

The Brief Profile summarizes the non-confidential data on substances as it is held in the databases of the European Chemicals Agency (ECHA), including data provided by third parties. The Brief Profile is automatically generated; note that it does not currently distinguish between harmonised classification and minimum classification; information requirements under different legislative frameworks may therefore not be fully up to date or complete. For accuracy reasons, substance manufacturers and imports have the responsibility to consult official sources, e.g. the electronic edition of the Official Journal of the European Union. This Brief Profile is covered by the ECHA Legal Notice.


## (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione

Brief Profile - Last updated: 15/01/2021



### Substance Description

#### Substance identity

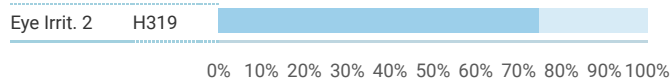
	EC / List name:	SMILES:
	IUPAC name:	InChI:
	Substance names and other identifiers	Type of substance: Mono constituent substance
		Origin: Organic
EC / List no.: 603-436-5		Registered compositions: 2
CAS no.: 13076-17-0		Of which contain: 0 impurities relevant for classification
Index number:		0 additives relevant for classification
Molecular formula:		Substance Listed:

#### Hazard classification & labelling



**Warning!** According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye irritation.

#### Breakdown of all 4 C&L notifications submitted to ECHA



- ✓ Harmonised Classification
- REACH registration dossiers notifications
- CLP notifications

#### Properties of concern

## Regulatory context

### Registration, Evaluation, Authorisation & Restriction of Chemicals (REACH)

#### Registration

**Pre-registration:** Substance pre-registered under REACH.

**Registration:** This substance has 3 active registrations under REACH, 1 Joint Submission(s) and 0 Individual Submission(s).

#### Evaluation

**Dossier Evaluation:** Registration dossiers submitted to ECHA for this substance have been evaluated under REACH.

Substance Evaluation:

#### Authorisation

Candidate List:

Annex XIV (Authorisation List):

#### Restriction

Annex XVII (Restriction List):

### Persistent Organic Pollutants Regulation (POPs)

List of substances subject to the POPs Regulation:

List of substances proposed as POPs:

### Classification Labelling & Packaging (CLP)

Harmonised C&L:

Seveso Annex I:

**Notified C&L:** Classification & Labelling has been notified by industry to ECHA for this substance.

### Biocidal Products Regulation (BPR)

Active Substance:

Biocidal Products:

### Prior Informed Consent (PIC)

Annex I:

Annex V:

### European Union Observatory for Nanomaterials (EUON)

EUON:

## About this substance

### General

This substance has not been registered under the REACH Regulation, therefore as yet ECHA has not received any data about this substance from registration dossiers.

This substance is used by consumers, in formulation or re-packing, at industrial sites and in manufacturing.

### Consumer Uses

This substance is used in the following products: cosmetics and personal care products.

Other release to the environment of this substance is likely to occur from: indoor use as processing aid.

### Article service life

ECHA has no public registered data on the use of this substance in activities or processes at the workplace.

ECHA has no public registered data on the routes by which this substance is most likely to be released to the environment.

ECHA has no public registered data indicating whether or into which articles the substance might have been processed.

### Widespread uses by professional workers

ECHA has no public registered data indicating whether or in which chemical products the substance might be used.

ECHA has no public registered data on the types of manufacture using this substance.

ECHA has no public registered data on the use of this substance in activities or processes at the workplace.

ECHA has no public registered data on the routes by which this substance is most likely to be released to the environment.

### Formulation or re-packing

This substance is used in the following products: cosmetics and personal care products.

This substance is used in the following activities or processes at workplace: transfer of chemicals, closed processes with no likelihood of exposure, closed, continuous processes with occasional controlled exposure, closed batch processing in synthesis or formulation, mixing in open batch processes, transfer of substance into small containers, production of mixtures or articles by tableting, compression, extrusion or pelletisation and laboratory work.

Release to the environment of this substance can occur from industrial use: formulation of mixtures.

### Uses at industrial sites

ECHA has no public registered data indicating whether or in which chemical products the substance might be used.

This substance is used for the manufacture of: plastic products.

This substance is used in the following activities or processes at workplace: closed batch processing in synthesis or formulation and batch processing in synthesis or formulation with opportunity for exposure.

Release to the environment of this substance can occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates).

### Manufacture

This substance is used in the following activities or processes at workplace: closed batch processing in synthesis or formulation and batch processing in synthesis or formulation with opportunity for exposure.

Release to the environment of this substance can occur from industrial use: manufacturing of the substance.

### Precautionary Measures and safe use

Precautions for using this substance have been recommended by its registrants under REACH, as follows:

#### Prevention statements

When handling this substance: wash parts of the body (as specified by manufacturer/supplier) in contact with substance thoroughly after handling; wear protective gloves and/or clothing, and eye and/or face protection as specified by manufacturer/supplier.

#### Response statements

In case of incident: If in eyes: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. If eye irritation persists get medical advice/attention.

Guidance on the safe use of the substance provided by manufacturers and importers of this substance.

## Registrants/suppliers

### Active

- Evonik Operations GmbH, Rellinghauser Straße 1-11 45128 Essen Germany
- PURAC Biochem, Arkelsedijk 46 4206AC Gorinchem Netherlands
- Total Corbion PLA bv, Arkelsedijk 46 4206AC Gorinchem Netherlands

Inactive

## Substance names and other identifiers

### Regulatory process names

1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)- REACH pre-registration

Translated names

CAS names

### IUPAC names

(3R,6R)-3,6-Dimethyl-1,4-dioxane-2,5-dione C&L Inventory, Registration dossier

Trade names

Other names

### Other identifiers





13076-17-0	CAS number	C&L Inventory, Registration dossier, REACH pre-registration, Other	17699-82-0	Deleted CAS number	Other

## Scientific properties

### Physical and chemical properties

This section provides physicochemical information compiled from all automatically processable data from REACH registration dossiers that is available to ECHA at the time of generation. The quality and correctness of the information remains the responsibility of the data submitter. The Agency thus cannot guarantee the correctness of the information displayed.

## Appearance/physical state / colour

<b>Study results</b>	1 study submitted 1 study processed	<b>Type of Study provided</b>	<input checked="" type="checkbox"/> <b>Summaries</b>	1 summary submitted 1 summary processed
<input checked="" type="checkbox"/> <b>Physical state at 20°C and 1013 hPa</b>	Solid (100%) [1]	<b>Studies with data</b>	<b>Data waiving</b>	<b>Physical state at 20°C and 1013 hPa</b>
		   	no waivers	Solid (100%)
<input checked="" type="checkbox"/> <b>Form</b>	Flakes (100%) [1]	Key study	1	
<input checked="" type="checkbox"/> <b>Substance type</b>	Organic (100%) [1]			

### Melting/freezing point

#### Study results

1 study submitted  
1 study processed

#### Type of Study provided

[R](#) [Summaries](#)

1 summary submitted  
1 summary processed

[R](#) **Melting / freezing point**  
97 °C @ 102.1 kPa [1]

#### Studies with data

Key study 1

**Data waiving**  
no waivers

**Melting / freezing point at 101 325 Pa**  
97 °C

### Boiling point

#### Study results

1 study submitted  
1 study processed

#### Type of Study provided

[R](#) [Summaries](#)

1 summary submitted  
1 summary processed

[R](#) **Boiling point**  
268 °C @ 102.1 kPa [1]

#### Studies with data

Key study 1

**Data waiving**  
no waivers

**Boiling point at 101 325 Pa**  
268 °C

### Density

#### Study results

1 study submitted  
1 study processed

#### Type of Study provided

[R](#) [Summaries](#)

1 summary submitted  
1 summary processed

[R](#) **Density**  
1.31 g/cm<sup>3</sup> @ 20 °C [1]

#### Studies with data

Key study 1

**Data waiving**  
no waivers

**Relative density at 20 °C**  
1.31

### Vapour pressure

#### Study results

1 study submitted  
1 study processed

#### Type of Study provided

[R](#) [Summaries](#)

1 summary submitted  
1 summary processed

[R](#) **Vapour pressure**  
0.28 Pa @ 25 °C [1]

#### Studies with data

Key study 1

**Data waiving**  
no waivers

**Vapour pressure**  
0.28 Pa @ 25 °C

### Partition coefficient

#### Study results

1 study submitted  
1 study processed

#### Type of Study provided

[R](#) [Summaries](#)

1 summary submitted  
1 summary processed

[R](#) **Pow**  
2.7 @ 25 °C [1]

#### Studies with data

Key study 1

**Data waiving**  
no waivers

**Log Kow (Log Pow)**  
0.4 @ 25 °C

[R](#) **Log Pow**  
0.4 @ 25 °C [1]

### Water solubility

#### Study results

1 study submitted  
1 study processed

#### Type of Study provided

[R](#) [Summaries](#)

1 summary submitted  
1 summary processed

[R](#) **Water solubility (mass/vol.)**  
16.3 g/L @ 20.1 °C and pH 2 [1]

#### Studies with data

Key study 1

**Data waiving**  
no waivers

**Water solubility**  
16.3 g/L @ 20 °C

## Solubility in organic solvents / fat solubility

Study results

1 study submitted  
0 studies processed

Type of Study provided

Summaries

0 summaries submitted  
0 summaries processed

 No automatically processable data submitted

Studies  
with data



Key study

1

Data waiving

no waivers

 No data available

## Surface tension

Study results

1 study submitted  
1 study processed

Type of Study provided

**R** Summaries

1 summary submitted  
1 summary processed

**R** Surface tension

70.7 mN/m @ 1 g/L and 20 °C [1]

Studies  
with data



Key study

1

Data waiving

no waivers

Surface tension at 20 °C

70.7 mN/m @ 1 000 mg/L

## Flash point

Study results

1 study submitted  
0 studies processed

Type of Study provided

Summaries

0 summaries submitted  
0 summaries processed

 No automatically processable data submitted

Studies  
with data



Data waiving

Sci.  
unjustified 1

 No data available

## Auto flammability

Study results

1 study submitted  
0 studies processed

Type of Study provided

Summaries

0 summaries submitted  
0 summaries processed

 No automatically processable data submitted

Studies  
with data



Data waiving

Sci.  
unjustified 1

 No data available

## Flammability

Study results

1 study submitted  
1 study processed

Type of Study provided

**C** Summaries

1 summary submitted  
1 summary processed

**C** Interpretation of results

Non flammable (100%) [1]

Studies  
with data



Key study

1

Data waiving

no waivers

Flammability

Non flammable (100%)

## Explosiveness

Study results

1 study submitted  
0 studies processed

Type of Study provided

Summaries

0 summaries submitted  
0 summaries processed

 No automatically processable data submitted


Studies  
with data



Data waiving


Sci.  
unjustified 1


 No data available

Oxidising					
Study results	1 study submitted 0 studies processed	Type of Study provided		Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		<b>Studies with data</b> 		⚠ No data available	
		<b>Data waiving</b> Sci. unjustified		1	

