SAFETY DATA SHEET

Release Date: 08-07-2015, Revision 2.0

REF Number	Name
16002A	**Bile Acids Controls (2 levels) 2x(2x3) mL**

COMPOSITION:

1) Bile Acids TBA CONTROL 1/2 Lyo x 3 mL (pag. 2)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Mixture identification:

Trade name: Bile Acids TBA CONTROL 1/2 Lyo x 3 mL

Trade code: 27002X/Y

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

Recommended use:

For In Vitro Diagnostic use only.

For professional users only.

1.3. Details of the supplier of the safety data sheet

Company:

SENTINEL CH. SpA - Via Robert Koch 2 - 20152 Milan - Italy

SENTINEL CH. SpA - Phone n. [(+)39] 02 3455 141 working time.

Competent person responsible for the safety data sheet:

customerservice@sentinel.it

1.4. Emergency telephone number

SENTINEL CH. SpA - Phone n. [(+)39] 02 3455 1495 working time: Mon-Fri 9.00 am - 1.00 pm, 2.00 pm - 6.00 pm

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Symbols:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards:

ATTENTION: For the production of preparation has been used serum of human origin. The serum has been controlled with approved reagents and has proved negative for HBsAg, HCV and antibody anti-HIV1 and anti- HIV2. Neverthless as no test is able to assure that products from human origin do not imply the risk of transmitting infectious agents we recommend to treat this product with the same cautions used for each material of human origin.

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

N.A.

vPvB Substances: None - PBT Substances: None

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number		Classification
48 ppm	MIT (Metil-Isotiazolone Cloridrato)	CAS: EC:	26172-54-3 247-499-3	3.1/3/Inhal Acute Tox. 3 H331

		REACH No.: 247-499-33	3.1/4/Oral Acute Tox. 4 H302 3.2/1A Skin Corr. 1A H314 3.8/3 STOT SE 3 H335 4.1/A1 Aquatic Acute 1 H400 3.4.1/1-1A-1B Resp. Sens. 1,1A,1B H334 3.4.2/1-1A-1B Skin Sens. 1,1A,1B H317

4. FIRST AID MEASURES

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

In case of Ingestion:

Get Medical advice/attention if you feel unwell.

In case of Inhalation:

Remove victim to fresh air and keep at rest in a position comfortable for breathing.

4.2. Most important symptoms and effects, both acute and delayed

None

4.3. Indication of any immediate medical attention and special treatment needed

Treatment:

None

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Remove all sources of ignition.

Remove persons to safety.

See protective measures under point 7 and 8.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.
Do not eat or drink while working.
See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

2 - 8°C
Keep away from food, drink and feed.
Incompatible materials:
None in particular.
Instructions as regards storage premises:
Adequately ventilated premises.

7.3. Specific end use(s)

None in particular

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit available

DNEL Exposure Limit Values

N.A.

PNEC Exposure Limit Values

N.A.

8.2. Exposure controls

Eye protection:

Eye glasses.

Protection for skin:

Lab coat.

Protection for hands:

One-time gloves.

Respiratory protection:

Not needed for normal use.

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes:
Appearance and colour:	Pale yellow lyophile	--	--
Odour:	Odorless	--	--
Odour threshold:	N.A.	--	--
pH:	7.5 (after reconsitution)	--	--
Melting point / freezing point:	N.A.	--	--
Initial boiling point and boiling range:	N.A.	--	--
Flash point:	N.A.	--	--
Evaporation rate:	N.A.	--	--
Solid/gas flammability:	N.A.	--	--
Upper/lower flammability or explosive limits:	N.A.	--	--
Vapour pressure:	N.A.	--	--
Vapour density:	N.A.	--	--
Relative density:	1.038 (after	--	--

	reconsitution)		
Solubility in water:	Soluble	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient (n-octanol/water):	N.A.	--	--
Auto-ignition temperature:	N.A.	--	--
Decomposition temperature:	N.A.	--	--
Viscosity:	N.A.	--	--
Explosive properties:	N.A.	--	--
Oxidizing properties:	N.A.	--	--

9.2. Other information

Properties	**Value**	**Method:**	**Notes:**
Miscibility:	N.A.	--	--
Fat Solubility:	N.A.	--	--
Conductivity:	N.A.	--	--
Substance Groups relevant properties	N.A.	--	--

10. STABILITY AND REACTIVITY

10.1. Reactivity
No hazardous reactions known.
10.2. Chemical stability
Stable when properly stored.
10.3. Possibility of hazardous reactions
None
10.4. Conditions to avoid
Stable under normal conditions.
10.5. Incompatible materials
None in particular.
10.6. Hazardous decomposition products
None.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
Toxicological information of the mixture:
N.A.
Toxicological information of the main substances found in the mixture:
MIT (Metil-Isotiazolone Cloridrato) - CAS: 26172-54-3
b) skin corrosion/irritation:
Test: Skin Corrosive - Route: Skin Positive
c) serious eye damage/irritation:
Test: Eye Corrosive - Route: Inhalation Dust Positive
d) respiratory or skin sensitisation:
Test: Respiratory Sensitization - Route: Inhalation Positive
Test: Skin Sensitization - Route: Skin Positive

If not differently specified, the information required in Regulation 453/2010/EC listed below must be considered as N.A.:

a) acute toxicity;
b) skin corrosion/irritation;
c) serious eye damage/irritation;
d) respiratory or skin sensitisation;
e) germ cell mutagenicity;
f) carcinogenicity;
g) reproductive toxicity;
h) STOT-single exposure;
i) STOT-repeated exposure;

j) aspiration hazard.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
Adopt good working practices, so that the product is not released into the environment.
Do not use when plants are in flower: the product is toxic for bees.
N.A.

12.2. Persistence and degradability
None
N.A.

12.3. Bioaccumulative potential
N.A.

12.4. Mobility in soil
N.A.

12.5. Results of PBT and vPvB assessment
vPvB Substances: None - PBT Substances: None

12.6. Other adverse effects
None

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods
Recover if possible. In so doing, comply with the local and national regulations currently in force.

14. TRANSPORT INFORMATION

14.1. UN number
Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name
N.A.

14.3. Transport hazard class(es)
N.A.

14.4. Packing group
N.A.

14.5. Environmental hazards
N.A.

14.6. Special precautions for user
N.A.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
N.A.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Dir. 67/548/EEC (Classification, packaging and labelling of dangerous substances). Dir. 99/45/EEC (Classification, packaging and labelling of dangerous preparations). Dir. 98/24/EC (Risks related to chemical agents at work). Dir. 2000/39/EC (Occupational exposure limit values); Dir. 2006/8/CE. Regulation (CE) n. 1907/2006 (REACH), Regulation (CE) n.1272/2008 (CLP), Regulation (CE) n.790/2009.
Where applicable, refer to the following regulatory provisions :
Directive 2003/105/CE ('Activities linked to risks of serious accidents') and subsequent amendments.
Regulation (EC) nr 648/2004 (detergents).
1999/13/EC (VOC directive)

Provisions related to directives 82/501/EC(Seveso), 96/82/EC(Seveso II):
N.A.

15.2. Chemical safety assessment
No

16. OTHER INFORMATION

Full text of phrases referred to in Section 3:
H331 Toxic if inhaled.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

This document was prepared by a competent person who has received appropriate training.
Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold
CCNL - Appendix 1
Insert further consulted bibliography

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