



Vers 2.1	sion	Revision Date: 2023/09/30	-	S Number: /6740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14		
1. P	1. PRODUCT AND COMPANY IDENTIFICATION						
	Produc	t name	:	Ketamine (5%) F	ormulation		
	Manufa	acturer or supplier's d	letai	ls			
	Compa	iny	:	MSD			
	Addres	s	:	126 E. Lincoln Av Rahway, New Je	venue ersey U.S.A. 07065		
	Teleph	one	:	908-740-4000			
	Emergency telephone number		·:	1-908-423-6000			
	E-mail	address	:	EHSDATASTEWARD@msd.com			
	Recom	nmended use of the ch	nem	ical and restriction	ons on use		
		mended use tions on use	:	Veterinary produ Not applicable	ct		
	Result		•				
2. H	IAZARD	S IDENTIFICATION					
	GHS C	lassification					
		luctive toxicity	:	Category 2			
		hal alamarta					
		ibel elements I pictograms	:				
			-				
	Signal	word	:	Warning			

: H361d Suspected of damaging the unborn child.

Precautionary statements

Hazard statements

Prevention:

:

P201 Obtain special instructions before use.P202 Do not handle until all safety precautions have been read and understood.P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.



Version Revision Date: 2.1 2023/09/30

SDS Number: 3976740-00008

Date of last issue: 2023/04/04 Date of first issue: 2019/02/14

Storage:

P405 Store locked up.

Disposal:

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

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 5 %

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
---------------------	---	---------

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ketamine hydrochloride	1867-66-9	>= 3 -< 10

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice 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	:	Suspected of damaging the unborn child.
Protection of first-aiders	:	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 to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

SAFETY DATA SHEET



Ketamine (5%) Formulation

Version 2.1	Revision Date: 2023/09/30		0S Number: 76740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14
Suitat	ble extinguishing media	:	Water spray Alcohol-resistant	
Unsui media	table extinguishing	:	Carbon dioxide (C Dry chemical None known.	202)
	fic hazards during fire-	:	Exposure to com	bustion products may be a hazard to health.
	rdous combustion prod-	:	Carbon oxides Chlorine compou Nitrogen oxides (
Speci ods	fic extinguishing meth-	:	cumstances and Use water spray	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
	al protective equipment efighters	:	In the event of fire	e, wear self-contained breathing apparatus. tective equipment.
6. ACCIDE	ENTAL RELEASE MEAS	SUF	RES	
tive e	nal precautions, protec- quipment and emer- procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
Enviro	onmental precautions	:	Prevent spreadin barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or oi se of contaminated wash water. should be advised if significant spillages
	ods and materials for inment and cleaning up	:	For large spills, p ment to keep man be pumped, store Clean up remaini bent. Local or national posal of this mate employed in the o mine which regula Sections 13 and	t absorbent material. rovide dyking or other appropriate contain- terial from spreading. If dyked material can a recovered material in appropriate container, ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. 15 of this SDS provide information regarding ational requirements.

7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE		
		CONTROLS/PERSONAL PROTECTION section.		



Version 2.1	Revision Date: 2023/09/30	SDS Number: 3976740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14
	al/Total ventilation ice on safe handling	: Do not get on Do not breath Do not swallow Avoid contact Handle in acc practice, base sessment	
Cor	ditions for safe storage	: Keep in prope Store locked u	•
Mat	erials to avoid		dance with the particular national regulations. vith the following product types: ng agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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 informa	ation: Skin			
		Wipe limit	100 µg/100 cm²	Internal	
Engineering measures :	Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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 equipmen	t				
Respiratory protection:Filter type:Hand protection	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type				
Material :	Chemical-resi	stant gloves			
Remarks:Eye protection:	 Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, 				



Version 2.1	Revision Date: 2023/09/30	SDS Number: 3976740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14				
			ls, wear the appropriate goggles. eld or other full face protection if there is a				
Skin a	and body protection	 potential for direct contact to the face with dusts, mists, or aerosols. 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. 					
Hygiene measures		 Use appropriate degowning techniques to remove potent contaminated clothing. If exposure to chemical is likely during typical use, provid eye flushing systems and safety showers close to the wo ing place. When using do not eat, drink or smoke. 					
		Wash contamin The effective op engineering cor appropriate deg	ated clothing before re-use. beration of a facility should include review of htrols, proper personal protective equipment, jowning and decontamination procedures, he monitoring, medical surveillance and the				

