

## SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006.

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


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**1.1 Product identifier:**

Diagnostic Tablets – Diatabs 6 mm / 9 mm

**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

Phone: +45 - 43 99 33 77

DK-2630 Taastrup

Fax.: +45 - 43 52 73 74

Responsible person for the safety data sheet (e-mail): info@rosco.dk

**1.4 Emergency telephone:**

+45 - 43 99 33 77 (within office hours)

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**SECTION 2: Hazards identification**


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**2.1 Classification of the substance or mixture:**

ALTox a/s has concluded that the mixture is not to be classified according to 1999/45 or 1272/2008.

EC (67/548 or 1999/45): No classification.

CLP (1272/2008): No classification.

**2.2 Label elements:**

Safety data sheet available on request.

EUH 208: Contains "name of active substance". May produce an allergic reaction.

**2.3 Other hazards:** None known.

PBT/vPvB: The ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

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**SECTION 3: Composition/information on ingredients**


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**3.2 Mixtures:** Tablet containing Barium sulphate, Potato Starch, Povidone (Ph. Eur.), Magnesium Stearate, Talcum, Buffer, Colour and active substance;

| % w/w | Name               | CAS-no. | EC-no. | Index-no. | REACH-reg.no. | Classification   |
|-------|--------------------|---------|--------|-----------|---------------|--|
| 1-10  | Active substance * | *       | *      | -         | -             | EC: Xn;R22 Xi;R36/37/38<br>CLP: Acute Tox. 4;H302 Eye Irrit. 2;H319<br>STOT SE 3;H335 Skin Irrit. 2;H315 |
| < 0.5 | Active substance * | *       | *      | -         | -             | EC: R42/43<br>CLP: Resp. Sens. 1A;H334 Skin Sens. 1A;H317  |

\* Diagnostic Tablets - Diatabs contains active substance that differs (please see the label for indication of active substance).

Worst-case classification of active substance (relating to labelling) is R42/43 (Resp. Sens. 1A;H334 Skin Sens. 1A;H317)

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

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**SECTION 4: First-aid measures**


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**4.1 Description of first aid measures:**

Inhalation: Unlikely route of exposure. If accident occurs: Move the affected person to fresh air. Keep at rest. If symptoms persists: Seek medical advice.

Skin contact: Remove contaminated clothing. Wash skin with water and mild soap. If irritation persists: Seek medical advice.

Eye contact: Flush with water or physiological salt water for at least 5 minutes. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. In case of discomfort: Seek medical advice.

**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.

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**SECTION 5: Fire-fighting measures**


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**5.1 Extinguishing media:**

Carbon dioxide, 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, hazardous decomposition products may be formed, such as oxides of carbon.

**5.3 Advice for fire-fighters:**

When entering burning area: Wear self contained breathing apparatus.

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## SECTION 6: Accidental release measures

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**6.1 Personal precautions, protective equipment and emergency procedures:**

Use personal protective equipment - see section 8.

**6.2 Environmental precautions:**

Do not empty into drains - 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.

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## SECTION 7: Handling and storage

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**7.1 Precautions for safe handling:**

Avoid generation and spreading of dust. Avoid breathing dust. Provide efficient ventilation.

**7.2 Conditions for safe storage, including any incompatibilities:**

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

**7.3 Specific end use(s):**

See section 1.

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## SECTION 8: Exposure controls/Personal protection

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**8.1 Control parameters:**

Occupational exposure limits (EH40/2007): None.

DNEL/PNEC: No CSR.

**8.2 Exposure controls:**

Appropriate engineering controls: Provide efficient ventilation e.g. by working in a fume cupboard.

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.

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## SECTION 9: Physical and chemical properties

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**9.1 Information on basic physical and chemical properties:**

Appearance: Tablet (6 mm / 9 mm in diameter)

Odour: Odourless

Odour threshold: Not relevant

pH: No available data

Melting point/freezing point (°C): No available data

Initial boiling point and boiling range (°C): No available data

Decomposition temperature (°C): No available data

Flash point (°C): No available data

Evaporation rate (water = 1): No available data

Flammability (solid, gas): No available data

Upper/lower flammability or explosive limits (vol-%): No available data

Vapour pressure (mmHg, 20°C): No available data

Vapour density (Water = 1): No available data

Relative density (Water = 1): No available data

Solubility (water): Miscible with water.

Partition coefficient: n-octanol/water: No available data

Auto-ignition temperature (°C): No available data

Viscosity: Not relevant

Explosive properties: Not relevant

Oxidising properties: Not relevant

**9.2 Other information:**

None relevant.

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## SECTION 10: Stability and reactivity

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### 10.1 Reactivity:

No available information.

### 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:

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.

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## SECTION 11: Toxicological information

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### 11.1 Information on toxicological effects:

No available data for the tablets. Data for each active substance: See safety data sheet specific for the active substance.

Information on likely routes of exposure: Lungs, skin and gastrointestinal tract.

Symptoms:

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.

Chronic effects: Prolonged or frequent contact or inhalation can cause eczema and inflammation of the skin and airways.

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## SECTION 12: Ecological information

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### 12.1 Toxicity:

No available data for the tablets. Data for each active substance: See safety data sheet specific for the active substance.

### 12.2 Persistence and degradability:

No available data for the tablets. Data for each active substance: See safety data sheet specific for the active substance.

### 12.3 Bioaccumulative potential:

No available data for the tablets. Data for each active substance: See safety data sheet specific for the active substance.

### 12.4 Mobility in soil:

No available data for the tablets. Data for each active substance: See safety data sheet specific for the active substance.

### 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.

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## SECTION 13: Disposal considerations

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### 13.1 Waste treatment methods:

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

EWC-Code:

16 05 09 (tablets)

15 02 03 (paper contaminated with product).

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## SECTION 14: Transport information

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Not dangerous goods (ADR/RID).

14.1. UN-no.: None.

14.2. UN proper shipping name: None.

14.3. Transport hazard class(es): None.

14.4. Packing group: None.

14.5. Environmental hazards: None.

14.6. Special precautions for user: None.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not relevant.

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**SECTION 15: Regulatory information**

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

None.

**15.2. Chemical Safety Assessment:**

No CSR.

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**SECTION 16: Other information**

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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.  
R 42/43: May cause sensitisation by inhalation and skin contact.  
H302: Harmful if swallowed.  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.  
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H335: May cause respiratory irritation.

**Abbreviations:**

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.  
CSR = Chemical Safety Report  
DNEL = Derived No-Effect Level  
EC<sub>50</sub> = Effect Concentration 50 %  
FW = Fresh Water  
LC<sub>50</sub> = Lethal Concentration 50 %  
LD<sub>50</sub> = Lethal Dose 50 %  
PBT = Persistent, Bioaccumulative, Toxic  
PNEC = Predicted No-Effect Concentration  
vPvB = very Persistent, very Bioaccumulative

**Literature:**

EPA Ecotox = The US Environmental Protection Agency's database on ecotoxicological effects for chemicals.  
IUCLID = International Uniform Chemical Information Database.  
RTECS = Register of Toxic Effects of Chemical Substances.

**Training advice:**

No special training is 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.

**Changes since the previous edition:**

Section 1-16 (updating according to 453/2010)

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