Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Ketamine (10%) Formulation
1.2	Relevant identified uses of th	ie s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	safe	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2 Eye irritation, Category 2 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure, Category 2

exposure, Category 2 longed

5

H315: Causes skin irritation.H319: Causes serious eye irritation.H361d: Suspected of damaging the unborn child.H373: May cause damage to organs through prolonged or repeated exposure.

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Hazard statements

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version 1.12	Revision Date: 28.09.2024	SDS Number: 3983718-00013	Date of last issue: 06.04.2024 Date of first issue: 14.02.2019
		H361d Suspec	s serious eye irritation. cted of damaging the unborn child. use damage to organs through prolonged or sure.
Preca	utionary statements	P264 Wash s	special instructions before use. skin thoroughly after handling. protective gloves/ protective clothing/ eye protec- ction.
		Response: P308 + P313 attention. P332 + P313 attention. P337 + P313 attention.	IF exposed or concerned: Get medical advice/ If skin irritation occurs: Get medical advice/ If eye irritation persists: Get medical advice/

Hazardous components which must be listed on the label:

Ketamine hydrochloride

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Ketamine hydrochloride	1867-66-9	Acute Tox. 4; H302	>= 10 - < 20
	217-484-6	Skin Irrit. 2; H315	
		Eye Irrit. 2; H319	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version 1.12	Revision Date: 28.09.2024	SDS Number: 3983718-00013	Date of last issue: 06.04.2024 Date of first issue: 14.02.2019	
			Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Brain)	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
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).
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 for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
4.2 Most important symptoms ar	nd e	effects, both acute and delayed
Risks	:	Causes skin irritation. Causes serious eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
4.3 Indication of any immediate	med	dical attention and special treatment needed
Treatment	:	Treat symptomatically and supportively.



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

SECTION 5: Firefighting measures

5.1 Extinguishing media

	Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
	Unsuitable extinguishing media	:	None known.
5.2	Special hazards arising from	the	substance or mixture
	Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	Carbon oxides Chlorine compounds Nitrogen oxides (NOx)
5.3	Advice for firefighters		
	Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
	Specific extinguishing meth- ods	:	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 do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
1.12		3983718-00013	Date of first issue: 14.02.2019
		ment to keep ma be pumped, store Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	provide dyking or other appropriate contain- terial from spreading. If dyked material can e 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- lations are applicable. 15 of this SDS provide information regarding ational requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling	:	Use only with adequate ventilation. Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami- nated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
7.2 Conditions for safe storage,	inc	luding any incompatibilities
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Gases
7.3 Specific end use(s)		
Specific use(s)	:	No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Ketamine hydro- chloride	- 1867-66-9 TWA		10 µg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	100 μg/100 cm²	Internal	

8.2 Exposure controls

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.

:	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 aerosols.
:	Chemical-resistant gloves
:	Consider double gloving. 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.
:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143 Particulates type (P)
	: :: :: :: :: :: :: :: :: :: :: :: :: :



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Flash point Auto-ignition temperature	:	No data available No data available
	: : :	
Auto-ignition temperature		No data available
Auto-ignition temperature Decomposition temperature		No data available No data available
Auto-ignition temperature Decomposition temperature pH Viscosity		No data available No data available No data available
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies)	:	No data available No data available No data available No data available
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n-	:	No data available No data available No data available No data available soluble
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n- octanol/water	:	No data available No data available No data available No data available soluble Not applicable
Auto-ignition temperature Decomposition temperature pH Viscosity Viscosity, kinematic Solubility(ies) Water solubility Partition coefficient: n- octanol/water Vapour pressure	:	No data available No data available No data available No data available soluble Not applicable No data available

Ketamine (10%) Formulation

Version 1.12	Revision Date: 28.09.2024		S Number: 83718-00013	Date of last issue: 06.04.2024 Date of first issue: 14.02.2019
Re	lative vapour density	:	No data availabl	e
Pa	rticle characteristics Particle size	:	Not applicable	
• • • • •	er information blosives	:	Not explosive	
Oxidizing properties		:	The substance c	r mixture is not classified as oxidizing.
Eva	aporation rate	:	No data availabl	e
Мс	lecular weight	:	No data availabl	e

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.
10.2 Chemical stability
Stable under normal conditions.
10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.
10.4 Conditions to avoid
Conditions to avoid : None known.
10.5 Incompatible materials
Materials to avoid : Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.
SECTION 11: Toxicological information
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

Components:

Ketamine hydrochloride:		
Acute oral toxicity	:	LD50 (Rat): 447 mg/kg
		LD50 (Mouse): 617 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 59 mg/kg Application Route: Intravenous
		LD50 (Mouse): 59 mg/kg Application Route: Intramuscular
		LD50 (Mouse): 356 mg/kg Application Route: Intramuscular
		LD50 (Guinea pig): 361 mg/kg Application Route: Intramuscular
		LD50 (Rat): 224 mg/kg Application Route: Intraperitoneal
Skin corrosion/irritation		

Causes skin irritation.

