



Procalcitonin Assay Reagents, Calibrators and Controls Safety Data Sheet 1151

according to Regulation (EC) No. 453/2010

Date of issue: 04/06/2015

Revision date: 04/06/2015

Version: A

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

1.1. Product identifier

Product form Mixture
Product name Procalcitonin Assay
Reagent R1, Reagent R2, Calibrators and Controls
Product code DZ558A
DZ558A-R1, DZ558A-R2, DZ558A-CAL, DZ558A-CON
Product group Blend

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier: Diazyme Laboratories
12889 Gregg Court
92064 Poway
T 858-455-4768

Authorized Representative: MDSS GmbH
Schiffgraben 41
Germany
(+49) 511-6262-8630

1.4. Emergency telephone number

Emergency number Contact your local health authority or poison control center in an emergency. Manufacturer contact number for the US is as follows: (858) 455-4768

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified (for all components)

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements (**Reagent R1 only**) EUH210 - Safety data sheet available on request

2.3. Other hazards

Contains PBT/vPvB substances \geq 0.1% assessed in accordance with REACH Annex XIII (**Reagent R1 only**)

SECTION 3 Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Trizma Base	(CAS No) 77-86-1 (EC no) 201-064-4	1.21 (Reagent R1 only)	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315

Procalcitonin Assay

Reagents, Calibrators and Controls

Safety Data Sheet 1151

according to Regulation (EC) No. 453/2010

Triton X-100 substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]) non-classified PBT substance non-classified vPvB substance	(CAS No) 9002-93-1	0.1 (Reagent R1 only)	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
--	--------------------	-----------------------	---

Full text of H-phrases: see section 16

SECTION 4 First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	Wash skin with plenty of water.
First-aid measures after eye contact	Rinse eyes with water as a precaution.
First-aid measures after ingestion	Call a poison center or a doctor if you feel unwell.

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

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Take up liquid spill into absorbent material.
Other information Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

No additional information available

Procalcitonin Assay

Reagents, Calibrators and Controls

Safety Data Sheet 1151

according to Regulation (EC) No. 453/2010

8.2. Exposure controls

Appropriate engineering controls	Ensure good ventilation of the work station.
Hand protection	Protective gloves
Eye protection	Safety glasses
Skin and body protection	Wear suitable protective clothing
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment
Environmental exposure controls	Avoid release to the environment.

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Colour	No data available
Odour	No data available
Odour threshold	No data available
pH	No data available
Relative evaporation rate (butylacetate=1)	No data available
Melting point	Not applicable
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Flammability (solid, gas)	Not applicable
Vapour pressure	No data available
Relative vapour density at 20 °C	No data available
Relative density	No data available
Solubility	No data available
Log Pow	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosive properties	No data available
Oxidising properties	No data available
Explosive limits	No data available

9.2. Other information

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Acute toxicity	Not classified
----------------	----------------

Procalcitonin Assay

Reagents, Calibrators and Controls

Safety Data Sheet 1151

according to Regulation (EC) No. 453/2010

Triton X-100 (9002-93-1)	
LD50 oral rat	1800 mg/kg (Rat)
LD50 dermal rabbit	> 3000 mg/kg (Rabbit)
Trizma Base (77-86-1)	
LD50 oral rat	5900 mg/kg (Rat)
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
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified

SECTION 12 Ecological information

12.1. Toxicity

Ecology - general The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

Triton X-100 (9002-93-1)	
LC50 fish 1	> 10 mg/l (96 h; Lepomis macrochirus; Toxicity test)
EC50 Daphnia 1	26 mg/l (48 h; Daphnia magna)
EC50 other aquatic organisms 1	10 mg/l (336 h; Lemna sp.; Biomass)
LC50 fish 2	8.9 mg/l (96 h; Pimephales promelas)
Threshold limit algae 1	500 mg/l (504 h; Selenastrum capricornutum; Cell numbers)

12.2. Persistence and degradability

Triton X-100 (9002-93-1)	
Persistence and degradability	Biodegradable in water.
ThOD	2.16 g O ₂ /g substance
Trizma Base (77-86-1)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Triton X-100 (9002-93-1)	
Log Pow	4.86 (Estimated value)
Trizma Base (77-86-1)	
Log Pow	-1.56
Bioaccumulative potential	Bioaccumulation: not applicable.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Component	
Triton X-100 (9002-93-1)	This substance/mixture meets the PBT criteria of REACH regulation, annex XIII This substance/mixture meets the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Waste treatment methods Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14 Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

Procalcitonin Assay

Reagents, Calibrators and Controls

Safety Data Sheet 1151

according to Regulation (EC) No. 453/2010

14.2. UN proper shipping name

Proper Shipping Name (ADR)	Not applicable
Proper Shipping Name (IMDG)	Not applicable
Proper Shipping Name (IATA)	Not applicable
Proper Shipping Name (ADN)	Not applicable
Proper Shipping Name (RID)	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	Not applicable
----------------------------------	----------------

IMDG

Transport hazard class(es) (IMDG)	Not applicable
-----------------------------------	----------------

IATA

Transport hazard class(es) (IATA)	Not applicable
-----------------------------------	----------------

ADN

Transport hazard class(es) (ADN)	Not applicable
----------------------------------	----------------

RID

Transport hazard class(es) (RID)	Not applicable
----------------------------------	----------------

14.4. Packing group

Packing group (ADR)	Not applicable
Packing group (IMDG)	Not applicable
Packing group (IATA)	Not applicable
Packing group (ADN)	Not applicable
Packing group (RID)	Not applicable

14.5. Environmental hazards

Dangerous for the environment	No
Marine pollutant	No
Other information	No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Carriage prohibited (ADN)	No
Not subject to ADN	No

- Rail transport

Carriage prohibited (RID)	No
---------------------------	----

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

Contains no substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9002-93-1)

Procalcitonin Assay

Reagents, Calibrators and Controls

Safety Data Sheet 1151

according to Regulation (EC) No. 453/2010

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference

Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen

None of the components are listed

SZW-lijst van mutagene stoffen

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid

None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

None of the components are listed

Denmark

Recommendations Danish Regulation

Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No additional information available

SECTION 16 Other information

Full text of H- and EUH-statements

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
EUH210	Safety data sheet available on request

SDS EU Diazyme with CLP

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product