EU: Regulation 10/2011

TEGO® AddBond DS 1300 is not fully in compliance with EU-Regulation 10/2011 on plastic materials and articles intended to come into contact with food and its amendments, as one component is not included in the Union List as such.

This component is a biocide (1,2-Benzisothiazol-3(2H)-one; CAS# 2634–33–5; 0.008 wt.-%) which 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.

Please note that the other components used in TEGO® AddBond DS 1300 are listed in EU-Regulation 10/2011. Some of these do not have any SML or restriction/specification, while others do.

Further it contains a dual-use additive.

BfR Recommendation XIV

The components of TEGO® AddBond DS 1300 are listed in BfR-Recommendation XIV (polymer dispersions), considering the remarks mentioned above for EU Regulation 10/2011, with the difference, that the above mentioned biocide is explicitly listed in BfR Recommendation XIV.

Please note that TEGO® AddBond DS 1300 contains the following biocides:

- 3(2H)-isothiazoline, 2-methyl- (CAS# 2682–20–4): 0.008 wt.-%
- 1,2-Benzisothiazol–3(2H)–one (CAS# 2634–33–5): 0.008 wt.-%

According to BfR Recommendation XIV the above mentioned biocides shall not exceed 40 µg/dm² respectively 80 µg/dm² in the dispersion layer.
Switzerland: SR 817.023.21

TEGO® AddBond DS 1300 is in compliance with the “Ordinance of the FDHA on Materials and Articles (SR 817.023.21)” – status 1 May 2017. All components (additives and / or monomers) are listed in Annex 10 in the lists for evaluated (A) substances.

Please note that some of the components of TEGO® AddBond DS 1300 do not have any SML or restriction/ specification, while others do.

China: GB9685 – 2016

TEGO® AddBond DS 1300 is not in compliance with GB 9685.

USA: FDA

TEGO® AddBond DS 1300 may be used as a component of adhesives compliant with 21 CFR 175.105 for food contact applications at room temperature or below.

For the use of TEGO® AddBond DS 1300 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.

TEGO® AddBond DS 1300 contains a preservative (1,2-Benzisothiazol-3(2H)-one (CAS# 2634-33-5): 0.01 wt.-%) which is not listed in 21 CFR 175.300.

However, TEGO® AddBond DS 1300 may be used as a component of can coatings according to 21 CFR 175.300 in the manufacture of articles or components of articles for contact with food if BIT is not detectable. Can coatings containing TEGO® AddBond DS 1300 may contact non-alcoholic food types under Conditions of Use A through H, as described in Table 2. of 21 CFR 176.170.
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.