

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 1 of 8

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

1.1. Product identifier

Ezetimibe phenoxy-beta-D-glucuronide

Further trade names

Ezetimibe phenoxy-beta-D-glucuronide

CAS No: 190448-57-8

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

Use of the substance/mixture

Laboratory chemical. Manufacture of the substance.

Uses advised against

Do not use for private purposes (household).

1.3. Details of the supplier of the safety data sheet

Company name: Iris Biotech GmbH
Street: Adalbert-Zoellner-Straße 1
Place: D-95615 Marktredwitz, Germany
Post-office box: 568
D-95605 Marktredwitz, Germany

Telephone: +49 9231 97121 0
e-mail: info@iris-biotech.de
Internet: www.iris-biotech.de

Telefax: +49 9231 97121 99

1.4. Emergency telephone number:

+49 (0)89 19240

Further Information

This product does not meet the criteria for classification into a hazardous class according to Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures. A safety data sheet is provided which does not fully comply with Article 31 and Annex II of REACH.

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This substance is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements

Regulation (EC) No. 1272/2008

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Additional advice on labelling

Warning - substance not yet tested completely.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 2 of 8

3.1. Substances

Chemical characterization

Ezetimibe phenoxy-beta-D-glucuronide

Sum formula: C₃₀H₂₉F₂NO₉

Molecular weight: 585,55 g/mol

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air. Remove casualty to fresh air and keep warm and at rest. In case of irregular breathing or respiratory arrest provide artificial respiration.

In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse. After contact with skin, wash immediately with plenty of water and soap.

In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person or a person with cramps.

In all cases of doubt, or when symptoms persist, seek medical advice.

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

No information available.

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

Co-ordinate fire-fighting measures to the fire surroundings. Water spray. alcohol resistant foam. Dry extinguishing powder. Carbon dioxide (CO₂). Sand.

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Non-flammable. Thermal decomposition can lead to the escape of irritating gases and vapours.

In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide (CO). Nitrogen oxides (NO_x).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Usual measures for fire prevention.

SECTION 6: Accidental release measures

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 3 of 8

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Provide adequate ventilation. Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact with skin, eyes and clothes.
Wear personal protection equipment.
In case of fire: Evacuate area.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation.
Clear contaminated areas thoroughly.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Provide adequate ventilation.
Avoid dust formation. Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact with skin, eyes and clothes.

Advice on protection against fire and explosion

Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep container tightly closed in a cool, well-ventilated place.
Handle and store contents under inert gas. Protect from moisture.
storage temperature: -20°C

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Protective and hygiene measures

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. Provide adequate ventilation. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Eye/face protection

Wear eye protection/face protection.

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 4 of 8

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Wear suitable gloves.

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

Environmental exposure controls

Discharge into the environment must be avoided.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid Powder	
Colour:	white/ whitish	
Odour:	No data available	
pH-Value:		not determined

Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Flash point:	No data available
Sustaining combustion:	No data available

Flammability

Solid:	not determined
Gas:	not applicable

Explosive properties

The product is not: Explosive. No data available

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	not determined

Auto-ignition temperature

Solid:	not determined
Gas:	not applicable

Decomposition temperature:	not determined
----------------------------	----------------

Oxidizing properties

No data available

Vapour pressure:	not determined
Density:	not determined
Water solubility:	No data available

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 5 of 8

Solubility in other solvents

not determined

Partition coefficient:

not determined

Vapour density:

not determined

Evaporation rate:

not determined

Solvent content:

No data available

9.2. Other information

Solid content:

not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Protect from moisture.

Keep away from heat.

10.5. Incompatible materials

Oxidizing agents, strong.

10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours.

In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide (CO). Nitrogen oxides (NO_x).

Further information

In case of fire: See chapter 5.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicokinetics, metabolism and distribution

No data available

Acute toxicity

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

Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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.

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 6 of 8

Aspiration hazard

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

Specific effects in experiment on an animal

No data available

Additional information on tests

The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

Practical experience

Observations relevant to classification

No data available

Further information

RTECS: No data available

Caution! To the best of our knowledge the toxicological properties of this material have not been thoroughly investigated.

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6. Other adverse effects

Warning - substance not yet tested completely.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

Consult the appropriate local waste disposal expert about waste disposal.

Handle contaminated packages in the same way as the substance itself.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.2. UN proper shipping name:

No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)

14.2. UN proper shipping name:

No dangerous good in sense of these transport regulations.

Marine transport (IMDG)

14.2. UN proper shipping name:

No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 7 of 8

14.2. UN proper shipping name: No dangerous good in sense of these transport regulations.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No information available.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water contaminating class (D): - - not water contaminating

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport 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 Harmonized 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
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules

according to Regulation (EC) No 1907/2006

Ezetimibe phenoxy-beta-D-glucuronide

Revision date: 06.05.2019

Product code: GBB1655

Page 8 of 8

MFAG: Medical First Aid Guide

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.