

June 28, 2024

TEGO® Foamex 1488

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 (latest published version)

TEGO® Foamex 1488 as an additive is in compliance with EU-Regulation 10/2011 on plastic materials and articles intended to come into contact with food and its amendments.

Please note that TEGO® Foamex 1488 contains the following additional compounds (biocides):

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no.247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no.220-239-6] (CAS# 55965-84-9) (< 0.02 wt.-%)

It is not included in the Union List with the respective restrictions. It can be seen as PPA for plastic in food contact, as it has no function in the end product.

1,2-Benzisothiazol-3(2H)-one; CAS# 2634-33-5 (< 0.02 wt.-%) – has a positive evaluation by EFSA (European Food Safety Authority, 16th list of substances for food contact materials, 09.2007) but is not yet included in the Union List with the respective restrictions. It can also be seen as PPA for plastic in food contact, as it has no function in the end product.

Please note that the other components used in TEGO® Foamex 1488 are listed in EU-Regulation 10/2011. Some of these do not have any SML or restriction/ specification, while others do.

It also contains 2 dual-use additives.

BfR Recommendation XIV

The components of TEGO® Foamex 1488 can be used in compliance with the BfR-Recommendation XIV (polymer dispersions), considering the remarks mentioned

above for EU Regulation 10/2011, with the difference, that one of the above mentioned biocides is explicitly listed in BfR Recommendation XIV.

Please note that TEGO® Foamex 1488 contains the following biocides:

- Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no.247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no.220-239-6] (CAS# 55965-84-9) (< 0.02 wt.-%)

According to BfR Recommendation XIV the below mentioned biocide shall not exceed 80 µg/dm² in the dispersion layer.

- 1,2-Benzisothiazol-3(2H)-one (CAS# 2634-33-5): (<0.02 wt.-%)

BfR Recommendation XXXVI

TEGO® Foamex 1488 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.

TEGO® Foamex 1488 is not in compliance with BfR-Recommendation XXXVI/2.

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

TEGO® Foamex 1488 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 apply.

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

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

TEGO® Foamex 1488 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 apply.

China: GB 9685 – 2016

TEGO® Foamex 1488 is listed with respect to its active standard composition in GB 9685 for the use in Coatings with Food Contact only.

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 1488 may be used for the manufacturing of products in compliance with 21 CFR sections 21 CFR 175.105, 175.300, 176.170 and 176.180, if used with not more than 3 % in the wet formulation of such products.

Mercosur

TEGO® Foamex 1488 is in compliance with the following Mercosur regulations: 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 together with Mercosur Reg. MERCOSUR/GMC/RES.N° 02/12 – MERCOSUR Technical Regulation on the positive List of monomers and other starting substances for plastics.

TEGO® Foamex 1488 is compliant with MERCOSUR/GMC/RES. No. 40/15 CELLULOSIC MATERIALS, PACKAGING AND EQUIPMENT intended to come into contact with food.

It is not compliant with MERCOSUR/GMC/RES. No. 41/15 on cellulosic materials for COOKING and HOT FILTRATION and for MERCOSUR/GMC/RES. No. 42/15 on cellulosic materials, packaging and equipment to be intended to be in contact with food during COOKING or BAKING.

Brazil:

TEGO® Foamex 1488 is compliant with Brazilian RDC N° 88/2016, incorporating MERCOSUR/GMC/RES. No. 40/15 into national law.

TEGO® Foamex 1488 may be used according to Brazilian RDC N° 326/2019 establishing a positive list for the preparation of plastic materials and polymeric coatings intended to contact food, incorporating MERCOSUR GMC/RES. N° 39/19 into national law with SML (Specific Migration Limits)

**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 1488.

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 1488.

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.

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