

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

1.1. Product identifier

Product form	: Substance
Substance name	: Levodropropizine impurity C
Chemical name	: 2,3-epoxypropan-1-ol; glycidol; oxiranemethanol
EC Index-No.	: 603-063-00-8
EC-No.	: 209-128-3
CAS-No.	: 556-52-5
Product code	: 201601050

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

1.2.1. Relevant identified uses

Main use category	: The product is intended for research, analysis and scientific education.
Use of the substance/mixture	: For professional use only
Function or use category	: Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
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1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Carcinogenicity, Category 1B	H350
Germ cell mutagenicity, Category 2	H341
Reproductive toxicity, Category 1B	H360F
Acute toxicity (inhal.), Category 3	H331
Acute toxicity (dermal), Category 4	H312
Acute toxicity (oral), Category 4	H302
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335
Skin corrosion/irritation, Category 2	H315
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

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2.2. Label elements

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

Hazard pictograms (CLP) :



GHS06

GHS08

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H350 - May cause cancer.
H341 - Suspected of causing genetic defects.
H360F - May damage fertility.
H331 - Toxic if inhaled.
H312 - Harmful in contact with skin.
H302 - Harmful if swallowed.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H315 - Causes skin irritation.

Precautionary statements (CLP) :

P202 - Do not handle until all safety precautions have been read and understood.
P308+P311 - IF exposed or concerned: Call a doctor.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP) :



GHS06

GHS08

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2,3-epoxypropan-1-ol; glycidol; oxiranemethanol	CAS-No.: 556-52-5 EC-No.: 209-128-3 EC Index-No.: 603-063-00-8	≤ 100	Carc. 1B, H350 Muta. 2, H341 Repr. 1B, H360F Acute Tox. 3 (Inhalation), H331 Acute Tox. 4 (Dermal), H312 (ATE=1980 mg/kg bodyweight) Acute Tox. 4 (Oral), H302 (ATE=420 mg/kg bodyweight) Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315

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

3.2. Mixtures

Not applicable

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Move to fresh air. Allow affected person to breathe fresh air.
First-aid measures after skin contact	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water/....
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion	: Rinse mouth.

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

Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.

4.3. Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Extinguishing blanket.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: See Heading 2.2.
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5.3. Advice for firefighters

Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Ensure waste is collected and contained. Clean thoroughly.
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6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.
Precautions for safe handling	: Material should be handled with caution. Avoid any direct contact with the product.

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Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.
Storage conditions : Store locked up.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Skin and body protection:

Use chemically protective clothing. DIN EN 13034

Hand protection:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Odour	: Not applicable.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: 160 – 161 °C
Flammability	: Not available
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: 71 °C
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 5
Viscosity, kinematic	: Not available
Solubility	: Water: ≥ 1 g/l Miscible.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

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SECTION 11: Toxicological information

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

Acute toxicity (oral) : Harmful if swallowed.
Acute toxicity (dermal) : Harmful in contact with skin.
Acute toxicity (inhalation) : Toxic if inhaled.

2,3-epoxypropan-1-ol; glycidol; oxiranemethanol (556-52-5)	
LD50 dermal rabbit	1980 mg/kg
LC50 Inhalation - Rat	1980 mg/kg

Skin corrosion/irritation : Causes skin irritation.
pH: 5
Serious eye damage/irritation : Causes serious eye irritation.
pH: 5
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Suspected of causing genetic defects.
Carcinogenicity : May cause cancer.
Reproductive toxicity : May damage fertility.
STOT-single exposure : May cause respiratory irritation.
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Hazardous waste. Use suitable disposal containers.
Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

2,3-epoxypropan-1-ol; glycidol; oxiranemethanol (556-52-5)	
LC50 - Fish [1]	280 mg/l LC50-96 Hour - fish

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 2810	UN 2810	UN 2810
14.2. UN proper shipping name		
TOXIC LIQUID, ORGANIC, N.O.S.	TOXIC LIQUID, ORGANIC, N.O.S.	Toxic liquid, organic, n.o.s.
Transport document description		
UN 2810 TOXIC LIQUID, ORGANIC, N.O.S., 6.1, III, (E)	UN 2810 TOXIC LIQUID, ORGANIC, N.O.S., 6.1, III	UN 2810 Toxic liquid, organic, n.o.s., 6.1, III
14.3. Transport hazard class(es)		
6.1	6.1	6.1
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: T1
Special provisions (ADR)	: 274, 614
Limited quantities (ADR)	: 5I
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P001, IBC03, LP01, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T7
Portable tank and bulk container special provisions (ADR)	: TP1, TP28
Tank code (ADR)	: L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Packages (ADR)	: V12
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9
Hazard identification number (Kemler No.)	: 60

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Orange plates : 

Tunnel restriction code (ADR) : E

Transport by sea

Special provisions (IMDG) : 223, 274
Limited quantities (IMDG) : 5 L
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P001, LP01
IBC packing instructions (IMDG) : IBC03
Tank instructions (IMDG) : T7
Tank special provisions (IMDG) : TP1, TP28
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-A
Stowage category (IMDG) : A
Properties and observations (IMDG) : Toxic if swallowed, by skin contact or by inhalation.
MFAG-No : 154

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y642
PCA limited quantity max net quantity (IATA) : 2L
PCA packing instructions (IATA) : 655
PCA max net quantity (IATA) : 60L
CAO packing instructions (IATA) : 663
CAO max net quantity (IATA) : 220L
Special provisions (IATA) : A3, A4, A137
ERG code (IATA) : 6L

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

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Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:	
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 1B	Carcinogenicity, Category 1B
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H360F	May damage fertility.
Muta. 2	Germ cell mutagenicity, Category 2
Repr. 1B	Reproductive toxicity, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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