


**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL**

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

- 1.1 Product identifier:** Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1 10 x 5 mL
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: In vitro diagnostic. For professional use 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:**
ABLIANCE SAS
21 quai du Clos de Roses
60200 Compiègne - France
Phone.: 33 (0)3 44 20 61 30 -
Fax: 33 (0) 3 44 20 62 55
support@abliance.com
www.abliance.com
- 1.4 Emergency telephone number:**

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
Directive 67/548/EC and Directive 1999/45/EC:
This product was classified in accordance with Directive 67/548/EC and Directive 1999/45/EC, adapting the requirements to Regulation (EC) n°1907/2006 (REACH regulation).
Xn: R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed
R33 - Danger of cumulative effects
CLP Regulation (EC) n° 1272/2008:
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**
Directive 67/548/EC and Directive 1999/45/EC:
In accordance with the legislation, the elements on the label are as follows:
- Xn

Harmful
- R Phrases:**
R20/21/22: Harmful by inhalation, in contact with skin and if swallowed
R33: Danger of cumulative effects
- S Phrases:**
S20/21: When using do not eat, drink or smoke
S36/37: Wear suitable protective clothing and gloves
S51: Use only in well-ventilated areas
- Supplementary information:**
Non-applicable
- CLP Regulation (EC) n° 1272/2008:**
None
- 2.3 Other hazards:**
Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Mixture of substances
Components:

- CONTINUED ON NEXT PAGE -

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL****SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continue)**

None of the substances contained in the mixture are above the values fixed in Annex II of Regulation (EC) n°1907/2006

SECTION 4: FIRST AID MEASURES**4.1 Description of first aid measures:**

Consult a doctor in case of discomfort with this Safety data Sheet.

By inhalation:

In case of symptoms, move the person affected into fresh air.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor with the SDS of this product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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:**

Product is non-flammable, low risk of fire by the inflammability characteristics of the product in normal conditions of storage, manipulation and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

5.2 Special hazards arising from the substance or mixture:

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

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. 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. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, 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:**

Isolate leaks provided that there is no additional risk for the people performing this task.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

- CONTINUED ON NEXT PAGE -

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL**

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

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

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

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

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

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 work environment

There are no environmental limits for the substances contained in the product

8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more 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

The use of protection equipment will be necessary if a mist forms or if the professional exposure limits are exceeded.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

D.- Ocular and facial protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Bodily protection

- CONTINUED ON NEXT PAGE -

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL**

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			For professional use only.
	Anti-slip work shoes		EN ISO 20347:2012	None

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

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: Liquid
Appearance: Compact
Color: White
Odor: Not available

Volatility:

Boiling point at atmospheric pressure: 100 °C
Vapour pressure at 20 °C: 2350 Pa
Vapour pressure at 50 °C: 12381 Pa (12 kPa)
Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: 1561 kg/m³
Relative density at 20 °C: 1,561
Dynamic viscosity at 20 °C: 3,31 cP
Kinematic viscosity at 20 °C: 2,12 cSt
Kinematic viscosity at 40 °C: >20,5 cSt
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 Flammable (>60 °C)
Autoignition temperature: Non-applicable *
Lower flammability limit: Non-applicable *

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

- CONTINUED ON NEXT PAGE -

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL**
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

Upper flammability limit: Non-applicable *

9.2 Other information:

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.

10.2 Chemical stability:

Chemically stable under the 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:

Acids	Water	Combustive materials	Combustible materials	Others
Not applicable	Not applicable	Not applicable	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 toxicological effects:

LD50 oral > 2000 mg/kg (rat)

Dangerous health implications:

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

A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

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

- Carcinogenicity: Based on available data, the classification criteria are not met
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Cutaneous: Based on available data, the classification criteria are not met

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

Based on available data, the classification criteria are not met

- CONTINUED ON NEXT PAGE -

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL**

SECTION 11: TOXICOLOGICAL INFORMATION (continue)

- G- Specific target organ toxicity (STOT)-repeated exposure:
- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
 - Skin: Based on available data, the classification criteria are not met
- H- Aspiration hazard:
Based on available data, the classification criteria are not met
- Other information:**
Non-applicable
- Specific toxicology information on the substances:**
Not available

SECTION 12: ECOLOGICAL INFORMATION

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

- 12.1 Toxicity:**
Not available
- 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:**
Non-applicable
- 12.6 Other adverse effects:**
Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 09	Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non dangerous

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

Non-applicable

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. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°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)

- CONTINUED ON NEXT PAGE -

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL****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) 1907/2006 (REACH): Non-applicable

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

Regulation (EC) 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: Non-applicable

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

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 data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, 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:**

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

COMPOSITION/INFORMATION ON INGREDIENTS:

- Removed Content
Disodium tartrate (6106-24-7)

CLP Regulation (EC) n° 1272/2008:

- Supplementary information

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

Directive 67/548/EC and Directive 1999/45/EC:

Non-applicable

CLP Regulation (EC) n° 1272/2008:

Non-applicable

Classification procedure:

Non-applicable

Advice related to training:

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

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

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

Abbreviations and acronyms:

**Thromboplastin: Reagent 1 - REF PT02 R1 5 x 2 mL REF PT05 R1
10 x 5 mL****SECTION 16: OTHER INFORMATION (continue)**

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: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
CL50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol–water partition coefficient
Koc: Partition coefficient of organic carbon

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 -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**

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

- 1.1 Product identifier:** Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL PT05 R2 1 x 60 mL
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
 Relevant uses: In vitro diagnostic. For professional use 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:**
 ABLIANCE SAS
 21 quai du Clos de Roses
 60200 Compiègne - France
 Phone.: 33 (0)3 44 20 61 30 -
 Fax: 33 (0) 3 44 20 62 55
 support@abliance.com
 www.abliance.com
- 1.4 Emergency telephone number:**

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
Directive 67/548/EC and Directive 1999/45/EC:
 This product was classified in accordance with Directive 67/548/EC and Directive 1999/45/EC, adapting the requirements to Regulation (EC) n°1907/2006 (REACH regulation).
 Xi: R43 - May cause sensitisation by skin contact
- CLP Regulation (EC) n° 1272/2008:**
 Classification of this product has been carried out in accordance with CLP Regulation (EC) n° 1272/2008.
 Skin Sens. 1: Sensitisation, skin, Category 1, H317
- 2.2 Label elements:**
Directive 67/548/EC and Directive 1999/45/EC:
 In accordance with the legislation, the elements on the label are as follows:
- Xi

 Irritant
- R Phrases:**
 R43: May cause sensitisation by skin contact
- S Phrases:**
 S24: Avoid contact with skin
 S37: Wear suitable gloves
- Supplementary information:**
 Non-applicable
- Substances that contribute to the classification:**
 Nickel sulfate· 6 H2O
- CLP Regulation (EC) n° 1272/2008:**
Warning

- Hazard statements:**
 Skin Sens. 1: H317 - May cause an allergic skin reaction
- Precautionary statements:**

- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**

SECTION 2: HAZARDS IDENTIFICATION (continue)

P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P272: Contaminated work clothing should not be allowed out of the workplace
P280: Wear protective gloves/protective clothing/eye protection/face protection
P302+P352: IF ON SKIN: Wash with plenty of water
P333+P313: If skin irritation or rash occurs: Get medical advice/attention
P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively

Substances that contribute to the classification

Nickel sulfate· 6 H₂O

2.3 Other hazards:

Non-applicable

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) n°1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 26628-22-8 EC: 247-852-1 Index: 011-004-00-7 REACH: 01-2119457019-37-XXXX	sodium azide ATP CLP00	<1 %
	Directive 67/548/EC N: R50/53; T+: R28; R32	
	Regulation 1272/2008 Acute Tox. 2: H300; Aquatic Acute 1: H400; Aquatic Chronic 1: H410 - Danger	
CAS: 10101-97-0 EC: 232-104-9 Index: 028-009-00-5 REACH: 01-2119439361-44-XXXX	Nickel sulfate· 6 H₂O ATP CLP00	<1 %
	Directive 67/548/EC Carc. Cat 1: R49; Mut. Cat. 3: R68; N: R50/53; Repr. Cat 2: R61; T: R48/23; Xi: R38; Xn: R20/22, R42/43	
	Regulation 1272/2008 Acute Tox. 4: H302+H332; Aquatic Acute 1: H400; Aquatic Chronic 1: H410; Carc. 1A: H350i; Muta. 2: H341; Repr. 1B: H360D; Resp. Sens. 1: H334; Skin Irrit. 2: H315; Skin Sens. 1: H317; STOT RE 1: H372 - Danger	

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product is not classified as hazardous through inhalation, however, it is recommended in case of intoxication symptoms to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

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, as 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.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

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

- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**

SECTION 4: FIRST AID MEASURES (continue)

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

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 individual respiratory equipment. 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. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, 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:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilled product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

Avoid spillage into an aqueous medium as it contains substances potentially dangerous for this. Contain the product absorbed in hermetically sealed containers. In the case of serious spillage into an aqueous medium notify the relevant authority.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

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

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

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

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

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**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**
SECTION 7: HANDLING AND STORAGE (continue)
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 work environment

Identification	Environmental limits	
sodium azide CAS: 26628-22-8 EC: 247-852-1	IOELV (8h)	0,1 mg/m ³
	IOELV (STEL)	0,3 mg/m ³
	Year	2015



8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more 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		EN 405:2001+A1:2009	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	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN 172:1994/A1:2000 EN 172:1994/A2:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.


E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing		EN ISO 13688:2013	For professional use only.



- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Anti-slip work shoes		EN ISO 20347:2012 EN ISO 20344:2011	None

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

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: Liquid
Appearance: Colorless
Color: Colourless
Odor: Not available

Volatility:

Boiling point at atmospheric pressure: 100 °C
Vapour pressure at 20 °C: 2350 Pa
Vapour pressure at 50 °C: 12381 Pa (12 kPa)
Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: 1035 kg/m³
Relative density at 20 °C: 1,035
Dynamic viscosity at 20 °C: Non-applicable *
Kinematic viscosity at 20 °C: Non-applicable *
Kinematic viscosity at 40 °C: Non-applicable *
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 Flammable (>60 °C)
Autoignition temperature: Non-applicable *
Lower flammability limit: Non-applicable *

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

- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

Upper flammability limit: Non-applicable *

9.2 Other information:

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 if the following technical instructions storage of chemicals. See section 7.

10.2 Chemical stability:

Chemically stable under the 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:

Acids	Water	Combustive materials	Combustible materials	Others
Precaution	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 toxicological effects:

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 recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

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

- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**
SECTION 11: TOXICOLOGICAL INFORMATION (continue)

- Carcinogenicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with carcinogenic effects. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with mutagenic effects. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, however it does contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous with sensibilizing effects. For more information see section 3.
- Cutaneous: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.

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

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

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

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for inhalation. 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 dangerous 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 dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
sodium azide CAS: 26628-22-8 EC: 247-852-1	LD50 oral	10 mg/kg	Rat
	LD50 dermal	Non-applicable	
	LC50 inhalation	Non-applicable	
Nickel sulfate· 6 H ₂ O CAS: 10101-97-0 EC: 232-104-9	LD50 oral	325 mg/kg	Rat
	LD50 dermal	Non-applicable	
	LC50 inhalation	Non-applicable	

SECTION 12: ECOLOGICAL INFORMATION

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

12.1 Toxicity:

Identification	Acute toxicity		Specie	Genus
sodium azide CAS: 26628-22-8 EC: 247-852-1	LC50	5,7 mg/L (96 h)	N/A	Fish
	EC50	0,5 mg/L (48 h)	N/A	Crustacean
	EC50	0,35 mg/L (96 h)	Pseudokirchneriella subcapitata	Algae
Nickel sulfate· 6 H ₂ O CAS: 10101-97-0 EC: 232-104-9	LC50	15,3 mg/L (96 h)	Cyprinus carpio	Fish
	EC50	0,14 mg/L (48 h)	Ceriodaphnia dubia	Crustacean
	EC50	Non-applicable		

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:

Non-applicable

12.6 Other adverse effects:

- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**

SECTION 12: ECOLOGICAL INFORMATION (continue)

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 09	Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non dangerous

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

Non-applicable

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. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°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) 1907/2006 (REACH): Non-applicable

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

Regulation (EC) 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: Non-applicable

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

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 data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, 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:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Texts of the legislative phrases mentioned in section 2:

- CONTINUED ON NEXT PAGE -

**Thromboplastin: reconstitution Buffer - REF PT02 R2 1 x 12 mL
PT05 R2 1 x 60 mL**
SECTION 16: OTHER INFORMATION (continue)

H317: May cause an allergic skin reaction

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

Directive 67/548/EC and Directive 1999/45/EC:

R20/22: Harmful by inhalation and if swallowed

R28: Very toxic if swallowed

R32: Contact with acids liberates very toxic gas

R38: Irritating to skin

R42/43: May cause sensitisation by inhalation and skin contact

R48/23: Toxic: danger of serious damage to health by prolonged exposure through inhalation

R49: May cause cancer by inhalation

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R61: May cause harm to the unborn child (Category 2)

R68: Possible risk of irreversible effects

CLP Regulation (EC) n° 1272/2008:

Acute Tox. 2: H300 - Fatal if swallowed

Acute Tox. 4: H302+H332 - Harmful 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

Carc. 1A: H350i - May cause cancer by inhalation.

Muta. 2: H341 - Suspected of causing genetic defects

Repr. 1B: H360D - May damage the unborn child.

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Skin Irrit. 2: H315 - Causes skin irritation

Skin Sens. 1: H317 - May cause an allergic skin reaction

STOT RE 1: H372 - Causes damage to organs after prolonged or repeated exposure through inhalation

Classification procedure:

Skin Sens. 1: Calculation method

Advice related to training:

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

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<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: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

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 -