

March 12, 2025

# TEGO® Foamex 8420

## 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**

TEGO® Foamex 8420 may be used for the manufacturing of materials and articles within the scope of the current amendment of Regulation (EU) N° 10/2011, since the components are fully listed in Annex I, table 1. Specific Migration Limits (SML) may apply. It contains one dual-use additive.

### **BfR Recommendation XIV**

TEGO® Foamex 8420 is listed under BfR XIV, Part A.2. "Additives already permitted by the Commission Regulation (EU) No 10/2011 may be used in accordance with the restrictions laid down therein.

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

TEGO® Foamex 8420 may be used for the manufacturing of printing inks for packaging according to Swiss Ordinance 817.023.21. All components are either listed in ANNEX 10 or 2. Specific Migration Limits (SML) may apply.

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

TEGO® Foamex 8420 may be used for the manufacturing of printing inks for packaging intended for direct and indirect contact with food as defined in the German BedGgstV – status 2 December 2021. The components are either fully listed in Annex 14, table 1 or in Regulation (EU) No. 10/2011, Annex I, table 1. Specific Migration Limits (SML) may apply.

## **China: GB 9685 – 2016**

The active components of TEGO® Foamex 8420 are listed in GB 9685 for use in coatings with food contact.

## **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® Foamex 8420 may be used in compliance with FDA 21 CFR 175.105, when separated from food by a functional barrier or used in compliance with GMP such that it does not become a component of food at minimus levels.

TEGO® Foamex 8420 may be used in compliance with FDA 21 CFR 175.300, if used in concentrations not to exceed 1575 mg/sqm food contact area.

TEGO® Foamex 8420 may be used in compliance with FDA 21 CFR 176.170 and 176.180, if used as defoamer at the wet end of the production.

## **Mercosur**

TEGO® Foamex 8420 may be used for the preparation of plastic materials and polymeric coatings intended to contact food according to Brazilian RDC N° 326/2019, incorporating MERCOSUR GMC/RES. N° 39/19 into national law. Specific Migration Limits (SML) may apply.

## **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® Foamex 8420.

**Nestlé Guidance Note on Packaging Inks\***  
(Version April 2024)

We would like to confirm that we do not expect the presence of substances listed in the *Nestlé Guidance Note on Packaging Inks* in TEGO® Foamex 8420.

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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:**

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