

PHARMALENE® LLDPE grades

Polyethylene

Pharmalene is a Polyethylene (PE), produced by Versalis with approved components (monomer, additives, etc.) under a third party certified ISO 9001:2015 Quality Management System.

Regulated and declarable substances

In the manufacturing of all Pharmalene grades, the following substances or class of substances are either not intentionally used or the product complies with the applicable requirements of the regulatory reference cited:

SUBSTANCES	REGULATORY REFERENCE
Acrylamide	Reg. (EC) No 366/2011
Aromatic amines	Reg. (EC) No 1907/2006, Annex XVII
Asbestos fibres	Reg. (EC) No 1907/2006, Annex XVII
Azocolourants and Azodyes	Reg. (EC) No 1907/2006, Annex XVII
Benzophenone	Reg. (EC) No 1223/2009
Biocides	Reg. (EU) 528/2012
Bisphenols, including Bisphenol-A, -B -F, -S	Reg. (EC) No 321/2011
Butylhydroxytoluene(BHT); Butylhydroxyanisole (BHA)	---
Flame retardants (brominated, chlorinated, etc.)	---
Chlorinated aliphatic compounds; Alkanes, C ₁₀ -C ₁₃ , chloro (Short-Chain Chlorinated Paraffins - SCCPs)	Regulation (EC) 2019/1021 (POP) [recast of Reg. (EC) 850/2004]
Colorants, pigments	Resolution AP 89(1)
Conflict Minerals: Tantalum, Tungsten, Tin, Gold, Cassiterite, Columbite-Tantalite (Colran), Wolframite and their derivatives	Dodd-Frank Wall Street Reform and Consumer Protection Act (2010)
Di(ethylhexyl) adipate (DEHA); di(ethylhexyl) maleate (DEHM)	---
Dimethylfumarate (DMF)	Commission Decision 2009/251/EC
Dioxins and difurans	---
Epoxy derivatives (BADGE, NOGE, BFDGE)	Regulation (EC) No1895/2005
ESBO Epoxidized soy bean oil	Directive 2005/79/EC
Endocrine Disruptors	The product does not contain substances with endocrine disruptor (ED) properties according to current applicable legislation requirements in EU.
Food allergens	Regulation (EC) 1169/2011 - annex II
Forbidden halogen compounds (Cl, F, Br, I based)	---

SUBSTANCES	REGULATORY REFERENCE
Formaldehyde	EN 71-9
Genetically modified organisms (GMO)	Directive 2001/18/EC
Heavy metals: cadmium (Cd), hexavalent chromium (Cr VI), lead (Pb), mercury (Hg) and their compounds	Directive 94/62/EC "Packaging and packaging waste", Directive 2000/53/EC "End of Life Vehicles", Dir. 2011/65/EU "Restriction of Hazardous Substances - RoHS", US CONEG Legislation; GB/T 26572-2011 (China RoHS) GB/T 30512—2014 (China ELV).
Isoprophyltioxantone (ITX)	Reg. (EC) No 2023/2006
Jatropha plant derivatives and extracts	---
Melamine	Reg. (EU) 284/2011
Nanomaterials	Commission Recommendation 2011/696
Natural Latex, natural rubbers	---
Nitrosamines	Directive 1993/11/EEC
Nonylphenol, nonylphenol ethoxylates, TNPP, Alkylphenols etoxylated (APEO)	Reg. (EC) No 1907/2006, Annex XVII
Ozone depleting substances: chlorofluorohydrocarbons (CFC, HCFC)	Regulation (EC) No 1005/2009
Perfluorooctane sulfonates (PFOS), Perfluorooctanoic acid (PFOA) Perfluorinated alkyl substances (PFAS)	Reg. (EC) No 1907/2006, Annex XVII
Persistent Organic Pollutants (POP)	Regulation (EC) 2019/1021 (POP) [recast of Reg. (EC) 850/2004]
Pesticides, Herbicides	Regulation (EC) No 1107/2009
Phthalates (e.g. DEHP, DBP, BBP, DINP, DIDP, DIBP, DNOP, etc.)	Reg. (EC) No 1907/2006, Annex XVII; Directive 2011/65/EU "Restriction of Hazardous Substances, RoHS"; Directive 2015/863/EU.
Polychlorinated biphenyls, polychlorinated terphenyls (PCB, PCT)	Reg. (EC) No 1907/2006, Annex XVII
Polycyclic aromatic hydrocarbons (PAH)	Reg. (EC) No 1907/2006, Annex XVII
Polybrominated-diphenyl compounds (PBB, PBDE incl. penta- octa- and deca-BDE)	Reg. (EC) No 1907/2006, Annex XVII; Directive 2011/65/EU "RoHS", GB/T 26572-2011 (China RoHS); GB/T 30512—2014 (China ELV)
PVC, PVDC, vinyl chloride monomer (VCM)	---
Radioactive substances	Council Directive 2013/59
Recycled materials	---
Tin organic compounds (MTB, DBT, TBT, etc.)	Reg. (EC) No 1907/2006, Annex XVII; Commission Decision 2009/425/EC
Thiuram mix	---

