LEDERMIX Powder (Cement)

Aspen Pharmacare Australia

Chemwatch Hazard Alert Code: **3**

Chemwatch: **8186-88**
Version No: **5.1.1.1**
Material Safety Data Sheet according to NOHSC and ADG requirements

Issue Date: **01/05/2019**
Print Date: **30/04/2019**
S.Local.AUS.EN

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

Product Identifier

Product name	LEDERMIX Powder (Cement)
Synonyms	Ledermix Refill No. 3
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	**Aspen Pharmacare Australia**
Address	34-36 Chandos Street St. Leonards NSW 2065 Australia
Telephone	+61 2 8436 8300
Fax	+61 2 9901 3540
Website	Not Available
Email	enquiries@arrowpharma.com

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

Poisons Schedule	S4
Risk Phrases [1]	**R43** May cause SENSITISATION by skin contact. **R61(2)** May cause harm to the unborn child.
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI*

Relevant risk statements are found in section 2

Indication(s) of danger	Xi

SAFETY ADVICE

S02	Keep out of reach of children.
S21	When using do not smoke.
S22	Do not breathe dust.
S35	This material and its container must be disposed of in a safe way.
S36	Wear suitable protective clothing.
S37	Wear suitable gloves.
S40	To clean the floor and all objects contaminated by this material, use water and detergent.
S46	If swallowed, seek medical advice immediately and show this container or label.
S53	Avoid exposure - obtain special instructions before use.
S56	Dispose of this material and its container at hazardous or special waste collection point.

Other hazards

Ingestion may produce health damage*.

Cumulative effects may result following exposure*.

May produce discomfort of the eyes*.

May possibly be harmful to breastfed babies.*

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
64-73-3	<10	Demeclocycline Hydrochloride
76-25-5	<10	Triamcinolone
1314-13-2	NotSpec	ZINC OXIDE
1305-62-0	Not Spec	Calcium hydroxide
8007-47-4	Not Spec	Canada balsam

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	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

For corticosteroid overdose:

- 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.
- Corticosteroid overdose is usually treated by restoring fluid and electrolyte balance. Prognosis is good unless there are life-threatening symptoms, which is usually infrequent
- In case of severe symptoms that include high body temperature, increased blood pressure, abnormal heart rhythms and heart attack, stroke, or coma, the outlook can be guarded
- Nevertheless, the prognosis is dependent on the amount of drug consumed, time between overdose and treatment, severity of the symptoms, as well as general health status of the patient
- In general, overdoses are common situations in the emergency departments. A majority of the cases are often not fatal, when appropriate treatment is given.
- The management of psychiatric symptoms due to administration of corticosteroids includes the reduction of the dose or treatment discontinuation. The patient can be treated with medications normally used in patients with psychiatric or neurological disorders. Mood-stabilizing drugs, such as lithium and valproic acid, are able to control the symptoms caused by corticosteroids. Carbamazepine, inducing steroids metabolism, reduces their neurotoxic effects; atypical antipsychotics, such as olanzapine and fluoxetine (SSRI), are active on this symptoms. The effect of anti-depressive drugs are different, i.e., tricyclic antidepressants could lead to a significant worsening of symptoms, while a selective serotonin reuptake inhibitors, such as fluoxetine,[37] may improve symptoms of depression during corticosteroid therapy as well as phenytoin, lamotrigine, risperidone, quetiapine, and gabapentin.

