



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 25-Aug-2021

Revision Number 1

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

### 1.1. Product identifier

**Product Code(s)** TRC-E975080-50MG  
**Product Name** Ezetimibe Tetrahydropyran Impurity  
**Form** Not applicable

*NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II*

**EC No (EU Index No)** -  
**CAS No.** 1296129-15-1  
**Pure substance/mixture** Substance  
**Formula** C<sub>24</sub>H<sub>21</sub>F<sub>2</sub>NO<sub>3</sub>  
**Molecular weight** 409.43

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

**Recommended use** Laboratory use  
**Uses advised against** No information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

LGC Limited  
Queens Road  
Teddington  
Middlesex TW11 0LY  
UNITED KINGDOM  
:+44 (0) 20 8943 7000  
Fax :+44 (0) 20 8943 2767  
eMail : gb@lgcstandards.com

Web : [www.lgcstandards.com](http://www.lgcstandards.com)

For further information, please contact

**E-mail address** sds-request@lgcstandards.com



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## TRC-E975080-50MG - Ezetimibe Tetrahydropyran Impurity

### 1.4. Emergency telephone number

Emergency Telephone

For Hazardous Materials or Dangerous Goods Incident  
Spill, Leak, Fire Exposure, or Accident  
Call CHEMTREC:  
USA & Canada 1-800-424-9300  
Rest of the world +1 703-741-3877

Emergency Telephone - §45 - (EC)1272/2008	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### 2.2. Label elements



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This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### Hazard statements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### 2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances
Ezetimibe Tetrahydropyran Impurity	-	-

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ezetimibe Tetrahydropyran Impurity 1296129-15-1	100	-	-	-			

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures



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Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Rinse mouth.

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

Symptoms	No information available.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
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Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
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**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Advice on safe handling** Ensure adequate ventilation.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA.

### 7.3. Specific end use(s)

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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### Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

### Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

### Derived No Effect Level (DNEL)

No information available.

### Predicted No Effect Concentration (PNEC)

No information available.

## 8.2. Exposure controls

### Personal protective equipment

#### Eye/face protection

Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

#### Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves.

#### Skin and body protection

Wear suitable protective clothing.

#### Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

#### General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

#### Environmental exposure controls

Do not allow into any sewer, on the ground or into any body of water.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	Solid
Appearance	Solid
Colour	white to off-white
Odour	Odourless.



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Odour threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	237 - 239 °C	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	DMSO, Methanol, slightly soluble	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

### 9.2. Other information

Molecular weight 409.43  
Molecular formula C<sub>24</sub>H<sub>21</sub>F<sub>2</sub>NO<sub>3</sub>

9.2.1. Information with regards to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity No information available.



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### 10.2. Chemical stability

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

### 10.4. Conditions to avoid

**Conditions to avoid** None known based on information supplied.

### 10.5. Incompatible materials

**Incompatible materials** None known based on information supplied.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** None known based on information supplied.

## SECTION 11: Toxicological information

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

#### Information on likely routes of exposure

##### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available.

**Ingestion** Specific test data for the substance or mixture is not available.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

#### Numerical measures of toxicity

No information available





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### Acute toxicity

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

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

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitisation** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

**Reproductive toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

#### 11.2.2. Other information



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Other adverse effects No information available.

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

#### 12.2. Persistence and degradability

Persistence and degradability No information available.

#### 12.3. Bioaccumulative potential

Bioaccumulation No information available.

#### 12.4. Mobility in soil

Mobility in soil No information available.

#### 12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

#### 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.



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## SECTION 14: Transport information

### IATA

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

### IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special precautions for user	
Special Provisions	None No information available
14.7 Maritime transport in bulk according to IMO instruments	No information available

### RID

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

### ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

## SECTION 15: Regulatory information

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



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### National regulations

#### Germany

Water hazard class (WGK) non-hazardous to water (nwg)

#### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

#### Persistent Organic Pollutants

Not applicable

#### Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable

### International Inventories

#### TSCA

LGC has not confirmed that the chemical substances in this product are on the TSCA Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the requirements that apply to its use of this product.

#### DSL/NDSL

#### EINECS/ELINCS

#### ENCS

#### IECSC

#### KECL

Contact supplier for inventory compliance status

Contact supplier for inventory compliance status

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PICCS  
AIIC

Contact supplier for inventory compliance status  
Contact supplier for inventory compliance status

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

#### Chemical Safety Report

A Chemical Safety Assessment is not required for this substance

## SECTION 16: Other information

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method



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STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AELG(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme  
Organisation for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

Revision date 25-Aug-2021

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

### Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**End of Safety Data Sheet**