

Ethamsylate Formulation

Version 3.0	Revision Date: 06.04.2024	SDS Number: 5478659-000	
SECTION	N 1: Identification of	the substanc	e/mixture and of the company/undertaking
1.1 Produ	ıct identifier		
Trade	e name	: Ethamsyla	te Formulation
Use	ant identified uses of of the Sub- ce/Mixture	the substance of the su	or mixture and uses advised against product
Reco on us	mmended restrictions	: Not applic	able
1.3 Detail	s of the supplier of th	e safety data sh	eet
Com	pany	: MSD 20 Sparta 1619 Spa	n Road rtan, South Africa
Telep	bhone	: +2711923	9300
	il address of person onsible for the SDS	: EHSDATA	STEWARD@msd.com
	gency telephone num 08-423-6000	ber	
SECTION	N 2: Hazards identif	cation	
2.1 Class	ification of the substa	nce or mixture	
	sification (REGULATION (REGULATION) (REGUN) (RE	ON (EC) No 127	2/2008) H319: Causes serious eye irritation.
2.2 Label	elements		
	Iling (REGULATION (Ind pictograms	EC) No 1272/200)8)
Signa	al word	: Warning	
Haza	rd statements	: H319 Ca	uses serious eye irritation.
Preca	autionary statements	Preventior	1:

Prevention:
 P264 Wash skin thoroughly after handling.
 P280 Wear eye protection/ face protection.



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Response:

P337 + P313 If eye irritation persists: Get medical advice/ attention.

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ethamsylate	2624-44-4 220-090-7	Eye Irrit. 2; H319	>= 10 - < 20

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 if symptoms occur.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.



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Risks 4.3 Indica Treatr SECTION	•	: mea	Causes serious dical attention a Treat symptom	-
Risks 4.3 Indica Treatr SECTION	tion of any immediate ment I 5: Firefighting meas uishing media	: mea	Causes serious dical attention a Treat symptom	eye irritation.
Treati	ment I 5: Firefighting meas uishing media	:	Treat symptom	-
Treati	ment I 5: Firefighting meas uishing media	:	Treat symptom	-
SECTION	I 5: Firefighting meas uishing media	sur :	es	
	uishing media	sur :		
5.1 Exting	-	:		
	ble extinguishing media	:		
Suitat			Water spray	
			Alcohol-resista	
			Carbon dioxide Dry chemical	(COZ)
			-	
Unsui media	table extinguishing	•	None known.	
medic	4			
5.2 Specia	al hazards arising from	the	e substance or	mixture
	fic hazards during fire-	:	Exposure to co	mbustion products may be a hazard to health.
fightin	ig			
Hazaı	dous combustion prod-	:	Carbon oxides	
ucts			Nitrogen oxides	s (NOx)
			Sulphur oxides	
5.3 Advice	e for firefighters			
	al protective equipment	:		fire, wear self-contained breathing apparatus.
for fire	efighters		Use personal p	rotective equipment.
Speci	fic extinguishing meth-	:	Use extinguish	ing measures that are appropriate to local cir-
ods				d the surrounding environment.
				y to cool unopened containers. naged containers from fire area if it is safe to do
			so.	
			Evacuate area.	
SECTION	6: Accidental releas	se r	neasures	
6.1 Persoi	nal precautions, protec	tive	e equipment an	d emergency procedures
Perso	nal precautions	:		rotective 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.



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		Local authoritie cannot be conta	s should be advised if significant spillages ained.
6.3 Metho	ds and material for o	containment and clea	ning up
Methods for cleaning up		For large spills, ment to keep m be pumped, sto Clean up remain bent. Local or national posal of this ma employed in the mine which reg Sections 13 and	ert absorbent material. provide dyking or other appropriate contain- naterial from spreading. If dyked material can bre recovered material in appropriate container. ning materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national 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

	0				
Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.			
Local/Total ventilation	:	Use only with adequate ventilation.			
Advice on safe handling	:	Avoid inhalation of vapour or mist.			
5		Do not swallow.			
		Do not get in eyes.			
		Avoid prolonged or repeated contact with skin.			
		Wash skin thoroughly after handling.			
		Handle in accordance with good industrial hygiene and safety			
		practice, based on the results of the workplace exposure as-			
		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	7.2 Conditions for safe storage, including any incompatibilities				
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.			
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents			

Gases



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7.3 Specific end use(s)

Specific use(s)

: No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethamsylate	2624-44-4	TWA	100 μg/m3 (OEB 2)	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. Laboratory operations do not require special containment.

Personal protective equipment

Eye/face protection Hand protection Material		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
Skin and body protection Respiratory protection Filter type	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	Aqueous solution colourless No data available No data available
рН	:	6,0 - 7,0
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available



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Flash point	: No	data available	
Evaporation rate	: No	data available	
Flammability (solid, g	gas) : Not	t applicable	
Upper explosion limit flammability limit	:/Upper : No	data available	
Lower explosion limit flammability limit	:/Lower : No	data available	
Vapour pressure	: No	data available	
Relative vapour dens	sity : No	data available	
Relative density	: No	data available	
Density	: No	data available	
Solubility(ies) Water solubility Partition coefficient: r octanol/water Auto-ignition tempera	n- : Not	data available t applicable data available	
Decomposition temp		data available	
Viscosity			
Viscosity, kinema	tic : No	data available	
Explosive properties	: Not	t explosive	
Oxidizing properties	: The	e substance or	mixture is not classified as oxidizing.
9.2 Other information Flammability (liquids)) : No	data available	
Molecular weight	: No	data available	
Particle size	: Not	t applicable	

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.



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	litions to avoid itions to avoid	:	None known.	
	mpatible materials rials to avoid	:	Oxidizing agents	
	rdous decomposition paradous decomposition			
SECTION	N 11: Toxicological in	for	mation	
1.1 Infor	mation on toxicologica	l ef	fects	
Inforr expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	ble	information.	
Com	ponents:			
	msylate:			
Acute	e oral toxicity	:	LD50 (Rat): 7.500	
			LD50 (Mouse): 8.	
			LD50 (Guinea pig	ı): 3.500 mg/kg
	e toxicity (other routes of histration)	:	LD50 (Mouse): > Application Route	
			LD50 (Mouse): 29 Application Route	
			LD50 (Mouse): 76 Application Route	
			LD50 (Mouse): 6. Application Route	
			LD50 (Rat): > 4.0 Application Route	
			LD50 (Rat): 1.350 Application Route	



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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Ethamsylate:

: Rabbit
: Draize Test
: Moderate eye irritation
: Moderate eye irritation

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.

Components:

Ethamsylate:

Genotoxicity in vitro

: Test Type: Mutagenicity (Salmonella typhimurium - reverse mutation assay) Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Ethamsylate:

Effects on foetal develop- ment	:	Test Type: Reproduction/Developmental toxicity screening test Species: Rat, female Application Route: Oral General Toxicity Maternal: NOAEL: 300 mg/kg body weight Teratogenicity: NOAEL: 300 mg/kg body weight Result: No adverse effects
		Test Type: Reproduction/Developmental toxicity screening test Species: Mouse, female Application Route: Oral General Toxicity Maternal: NOAEL: 300 mg/kg body weight Teratogenicity: NOAEL: 300 mg/kg body weight Result: No adverse effects



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		test Application Rou General Toxicity	y Maternal: NOAEL: 300 mg/kg body weight NOAEL: 300 mg/kg body weight
	 single exposure assified based on avai 	lable information.	
	 repeated exposure assified based on avai 		
•	ation toxicity assified based on avai	lable information.	
Expe	ience with human ex	posure	
Comp	onents:		
Ingest	nsylate: ion er information		adache, hypotension, Nausea nost common side effects are: eding, pruritis
Comp	onents:		
	nsylate:	: The toxicologica investigated	al properties of this material have not been fully

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

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 0.1% or higher.



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12.6 Other adverse effects

Product:

Endocrine disrupting poten- tial	:	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 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

	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)		
	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



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14.4 Packi	ng group			
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 (Cargo)	: Not regulated as	a dangerous good	
ΙΑΤΑ (Passenger)	: Not regulated as	a dangerous good	
14.5 Environmental hazards Not regulated as a dangerous good				
14.6 Special precautions for user Not applicable				
14.7 Trans	port in bulk according	g to Annex II of Marp	ol and the IBC Code	
Remai	^r ks	: Not applicable fo	r product as supplied.	
SECTION 15: Regulatory information				

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

٦	The components of this product are reported in the following inventories:					
ŀ	AICS	:	not determined			
[DSL	:	not determined			
I	ECSC	:	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 H319	:	Causes serious eye irritation.
Full text of other abbreviation	ons :	Eye irritation

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 -



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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	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

H319

Classification of the mixture:

Eye Irrit. 2

Classification procedure:

Calculation method

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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.

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