

EU Safety Data Sheet



According to Regulation (EU) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830

Date of issue/revision: September 01, 2016

1. Identification of the substance/preparation and of the company/undertaking

1.1 Identification of the substance or preparation

Cholesterol Standard

The reagent is part of the following catalogue numbers:

D95113B

D95114

D95114V

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

General use: Reagent for in-vitro diagnostics in human samples
For professional use only

1.3 Details of the supplier of the safety data sheet

Company name: Dialab Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Ges.m.b.H
Street: Hondastraße, Objekt M55, IZ-NÖ Süd
Postal code, city, state: A-2351 Wr. Neudorf, Österreich
World Wide Web: www.dialab.at
E-mail: office@dialab.at
Telephone: +43 (0)2236 660910-0
Telefax: +43 (0)2236 660910-30
Dept. responsible for information: +43 (0)2236 660910-0

1.4. Emergency telephone number

Vienna General Hospital, Toxication Centre, phone: +43-(0)1-4064343

2. Hazards identification

2.1 Classification of the substance or mixture:

Classification according to EC regulation 1272/2008 (CLP):

Eye Irrit. 2; H 319 Causes serious eye irritation.
Skin Sens. 1; H317 May cause an allergic skin reaction.

2.2 Label elements:

Labelling (CLP):



Signal Word:

Warning

Hazard statements:

H317
H319

May cause an allergic skin reaction.
Causes serious eye irritation.

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Precautionary statements: P264 Wash hands and face thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 IF ON SKIN: Wash with plenty of water/soap
P337+P313 If eye irritation persists: Get medical advice/attention.

Special labelling

Text for labelling: Contains 2-Chloracetamide and Isotridecanol, ethoxylated.

2.3 Other hazards:

May be harmful if inhaled. May be harmful if swallowed.

Results of PBT and vPvB assessment: No data available

3. Composition / information on ingredients

3.1 Substances not applicable

3.2 Mixtures

Chemical characterization (preparation): Aqueous solution of anorganic salts and organic compounds.

Hazardous ingredients:

<u>Ingredient</u>	<u>General name</u>	<u>Content</u>	<u>Classification</u>
EC No. 206-132-7 CAS 302-95-4	Sodium 3-alpha, 12-alpha-dihydroxy-5-beta-cholan-24-oate	5 – 10 %	Acute Tox. 4; H302. STOT SE 3; H335.
EC No. 500-027-2 CAS 9043-30-5	Isotridecanol, ethoxylated	< 3 %	Acute Tox. 4; H302. Eye Dam. 1; H318.
EC No. 201-174-2 CAS 79-07-2	2-Chloracetamide	0.1 – 1 %	Acute Tox. 3; H301. Skin Sens. 1; H317. Repr. 2; H361f.

Full text of H- and EUH-statements: see section 16.

Additional information:

Contains sodium azide (0.95 g/L) as preservative.

4. First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.
Following skin contact: Take off contaminated clothing and wash it before reuse.
After contact with skin, wash immediately with plenty of water.
In case of skin reactions, consult a physician.
After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.
After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice.
Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

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4.2 Most important symptoms and effects, both acute and delayed

May cause sensitization by skin contact.
Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be liberated: Chlorine decomposition products, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information:

Hazchem-Code: -

Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid contact with skin, eyes and clothing. Take off contaminated clothing and wash it before reuse. Wear suitable protective clothing.
Have eye wash bottle or eye rinse ready at work place.
In enclosed areas: Provide fresh air.

6.2 Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

7. Handling and storage

7.1 Precautions for safe handling:

Advices on safe handling:

Provide adequate ventilation and local exhaust as needed.
Avoid contact with skin and eyes.
Take off contaminated clothing and wash it before reuse.

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Keep all containers, equipment and working place clean.
Wear appropriate protective equipment.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between +2 °C and +25 °C. Protect from light. Keep sterile.

Storage class:

12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

8. Exposure controls/personal protection

8.1 Control parameters

Additional information:

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: If vapours form, use respiratory protection.

Use combination filter type A/P according to EN 14387.

Hand protection:

Protective gloves according to EN 374.

Glove material: Nitrile rubber – breakthrough time: > 480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:

Tightly sealed goggles according to EN 166.

Body protection:

Lab coat.

