Commission Regulation (EU) 2020/878



Eptifibatide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.1	28.09.2024	44535-00026	Date of first issue: 05.01.2015

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

1.1	Product identifier Trade name	:	Eptifibatide Formulation
1.2	Relevant identified uses of th	e s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

responsible for the SDS

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - single exposure, 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	:	Prevent	tion:

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



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			n thoroughly after handling. t, drink or smoke when using this product.
		Response: P308 + P311 IF CENTER/ doctor.	exposed or concerned: Call a POISON
		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.

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. 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,



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			ecommended personal protective equipment ential 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			ater and soap as a precaution. attention if symptoms occur.		
In case of eye contact			ith water as a precaution. attention if irritation develops and persists.		
lf swa	allowed	so by medica Get medical a Rinse mouth	•		
4.2 Most i	4.2 Most important symptoms and effects, both acute and delayed				
Risks	i	: May cause da	amage to organs.		
4.3 Indication of any immediate medical attention and special treatment needed					

Treatment : Treat symptomatically and supportively.

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	ı the	e substance or mixture
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
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.



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			ay to cool unopened containers. maged containers from fire area if it is safe to do
		SO.	
		Evacuate area	a

SECTION 6: Accidental release measures

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.
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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	 Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
	mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or 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 breathe mist or vapours.
	Do not swallow.
	Avoid contact with eyes.
	Avoid prolonged or repeated contact with skin.
	Wash skin thoroughly after handling.

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Hygiene measures		practice, bas sessment Do not eat, o Take care to environment : If exposure t flushing syst place. When nated clothin The effective engineering appropriate o industrial hyst	cordance with good industrial hygiene and safety sed on the results of the workplace exposure as- trink or smoke when using this product. 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 using do not eat, drink or smoke. Wash contami- ting before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the histrative controls.
7.2 Condit	ions for safe storage,	, including any in	compatibilities
	rements for storage and containers		perly labelled containers. Store locked up. Store in with the particular national regulations.
Advice	e on common storage	Strong oxidi	substances and mixtures
-	ic end use(s)		
Specif	fic use(s)	: No data ava	lable

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.



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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 equipme	nt
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 tasl being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially
	contaminated clothing.
Respiratory protection	: 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
Filter type	: Particulates type (P)

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	colourless
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



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		explosion limit / Lower ability limit	:	No data available	9
	Flash p	point	:	No data available	9
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscos Viso	ity cosity, kinematic	:	No data available	9
	Solubil Wa	ity(ies) ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	No data available	9
	Vapou	rpressure	:	No data available	9
	Density	/	:	No data available	9
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	No data available	9
9.2	Other in	nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapoi	ation rate	:	No data available	9
	Molecu	ılar weight	:	No data available	3

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.			
	npatible materials	: Oxidizing age	ents		
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.

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.

Components:

Eptifibatide:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:

Eptifibatide:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)
		Result: negative

Test Type: Mouse Lymphoma

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			Result: negative	
				r chromatid exchange assay Iman lymphocytes
Genot	oxicity in vivo	:	cytogenetic assa Species: Mouse	te: Intraperitoneal injection
	n ogenicity assified based on avai	ilable	information.	
Repro	oductive toxicity			
Not cla	assified based on avai	ilable	information.	
<u>Comp</u>	onents:			
•	batide:			
Effects	s on fertility	:	 Test Type: Fertility/early embryonic development Species: Rat Fertility: NOAEL: < 72 mg/kg body weight Result: No effects on fertility 	
Effects ment	s on foetal develop-	:	Species: Rat Application Rou Developmental	ryo-foetal development te: Intravenous injection Toxicity: NOAEL: 72 mg/kg body weight ts on foetal development
			Species: Rabbit Application Rou Developmental	ryo-foetal development te: Intravenous injection Toxicity: NOAEL: 36 mg/kg body weight ts on foetal development
	- single exposure ause damage to organ	าร.		
<u>Comp</u>	oonents:			
Eptifil	batide:			
Target	sure routes t Organs sment	: : :	Ingestion Blood Causes damage	e to organs.

STOT - repeated exposure

Not classified based on available information.

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Repe	eated dose toxicity			
<u>Com</u>	ponents:			
Eptif	ibatide:			
Spec	ies	:	Rat	
NOA	EL	:	> 72 mg/kg	
Appli	cation Route	:	Intravenous	
Expo	sure time	:	28 d	
Rem	arks	:	No significant	adverse effects were reported
Spec	ies	:	Monkey	
NOA	EL	:	7,2 mg/kg	
Expo	sure time	:	28 d	

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Remarks

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.

: No significant adverse effects were reported

Experience with hur	Experience with human exposure					
Components:						
Eptifibatide:						
Ingestion	: Symptoms: bleeding					
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



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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.

12.6 Endocrine disrupting properties

Ρ	roduc	:t:

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

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RID		:	Not regulated as	a dangerous good
IMDG	i		-	a dangerous good
IATA			C	a dangerous good
	sport hazard class(es	:)	Not regulated as	
		·/		
ADN			-	a dangerous good
ADR		:	-	a dangerous good
RID		•	-	a dangerous good
IMDG	i	:	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	i	:	Not regulated as	a dangerous good
ΙΑΤΑ	(Cargo)	:	Not regulated as	a dangerous good
ΙΑΤΑ	(Passenger)	:	Not regulated as	a dangerous good
-	conmental hazards egulated as a dangerou	us go	od	
•	ial precautions for us	ser		
14.7 Marit	ime transport in bulk	acco	ording to IMO ins	truments
Rema	arks	:	Not applicable fo	r product as supplied.
SECTION	I 15: Regulatory inf	orma	ation	

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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

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				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.
	CH - Candidate List of cern for Authorisation (Substances of Very High (Article 59).	:	Not applicable
REA		s subject to authorisation	:	Not applicable
· ·	ulation (EC) on substa	nces that deplete the ozon	e :	Not applicable
Rég		l on persistent organic pol	lu- :	Not applicable
Reg men of da	ulation (ÉU) No 649/20 It and the Council conc angerous chemicals	012 of the European Parlia erning the export and impo	ort	Not applicable

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				
H370	: Causes damage to organs if swallowed.			
Full text of other abbrev	ations			
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 Inland Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-



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

Classification of the mixtur	e:	Classification procedure:	
STOT SE 2	H371	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

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