The beginning of the appearance of symptoms induced by corticosteroids is variable. They may arise in the first phases of treatment, during, or even at the end of therapy. In most cases (86%), they occur within the first 5 days of treatment. The analysis of several studies leads to an average of 11.5 days after the beginning of corticosteroid treatment to the onset of psychiatric symptoms] 89% of patients develop symptoms in the first six weeks, 62% within two weeks, and 39% in the first week. The duration of the neuropsychiatric effects is highly variable and depends on the severity, treatment discontinuation, and by other drug therapies.
Risk factors
Side effects of psychiatric type have been reported following different routes of administration, e.g., intra-articular injection, epidural, topical, and systemic.
Psychiatric side effects due to corticosteroids appear to be dose dependent; they occur in 1.3% of the cases when the dose is less than 40 mg daily and reaches 18.4% for doses of 80 mg daily.
It is not entirely clear whether gender affects the ability to manifest psychiatric symptoms, but some studies suggest that women are more prone.
Other studies show that 73% of the paediatric population receiving steroid therapy develops hyperactivity, irritability, insomnia as well as showing deficits of attention and memory, especially those under 10 years of age and/or high doses of the drug.
Miriam Ciriaco, et al Journal ListJ Pharmacol Pharmacotherv.4(Suppl1); 2013 Dec
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3853679/

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

Water spray or fog.
Foam.
Dry chemical powder.
BCF (where regulations permit).

Special hazards arising from the substrate or mixture

Fire Incompatibility	Avoid contamination with strong oxidising agents 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. Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	Combustible Decomposes on heating and produces toxic fumes of: carbon monoxide (CO) carbon dioxide (CO_2) nitrogen oxides (NOx) chlorides Avoid creating dust - may present dust explosion hazard. Dry dust can be electrostatically charged by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport. Build-up of electrostatic charge may be prevented by grounding.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment.
Major Spills	Remove all ignition sources. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment and dust respirator. Prevent spillage from entering drains, sewers or water courses.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	Remove all ignition sources. Limit all unnecessary personal contact. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. When handling **DO NOT** eat, drink or smoke.
Other information	Store in original containers. Keep containers securely sealed. No smoking, naked lights or ignition sources. Store in a cool, dry, well-ventilated area. Store below 30 deg. C.

Conditions for safe storage, including any incompatibilities

Suitable container	Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid contamination with strong oxidising agents as ignition may result

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)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	zinc oxide	Zinc oxide (fume)	5 mg/m3	10 mg/m3	Not Available	Not Available
Australia Exposure Standards	calcium hydroxide	Calcium hydroxide	5 mg/m3	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
ZINC OXIDE	Zinc oxide	10 mg/m3	15 mg/m3	2,500 mg/m3
Calcium hydroxide	Calcium hydroxide	1 mg/m3	240 mg/m3	1,500 mg/m3

Ingredient	Original IDLH	Revised IDLH
Demeclocycline Hydrochloride	Not Available	Not Available
Triamcinolone	Not Available	Not Available
ZINC OXIDE	500 mg/m3	Not Available
Calcium hydroxide	Not Available	Not Available
Canada balsam	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; or as required, 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. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience.
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. 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.

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:
LEDERMIX Powder (Cement)

Material	CPI
NATURAL RUBBER	A
NATURAL+NEOPRENE	A

* 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

Type A-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	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-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)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Fine cream coloured powder; partly mixes with water.

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

SECTION 10 STABILITY AND REACTIVITY

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	Generated dust may be discomforting
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. Tetracyclines produce nausea, abdominal pain and burning, vomiting, transitory yellowish-brown discolouration of the tongue, loss of appetite, and diarrhoea. Large oral doses may produce liver and kidney damage. The corticosteroids cause alterations in metabolism of fats, proteins and carbohydrates, and affect a range of organs in the body including the heart, muscle and kidneys. Blood chemistry may change and there is decreased activity and shrinkage of the thymus gland, adrenal glands, spleen and lymph nodes.
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	There is some evidence to suggest that this material can cause eye irritation and damage in some persons.
Chronic	Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population. There is some evidence from animal testing that exposure to this material may result in toxic effects to the unborn baby. 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.

