

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 9/1/2025 Version: 1.0

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

1.1. Product identifier

Product form	: Substance
Trade name	: ORLEvance ^{S-PURE+}
IUPAC name	: Propylene glycol
EC-No.	: 200-338-0
CAS-No.	: 57-55-6
REACH registration No.	: 01-2119456809-23-0273
Formula	: C ₃ H ₈ O ₂
Product group	: Trade product
Other means of identification	: MPG (propane-1,2-diol)

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

Relevant identified uses

Main use category	: Component for the production of
Use of the substance/mixture	: excipients in the pharmaceutical industry; for the production of hygiene products and cosmetics

Uses advised against

Restrictions on use	: Other uses
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1.3. Details of the supplier of the safety data sheet

Manufacturer

ORLEN Południe S.A.
Fabryczna 22
32-540 Trzebinia
Poland
T +48 24 201 00 00, F +48 24 367 74 14
E-mail address of competent person responsible for the SDS :
reach.poludnie@orlen.pl

1.4. Emergency telephone number

Emergency number	: +48 24 201 00 00 Emergency number 112
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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]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

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

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The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ORLEvance ^{S-PURE+}	CAS-No.: 57-55-6 EC-No.: 200-338-0 REACH-no: 01-2119456809-23-0273	99 – 100	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
 First-aid measures after skin contact : Wash skin with plenty of water.
 First-aid measures after eye contact : Rinse eyes with water as a precaution.
 First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional 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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures : Ventilate spillage area.

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For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Germany

Storage class (LGK, TRGS 510) : LGK 10 - Combustible liquids

Joint storage table	LGK 1	LGK 2A	LGK 2B	LGK 3	LGK 4.1A
	LGK 4.1B	LGK 4.2	LGK 4.3	LGK 5.1A	LGK 5.1B
	LGK 5.1C	LGK 5.2	LGK 6.1A	LGK 6.1B	LGK 6.1C
	LGK 6.1D	LGK 6.2	LGK 7	LGK 8A	LGK 8B
	LGK 10	LGK 11	LGK 12	LGK 13	LGK 10-13

Joint storage not permitted for : LGK 1, LGK 2A, LGK 5.1A, LGK 6.2, LGK 7
Joint storage with restrictions permitted for : LGK 4.1A, LGK 4.2, LGK 4.3, LGK 5.1B, LGK 5.1C, LGK 5.2
Joint storage permitted for : LGK 2B, LGK 3, LGK 4.1B, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

ORLEvance^{S-PURE+} (57-55-6)

Poland - Occupational Exposure Limits

Local name	Propano-1,2-diol
NDS (OEL TWA)	100 mg/m ³ pary i frakcja wdychalna
Remark	Frakcja wdychalna – frakcja aerozolu wnikaćca przez nos i usta, która stwarza zagrożenie dla zdrowia po zdeponowaniu w drogach oddechowych.

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ORLEvance ^{S-PURE+} (57-55-6)	
Regulatory reference	Dz. U. 2024 poz. 1017 wraz z późn. zm.

DNEL and PNEC

ORLEvance ^{S-PURE+} (57-55-6)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, inhalation	168 mg/m ³
Long-term - local effects, inhalation	10 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, inhalation	50 mg/m ³
Long-term - local effects, inhalation	10 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	260 mg/l
PNEC aqua (marine water)	26 mg/l
PNEC aqua (intermittent, freshwater)	183 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	572 mg/kg dwt
PNEC sediment (marine water)	57.2 mg/kg dwt
PNEC (Soil)	
PNEC soil	50 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	20000 mg/l

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

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Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: Practically odourless.
Odour threshold	: Not available
Melting point	: -60 °C
Freezing point	: Not available
Boiling point	: 184 °C Atm. press.: 100,32 kPa Decomposition: 'no'
Flammability	: Non flammable.
Lower explosion limit	: 12.5 vol %
Upper explosion limit	: 2.5 vol %
Flash point	: 104 °C Atm. press.: 100,01 kPa
Auto-ignition temperature	: > 400 °C
Decomposition temperature	: Not available
pH	: 6.5 – 7.5
Viscosity, kinematic	: 40 – 45 mm ² /s
Solubility	: diluted in water. Soluble in acetone. Soluble in ethanol. Soluble in chloroform. Soluble in ether.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: -1.07
Vapour pressure	: 20 Pa Temp.: 25 °C
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: 1.03 Type: 'relative density' Temp.: 20 °C
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

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10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
 Acute toxicity (dermal) : Not classified
 Acute toxicity (inhalation) : Not classified

ORLEvance^{S-PURE+} (57-55-6)

LD50 oral rat	22000 mg/kg bodyweight Animal: rat
LD50 dermal rabbit	> 2000 mg/kg bodyweight Animal: rabbit
LC50 Inhalation - Rat	> 44.9 mg/l air Animal: rat, Guideline: other:

Skin corrosion/irritation : Not classified
 pH: 6.5 – 7.5
 Serious eye damage/irritation : Not classified
 pH: 6.5 – 7.5
 Respiratory or skin sensitisation : Not classified
 Germ cell mutagenicity : Not classified
 Carcinogenicity : Not classified
 Reproductive toxicity : Not classified
 STOT-single exposure : Not classified
 STOT-repeated exposure : Not classified

