



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT

Blo TT Thrombin Time
REF 13980 R1 12x2mL

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** TT
Blo TT Thrombin Time
REF 13980 R1 12x2mL
- Other means of identification:**
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: In vitro diagnostic. For professional users/industrial user only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
BIOLABO SAS
Les Hautes Rives
02160 Maizy - France
Phone: 0323251550 - Fax: 0323256256
info@biolabo.fr
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 (08h00-18h00), ORFILA (33) (0)145 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.
Acute Tox. 2: Acute toxicity on contact with skin, Category 2, H310
Acute Tox. 3: Acute inhalation toxicity, Category 3, H331
Acute Tox. 4: Acute toxicity if swallowed, Category 4, H302
Aquatic Chronic 3: Hazardous to the aquatic environment, long-term hazard, Category 3, H412
STOT RE 2: Specific target organ toxicity — Repeated exposure, Hazard Category 2, H373
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Danger
-
- Hazard statements:**
Acute Tox. 2: H310 - Fatal in contact with skin.
Acute Tox. 3: H331 - Toxic if inhaled.
Acute Tox. 4: H302 - Harmful if swallowed.
Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects.
STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure.
- Precautionary statements:**
P264: Wash thoroughly after handling.
P271: Use only outdoors or in a well-ventilated area.
P280: Wear protective gloves/face protection/protective clothing/respiratory protection/protective footwear.
P302+P352: IF ON SKIN: Wash with plenty of water.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P310: Immediately call a poison center/doctor.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.
- Substances that contribute to the classification**
Thiomersal
- 2.3 Other hazards:**

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT Blo TT Thrombin Time REF 13980 R1 12x2mL

SECTION 2: HAZARDS IDENTIFICATION (continued)

Product does not meet PBT/vPvB criteria
Endocrine-disrupting properties: The product does not meet the criteria.
RECONSTITUTED WORKING REAGENT (vial R1) IS NOT CLASSIFIED AS DANGEROUS ACCORDING TO 1272/2008 (CLP) REGULATION

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Non-applicable

3.2 Mixture:

Chemical description: Mixture of substances

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 10035-04-8 EC: Non-applicable Index: Non-applicable REACH: 01-2119494219-28-XXXX	Calcium chloride · 2H₂O ¹ Self-classified	2.5 - <10 %
	Regulation 1272/2008 Eye Irrit. 2: H319 - Warning	
CAS: 54-64-8 EC: 200-210-4 Index: 080-004-00-7 REACH: Non-applicable	Thiomersal ¹ ATP CLP00	<1 %
	Regulation 1272/2008 Acute Tox. 1: H310; Acute Tox. 2: H300+H330; Aquatic Acute 1: H400; Aquatic Chronic 1: H410; STOT RE 2: H373 - Danger	

¹ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Other information:

Identification	Specific concentration limit
Thiomersal CAS: 54-64-8 EC: 200-210-4	% (w/w) >=0.1: STOT RE 2 - H373

Acute toxicity estimate for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation:

Identification	Acute toxicity		Genus
	LD50 oral	Non-applicable	
Thiomersal CAS: 54-64-8 EC: 200-210-4	LD50 dermal	Non-applicable	
	LC50 inhalation	0,05 mg/L (ATEi)	

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Request medical assistance immediately, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT Blo TT Thrombin Time REF 13980 R1 12x2mL

SECTION 4: FIRST AID MEASURES (continued)

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. In the case of loss of consciousness do not administer anything orally unless supervised by a doctor. Rinse out the mouth and throat, as they may have been affected during ingestion. Keep the person affected at rest.

4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Preferably use aspiration for cleaning. Given the danger of the product by inhalation, any cleaning method that involves exposure to the product in this way (sweeping, etc.) is not recommended

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed containers. Notify the relevant authority in case of exposure to the general public or the environment.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Preferably use aspiration for cleaning. Given the danger of the product by inhalation, any cleaning method that involves exposure to the product in this way (sweeping, etc.) is not recommended

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT
Blo TT Thrombin Time
REF 13980 R1 12x2mL

SECTION 7: HANDLING AND STORAGE (continued)

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

Preferably use aspiration for cleaning. Given the danger of the product by inhalation, any cleaning method that involves exposure to the product in this way (sweeping, etc.) is not recommended

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³



8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment



In accordance with the order of importance to control professional exposure (Directive 98/24/EC) it is recommended to use localized extraction in the work area as a collective protection measure to avoid exceeding the occupational exposure limits. In case of using personal protective equipment it should have CE marking in accordance with Directive 2016/425/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For additional information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours	 CAT III	EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves (Material: Nitrile, Breakthrough time: > 480 min, Thickness: 0.11 mm)	 CAT III	EN ISO 21420:2020	Replace the gloves at any sign of deterioration.

