

Eptifibatide Formulation

Version 5.7	Revision Date: 28.09.2024		S Number: 718-00023	Date of last issue: 30.09.2023 Date of first issue: 05.01.2015
SECTION	1. IDENTIFICATION			
Produ	Product identifier		Eptifibatide Forn	nulation
Manu	ifacturer or supplier's	s deta	ils	
Comp	bany	:	MSD	
Addre	ess	:	nº 1500 – Distrit	dador Antônio Loureiro Ramos, o Industrial - MG, Brazil 39404-620
Telep	Telephone		+55 (38) 3229 7000	
Emer	gency telephone	:	+55 (38) 3201 5	670
E-ma	il address	:	EHSDATASTEV	VARD@msd.com
Reco	mmended use of the	chem	ical and restricti	ons on use
Reco	mmended use	:	Pharmaceutical	
Restr	ictions on use	:	Not applicable	
SECTION	2. HAZARDS IDENTI	FICAT	ION	
GHS	Classification in acc	ordan	ce with ABNT NB	3R 14725 Standard
Speci	ific target organ toxicit e exposure (Oral)			

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms	:	
Signal Word	:	Warning
Hazard Statements	:	H371 May cause damage to organs (Blood) if swallowed.
Precautionary Statements	:	Prevention: P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.
		Response: P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
		Storage: P405 Store locked up.



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Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Eptifibatide	188627-80-7	STOT SE, (Oral)(Blood) , 1	>= 1 -< 5

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 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	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	May cause damage to organs if swallowed.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides



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Speci ods	fic extinguishing meth-	:	cumstances and tuse water spray to	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 c
	al protective equipment e-fighters	:		e, wear self-contained breathing apparatus. tective equipment.
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES	
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal nent recommendations (see section 8).
Enviro	onmental 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
	ods and materials for inment and cleaning up	:	For large spills, p containment to ke can be pumped, s container. Clean up remainin absorbent. Local or national disposal of this m employed in the c determine which Sections 13 and	t absorbent material. rovide diking or other appropriate eep material from spreading. If diked materia store recovered material in appropriate ng materials from spill with suitable regulations may apply to releases and aterial, as well as those materials and items cleanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding ational requirements.
SECTION	7. HANDLING AND ST	OR	AGE	
Techr	nical measures	:	See Engineering	measures under EXPOSURE

rechnical measures	•	See Engineering measures under EXPOSORE
		CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe mist or vapors.
		Do not swallow.
		Avoid contact with 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
		assessment
		Do not eat, drink or smoke when using this product.



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Hygiene measures		environment. If exposure to flushing syste place. When using of Wash contan The effective engineering of appropriate of industrial hyg	prevent spills, waste and minimize release to the o chemical is likely during typical use, provide eye ems and safety showers close to the working do not eat, drink or smoke. hinated clothing before re-use. operation of a facility should include review of controls, proper personal protective equipment, legowning and decontamination procedures, jiene monitoring, medical surveillance and the istrative controls.	
Conditions for safe storage		: Keep in properly labeled containers. Store locked up.		
Mate	rials to avoid	: Do not store Strong oxidiz	substances and mixtures	

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
Eptifibatide	188627-80-7	TWA	10 µg/m3 (OEB 3)	Internal
		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 equipmen	t
Respiratory protection :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type :	Particulates type
Hand protection	
Material :	Chemical-resistant gloves
Remarks :	Consider double gloving.



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Eye protection		If the work er mists or aero Wear a faces	glasses with side shields or goggles. wironment or activity involves dusty conditions, sols, wear the appropriate goggles. hield or other full face protection if there is a direct contact to the face with dusts, mists, or	
Skin and body protection		Additional bo task being pe disposable su Use appropri	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.	

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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



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ļ	Autoignition temperatur	e :	No data available	9
Γ	Decomposition tempera	ture :	No data available	9
	Viscosity Viscosity, kinematic Explosive properties	:	No data available Not explosive	9
(Oxidizing properties	:	The substance o	r mixture is not classified as oxidizing.
ľ	Molecular weight	:	No data available	9
-	Particle characteristics Particle size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Eptifibatide:

Test Type

: Maximization Test



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Rout Spec Resu		:	Skin contact Guinea pig Not a skin sensiti	zer.
	n cell mutagenicity classified based on availa	able	information.	
<u>Com</u>	ponents:			
Eptif	ibatide:			
Geno	otoxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Test Type: Mous Result: negative	e Lymphoma
				chromatid exchange assay man lymphocytes
Geno	otoxicity in vivo	:	cytogenetic assa Species: Mouse	malian erythrocyte micronucleus test (in v y) e: Intraperitoneal injection
	inogenicity classified based on availa	able	information.	
-	oductive toxicity classified based on availa	blo	information	
_	ponents:	abie	inionnation.	
-	ibatide: ts on fertility	:	Species: Rat	ty/early embryonic development < 72 mg/kg body weight s on fertility.
Effec	ts on fetal development	:	Species: Rat Application Route Developmental T	yo-fetal development e: Intravenous injection oxicity: NOAEL: 72 mg/kg body weight s on fetal development.
			Test Type: Embr Species: Rabbit	yo-fetal development e: Intravenous injection

May cause damage to organs (Blood) if swallowed.



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Com	ponents:			
Rout Targ	f ibatide: es of exposure et Organs essment	: Ingestion : Blood : Causes dama	ge to organs.	
	T-repeated exposure classified based on avai	lable information.		
Repe	eated dose toxicity			
<u>Com</u>	ponents:			
Spec NOA Appli	EL ication Route osure time	: Rat : > 72 mg/kg : Intravenous : 28 d : No significant	adverse effects were reported	
Spec NOA Expo Rem	EL osure time	 Monkey 7,2 mg/kg 28 d No significant adverse effects were reported 		
-	ration toxicity classified based on avai	lable information.		
Expe	erience with human ex	posure		
<u>Com</u>	ponents:			
Eptif Inges	f ibatide: stion	: Symptoms: bl	eeding	
SECTION	I 12. ECOLOGICAL IN	FORMATION		
	oxicity ata available			
	istence and degradab ata available	ility		
Bioa	ccumulative potential			

No data available

Mobility in soil No data available

Other adverse effects

No data available



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SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG Not regulated as a dangerous good

IATA-DGR Not regulated as a dangerous good

IMDG-Code Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH)	:	Not applicable
Brazil. List of chemicals controlled by the Federal Police	:	Not applicable

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

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

SECTION 16. OTHER INFORMATION

Revision Date	: 28.09.2024
Date format	: dd.mm.yyyy



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Further information

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

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

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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