	IRRITATION
	Oral (rat) LD50: >5000 mg/kg[1]	Eye (rabbit) : 500 mg/24 h - mild
		Skin (rabbit) : 500 mg/24 h- mild
triethanolamine	TOXICITY	IRRITATION
	dermal (rat) LD50: >18080 mg/kg[2]	Eye (rabbit): 0.1 ml -
	Oral (rat) LD50: 5559.6 mg/kg[2]	Eye (rabbit): 10 mg - mild
		Eye (rabbit): 5.62 mg - SEVERE
		minor conjunctival irritation
		no irritation *
		Skin (human): 15 mg/3d (int)-mild
		Skin (rabbit): 4 h occluded
		Skin (rabbit): 560 mg/24 hr- mild
calcium chloride	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg[1]	Eye (unknown): severe* [ICI]
	Oral (rat) LD50: 1000 mg/kg[2]	Skin (unknown): moderate*

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*

DEMECLOCYCLINE HYDROCHLORIDE	Oral (human) TDLo: 69 mg/kg/4d - I Nil reported Reproductive effector in woman
TRIAMCINOLONE ACETONIDE	Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Effects on fertility, effects on embryo, foetotoxicity, foetolethality, specific developmental abnormalities (craniofacial, central nervous system, body-wall, musculoskeletal, blood and lymphatic systems, respiratory system, gastrointestinal system, endocrine system, urogenital system, homeostasis), effects on newborn recorded.
POLYETHYLENE GLYCOL	for polyethylene glycols Pure polyethylene glycols have essentially similar toxicity, with toxicity being inverse to molecular weights. Absorption from the gastrointestinal tract decreases with increasing molecular weight The G.I. absorption of a series of polyethylene glycols has been studied. Polyethylene glycols having average molecular weights of 4000 and 6000 showed no absorption from the rat intestine over a five-hour period, while polyethylene glycols of 1000 and 1540 molecular weights showed a slight absorption amounting to less than 2% of the total dose during the same period. The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. for molecular weights (200-8000) * Oral (rat) LD50: 31000->50000 mg/kg Oral (mice) LD50: 38000->50000 mg/kg Oral (g.pig) LD50: 17000->50000 mg/kg Oral (rabbit) LD50: 14000->50000 mg/kg * AIHA WEEL Guides Intraperitoneal (mice) LD50: 3100-12900 mg/kg
TRIETHANOLAMINE	Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. While it is difficult to generalise about the full range of potential health effects posed by exposure to the many different amine compounds, characterised by those used in the manufacture of polyurethane and polyisocyanurate foams, it is agreed that overexposure to the majority of these materials may cause adverse health effects. ▸ Many amine-based compounds can induce histamine liberation, which, in turn, can trigger allergic and other physiological effects, including bronchoconstriction or bronchial asthma and rhinitis. ▸ Systemic symptoms include headache, nausea, faintness, anxiety, a decrease in blood pressure, tachycardia (rapid heartbeat), itching, erythema (reddening of the skin), urticaria (hives), and facial edema (swelling). Systemic effects (those affecting the body) that are related to the pharmacological action of amines are usually transient. Studies done show that triethanolamine is of low toxicity following high dose exposure by swallowing, skin contact or inhalation. It has not been shown to cause cancer, genetic defects, reproductive or developmental toxicity. The substance is classified by IARC as Group 3: **NOT** classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing. **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. Lachrymation, diarrhoea, convulsions, urinary tract changes, changes in bladder weight, changes in testicular weight, changes in thymus weight, changes in liver weight, dermatitis after systemic exposure, kidney, ureter, bladder tumours recorded. Equivocal tumourigen by RTECS criteria. Dermal rabbit value quoted above is for occluded patch in male or female animals * Union Carbide
CALCIUM CHLORIDE	for calcium: Toxicity from calcium is not common because the gastrointestinal tract normally limits the amount of calcium absorbed. Therefore, short-term intake of large amounts of calcium does not generally produce any ill effects aside from **constipation** and an increased risk of kidney stones . However, more severe toxicity can occur when excess calcium is ingested over long periods, or when calcium is combined with increased amounts of vitamin D, which increases calcium absorption. Calcium toxicity is also sometimes found after excessive intravenous administration of calcium.

Continued...

