

## SECTION 1: IDENTIFICATION

<b>1.1 Product identifier</b>	
<b>Product name:</b>	Intra-Epicaine® (20 mg/ml 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>	Mepivacaine is indicated for infiltration, nerve block, intra-articular and epidural anaesthesia in horses.
<b>Uses advised against:</b>	Care should be taken to avoid intra-vascular injection by aspiration prior to and during administration. The analgesic effect of mepivacaine, when used as part of a lameness investigation, begins to subside after 45-60 minutes. However, sufficient analgesia may persist to effect gait beyond two hours.
<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>Legend:</b>	1. Classified by Chemwatch

<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	No data available
<b>2.2 Label Elements</b>	
<b>Signal Word:</b>	No data available
<b>Hazard Statement(s)</b>	
No data available	
<b>Additional Statement(s)</b>	
None	
<b>Precautionary Statement(s) Prevention:</b>	
<b>P264</b>	Wash hands thoroughly after handling.
<b>P270</b>	Do not eat, drink or smoke when using this product.
<b>Precautionary Statement(s) Response:</b>	
<b>P301 + P310</b>	IF SWALLOWED: immediately call a POISON CENTER/doctor
<b>P330</b>	Rinse mouth.
<b>Precautionary Statement(s) Storage:</b>	
<b>P405</b>	Store locked up
<b>Precautionary Statement(s) Disposal:</b>	
<b>P501</b>	Dispose of contents / packaging according to local regulations
<b>2.3 Other Hazard Information</b>	

### 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	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 1722-62-9 2. 217-023-9 3. Not Available 4. Not Available	2%	Mepivacaine hydrochloride	Acute toxicity (oral) Category 4, Skin corrosion/irritation Category 2, Chronic aquatic hazard Category 3; H302, H315, H412
N/a	Proprietary	Other ingredients	N/a

		determined not to be hazardous	
<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 and show 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 and show the package leaflet or the label to the medical practitioner.
<b>Inhalation:</b>	Due to physical form of this product, inhalation exposure is unlikely. However, if inhalation occurs, remove to fresh air. Lie flat, and seek medical aid if required, showing the package leaflet or the label to the medical practitioner.
<b>Ingestion:</b>	If accidentally ingested, seek medical aid and show the package leaflet or the label to the medical practitioner.
<b>Self-injection:</b>	Care should be taken to avoid accidental ingestion or self-injection. In case of accidental ingestion or self-injection, seek medical advice immediately and show the package leaflet to the physician.
<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>	
Not available.	

**SECTION 5: FIRE FIGHTING MEASURES**

<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area.
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used.
<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>	Non-combustible.

**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>	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Place in a suitable, labelled container for waste disposal.
<b>Major Spills:</b>	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Large spills should be collected into an appropriate container for waste disposal.

**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	Care should be taken to avoid accidental self-injection or skin contact. Wear suitable protection gloves and clothing when handling the product. When handling, <b>DO NOT</b> eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Do not store above 25°C. Keep out of the reach and sight of children.

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

<b>Suitable Container:</b>	Shelf life of the veterinary medicinal product as packaged for sale: 5 years. This product does not contain an antimicrobial preservative. Once opened, use immediately. Discard any unused material.
<b>Storage incompatibility:</b>	Unknown.

**7.3 Specific end uses**

Not available

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

**8.1 Control parameters**

**DERIVED NO EFFECT LEVEL - DNEL (EU)**

Not Available

**PREDICTED NO EFFECT LEVEL - PNEC (EU)**

Not Available


**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

**INGREDIENT DATA:**

Not Available

**EMERGENCY LIMITS:**

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:** Intra-Epicaine®: A clear colourless mobile liquid, practically free from visible particles.  
 Mepivacaine hydrochloride: White, odourless crystalline powder.

**Container:** Stored in clear glass vials containing 10 ml, with a red chlorobutyl stopper and aluminium seals, are available in cartons of six.

**Physical state:** Liquid

**Odour:** Not available

**Odour Threshold:** Not available

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

**Melting point / freezing point (degrees C):** Not available

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

**Flash Point:** In water – no flash point.

**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):** Freely soluble

**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:** Mepivacaine hydrochloride: 282.8

**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. Hazardous polymerisation will not occur.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
<b>10.4 Conditions to avoid:</b>	See Section 7.

<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>	The product may cause respiratory irritation to some people. Due to physical form of this product, inhalation exposure is unlikely.	
<b>Ingestion:</b>	The product may cause irritation. Significant oral exposure is considered unlikely.	
<b>Skin contact:</b>	The product may produce skin irritation in some persons.	
<b>Eye contact:</b>	The product may produce eye irritation in some persons.	
<b>Self-injection:</b>	Transient, local soft tissue swelling may occur in a small proportion of cases following injection of the product.	
<b>Chronic:</b>	Local anaesthetics used in excess can cause systemic toxicity characteristics by CNS effects. If systemic toxicity occurs, as a result of inadvertent intra-vascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.	
<b>Intra-Epicaine®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Mepivacaine hydrochloride:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD <sub>50</sub> : >5000 mg/kg* <sup>2</sup>	Not Available
<p>1. Value obtained from Europe ECHA registered substances          2. Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</p>		
<b>Skin corrosion/ irritation:</b>		
The product does not cause any skin corrosion or irritation		
<b>Serious eye damage/ irritation:</b>		
The product does not cause any eye damage or irritation		
<b>Respiratory or skin sensitization:</b>		
The product is not a skin sensitizer		





<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>12.1 Toxicity</b>
Not Available
<b>DO NOT discharge into sewer or waterways.</b>
<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 bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a		

**SECTION 15: REGULATORY INFORMATION**

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

**MEPIVACAINE HYDROCHLORIDE (1722-62-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

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

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable:- 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC

**15.2 Chemical Safety Assessment**

**ECHA SUMMARY**

Ingredient	CAS number	Index Number	ECHA Dossier
Mepivacaine Hydrochloride	1722-62-9	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, Aquatic Chronic 3, Eye Irrit. 2	GHS06, Dgr	H301, H412, H319, H332

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

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (mepivacaine hydrochloride)
China - IECSC	N (mepivacaine hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (mepivacaine hydrochloride)
Korea - KECl	N (mepivacaine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (mepivacaine hydrochloride)
USA - TSCA	Y

**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**

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

**Full text Risk and Hazard codes:**

<b>H301</b>	Toxic if swallowed
<b>H319</b>	Causes severe eye irritation
<b>H332</b>	Harmful by inhalation

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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