

June 12, 2023

TEGO® Foamex 825

Food Contact Information

EU: Regulation 10/2011

TEGO® Foamex 825 as an additive is not in compliance with EU-Regulation 10/2011 on plastic materials and articles intended to come into contact with food and its amendments, as some components are not included in the Union List as such.

BfR Recommendation XIV

TEGO® Foamex 825 can be used in compliance with BfR Recommendation XIV (polymer dispersions), ONLY if the plastics dispersion is used for coatings. Some of the components do not have any SML or restriction/ specification, while others do.

Please note that TEGO® Foamex 825 contains the following biocides:

- 2-Pyridinethiol, 1-oxide, sodium salt (1:1) CAS# 3811-73-2 (< 0.04 wt.-%)
- 1,2-Benzisothiazol-3(2H)-one; CAS# 2634-33-5 (< 0.01 wt.-%)

It also contains a dual-use additive. (approx. 0.001 wt.-%)

BfR Recommendation XXXVI

TEGO® Foamex 825 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 (latest published version)

TEGO® Foamex 825 is in compliance with the "Ordinance of the FDHA on Materials and Articles (SR 817.023.21). 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 825 do not have any SML or restriction/ specification, while others do.

Following components are listed in the lists for not evaluated (B) substances:

- 2-Pyridinethiol, 1-oxide, sodium salt (1:1) CAS# 3811-73-2 (< 0.04 wt.-%)

The other components used in TEGO® Foamex 825 are listed in the lists for evaluated (A) substances. Some of the components do not have any SML or restriction/ specification, while others do.

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

TEGO® Foamex 825 complies with the compositional requirements for printing inks not intended for direct contact with food as defined in the German BedGgstV. Migration of single components must not exceed 10 µg/kg food.

China: GB 9685 – 2016

TEGO® Foamex 825 is not in compliance with GB 9685.

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® Foamex 825 may be used in compliance with 21 CFR 175.105, 21 CFR 176.170 and 21 CFR 176.180 if used as a defoamer up to max. of 56.25 mg/sqm.

TEGO® Foamex 825 may be used in compliance with 21 CFR 175.300 except for use in contact with infant formula and breast milk up to max. 56.25 mg/sqm.

Mercosur

TEGO® Foamex 825 is in compliance with MERCOSUR/GMC/RES.N° 39/19 and MERCOSUR/GMC/RES.N° 02/12 with SMLs.

EUIPA EXCLUSION LIST FOR PRINTING INKS AND RELATED PRODUCTS

(latest published version)

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 EUIPA "Exclusion List for Printing Inks and Related Products", in Selection Criteria C and Substances Lists D to G (listed substances in the table) in TEGO® Foamex 825.

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• 2-Ethoxyethanol 110-80-5• Monochlorobenzene• Dichlorobenzene• Volatile chlorinated hydrocarbons, such as trichloroethylene, perchlorethylene and methylenechloride• Volatile fluorochlorinated hydrocarbons• 2-Nitropropane• Methanol
Plasticisers: <ul style="list-style-type: none">• Chlorinated naphthalenes• Chlorinated paraffins• Monocresyl phosphate• Tricresyl phosphate• Monocresyl diphenyl phosphate
Various Compounds: <ul style="list-style-type: none">• Diaminostilbene and derivatives• 2,4-Dimethyl-6-tertiary-butylphenol• 4,4 Tetramethyldiaminobenzophenone (Michler's Ketone)• Hexachlorocyclohexane

Nestlé Guidance Note on Packaging Inks (latest published version)

We do not expect the presence of following substances within TEGO® Foamex 825:

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
Perfluoro compounds must not be used, except for PTFE waxes
Mineral oils containing aromatic substances (MOAH) must not be used
Mineral oils containing saturated hydrocarbons (MOSH) must be minimised, and their residual value must be below 0.1% of the dry film
Photoinitiators mentioned in the "EuPIA Suitability List of Photoinitiators and Photosynergists for Food Contact Materials - October 2020

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 81:5	45160:4	63022-06-0	B
Pigment Red 169	45160:2	12237-63-7	B
Pigment Green 1	42040:1	1325-75-3	B
Pigment Blue 1	42595:2	1325-87-7	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
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 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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