

Overensstemmelseserklæring

RIAS A/S bekræfter hermed at nedenstående produkt Vivak er i overensstemmelse med de nævnte forordninger.



Declaration, June 2019

Vivak® Food contact declaration

Applicable to following sheet types:

Vivak® clear 099

The Vivak® sheet types stated above are produced out of food contact grade polyester and may be used to manufacture articles intended for food contact.

Europe - Regulation (EC) 1935/2004

This statement has the purpose of a declaration of compliance as required by Regulation (EC) 1935/2004. The Vivak® types stated above are manufactured applying rules on Good Manufacturing Practice (GMP) which are considered appropriate for plastic raw materials as required by Regulations (EC) 1935/2004 and (EC) 2023/2006. This includes the use of procedures to cover traceability from the incoming starting materials to the outgoing food contact material.

Commission regulation (EU) 10/2011

The foodcontact grade polyester used as raw material to produce the sheet is manufactured only with monomers and additives that are authorized under the Commission Regulation (EU) No. 10/2011 of 14. January 2011 and its amendments such as 2016/1416, 2018/79, 2018/213, 2018/831 and 2019/37 on "plastic materials and articles intended to come into contact with food". Based on data obtained by the polyester manufacturer, the overall migration limit of 60 mg/kg food or 10 mg/square decimetre of the plastic, and the limits for terephthalic acid (7.5 mg/kg of food) and ethylene glycol or diethylene glycol (30 mg/kg of food) is met.

USA

FDA-Regulation Title 21 Code of Federal Regulations Sec.177.1315 "Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers".

The entire confirmation only applies to the sheets as supplied by Covestro.

Covestro Deutschland AG
Business Unit Polycarbonates
51365 Leverkusen
Germany

www.sheets.covestro.com
sales.sheetsEMEA@covestro.com

The manner in which you use and the purpose to which you put and utilize our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products, technical assistance, information and recommendations to determine to your own satisfaction whether our products, technical assistance and information are suitable for your intended uses and applications. This application-specific analysis must at least include testing to determine suitability from a technical as well as health, safety, and environmental standpoint. Such testing has not necessarily been done by Covestro. Unless we otherwise agree in writing, all products are sold strictly pursuant to the terms of our standard conditions of sale which are available upon request. All information and technical assistance is given without warranty or guarantee and is subject to change without notice. It is expressly understood and agreed that you assume and hereby expressly release us from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance, and information. Any statement or recommendation not contained herein is unauthorized and shall not bind us. Nothing herein shall be construed as a recommendation to use any product in conflict with any claim of any patent relative to any material or its use. No license is implied or in fact granted under the claims of any patent.

This product is not designated for the manufacture of a medical device or of intermediate products for medical devices (1). Nonetheless, any determination as to whether a product is appropriate for use in a medical device or intermediate products for medical devices, for food contact products or cosmetic applications must be made solely by the purchaser of the product without relying upon any representations by Covestro.

1) Please see the "Guidance on Use of Covestro Products in a Medical Application" document.

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Page 1/1