Oxidation reduction potential	⚠ Data not provided by the registrant
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pH	⚠ Data not provided by the registrant
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Dissociation constant					
Study results	1 study submitted 0 studies processed	Type of Study provided		Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		<b>Studies with data</b> 		⚠ No data available	
		<b>Data waiving</b> Sci. unjustified		1	

Viscosity					
Study results	1 study submitted 0 studies processed	Type of Study provided		Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		<b>Studies with data</b> 		⚠ No data available	
		<b>Data waiving</b> Sci. unjustified		1	

## Environmental fate and pathways

This section provides environmental fate and pathways information compiled from all automatically processable data from REACH registration dossiers that is available to ECHA at the time of generation. The quality and correctness of the information remains the responsibility of the data submitter. The Agency thus cannot guarantee the correctness of the information displayed.

Phototransformation in air	⚠ Data not provided by the registrant
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Hydrolysis					
Study results	2 studies submitted 0 studies processed	Type of Study provided		Summaries	0 summaries submitted 0 summaries processed
⚠ Study data not processed for brief profile		<b>Studies with data</b> 		⚠ No data available	
		Supporting study		1	
		<b>Data waiving</b> Sci. unjustified		1	

Phototransformation in water	⚠ Data not provided by the registrant
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Phototransformation in soil	⚠ Data not provided by the registrant
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## Biodegradation in water - screening tests

Study results	1 study submitted 1 study processed	Type of Study provided	<b>C</b> Summaries	1 summary submitted 1 summary processed
<b>C</b> Interpretation of results	Readily biodegradable (100%) [1]	Studies with data	Data waiving	Biodegradation in water
		Key study	no waivers	Readily biodegradable (100%)

## Biodegradation in water & sediment - simulation tests

⚠ Data not provided by the registrant

## Biodegradation in soil

Study results	1 study submitted 0 studies processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
⚠ Study data not processed for brief profile		Studies with data	Data waiving	⚠ No data available
		Key study	Sci. unjustified	1

## Bioaccumulation: aquatic / sediment

Study results	1 study submitted 0 studies processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
⚠ Study data not processed for brief profile		Studies with data	Data waiving	⚠ No data available
		Key study	Sci. unjustified	1

## Bioaccumulation: terrestrial

⚠ Data not provided by the registrant

## Adsorption/desorption

Study results	2 studies submitted 0 studies processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		Studies with data	Data waiving	⚠ No data available
		Supporting study	Not feasible	1

## Henry's law constant (H)

Study results	1 study submitted 1 study processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
<b>R</b> H - (pressure) m³/mol	0 Pa m³/mol [1]	Studies with data	Data waiving	⚠ No data available
		Key study	no waivers	

## Distribution modelling

⚠ Data not provided by the registrant

## Ecotoxicological information

This section provides ecotoxicological information compiled from all automatically processable data from REACH registration dossiers that is available to ECHA at the time of generation. The quality and correctness of the information remains the responsibility of the data submitter. The Agency thus cannot guarantee the correctness of the information displayed.



## Predicted No-Effect Concentration (PNEC)

R Summaries

1 summary submitted  
1 summary processed

The Predicted No-Effect Concentration (PNEC) value is the concentration of a substance below which adverse effects in the environment are not expected to occur. Please note that when more than one summary is provided, PNEC values may refer to constituents of the substance and not to the substance as a whole. More detailed information is available in the dossiers.

### Hazard for Aquatic Organisms

Freshwater	No hazard identified (1)
Intermittent releases (freshwater)	No hazard identified (1)
Marine water	No hazard identified (1)
Intermittent releases (marine water)	No hazard identified (1)
Sewage treatment plant (STP)	No hazard identified (1)
Sediment (freshwater)	No hazard identified (1)
Sediment (marine water)	No hazard identified (1)

### Hazard for Air

Air	No hazard identified (1)
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### Hazard for Terrestrial Organism

Soil	No hazard identified (1)
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### Hazard for Predators

Secondary poisoning	No potential for bioaccumulation (1)
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## Short-term toxicity to fish

Study results 5 studies submitted  
4 studies processed





### Type of Study provided

Summaries 1 summary submitted  
0 summaries processed

#### P/R Results

LC50 (4 days) 130 - 320 mg/L [5]  
NOEC (4 days) 180 - 320 mg/L [2]

#### Studies with data

				
Weight of evidence	1			4

#### Data waiving

no waivers

 No automatically processable data submitted

## Long-term toxicity to fish

Study results 2 studies submitted  
0 studies processed

### Type of Study provided

Summaries 1 summary submitted  
0 summaries processed

 No automatically processable data submitted

#### Studies with data

				
Other				1

#### Data waiving

Sci. unjustified 1

 No automatically processable data submitted

## Short-term toxicity to aquatic invertebrates

Study results 3 studies submitted  
1 study processed





### Type of Study provided

Summaries 1 summary submitted  
0 summaries processed

#### P/R Results

EC50 (48 h) 130 - 250 mg/L [2]

#### Studies with data

				
Key study				1
Supporting study				2

#### Data waiving

no waivers

 No automatically processable data submitted

## Long-term toxicity to aquatic invertebrates

### Study results

1 study submitted  
0 studies processed

### Type of Study provided

### Summaries

0 summaries submitted  
0 summaries processed

⚠ No automatically processable data submitted

### Studies with data



### Data waiving

Sci.  
unjustified 1

⚠ No data available

## Toxicity to aquatic algae and cyanobacteria

### Study results

1 study submitted  
1 study processed

### Type of Study provided

### R Summaries

1 summary submitted  
1 summary processed

### P/R Results

EC50 (72 h) 2.8 - 3.5 g/L [2]  
NOEC (72 h) 1.9 g/L [1]

### Studies with data



Key study

### Data waiving

no waivers

### EC50 for freshwater algae

2.8 g/L

### EC10 or NOEC for freshwater algae

1.9 g/L

## Toxicity to aquatic plants other than algae

⚠ Data not provided by the registrant

## Toxicity to microorganisms

### Study results

1 study submitted  
1 study processed

### Type of Study provided

### R Summaries

1 summary submitted  
1 summary processed

### P/R Results

EC50 (3 h) 88.2 mg/L [1]  
NOEC (3 h) 88.2 mg/L [1]

### Studies with data



Key study

### Data waiving

no waivers

### EC10 or NOEC for microorganisms

88.3 mg/L

## Sediment toxicity

### Study results

1 study submitted  
0 studies processed

### Type of Study provided

### Summaries

1 summary submitted  
0 summaries processed

⚠ No automatically processable data submitted

### Studies with data



### Data waiving

Sci.  
unjustified 1

⚠ No automatically processable data submitted

## Endocrine disrupter testing in aquatic vertebrates – in vivo

⚠ Data not provided by the registrant

## Toxicity to terrestrial macroorganisms except arthropods

### Study results

1 study submitted  
0 studies processed

### Type of Study provided

### Summaries

0 summaries submitted  
0 summaries processed

⚠ No automatically processable data submitted


### Studies with data





### Data waiving


Sci.  
unjustified 1

⚠ No data available

Toxicity to terrestrial arthropods				
Study results	1 study submitted 0 studies processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		<b>Studies with data</b> 	<b>Data waiving</b> Sci. unjustified 1	⚠ No data available

Toxicity to terrestrial plants				
Study results	1 study submitted 0 studies processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		<b>Studies with data</b> 	<b>Data waiving</b> Sci. unjustified 1	⚠ No data available

Toxicity to soil microorganisms				
Study results	1 study submitted 0 studies processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
⚠ No automatically processable data submitted		<b>Studies with data</b> 	<b>Data waiving</b> Sci. unjustified 1	⚠ No data available

Toxicity to birds				
Study results	4 studies submitted 1 study processed	Type of Study provided	Summaries	0 summaries submitted 0 summaries processed
<div>P/R</div> <b>Results</b> LC50 (14 days) 2 250 mg/kg bw [1]		<b>Studies with data</b> 	<b>Data waiving</b> Sci. unjustified 1	⚠ No data available
		Key study	1	
		Supporting study	2	

Toxicity to mammals	⚠ Data not provided by the registrant
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Toxicological information

This section provides toxicological information compiled from all automatically processable data from REACH registration dossiers that is available to ECHA at the time of generation. The quality and correctness of the information remains the responsibility of the data submitter. The Agency thus cannot guarantee the correctness of the information displayed.

## Derived No- or Minimal Effect Level (DN(M)EL)

M/C Summaries

1 summary submitted  
1 summary processed

The derived no- or minimum effect level (DN(M)EL) is the level of exposure above which a human should not be exposed to a substance. Please note that when more than one summary is provided, DN(M)EL values may refer to constituents of the substance and not to the substance as a whole. More detailed information is available in the dossiers.

### Data for WORKERS

INHALATION Exposure	Threshold	Most sensitive study
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#### Systemic Effects

Long-term:	No hazard identified
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Acute /short term:	No hazard identified
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#### Local Effects

Long-term:	Hazard unknown (no further information necessary)
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Acute /short term:	No hazard identified
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DERMAL Exposure	Threshold	Most sensitive study
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#### Systemic Effects

Long-term:	No hazard identified
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Acute /short term:	No hazard identified
--------------------	----------------------

#### Local Effects

Long-term:	Hazard unknown (no further information necessary)
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Acute /short term:	No hazard identified
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#### EYE Exposure

Low hazard (no threshold derived)

### Data for the GENERAL POPULATION

INHALATION Exposure	Threshold	Most sensitive study
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#### Systemic Effects

Long-term:	No hazard identified
------------	----------------------

Acute /short term:	No hazard identified
--------------------	----------------------

#### Local Effects

Long-term:	Hazard unknown (no further information necessary)
------------	---

Acute /short term:	Hazard unknown (no further information necessary)
--------------------	---

DERMAL Exposure	Threshold	Most sensitive study
-----------------	-----------	----------------------

#### Systemic Effects

Long-term:	No hazard identified
------------	----------------------

Acute /short term:	No hazard identified
--------------------	----------------------

#### Local Effects

Long-term:	Hazard unknown (no further information necessary)
------------	---

Acute /short term:	No hazard identified
--------------------	----------------------

ORAL Exposure	Threshold	Most sensitive study
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#### Systemic Effects

Long-term:	No hazard identified
------------	----------------------

Acute /short term:	No hazard identified
--------------------	----------------------

#### EYE Exposure

Low hazard (no threshold derived)