General protection and hygiene measures:

Avoid contact with skin, eyes, and clothing. Take off contaminated clothing and wash it before reuse. Do not breathe vapours. Wear appropriate protective equipment.

Have eye wash bottle or eye rinse ready at work place. Wash hands before breaks and after work.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:

Form: liquid

Colour: colourless, clear
characteristic

Odour:

no data available

Odour threshold:

at 25 °C: 8.5

pH value:

Melting point/freezing point:

no data available

Initial boiling point and boiling range:

no data available

Flash point/flash point range:

not combustible.

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<u>Evaporation rate:</u>	no data available
<u>Flammability:</u>	no data available
<u>Explosion limits:</u>	no data available
<u>Vapour pressure:</u>	no data available
<u>Vapour density:</u>	no data available
<u>Density:</u>	at 20 °C: 1.028 g/mL
<u>Water solubility:</u>	completely miscible
<u>Partition coefficient n-octanol/water:</u>	no data available
<u>Auto-ignition temperature:</u>	no data available
<u>Decomposition demperature:</u>	no data available
<u>Viscosity, kinematic:</u>	no data available
<u>Explosive properties:</u>	no data available
<u>Oxidizing characteristics:</u>	no data available

9.2 Other information

Additional information: No data available

10. Stability and reactivity

10.1 Reactivity

Refer to 10.3.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat/sun rays.

10.5 Incompatible materials

Strong acids and alkalis

10.6 Hazardous decomposition products

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be liberated: Chlorine decomposition products, nitrogen oxides (NO_x), carbon monoxide and carbon dioxide.

Thermal decomposition: No data available

11. Toxicological information

11.1 Information on toxicological effects

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.
Acute toxicity (oral): Based on available data, the classification criteria are not met.
ATEmix (calculated): 2000 < ATE <= 5000 mg/kg.
Acute toxicity (dermal): Lack of data
Acute toxicity (inhalative): Based on available data, the classification criteria are not met.
Skin corrosion/irritation: Lack of data
Eye damage/irritation: Eye Irrit. 2; H319 = Causes serious eye irritation.

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Sensitisation to the respiratory tract: Lack of data
Skin sensitisation: Skin Sens. 1; H317 = may cause an allergic skin reaction.
Germ cell mutagenicity/Genotoxicity: Lack of data
Carcinogenicity: Lack of data
Reproductive toxicity: Lack of data
Effects on or via lactation: Lack of data
Specific target organ toxicity (single exposure): Lack of data
Specific target organ toxicity (repeated exposure): Lack of data
Aspiration hazard: Lack of data

Other information: Information about Sodium 3-alpha, 12-alpha-dihydroxy-5-beta-cholan-24-oate:
LD50 rat, oral: 1370 mg/kg
Contains sodium azide (0.95 g/L):
After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

12. Ecological information

12.1 Toxicity

Water Hazard Class: 1 = slightly hazardous to water

12.2 Persistence and degradability

Further details: No data available.

12.3 Bioaccumulative potential

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

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

General information: Contains surfactants: Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

13.1 Waste treatment methods

Product:

Waste key number: 06 05 06 = Laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

Contaminated packaging:

Waste key number: 15 01 02 = Plastic packaging; 15 01 07 = Glass packaging.
Recommendation: Dispose of waste according to applicable legislation.

Non-contaminated containers may be recycled.

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14. Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR: not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR: not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR: not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR: not applicable

14.5 Environmental hazards

Marine Pollutant: No

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

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

No data available

15. Regulatory information

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

National regulations – Great Britain:

Hazchem-Code: -

National regulations – Germany:

Storage Class: 12 = Non-combustible liquids

Water Hazard Class: 1 = slightly hazardous to water

15.2 Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information

Further information

Wording of the H-phrases under paragraph 2 and 3:

H301 = Toxic if swallowed.

H302 = Harmful if swallowed.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H335 = May cause respiratory irritation.

H361f = Suspected of damaging fertility.

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Reason of change: Changes in section 2 (classification), 3 (information on ingredients classification Sodium 3-alpha, 12-alpha-dihydroxy-5- β -cholan-24-oate), 4, 6, 7, 11, 12, 15, 16

Group that issues data sheet

Contact person: see section 1, department responsible for information.

For abbreviations and acronyms, see; ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

The information in this data sheet has been established to our best knowledge and was up-to-date of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

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