

SAFETY DATA SHEET

DIATABS™ (used in liquid)

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Identification**
Diatabs (used in liquids)
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
In vitro laboratory use
- 1.3 Details of the supplier of the safety data sheet**
Rosco Diagnostica A/S
Taastrupgaardsvej 30
DK-2630 Taastrup
Denmark
Tel: (+45) 43 99 33 77
Fax: (+45) 43 52 73 74
info@rosco.dk
- 1.4 Emergency telephone number**
(+45) 43 99 33 77

Section 2: Hazards Identification

- 2.1 Classification of the substance or mixture**
Not applicable as the product is not classified as hazardous according to regulation EC (1999/45) or CLP (1272/2008).
- 2.2 Label elements**
According to EU-directives and Danish legislation, the product needs no label.
- 2.3 Other hazards**
None known.

Section 3: Composition/Information on Ingredients

Contains: Barium sulphate, Potato Starch, Povidone (Ph.Eur.), Polyplasdone, Buffering agents (phosphate or carbonate), Chelating agents (TRIS), Indicator (Bromcresol purple / Phenol red), Magnesium Stearate, Talcum, and active substance

| % w/w | Substance Name | CAS-no | EC-no. | Index-no. | REACH-Reg.no | Classification |
|-------|------------------|--------|--------|-----------|--------------|----------------|
| < 4.5 | Active substance | * | * | - | - | * |

*Diatabs contains active substances that differs (please see the label for exact substance name). Worst-case classification of the active substance (relating to labelling) is R42/43 (Resp. Sens. 1A; H334 Skin Sens. 1A; H317).

Wording of R-phrases and hazards statements - see section 16.

Section 4: First-Aid Measures

- 4.1 Description of first aid measures**
- Inhalation Unlikely route of exposure. If accident occurs, move the affected person to fresh air. If symptoms persists, seek medical advice.
- Skin contact Remove contaminated clothing. Wash skin with water and mild soap.

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| | |
|-------------|---|
| | If irritation persists, seek medical attention. |
| Eye contact | Flush with water or physiological salt water for at least 5 minutes. If irritation persists seek medical attention. |
| Ingestion | Rinse mouth and drink plenty of water. In case of discomfort, seek medical attention. |

4.2 Most important symptoms and effects, both acute and delayed

May cause irritation of the skin, eyes and airways.

4.3 Indication of any immediate medical attention and special treatment needed

Show this Safety Data Sheet to a physician or emergency ward.

Section 5: Fire-Fighting Measures

5.1 Extinguishing media

Use extinguishing media that are appropriate to circumstances and the surrounding environment, ex. carbon dioxide (CO₂), dry chemical, sand, foam or water fog. Do not use water jet.

5.2 Special hazards arising from the substance or mixture.

Do not breathe smoke fumes. In case of fire, the products may form hazardous decomposition such as oxides of carbon.

5.3 Advice for firefighters

When entering burning area wear self-contained breathing apparatus.

5.4 Other information

No available data.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment – see section 8.

6.2 Environmental precautions

Do not empty into drain – see section 12. Inform appropriate authorities in accordance with local regulations.

6.3 Methods and material for containment and cleaning up

Take up with wet paper. Clean with water. Further handling of spillage – see section 13.

6.4 Reference to other sections

See above

Section 7: Handling and Storage

7.1 Precautions for safe handling

Avoid generation and spreading of dust. Avoid breathing dust. Provide efficient ventilation. Wash hands before and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Store in a well-closed original package. Keep dry and at room temperature. Avoid direct light and humidity.

7.3 Specific end use(s)

Use in laboratory.

Section 8: Exposure Controls/Personal Protection

8.1 Control parameters

This product does not contain substances with occupational exposure limit values.

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8.2 Exposure controls

Appropriate measures

Appropriate engineering controls: Provide efficient ventilation e.g. by working in a fume cupboard. General practice of industrial hygiene.

Personal Protective Equipment

Respiratory protection:

Normally not necessary if working in fume cupboard.

Skin protection:

Wear protective gloves of e.g. butyl rubber or nitrile rubber. It has not been possible to find data for breakthrough time, so it must be recommended to change the glove if spilled on it.

Eye protection:

Wear tight fitting safety goggles when risk of eye contact.

Environmental exposure controls:

None particular.

