

Safety Data Sheet

According to Regulation (EC) Nr. 2015/830

Trade name: TOSI® Test Object Surgical Instrument
Revision Date: 08.08.2016
Version: 3.0



01. Identification of the substance / mixture and of the company

Trade name

TOSI® Test Object Surgical Instrument

Relevant identified uses

Monitoring and Validation of cleaning efficacy

Manufacturer / supplier

Pereg GmbH

Street

Porschestraße 12

Postal code

DE – 84478 Waldkraiburg

Telephone / Fax / E-Mail

+49 (0) 8638 84100 / +49 (0) 8638 84162 / E-mail: info@pereg.de

Emergency Telephone Number

Tel. +49 89 19240 (Poison Centre Munich)

02. Hazards identifications

Classification of the substance or mixture

This substance does not meet the criteria for classification in accordance with Regulation No1272/2008/EC.

Adverse environmental and human health effects

Not required.

03. Composition / information on ingredients

Description of the mixture

Mixture of purified bovine proteins, coagulated on stainless steel plate with Polycarbonate clip.

The test soil comprises less than 0,1% by weight of the product.

Hazardous ingredients

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04. First aid measures

General information

No special measures required

Following inhalation

Not applicable

Following skin contact

Rinse with water

Following eye contact

Rinse with water. In case of irritating effect get medical attention.

Following ingestion

Get medical attention

Notes for the doctor

Not applicable

05. Firefighting measures

Suitable extinguishing media

Foam, Carbon dioxide, extinguishing powder. Subject to normal conditions incombustible. Use fire extinguishing methods suitable to surrounding conditions.

Unsuitable extinguishing media

No data

Special hazards arising from the substance and combustion products

Toxic and irritating gases/fumes may be given off during burning or thermal decomposition.

Advice for fire-fighters

Fire-fighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

06. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid substance contact.

Environmental precautions

No

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Methods and material for containment and cleaning up

Take material and, if necessary, place in an appropriate waste disposal container. Disposal considerations: see section 13.

Advices on how to clean up a spill

Wash affected area as usual.

07. Handling and storage

Precautions for safe handling

Open package carefully and handle with care.

Advice on general occupational hygiene

Don't eat and drink at work. No smoking. Keep away from food. Avoid contact with skin and eyes.

Conditions for safe storage, including any incompatibilities

Store in original packaging. Store at +2 °C to +25 °C.
Store protected from light, heat and chemicals.
When the container is closed no incompatibilities are known.

Incompatible substances or mixtures

When the container is closed no incompatibilities are known.

Specific end use(s)

TOSI® is a test item to verify the cleaning performance of washing disinfectant.

08. Exposure controls / personal protection

Control parameters

National limit values

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Relevant DNELs/DMELs/PNECs and other threshold levels

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Exposure controls

Individual protection measures (personal protective equipment)

Eye protection

On principle during handle with chemicals eye protection is necessary.

Hand protection

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Inhalation protection

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Environmental exposure controls

No further data; see item 6 and 7.



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09. Physical and chemical properties

Appearance

Physical state: solid (metal carrier with polymer cover)
Colour: red test spot on stainless steel
Odour: neutral
Odour threshold: no data available

Other physical and chemical parameters

pH (value): Not applicable
Melting point/freezing point: Not applicable
Initial boiling point/range: Not applicable
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (gas, solid) no data available
Explosion limits: Not applicable
Vapour pressure: Not applicable
Vapour density: Not applicable
Density: Not applicable
Solubility: Test spot partial soluble in Water
Partition coefficient: no data available
n-octanol/water
Auto-ignition temperature: Not applicable
Decomposition temperature: no data available
Viscosity: Not applicable
Explosive properties: no
Oxidizing properties: no

10. Stability and reactivity

Reactivity

TOSI® is not reactive under normal ambient conditions.

Chemical stability

No decomposition if stored and handled as intended.

Possibility of hazardous reactions

No data.

Conditions to avoid

Avoid temperatures above 60 °C

Incompatible materials

No data

Hazardous decomposition products

In case of fire: see section 5

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11. Toxicological information

Acute toxicity

No data

Skin corrosion/irritation

No data

Serious eye damage/eye irritation

No data

Respiratory or skin sensitisation

No data

Summary of evaluation of the CMR properties:

Carcinogenicity:

No data

Reproductive toxicity:

No data

Specific target organ toxicity - single exposure

No data

Specific target organ toxicity - repeated exposure

No data

Aspiration hazard

No data

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Irritation of the mouth, throat, esophagus and gastrointestinal tract

If in eyes

No data

If inhaled

No data

If on skin

No data

Other information

No

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12. Ecological information

Toxicity

No data

Process of degradability

No data

Bioaccumulative potential

No data

Mobility in soil

No data

Results of PBT and vPvB assessment

No data

Other adverse effects

No data.

13. Disposal considerations

Product

The disposal is regionally differently regulated, therefore the kind of disposal is to be inquired at the responsible authorities.

Additional information

Disposal of this product should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Contaminated packaging

Disposal according to official regulations.

Uncontaminated packaging

Disposal according to official regulations.

14. Transport information

UN number

Void

UN proper shipping name

Void

Transport hazard class(es)

Void

Packing group

Void

Environmental hazards

No

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Special precautions for user

No

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

15. Regulatory information

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

Material safety evaluation

A material safety evaluation has not been carried out.

Regulation on combustible liquids

Class according 2009/104/EG (BetrSichV):

No

Water hazard class

No

Storage according TRGS 510 (Storage of hazardous substances in nonstationary containers)

Storage classes 10 to 13

16. Other information

Recommended application

For commercial purposes only.
Take notice of label / instruction for use.

Relevant R-, H- and EUH-phrases

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Disclaimer

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Key literature references and sources for data

Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU
Regulation (EC) No. 1272/2008 (CLP, EU GHS)

Changes to the previous version

Section 2: new regulation

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Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Comission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
index No	the Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals