



Product Safety Sheet

The document drafted on a voluntary basis is not required under Article 31 of Regulation (EC) No 1907/2006 and subsequent amendments

Printing date 26.06.2023

Version number 3 (replaces version 2)

Revision: 26.06.2023

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

1.1 Product identifier

Trade name:	PHARMALENE LDPE
Chemical name	LOW DENSITY POLYETHYLENE (LDPE)
(e-)SDS code	11575

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

Application of the substance / the mixture	No further relevant information available. Production of final articles for application in the pharmaceutical and medical industry
Uses advised against	No further relevant information available.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:	Versalis S.p.A. Piazza Boldrini, 1 I-20097 San Donato Milanese (MI) Phone: +39 02 520 1
E-mail address of the competent person responsible for the SDS:	e-mail: SDS.versalis@versalis.eni.com
1.4 Emergency telephone number:	CNIT (24h): (+39) 0382100

* SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008	Based on the requirements of the CLP Regulation, the product is not classified.
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2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008	Not applicable
Hazard pictograms	Not applicable
Signal word	Not applicable

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Hazard statements

Not applicable

2.3 Other hazards

Results of PBT and vPvB assessment

Not applicable.

PBT:

This substance / mixture is not a PBT applying the criteria of REACH Regulation, Annex XIII.

vPvB:

This substance / mixture is not a vPvB applying the criteria of REACH Regulation, Annex XIII.

Determination of endocrine-disrupting properties

The mixture does not contain one or more substances with endocrine-disrupting properties at a concentration of 0.1% or more

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description:

Mixture, composed of a polymer and of substances below the applicable classification limits or not dangerous
Polymer: Polyethylene, CAS: 9002-88-4

Dangerous components:

Not applicable

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

No special measures required.

After inhalation:

Dust or gas/vapours released by heat: move the affected person away from the contaminated area into fresh air; seek medical assistance.

After skin contact:

In case of contact with melted material, cool down with cold water and seek medical assistance. Do not remove the product that solidified on skin. Treat as a burn.

After eye contact:

Rinse opened eye for several minutes under running water.

After swallowing:

No specific measure requested in case of ingestion. If needed seek medical assistance.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

Water, water spray, foam, dry chemicals, carbon dioxide.

For safety reasons unsuitable extinguishing agents:

Water with full jet

5.2 Special hazards arising from the substance or mixture

Combustion products: carbon dioxide, carbon monoxide (when starved of air / oxygen), and possible unburned hydrocarbons.

Overheating/pyrolysis may evolve vapours made up of monomers, low molecular weight polymers and their oxidation products.

Powders have specific fire risks.

5.3 Advice for firefighters

Protective equipment:

Wear suitable protective clothing (helmet, goggles, fire resistant gloves, boots) and protect respiratory organs (self contained breathing apparatus).

Additional information

The product is combustible.

Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not walk on granules to avoid slipping.

6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up:

Collect by mechanical means.

Dispose of the material collected according to regulations.

6.4 Reference to other sections

For information on disposal of contaminated material, see section 13.

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No dangerous substances are released.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Powder formation by abrasion must be avoided during handling and transportation, especially when unloading; if such formation occurs, the powder must be eliminated immediately.
During the processing of the product, avoid inhalation of fumes or powders, by providing good ventilation of the workroom and, if necessary, by a suitable exhaust system.

Information about fire - and explosion protection: Avoid dispersion of dust in air to reduce potential for ignition or explosion.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Earth storage silos as precautionary measure against the static electricity build-up.

Information about storage in one common storage facility:

Not required.

Further information about storage conditions:

In storage and working areas avoid pellets spilling as a possible cause of slipping.

Store out of direct sunlight, in well ventilated, cool and dry place.

Product should be stored in a safe manner, to avoid danger from unstable or damaged packaging units (octabins/bags/boxes on pallet). In particular, stacking of packaged units can be dangerous to warehouse personnel.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Appropriate engineering controls

No further data; see item 7.

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General protective and hygienic measures:	Traces of monomers and other volatile substances may be given off during processing, particularly at unusually high processing temperatures. Work rooms must be provided with adequate ventilation and exhaust equipment to collect dust and gas/vapours that may be evolved during the conversion.
Suitable technical controls	Ensure good ventilation / exhaustion at the workplace.
Personal protection measures	The personal protective equipment will vary according to the possible exposure and danger of working conditions.
Respiratory protection:	In normal conditions masks with antidust filters should be available for use when requested.
Protection of skin	
Hand protection	Protective gloves
Eye/face protection	Safety glasses
Other:	Standard work clothes.
Thermal dangers	No information available
Environmental exposure controls	No information available.

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* SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	Solid
Form:	Granulate
Colour:	White
Odour:	Weak, characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	>100 °C
Boiling point or initial boiling point and boiling range	Undetermined.
Flammability	Product is not flammable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Ignition temperature:	~340 °C
Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.

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pH	Not applicable.
Viscosity:	
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	
Density at 20 °C:	0.91-0.93 g/cm ³
Relative density	Not determined.
Bulk density at 20 °C:	450-600 kg/m ³
Vapour density	Not applicable.
Particle characteristics	Not determined.

9.2 Other information

Change in condition	
Evaporation rate	Not applicable.