	TOXICITY	IRRITATION
LEDERMIX Powder (Cement)	Not Available	Not Available
Demeclocycline Hydrochloride	Oral (rat) LD50: 2107 mg/kg[1]	Not Available
Triamcinolone	Oral (rat) LD50: 1451 mg/kg[2]	Not Available
ZINC OXIDE	dermal (rat) LD50: >2000 mg/kg[1] Inhalation (rat) LC50: >1.79 mg/l4 h[1] Oral (rat) LD50: >5000 mg/kg[2]	Eye (rabbit) : 500 mg/24 h - mild Eye: no adverse effect observed (not irritating)[1] Skin (rabbit) : 500 mg/24 h- mild Skin: no adverse effect observed (not irritating)[1]
Calcium hydroxide	dermal (rat) LD50: >2000 mg/kg[1] Oral (rat) LD50: ~500-2000 mg/kg[2]	Eye (rabbit): 10 mg - SEVERE Eye: adverse effect observed (irritating)[1] Skin: adverse effect observed (irritating)[1]
Canada balsam	Dermal (rabbit) LD50: >5000 mg/kg[2] Oral (rat) LD50: >5000 mg/kg[2]	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*	

DEMECLOCYCLINE HYDROCHLORIDE	Oral (human) TDLo: 69 mg/kg/4d - I Nil reported Reproductive effector in woman
TRIAMCINOLONE	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.
ZINC OXIDE	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.
CALCIUM HYDROXIDE	The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
CANADA BALSAM	No significant acute toxicological data identified in literature search. Epoxidation of double bonds is a common bioactivation pathway for alkenes. The allylic epoxides formed were found to be sensitizing. Research has shown that conjugated dienes in or in conjunction with a six-membered ring are prohaptens, while related dienes containing isolated double bonds or an acrylic conjugated diene were weak or non-sensitising.

	Adverse reactions to fragrances in perfumes and fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, sensitivity to light, immediate contact reactions, and pigmented contact dermatitis. Airborne and connubial contact dermatitis occurs. Contact allergy is a lifelong condition, so symptoms may occur on re-exposure. Allergic contact dermatitis can be severe and widespread, with significant impairment of quality of life and potential consequences for fitness for work. Fragrance allergens act as haptens, which are small molecules that cause an immune reaction only when attached to a carrier protein. However, not all sensitizing fragrance chemicals are directly reactive, but some require previous activation. A prehapten is a chemical that itself causes little or no sensitization, but it is transformed into a hapten outside the skin by a chemical reaction (oxidation in air or reaction with light) without the requirement of an enzyme. For prehaptens, it is possible to prevent activation outside the body to a certain extent by different measures, for example, prevention of air exposure during handling and storage of the ingredients and the final product, and by the addition of suitable antioxidants.
DEMECLOCYCLINE HYDROCHLORIDE & CANADA BALSAM	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.
CALCIUM HYDROXIDE & CANADA BALSAM	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.

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 either not available or does not fill the criteria for classification*
– Data available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

LEDERMIX Powder (Cement)

ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Not Available	Not Available	Not Available	Not Available	Not Available

Demeclocycline Hydrochloride

ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Not Available	Not Available	Not Available	Not Available	Not Available

Triamcinolone

ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
LC50	96	Fish	23.137mg/L	3
EC50	96	Algae or other aquatic plants	26.095mg/L	3

ZINC OXIDE

ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
LC50	96	Fish	0.001-0.58mg/L	2
EC50	48	Crustacea	0.001-0.014mg/L	2
EC50	72	Algae or other aquatic plants	0.037mg/L	2
BCF	336	Fish	4376.673mg/L	4
NOEC	72	Algae or other aquatic plants	0.00008138mg/L	2

Calcium hydroxide

ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
LC50	96	Fish	4-630mg/L	2
EC50	48	Crustacea	49.1mg/L	2
EC50	72	Algae or other aquatic plants	>4-mg/L	2
NOEC	72	Algae or other aquatic plants	14mg/L	2

Canada balsam

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*

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Triamcinolone	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
Triamcinolone	LOW (LogKOW = 2.53)
ZINC OXIDE	LOW (BCF = 217)

Mobility in soil

Ingredient	Mobility
Triamcinolone	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 Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO Not Applicable
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)
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Index
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

