

according to the Hazardous Products Regulations

Ketamine (5%) Formulation

1.8 09/30/2023 3976736-00009 Date of first issue: 02/14/2019	Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
	1.8	09/30/2023	3976736-00009	Date of first issue: 02/14/2019

SECTION 1. IDENTIFICATION

Product name	:	Ketamine (5%) Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

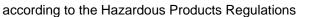
Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com
	-	

Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

SECTION 2. HAZARDS IDENTIFICATION

Reproductive toxicity : Category 2 (Kidney, Liver, Brain) - repeated exposure (Dermal) : Category 2 (Kidney, Liver, Brain) GHS label elements : : Hazard pictograms : : Signal Word : Warning Hazard Statements : 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 and face protection. Response: P308 + P313 IF exposed or concerned: Get medical attention.	GHS classification in accordance with the Hazardous Products Regulations					
 repeated exposure (Dermal) GHS label elements Hazard pictograms Signal Word Warning Hazard Statements 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 and face protection. Response: 	Reproductive toxicity	:	Category 2			
Hazard pictograms:iSignal Word:WarningHazard Statements: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 and face protection. Response:	- repeated exposure	:	Category 2 (Kidney, Liver, Brain)			
Signal Word:WarningHazard Statements: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 and face protection. Response:	GHS label elements					
 Hazard Statements 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 and face protection. Response: 	Hazard pictograms	:				
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 and face protection. Response:	Signal Word	:	Warning			
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 and face protection. Response:	Hazard Statements	:	H373 May cause damage to organs (Kidney, Liver, Brain)			
•	Precautionary Statements	:	 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 			
			•			
Storage:			·			





Ketamine (5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	3976736-00009	Date of first issue: 02/14/2019

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

 Common Name/Synonym	CAS-No.	Concentration (% w/w)
No data availa- ble		>= 5 - < 10 *

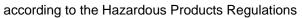
* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed Protection of first-aiders	:	Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure in contact with skin. First Aid responders should pay attention to self-protection,
Notes to physician	:	and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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





Ketamine (5%) Formulation

Version 1.8	Revision Date: 09/30/2023		9S Number: 76736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
media Specif	able extinguishing ic hazards during fire	:	None known. Exposure to comb	pustion products may be a hazard to health.
fighting Hazar ucts	dous combustion prod-	:	Carbon oxides Chlorine compour Nitrogen oxides (N	
Specif ods	ic extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to d so. Evacuate area.	
•	al protective equipment -fighters	:	In the event of fire Use personal prot	 wear self-contained breathing apparatus. ective equipment.
SECTION	6. ACCIDENTAL RELE	ASE	E MEASURES	
tive ec	nal precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
Enviro	nmental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		For large spills, pr containment to ke can be pumped, s container. Clean up remainin absorbent. Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	absorbent material. ovide diking or other appropriate ep material from spreading. If diked material tore recovered material in appropriate ng materials from spill with suitable egulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional 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.



according to the Hazardous Products Regulations

Ketamine (5%) Formulation

Version 1.8	Revision Date: 09/30/2023	SDS Number: 3976736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
		practice, based or assessment	th eyes. dance with good industrial hygiene and safety on the results of the workplace exposure event spills, waste and minimize release to the
Cond	itions for safe storage	Store locked up.	labeled containers.
Mate	rials to avoid		n the following product types:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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 information: Skin			
		Wipe limit	100 µg/100 cm²	Internal

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 Filter type Hand protection		If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type
Material		Chamical registrant days
Material	•	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or
Skin and body protection	:	aerosols. Work uniform or laboratory coat.



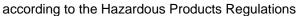
according to the Hazardous Products Regulations

Ketamine (5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
1.8	09/30/2023	3976736-00009	Date of first issue: 02/14/2019
Hygie	ne measures	task being perfo disposable suits Use appropriate contaminated cl : If exposure to cl eye flushing sys working place. When using do Wash contamin The effective op engineering con appropriate deg	hemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. ated clothing before re-use. beration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, he monitoring, medical surveillance and the

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 (solid, gas) Flammability (liquids)	:	Not applicable No data available
	:	
Flammability (liquids) Upper explosion limit / Upper	:	No data available
Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower	:	No data available No data available
Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower flammability limit	:	No data available No data available No data available
Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower flammability limit Vapor pressure	:	No data available No data available No data available No data available





Ketamine (5%) Formulation

Versior 1.8	Revision Date: 09/30/2023		S Number: 76736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
Solubility(ies) Water solubility Partition coefficient: n- octanol/water Autoignition temperature		::	soluble Not applicable No data available	9
Decomposition temperature		:	No data available	9
	scosity Viscosity, kinematic plosive properties	:	No data available Not explosive	9
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мо	blecular weight	:	No data available	9
Pa	rticle 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 routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg
		Method: Calculation method

Components:

Ketamine hydrochloride:

according to the Hazardous Products Regulations



Ketamine (5%) Formulation

Version 1.8	Revision Date: 09/30/2023		S Number: 76736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
Acute oral toxicity		:	LD50 (Rat): 447 m	ng/kg
			LD50 (Mouse): 61	7 mg/kg
	toxicity (other routes of istration)	:	LD50 (Rat): 59 mg Application Route	
			LD50 (Mouse): 59 Application Route	
			LD50 (Mouse): 35 Application Route	
			LD50 (Guinea pig Application Route	
			LD50 (Rat): 224 m Application Route	

Skin corrosion/irritation

Not classified based on available information.