From the foregoing we can confirm that there is no reason that said substances may be found in the above mentioned materials as supplied in original sealed packaging.

Regarding other substances not listed in this statement, we confirm that our mentioned products comply with all the applicable restrictions set by the REACH Regulation (EC) No 1907/2006, annex XVII "Restrictions on the manufacture, placing on the market and use of

certain dangerous substances, preparations and articles” and following amendments: these laws and their amendments represent our applicable regulatory reference in case of claims.

Compliance with specific Regulations

The Pharmalene PE grades comply with the applicable requirements of the following regulations:

BSE/TSE: The products do not contain specified risk materials as defined by Regulation (EC) 999/2001/EC and by the EMEA guideline 410/01 rev. 3.

Toy safety standards: The products are compliant with the applicable requirements of Directive 2009/48/EC on the safety of toys and in compliance with the compositional requirements of EN 71-3 “Safety of toys - Migration of certain elements”.

The products are compliant with the compositional requirements of the Consumer Product Safety Improvement Act of 2008 (CPSIA - USA); no lead and lead-based compounds (section 101 of the Act) and phthalates (section 108 of the Act) are used in the production.

Proposition 65: we do not intentionally use chemicals listed in Proposition 65 (latest list issued 13/09/2019) in the production of our mentioned materials.

RoHS, ELV, Packaging and Packaging Waste: as mentioned in the table above, the products comply with the applicable requirements of these EU Regulations.

Switzerland VOC ordinance: the products are exempted by the Ordinance 814.018 (OCOV) as the residual volatile compounds are below the regulation’s 3% limit.

CMR substances: no substances classified in Category 1A, 1B and 2 by Regulation (EC) 1272/2008 is used in the production of these materials.

Reused/Recycled materials: No reused or recycled materials are used in the production of the mentioned Versalis products; Reg. (EC) No 282/2008 is not applicable to our products.

National Chemical Inventories

Pharmalene base polymer (Polyethylene) and the additives used in its formulation are listed in the following national chemical inventories:

USA: Toxic Substances Control Act (TSCA): active.

Canada: Domestic Substances List (DSL)

Europe: EINECS/ELINCS; REACH pre-registration and Registration procedure (where applicable)

Australia: Inventory of chemical substances (AICS)

New Zealand: Inventory of chemical substances (NZIoC)

Korea: Existing Chemical List (ECL)

Japan: Inventory of Existing and new chemical substances (ENCS)

Philippines: Inventory of Chemicals and Chemical Substances (PICCS)

China: Inventory of Exist. Chem. Substances Manufactured or Imported in China (IECSC)


Taiwan: Taiwan Chemical Substances Inventory (TCSI).

Food Contact and Pharmacopoeia Status

The Pharmalene grades comply with the rules in force in Europe for plastic materials intended

for food contact applications (Regulation EC n.10/2011 and following amendments) as well as in other Countries. Pharmalene grades comply with the applicable monographs on polyolefins in the current European Pharmacopoeia. Specific statements of compliance are available upon request.

This document is issued by the Product Compliance Dept. of Versalis SpA



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This statement is valid three years and replaces those issued earlier.

TDS, SDS, product leaflets and company certifications are available in www.versalis.eni.com.