DEMECLOCYCLINE HYDROCHLORIDE & TRIETHANOLAMINE	The following information refers to contact allergens as a group and may not be specific to this product. 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.
POLYETHYLENE GLYCOL & ZINC OXIDE & TRIETHANOLAMINE & CALCIUM CHLORIDE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
TRIETHANOLAMINE & CALCIUM CHLORIDE	The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

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 required to make classification available*
⊘ *– Data Not Available to make classification*

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
triamcinolone acetonide	LC50	96	Fish	23.137mg/L	3
triamcinolone acetonide	EC50	96	Algae or other aquatic plants	26.095mg/L	3
triamcinolone acetonide	EC50	96	Algae or other aquatic plants	44.338mg/L	3
polyethylene glycol	LC50	96	Fish	>1000mg/L	4
polyethylene glycol	EC50	96	Algae or other aquatic plants	20935.086mg/L	3
polyethylene glycol	EC50	384	Crustacea	509.184mg/L	3
zinc oxide	LC50	96	Fish	0.439mg/L	2
zinc oxide	EC50	48	Crustacea	0.105mg/L	2
zinc oxide	EC50	72	Algae or other aquatic plants	0.042mg/L	4
zinc oxide	BCF	336	Fish	4376.673mg/L	4
zinc oxide	EC20	72	Algae or other aquatic plants	0.023mg/L	4
zinc oxide	NOEC	72	Algae or other aquatic plants	0.0049mg/L	2
triethanolamine	LC50	96	Fish	11800mg/L	4
triethanolamine	EC50	96	Algae or other aquatic plants	169mg/L	1
triethanolamine	EC10	96	Algae or other aquatic plants	7.1mg/L	1
triethanolamine	NOEC	504	Crustacea	16mg/L	1
calcium chloride	LC50	96	Fish	=3mg/L	1
calcium chloride	EC50	48	Crustacea	=52mg/L	1
calcium chloride	EC50	96	Algae or other aquatic plants	3130mg/L	4
calcium chloride	BCFD	48	Crustacea	0.0832425mg/L	4
calcium chloride	EC50	48	Crustacea	=52mg/L	1
calcium chloride	NOEC	48	Crustacea	260.12mg/L	4
Legend:	*Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - 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*				

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
triamcinolone acetonide	HIGH	HIGH
polyethylene glycol	LOW	LOW
triethanolamine	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
triamcinolone acetonide	LOW (LogKOW = 2.53)
polyethylene glycol	LOW (LogKOW = -1.1996)
zinc oxide	LOW (BCF = 217)

Continued...

triethanolamine	LOW (BCF = 3.9)

Mobility in soil

Ingredient	Mobility
triamcinolone acetonide	LOW (KOC = 10)
polyethylene glycol	HIGH (KOC = 1)
triethanolamine	LOW (KOC = 10)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	▸ Recycle wherever possible or consult manufacturer for recycling options. ▸ Consult State Land Waste Authority for disposal. ▸ Bury or incinerate residue at an approved site. ▸ Recycle containers if possible, or dispose of in an authorised landfill.

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

DEMECLOCYCLINE HYDROCHLORIDE(64-73-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

TRIAMCINOLONE ACETONIDE(76-25-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

POLYETHYLENE GLYCOL(25322-68-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

ZINC OXIDE(1314-13-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards
Australia Hazardous Substances Information System - Consolidated Lists
Australia Inventory of Chemical Substances (AICS)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

TRIETHANOLAMINE(102-71-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards
Australia Hazardous Substances Information System - Consolidated Lists
Australia Inventory of Chemical Substances (AICS)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

CALCIUM CHLORIDE(10043-52-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

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

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (triamcinolone acetonide; demeclocycline hydrochloride)
Canada - NDSL	N (polyethylene glycol; triethanolamine; calcium chloride; demeclocycline hydrochloride)
China - IECSC	N (triamcinolone acetonide; demeclocycline hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (triamcinolone acetonide; demeclocycline hydrochloride)
Korea - KECI	N (triamcinolone acetonide; demeclocycline hydrochloride)
New Zealand - NZIoC	N (demeclocycline hydrochloride)
Philippines - PICCS	N (triamcinolone acetonide; demeclocycline hydrochloride)
USA - TSCA	N (demeclocycline hydrochloride)

Continued...

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)*

SECTION 16 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
polyethylene glycol	25322-68-3, 8038-37-7, 9081-95-2, 9085-02-3, 9085-03-4, 12676-74-3, 12770-93-3, 25104-58-9, 25609-81-8, 34802-42-1, 37361-15-2, 50809-04-6, 50809-59-1, 54510-95-1, 54847-64-2, 59763-40-5, 60894-12-4, 61840-14-0, 64441-68-5, 64640-28-4, 67411-64-7, 70926-57-7, 75285-02-8, 75285-03-9, 77986-38-0, 79964-26-4, 80341-53-3, 85399-22-0, 85945-29-5, 88077-80-9, 88747-22-2, 90597-70-9, 99264-61-6, 99333-89-8, 101677-86-5, 106186-24-7, 107502-63-6, 107529-96-4, 109550-27-8, 112384-37-9, 112895-21-3, 114323-93-2, 116549-90-7, 119219-06-6, 125223-68-9, 133573-31-6, 134919-43-0, 150872-82-5, 154394-38-4, 156948-19-5, 169046-53-1, 174460-08-3, 174460-09-4, 188364-77-4, 188924-03-0, 189154-62-9, 191743-71-2, 196696-84-1, 201163-43-1, 206357-86-0
zinc oxide	1314-13-2, 175449-32-8

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

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

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end of SDS