

SAFETY DATA SHEETS

This SDS packet was issued with item:



078948462

N/A

SECTION 1: IDENTIFICATION

1.1 Product identifier	
Product name	Ketamine hydrochloride Injection
Chemical name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available
1.2 Recommended use of the chemical and restrictions on use	
Relevant identified uses	Anesthetic
1.3 Details of the supplier of the substance or mixture	
Registered company name (US)	Dechra Veterinary Products
Address	7015 College Blvd Suite 525 Overland Park, KS 66211 USA
Telephone	866-933-2472
Fax	Not Available
Email	Not Available
1.4 Emergency telephone numbers	
Dechra (US)	866-933-2472

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture	
NFPA 704 diamond  <p>Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)</p>	
Classification	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Reproductive Toxicity Category 2, Specific Target Organ Toxicity - Repeated Exposure Category 2
2.2 Label elements	
Hazard pictogram(s)	
Signal word	Warning
Hazard statement(s)	
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
Hazard(s) not otherwise classified	
Not Applicable	
Precautionary statement(s) prevention	
P201	Obtain special instructions before use.
P260	Do not breathe mist/vapours/spray.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash all exposed external body areas thoroughly after handling.
Precautionary statement(s) response	
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314	Get medical advice/attention if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Precautionary statement(s) storage	
P405	Store locked up.
Precautionary statement(s) disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

See section above for composition of Mixtures.

3.2 Mixtures

CAS No.	% [weight]	Name
1867-66-9	10-30	ketamine hydrochloride
121-54-0	<1	benzethonium chloride
Not Available	>60	Ingredients determined not to be hazardous

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact	Wash out immediately with fresh running water. Seek medical attention without delay; if pain persists or recurs seek medical attention.
Skin contact	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 dust is inhaled remove from contaminated area. Encourage patient to blow nose to ensure clear passage of breathing. If irritation or discomfort persists seek medical attention.
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. 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.

4.2 Most important symptoms and effects, both acute and delayed

See section 11

4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically.

Many drugs have been found that lessen the risk of neurotoxicity from NMDA receptor antagonists. Centrally acting alpha 2 agonists such as clonidine and guanfacine are thought to most directly target the etiology of NMDA neurotoxicity. Other drugs acting on various neurotransmitter systems known to inhibit NMDA antagonist neurotoxicity include: anticholinergics, diazepam, barbiturates, ethanol 5-HT2A serotonin receptor agonists, anticonvulsants and muscimol.

Psychedelic-induced personality disorders can be severe and prolonged.

Appropriate treatment often requires antipsychotic medication (antipsychotics, neuroleptics, major tranquillizers) and residential care in a mental health facility. In certain cases, psychedelic-induced chronic psychological problems lead to complicated patterns of polydrug abuse that requires additional treatment approaches.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas. Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider: foam, dry chemical powder, carbon dioxide

5.2 Special hazards arising from the substance or mixture

Fire incompatibility | None known

5.3 Special protective actions for fire-fighters:

Firefighting	Wear full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use firefighting procedures suitable for surrounding area. Avoid spraying water onto liquid pools. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire.
Fire / explosion hazard	The material is not readily combustible under normal conditions. However, it will break down under fire conditions and the organic component may burn. Not considered to be a significant fire risk. Heat may cause expansion or decomposition with violent rupture of containers. Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). May emit acrid smoke. Decomposes on heating and produced toxic fumes of carbon dioxide, hydrogen chloride, phosgene, nitrogen oxides, other pyrolysis products typical of burning organic material. May emit poisonous/corrosive fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

See Section 8

6.2 Environmental precautions

See Section 12

6.3 Methods and material for containment and cleaning up

Minor spills | Clean up all spills immediately. Avoid breathing vapors 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. Wipe up. Place in a suitable, labelled container for waste disposal.
Major spills	Moderate hazard. Clear area of personnel and move upwind. 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 course. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Neutralise/decontaminate residue (see Section 13 for specific agent). Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. After cleanup operations, decontaminate and launder all protective clothing and equipment before storing and re-using. If contamination of drains or waterways occurs, advise emergency services.
Personal Protective Equipment advice is contained in Section 8 of the SDS.	

