

TEGO[®] AddBond LTH

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)

The active component (polymer) of TEGO[®] AddBond LTH 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 one monomer (residual amount 0.5%) has a SML=0.05 mg/kg food.

Further it contains a dual-use additive (amount 0.02%).

BfR Recommendation XIV

The active component (polymer) of TEGO® AddBond LTH is in compliance with BfR-Recommendation XIV (polymer dispersions).

Please note that one monomer (residual amount 0.5%) has a SML=0.05 mg/kg food.

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

TEGO® AddBond LTH 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 with SML.

To conduct a preliminary compliance check, we suggest using our <u>COATINO® SML Calculator.</u>

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

TEGO® AddBond LTH 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. Specific SML restrictions apply.

China: GB 4806.10 - 2016

The polymer of TEGO® AddBond LTH is approved as a resin used in food contact coatings in China via NHC announcement. Maximum dosage of TEGO® AddBond LTH must be lower than 15% (expressed as coating film dry weight). The usage temperature of the food contact article (includes cured coating produced with TEGO® AddBond LTH) needs to be below a maximum of 121°C.

Please notice that maximum migration of a monomer of TEGO® AddBond LTH is restricted by specific limit value.

Additionally, TEGO® AddBond LTH also contains solvents. The manufacturer of the finished articles has to ensure that in the finished articles intended to come into contact with food the solvents will be completely removed or reduced to such amounts that the residual traces in the finished articles do not migrate into the food in amounts that may endanger the human health. Furthermore, these solvent traces must not bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristics thereof.

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 21 CFR 175.300

FCN 918

1) As a monomer, alone, or in combination with the polyhydric alcohols listed in 21 CFR 175.300 (b)(3)(Xi)(c), in the production of polyester can coatings used in the manufacture of articles or component of articles for contact with food.

2) As a monomer in the production of polyester resins used as components of adhesives for food contact applications, compliant with 21 CFR 175.105 and 175.125. With Limitations specified in FCN

Limitations/Specifications:

1) Polyester can coatings containing the FCS may contact non-alcoholic food types under Conditions of Use A through H, as described in Table 2.

2) Polyester resins containing the FCS used as components of adhesives complying with 21 CFR 175.105 and175.125 may be used at room temperature or below. For use of the FCS in adhesives at temperatures not to exceed 120°F, we assume that the adhesive either will be separated from the food by a functional barrier or will contact the food only in trace amounts at the seams and at the edges between packaging laminates

Mercosur:

TEGO® AddBond LTH is in compliance with Mercosur Plastics regulations MERCOSUR/GMC/RES. N° 39/19 and MERCOSUR/GMC/RES.N° 02/12 with two SML substances.

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® AddBond LTH.

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® AddBond LTH.

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 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.

the food or deterioration in the organoleptic characteristics thereof.

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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