

Ledermix Paste

Aspen Pharmacare Australia

Chemwatch Hazard Alert Code: 3

Chemwatch: 5328-31

Issue Date: 06/11/2018

Version No: 3.1.1.1

Print Date: 06/11/2018

Material Safety Data Sheet according to NOHSC and ADG requirements

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

Product Identifier

Product name	Ledermix Paste
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.
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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 HSIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI



Relevant risk statements are found in section 2

Indication(s) of danger	Xi
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SAFETY ADVICE

Continued...

S02	Keep out of reach of children.
S21	When using do not smoke.
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*.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
64-73-3	<10	<u>Demeclocycline Hydrochloride</u>
76-25-5	<10	<u>Triamcinolone</u>
	>60	Ingredients determined not to be hazardous

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ 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	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ 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.
- ▶ Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered to be a significant fire risk. ▶ Expansion or decomposition on heating may lead to violent rupture of containers. ▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). <p>Decomposes on heating and produces toxic fumes of: carbon dioxide (CO₂) nitrogen oxides (NO_x) chlorides fluorides</p>
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid contact with skin and eyes. ▶ Wear impervious gloves and safety goggles. ▶ Trowel up/scrape up.
Major Spills	<p>Minor hazard.</p> <ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

Continued...


Ledermix Paste

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Ledermix Paste	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Demeclocycline Hydrochloride	Not Available	Not Available
Triamcinolone	Not Available	Not Available

Exposure controls

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ Eyewash unit.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Paste.		
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 Available
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	Not Available	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)	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Applicable

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ 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	Not normally a hazard due to non-volatile nature of product
Ingestion	<p>Accidental ingestion of the material may be damaging to the health of the individual.</p> <p>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.</p> <p>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.</p>
Skin Contact	<p>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.</p> <p>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.</p>
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	<p>Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.</p> <p>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.</p> <p>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.</p>

Ledermix Paste	TOXICITY	IRRITATION
	Not Available	Not Available
Demeclocycline Hydrochloride	TOXICITY	IRRITATION
	Oral (rat) LD50: 2-107 mg/kg ^[1]	Not Available
Triamcinolone	TOXICITY	IRRITATION
	Oral (rat) LD50: 1451 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	<p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>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.</p> <p>Oral (human) TDL₀: 69 mg/kg/4d - I Nil reported Reproductive effector in woman</p>
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Ledermix Paste

TRIAMCINOLONE	Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Effects on fertility, effects on embryo, foetotoxicity, foetoletality, 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.	
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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

	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
Ledermix Paste	Not Available	Not Available	Not Available	Not Available	Not Available
Demeclocycline Hydrochloride	Not Available	Not Available	Not Available	Not Available	Not Available
Triamcinolone	LC50	96	Fish	23.137mg/L	3
	EC50	96	Algae or other aquatic plants	26.095mg/L	3

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)

Mobility in soil

Ingredient	Mobility
Triamcinolone	LOW (KOC = 10)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ 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.
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Ledermix Paste

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) - Schedule 5
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4	

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) - Schedule 3
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) - Schedule 4
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2	

National Inventory Status

National Inventory	Status
Australia - AICS	N (Ingredients determined not to be hazardous) Non-disclosed ingredients
Canada - DSL	N (Triamcinolone; Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
Canada - NDSL	N (Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
China - IECSC	N (Triamcinolone; Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
Europe - EINEC / ELINCS / NLP	N (Ingredients determined not to be hazardous) Non-disclosed ingredients
Japan - ENCS	N (Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
Korea - KECL	N (Triamcinolone; Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
New Zealand - NZIoC	N (Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
Philippines - PICCS	N (Triamcinolone; Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
USA - TSCA	N (Demeclocycline Hydrochloride; Ingredients determined not to be hazardous) Non-disclosed ingredients
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

Revision Date	06/11/2018
Initial Date	05/11/2018

SDS Version Summary

Version	Issue Date	Sections Updated
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2.1.1.1	05/11/2018	Acute Health (eye), Acute Health (inhaled), Chronic Health, Classification, Personal Protection (other), Personal Protection (eye), Personal Protection (hands/feet), Spills (major), Spills (minor)
3.1.1.1	06/11/2018	Fire Fighter (fire/explosion hazard), Use

Other information

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

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