



versalis

Direzione e Uffici Amministrativi

Piazza Boldrini, 1
20097 San Donato Milanese (MI)
Tel. centralino: +39 02 5201
www.versalis.eni.com - info@versalis.eni.com

FOOD GRADE STATEMENT

Pharmalene MR 50 PH

Our mentioned product, as supplied in original packaging, complies by composition with the regulations currently in force for plastic materials intended to come into contact with foodstuffs in the following Countries:

- **Italy:** Decreto Ministeriale 21.03.73 "Disciplina igienica degli imballaggi, recipienti, utensili destinati a venire a contatto con le sostanze alimentari e le sostanze d'uso personale" and following amendments.
- **Germany:** Bedarfsgegenständeverordnung of 23/12/1997 as modified by Verordnung 24/06/2013 and following amendments.
- **Austria:** Kunststoffverordnung 2003, BGBl. teil II 476/2003 and following amendments.
- **France:** Applicable regulations published in the Brochure N°1227. Arrêté du 02/01/2003 "Matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires" as modified by Arrêté 01/04/2011 and following amendments.
- **The Netherlands:** Verpakkingen en Gebruikaartikelen Besluit (Warenwet) Deel A, Hofdstuck 1 Kunststoffen - Dec. 2013 and following amendments.
- **Belgium:** Arrêté Royal 03/07/2005 "Materiaux et object destines a entrer en contact avec les denrées alimentaires" as amended by Arrêté Royal 10/02/2011 and following amendments.
- **United Kingdom:** Statutory Instrument 2012, No. 2619 "The Plastic Materials and Articles in Contact with Food, Regulations 2012" and following amendments.
- **Spain:** Real Decreto 886/2008 of 23/05/2008 and following amendments. Real Decreto 103/2009 of 06.02.2009. Real Decreto 847/2011 of 17/06/2011.
- **Switzerland:** RS 817.023.21 "Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires" dated 16.12.2016 (status 01.05.2017).
- **China:** GB 4806.1-2016 "General safety requirements on food contact materials and articles". GB 4806.6-2016 "Plastic resins for food contact". GB 9685-2016 "National food safety standard on use of additives for food contact materials and articles".
- **USA:** Code of Federal Regulations, 2018 Food and Drug Administration (FDA) Title 21 §177.1520 (Olefin polymers) – paragraph (c) point 3.1.a.
- **European Union:** Commission Regulation (EU) No 10/2011 "Plastic materials and articles intended to come into contact with food" and following amendments.

The monomers have no migration limits.

The products contain an additive with migration restriction:

- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate

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Sede Legale: San Donato Milanese (MI) - Piazza Boldrini, 1 - Italia
Capitale sociale interamente versato: Euro 1.364.790.000,00
Codice Fiscale e Registro Imprese di Milano-Monza-Brianza-Lodi 03823300821
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Società soggetta all'attività di direzione e coordinamento di Eni S.p.A.
Società con socio unico



pm/ref 68320, SML=6mg/kg (max. use concentration 320ppm).

The product in subject contains an inorganic aluminium additive (aluminium: SML: 1 mg/kg in food or food simulant).

Overall and specific migration testing has to be performed by the end-user on the final item, according to the expected use conditions, to verify the compliance with the applicable statutory limits.

The products do not contain substances authorized as flavourings, nor as direct food additives with restrictions in Regulation (EC) No1333/2008 (Dual Additives) and following amendments.

We confirm that our mentioned products are manufactured using the Good Manufacturing Practices (GMP) recommended by Commission Regulation (EC) No 2023/2006.

With our mentioned products can be manufactured materials (e.g. foils) and articles (cups, packaging, cookware, etc.) complying with the applicable requirements of the Framework Regulation (EC) No 1935/2004 "Materials and articles intended to come into contact with foodstuffs".

We point out that it is a responsibility of the end users to ensure that materials and articles, manufactured under good manufacturing practices (Regulation (EC) 2023/2006), under the normal or foreseeable conditions of use, do not transfer their constituents to foodstuffs in quantities which could endanger human health and/or bring unacceptable changes in the composition of the foodstuffs or a deterioration in the organoleptic properties (Regulation (EC) No 1935/2004).

Product Compliance Mgr.
Salvatore Minardi

Revision 26/03/2020

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