

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

1.1 Product identifier

Trade name: Bile Acids Quality Control Samples QC1

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

Application of the substance / the mixture

Quality control material (lyophilized)

For research use only. Not for use in diagnostic procedures.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

biocrates life sciences ag

Eduard-Bodem-Gasse 8

A-6020 Innsbruck

T: +43 512 57 98 23

F: +43 512 57 98 23 329

Further information obtainable from: Email: office@biocrates.com

1.4 Emergency telephone number:

+43 512 57 98 23

Available during office hours:

Mo-Fr: 9 a.m. - 5 p.m.

Call the national emergency number!

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 void

Hazard pictograms void

Signal word void

Hazard statements void

Additional information:

100 % of the mixture consists of component(s) of unknown toxicity.

Contains 100 % of components with unknown hazards to the aquatic environment.

2.3 Other hazards

The product contains not fully tested substances and must be used with the required caution.

May irritate eyes and skin.

Results of PBT and vPvB assessment

PBT: No data available.

vPvB: No data available.

Determination of endocrine-disrupting properties

The product does not contain substances with endocrine-disrupting properties ≥ 0.1 % (w/w).

(Contd. on page 2)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components: void

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of discomfort or doubt, seek medical advice.

If unconscious, use a stable lateral position and do not administer anything through mouth.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Wash with plenty of soap and water.

Seek medical treatment in case of complaints.

After eye contact:

Rinse opened eye for several minutes under running water.

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

Seek medical treatment in case of complaints.

After swallowing:

Rinse mouth.

Do not induce vomiting; call for medical help immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Depending on the condition of the patients, the doctor must assess the symptoms and the overall general condition.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

CO_x

Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

(Contd. on page 3)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 2)

Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Restricted access to the affected area until cleaning work is completed.

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

Avoid contact with skin and eyes.

Avoid formation of dust.

Avoid breathing dust.

Keep away from ignition sources.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Avoid the formation of dust.

Dispose of the material collected according to regulations.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

The product contains not fully tested substances and must be used with the required caution.

Keep receptacles tightly sealed.

Avoid contact with skin and eyes.

Prevent formation of dust.

Avoid breathing dust.

Use personal protective equipment as required.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities**Storage:****Requirements to be met by storerooms and receptacles:**

Store in a dry, cool, well-ventilated area.

Store in accordance with local/regional/national/international regulations.

Information about storage in one common storage facility:

Store away from oxidising agents.

Store away from foodstuffs.

Further information about storage conditions:

Store in dry conditions.

Keep container tightly sealed.

Storage class: 11

(Contd. on page 4)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 3)

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

DNELs No data available.

PNECs No data available.

Regulatory information

Additional Occupational Exposure Limit Values for possible hazards during processing:

The national dust limits must be observed in the event of dust generation.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls No further data; see section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Do not eat, drink, smoke or sniff while working.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Avoid breathing dust.

Prevent formation of dust.

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

Hand protection



Protective gloves

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 4)

Eye/face protection



Tightly sealed goggles

Body protection: Protective work clothing

Environmental exposure controls Do not allow to enter sewers/ surface or ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	Solid
Colour:	Yellowish
Odour:	Characteristic
Odour threshold:	No information available.
Melting point/freezing point:	No information available.
Boiling point or initial boiling point and boiling range	No information available.
Flammability	No information available.
Lower and upper explosion limit	
Lower:	No information available.
Upper:	No information available.
Flash point:	Not applicable.
Decomposition temperature:	No information available.
pH	Not applicable.
Viscosity:	
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	No information available.
Partition coefficient n-octanol/water (log value)	No information available.
Vapour pressure:	Not applicable.
Density and/or relative density	
Density:	No information available.
Relative density	No information available.
Vapour density	Not applicable.
Particle characteristics	
See section 3.	

9.2 Other information

Appearance:

Form: Solid

(Contd. on page 6)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 5)

Important information on protection of health and environment, and on safety.

Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
VOC (EC)	0.00 %
Change in condition	
Softening point/range	
Oxidising properties	No information available.
Evaporation rate	No information available.

Information with regard to physical hazard classes

Explosives	void
Flammable gases	void
Aerosols	void
Oxidising gases	void
Gases under pressure	void
Flammable liquids	void
Flammable solids	void
Self-reactive substances and mixtures	void
Pyrophoric liquids	void
Pyrophoric solids	void
Self-heating substances and mixtures	void
Substances and mixtures, which emit flammable gases in contact with water	void
Oxidising liquids	void
Oxidising solids	void
Organic peroxides	void
Corrosive to metals	void
Desensitised explosives	void

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions

As the product is supplied it is not capable of dust explosion; however enrichment with fine dust causes risk of dust explosion.

10.4 Conditions to avoid No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No dangerous decomposition products known.

(Contd. on page 7)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 6)

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

The product contains not fully tested substances and must be used with the required caution.

100 % of the mixture consists of component(s) of unknown toxicity.

Acute toxicity Based on available data, the classification criteria are not met.

Skin corrosion/irritation May be irritating to skin.

Serious eye damage/irritation May be irritating to eyes.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Contains 100 % of components with unknown hazards to the aquatic environment.

May be harmful to aquatic organisms.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: No data available.

vPvB: No data available.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Additional ecological information:

General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

(Contd. on page 8)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 7)

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Only dispose of product residues via authorised companies according to local legislation.

European waste catalogue

Notes: The European Waste Catalogue (EWC) classifies waste materials and categorises them according to what they are and how they were produced. This may cause other classifications. The final decision belongs to the last user.

16 03 06	organic wastes other than those mentioned in 16 03 05
----------	---

Uncleaned packaging:

Recommendation:

Dispose of packaging according to regulations on the disposal of packagings.
Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN, ADN, IMDG, IATA not regulated

14.2 UN proper shipping name

ADR/RID/ADN, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR/RID/ADN, ADN, IMDG, IATA

Class not regulated

14.4 Packing group

ADR/RID/ADN, IMDG, IATA not regulated

14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user Not applicable.

14.7 Maritime transport in bulk according to IMO

instruments Not applicable.

UN "Model Regulation": not regulated

SECTION 15: Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

(Contd. on page 9)

Trade name: Bile Acids Quality Control Samples QC1

(Contd. of page 8)

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

National regulations:

Information about limitation of use: Employment restrictions concerning juveniles must be observed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

* **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

Department issuing SDS:

UmEnA GmbH

<http://umena.at>

Email: office@umena.at

Date of previous version: 11.09.2023

Version number of previous version: 1.6

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

* **Data compared to the previous version altered.**