

## SECTION 1: IDENTIFICATION

<b>1.1 Product identifier</b>	
<b>Product name:</b>	Lignol® (2.0 % w/v solution for injection).
<b>Synonyms:</b>	Not Available
<b>Proper Shipping name:</b>	Not Available
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	A local anaesthetic agent for regional nerve block, paravertebral nerve block and infiltration anaesthesia, for use in cats, dogs and horses.
<b>Uses advised against:</b>	Not for human use. Do not use in cardiac or hepatic insufficiency. Do not administer by intravenous injection. Do not use for more than one induction of anaesthesia in any 24 hours. Use with caution in pregnant animals.
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Dechra Ltd
<b>Address:</b>	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Email:</b>	Not available
<b>1.4 Emergency Telephone Numbers</b>	
	+44 (0) 1756 791311

## SECTION 2: HAZARDS IDENTIFICATION

<b>2.1 Classification of the substance or mixture</b>	
<b>DSD Classification (EU):</b>	Not Available
<b>DPD Classification (EU)<sup>1</sup>:</b>	Not Available

<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not Available
<b>2.2 Label Elements</b>	
<b>Signal Word:</b>	Not Available
<b>Hazard Statement(s)</b>	
Not Available	
<b>Additional Statement(s)</b>	
Not Available	
<b>Precautionary Statement(s) Prevention:</b>	
Not Available	
<b>Precautionary Statement(s) Response:</b>	
Not Available	
<b>Precautionary Statement(s) Storage:</b>	
Not Available	
<b>Precautionary Statement(s) Disposal:</b>	
Not Available	
<b>2.3 Other Hazard Information</b>	
Not Available	

### SECTION 3: INFORMATION ON THE INGREDIENTS

#### 3.1 Substances

See section below for composition of mixtures

#### 3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% w/v	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 73-78-9 2. 200-803-8 3. Not Available 4. Not Available	2.0	Lidocaine hydrochloride	Acute Toxicity (Oral) Category 4; H302 <sup>1</sup>
1. Not Available 2. Not Available	0.00198	Adrenaline acid tartrate	Not available



3. Not Available			
4. Not Available			
<b>Legend:</b>	1. Classified by Chemwatch		

<b>SECTION 4: FIRST AID MEASURES</b>	
<b>4.1 Description of first aid measures</b>	
<b>Eye contact:</b>	In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	In case of accidental contact of the product with the skin rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Not considered to be a hazard. If inhaled, remove to fresh air and encourage to rest.
<b>Ingestion:</b>	Following accidental ingestion, seek medical advice, showing the package leaflet to the medical practitioner.
<b>Self-injection:</b>	Following accidental self-injection, seek medical advice taking the vial with you and show the package leaflet to the doctor.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
See Section 11	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
N/a	



**SECTION 5: FIRE FIGHTING MEASURES**

<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	All systems may be used.
<b>Unsuitable:</b>	None.
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known.
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.
<b>Fire / explosion hazard:</b>	None.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	
For information on protective equipment, see section 8.	
<b>6.2 Environmental Precautions</b>	
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.	
<b>6.3 Methods and material for containment and cleaning up</b>	
<b>Minor Spills:</b>	Collect into a sealable container for disposal. Wash affected area with water.
<b>Major Spills:</b>	Clean up all spills immediately. Collect into a sealable container for disposal. Wash affected area with water. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Control personal contact with the substance, by using protective equipment. Avoid contact with skin and eyes.



**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	Wear suitable protection gloves and clothing when handling the product. Wash hands after use. When handling, <b>DO NOT</b> eat, drink or smoke. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Keep out of the reach and sight of children.

**7.2 Conditions for safe storage, including any incompatibilities**

<b>Suitable Container:</b>	Do not store above 25°C. Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Shelf life after first opening the immediate packaging: 28 days.
<b>Storage incompatibility:</b>	No major incompatibilities known.

**7.3 Specific end uses**

Not available

**SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

**DERIVED NO EFFECT LEVEL - DNEL**

Not Available

**PREDICTED NO EFFECT LEVEL - PNEC**

Not Available

**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA:**


Not Available

**EMERGENCY LIMITS:**

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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Not Available

Ingredient	Original IDLH	Revised IDLH
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Not Available	
<b>8.2 Exposure controls</b>	
<b>Appropriate engineering controls:</b>	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
<b>Personal protection:</b>	
<b>Eye and face protection:</b>	Safety glasses with side shields / chemical goggles
<b>Skin protection:</b>	See hand protection below
<b>Hands/ feet protection:</b>	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	No special equipment needed when handling small quantities
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	Not applicable
<b>8.3 Environmental exposure controls</b>	
See Section 12	

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

**Appearance:** Lidocaine Hydrochloride: white, crystalline powder  
 Adrenaline acid tartrate: light brown-white crystalline powder

**Container:** 100 ml neutral amber glass vial fitted with a red rubber plug and an aluminium seal, containing a sterile, aqueous solution.