## Toxicokinetics, metabolism, and distribution

### Study results

Study data: basic toxicokinetics    3 studies submitted  
0 studies processed

⚠ Study data not processed for brief profile

### Type of Study provided

Study data: basic toxicokinetics

#### Studies with data

			
			3

Weight of evidence

#### Data waiving

no waivers

M/C

Summaries

1 summary submitted  
1 summary processed

### Bioaccumulation potential:

No bioaccumulation potential

Study data: dermal absorption    2 studies submitted  
0 studies processed

⚠ Study data not processed for brief profile

Study data: dermal absorption

#### Studies with data

			
			1

Key study

Supporting study

#### Data waiving

no waivers

## Acute toxicity

### Study results

oral 2 studies submitted  
1 study processed

#### P/R Results

LD0 2 000 mg/kg bw (rat) [1]

#### M/C Interpretations of results

Practically nontoxic [1]

inhalation 1 study submitted  
1 study processed

#### P/R Results

LC50 (4 h) 7.94 mg/L air (rat) [1]

#### M/C Interpretations of results

Practically nontoxic [1]

dermal 2 studies submitted  
1 study processed

#### P/R Results

LD0 2 000 mg/kg bw (rat) [1]

#### M/C Interpretations of results

Practically nontoxic [1]

other routes 0 studies submitted  
0 studies processed

 No data available

### Type of Study provided

oral

#### Studies with data

Key study 1

Supporting study 1

#### Data waiving

no waivers

inhalation

#### Studies with data

Key study 1

#### Data waiving

no waivers

dermal

#### Studies with data

Key study 1

Supporting study 1

#### Data waiving

no waivers

other routes

#### Studies with data

#### Data waiving

no waivers

M/C

Summaries

1 summary submitted  
1 summary processed

#### Inhalation route:

Adverse effect observed LC50 7 940 mg/m<sup>3</sup>

## Irritation / corrosion

### Study results

Study data: skin 1 study submitted  
0 studies processed

⚠ Study data not processed for brief profile

Study data: eye 1 study submitted  
0 studies processed

⚠ Study data not processed for brief profile

### Type of Study provided

Study data: skin

Studies  
with data



Key study

1

Data waiving

no waivers

Study data: eye

Studies  
with data



Key study

1

Data waiving

no waivers

M/C

Summaries

1 summary submitted  
1 summary processed

### Skin

No adverse effect observed (not irritating)

### Eye

Adverse effect observed (irritating)

### Respiratory

No study available

## Sensitisation

### Study results

Study data: skin 1 study submitted  
0 studies processed

⚠ Study data not processed for brief profile

Study data: respiratory 0 studies submitted  
0 studies processed

⚠ Study data not processed for brief profile

### Type of Study provided

Study data: skin

Studies  
with data



Key study

1

Data waiving

no waivers

Study data: respiratory

Studies  
with data



Data waiving

no waivers

M/C

Summaries

1 summary submitted  
1 summary processed

### Skin sensitisation

No adverse effect observed (not sensitising)

### Respiratory sensitisation

No study available

## Repeated dose toxicity

### Study results

Study data: oral 3 studies submitted  
2 studies processed

#### P/R Results

NOAEL (dog): 20 - 1 000 mg/kg bw/day [4]

LOAEL (dog): 100 - 2 500 mg/kg bw/day [3]

### Type of Study provided

Study data: oral

#### Studies with data

Key study

Supporting study



#### Data waiving

no waivers

M/C

Summaries

1 summary submitted  
1 summary processed

### Oral route - systemic effects:

Adverse effect observed NOAEL 100 mg/kg bw/day (subchronic, dog)

Study data: inhalation 0 studies submitted  
0 studies processed

⚠ No data available

Study data: inhalation

#### Studies with data



#### Data waiving

no waivers

Study data: dermal 0 studies submitted  
0 studies processed

⚠ No data available

Study data: dermal

#### Studies with data



#### Data waiving

no waivers

## Genetic toxicity

### Study results

Study data: in vitro 8 studies submitted  
0 studies processed

⚠ Study data not processed for brief profile

### Type of Study provided

Study data: in vitro

#### Studies with data

Weight of evidence



#### Data waiving

no waivers

M/C

Summaries

1 summary submitted  
1 summary processed

### Toxicity - InVitro

No adverse effect observed (negative)

Study data: in vivo 0 studies submitted  
0 studies processed

⚠ Study data not processed for brief profile

Study data: in vivo

#### Studies with data



#### Data waiving

no waivers






Carcinogenicity				
Study results	2 studies submitted 0 studies processed	Type of Study provided		Summaries 1 summary submitted 0 summaries processed
⚠ Study data not processed for brief profile		<div> <div>Studies with data</div> <div> <div> <div>🧪</div> <div>📄</div> <div>📊</div> <div>🏔</div> </div> <div> <div>Key study</div> <div>1</div> </div> <div> <div>Supporting study</div> <div>1</div> </div> </div> </div>		<div> <div>Data waiving</div> <div>no waivers</div> </div>
		⚠ No automatically processable data submitted		

Toxicity to reproduction				
Study results		Type of Study provided		Summaries 1 summary submitted 0 summaries processed
Study data: reproduction	1 study submitted 0 studies processed	Study data: reproduction		⚠ No automatically processable data submitted
⚠ Study data not processed for brief profile		<div> <div>Studies with data</div> <div> <div> <div>🧪</div> <div>📄</div> <div>📊</div> <div>🏔</div> </div> <div> <div>Sci. unjustified</div> <div>1</div> </div> </div> </div>		
Study data: developmental	1 study submitted 0 studies processed	Study data: developmental		
⚠ Study data not processed for brief profile		<div> <div>Studies with data</div> <div> <div> <div>🧪</div> <div>📄</div> <div>📊</div> <div>🏔</div> </div> <div> <div>Sci. unjustified</div> <div>1</div> </div> </div> </div>		
Study data: other studies	0 studies submitted 0 studies processed	Study data: other studies		
⚠ Study data not processed for brief profile		<div> <div>Studies with data</div> <div> <div> <div>🧪</div> <div>📄</div> <div>📊</div> <div>🏔</div> </div> <div> <div>Data waiving</div> <div>no waivers</div> </div> </div> </div>		