9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

| | |
|--|--------------------------|
| a) Appearance | Tablet (6mm in diameter) |
| b) Odour: | Odourless |
| c) Odour threshold | Not relevant |
| d) pH | No available data |
| e) Melting point/freezing point | No available data |
| f) Initial boiling point and boiling range | No available data |
| g) Flash point | No available data |
| h) Evaporation rate | No available data |
| i) Flammability (solid, gas) | No available data |
| j) Upper/lower flammability or explosive limit | No available data |
| k) Vapour pressure | No available data |
| l) Vapour density | No available data |
| m) Relative density (g/ml) v25°C | No available data |
| n) Water solubility: | Miscible with water |
| o) Partition coefficient | No available data |
| p) Auto-ignition temperature | No available data |
| q) Decomposition temperature | No available data |
| r) Viscosity | Not relevant |
| s) Explosive properties | Not relevant |
| t) Oxidising properties | Not relevant |

9.2 Other information

None relevant

10: Stability and Reactivity

10.1 Reactivity

No specific test data related to reactivity available for this product.

10.2 Chemical Stability

Stable under the recommended storage conditions (see section 7).

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

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Avoid humidity.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

When heated to high temperatures (decomposition) it emits toxic fumes such as oxides of carbon.

11: Toxicological Information

11.1 Information on toxicological effects acute toxicity

No available data for Diatabs tablets. See safety data sheet specific for the active substance.

| | |
|------------|---|
| Inhalation | Unlikely route of exposure. Dust may cause irritation to the airways. |
| Skin | May cause irritation. |
| Eyes | May cause irritation with redness. |
| Ingestion | May irritate the mucous membranes. |

The active substance contained in some of the Diatabs is an antimicrobial (according to the product number).

However, the amount of antimicrobial contained in each of the aforementioned Diatabs is so low that an allergic reaction due to its content is extremely unlikely.

Skin corrosion/irritation

No available data

Serious eye damage/irritation

No available data

Respiratory or skin sensitization

No available data

Germ cell mutagenicity

No available data

Carcinogenicity

There are no known carcinogenic chemicals in this product.

Reproductive toxicity

No available data

STOT-single exposure

No available data

STOT-repeated exposure

No available data

Aspiration hazard

No available data

Additional information

None

12: Ecological Information

12.1 Toxicity

No available data

12.2 Persistence and degradability

No available data

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12.3 Bioaccumulative potential

No available data

12.4 Mobility in soil

No available data.

12.5 Results of PBT and vPvB assessment

Ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

12.6 Other adverse effects

The active substances may have antibiotic effect and therefore cause a potential hazard to the environment.

13: Disposal Considerations

13.1 Waste treatment measures

Disposal should be according to local, state or national legislation. Dispose through authority facilities or pass to chemical disposal company.

EWC Code: 16 05 09 (tablets)
15 02 03 (paper contaminated with product)

14: Transport Information

14.1 UN number

Not applicable

14.2 UN proper shipping name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

14.5 Environmental hazards

Not applicable

14.6 Special precautions for user

No special precautions required

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

Not relevant.

15: Regulatory Information

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

This safety data sheet complies with the requirements of Regulation (EU) 1907/2006.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment (CSA) is not required.

16: Other Information

Training Advice

No special training required. However, the user should be well instructed in the execution of the task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

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R-phrases and hazard statements mentioned in section 2 and 3

| | |
|------------|---|
| R 22 | Harmful if swallowed |
| R 36/37/38 | Irritating to eyes, respiratory system and skin |
| H302 | Harmful if swallowed |
| H315 | Causes skin irritation |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |

Abbreviation

| | |
|------|---|
| CMR | Carcinogenicity, mutagenicity and reproductive toxicity |
| CSR | Chemical Safety Report |
| DNEL | Derived No-Effect Level |
| PNEC | Predicted No-Effect Concentration |
| STOT | Specific Target Organ Toxicity |
| EWC | European Waste Catalogue |
| PBT | Persistent, Bioaccumulative, Toxic |
| vPvB | very Persistent; very Bioaccumulative |

Additional information

The information provided on this Safety Data Sheet is correct to the best of our knowledge. The information given is intended only as a guide for safe handling, storage, processing, transport and disposal and is not to be considered as a warranty or quality specification. The information relates only to the specific product and cannot be used in combination with other products unless specified.