9.2.1 Information with regard to physical hazard classes

Explosive properties:	Product does not present an explosion hazard.
Explosives	Not applicable
Flammable gases	Not applicable
Aerosols	Not applicable
Oxidising gases	Not applicable
Gases under pressure	Not applicable
Flammable liquids	Not applicable
Flammable solids	Not applicable
Self-reactive substances and mixtures	Not applicable
Pyrophoric liquids	Not applicable
Pyrophoric solids	Not applicable
Self-heating substances and mixtures	Not applicable
Substances and mixtures, which emit flammable gases in contact with water	Not applicable
Oxidising liquids	Not applicable
Oxidising solids	Not applicable
Organic peroxides	Not applicable
Corrosive to metals	Not applicable

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Desensitised explosives

Not applicable

9.2.2 Other safety characteristics

Not determined.

SECTION 10: Stability and reactivity

10.1 Reactivity

The product does not participate to dangerous reactions if stored and handled as prescribed/indicated

10.2 Chemical stability

Thermal decomposition:

Prevent the formation of noxious gases and vapours by using the advised conversion conditions.

Prolonged exposure to temperatures above 250°C may cause resin degradation.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials:

Avoid the contact with oxidising substances.

10.6 Hazardous decomposition products:

The product, when involved in a fire, release fumes made up of water, carbon dioxide, carbon monoxide (when starved of oxygen) and other combustion products.

* SECTION 11: Toxicological information

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

Acute toxicity

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

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11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

The mixture does not contain one or more substances with endocrine-disrupting properties at a concentration of 0.1% or more

11.2.2 Other information

Not determined.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

The product is essentially a high molecular weight polymer, not regarded as ecotoxic.

12.2 Persistence and degradability

The product is a non biodegradable polymer.

12.3 Bioaccumulative potential

Does not accumulate in organisms

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT:

This substance / mixture is not a PBT applying the criteria of REACH Regulation, Annex XIII.

vPvB:

This substance / mixture is not a vPvB applying the criteria of REACH Regulation, Annex XIII.

12.6 Endocrine disrupting properties

The mixture does not contain one or more substances with endocrine-disrupting properties at a concentration of 0.1% or more

12.7 Other adverse effects

No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

The same safety considerations that apply to the product as it is, apply to scraps/waste as well.
Residues should be disposed of as required by national and local regulations. The incineration must be done under approved conditions, possibly with energy recovery and only at suitable facilities equipped with a scrubber for the treatment of fumes before their release into the atmosphere.

Uncleaned packaging:
Recommendation:

Disposal must be made according to official regulations.

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Recommended cleansing agents: Not applicable.

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* SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN, ADN, IMDG, IATA Not applicable

14.2 UN proper shipping name

ADR/RID/ADN, ADN, IMDG, IATA Not applicable

14.3 Transport hazard class(es)

ADR/RID/ADN, ADN, IMDG, IATA

Class Not applicable

14.4 Packing group

ADR/RID/ADN, IMDG, IATA Not applicable

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

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Annex II - REPORTABLE EXPLOSIVES PRECURSORS
None of the ingredients is listed.
Regulation (EC) No 273/2004 on drug precursors
None of the ingredients is listed.
Regulation (EC) No 1111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors
None of the ingredients is listed.

National regulations:

Not applicable

Regulations of the European Union

Not applicable

15.2 Chemical safety assessment:

Assesment not required.

SECTION 16: Other information

Relevant phrases

Not applicable.

Department issuing SDS:

QHSE/SIPR

Date of previous version:

07.10.2022

Version number of previous version:

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
 RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative

Sources

- 1) NIOSH - Registry of Toxic Effects of Chemical Substances
- 2) WEAST - Handbook of Chemistry and Physics
- 3) INRS - Fiches toxicologiques
- 4) A.C.G.I.H. - Documentation of the Threshold Limit Values
- 5) ITI - Toxic and Hazardous Industrial Chemicals Safety Manual
- 6) BRETHERICK - Handbook of Reactive Chemical Hazards
- 7) NIOSH/OSHA - Pocket Guide to Chemical Hazards

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- 8) PATTY - Industrial Hygiene and Toxicology
- 9) SAX - Dangerous Properties of Industrial Materials
- 10) ILO - Encyclopedia of Occupational Health and Safety
- 11) NATIONAL TOXICOLOGY PROGRAM (NTP) - Annual Report on Carcinogens
- 12) NTP - Review of current DHHS, DOE, and EPA-Research related to Toxicology - FY
- 13) IARC - Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans
- 14) NIOSH/OSHA - Occupational Health Guidelines for Chemical Hazards
- 15) CCTN - Commissione Consultiva Tossicologica Nazionale - Ministero della Sanità - Roma
- 16) MERCK & Co. - The Merck Index
- 17) VERSCHUEREN K. - Handbook of Environmental Data on Organic Chemicals
- 18) EPA - Chemical Emergency Preparedness Program - Interim Guidance - Chemical profiles
- 19) Marrubini, Laurenzi, Uccelli: Intossicazioni acute
- 20) LENGA - The SIGMA-ALDRICH Library of Chemical Safety Data
- 21) INRS - Réaction Chimiques Dangereuses
- 22) DUTCH CHEMICAL INDUSTRY ASSOCIATION - Chemical Safety Sheets
- 23) NFPA - "National Fire Codes"
- 24) Perry's Chemical Engineers' Handbook
- 25) Producer's data

* Data compared to the previous version altered.

Data and information contained in this Safety Data Sheet are based on our available knowledge at the last revision date. No guarantee can be given as to the sufficiency of any safety measures contained in this Safety Data Sheet, nor can it be assumed that other or additional measures may not be required under particular or exceptional circumstances. The user must make sure of the fitness and completeness of the information, according to the specific use they want to do.