



versalis

# Declaration of Compliance Food grade statement

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## Pharmalene®

### PHARMALENE MT 10 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. BfR III "Polyethylen" issue 01/04/2021.

**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" as amended by Statutory Instrument 2019, No. 704.

**Spain:** Real Decreto 846/2011 of 17/06/2011; 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 01.12.2020).

**Latin America:** MERCOSUR GMC n.39/19 "Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coating in contact with foodstuffs". The polymer is listed in the Technical Regulation GMC n.02/12 as amended by GMC n.19/21.

The product does not contain additives with migration restriction in GMC n.39/19.

**Japan:** MHLW Public Notice No.196. The base polymer is approved for use with all food categories. The additives used in the production of the material are all listed in the Positive List of additives.

The base polymer (ethylene homopolymer – table 1-1; ref.n.985) is approved for use with all food categories; the maximum allowed temperature that can be reached in use exceeds 100°C (III).

**China:** GB 4806.1-2016 "General safety requirements on food contact materials and articles" The polymer is listed as polyethylene, No.91. 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".

The product does not contain additives with migration restriction in GB 9685-2016.

The good manufacturing practices according to the requirements of GB 31603-2015 "General Hygienic Practice for Production of Food Contact Materials and Its Products" are applied.

**USA:** Code of Federal Regulations, 2021 Food and Drug Administration (FDA) Title 21 §177.1520 (Olefin polymers) – paragraph (c) 2.1.

**European Union:** Commission Regulation (EU) No 10/2011 "Plastic materials and articles intended to come into contact with food" and following amendments.

The product is a polyethylene (monomer: Ethylene, Ref. No 16950) that does not contain additives with migration restriction.

Based the tests performed, the substances listed in Annex II of Regulation (EU) 10/2011 were not detected or their migration were below the limits prescribed in Annex II.

With regard to substances resulting from intentional use during the manufacturing, potentially present in quantities that could be expected to result in migration from the finished material of more than 0.00015mg/kg food simulant and whose genotoxicity has not been ruled out, we state that, to the best of our current knowledge, such substances are not present in our product, based on screening of specimens made from granules of our material.

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

The product does not contain substances authorized as flavourings, nor as direct food additives with restrictions in Regulation (EC) No1333/2008 and Regulation (EC) No 1334/2008 (Dual Additives) and following amendments.

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

With our mentioned product can be manufactured materials and articles 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).

*Declaration of compliance issued by the  
Product Sustainability Dept. of Versalis SpA*

Updated 30/08/2022

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

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Disclaimer: the information and data presented herein are to the best of our knowledge true and accurate; no warranty or guarantee, expressed or implied, is made nor is any liability accepted with respect to the use of such information and data. The reference are the applicable regulatory requirements. Please refer to the relevant Safety Data Sheet and to the Technical Data Sheet for additional product's information.

*TDS, SDS, product leaflets and company system certifications are available in*  
[www.versalis.eni.com](http://www.versalis.eni.com).