



#### Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

#### 1.1. Product identifier : Substance Product form Substance name : Ticagrelor Product code 202000099 : 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.2.1. Relevant identified uses : The product is intended for research, analysis and scientific education. Main use category Use of the substance/mixture : For professional use only : Laboratory chemicals Function or use category 1.2.2. Uses advised against Restrictions on use : Do not use : Ingestion, Inhalation, Dermal 1.3. Details of the supplier of the safety data sheet European Directorate for the Quality of Medicines & Healthcare EDQM, Council of Europe 7, Allée Kastner, CS30026 F-67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771 sds@edqm.eu - www.edqm.eu 1.4. Emergency telephone number

Emergency number

: +33(0)390215608

# SECTION 2: Hazards identification 2.1. Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP] Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411 Full text of H- and EUH-statements: see section 16 Adverse physicochemical, human health and environmental effects Expert judgement and weight of evidence determination. 2.2. Label elements

Labelling according to Regulation (EC)	No. 1272/2008 [CLP]
Hazard pictograms (CLP)	: GHS09
Signal word (CLP)	:-
Hazard statements (CLP)	: H411 - Toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P273 - Avoid release to the environment.
	P391 - Collect spillage.
	P501 - Dispose of contents/container to hazardous or special waste collection point, in
	accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

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#### No labelling required

2.3. Other hazards

No additional information available

#### **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ticagrelor	-	≤ 100	Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

#### 3.2. Mixtures

Not applicable

# SECTION 4: First aid measures 4.1. Description of first aid measures First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material). First-aid measures after eye contact : Rinse eyes with water as a precaution.

#### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable extinguishing media	: Extinguishing blanket.	
5.2. Special hazards arising from the sul	bstance or mixture	
Fire hazard	: See Heading 2.2.	
5.3. Advice for firefighters		
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.	

SECTION 6: Accidental release measures		
6.1. Personal precautions, prote	ective equipment and emergency procedures	
6.1.1. For non-emergency personne		
Emergency procedures	: Avoid all unnecessary exposure.	

#### 6.1.2. For emergency responders

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#### 6.2. Environmental precautions

#### No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

#### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

#### No additional information available

#### 7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

#### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

No additional information available

#### 8.2.2.2. Skin protection

#### Skin and body protection: Lab coat

Hand protection: Protective gloves

#### 8.2.2.3. Respiratory protection

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#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

No additional information available

#### **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	Not available
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
рН	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: < 0,1 g/l
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

#### 9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

#### **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

Stable under normal conditions.

**10.2. Chemical stability** 

No additional information available

#### 10.3. Possibility of hazardous reactions

None known.

#### **10.4. Conditions to avoid**

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#### **10.5. Incompatible materials**

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

#### **SECTION 11: Toxicological information**

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) Acute toxicity (dermal)	•	Not classified Not classified
Acute toxicity (inhalation)	:	Not classified
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

#### 11.2. Information on other hazards

SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general Hazardous to the aquatic environment, short-term (acute) Hazardous to the aquatic environment, long-term (chronic)	<ul> <li>Presents no specific risk for the environment.</li> <li>Not classified</li> <li>Toxic to aquatic life with long lasting effects.</li> </ul>
12.2. Persistence and degradability	
No additional information available	
12.3. Bioaccumulative potential	
No additional information available	
12.4. Mobility in soil	
No additional information available	
12.5. Results of PBT and vPvB assessment	t de la constante d
No additional information available	
12.6. Endocrine disrupting properties	
No additional information available	
12.7. Other adverse effects	
No additional information available	

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#### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

No additional information available

#### **SECTION 14: Transport information**

n accordance with ADR / IMDG / IATA			
ADR	IMDG	ΙΑΤΑ	
14.1. UN number or ID number			
Not applicable	Not applicable	Not applicable	
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	
14.4. Packing group			
Not applicable	Not applicable	Not applicable	
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	
No supplementary information available			

#### 14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

#### Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

#### **SECTION 15: Regulatory information**

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

#### 15.1.1. EU-Regulations

#### **REACH Annex XVII (Restriction List)**

Not listed on REACH Annex XVII

#### **REACH Annex XIV (Authorisation List)**

Not listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

#### **PIC Regulation (Prior Informed Consent)**

Not applicable.

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#### **POP Regulation (Persistent Organic Pollutants)**

Not applicable.

#### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

#### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

#### **SECTION 16: Other information**

Full text of H- and EUH-statements:	
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
H411	Toxic to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.