ORLEvance^{S-PURE+} (57-55-6)

NOAEL (subchronic, oral, animal/male, 90 days)	443 mg/kg bodyweight Animal: cat, Animal sex: male
Aspiration hazard	: Not classified

ORLEvance^{S-PURE+} (57-55-6)

Viscosity, kinematic	40 – 45 mm ² /s
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11.2. Information on other hazards

Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
 Hazardous to the aquatic environment, short-term (acute) : Not classified
 Hazardous to the aquatic environment, long-term (chronic) : Not classified

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LC50 - Fish [1]	51600 mg/l Test organisms (species): <i>Oncorhynchus mykiss</i> (previous name: <i>Salmo gairdneri</i>)
LC50 - Fish [2]	51400 mg/l Test organisms (species): <i>Pimephales promelas</i>
EC50 72h - Algae [1]	24200 mg/l Test organisms (species): <i>Raphidocelis subcapitata</i> (previous names: <i>Pseudokirchneriella subcapitata</i> , <i>Selenastrum capricornutum</i>)
EC50 72h - Algae [2]	19300 mg/l Test organisms (species): <i>Skeletonema costatum</i>
EC50 96h - Algae [1]	19000 mg/l Test organisms (species): <i>Raphidocelis subcapitata</i> (previous names: <i>Pseudokirchneriella subcapitata</i> , <i>Selenastrum capricornutum</i>)
EC50 96h - Algae [2]	19100 mg/l Test organisms (species): <i>Skeletonema costatum</i>

12.2. Persistence and degradability

ORLE Vance ^{S-PURE+} (57-55-6)	
Persistence and degradability	rapidly degradable

12.3. Bioaccumulative potential

ORLE Vance ^{S-PURE+} (57-55-6)	
Partition coefficient n-octanol/water (Log Pow)	-1.07

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

ORLE Vance ^{S-PURE+} (57-55-6)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR	IMDG	IATA	RID
NOT SUBJECT	NOT SUBJECT	NOT SUBJECT	

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ADR	IMDG	IATA	RID
14.1. UN number or ID number			
Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available			

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

Air transport

No data available

Rail transport

No data 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-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 listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

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Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

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

Drug Precursors Regulation (EC 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)

National regulations

Germany

VOC ordinance (ChemVOCFarbV)

:

Employment restrictions

: Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).

Water hazard class (WGK)

: WGK 1, Slightly hazardous to water (Classification according to AwSV; ID No. 280).

Major Accidents Ordinance (12. BImSchV)

: Is not subject to the Major Accidents Ordinance (12. BImSchV)

Poland

Polish National Regulations

: Regulation of the Minister of Economy of 21 December 2005 on the essential requirements for personal protective equipment (J. o L. No. 259, item 2173).
Decree of the Minister of Environment of 14 December 2014 on the catalogue of waste (J. o L. 2014, item 1923).
Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on the highest permissible concentration and intensity of noxious agents for health at work environment (J. o L. item 1286 as amended).
Regulation of the Minister of Health of 10 August 2012 on the criteria and classification method of chemical substances and their mixtures (consolidated text: J. o L. 2015, item 208).
Regulation of the Minister of Health of 2 February 2011 on tests and measurements of the noxious agents for health at work environment (J. o L. No. 33, item 166 as amended).
Regulation of the Minister of Health of 20 April 2012 on labelling of hazardous substances and hazardous mixtures and certain mixtures (consolidated text: J. o L. 2015, item 450)
The announcement of Minister of Health dated 9 September 2016 concerning the consolidated text announcement of the decree of the Minister of Health of 30 December 2004 on health and safety at work related to exposure to chemical agents at work (J. o L. of 16 September 2016, item 1488)
Regulation of the Minister of Environment of 3 September 2014 on designs of packaging labelling (J. o L. 2014 item 1298)
Regulation of the Minister of Environment of 9 December 2003 on particularly hazardous substances to the environment (J. o L. No. 217, item 2141).
Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
The ADR Agreement - Annex to the J. o L. of 26 April 2019 Government Statement of 18 February 2019 on the entry into force of the amendments to Annex A and B to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), signed in Geneva on 30 September 1957 (J. o L. 2019, item 769)
The announcement of Marshal of the Sejm of the Republic of Poland dated 19 October 2016 concerning the consolidated text announcement of the decree on the management of packaging and packaging waste (J. o L. 2016, item 1863 as amended).
Act of 14 December 2012 on waste (J. o L. 2013, item 322 as amended; consolidated text J. o L. 2020, item 797).
Act of 19 August 2011 on the Carriage of Dangerous Goods (J. o L. 2011 No. 227, item 1367 as amended; consolidated text J. o L. 2020, item 154).
Act of 25 February 2011 on chemical substances and their mixtures (J. o L. No. 63, item 322 as amended; consolidated text J. o L. 2019, item 1225).
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15.2. Chemical safety assessment

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]
 No chemical safety assessment has been carried out for the substance or the mixture by the supplier
 No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Not applicable.

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit

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Abbreviations and acronyms:

VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disruptor

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Training advice : Personal monitoring. As from 24 August 2023 adequate training is required before industrial or professional use.

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU