EU: Regulation 10/2011

Product in compliance with EU–Regulation 10/2011 up to a use level of 0.16 % in the final plastic a/o up to 400 mg/sqm food contact area. The max. use level is a result of the risk assessment of two polymer production aids (PPAs), which are not included in the Union List. All other components used in TEGO® Foamex 3062 are listed in EU–Regulation 10/2011 and do not have any SML or restriction/ specification.

Germany: BfR Recommendations

Product in compliance with BfR–Recommendation XIV (polymer dispersions), based on compliance with EU–Regulation 10/2011. The polymer production aids (PPAs) are seen as residues, Risk Assessment principles apply. Use restrictions apply: Maximum use level is 0.16 % (surface thickness dry 250µm) in the dispersion and max. 400 mg/sqm food contact area.

TEGO® Foamex 3062 can be used in compliance with BfR XXXVI as a defoamer according part B production aids, VI defoamers No.1.

Maximum use level is 0.16 % in the dispersion and max. 400 mg/sqm food contact area.

Switzerland: SR 817.023.21

TEGO® Foamex 3062 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) or not evaluated (B) substances.

Please note that some of the components of TEGO® Foamex 3062 do not have any SML or restriction/ specification, while others do.

China: GB 9685–2016

TEGO® Foamex 3062 is not in compliance with GB 9685.
FDA Regulations

Based on a no-migration principle, TEGO® Foamex 3062 can be used in compliance with FDA’s rules for food contact if used as an additive up to a maximum use level of 800 mg/sqm food contact area.

The field of application includes all types of plastics, paper, coatings or adhesives. The use should be consist with 21 CFR, including e.g. 21 CFR 175.105, 21 CFR 175.300, 21 CFR 176.170 and 21 CFR 176.180.

Mercosur

TEGO® Foamex 3062 in compliance with Mercosur/GMC/Res. No. 39/19 up to a use level of 0.16 % in the final plastic a/o up to 400 mg/sqm food contact area.
Finished food contact materials or articles containing this product as a component, need to comply inter alia with Overall Migration Limit (OML) requirements – as specified in the regulations. Verification of compliance with migration limits (OML and SML) 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. 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.

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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