

Safety Data Sheet

according to UK REACH Regulation

Sulfo-NHS-Biotin

Revision date: 22.05.2025

Product code: LS-1680

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Sulfo-NHS-Biotin

Further trade names

Biotin 3-sulfo-N-hydroxysuccinimide ester sodium salt

Sulfo-NHS-Biotin sodium

sodium 2,5-dioxo-1-((5-

((3aS,4S,6aR)-2-oxohexahydro-1H-thieno[3,4-d]imidazol-4-yl)pentanoyl)oxy)pyrrolidine-3-sulfonate

Component: CAS 190598-55-1

Substance name: Sulfo-NHS-Biotin

CAS No: 194041-65-1

EC No: 811-927-2

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).

Restrictions on use: Pharmaceutical substance

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

Telephone: +49 9231 97121 0

Telefax: +49 9231 97121 99

E-mail: info@iris-biotech.de

Contact person: Health & Safety Department

Telephone: +49 9231 97121 0

E-mail: sds@iris-biotech.de

Internet: www.iris-biotech.de

Responsible Department: Only available during office hours.

1.4. Emergency telephone

+49 (0)89 19240 (POISON CENTER Munich: 24 h)

number:**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****GB CLP Regulation**

Repr. 2; H361

Acute Tox. 4; H332

Acute Tox. 4; H312

Acute Tox. 4; H302

Skin Irrit. 2; H315

Eye Irrit. 2; H319

STOT SE 3; H335

Full text of hazard statements: see SECTION 16.

2.2. Label elements**GB CLP Regulation**

Signal word: Warning

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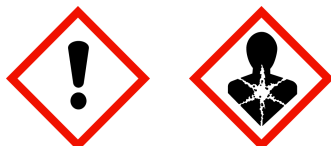
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Pictograms:**Hazard statements**

H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.

Precautionary statements

P201	Obtain special instructions before use.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352	IF ON SKIN: Wash with plenty of Water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container to an approved disposal site.

Additional advice on labelling

Warning - substance not yet tested completely.

Labelling of packages where the contents do not exceed 125 ml**Signal word:** Warning**Pictograms:****Hazard statements**

H361

Precautionary statements

P201-P280-P308+P313-P501

2.3. Other hazards

Product is not dust explosive in its original delivery form. The addition of particulate matter, however, results in a dust explosion risk.

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.1. Substances****Chemical characterization**

Biotin 3-sulfo-N-hydroxysuccinimide ester sodium salt

Sum formula: C₁₄H₁₈N₃NaO₈S₂

Molecular weight: 443,42 g/mol

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Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
194041-65-1	Sulfo-NHS-Biotin			100 %
	811-927-2			
	Repr. 2, Acute Tox. 4, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H361 H332 H312 H302 H315 H319 H335			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
194041-65-1	811-927-2	Sulfo-NHS-Biotin	100 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: LC50 = 1,5 mg/l (dusts or mists); dermal: LD50 = 1100 mg/kg; oral: LD50 = 500,1 mg/kg		

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).

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

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice. Remove casualty to fresh air and keep warm and at rest. In case of irregular breathing or respiratory arrest provide artificial respiration.

After contact with skin

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

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. 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

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

Never give anything by mouth to an unconscious person or a person with cramps.

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. Sand.

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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). Sulfur oxides. Sodium oxides (NaO).**5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water. Usual measures for fire prevention.

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

Provide adequate ventilation. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment. 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.

For non-emergency personnel

Remove all sources of ignition. Provide adequate ventilation.

Use personal protection equipment.

Evacuate the danger area, observe emergency procedures, consult an expert.

For emergency responders

Wear personal protection equipment (refer to section 8).

Take up mechanically, placing in appropriate containers for disposal. Take up dust-free and set down dust-free.

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**For containment**

Avoid dust formation.

For cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Take up mechanically.

Other information

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

Treat the recovered material as prescribed in the section on waste disposal.

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

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Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust. Provide adequate ventilation.

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.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat,

drink, smoke, sniff. 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.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations. Keep container tightly closed in a cool, well-ventilated place.

Handle and store contents under inert gas. Protect from moisture.

storage temperature: +2°C - 8°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**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Suitable eye protection: goggles.

Tightly fitting safety goggles. Face shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

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.

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without

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touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

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.

