

Eptifibatide Formulation

Version 6.0	Revision Date: 06.04.2024	SDS Number: 42735-00025	Date of last issue: 30.09.2023 Date of first issue: 05.01.2015	
SECTIC	ON 1: Identification of	the substance/	mixture and of the company/undertaking	
1.1 Prod	luct identifier			
Tra	de name	: Eptifibatide I	Formulation	
1.2 Rele	vant identified uses of	he substance or	mixture and uses advised against	
Use	e of the Sub- nce/Mixture	: Pharmaceut		
Rec on u	commended restrictions use	: Not applicab	le	
1.3 Deta	ils of the supplier of the	e safety data she	et	
Cor	npany	: MSD 117 16th Ro 1685 Halfwa	ad ay house, Midrand, South Africa	
Tele	ephone	: +27 11 655	3000	
	nail address of person consible for the SDS	: EHSDATAS	TEWARD@msd.com	
1.4 Eme	rgency telephone numb	ber		
+1-9	908-423-6000			
	ON 2: Hazards identifients of the substance of the substa			
Cla	ssification (REGULATIO	ON (EC) No 1272/2	2008)	
	Specific target organ toxicity - single ex- posure, Category 2 H371: May cause damage to organs.			

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H371 May cause damage to organs.
Precautionary statements	:	Prevention: P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.



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		Response: P308 + P311 CENTER/ doc	IF exposed or concerned: Call a POISON tor.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label: Eptifibatide

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Eptifibatide	188627-80-7	STOT SE 1; H370 (Blood)	>= 1 - < 10

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	:	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



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4.2 Most i	mportant symptoms a	nd e	effects, both ac	ute and delayed
Risks	:	:	May cause dar	nage to organs.
4.3 Indica	tion of any immediate	med	dical attention a	and special treatment needed
Treat	ment	:	Treat symptom	atically and supportively.
SECTION	N 5: Firefighting meas	sur	es	
5.1 Exting	uishing media			
Suita	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsu media	itable extinguishing a	:	None known.	
5.2 Specia	al hazards arising from	the	e substance or	mixture
Spec fightir		:	Exposure to co	mbustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides	
5.3 Advic	e for firefighters			
	ial protective equipment efighters	:		fire, wear self-contained breathing apparatus. protective equipment.
Spec ods	ific extinguishing meth-	:	cumstances ar Use water spra	ing measures that are appropriate to local cir- id the surrounding environment. iy to cool unopened containers. naged containers from fire area if it is safe to d

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

Environmental precautions : Avoid release to the environment.



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		Prevent sprea barriers). Retain and dis	r leakage or spillage if safe to do so. ding over a wide area (e.g. by containment or oil spose of contaminated wash water. es should be advised if significant spillages tained.
6.3 Metho	ods and material for o	containment and clea	aning up
Meth	ods for cleaning up	For large spills ment to keep i be pumped, st	nert absorbent material. s, provide dyking or other appropriate contain- material from spreading. If dyked material can ore recovered material in appropriate container. aining materials from spill with suitable absor-
		Local or nation posal of this m employed in th mine which re Sections 13 an	nal regulations may apply to releases and dis- naterial, as well as those materials and items ne cleanup of releases. You will need to deter- gulations are applicable. Ind 15 of this SDS provide information regarding r 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

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 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 as- sessment
		Do not eat, drink or smoke when using this product.
		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, including any incompatibilities

Requirements for storage : Keep in properly labelled containers. Store locked up. Store in



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areas and containers		accordance with	the particular national regulations.
Advice on common storage		Strong oxidizing	stances and mixtures
7.3 Specific end use(s) Specific use(s)		: No data available	9

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Eptifibatide	188627-80- 7	TWA	10 µg/m3 (OEB 3)	Internal
		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.

Personal protective equipment

Eye/face 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 aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	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



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Resp	iratory protection	sure assessme	clothing. cal exhaust ventilation is not available or expo- ent demonstrates exposures outside the rec- idelines, use respiratory protection.	
Filter type		: Particulates type (P)		

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

9.1	Information on basic physical	an	d chemical properties
	Appearance	:	liquid
	Colour	:	colourless
	Odour Odour Threshold	÷	No data available No data available
		•	NO data avaliable
	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
	Upper explosion limit / Upper flammability limit	:	No data available
	Lower explosion limit / Lower flammability limit	:	No data available
	Vapour pressure	:	No data available
	Relative vapour density	:	No data available
	Density	:	No data available
	Solubility(ies)		
	Water solubility	:	No data available
	Partition coefficient: n- octanol/water	:	No data available
	Auto-ignition temperature	:	No data available
	Decomposition temperature	:	No data available
	Viscosity Viscosity, kinematic	:	No data available
	Explosive properties	:	Not explosive
	Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information



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Flammability (liquids)		: No data avail	able	
Molecular weight		: No data available		
Particle size		: No data avail	able	

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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10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

:	Oxidizing agents
	:

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.



