

March 11, 2024

# TEGO® Foamex 825

## 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 825 as an additive is not in compliance with EU-Regulation 10/2011 on plastic materials and articles intended to come into contact with food and its amendments, as some components are not included in the Union List as such.

### **BfR Recommendation XIV**

TEGO® Foamex 825 can be used in compliance with BfR Recommendation XIV (polymer dispersions), **ONLY** if the plastics dispersion is used for coatings. Some of the components do not have any SML or restriction/ specification, while others do.

Please note that TEGO® Foamex 825 contains the following biocides:

- 2-Pyridinethiol, 1-oxide, sodium salt (1:1) CAS# 3811-73-2 (< 0.04 wt.-%)
- 1,2-Benzisothiazol-3(2H)-one; CAS# 2634-33-5 (< 0.01 wt.-%)

It also contains a dual-use additive. (approx. 0.001 wt.-%)

### **BfR Recommendation XXXVI**

TEGO® Foamex 825 is in compliance with the following section of the BfR-Recommendation XXXVI:

Part B N. I No. 10 Polymer-Dispersions

The Siloxane itself complies with: Part B N. VI defoamer No. 1 Organopolysiloxanes

The usage as additive in the paper production, respective the mentioned functions, is possible.

Some of the components do not have any SML or restriction/ specification, while others do.

#### **Switzerland: SR 817.023.21 (Amended by Version from 08. December 2023)**

TEGO® Foamex 825 may be used for the manufacturing of printing inks for packaging according to Swiss Ordinance 817.023.21.

The main components are either listed in ANNEX 10 or 2 with or without SML. The product also contains one non-listed, non CMR substances with a generic migration limit of 0.01 mg/kg Food.

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

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

TEGO® Foamex 825 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.

#### **China: GB 9685 – 2016**

TEGO® Foamex 825 is not in compliance with GB 9685.

#### **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**

TEGO® Foamex 825 may be used in compliance with 21 CFR 175.105, 21 CFR 176.170 and 21 CFR 176.180 if used as a defoamer up to max. of 56.25 mg/sqm.

TEGO® Foamex 825 may be used in compliance with 21 CFR 175.300 except for use in contact with infant formula and breast milk up to max. 56.25 mg/sqm.

## **Mercosur**

TEGO® Foamex 825 is in compliance with MERCOSUR/GMC/RES.N° 39/19 and MERCOSUR/GMC/RES.N° 02/12 with SMLs.

### **EUPIA EXCLUSION LIST FOR PRINTING INKS AND RELATED PRODUCTS\* (5th Edition of June 2023)**

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 825.

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 825.

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Finished food contact materials or articles containing this product as a component, need to comply inter alia with Overall Migration Limit (OML) requirements – as specified in the regulations. Verification of compliance with migration limits (OML and SML) should be carried out in accordance with the rules laid down there. 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 with the OML/SML requirements 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.

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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