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling	DO NOT allow clothing wet with material to stay in contact with skin. Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. Keep containers securely sealed when not in use. Avoid physical damage to containers. Observe manufacturer's storage and handling recommendations.
Other information	NOTE: Special security requirements may be mandated under Federal/State Regulation(s).. Store in original containers. Store in vault fitted with warning devices or detectors recommended by various Federal/State authorities. Store in vault used only for the purpose of storage of drugs of addiction. Vault must be locked at all times except when the materials stored therein are required. Keep containers securely sealed. Keep dry. Protect containers against physical damage and check regularly for leaks.

7.2 Conditions for safe storage, including any incompatibilities

Suitable container	Glass vials. Packaging as recommended by manufacturer. Check that containers are clearly labelled. Tamper-proof containers. Polyethylene or polypropylene containers. Metal drum with sealed plastic liner. Glass container is suitable for laboratory quantities
Storage incompatibility	None known.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)
INGREDIENT DATA
Not Available

Emergency limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Ketamine Hydrochloride Injection	Not Available	Not Available	Not Available
Ingredient	Original IDLH	Revised IDLH	
ketamine hydrochloride	Not Available	Not Available	
benzethonium chloride	Not Available	Not Available	

Occupational Exposure Banding






Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
ketamine hydrochloride	E	≤ 0.01 mg/m ³
benzethonium chloride	E	≤ 0.01 mg/m ³

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

8.2 Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.
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Personal protection	    
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs, use safety glasses with side shields or chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.
Skin protection	See Hand protection below.
Hands/feet protection	Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
Body protection Other protection	See Other protection below For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. Eye wash unit. Ensure there is ready access to an emergency shower. For Emergencies: Vinyl suit
Respiratory protection	Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear, colorless liquid	Vapor density: NA
Physical state: Liquid	Auto ignition temperature (°C): NA
Odor: Not available	Decomposition temperature (°C): NA
Odor threshold: NA	Viscosity (°C): NA
pH (as supplied): 3.5-5.5	Explosive properties: NA
Melting point / freezing point (°C): NA	Oxidizing properties: NA
Initial boiling point and boiling range: NA	Partition coefficient: NA
Flash point: NA	Molecular weight: NA
Evaporation rate: NA	Taste: NA
Flammability: NA	Surface tension: NA
Upper/lower flammability or explosive limits: NA	Volatile component (%vol): NA
Vapor pressure: NA	Gas group: NA
Relative density (at °C): 1.02-1.04	pH as a solution: NA
Solubility in water (mg/l): Miscible	VOC g/L: NA
	Specific gravity @ 20°C (water = 1): NA

10: STABILITY AND REACTIVITY

Reactivity	See Section 7
Chemical stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.
Possibility of hazardous reactions	See Section 7
Conditions to avoid	See Section 7
Incompatible materials	See Section 7
Hazardous composition	See Section 5

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Ketamine exposure may produce psychological manifestations such as hallucinations, dream-like states.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
Skin contact	Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The material may accentuate any pre-existing dermatitis condition.
Eye contact	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Repeated or prolonged eye contact may cause inflammation.

Chronic	On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment. Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems.	
Ketamine Hydrochloride Injection	Acute toxicity	Irritation
	Not Available	Not Available
ketamine hydrochloride	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 447 mg/kg ^[2]	Not Available
benzethonium chloride	Acute toxicity	Irritation
	Dermal (rabbit) LD ₅₀ : 3000 mg/kg ^[2] Oral (rat) LD ₅₀ : 295 mg/kg ^[1]	Eye (rabbit): 0.03 mg - SEVERE Eye: no adverse effect observed (not irritating) ^[1] Skin (rabbit): SEVERE* Skin: adverse effect observed (corrosive) ^[1]
1 Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		
Acute Toxicity		Carcinogenicity
Skin Irritation/Corrosion		Reproductivity
Serious Eye Damage/Irritation		STOT – Single Exposure
Respiratory or Skin Sensitization		STOT – Repeated Exposure
Mutagenicity		Aspiration Hazard
* - Data either not available or does not fill the criteria for classification, ✓ - Data available to make classification.		