Components:

Ketamine hydrochloride:

Species	:	Rabbit
Result	:	irritating

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ketamine hydrochloride:

Species	:	Rabbit
Result	:	irritating

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

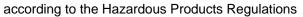
Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging the unborn child.





Ketamine (5%) Formulation

Vers 1.8	sion	Revision Date: 09/30/2023		9S Number: 76736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
	Compo	onents:			
	Ketam	ine hydrochloride: on fetal development	:	Target Organs: Ki Result: No teratog Test Type: Develo Species: Rabbit Application Route Developmental To Symptoms: Skele Result: Effects on Test Type: Develo Species: Rat Application Route Symptoms: Skele Result: Effects on Test Type: Develo Species: Rabbit Application Route Developmental To Symptoms: Skele	 Intramuscular bxicity: NOAEL: 120 mg/kg body weight dney, Liver, Heart genic effects. opment Intramuscular bxicity: LOAEL: 20 mg/kg body weight tal and visceral variations . prenatal and postnatal growth. opment Intramuscular tal and visceral variations . prenatal and postnatal growth. opment Intramuscular bxicity: LOAEL: 60 mg/kg body weight tal and visceral variations . prenatal and postnatal growth. opment Intramuscular bxicity: LOAEL: 60 mg/kg body weight tal and visceral variations . prenatal and postnatal growth.
	Derry	Lucations described in the Aug		Result: Effects on	prenatal and postnatal growth.
	sessme	luctive toxicity - As- ent	:	Suspected of dam	aging the unborn child.
		single exposure ssified based on availa	able	information.	

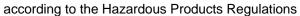
STOT-repeated exposure

May cause damage to organs (Kidney, Liver, Brain) through prolonged or repeated exposure in contact with skin.

Components:

Ketamine hydrochloride:

	:	Skin contact Kidney, Liver, Brain May cause damage to organs through prolonged or repeated
A3563511611	•	exposure.





Ketamine (5%) Formulation

Version 1.8	Revision Date: 09/30/2023		DS Number: 976736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
Re	peated dose toxicity			
<u>Co</u>	mponents:			
Ke	tamine hydrochloride:			
LÖ Apj Exj Tai	ecies AEL plication Route posure time rget Organs marks	:	Mouse 30 mg/kg Intraperitoneal 3 Months Kidney, Liver, Bla Significant toxicity	adder y observed in testing
LÔ Apj Exj Tai	ecies AEL plication Route posure time rget Organs marks	:	Mouse 30 mg/kg Intraperitoneal 6 Months Kidney, Liver, Bla Significant toxicity	adder y observed in testing
LÔ Apj Exj Tai	ecies AEL plication Route posure time rget Organs marks	:	Mouse 30 mg/kg Intraperitoneal 28 Weeks Kidney Significant toxicity	y observed in testing
LÖ Apj Exj Tai	ecies AEL plication Route posure time rget Organs marks	:	Mouse 30 mg/kg Intraperitoneal 30 Days Brain, Liver Significant toxicity	y observed in testing
LÔ Apj Exj Tai	ecies AEL plication Route posure time rget Organs marks	:	Monkey 1 mg/kg Intraperitoneal 6 Months Brain Significant toxicity	y observed in testing
10	ninetien tewieitu			

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ketamine hydrochloride:

Ingestion

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



according to the Hazardous Products Regulations

Ketamine (5%) Formulation

Version 1.8	Revision Date: 09/30/2023	SDS Number: 3976736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
SECTION	I 12. ECOLOGICAL IN	FORMATION	
Ecot	oxicity		
<u>Com</u>	ponents:		
Keta	mine hydrochloride:		
Ecot	oxicology Assessme	ent	
Acute	e aquatic toxicity	: Toxic effects	cannot be excluded
Chro	nic aquatic toxicity	: Toxic effects	cannot be excluded
	istence and degrada ata available	bility	
Bioa	ccumulative potentia	al	
Com	ponents:		
Parti	mine hydrochloride: tion coefficient: n- nol/water	: log Pow: 2.18	3
	ility in soil ata available		
	e r adverse effects ata available		

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
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

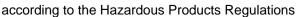
Not regulated as a dangerous good

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.





Ketamine (5%) Formulation

1.8 09/30/2023 3976736-00009 Date of first issue: 02/14/2019	Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
	1.8	09/30/2023	3976736-00009	Date of first issue: 02/14/2019

Domestic regulation

TDG Not regulated as a dangerous good

Special precautions for user Not applicable

SECTION 15. REGULATORY INFORMATION

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

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

SECTION 16. OTHER INFORMATION

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



according to the Hazardous Products Regulations

Ketamine (5%) Formulation

Version 1.8	Revision Date: 09/30/2023		S Number: 6736-00009	Date of last issue: 04/04/2023 Date of first issue: 02/14/2019
comp	ces of key data used to ile the Material Safety Sheet			data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
	ion Date format	-	09/30/2023 mm/dd/yyyy	

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8