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Thermal hazards

No data available

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	
Colour:	white/ whitish	
Odour:	No data available	
Odour threshold:	No data available	
Melting point/freezing point:		No data available
Boiling point or initial boiling point and boiling range:		No data available
Flammability:		not determined
Lower explosion limits:		No data available
Upper explosion limits:		No data available
Flash point:		No data available
Auto-ignition temperature:		No data available
Decomposition temperature:		No data available
pH-Value:		No data available
Viscosity / kinematic:		not applicable
Water solubility:		No data available
Solubility in other solvents		
not determined		
Dissolution rate:		No data available
Partition coefficient n-octanol/water:		No data available
Dispersion stability:		No data available
Vapour pressure:		No data available
Density:		No data available
Relative density:		No data available
Bulk density:		No data available
Relative vapour density:		No data available
Particle characteristics:		No data available

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9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The product is not: Explosive. Product is not dust explosive in its original delivery form. The addition of particulate matter, however, results in a dust explosion risk.

Sustained combustibility:

No data available

Self-ignition temperature**Solid:**

No data available

Gas:

not applicable

Oxidizing properties

No data available

Other safety characteristics**Solvent content:**

No data available

Viscosity / dynamic:

not applicable

Flow time:

not applicable

SECTION 10: Stability and reactivity**10.1. Reactivity**

The following applies to flammable, organic substances and mixtures in general: With appropriately fine distribution, when whirled up, a dust explosion potential can generally be assumed.

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). Sulfur oxides. Sodium oxides (NaO).

Further information

In case of fire: See chapter 5.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in GB CLP Regulation****Toxicokinetics, metabolism and distribution**

No data available

Acute toxicity

Harmful if inhaled.

Harmful in contact with skin.

Harmful if swallowed.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
194041-65-1	Sulfo-NHS-Biotin				
	oral	LD50 500,1 mg/kg		(External SDS)	
	dermal	LD50 1100 mg/kg	Acute toxicity estimate (ATE)	(External SDS)	
	inhalation vapour	ATE 11 mg/l			
	inhalation (4 h) dust/mist	LC50 1,5 mg/l		(External SDS)	

Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/eye irritation: Causes serious eye irritation.

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of damaging fertility or the unborn child. (Sulfo-NHS-Biotin)

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

Carcinogenicity: 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

May cause respiratory irritation. (Sulfo-NHS-Biotin)

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.

Information on likely routes of exposure

No data available

Specific effects in experiment on an animal

No data available

Practical experience

No data available

11.2. Information on other hazards
Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information

The substance is classified as hazardous within the meaning of Regulation (EC) no. 1272/2008 [GHS].

Special hazards arising from the substance or mixture!

Prolonged or repeated exposure may cause: Vomiting, Diarrhea, Abdominal pain, Rats exposed to 1-methyl-2-pyrrolidinone at a concentration of 1 mg/L as an aerosol for 10 days showed depletion of hematopoietic cells in the bone marrow and atrophy of the lymphoid tissues of the thymus, spleen, and lymph nodes.

Symptoms:

Depression of central nervous system

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Avoid prolonged or repeated exposure.

Symptoms:

Nausea. Headache.

Further information

RTECS: No data available

To our knowledge, the chemical, physical and toxicological properties have not been extensively studied. Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12: Ecological information**12.1. Toxicity**

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

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

This substance does not meet the PBT/vPvB criteria of UK REACH.

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms.

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. Other adverse effects

Warning - substance not yet tested completely.

Further information

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

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

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

Hazardous waste according to Directive 2008/98/EC (waste framework directive). Handle contaminated packages in the same way as the substance itself.

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.

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Marine transport (IMDG)**14.2. UN proper shipping name:** No dangerous good in sense of these transport regulations.**Air transport (ICAO-TI/IATA-DGR)****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. Maritime transport in bulk according to IMO instruments

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

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Permeates easily through outer skin and causes poisoning.

15.2. Chemical safety assessment

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

SECTION 16: Other information

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Abbreviations and acronyms

Acute Tox: Acute toxicity

Skin Irrit: Skin irritation

Eye Irrit: Eye irritation

Repr: Reproductive toxicity

STOT SE: Specific target organ toxicity - single exposure

ADR: Accord relatif au transport international des marchandises dangereuses par route
(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

CAS: Chemical Abstracts Service

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

MFAG: Medical First Aid Guide

IATA: International Air Transport Association

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>

EC/EEC: European Community/European Economic Community

EU: European Union

M-factor: Multiplying factor

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IATA: International Air Transport Association

DGR: Dangerous Goods Regulations

ICAO: International Civil Aviation Organization

TI: Technical Instructions

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety
assessment, chapter R.20 (Table of terms and abbreviations).

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Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.

Further Information

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

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.