

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

1.1 Product identifier

Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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

Application of the substance / the mixture

Internal standard mixture (dried).

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

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

Additional information: For the wording of the hazard categories, see section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS09

Signal word Warning

Hazard statements

H410 Very toxic to aquatic life with long lasting effects.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

(Contd. of page 1)

Precautionary statements

P273 Avoid release to the environment.

P391 Collect spillage.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

36.3 % of the mixture consists of component(s) of unknown toxicity.

Contains 36.3 % 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

CAS: 128-37-0 Butylhydroxytoluene

List II


SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

[% (w/w)]

CAS: 128-37-0 EINECS: 204-881-4 RTECS: GO 7875000 Reg.nr.: 01-2119555270-46-XXXX	Butylhydroxytoluene  Aquatic Acute 1, H400; Aquatic Chronic 1, H410	> 50 – ≤ 100%
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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:

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.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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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

Combustible.

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.

Additional information

Collect contaminated fire fighting water separately. It must not enter the sewage system.

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:

Inform respective authorities in case of seepage into water course or sewage system.

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

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Avoid the formation of dust.

Dispose contaminated material as waste according to section 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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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.

Avoid breathing dust.

Use personal protective equipment as required.

Information about fire - and explosion protection: Keep ignition sources away - Do not smoke.**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: Store away from oxidising agents.**Further information about storage conditions:**

Protect from heat and direct sunlight.

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:**

Observe the member state specific regulations!

CAS: 128-37-0 Butylhydroxytoluene

MAK (Austria)	Long-term value: 10 mg/m ³
AGW (Germany)	Long-term value: 10 E mg/m ³ 4 (II); DFG, Y, 11
LEP (Spain)	Long-term value: 10 mg/m ³
VLEP (France)	Long-term value: 10 mg/m ³
WEL (Great Britain)	Long-term value: 10 mg/m ³
TWA (Italy)	Long-term value: 2 mg/m ³ A4, (i, h)

Regulatory information

MAK (Austria): GKV 2020, 156. Verordnung, 09.04.2021, Teil II

AGW (Germany): TRGS 900

LEP (Spain): Límites de exposición profesional para agentes químicos

VLEP (France): ED 1487 26.04.2024

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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WEL (Great Britain): EH40/2020

TWA (Italy): Valori Limite di Soglia

DNELs**CAS: 128-37-0 Butylhydroxytoluene**

Oral	Long-term exposure - systemic effects	0.25 mg/kg bw/d (consumer)
Dermal	Long-term exposure - systemic effects	0.25 mg/kg bw/d (consumer)
		0.5 mg/kg bw/d (workers)
Inhalative	Long-term exposure - systemic effects	0.435 mg/m ³ (consumer)
		1.76 mg/m ³ (workers)

PNECs**CAS: 128-37-0 Butylhydroxytoluene**

fresh water	0.199 µg/l
sea water	0.02 µg/l
intermittent release (fresh water)	1.99 µg/l
STP	0.017 mg/l
sediment (fresh water)	0.458 mg/kg dw
sediment (sea water)	0.046 mg/kg dw
soil	0.054 mg/kg dw
oral	16.67 mg/kg food

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.

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.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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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.

Eye/face protection



Tightly sealed goggles

Body protection: Protective work clothing

Environmental exposure controls

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

Inform respective authorities in case of seepage into water course or sewage system.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state

Solid

Colour:

Colourless

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 determined.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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Viscosity:

Kinematic viscosity

Not applicable.

Dynamic:

Not applicable.

Solubility

water:

No information available.

Partition coefficient n-octanol/water (log value)

No information available.

128-37-0	Butylhydroxytoluene	5,03 log Kow
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Vapour pressure:

No information available.

Density and/or relative density

Density:

No information available.

Vapour density

No information available.

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 %

Solids content:

100.0 %

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

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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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.

Violent reactions with:

Alkalis, base, oxidizing agents, peroxides, acid chlorides inorganic, strong acids

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Protect from exposure to the light.

