

Safety Data Sheet

Puralact® L

Revision Date 15/08/2018
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Date previous version 23/11/2017
Version 3.1 - EN

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name	L-Lactide
Trade name	Puralact® L Polymer Grade Lumilact L Polymer Grade
Synonyms	Dilactide
CAS-No	4511-42-6
EC-No	224-832-0
REACH Registration Number	01-2119489904-22-0002

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

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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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.
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Chemical Name	EC-No	CAS-No	Weight %	Classification (1272/2008/EC)	REACH Registration Number
(3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione	224-832-0	4511-42-6	>98	Eye Irrit. 2 H319	01-2119489904-22-0002

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



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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, Pain.

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

Notes to physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Water spray, Foam, Dry powder, Carbon dioxide (CO ₂).
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 Dust can form an explosive mixture in air.

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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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. Avoid dust formation. Fine dust dispersed in air may ignite. 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	Not available.



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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) Not determined.

Predicted No Effect Concentration (PNEC)

Chemical Name	Freshwater	Marine water	Intermittent release	Sewage treatment plant	Freshwater sediment	Marine sediment	Soil	Oral
(3S-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. Keep at temperatures below 150 °C / 302 °F. 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 inadequate ventilation wear respiratory protection.

Recommended Filter Type

A1P3

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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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	No information available
Melting/freezing point	97 °C / 206.6 °F (@ 1019 hPa)
Boiling point/boiling range	266 °C / 510.8 °F (@ 1019 hPa)
Flash point	150 °C / 302 °F
Evaporation rate	Not applicable
Flammability (solid, gas)	Not flammable
Flammability Limits in Air	Not applicable
Explosive limits	Not applicable
Vapour pressure	0.28 Pa (@25°C)
Vapour density	Not applicable
Relative density	1.33 (water = 1)
Solubility	
Water solubility	16.7 g/L (@ 20.1 °C / 68.2 °F)
Solubility in other solvents	Toluene: > 167 g/L
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/cm ³ (Flakes) / 1.33 g/cm ³ (Solid)
Danger of dust explosions	Yes



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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

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

10.4. Conditions to avoid

Protect from water.

10.5. Incompatible materials

Water, Moisture (Air).

10.6. Hazardous decomposition products

Carbon oxides.



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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity
Ingestion No known effect.
Skin contact No known effect.
Inhalation No known effect.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
(3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione	>2000 mg/kg (Rat)	>2000 mg/kg (Rabbit)	>7.94 mg/L (Rat) 4h

Skin corrosion/irritation No known effect.

Serious eye damage/irritation Causes serious eye irritation. OECD 405, Rabbit, 24h: Moderate eye irritation.

Chemical Name	Skin corrosion/irritation	Serious eye damage/irritation
(3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione	OECD 404 Rabbit 72h Result Non-irritating	OECD 405 Rabbit 24h Result Moderate eye irritation

Respiratory or skin sensitisation No known effect. Did not cause sensitisation on laboratory animals (Skin Sensitisation, OECD 429, mouse).

Germ cell mutagenicity Not known to cause heritable genetic damage.

Carcinogenicity Contains no ingredient listed as a carcinogen.

Reproductive toxicity Not known to cause birth defects or have a deleterious effect on a developing fetus. Not known to adversely affect reproductive functions and organs.

STOT-single exposure No known effect.

STOT-repeated exposure No known effect.

Aspiration hazard 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.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Toxicity to daphnia and other aquatic invertebrates
(3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione			LC50: > 100 mg/L 3h	

12.2. Persistence and degradability

Readily biodegradable.

12.3. Bioaccumulative potential

Does not bioaccumulate.

Chemical Name	Log P _{ow}	Bioconcentration factor (BCF)
(3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione	1.65	

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

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.



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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.



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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: REACH Registration Number, Section 3.
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.	CO00123
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. CO10003 /COTG



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ANNEX TO THE SAFETY DATA SHEET

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

Product characteristics	
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).
Other operational conditions affecting worker exposure	Assumes a good basic standard of occupational hygiene is implemented.
Work area	Indoor/outdoor use.
Technical conditions and measures to control dispersion from source towards the worker	Avoid temperatures above 150 °C / 302 °F. Ensure adequate ventilation, especially in confined areas.
General measures	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
General measures applicable to all activities	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® L

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.

Annex No. CO20005 /CTES



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