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour 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
Vapour pressure	:	No data available

SAFETY DATA SHEET



Ketamine (5%) Formulation

ersion 1	Revision Date: 2023/09/30	SDS Number: 3976740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14
Relati	ve vapour density	: No data ava	ilable
Relati	ve density	: No data ava	ilable
Densi	ty	: No data ava	ilable
	ility(ies)		
VVa	ater solubility	: soluble	
	on coefficient: n- ol/water	: Not applicat	ble
	ignition temperature	: No data ava	ilable
Deco	mposition temperature	: No data ava	ilable
Viscosity			
Vis	scosity, kinematic	: No data ava	ilable
Explo	sive properties	: Not explosiv	e
Oxidiz	zing properties	: The substar	ce or mixture is not classified as oxidizing.
Molec	cular weight	: No data ava	ilable
Partic	le size	: Not applicat	ble
). STABI	LITY AND REACTIVIT	Y	
React			d as a reactivity hazard.
	nical stability		r normal conditions.
Possi tions	bility of hazardous reac-	: Can react w	ith strong oxidizing agents.
	itions to avoid	: None knowr].
	patible materials	: Oxidizing ag	
	dous decomposition	: No hazardo	us decomposition products are known.

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



rsion	Revision Date: 2023/09/30		DS Number: 76740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14
			Method: Calculati	an mathad
			Method: Calculati	on method
Com	ponents:			
Ketai	mine hydrochloride:			
Acute	e oral toxicity	:	LD50 (Rat): 447 r	ng/kg
			LD50 (Mouse): 61	17 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): 59 m Application Route	
aurin	istration			
			LD50 (Mouse): 59 Application Route	
			LD50 (Mouse): 35 Application Route	
			LD50 (Guinea pig Application Route	
			LD50 (Rat): 224 r Application Route	
Skin	corrosion/irritation			
Not c	lassified based on availa	ble	information.	
Com	ponents:			
Ketai	mine hydrochloride:			
Spec	ies	:	Rabbit	
Resu	lt	:	irritating	
	ous eye damage/eye irri			
Not c	lassified based on availa	ble	information.	
Com	ponents:			
Ketai	mine hydrochloride:			
Speci Resu		:	Rabbit irritating	
1.000		•	intailig	
Resp	iratory or skin sensitis	atic	on	
-	sensitisation			
Not c	lassified based on availa	ble	information.	
Docn	iratory consitisation			

Respiratory sensitisation

Not classified based on available information.



Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	3976740-00008	Date of first issue: 2019/02/14

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Ketamine hydrochloride:

Effects on foetal develop- : ment	Test Type: Development Species: Rat Application Route: Intramuscular Developmental Toxicity: NOAEL: 120 mg/kg body weight Target Organs: Kidney, Liver, Heart Result: No teratogenic effects
	Test Type: Development Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 20 mg/kg body weight Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.
	Test Type: Development Species: Rat Application Route: Intramuscular Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.
	Test Type: Development Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 60 mg/kg body weight Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.
	Test Type: Development Species: Monkey Application Route: Intramuscular Target Organs: Brain Result: Effects on prenatal and postnatal growth.
Reproductive toxicity - As- : sessment	Suspected of damaging the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.



ersion 1	Revision Date: 2023/09/30	SDS Number: 3976740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14
Ketar Expos Targe	oonents: nine hydrochloride: sure routes at Organs ssment	: Skin contact : Kidney, Liver, E : May cause dam exposure.	arain hage to organs through prolonged or repeated
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Ketar	nine hydrochloride:		
Expos	L cation Route sure time t Organs	: Mouse : 30 mg/kg : Intraperitoneal : 3 Months : Kidney, Liver, E : Significant toxic	ladder ity observed in testing
Expos	L cation Route sure time t Organs	: Mouse : 30 mg/kg : Intraperitoneal : 6 Months : Kidney, Liver, E : Significant toxic	Bladder ity observed in testing
Expos	L cation Route sure time t Organs	: Mouse : 30 mg/kg : Intraperitoneal : 28 Weeks : Kidney : Significant toxic	ity observed in testing
Expos	L cation Route sure time t Organs	: Mouse : 30 mg/kg : Intraperitoneal : 30 Days : Brain, Liver : Significant toxic	ity observed in testing
Expos	L cation Route sure time t Organs	: Monkey : 1 mg/kg : Intraperitoneal : 6 Months : Brain : Significant toxic	ity observed in testing

Aspiration toxicity

Not classified based on available information.