10.5 Incompatible materials: No further relevant information available.

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

36.3 % of the mixture consists of component(s) of unknown toxicity.

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

LD/LC50 values relevant for classification:

CAS: 128-37-0 Butylhydroxytoluene

Oral LD50 > 6,000 mg/kg (rat)

Dermal LD50 > 2,000 mg/kg (rat)

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

CAS: 128-37-0 Butylhydroxytoluene

List II

(Contd. on page 9)

Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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SECTION 12: Ecological information**12.1 Toxicity****Aquatic toxicity:**

Contains 36.3 % of components with unknown hazards to the aquatic environment.

CAS: 128-37-0 Butylhydroxytoluene

LC50 (96 h)	1.1 mg/l (fish) (<i>Oryzias latipes</i>)
LC50 (48 h)	0.84 mg/l (daphnia) (<i>Daphnia magna</i>)
EC50 (96 h)	> 7 mg/l (algae) (<i>Pseudokirchneriella subcapitata</i>)
NOEC (21 d)	0.069 mg/l (daphnia) (<i>Daphnia magna</i>)

12.2 Persistence and degradability No further relevant information available.**12.3 Bioaccumulative potential**

128-37-0	Butylhydroxytoluene	5,03 log Kow
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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** For information on endocrine disrupting properties see section 11.**12.7 Other adverse effects****Remark:** Very toxic for fish**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.

Danger to drinking water if even extremely small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Very toxic to aquatic life with long lasting effects.

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 05*	organic wastes containing hazardous substances
HP14	Ecotoxic

Uncleaned packaging:**Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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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, IMDG, IATA

UN3077

14.2 UN proper shipping name

ADR/RID/ADN

3077 ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (Butylhydroxytoluene)
ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
SOLID, N.O.S. (Butylhydroxytoluene), MARINE
POLLUTANT

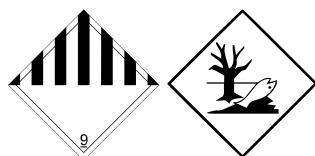
IMDG

IATA

ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
SOLID, N.O.S. (Butylhydroxytoluene)

14.3 Transport hazard class(es)

ADR/RID/ADN, IMDG, IATA



Class

9 Miscellaneous dangerous substances and articles.

Label

9

14.4 Packing group

ADR/RID/ADN, IMDG, IATA

III

14.5 Environmental hazards:

Marine pollutant:

Symbol (fish and tree)

Special marking (ADR/RID/ADN):

Symbol (fish and tree)

Special marking (IATA):

Symbol (fish and tree)

14.6 Special precautions for user

Warning: Miscellaneous dangerous substances and
articles.

Hazard identification number (Kemler code):

90

EMS Number:

F-A,S-F

Stowage Category

A

Stowage Code

SW23 When transported in BK3 bulk container, see
7.6.2.12 and 7.7.3.9.

**14.7 Maritime transport in bulk according to IMO
instruments**

Not applicable.

Transport/Additional information:

ADR/RID/ADN

Limited quantities (LQ)

5 kg

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

Transport category

3

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

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Tunnel restriction code

(-)

IMDG

Limited quantities (LQ)

5 kg

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

UN "Model Regulation":

UN 3077 ENVIRONMENTALLY HAZARDOUS
S U B S T A N C E , S O L I D , N . O . S .
(BUTYLHYDROXYTOLUENE), 9, III

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.

Seveso category E1 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t

Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

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.

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.

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Trade name: Bile Acids Kit Internal Standard Mix (ISTD)

(Contd. of page 11)

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

Relevant phrases

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Training hints

Before handling, storage or use for the first time, employees must be informed about the properties of the substance and about measures taken to ensure safety and environmental protection.

Regular training of staff involved in the transport of dangerous goods (in accordance with Chapter 1.3 ADR).

Classification according to Regulation (EC) No 1272/2008

Hazardous to the aquatic environment - short-term (acute) aquatic hazard
 Hazardous to the aquatic environment - long-term (chronic) aquatic hazard

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

ATE: Acute toxicity estimate values

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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