

July 5, 2024

TEGO® Dispers 761 W

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)

TEGO® Dispers 761 W 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 TEGO® Dispers 761 W contains the following additional compounds (biocides):

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no.247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no.220-239-6] (CAS# 55965-84-9) (< 0.02 wt.-%)

It is not included in the Union List with the respective restrictions. It can be seen as PPA for plastic in food contact, as it has no function in the end product.

1,2-Benzisothiazol-3(2H)-one; CAS# 2634-33-5 (< 0.02 wt.-%) – 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. It can also be seen as PPA for plastic in food contact, as it has no function in the end product.

Please note that the other components used in TEGO® Dispers 761 W are listed in EU-Regulation 10/2011. Some of these do not have any SML or restriction/ specification, while others do.

It also contains 3 dual-use additives.

BfR Recommendation XIV

TEGO® Dispers 761 W is in compliance with the BfR-Recommendation XIV (polymer dispersions).

Please note that TEGO® Dispers 761 W contains the following biocides:

- Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no.247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no.220-239-6] (CAS# 55965-84-9) (< 0.02 wt.-%)

According to BfR Recommendation XIV the below mentioned biocide shall not exceed 80 µg/dm² in the dispersion layer.

- 1,2-Benzisothiazol-3(2H)-one (CAS# 2634-33-5): (<0.02 wt.-%)

Please note that the other components used in TEGO® Dispers 761 W do not have any SML or restriction/ specification, while others do.

It also contains 3 dual-use additives.

Switzerland: SR 817.023.21 (Amended on 8. Dec. 2023; in force since 1. Feb. 2024)

TEGO® Dispers 761 W 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 or without SML. To conduct a preliminary compliance check, we suggest using our [COATINO® SML Calculator](#).

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

TEGO® Dispers 761 W 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 9685 – 2016

TEGO® Dispers 761 W is listed with respect to its active standard composition in GB 9685-2016 for use in Adhesive, Coating, Paper and Plastic (PE-PP-PS-AS-ABS-PA-PET) with Food Contact Only.

For the allowed maximum usage of this product in Food Contact Material indifferent applications, please contact Evonik application technical expert to get the technical support.

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

TEGO® Dispers 761 W may be used as a dispersing additive in compliance with FDA 21 CFR 175.105, 21 CFR 175.300, 21 CFR 176.170 and 21 CFR 176.180.

Mercosur:

TEGO® Dispers 761 W is in compliance MERCOSUR/GMC/RES. N° 39/19 superseding MERCOSUR/GMC/RES. No. 32/07 – MERCOSUR Technical Regulation on the Positive List of Additives for Plastics Materials and Mercosur Reg.: MERCOSUR/GMC/RES.N° 02/12 – MERCOSUR Technical Regulation on the positive List of monomers with two SML substances.

TEGO® Dispers 761 W complies with the compositional requirements of MERCOSUR/GMC/RES. N° 40/15, when used in amounts of up to 19 mg/dm² and MERCOSUR/GMC/RES. N° 41/15, when used in amounts of up to 38 mg/dm².

TEGO® Dispers 761 W is not in compliance with the requirements of MERCOSUR/GMC/RES. N° 42/15.

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® Dispers 761 W.

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® Dispers 761 W.

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.

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