Neurotoxicity	⚠ Data not provided by the registrant
Immunotoxicity	⚠ Data not provided by the registrant
Endocrine disrupter mammalian screening - in vivo	⚠ Data not provided by the registrant

Legend

Type of study	Type of aggregation
 Experimental results	<input type="checkbox"/> C Concatenated distinct values
Read across based on grouping of substance (category approach) or	<input type="checkbox"/> R Range of values
 Read-across from supporting substance (structural analogue or surrogate)	<input type="checkbox"/> P/R Prioritisation (Eco)Toxicology AND Range of values
 Estimated by calculation or (Q)SAR	<input type="checkbox"/> M/C Most Conservative of values
Experimental study planned, other or unspecified	

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# Safety Data Sheet

## Puralact® D

Revision Date 15/08/2018  
Page 1 of 13  
Date previous version 23/11/2017  
Version 3.1 - EN

### SAFETY DATA SHEET

Interested in solutions for bioplastics? Please contact us at  
[www.total-corbion.com](http://www.total-corbion.com) [pla@total-corbion.com](mailto:pla@total-corbion.com)

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product Name	D-lactide
Trade name	Puralact® D Polymer Grade Lumilact D Polymer Grade
Chemical Name	(3R-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione
CAS-No	13076-17-0
EC-No	603-436-5
REACH Registration Number	01-2119516231-55-0002

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

Recommended Use	Polymer. See annex for more detailed information.
Uses advised against	No information available.

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

Total Corbion PLA  
Arkelsedijk 46  
4206 AC Gorinchem  
The Netherlands  
Tel: +31 183 695695  
Fax: +31 183 695604  
Email: [pla@total-corbion.com](mailto:pla@total-corbion.com)

### 1.4. Emergency telephone number

UK National Health Service (NHS) call 111 or, in life-threatening emergencies, call 999

WAL National Health Service (NHS) call 0845 46 47

IE National Poisons Information Centre  
+353 1 809 2566 or +353 1 837 9964 (only for healthcare professionals)

Total Corbion PLA  
+31 183 695695

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

Classification according to EU  
Regulation 1272/2008/EC  
Serious eye damage/eye irritation Category 2 - H319

For the full text of the H-Statements mentioned in this section, see Section 16

### 2.2. Label elements



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# Safety Data Sheet

Puralact® D

Revision Date  
Page

15/08/2018  
2 of 13



Signal word

Warning

Hazard Statements

H319 - Causes serious eye irritation

Precautionary Statements

P264 - Wash hands thoroughly after handling  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention

## 2.3 Other hazards

This product does not meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Chemical Name	EC-No	CAS-No	Weight %	Classification (1272/2008/EC)	REACH Registration Number
(3R-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione	603-436-5	13076-17-0	>98	Eye Irrit. 2 H319	01-2119516231-55-0002

For the full text of the H-Statements mentioned in this section, see Section 16.



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# Safety Data Sheet

## Puralact® D

Revision Date 15/08/2018  
Page 3 of 13

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

General advice	Keep person warm and at rest. When symptoms persist or in all cases of doubt seek medical advice. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Consult a physician.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention immediately if symptoms occur.
Ingestion	Rinse mouth. Get medical attention immediately if symptoms occur.
Inhalation	Move to fresh air. Get medical attention immediately if symptoms occur.
Protection of first-aiders	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

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

Main symptoms	If in eyes: Redness, Itching.
---------------	-------------------------------

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

Notes to physician	Treat symptomatically.
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## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

Suitable Extinguishing Media	Water spray, Foam, Dry powder, Carbon dioxide (CO <sub>2</sub> ).
Unsuitable Extinguishing Media	Do not use a solid water stream as it may scatter and spread fire.

### 5.2. Special hazards arising from the substance or mixture

Special Hazard	Hazardous decomposition products formed under fire conditions: Carbon oxides.
----------------	---

### 5.3. Advice for firefighters

Fire fighting measures	Evacuate non-essential personnel. Move containers from fire area if you can do it without risk. Keep containers and surroundings cool with water spray. Prevent fire extinguishing water from contaminating surface water or the ground water system.
Special protective equipment for fire-fighters	Wear self-contained breathing apparatus and protective suit.



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# Safety Data Sheet

## Puralact® D

Revision Date 15/08/2018  
Page 4 of 13

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

Evacuate personnel to safe areas. Do not touch or walk through spilled material. Avoid contact with skin, eyes and clothing. Do not breathe dust. Use personal protective equipment. Ensure adequate ventilation.

### 6.2. Environmental precautions

Should not be released into the environment. Prevent further leakage or spillage if safe to do so.

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

Large amounts: Prevent further leakage or spillage if safe to do so. Dike to collect large spills. Cover with plastic sheet to prevent spreading. Sweep up and shovel into suitable containers for disposal. Following product recovery, flush area with water. Small amounts: Shovel or sweep up. After cleaning, flush away traces with water. Never return spills in original containers for re-use.

