

SAFETY DATA SHEET

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

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

1.1. Product identifier:

Diagnostic Tablets – Diatabs (used in liquids (C))

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)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

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

EC (67/548 or 1999/45): None.

CLP (1272/2008): None.

2.2. Label elements:

Safety data sheet available on request.

2.3. Other hazards:

None known.

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures:

Contains: Barium sulphate, Potato Starch, Povidone (Ph. Eur.), Polyplasdone, Buffering agents (phosphate or carbonate), Chelating agents (TRIS), Indicator (Bromocresol 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	*	*	-	-	EC: Xn;R22 Xi;R36/37/38 CLP: Acute Tox. 4;H302 Eye Irrit. 2;H319 STOT SE 3;H335 Skin Irrit. 2;H315

* Diagnostic Tablets – Diatabs contains active substance that differs (please see the label for exact substance name).

Worst-case classification of the active substance is EC: Xn;R22 Xi;R36/37/38 (CLP: Acute Tox. 4;H302 Eye Irrit. 2;H319 STOT SE 3;H335 Skin Irrit. 2;H315).

Wording of R-phrases and hazard 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. Keep at rest. If symptoms persist: 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.

Most important symptoms and effects, both acute and delayed:

May cause irritation of the skin, eyes and airways.

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:

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, the product may form hazardous decomposition products such as oxides of carbon.

5.3. Advice for fire-fighters:

When entering burning area: Wear self contained breathing apparatus.

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 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.

SECTION 7: Handling and storage

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 a well-closed original package. Dry and at room temperature. Keep protected from direct light and avoid high humidity. Keep out of the reach of children.

7.3. Specific end use(s):

See section 1.

SECTION 8: Exposure controls/Personal protection

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Appearance:	Tablet (6 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.

SECTION 10: Stability and reactivity

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.

SECTION 11: Toxicological information

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: None known.

SECTION 12: Ecological information

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.

SECTION 13: Disposal considerations

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).

SECTION 14: Transport information

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.

SECTION 15: Regulatory information

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

None.

15.2. Chemical Safety Assessment:

No CSR.

SECTION 16: Other information

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.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC₅₀ = Effect Concentration 50 %
FW = Fresh Water
LC₅₀ = Lethal Concentration 50 %
LD₅₀ = 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 his/her 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 REACH/CLP)

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