

SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Libromide® (325mg tablets for dogs)
<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>	An anti-epileptic agent for use as an adjunct to phenobarbital in the control of refractory cases of epilepsy in dogs.
<b>Uses advised against:</b>	Do not use in cases of known hypersensitivity to bromide, or to any of the excipients. Do not use in dogs with severe renal insufficiency. It is advisable not to change the dog's diet during therapy due to the effect of chloride intake on serum bromide concentrations. <b>Do not handle this product if you are pregnant, think you are pregnant or if you are breast feeding.</b> Do not handle this product if you have a known sensitivity to bromide.
<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:</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>	
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>	

<b>SECTION 3: INFORMATION ON THE INGREDIENTS</b>			
<b>3.1 Substances</b>			
See section below for composition of mixtures			
<b>3.2 Mixtures</b>			
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. 7758-02-3 2. Not Available 3. Not Available 4. Not Available	72%	Potassium bromide	Acute toxicity (oral) category 3, Eye Irritation Category 2, STOT - SE (.resp. Irr) Category 3; H315, H319, H335 <sup>1</sup>
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a
<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>	In case of dust inhalation or breathing fumes released from heated material, remove person to fresh air.		
<b>Ingestion:</b>	If conscious and alert give a least 1 litre of water or milk. Never give anything by mouth to an unconscious person. Seek medical attention immediately, showing 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>	
TO THE MEDICAL PRACTITIONER: Bromide intoxication can be treated by administration of sodium chloride or a suitable chloruretic agent.	
<b>SECTION 5: FIRE FIGHTING MEASURES</b>	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area.
<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. Cool containers with water spray. Wear full breathing apparatus and self-contained breathing apparatus.
<b>Fire / explosion hazard:</b>	The product is not directly flammable. Avoid inhalation of vapour and flue gases – seek fresh air.

<b>SECTION 6: ACCIDENTAL RELEASE MEASURES</b>	
<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>	If tablets are broken, sweep up dust and fragments and put into a suitable container for disposal.
<b>Major 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. If tablets are broken, sweep up dust and fragments and put into a suitable container for disposal.



**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	<p><b>Do not handle this product if you are pregnant, think you are pregnant or if you are breast feeding.</b>  <b>Do not handle this product if you have a known sensitivity to bromide.</b>          Wear suitable protection gloves and clothing when handling the product.          Wash hands thoroughly immediately after breaking or handling any tablets.          When handling, <b>DO NOT</b> eat, drink or smoke.          Observe manufacturer's storage and handling recommendations.</p>
<b>Other Information:</b>	<p>Do not store above 25°C.          Keep out of the reach and sight of children.</p>

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

<b>Suitable Container:</b>	<p>Keep the container tightly closed in order to protect from moisture.          Shelf life of the veterinary medicinal product as packaged for sale: 3 years.          Shelf life after first opening the container: 3 months.          Use any halved tablet within 12 hours.</p>
<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

<b>EMERGENCY LIMITS:</b>				
<b>Ingredient</b>	<b>Material Name</b>	<b>TEEL-1</b>	<b>TEEL-2</b>	<b>TEEL-3</b>
Potassium bromide	Potassium bromide	9.2 mg/m <sup>3</sup>	100 mg/m <sup>3</sup>	610 mg/m <sup>3</sup>
<b>Ingredient</b>		<b>Original IDLH</b>		<b>Revised IDLH</b>
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:** Libromide®: plain white circular biconvex 9.5 mm tablet with a single scored line on one face.  
 Potassium bromide: white solid

**Container:** White, polypropylene container with polyethylene, child resistant closure (100s)  
 White, polypropylene container with polyethylene, tamper-evident, push-fit closure (500s)

**Physical state:** Libromide®: tablet

**Odour:** Potassium bromide: odourless

**Odour Threshold:** Not available

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

**Melting point / freezing point (degrees C):** Potassium bromide melting point: 734°C

**Initial boiling point and boiling range:** Potassium bromide boiling point: 1435°C

**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:** Atipamezole hydrochloride: 248.75

**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. Reacts explosively with bromine trifluoride.
<b>10.4 Conditions to avoid:</b>	Avoid contact with strong acids, strong oxidants and heavy metal salts.

<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>	There is some evidence that suggests that this substance may cause respiratory irritation to some people. Due to physical form of this product, inhalation exposure is unlikely.	
<b>Ingestion:</b>	This product may cause irritation to the mucous membranes. 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>Chronic:</b>	Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremor). If necessary, these symptoms may be reversed by a medetomidine hydrochloride dose which is lower than the usually used clinical dose.	
<b>Atipam®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Atipamezole hydrochloride:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD <sub>50</sub> : 80 mg/kg*e <sup>1</sup>	Eye: moderate Skin: moderate

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>
Not Available
<b>Serious eye damage/ irritation:</b>
Not available
<b>Respiratory or skin sensitization:</b>
Not available
<b>Germ cell mutagenicity:</b>
Not available
<b>Carcinogenicity:</b>



SECTION 11: TOXICOLOGICAL INFORMATION
Not available
<b>Reproductive toxicity:</b>
Although there was no evidence of reproductive toxicity in laboratory animals, bromide can cross the placenta and cases of neonatal bromide toxicity have been reported in humans.
<b>STOT – single exposure:</b>
Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

SECTION 12: ECOLOGICAL INFORMATION					
<b>12.1 Toxicity</b>					
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Potassium bromide	LC50	96	Fish	>30mg/L	3
Potassium bromide	EC50	96	Not Available	7396.125mg/L	2
Potassium bromide	NOEC	504	Crustacea	<=3-19mg/L	1
Legend:	<i>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)</i>				
Harmful to aquatic organisms. <b>DO NOT discharge into sewer or waterways.</b>					
<b>12.2 Persistence and degradability</b>					
Ingredient	Persistence: Water/Soil		Persistence: Air		
Potassium bromide	HIGH		HIGH		
<b>12.3 Bioaccumulative potential</b>					
Ingredient	Bioaccumulative potential				
Potassium bromide	LOW (LogKOW = -0.3713)				
<b>12.4 Mobility in Soil</b>					



Ingredient	Mobility
Potassium bromide	LOW (KOC = 14.3)
<b>12.5 Results of PBT and vPvB assessment</b>	
Not Available	
<b>12.6 Other adverse effects</b>	
Not Available	

<b>SECTION 13: DISPOSAL CONSIDERATIONS</b>	
<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>
<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

**POTASSIUM BROMIDE (7758-02-3) 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)

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
Potassium Bromide	7758-02-3	Not Available	01-2119962195-33-XXXX
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Eye Irrit. 2	GHS07, Wng	H319
2	Eye Irrit. 2, Not	GHS08, GHS05,	H315, H335, H336,



	Classified, Skin Irrit. 2, STOT SE 3, STOT RE 2, Eye Dam. 1, Water-react. 1, Aquatic Chronic 3, Acute Tox. 4, Skin Sens. 1, STOT SE 1	Dgr	H318, H412, H302, H317, H371, H373
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Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (potassium bromide)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
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.

### Full text Risk and Hazard codes:

<b>H302</b>	Harmful if swallowed.
<b>H317</b>	May cause an allergic skin reaction.
<b>H318</b>	Causes serious eye damage.
<b>H336</b>	May cause drowsiness or dizziness.
<b>H371</b>	May cause damage to organs.
<b>H373</b>	May cause damage to organs through prolonged or repeated exposure.
<b>H412</b>	Harmful to aquatic life with long lasting effects.

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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