### 6.4. Reference to other sections

See sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Do not breathe dust. Ensure adequate ventilation. Wear personal protective equipment. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Handle under nitrogen and protect from moisture. See annex for more detailed information.

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

Store in accordance with local regulations. Keep containers tightly closed in a cool, well-ventilated place. Protect from moisture.

### 7.3. Specific end use(s)

Exposure scenario See annex.

Other information See annex.



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# Safety Data Sheet

Puralact® D

Revision Date 15/08/2018  
Page 5 of 13

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

**Exposure Limits** Contains no substances with occupational exposure limit values.

**Biological Limit Values** Not established.

**Recommended monitoring procedures** No information available.

**Derived No Effect Level (DNEL)** For: Workers.

Chemical Name	Worker - inhalative, long-term - local	Worker - dermal, long-term - local	Worker - inhalative, short-term - local	Worker - dermal, short-term - local
(3R-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione			592 mg/m <sup>3</sup>	

### Predicted No Effect Concentration (PNEC)

Chemical Name	Freshwater	Marine water	Intermittent release	Sewage treatment plant	Freshwater sediment	Marine sediment	Soil	Oral
(3R-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione	1.3 mg/L			10 mg/L				

### 8.2. Exposure controls

**Appropriate engineering controls** Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location. See annex for more detailed information.

#### Individual protection measures, such as personal protective equipment

**Eye protection** Safety glasses with side-shields (EN166).  
**Hand Protection** Protective gloves (EN374): Butyl rubber. Glove thickness: 0.5 mm. Break through time: >8 hours.  
**Skin and body protection** Long sleeved clothing.  
**Respiratory protection** In case of insufficient ventilation wear suitable respiratory equipment (APF).  
**Recommended Filter Type** A1P2

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice. Workers must be trained in the proper use and handling of this product as required under applicable regulations. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Remove and wash contaminated clothing before re-use.

**Environmental Exposure Controls** The product should not be allowed to enter drains, water courses or the soil.



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# Safety Data Sheet

## Puralact® D

Revision Date 15/08/2018  
Page 6 of 13

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Physical state @20°C	Solid
Appearance	Flakes
Colour	White
Odour	Odourless
pH	Not applicable
Melting/freezing point	97 °C / 206.6 °F (@ 1013 hPa)
Boiling point/boiling range	266 °C / 510.8 °F (@ 1013 hPa)
Flash point	150 °C / 302 °F
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	No information available
Explosive limits	Not applicable
Vapour pressure	Not applicable
Vapour density	Not applicable
Relative density	1.33 (@20°C / 68°F)
Solubility	
Water solubility	No information available
Partition Coefficient (n-octanol/water)	No information available
Autoignition temperature	Not applicable
Decomposition temperature	No information available
Viscosity, dynamic	No information available
Explosive properties	Not applicable
Oxidising properties	Not applicable

### 9.2 Other information

Density	0.8 g/cm³
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Revision Date 15/08/2018  
Page 7 of 13

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

None known.

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No information available.

### 10.4. Conditions to avoid

Protect from water.

### 10.5. Incompatible materials

Water, Moisture ( Air ).

### 10.6. Hazardous decomposition products

Hazardous decomposition products formed under fire conditions: Carbon oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	
Ingestion	No known effect.
Skin contact	No known effect.
Inhalation	No known effect.
<b>Skin corrosion/irritation</b>	No known effect.
<b>Serious eye damage/irritation</b>	Causes serious eye irritation.
<b>Respiratory or skin sensitisation</b>	No known effect.
<b>Germ cell mutagenicity</b>	Not known to cause heritable genetic damage.
<b>Carcinogenicity</b>	Contains no ingredient listed as a carcinogen.
<b>Reproductive toxicity</b>	Not known to cause birth defects or have a deleterious effect on a developing fetus. Not known to adversely affect reproductive functions and organs.
<b>STOT-single exposure</b>	No known effect.
<b>STOT-repeated exposure</b>	No known effect.
<b>Aspiration hazard</b>	No known effect.



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## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

This product is not known to be hazardous to the environment.

### 12.2. Persistence and degradability

Readily biodegradable.

### 12.3. Bioaccumulative potential

Bioaccumulation is unlikely.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

This product is not considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

### 12.6. Other adverse effects

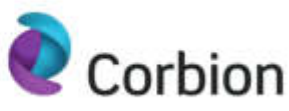
No information available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste from residues / unused products** Dispose of in accordance with local regulations.

**Contaminated packaging** Dispose of in accordance with local regulations. Do not re-use empty containers.



## SECTION 14: TRANSPORT INFORMATION

According to: ADR, RID, ADN, IMDG, IATA/ICAO.

### 14.1. UN 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

Not applicable.

### 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

## SECTION 15: REGULATORY INFORMATION

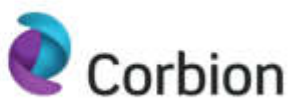
### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Restrictions on use None.

Other Regulations No information available.

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for this substance. See annex for more detailed information.



Revision Date 15/08/2018  
Page 10 of 13

## SECTION 16: OTHER INFORMATION

**Full text of H-Statements referred to under sections 2 and 3** H319 - Causes serious eye irritation

**Revision Note** Indication of the changes made to the previous version of the SDS: Section 3, REACH Registration Number.

**Training Advice** Workers must be trained in the proper use and handling of this product as required under applicable regulations.

