

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

1.1 Product identifier

Trade name: Bile Acids Kit Calibration Standards 1-7

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

Application of the substance / the mixture

Calibration standards (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

2.3 Other hazards

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).

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components: void

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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: Rinse skin with water.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

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

No further relevant information available.

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.

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 breathing dust.

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.

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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.

Keep receptacles tightly sealed.

Avoid contact with skin and eyes.

Prevent formation of dust.

Do not breathe 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 accordance with local/regional/national/international regulations.

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

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Store in dry conditions.

Keep container tightly sealed.

Storage class: 11

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.

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Avoid contact with the eyes and skin.
Avoid breathing 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: Wear respiratory protection during dust formation.

Hand protection Protective gloves recommended.

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.

Eye/face protection Safety glasses

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:	White
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.

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Vapour density Not applicable.

Particle characteristics

See section 3.

9.2 Other information

Appearance:

Form: Solid

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.

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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.

Reacts with strong oxidising agents.

Reacts with alkali (lyes).

Reacts with acids.

10.4 Conditions to avoid No further relevant information available.

10.5 Incompatible materials:

Acids, alkalis

strong oxidizing agents

10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

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

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation 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: No further relevant information available.

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 2 (German Regulation) (Self-assessment): hazardous for water

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Do not allow product to reach ground water, water course or sewage system.

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
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Uncleaned packaging:**Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.
 Packagings that may not be cleansed are to be disposed of in the same manner as the product.

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.

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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.

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:** 1.5**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.**