/ersion 2.1	Revision Date: 2023/09/30		OS Number: 76740-00008	Date of last issue: 2023/04/04 Date of first issue: 2019/02/14
Expe	erience with human exp	osi	ire	
<u>Com</u>	ponents:			
Keta	mine hydrochloride:			
Inges	stion	:		nost common side effects are:, central nerves, hypertension, Dizziness, Headache, Nau
2. ECOL	OGICAL INFORMATIO	N		
Ecot	oxicity			
<u>Com</u>	ponents:			
Keta	mine hydrochloride:			
Ecot	oxicology Assessment			
Acute	e aquatic toxicity	:	Toxic effects can	not be excluded
Chro	nic aquatic toxicity	:	Toxic effects can	not be excluded
	istence and degradabil ata available	ity		
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	mine hydrochloride: tion coefficient: n- nol/water	:	log Pow: 2.18	
	i lity in soil ata available			
Othe	r adverse effects			
No da	ata available			
3. DISPO	DSAL CONSIDERATION	IS		
Disp	osal methods			
Wast	e from residues	:		waste into sewer.
Conta	aminated packaging	:	Empty containers dling site for recy	ordance with local regulations. should be taken to an approved waste han cling or disposal. pecified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations



UNRTD UN num Propers				
UN num				
	G			
Proper o	ber	:	Not applicable	
Tiopera	shipping name	:	Not applicable	
Class		:	Not applicable	
Subsidia		:	Not applicable	
Packing	group	:	Not applicable	
Labels		:	Not applicable	
IATA-D	GR			
UN/ID N		:	Not applicable	
•	shipping name	:	Not applicable	
Class		:	Not applicable	
Subsidia		÷	Not applicable	
Packing Labels	group	÷	Not applicable Not applicable	
	instruction (cargo	:	Not applicable	
aircraft)	instruction (cargo	•		
	instruction (passen-	:	Not applicable	
ger aircr				
IMDG-C	ode			
UN num			Not applicable	
	shipping name	÷	Not applicable	
Class		÷	Not applicable	
Subsidia	ary risk	:	Not applicable	
Packing	group	:	Not applicable	
Labels		:	Not applicable	
EmS Co		:	Not applicable	
Marine p	pollutant	:	Not applicable	
Transpo	ort in bulk according	g to A	Annex II of MARF	POL 73/78 and the IBC Code
Not app	licable for product as	supp	blied.	
Special	precautions for use	er		
Not app	licable			

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use

: Not applicable





Vers 2.1	sion	Revision Date: 2023/09/30		DS Number: 76740-00008			e of last issue: 2023/04/04 e of first issue: 2019/02/14	
	Prohibit	ted substances				:	Not applicable	
	Restric	ted substances				:	Not applicable	
	Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardou Materials							
	Type of hazardous materials subject to distribution and : Not applicable control, Annex I							
	Type of hazardous materials subject to distribution and : Not applicable control, Annex II							
	The co AICS	mponents of this pro	duc :	ct are reported in t not determined	th	e fo	llowing inventories:	
	DSL		:	not determined				
	IECSC		:	not determined				
16.	OTHER	INFORMATION						
	Revisio	n Date	:	2023/09/30				
	Furthe	r information						
		s of key data used to the Safety Data	:		ar	ch re	data from raw material SDSs, OECD esults and European Chemicals Agen- eu/	
	Date fo	rmat	:	yyyy/mm/dd				
	Full tex	t of other abbreviation	ons					
	Land of Carcino	f Brazil; ASTM - Amer ogen, Mutagen or Re	icar proc	n Society for the Te ductive Toxicant; I	es Di	sting N -	TT - National Agency for Transport by of Materials; bw - Body weight; CMR - Standard of the German Institute for	

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 Organization 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

SAFETY DATA SHEET



Ketamine (5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	3976740-00008	Date of first issue: 2019/02/14

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

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.

ID / EN