**Physical state:** Lignol®: Liquid

**Odour:** Not available

**Odour Threshold:** Not available

**pH (as supplied):** Not available

**Melting point / freezing point (degrees C):** Lidocaine HCl melting point: 74-79°C  
 Adrenaline acid tartrate melting point: 211-212°C

**Initial boiling point and boiling range:** Not available

**Flash Point:** Not available

**Evaporation rate:** Not available

**Flammability:** Not available

**Upper/lower flammability or explosive limits:** Not available

**Vapour pressure:** Not available

**Relative Density (at degrees C):** Not available

**Solubility in water and solvents (mg/l):** Not available

**Vapour density:** Not available

**Auto ignition temperature (degrees C):** Not available

**Decomposition temperature (degrees C):** Not available

**Viscosity: (degrees C):** Not available

**Explosive properties:** Not available

**Oxidising properties:** Not available

**Partition Coefficient:** Not available

**Molecular weight:** Lidocaine Hydrochloride: 288.8  
 Adrenaline acid tartrate: 183.2

**Taste:** Not available

**Surface tension:** Not available

**Volative component:** Not available

**Gas group:** Not available

**pH as a solution:** Not available

**VOC g/L:** Not available

### 9.2 Other information

Not Available

## 10: REACTIVITY AND STABILITY

<b>10.1 Reactivity:</b>	See Section 7
<b>10.2 Chemical stability:</b>	Product is considered stable.
<b>10.3 Possibility of hazardous reactions:</b>	Stable under normal temperatures and conditions.
<b>10.4 Conditions to avoid:</b>	None known.

<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.

**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>Inhalation:</b>	Not considered to be a hazard.	
<b>Ingestion:</b>	Lidocaine hydrochloride may produce CNS toxicity. Adrenaline acid tartrate may result in nausea and vomiting, with weakness and dizziness	
<b>Skin contact:</b>	Adrenaline acid tartrate may produce contact sensitivity.	
<b>Eye contact:</b>	Adrenaline acid tartrate may produce contact sensitivity.	
<b>Self-injection:</b>	Lidocaine has rapid onset of action when injected and spreads rapidly through surrounding tissues. The speed of onset and duration of action of Lidocaine may be increased by the addition of a vasoconstrictor. Adrenaline is added to local anaesthetics, such as Lidocaine hydrochloride, to slow diffusion and limit absorption as it constricts arterioles and capillaries, so prolonging the duration of the effect and lessening the danger of toxicity.	
<b>Chronic:</b>	Local anaesthetics may have systemic adverse effects as a result of the raised plasma concentrations which occur when the rate of absorption exceeds the rate of breakdown. Toxicity causes excitation of the central nervous system, which may be followed by systemic depression leading to coma. Convulsions may be controlled with Diazepam.	
<b>Lignol®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Lidocaine hydrochloride:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (mouse) LD <sub>50</sub> : 220 mg/kg <sup>1</sup>	Not Available

1. \* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances

<b>Skin corrosion/ irritation:</b>
Irritation may occur after excessive skin contact.
<b>Serious eye damage/ irritation:</b>
May cause irritation in some people.
<b>Respiratory or skin sensitization:</b>
Not available



<b>SECTION 11: TOXICOLOGICAL INFORMATION</b>
<b>Germ cell mutagenicity:</b>
Not available
<b>Carcinogenicity:</b>
Not available
<b>Reproductive toxicity:</b>
Not available
<b>STOT – single exposure:</b>
Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

<b>SECTION 12: ECOLOGICAL INFORMATION</b>
<b>Not expected to be an environmental hazard.</b>
<b>12.1 Toxicity</b>
Not Available
<b>12.2 Persistence and degradability</b>
Not Available
<b>12.3 Bioaccumulative potential</b>
Not Available
<b>12.4 Mobility in Soil</b>
Not Available
<b>12.5 Results of PBT and vPvB assessment</b>
Not Available
<b>12.6 Other adverse effects</b>
Not Available



**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.  Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.  Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b>	None
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not Applicable

<b>Land transport (ADR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	Class	N/a
	Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	

<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Air transport (ICAO-IATA / DGR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a



<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Sea transport (IMDG-Code / GGVSee):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	IMDG Class	N/a
	IMDG Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Inland waterways transport (ADN):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazard</b>	N/a	
<b>14.6 Special precautions for user</b>	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
<b>14.7 Transport in</b>	N/a	

<b>bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	
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## SECTION 15: REGULATORY INFORMATION

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

#### LIDOCAINE HYDROCHLORIDE (73-78-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)
- International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

### 15.2 Chemical Safety Assessment

#### ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Lidocaine hydrochloride	73-78-9	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 3	GHS06, Dgr	H301
2	Acute Tox. 3, Acute Tox. 4, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2, Resp. Sens. 1, Aquatic Chronic 3, STOT SE 3	GHS06, Dgr, GHS08	H301, H315, H317, H319, H334, H335, H412, H311, H331
1	Acute Tox. 4	GHS07, Wng	H302
2	Acute Tox. 4, Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1, STOT SE 3, Aquatic Chronic 3	GHS08, GHS06, Dgr	H301, H315, H319, H334, H335, H412

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Australia - AICS	Y
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Canada - DSL	Y
Canada - NDSL	N (lidocaine hydrochloride)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (lidocaine hydrochloride)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
<b>Legend:</b>	<i>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)</i>

## SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

### Ingredients with multiple CAS numbers:

Lidocaine hydrochloride	73-78-9, 6108-05-0
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For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

### Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

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