

April 5, 2024

TEGO® AddBond LTW

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 LTW 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 content approx. 0.4 wt.-%) has a SML=0.05 mg/kg food.

Please also note that TEGO® AddBond LTW contains solvents which are not regulated by the EU-Regulation 10/2011 (national regulations apply):

Xylene (CAS# 1330-20-7): 28.4 wt.-%

Ethylbenzene (CAS# 100-41-4): 11.6 wt.-%

BfR Recommendation XIV

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

Please note that one monomer (residual content approx. 0.4 wt.-%) has a SML=0.05 mg/kg food.

Please also note that TEGO® AddBond LTW contains solvents which are not listed:

Xylene (CAS# 1330-20-7): 28.4 wt.-%

Ethylbenzene (CAS# 100-41-4): 11.6 wt.-%

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

TEGO® AddBond LTW 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/Restrictions apply.

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

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

TEGO® AddBond LTW 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 apply.

China: GB 4806.10

The polymer of TEGO® AddBond LTW is approved as a resin used in food contact coatings in China via NHC announcement. Maximum dosage of TEGO® AddBond LTW must be lower than 18% (expressed as coating film dry weight). The usage temperature of the food contact article (includes cured coating produced with TEGO® AddBond LTW) needs to be below a maximum of 121°C.

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

Additionally, TEGO® AddBond LTW 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 Regulation

TEGO® AddBond LTW may be used in compliance with 21 CFR 175.105 and may be subject to any applicable limitations.

Regarding the suitability of TEGO® AddBond LTW for food contact applications, we would like to explain our current position on this topic. The product, as supplied, is 60% solids cut in xylene. The polymeric portion of the product is comprised of materials with known suitability for this application and would at 100% solids, meet the criteria for 21 CFR 175.300 applications. This product contains a monomer that restricts uses of this product to can coatings for non-alcoholic food types under Conditions of Use A through H, as described by Table 2.2).

On the other hand, because the product is delivered in the afore mentioned solvent, and because Evonik has no way to ensure compliance in the end use product, we asked Keller and Heckman for an opinion regarding our obligations for ensuring suitable purity under FDA's Good Manufacturing Practices regulations. In summary, the opinion developed by Keller & Heckman claims that *"companies marketing food contact substances are legally responsible to evaluate the safety of their products, including components that are constituents. Even though such constituents (including solvents and impurities) are not ultimately intended to be in the food contact substance, they may, nonetheless, be present at low levels and therefore the manufacturer has the obligation to ensure that these constituents will not lead to the adulteration of contacted food."*

Based on the available information above TEGO® AddBond LTW may be used in compliance with 21 CFR 175.300, for use in can coatings with the restrictions stated above, whereby it is the responsibility of the customer to ensure the proper curing recommendations are followed and all solvent has been removed. Suitability for use in food contact applications ultimately must be determined only by our customers testing of the final cured film.

Mercosur:

TEGO® AddBond LTW consists of a polymer and solvent. The polymer is manufactured with monomers listed on MERCOSUR /GMC/ Res. No. 02/12 (Positive List of Monomers, other starting substances and Polymers authorized for the Manufacture of Food Contact plastic packaging and equipment). The solvent is listed as an additive in MERCOSUR/GMC/RES. No. 39/19 superseding MERCOSUR/GMC/RES. No. 32/07 – MERCOSUR Technical Regulation on the positive list of Additives for Plastic Materials.

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 LTW.

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, except of one component, we do not expect the presence of substances listed in the ***Nestlé Guidance Note on Packaging Inks*** in TEGO® AddBond LTW

TEGO® AddBond LTW contains <0.1% of Toluene** CAS# 108-88-3 as impurity of used raw material, which is aromatic hydrocarbon of petrol origin.

**Toluene is not considered als MOAH according to EFSA Scientific Opinion on Mineral Oil Hydrocarbons in Food, 28 August 2013

<https://www.efsa.europa.eu/en/efsajournal/pub/2704>

**Toluene may fall under the definition as MOAH according to articles D. 543-45-1 and D. 543-213 of the Environmental Code (Arrêté du 13 avril 2022 précisant les substances contenues dans les huiles minérales dont l'utilisation est interdite sur les emballages et pour les impressions à destination du public) <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000045733481>

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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