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

Australia Inventory of Chemical Substances (AICS)
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Appendix F (Part 3)
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Appendix H
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Index
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 3
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

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

Australia Dangerous Goods Code (ADG Code) - Dangerous Goods List
Australia Dangerous Goods Code (ADG Code) - List of Emergency Action Codes
Australia Exposure Standards
Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Inventory of Chemical Substances (AICS)
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Index
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4
International Air Transport Association (IATA) Dangerous Goods Regulations
International Maritime Dangerous Goods Requirements (IMDG Code)
United Nations Recommendations on the Transport of Dangerous Goods Model Regulations (English)

CALCIUM HYDROXIDE(1305-62-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Dangerous Goods Code (ADG Code) - Dangerous Goods List
Australia Dangerous Goods Code (ADG Code) - List of Emergency Action Codes
Australia Exposure Standards
Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Inventory of Chemical Substances (AICS)
GESAMP/EHS Composite List - GESAMP Hazard Profiles
IMO IBC Code Chapter 17: Summary of minimum requirements
IMO MARPOL (Annex II) - List of Noxious Liquid Substances Carried in Bulk
International Air Transport Association (IATA) Dangerous Goods Regulations
International Maritime Dangerous Goods Requirements (IMDG Code)
United Nations Recommendations on the Transport of Dangerous Goods Model Regulations (English)

CANADA BALSAM(8007-47-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Dangerous Goods Code (ADG Code) - Dangerous Goods List
Australia Dangerous Goods Code (ADG Code) - List of Emergency Action Codes
Australia Inventory of Chemical Substances (AICS)
IMO MARPOL (Annex II) - List of Noxious Liquid Substances Carried in Bulk
International Air Transport Association (IATA) Dangerous Goods Regulations
International Maritime Dangerous Goods Requirements (IMDG Code)
United Nations Recommendations on the Transport of Dangerous Goods Model Regulations (English)

National Inventory Status

National Inventory	Status
Australia - AICS	Yes
Canada - DSL	No (Triamcinolone; Demeclocycline Hydrochloride)
Canada - NDSL	No (Canada balsam; Calcium hydroxide; Demeclocycline Hydrochloride)
China - IECSC	No (Triamcinolone; Demeclocycline Hydrochloride)

Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (Canada balsam; Demeclocycline Hydrochloride)
Korea - KECI	No (Triamcinolone; Demeclocycline Hydrochloride)
New Zealand - NZIoC	No (Demeclocycline Hydrochloride)
Philippines - PICCS	No (Triamcinolone; Demeclocycline Hydrochloride)
USA - TSCA	No (Demeclocycline Hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	No (Triamcinolone; Canada balsam; Demeclocycline Hydrochloride)
Vietnam - NCI	No (Demeclocycline Hydrochloride)
Russia - ARIPS	No (Triamcinolone; Demeclocycline Hydrochloride)
Thailand - TECI	No (Canada balsam; Demeclocycline Hydrochloride)
Legend:	*Yes = All declared ingredients are on the inventory* *No = 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

Revision Date	01/05/2019
Initial Date	06/09/2006

SDS Version Summary

Version	Issue Date	Sections Updated
4.1.1.1	30/04/2019	Classification, Ingredients, Supplier Information, Synonyms, Name
5.1.1.1	01/05/2019	Acute Health (inhaled), Appearance, Chronic Health, Classification, Fire Fighter (extinguishing media), Fire Fighter (fire/explosion hazard), Fire Fighter (fire fighting), Fire Fighter (fire incompatibility), Handling Procedure, Ingredients, Personal Protection (eye), Personal Protection (hands/feet), Physical Properties, Spills (major), Storage (storage incompatibility), Storage (storage requirement), Use

Other information

Ingredients with multiple cas numbers

Name	CAS No
ZINC OXIDE	1314-13-2, 175449-32-8
Calcium hydroxide	1305-62-0, 1332-69-0

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