

Ketamine (5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	3976743-00008	Date of first issue: 14.02.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ketamine (5%) Formulation Manufacturer or supplier's details

Company name of supplier	:	MSD			
Address	:	126 E. Lincoln Avenue			
		Rahway, New Jersey U.S.A. 07065			
Telephone	:	908-740-4000			
Emergency telephone	:	1-908-423-6000			
E-mail address	:	EHSDATASTEWARD@msd.com			
Recommended use of the chemical and restrictions on use					

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Skin corrosion/irritation	:	Category 3
Reproductive toxicity :	:	Category 2
Specific target organ toxicity : - repeated exposure (Dermal)	:	Category 2 (Kidney, Liver, Brain)
GHS label elements Hazard pictograms :	:	
Signal Word :	:	Warning
Hazard Statements :	:	H316 Causes mild skin irritation. H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Kidney, Liver, Brain) through prolonged or repeated exposure in contact with skin.
Precautionary Statements :	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapors. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
		P332 + P313 If skin irritation occurs: Get medical advice/ atten-



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		tion.			
		Storage: P405 Store loc	ked up.		
		Disposal:			
		posal plant.	of contents/ contai	ner to an approved waste dis-	
Othe	r hazards				
None	known.				
ECTION	3. COMPOSITION/INF	ORMATION ON INC			
	tance / Mixture	: Mixture			
		. MIXIUIE			
	ponents nical name		CAS-No.	Concentration (% w/w)	
	nine hydrochloride		1867-66-9	>= 5 -< 10	
ECTION	4. FIRST AID MEASUR	RES			
Gene	ral advice	advice immedi	ately.	eel unwell, seek medical cases of doubt seek medical	
lf inha	aled	: If inhaled, remo Get medical at	ove to fresh air. tention		
In cas	se of skin contact	: In case of cont Remove conta Get medical at Wash clothing	act, immediately flu minated clothing an tention.		
In cas	se of eye contact	: Flush eyes with	n water as a preca	ution.	
lf swa	allowed	: If swallowed, D Get medical at	 Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Binse mouth thoroughly with water. 		
	important symptoms iffects, both acute and ed	: Causes mild sl Suspected of c May cause dar	Rinse mouth thoroughly with water. Causes mild skin irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated		
Prote	ction of first-aiders	: First Aid respo and use the re-	exposure in contact with skin. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).		
Notes	s to physician		atically and suppo		

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray
		Alcohol-resistant foam
		Carbon dioxide (CO2)
		Dry chemical



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	Unsuita media	ble extinguishing	:	None known.	
	Specific hazards during fire fighting Hazardous combustion prod- ucts		:	Exposure to comb	pustion products may be a hazard to health.
			:	Carbon oxides Chlorine compour Nitrogen oxides (I	
	Specific extinguishing meth- ods		:	cumstances and t Use water spray t	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
	Special protective equipment for fire-fighters		:		e, wear self-contained breathing apparatus. tective equipment.

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	 Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Avoid contact with eyes.



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Hygi	ene measures	 Handle in accordance with good industrial hygiene and practice, based on the results of the workplace exposu assessment Take care to prevent spills, waste and minimize releas environment. If exposure to chemical is likely during typical use, prov flushing systems and safety showers close to the work place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include revie engineering controls, proper personal protective equipappropriate degowning and decontamination procedure industrial hygiene monitoring, medical surveillance and 				
Conditions for safe storage		use of administrative controls.Keep in properly labeled containers.Store locked up.				
Materials to avoid			lance with the particular national regulations. ith the following product types: g agents			

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Ketamine hydrochloride	1867-66-9	TWA	10 µg/m3 (OEB 3)	Internal
	Further inform	Further information: Skin		
		Wipe limit	100 µg/100 cm ²	Internal

Ingredients with workplace control parameters

Engineering measures :	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip- less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.
Personal protective equipment	
Respiratory protection :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type



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	emarks protection	If the work envir mists or aerosol Wear a faceshie	e gloving. sses with side shields or goggles. onment or activity involves dusty conditions, s, wear the appropriate goggles. eld or other full face protection if there is a ect contact to the face with dusts, mists, or	
Skin and body protection		: Work uniform or Additional body task being perfo disposable suits Use appropriate	 Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. 	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	soluble



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octan Autoig Decor Visco		:	Not applicable No data available No data available	2
	scosity, kinematic sive properties	:	No data available	2
	zing properties cular weight	:	The substance o	r mixture is not classified as oxidizing.
Partic	le size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products		None known. Oxidizing agents No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely route	s of exposure
Inhalation Skin contact	
Ingestion Eye contact	
Acute toxicity	
Not classified based on avail	able information.
Product:	
Acute oral toxicity	: Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Components:	
Ketamine hydrochloride:	
Acute oral toxicity	: LD50 (Rat): 447 mg/kg
	LD50 (Mouse): 617 mg/kg



