

November 25, 2020

TEGO® Foamex 1488

Food Contact Information

EU: Regulation 10/2011

TEGO® Foamex 1488 as an additive 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® Foamex 1488 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® Foamex 1488 are listed in EU-Regulation 10/2011. Some of these do not have any SML or restriction/ specification, while others do.

It also contains 2 dual-use additives.

BfR Recommendation XIV

The components of TEGO® Foamex 1488 can be used in compliance with the BfR-Recommendation XIV (polymer dispersions), considering the remarks mentioned above for EU Regulation 10/2011, with the difference, that one of the above mentioned biocides is explicitly listed in BfR Recommendation XIV.

Please note that TEGO® Foamex 1488 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.-%)

BfR Recommendation XXXVI

TEGO® Foamex 1488 is in compliance with the following section of the BfR-Recommendation XXXVI:

Part B N. I No. 10 Polymer-Dispersions

The Siloxane itself complies with: Part B N. VI defoamer No. 1 Organopolysiloxanes

The usage as additive in the paper production, respective the mentioned functions, is possible.

Some of the components do not have any SML or restriction/ specification, while others do.

Switzerland: SR 817.023.21

TEGO® Foamex 1488 is in compliance with the “Ordinance of the FDHA on Materials and Articles (SR 817.023.21)” – status 1 December 2019. 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® Foamex 1488 do not have any SML or restriction/ specification, while others do.

China: GB 9685 – 2016

TEGO® Foamex 1488 is not in compliance with GB 9685 because the main component is listed for coatings only and the other mayor components are listed for other applications.

USA: FDA

TEGO® Foamex 1488 may be used as a defoaming agent in adhesives, paper and paperboard and as a component in polymeric coatings, and is in compliance with 21 CFR 175.105, 175.125, 175.300, 176.170, 176.180. The maximum concentration for all uses is 2.5% with a maximum film thickness (where applicable) of 0.5 microns.

All of the components within TEGO® Foamex 1488 are either listed within the specific CFR reference or calculations have confirmed will not exceed the threshold of migration when applying the FDA's default assumptions regarding quantity of food that is exposed to a food contact surface and standard FDA consumption factors.

Mercosur

TEGO® Foamex 1488 is in compliance with the following Mercosur regulations:

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 together with Mercosur Reg. MERCOSUR/GMC/RES.N° 02/12 – MERCOSUR Technical Regulation on the positive List of monomers and other starting substances for plastics.

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

All components of TEGO® Foamex 1488 are listed on the Japan Positive List as additive. For detailed information of the approved food categories, usage levels and other requirements please contact us.

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 EUPIA “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® Foamex 1488.

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:

- 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® Foamex 1488:

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

*Please note that TEGO® Foamex 1488 contains one component of vegetable origin without strong odour.

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
Ethyldiglycol	111-90-0	A
Butyldiglycol	112-34-5	A
Hexylene glycol	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 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:

Evonik Operations GmbH
Goldschmidtstraße 100
45127 Essen
Germany
www.evonik.de
www.coating-additives.com

Please contact for region Europe, Middle East, Russia and Afrika
regulatory-coating-additives-europe@evonik.com

Please contact for region Americas
regulatory-coating-additives-americas@evonik.com

Please contact for region Asia, Australia and New Zealand
regulatory-coating-additives-asia@evonik.com