

January 25, 2021

TEGO® AddBond LTW-B

Food Contact Information

EU: Regulation 10/2011

The active component (polymer) of TEGO® AddBond LTW-B 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 amount 0.4%) has a SML = 0.05 mg/kg food.

Please also note that TEGO® AddBond LTW-B contains a solvent that is listed in EU-Regulation 10/2011 as additive:

N-butyl acetate (CAS# 123-86-4): 40 wt.-%

BfR Recommendation XIV

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

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

Switzerland: SR 817.023.21

TEGO® AddBond LTW-B is in compliance with the “Ordinance of the FDHA on Materials and Articles (SR 817.023.21)” – status 1 December 2019. All components (additives / monomers / solvents) are listed in Annex 10 in the lists for evaluated (A) substances. Please note that one monomer (residual amount of 0.4%) has a SML = 0.05 mg/kg food.

China: GB 9685 - 2016

TEGO® AddBond LTW-B is formally not in compliance with GB 9685 but with GB 4606.6. 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, above mentioned product 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 21 CFR 175.300

Regarding the suitability of TEGO® AddBond LTW–B for food contact applications, we would like to explain our current position on this topic. The product, as supplied, is 60% solids cut in n–butyl acetate. 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–B 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-B is in compliance with Mercosur Plastics regulations MERCOSUR/GMC/RES. N° 39/19 and MERCOSUR/GMC/RES.N° 02/12 – Technical Regulation on the positive List of monomers with one SML.

Japan: Japanese Positive List (PL) for Direct Food Contact

All components of TEGO® AddBond LTW-B are listed on the Japan Positive List as polymer. For detailed information of the approved food categories, usage levels and other requirements please contact us.

EUIA EXCLUSION LIST FOR PRINTING INKS AND RELATED PRODUCTS

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 EUIA “Exclusion List for Printing Inks and Related Products”, 3rd edition (November 2016) in Selection Criteria C and Substances Lists D to G (listed substances in the table) in TEGO® AddBond LTW-B.

Substances
Pigments and substances based on: <ul style="list-style-type: none">• Antimony• Arsenic• Cadmium• Chromium (VI)• Lead• Mercury• Selenium
Pigment colourants: <ul style="list-style-type: none">• Auramin (Basic Yellow 2 – CI 41000)• Chrysoidin (Basic Orange 2 – CI 11270)• Fuchsin (Basic Violet 14 – CI 42510)• Indulin (Solvent Blue 7 – CI 50400)• Kresylen (Basic Brown 4 – CI 21010)
Solvents: <ul style="list-style-type: none">• 2-Methoxyethanol 109-86-4• 2-Methoxyethyl acetate 110-49-6• 2-Ethoxyethyl acetate 111-15-9• Monochlorobenzene• Dichlorobenzene• Volatile chlorinated hydrocarbons, such as trichloroethylene, perchlorethylene and methylenechloride• Volatile fluorochlorinated hydrocarbons• 2-Nitropropane• Methanol

Plasticisers:

- Chlorinated naphthalenes
- Chlorinated paraffins
- Monocresyl phosphate
- Tricresyl phosphate
- Monocresyl diphenyl phosphate

Various Compounds:

- Diaminostilbene and derivatives
- 2,4-Dimethyl-6-tertiary-butylphenol
- 4,4 Tetramethyldiaminobenzophenone (Michler's Ketone)
- Hexachlorocyclohexane

Nestlé Guidance Note on Packaging Inks (2018)

We do not expect the presence of following substances within TEGO® AddBond LTW-B:

General exclusions

Titanium Acetyl Acetonate (TAA)
<i>Ortho</i> -Phthalate plasticizers
Bisphenol A (BPA) and materials manufactured from or incorporating BPA in reacted form as part of the chemical structure
Nitrocellulose resins
Vegetable oils/fatty acid esters with strong odours
Heavy/Toxic metal in amounts exceeding the respective limits mentioned in the Swiss ordinance
Solvents and other chemicals which give off-odour or taint to the food

