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S. Donato Milanese, 20/03/13

PLASTCOM

c/o Polimeri Europa Norden A/S

attn. Mrs. Pia N. Villefrance

Re.: Suitability for food contact and medical applications – European Pharmacopoeia.

Our plastic material Edistir R 321 P nat, as supplied in original packaging, is suitable for the manufacturing of items intended to come into contact with foodstuffs, complying with the prescriptions set by the regulations currently in force in the following Countries:

- **Italy:** Decreto Ministeriale del 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 von 13.07.2005 and following amendments.
- **France:** Applicable regulations published in the Brochure N°1227 - Journal Officiel de la République Française. 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" and following amendments.
- **The Netherland:** Verpakkingen en Gebruiksartikelen Besluit (Warenwet) 21.08.1991 and following amendments.
- **United Kingdom:** Statutory Instrument 2002, No. 2364 "The Plastic Materials and Articles in Contact with Food, Regulations 2002" and following amendments.
- **Belgium:** Arrêté Royal of 25.08.76 and following modifications. Arrêté Royal 11 Mai 1992 "Materiaux et object destines a entrer en contact avec les denrées alimentaires" and following amendments.
- **USA:** Code of Federal Regulations, Title 21 - Food and Drug Administration (FDA) § 177.1640 (a) (2) (rubber modified polystyrene).
- **EU:** Commission Regulation (EU) N°10/2011 "Plastic materials intended to come into contact with food" and following amendments.

We remind, however, that it is end-user's duty to ascertain that the finished items, manufactured according to a skilled technique with said product, correspond to all requirements of the application they are intended for.

We can also confirm that our material in ref., as supplied in original packaging, can be used in the production of containers and closures, as described in European Pharmacopoeia Chapter VI 3.2.2 "Plastic containers and closures" (version 01/2008) or of other final medical applications providing that a specific approval be issued by the Local Authorities responsible for the licensing for sale of the preparation in the container or of the medical application (see chapter 3.1).

We are willing to disclose the formulation details to the Certification Body, in case it should be needed to achieve a certification, under secrecy agreement.

We remind, once again, that it is implicit in European Pharmacopoeia that the Producer of the container have to submit the material to testing, reproducing the conditions of the intended use, to verify the compatibility of the container itself with the preparation in order to apply for the authorisation to the National Authorities.

Yours sincerely

  
Product Compliance Mgr.  
Salvatore Minardi

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