

June 4, 2024

TEGO® VariPlus SK

Food Contact Information

Food Contact legislation pertains to the end product, such as food packaging and kitchen utensils. While information on raw materials can aid in compliance, ultimate legal adherence can only be confirmed upon completion of the finished product.

The following conformities are contingent upon the product being utilized in accordance with technical data sheet specifications, such as its use as an additive or co-binder, and at the designated usage level.

EU: Regulation 10/2011

Germany: BfR Recommendations

China: GB 9685 – 2016

Mercosur: MERCOSUR/GMC/RES No 39/19 and MERCOSUR/GMC/RES No 02/12

TEGO® VariPlus SK is not in compliance with the above mentioned regulations.

Switzerland: SR 817.023.21 (Amended on 8. Dec. 2023; in force since 1. Feb. 2024)

TEGO® VariPlus SK may be used for the manufacturing of printing inks for packaging according to Swiss Ordinance 817.023.21. The main component(s) (non CMR) of this product is/are not listed in ANNEX 10 or 2 and can only be used under the very strict migration limit of 0.01 mg/kg Food.

The product also contains substances either listed in ANNEX 10 or 2 with or without SML.

To conduct an preliminary compliance check, we suggest using our *COATINO® SML Calculator*

German Ink Ordinance (GIO) / Consumer Goods Regulation (BedGgstV)

TEGO® VariPlus SK complies with the compositional requirements for printing inks not intended for direct contact with food as defined in the German BedGgstV. Migration of single components must not exceed 10 µg/kg food.

Japan: Japanese Positive List (PL) for Direct Food Contact

The Japanese positive list of substances used in synthetic resins for utensils, containers and packaging (UCP) in accordance with the implementation of the amended Food Sanitation Act came into force *on 1 June 2020. Since then*, Japan's Ministry of Health, Labour and Welfare (MHLW) published several draft versions of revised and restructured lists and continues to amend the lists and provisions during the granted five-year grace period. Therefore, the status of our products varies with the activities of MHLW and cannot be confirmed finally. Please, do not hesitate to ask for a temporary status in urgent cases.

USA: FDA Regulations

TEGO® VariPlus SK may be used in compliance with FDA 21 CFR 175.105.

TEGO® VariPlus SK is not in compliance with FDA 21 CFR 175.300, 21 CFR 176.170 and 21 CFR 176.180.

EUPIA EXCLUSION LIST FOR PRINTING INKS AND RELATED PRODUCTS* (6th Edition of March 2024)

For Selection Criteria A and B: Please refer to Safety Data Sheet (Chapter 3).

We would like to confirm that we do not expect the presence of substances listed in the EUPIA "Exclusion List for Printing Inks and Related Products", in Selection Criteria C and Substances Lists D to G in TEGO® VariPlus SK.

Detailed information of the guidance can be found under the following Link:

EUPIA Exclusion List for Printing Inks

Nestlé Guidance Note on Packaging Inks* (Version October 2018)

We would like to confirm that, except of one substance, we do not expect the presence of substances listed in the ***Nestlé Guidance Note on Packaging Inks*** in TEGO® VariPlus SK.

Please note, that TEGO® VariPlus SK contains approx. 9 ppm Methanol (CAS#67-56-1) as impurity.

Finished food contact materials or articles containing this product as a component, need to comply inter alia with migration and/or extraction limits or any other restrictions – as specified in the applicable regulations. Verification of compliance with above mentioned limits/restrictions should be carried out in accordance with the respective rules. We would like to point out that it is in the sole responsibility of the manufacturer of the final material or article to assure the compliance under actual and foreseeable conditions of use, and to check it on a regular basis. The manufacturer of food contact materials or articles, containing this product as a component, must in particular ascertain that these finished materials or articles meet the general regulatory requirement that they do not endanger human health, or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof.

*The given information is based on and represents our current compositional knowledge (based on the knowledge of the production process, supplier information for raw materials and analytical data where applicable). In case of provided values these are considered to be typical concentrations and are not part of product specification.

Furthermore, the given information is intended for persons having the required skill and know-how and it does not relieve you from verifying the suitability of the information given for a specific purpose prior to use by testing, which should be carried out only by qualified experts. Use or application of such information is at your sole responsibility and risk, without any liability on the part of Evonik Operations GmbH.

All provided information is based on our present knowledge and experience and is true and complete to the best of our knowledge and belief. However, no warranty, whether expressed or implied, or guarantee of product properties in the legal sense is intended or implied.

In case of any questions concerning the provided information or if you need additional advice you are welcome to contact us:

Evonik Operations GmbH
Goldschmidtstraße 100
45127 Essen
Germany
www.evonik.de
www.coating-additives.com

Please contact for region Europe, Middle East, Russia and Afrika
regulatory-coating-additives-europe@evonik.com

Please contact for region Americas
regulatory-coating-additives-americas@evonik.com

Please contact for region Asia, Australia and New Zealand
regulatory-coating-additives-asia@evonik.com