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ketamine Hydrochloride Injection	Endpoint	Test Duration	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
ketamine hydrochloride	Endpoint	Test duration	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
benzethonium chloride	Endpoint	Test duration	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	0.12mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	0.038mg/l	2
	LC50	96h	Fish	1.4-53mg/l	Not Available
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					

NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
benzethonium chloride	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
ketamine hydrochloride	LOW (LogKOW = 2.18)
benzethonium chloride	HIGH (LogKOW = 5.9969)

12.4 Mobility in soil

Ingredient	Mobility
benzethonium chloride	LOW (KOC = 443300)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/ packaging disposal	Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/recycling if possible. Otherwise, if container cannot be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. DO NOT reuse containers. Bury empty containers in an authorised landfill. DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. Observe all label safeguards until containers are cleaned and destroyed. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.
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SECTION 14: TRANSPORT INFORMATION

Labels required	
Marine pollutant	NO
Land transport (US: DOT)	

Not regulated for transport of dangerous goods	
Land transport (ICAO-IATA / DGR)	
Not regulated for transport of dangerous goods	
Land 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	
Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	
Product name	Group
ketamine hydrochloride	Not Available
benzethonium chloride	Not Available
Transport in bulk in accordance with the ICG Code	
Product name	Ship type
ketamine hydrochloride	Not Available
benzethonium chloride	Not Available

SECTION 15: REGULATORY INFORMATION

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

Product regulated by FDA as a veterinary product.

ketamine hydrochloride is found on the following regulatory lists

Not Applicable

benzethonium chloride is found on the following regulatory lists

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	Yes
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	Yes
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None reported

State Regulations

US. California Proposition 65

None reported

National Inventory Status

Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (ketamine hydrochloride)
Canada - NDSL	No (ketamine hydrochloride; benzethonium chloride)
China - IECSC	No (ketamine hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (ketamine hydrochloride)
Korea - KECI	No (ketamine hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	No (ketamine hydrochloride)
Taiwan - TCSI	Yes

Mexico - INSQ	No (ketamine hydrochloride)
Vietnam - NCI	No (ketamine hydrochloride)
Russia - FBEPH	No (ketamine hydrochloride)
Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration	

SECTION 16: OTHER INFORMATION

Initial date: 10 August 2022

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	STEL: Short Term Exposure Limit
PC—STEL: Permissible Concentration-Short Term Exposure Limit	TEEL: Temporary Emergency Exposure Limit
IARC: International Agency for Research on Cancer	ES: Exposure Standard
ACGIH: American Conference of Governmental Industrial Hygienists	OSF: Odour Safety Factor
IDLH: Immediately Dangerous to Life or Health Concentrations	NOAEL :No Observed Adverse Effect Level
AIC: Australian Inventory of Industrial Chemicals	LOAEL: Lowest Observed Adverse Effect Level
IECSC: Inventory of Existing Chemical Substance in China	TLV: Threshold Limit Value
EINECS: European INventory of Existing Commercial chemical Substances	LOD: Limit Of Detection
ELINCS: European List of Notified Chemical Substances	OTV: Odour Threshold Value
ENCS: Existing and New Chemical Substances Inventory	BCF: BioConcentration Factors
PICCS: Philippine Inventory of Chemicals and Chemical Substances	BEI: Biological Exposure Index
INSQ: Inventario Nacional de Sustancias Químicas	DSL: Domestic Substances List
NCI: National Chemical Inventory	NDSL: Non-Domestic Substances List
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances	NLP: No-Longer Polymers
NZIoC: New Zealand Inventory of Chemicals	KECI: Korea Existing Chemicals Inventory
	TSCA: Toxic Substances Control Act
	TCSI: Taiwan Chemical Substance Inventory

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