

July 8, 2024

TEGO® Foamex 8850

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 8850 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.

BfR Recommendation XIV

The components of TEGO® Foamex 8850 are listed in BfR- XIV (polymer dispersions) and do not have any SML or restriction/ specification.

BfR Recommendation XXXVI

The components of TEGO® Foamex 8850 are listed in BfR-XXXVI (paper & paperboard) Part B Production Aids VI defoamers.

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

TEGO® Foamex 8850 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.

To conduct a preliminary compliance check, we suggest using our [COATINO® SML Calculator](#)

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

TEGO® Foamex 8850 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

All components of TEGO® Foamex 8850 are in compliance with coatings and plastics when used as defoamer. Product is also in compliance with paper via a cross link from GB 4806.6 to GB 4806.8.

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 8850 can be used in compliance with the following section(s) and may be subject to any applicable limitations:

FDA 21 CFR 175.105
FDA 21 CFR 175.300
FDA 21 CFR 176.170
FDA 21 CFR 176.180

Mercosur:

The product TEGO® Foamex 8850 is in compliance with the following Mercosur standards without restrictions:

MERCOSUR/GMC/RES. N° 39/19 superseding MERCOSUR/GMC/RES. No. 32/07 –
MERCOSUR Technical Regulation on the Positive List of Additives for Plastics Materials

Mercosur Reg.: MERCOSUR/GMC/RES.N° 02/12 – MERCOSUR Technical Regulation on
the Positive List of Monomers.

MERCOSUR/GMC/RES No. 27/99 General Criteria on adhesives used in the
manufacture of Packaging and Equipment intended to come in contact with Food.

MERCOSUR/GMC/RES. No. 40/15 Technical Regulation on cellulosic materials, packaging and equipment intended to come in contact with Food, if used as a defoamer according to point 4.4. of the standard.

MERCOSUR/GMC/RES N° 28/99 Technical Regulation on the positive list for elastomeric materials used in packaging and equipment intended to come in contact with Food, if used as an additive according to part 3 of the standard.

**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 8850.

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 8850.

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