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	e toxicity (other routes of nistration)	:	LD50 (Rat): 59 mg Application Route	
			LD50 (Mouse): 59 Application Route	
			LD50 (Mouse): 35 Application Route	
			LD50 (Guinea pig Application Route	
			LD50 (Rat): 224 n Application Route	
	corrosion/irritation es mild skin irritation.			
<u>Com</u>	ponents:			
Keta	mine hydrochloride:			
Speci Resu		:	Rabbit irritating	
Not c	bus eye damage/eye irr lassified based on availa			
Not c <u>Com</u>	lassified based on availa ponents:			
Not c <u>Com</u>	lassified based on availa ponents: mine hydrochloride: ies			
Not c <u>Com</u> Ketai Speci Resu	lassified based on availa ponents: mine hydrochloride: ies	able :	information. Rabbit irritating	
Not c Com Ketar Spec Resu Resp Skin	lassified based on availa ponents: mine hydrochloride: ies It	able : : atic	information. Rabbit irritating	
Not c Com Ketar Spec Resu Resp Skin Not c Resp	lassified based on availa ponents: mine hydrochloride: ies It iratory or skin sensitiz sensitization	able : atic	information. Rabbit irritating n information.	
Not c Com Ketar Speci Resu Resp Skin Not c Resp Not c Germ	lassified based on availa ponents: mine hydrochloride: ies It iratory or skin sensitiz sensitization lassified based on availa iratory sensitization	able : aatic	information. Rabbit irritating on information. information.	
Not c Com Ketar Speci Resu Resp Skin Not c Resp Not c Germ Not c	lassified based on availa ponents: mine hydrochloride: ies lt iratory or skin sensitiz sensitization lassified based on availa iratory sensitization lassified based on availa	able : able able	information. Rabbit irritating on information. information.	
Not c Com Ketai Speci Resu Resp Skin Not c Germ Not c Carci Not c Repr	lassified based on availa ponents: mine hydrochloride: ies lt iratory or skin sensitiz sensitization lassified based on availa iratory sensitization lassified based on availa n cell mutagenicity lassified based on availa	able : able able able	information. Rabbit irritating on information. information. information.	
Not c Com Speci Resu Resp Skin Not c Resp Not c Germ Not c Carci Not c Susp	lassified based on availa ponents: mine hydrochloride: ies lt ies sensitization lassified based on availa iratory sensitization lassified based on availa n cell mutagenicity lassified based on availa inogenicity lassified based on availa	able : able able able	information. Rabbit irritating on information. information. information.	
Not c Com Speci Resu Resp Skin Not c Resp Not c Germ Not c Carci Not c Susp Susp	lassified based on availa ponents: mine hydrochloride: ies lt iratory or skin sensitiz sensitization lassified based on availa iratory sensitization lassified based on availa inogenicity lassified based on availa inogenicity lassified based on availa oductive toxicity ected of damaging the u	able : able able able	information. Rabbit irritating on information. information. information.	



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rsion	Revision Date: 30.09.2023		DS Number: 76743-00008	Date of last issue: 04.04.2023 Date of first issue: 14.02.2019
			Developmental	te: Intramuscular Toxicity: NOAEL: 120 mg/kg body weight Kidney, Liver, Heart ogenic effects.
			Developmental Symptoms: Ske	
			Symptoms: Ske	elopment te: Intramuscular letal and visceral variations . on prenatal and postnatal growth.
			Developmental Symptoms: Ske	
			Target Organs:	te: Intramuscular
Repro sessn	oductive toxicity - As- nent	:	Suspected of da	amaging the unborn child.
	-single exposure assified based on avail	lable	information.	
STOT May c	-repeated exposure			n) through prolonged or repeated exposure in
<u>Comp</u>	oonents:			
Ketar	nine hydrochloride:			
Targe	es of exposure et Organs ssment	:	Skin contact Kidney, Liver, B May cause dam exposure.	rain age to organs through prolonged or repeated
Repe	ated dose toxicity			
-	oonents:			
<u></u>				

Ketamine hydrochloride:

Species	: Mouse
LOAEL	: 30 mg/kg



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Application Route Exposure time Target Organs Remarks	 Intraperitoneal 3 Months Kidney, Liver, Bladder Significant toxicity observed in testing
Species LOAEL Application Route Exposure time Target Organs Remarks	 Mouse 30 mg/kg Intraperitoneal 6 Months Kidney, Liver, Bladder Significant toxicity observed in testing
Species LOAEL Application Route Exposure time Target Organs Remarks	 Mouse 30 mg/kg Intraperitoneal 28 Weeks Kidney Significant toxicity observed in testing
Species LOAEL Application Route Exposure time Target Organs Remarks	 Mouse 30 mg/kg Intraperitoneal 30 Days Brain, Liver Significant toxicity observed in testing
Species LOAEL Application Route Exposure time Target Organs Remarks	 Monkey 1 mg/kg Intraperitoneal 6 Months Brain Significant toxicity observed in testing
Aspiration toxicity Not classified based on	available information.
Experience with huma	

Components:

Ketamine hydrochloride:

Ingestion

Symptoms: The most common side effects are:, central nervous system effects, hypertension, Dizziness, Headache, Nausea, Drowsiness

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ketamine hydrochloride:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

:



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(Chronic aquatic toxicity	: Toxic effects ca	nnot be excluded	
I	Persistence and degradabil No data available Bioaccumulative potential	lity		
<u>(</u>	Components:			
I	Ketamine hydrochloride: Partition coefficient: n- octanol/water	: log Pow: 2.18		
	Mobility in soil No data available			
	Other adverse effects No data available			
SEC	FION 13. DISPOSAL CONSI	DERATIONS		
	Disposal methods	. Do not dianaca	of waste into sower	

Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT Not regulated as a dangerous good

Special precautions for user

Not applicable





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SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Revision Date	: 30.09.2023
Date format	: dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-



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mendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Material Safety Data Sheet		eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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