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

D.- Eye and face protection

- CONTINUED ON NEXT PAGE -





Safety data sheet





This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT
Blo TT Thrombin Time
REF 13980 R1 12x2mL



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Face shield		EN 166:2002 EN 167:2002 EN 168:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory complete body protection	Disposable clothing for protection against chemical risks		EN 13034:2005+A1:2009 EN 168:2002 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2013 EN ISO 6530:2005 EN 464:1994	For professional use only. Clean periodically according to the manufacturer's instructions.
 Mandatory foot protection	Safety footwear for protection against chemical risk		EN ISO 20345:2011 EN 13832-1:2019	Replace boots at any sign of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Solid
 Appearance: Compact
 Colour: White
 Odour: Not available
 Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: Non-applicable *
 Vapour pressure at 20 °C: Non-applicable *
 Vapour pressure at 50 °C: Non-applicable *
 Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: Non-applicable *
 Relative density at 20 °C: Non-applicable *
 Dynamic viscosity at 20 °C: Non-applicable *
 Kinematic viscosity at 20 °C: Non-applicable *
 Kinematic viscosity at 40 °C: >20,5 mm²/s

*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT Blo TT Thrombin Time REF 13980 R1 12x2mL

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Flammability:	
Flash Point:	Non-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Explosive (Solid):	
Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *
Particle characteristics:	
Median equivalent diameter:	Non-applicable *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

Other safety characteristics:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT Blo TT Thrombin Time REF 13980 R1 12x2mL

SECTION 10: STABILITY AND REACTIVITY (continued)

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Inhalation after prolonged exposure may be lethal.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Can be fatal if the product is absorbed through the skin. For more information on the secondary effects of skin contact see section 2.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Exposure in high concentration can interfere with the central nervous system causing headache, dizziness, vertigo, nausea, vomiting, confusion, and in serious cases, loss of consciousness.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT Blo TT Thrombin Time REF 13980 R1 12x2mL

SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Thiomersal CAS: 54-64-8 EC: 200-210-4	LD50 oral	5 mg/kg	
	LD50 dermal	5 mg/kg	
	LC50 inhalation	0,05 mg/L (ATEi)	
Calcium chloride · 2H2O CAS: 10035-04-8 EC: Non-applicable	LD50 oral	2031 mg/kg	Rat
	LD50 dermal	Non-applicable	
	LC50 inhalation	Non-applicable	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Non-applicable

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Harmful to aquatic life with long lasting effects.

12.1 Toxicity:

Acute toxicity:

Identification	Concentration		Species	Genus
Calcium chloride · 2H2O CAS: 10035-04-8 EC: Non-applicable	LC50	4630 mg/L (96 h)	Pimephales promelas	Fish
	EC50	2400 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	Non-applicable		
Thiomersal CAS: 54-64-8 EC: 200-210-4	LC50	>0.1 - 1 mg/L (96 h)		Fish
	EC50	>0.1 - 1 mg/L (48 h)		Crustacean
	EC50	>0.1 - 1 mg/L (72 h)		Algae

Chronic toxicity:

Identification	Concentration		Species	Genus
Calcium chloride · 2H2O CAS: 10035-04-8 EC: Non-applicable	NOEC	230 mg/L	Oncorhynchus mykiss	Fish
	NOEC	481 mg/L	Daphnia magna	Crustacean

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT Blo TT Thrombin Time REF 13980 R1 12x2mL

SECTION 13: DISPOSAL CONSIDERATIONS (continued)

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 06*	laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP14 Ecotoxic, HP6 Acute Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Contains Thiomersal

Seveso III:

Section	Description	Lower-tier requirements	Upper-tier requirements
H2	ACUTE TOXIC	50	200

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc)

:

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

- CONTINUED ON NEXT PAGE -



Safety data sheet

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

TT

Blo TT Thrombin Time
REF 13980 R1 12x2mL

SECTION 16: OTHER INFORMATION (continued)

COMMISSION REGULATION (EU) 2020/878

Texts of the legislative phrases mentioned in section 2:

H373: May cause damage to organs through prolonged or repeated exposure.

H412: Harmful to aquatic life with long lasting effects.

H310: Fatal in contact with skin.

H302: Harmful if swallowed.

H331: Toxic if inhaled.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Acute Tox. 1: H310 - Fatal in contact with skin.

Acute Tox. 2: H300+H330 - Fatal if swallowed or if inhaled.

Aquatic Acute 1: H400 - Very toxic to aquatic life.

Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.

Eye Irrit. 2: H319 - Causes serious eye irritation.

STOT RE 2: H373 - May cause damage to organs through prolonged or repeated exposure.

Classification procedure:

STOT RE 2: Calculation method

Aquatic Chronic 3: Calculation method

Acute Tox. 2: Calculation method

Acute Tox. 4: Calculation method

Acute Tox. 3: Calculation method

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -