

June 19, 2024

# TEGO® Foamex N

## 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**

The components of TEGO® Foamex N are listed in EU-Regulation 10/2011 on plastic materials and articles intended to come into contact with food and its amendments and do not have any SML or restriction/ specification.

Further it contains a dual-use additive. (Dimethylpolysiloxane)

### **BfR Recommendation XIV**

The components of TEGO® Foamex N are listed in BfR-Recommendation XIV (polymer dispersions) and do not have any SML or restriction/ specification.

Further it contains a dual-use additive. (Dimethylpolysiloxane)

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

TEGO® Foamex N 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 without SML.

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

TEGO® Foamex N complies with the compositional requirements for printing inks intended for direct and indirect contact with food as defined in 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. SML or specific restrictions do not apply.

### China: GB 9685 – 2016

TEGO® Foamex N is listed with respect to its active agents in GB 9685 for plastic application of PP and PET. The final food contact materials or articles, containing this product as a component, cannot be used for 100 °C and above. The product contains below ingredients with restrictions:

	Maximum level
Dimethyl polysiloxane	PET: 0.3%
surface modified silica	PP: 0.5%; PET: 0.1%

### 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

Based on the "no-migration"-Principle TEGO® Foamex N can be used in compliance with FDA – rules for Food Contact (e.g. Sec 175.105, Sec. 175.300, Sec.176.170, Sec.176.180, Sec.176.200 etc.), if used as a defoamer up to 0.5 % in food contact materials with a maximum thickness of 250 µm.

For all applications a final maximum level of 1250 mg Additive m<sup>2</sup> Food Contact Area should be respected.

The above clearances are subject to the end-use and extractive limitations cited in the specific regulations.

### Mercosur:

TEGO® Foamex N is in compliance with Mercosur Plastics Regulations MERCOSUR/GMC/RES. N° 39/19 and MERCOSUR/GMC/RES.N° 02/12.

**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 N.

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 we do not expect the presence of substances listed in the ***Nestlé Guidance Note on Packaging Inks*** in TEGO® Foamex N.

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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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