

Declaration of Conformity

Series Standard Pharma-Tech
Version 23_011_EN
Date 02.01.2023

Declaration of conformity according to Annex IV of the EU directive 10/2011

(1) PHACOTEC Produkt-Service GmbH, Am Pfeilshof 9A, 22393 Hamburg (DE)

(2) Pharma-Tech, Messingvej 23, 8940 Randers SV (DK)

(3) HDPE

(4) 02.01.2023

(5) The manufacturer (2) declares that the plastic materials or articles, the products from intermediate stages of manufacture or the substances comply with the relevant requirements of the updated Regulation EU 10/2011, the Framework Regulation (EC) No 1935/2004 or No 2015/174 respectively

(6) Substances with SML or QM values or substances with specific migration limits shall be used for colouring the final product. Compliance with the limit values shall be confirmed for the specified food types and conditions of use.

(7) The raw material (3) and/or the pigments for colouring may contain the following dual-use additives:

- E470a (calcium salts of fatty acids)
- E170, E171, E172, E173, E551, E570

The specific migration and/or the total migration are below the legal limits when applied according to specifications.

(8) The material is suitable for all types of food (at a filling temperature < 70°C and long-term storage of more than 6 months at room temperature and below).

Ratio of food contact surface area to volume used to establish the compliance of the material or article: 11,7 dm² per 1 kg of food.

In addition to the data provided, we recommend the customer to perform further tests and analyses himself to determine whether the packaging used is suitable for the particular application. The customer is obliged to check whether the final product, i.e. the packaging with a particular application, meets all safety and legal requirements.

(9) Multilayer materials are not used.

Applies to the following products

213487 213488 213508 213509 213510 213511 213512 213533 213534 213535 213536 213537