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<u>Comp</u>	oonents:		
Eptifi	batide:		
Test		: Maximisation	Test
Expos Speci	sure routes	: Skin contact : Guinea pig	
Resu		: Not a skin sei	nsitizer.
	cell mutagenicity assified based on avai	lable information.	
Com	oonents:		
Eptifi	batide:		
Geno	toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
		Test Type: M Result: negat	ouse Lymphoma ive
			ster chromatid exchange assay Human lymphocytes ive
Geno	toxicity in vivo	cytogenetic a Species: Mou	se oute: Intraperitoneal injection
Not cl Repro	nogenicity assified based on avai oductive toxicity assified based on avai		
	oonents:		
	batide: s on fertility	Species: Rat Fertility: NOA	ertility/early embryonic development EL: < 72 mg/kg body weight fects on fertility
Effect ment	s on foetal develop-	Species: Rat Application R Development	nbryo-foetal development oute: Intravenous injection al Toxicity: NOAEL: 72 mg/kg body weight fects on foetal development
		Species: Rab Application R Development	nbryo-foetal development bit oute: Intravenous injection al Toxicity: NOAEL: 36 mg/kg body weight fects on foetal development



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May o <u>Com</u> Eptifi Expo Targe	F - single exposure cause damage to organ ponents: ibatide: sure routes et Organs ssment	: Ingestior : Blood	on a damage to organs.
Not c	F - repeated exposure lassified based on avail	able informatic	ion.
-	ated dose toxicity ponents:		
Eptifi Speci NOAI Applie Expoi Rema Speci NOAI Expoi Rema Aspin Not c Expe Com	ibatide: EL cation Route sure time arks EL sure time	: Monkey : 7,2 mg/k : 28 d : No signif	nous ificant adverse effects were reported / /kg ificant adverse effects were reported
Inges		: Sympton	oms: bleeding
12.1 Toxic	N 12: Ecological info city ata available	ormation	
	istence and degradab ata available	ility	
	ccumulative potential ata available		
	lity in soil ata available		



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12.5 Results of PBT and vPvB assessment							
Proc	luct:						
Asse	essment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of			
12.6 Othe	er adverse effects						
Proc	luct:						
Endo tial	ocrine disrupting poten-	:	ered to have end REACH Article 5	ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at 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 Cod are not product specific, but application specific. Waste codes should be assigned by the user, preferably discussion with the waste disposal authorities. Do not dispose of waste into sewer. 	
Contaminated packaging	: Empty containers should be taken to an approved waste 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
ADN ADR	:	Not regulated as a dangerous good Not regulated as a dangerous good
	::	c c c
ADR	::	Not regulated as a dangerous good
ADR RID	::	Not regulated as a dangerous good Not regulated as a dangerous good

14.3 Transport hazard class(es)



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ADN		: N	Not regulated as a	a dangerous good			
ADR		: N	Not regulated as a	a dangerous good			
RID : Not regulated as a dangerous good							
IMDG		: N	Not regulated as a	a dangerous good			
ΙΑΤΑ		: N	Not regulated as a	a dangerous good			
14.4 Packi	ng group						
ADN		: N	Not regulated as a	a dangerous good			
ADR		: N	Not regulated as a	a dangerous good			
RID		: N	Not regulated as a	a dangerous good			
IMDG		: N	Not regulated as a	a dangerous good			
IATA ((Cargo)	: N	Not regulated as a	a dangerous good			
IATA ((Passenger)	: N	Not regulated as a	a dangerous good			
14.5 Enviro	onmental hazards						
Not regulated as a dangerous good							
14.6 Special precautions for user							

Not applicable

Remarks

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mix-ture

	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		
H370	:	Causes damage to organs if swallowed.
Full text of other abbreviation	ons	



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STOT SE

: Specific target organ toxicity - single 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 -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/

Classification of the mixture:

H371

Classification procedure:

Calculation method

STOT SE 2

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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



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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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