EU: Regulation 10/2011

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

TEGO® AddBond LTW is in compliance with the “Ordinance of the FDHA on Materials and Articles (SR 817.023.21)” – status 1 May 2017. All components (additives / monomers / solvents) are listed in Annex 10 in the lists for evaluated (A) substances.

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 with SML:

Xylene (CAS# 1330-20-7): SML=1 mg/kg food; 28.4 wt.-%
Ethylbenzene (CAS# 100-41-4): SML=0.6 mg/kg food; 11.6 wt.-%

China: GB 9685 – 2016

TEGO® AddBond LTW is formally not in compliance with GB 9685 but above mentioned product is included with respect to its active polymer composition in GB 4806.6–20161) in a generic listing with the restriction of QM = 0.2 % (resin plate, styrene).

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.

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 requirements according to GB 4806.1–20162). Finished food contact materials or articles containing this product as a component, need to comply inter alia with Overall Migration Limit (OML) requirements and other requirements—as specified in GB 4806.6–20161). Verification of compliance with migration limits (OML and SML) and other requirements 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.

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.
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 information given above 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 Resource Efficiency 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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