Odour: Specific to the product

Table 1: Exclusion list for pigments

Pigments	Color index	CAS number	Swiss Ordinance
Pigment Red 81	45160:1	12224-98-5	B
Pigment Red 81:1	45160:3	80083-40-5	B
Pigment Red 81:2	45161:1	75627-12-2	B
Pigment Red 81:3	45161:2	68310-07-6	B
Pigment Red 81:5	45160:4	63022-06-0	B
Pigment Red 169	45160:2	12224-98-5	B
Pigment Green 1	42040:1	1325-75-3	B
Pigment Blue 1	42595.2	1325-87-7	B
Pigment Blue 62	44084	57485-98-0	B
Pigment Violet 1	45170:2	1326-03-0	B
Pigment Violet 2	45175:1	1326-04-1	B
Pigment Violet 3	42535:2	1325-82-2 67989-22-4	B

Pigment Violet 27	42535:3	12237-62-6	B
Pigment Violet 39	42555:2	64070-98-0	B

Table 2: Exclusion list for Photo-Initiators

PI Name	CAS Number	Swiss Ordinance
2-Hydroxy 2-methyl propiophenone	7473-98-5	B
2-(Dimethylamino)ethyl benzoate	2208-05-1	B
- Benzophenone	119-61-9	A
- 2-Methyl benzophenone	131-58-8	A
- 4-Methyl benzophenone	134-84-9	A
- 2,4,6-trimethylbenzo- phenone	954-16-5	B
1-Hydroxycyclohexyl phenylketone	947-19-3	B
2,2-Dimethoxy 2-phenyl acetophenone	24650-42-8	B
2-Methyl 4'-(methylthio) 2-morpholinopropiophenone	71868-10-5	B
- 4-Isopropyl 9H-thioxanthen-9-one	83846-86-0	A
- 2-Isopropyl 9H-thioxanthen-9-one	5495-84-1	A
2,4-Diethyl 9H-thioxanthen-9-one	82799-44-8	B
Diphenyl (2,4,6-trimethyl benzoyl) phosphine oxide	75980-60-8	A

Table 3: Minimize list for Photo-Initiators

PI Name	CAS Number	Swiss Ordinance
Irgacure	119313-12-1	A
Other monomeric Benzophenones (not forbidden above) benzoate	various	A / B

Table 4: Exclusion list for acrylates

Chemical name	CAS number	Swiss Ordinance
Butanediol Diacrylate (BDDA)	1070-70-8	B
Diethylene glycol diacrylate (DEGDA)	4074-88-8	B
Isodecyl acrylate (IDA)	1330-61-6	B
Octyl acrylate (ODA)	2499-59-4	A
Phenoxy ethyl acrylate	48145-04-6	B

Table 5: Minimize list for acrylates

Chemical name	CAS number	Swiss Ordinance
Trimethylol propane triacrylate (TMPTA)	15625-89-5	B

Dipropylene glycol diacrylate (DPGDA)	57472-68-1	B
1, 6-Hexanediol diacrylate (HDDA)	13048-33-4	B
2-Ethyl hexyl acrylate (2EHA)	103-11-7	A
Mixtures of pentaerythritol tri- and tetra-acrylates (PETA)	3524-68-3	B
Tetraethylene glycol diacrylate (TEGDA)	17831-71-9	B

Table 6: Exclusion list for solvents

Chemical name	CAS number	Swiss Ordinance
2-Methoxyethanol (methyl glycol)	109-86-4	A
2-Ethoxyethanol (Ethyl glycol)	110-80-5	A
Monochlorobenzene	108-90-7	A
Toluene	108-88-3	A
1-methyl-2-pyrrolidone	872-50-4	A

Table 7: Minimize list for solvents

Chemical name	CAS number	Swiss Ordinance
Methanol	67-56-1	A
Cyclohexane	110-82-7	A
Methylethylketone (MEK)	78-93-3	A
Methylisobutylketone (MiBK)	108-10-1	A
Hexanol	111-27-3	A
2-Ethyl-1-hexanol	104-76-7	A
n-Octanol	111-87-5	A
Butylglycol	111-76-2	A
Butyldiglycol	112-34-5	A
Ethyldiglycol	111-90-0	A
Hexyleneglycol	107-41-5	A
Butoxypropanol	5131-66-8	A
Butoxypropoxypropanol	29911-28-2	A
Ethanediol	107-21-1	A
Diethyleneglycol	111-46-6	A
Triethyleneglycol	112-27-6	A
Butylglycolacetate	112-07-2	A
1-Methoxy-2-propylacetate	108-65-6	A
Ethylbenzene	100-41-4	A
1-Pentanol	71-41-0	A

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 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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