Components:

Ketamine hydrochloride:

Species	:	Rabbit
Result	:	irritating

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Ketamine hydrochloride:

Species	:	Rabbit
Result	:	irritating

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Ketamine hydrochloride:

Effects on foetal develop-	: Test Type: Development
ment	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	

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version 1.12	Revision Date: 28.09.2024	SDS Number: 3983718-00013	Date of last issue: 06.04.2024 Date of first issue: 14.02.2019
Com	oonents:		
Kotar	nine hydrochloride:		
Expo Targe	sure routes et Organs ssment	 Skin contact Kidney, Liver, May cause da exposure. 	Brain mage to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	oonents:		
Ketar	nine hydrochloride:		
Expo	EL cation Route sure time et Organs	: Mouse : 30 mg/kg : Intraperitonea : 3 Months : Kidney, Liver, : Significant tox	
Expo	EL cation Route sure time et Organs	: Mouse : 30 mg/kg : Intraperitonea : 6 Months : Kidney, Liver, : Significant tox	
Expo	EL cation Route sure time et Organs	: Mouse : 30 mg/kg : Intraperitonea : 28 Weeks : Kidney : Significant tox	icity observed in testing
Expo	EL cation Route sure time et Organs	: Mouse : 30 mg/kg : Intraperitonea : 30 Days : Brain, Liver : Significant tox	icity observed in testing
Expo	EL cation Route sure time et Organs	: Monkey : 1 mg/kg : Intraperitonea : 6 Months : Brain : Significant tox	icity observed in testing

Aspiration toxicity

Not classified based on available information.



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Ketamine hydrochloride:

Ingestion	

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

Ketamine hydrochloride:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
------------------------	---	----------------------------------

Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Ketamine hydrochloride:

Partition coefficient: n- : log Pow: 2,18 octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of



Ketamine (10%) Formulation

1.12 28.09.2024 3983718-00013 Date of first issue: 14.02.2019	Version 1.12	Revision Date: 28.09.2024	SDS Number: 3983718-00013	Date of last issue: 06.04.2024 Date of first issue: 14.02.2019	
---	-----------------	---------------------------	------------------------------	---	--

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in
		discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good

14.3 Transport hazard class(es)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version 1.12	Revision Date: 28.09.2024	SDS Number:Date of last issue: 06.04.20243983718-00013Date of first issue: 14.02.2019	
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	6	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.4 Pack	ing group		
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	6	: Not regulated as a dangerous good	
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good	
ΙΑΤΑ	(Passenger)	: Not regulated as a dangerous good	
	ronmental hazards egulated as a dangero	s good	
•	ial precautions for ι pplicable	ər	
14.7 Marit	time transport in bul	according to IMO instruments	
Rema	arks	: Not applicable for product as supplied.	

ture)	-		
	REACH - Restrictions on the manufacture the market and use of certain dangerour mixtures and articles (Annex XVII)		:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
				Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
	REACH - Candidate List of Substances Concern for Authorisation (Article 59).	of Very High	:	Not applicable
	REACH - List of substances subject to a (Annex XIV)	authorisation	:	Not applicable
	Regulation (EC) on substances that deplayer	plete the ozone	:	Not applicable
_	Regulation (EU) 2019/1021 on persiste	nt organic pollu	- :	Not applicable



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information		
Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H302	:	Harmful if swallowed.
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H361d	:	Suspected of damaging the unborn child.
H373	:	May cause damage to organs through prolonged or repeated exposure in contact with skin.
Full text of other abbreviat	ions	
Acute Tox.	:	Acute toxicity

Acute Tox. :	Acute toxicity
Eye Irrit. :	Eye irritation
Repr. :	Reproductive toxicity
Skin Irrit.	Skin irritation
STOT RE :	Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -



Ketamine (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.12	28.09.2024	3983718-00013	Date of first issue: 14.02.2019

European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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

Classification of the mixtur	Classification procedure:	
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Repr. 2	H361d	Calculation method
STOT RE 2	H373	Calculation method

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.

NO / EN

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ketamine (10%) Formulation

Version	Revision Date:
1.12	28.09.2024

SDS Number: 3983718-00013

Date of last issue: 06.04.2024 Date of first issue: 14.02.2019