**Abbreviations and acronyms**

REACH: Registration, Evaluation, Authorisation and Restriction of Chemical substances  
EC: European Commission  
STOT: Specific Target Organ Toxicity  
PBT: Persistent, Bioaccumulative, Toxic  
vPvB: very Persistent and very Bioaccumulating  
ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement concernant le transport international ferroviaire des marchandises dangereuses (Regulations for the International Transport of Dangerous Goods by Rail)  
ADN: Accord européen relatif au transport international des marchandises Dangereuses par voies de Navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)  
IMDG: International Maritime Dangerous Goods Code  
ICAO: International Civil Aviation Organization

**SDS No.** CO00020  
**Subformat** CTEU

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 2015/830. Label element according to Regulation (EC) No 1272/2008.

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End of Safety Data Sheet



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## READER'S GUIDE

The generic Exposure Scenario GES1 is covering following identified uses:

1. Production of polylactic acid
2. Manufacture of cosmetic products

Generic Exposure Scenario GES1: Production, transport and downstream use of L-lactide:

Lactide is a cyclic dimer of lactic acid, which rapidly hydrolyses into lactic acid in vivo and in the presence of water. Except for local effects (skin and eye contact), all lactide toxicology can be understood in terms of lactic acid toxicology.

Lactic acid is a non-toxic substance that is a basic metabolic and energetic building block in practically all life-forms, from bacteria to primates. It is not labelled for environmental effects or ecotoxicity, and is also not labelled for any human effects, with the exception of skin and eye irritation (Lactic acid is classified for skin as Xi; R38, GHS: Category 2, and for eyes as Xi; R41, GHS: Category 1). Note that the skin and eye irritation potential of lactic acid is a pH effect - buffered lactic acid, even up to 70% aqueous solutions is not irritating.

As such, no risk assessment for the environment is required, and no environmental exposure assessment is necessary. For human health, lactic acid is not labelled for any 'dose-effect' endpoint, and thus no quantitative risk assessment is necessary or possible.

Lactide is labelled for eye irritation (Xi; R36, GHS: Category 2). Under the current classification and labelling requirements for preparations, preparations containing less than 20% lactide do not have to be classified for eye irritation.

In all production, storage and transportation conditions and processes, regardless of use, where PURAC's lactide is handled, i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', Risk Management Measures are already prescribed, and enforced, that exclude any possible eye exposure to lactide. In all identified downstream uses where lactide is handled (such as the receipt of transported lactide, the storage of lactide, the introduction of lactide in any relevant process, i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', Risk Management Measures are already prescribed, and enforced, that exclude any possible eye exposure to lactide.

As such, a generic exposure scenario for all identified uses of lactide can be defined:

- For the environment, no hazards are identified, and no exposure assessment is required.
- For human exposure, the only identified hazard is eye irritation, and due to RMM, no exposure to lactide is possible. Exposure is 0.

Annex No. CO10004 /COTG



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## 1. EXPOSURE SCENARIO

Exposure scenario	GES1
Title	Production, transport and downstream use of L-lactide (pure substance or >=20% in a mixture)
<u>Use Descriptor</u>	
Sector of use	SU10, SU12
Environmental release categories	ERC1, ERC2, ERC6a, ERC6c, ERC7
Product category	PC32, PC39
Process categories	PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15
Article categories	-

## 2. CONDITIONS OF USE AFFECTING EXPOSURE

### 2.1 Contributing Scenario - Environment

Not applicable.

### 2.2 Contributing Scenario - Worker & Consumer

<b>Product characteristics</b>	
Physical state @20°C	Solid
Concentration of substance in product	Covers percentage substance in the product up to 100 %.
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently).
<b>Other operational conditions affecting worker exposure</b>	
Work area	Indoor/outdoor use.
<b>Technical conditions and measures to control dispersion from source towards the worker</b>	Avoid temperatures above 150 °C / 302 °F. Ensure adequate ventilation, especially in confined areas.
<b>General measures</b>	
	Use suitable eye protection (safety glasses with side-shields, tested to EN166)
	Provide basic employee training to prevent/minimize exposures and to report any eye problems that may develop
<b>General measures applicable to all activities</b>	No other specific measures identified.

## 3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Environment Exposure Estimation	L-lactide is not classified as hazardous for environmental endpoints. A quantitative exposure assessment for the environment has not been conducted.
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# Safety Data Sheet

Puralact® D

## Health Exposure Estimation

L-Lactide is classified as a skin and eye irritant, which requires a qualitative risk characterization of any dermal or eye exposures according to REACH guidance Chapter E. A quantitative assessment of dermal and eye exposures has not been conducted.

## 4. GUIDANCE TO CHECK COMPLIANCE WITH THE EXPOSURE SCENARIO

### Environmental Exposure Controls

**Control of environmental exposure** Not applicable.

**Used EUSES model** No information available.

**Non-standard assumptions** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

### Control of worker exposure

**ECETOC TRA** No information available.

**Derived No Effect Level (DNEL)** Available hazard data do not enable the derivation of a DNEL for dermal or eye irritant effects. Risk Management Measures are based on qualitative risk characterization.

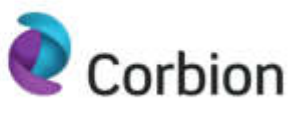
Available hazard data do not support the need for a DNEL to be established for other health effects. Users are advised to consider national Occupational Exposure Limits or other equivalent values.

Where other risk management measures/operational conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

### Guidance to check compliance with the exposure scenario

No information available.

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