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

1.1 Product identifier

Trade name: Cholesterol Standard FS
As part of the kits: 1 1300 XX XX 030
(The positions X code different packages.)

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: DiaSys Diagnostic Systems GmbH
Street/POB-No.: Alte Strasse 9
Postal Code, city: 65558 Holzheim
WWW: http://www.diasys.de
E-mail: mail@diasys.de
Telephone: +49 (0) 6432-9146-0
Telefax: +49 (0) 6432-9146-32

Department responsible for information:
Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: mail@diasys.de

1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

Eye Irrit. 2; H319 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 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements:
P264 Wash hands and face thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye 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

SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution of inorganic salts and organic compounds.

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 206-132-7 CAS 302-95-4	Sodium 3-alpha,12-alpha-dihydroxy-5-ß-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.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: If medical advice is needed, have product container or label at hand.

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. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently 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.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according to 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 compounds, nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus. Wear suitable protective clothing.

Additional information: Hazchem-Code: -

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

SECTION 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. Do not breathe vapours.

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, siliceus 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Have eye wash bottle or eye rinse ready at work place.

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 8 °C. Protect from light. Keep sterile.

7.3 Specific end use(s)

No information available.

SECTION 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: Wear suitable protective clothing.

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Colour: colourless, clear
Odour:	no characteristic odour
Odour threshold:	No data available
pH:	at 25 °C: 8.5
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 °C: 1.028 g/mL
Water solubility:	completely miscible

Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available

9.2 Other information

Additional information: No data available

SECTION 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

No decomposition when used properly.

Thermal decomposition: No data available

SECTION 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.

Serious eye damage/irritation: Eye Irrit. 2; H319 = Causes serious eye irritation.

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-ß-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.

Symptoms

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

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.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 05 06* = Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.
* = Evidence for disposal must be provided.

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

Package

Waste key number: 15 01 02 = Plastic packaging

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

SECTION 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 and the IBC Code

No data available

SECTION 15: Regulatory information

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

National regulations - Great Britain

Hazchem-Code: -

No data available

National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 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.

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
AS/NZS: Australian Standards/New Zealand Standards
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
CNS: Central Nervous System
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EN: European Standard
EU: European Union
IATA: International Air Transport Association
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
LD50: Lethal dose 50%
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
STOT SE: Specific target organ toxicity - single exposure
vPvB: Very persistent and very bioaccumulative
CNS: Central Nervous System

Reason of change: General revision
Date of first version: 4/3/2008

Department issuing data sheet

Contact person: see section 1: Department responsible for information

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