

September 1, 2023

SURFYNOL® 355

Food Contact Information

EU: Regulation 10/2011 (latest published version)

SURFYNOL® 355 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. One SML= 5 mg/kg Food

BfR Recommendation XXXVI

The components of SURFYNOL® 355 are in compliance with BfR-Recommendation XXXVI up to max. 0.0025%, based on the dry fibres weight, if used under Part VI. Defoamers.

If the product is used as production aid/sizing agent according to chapter B. production aid, part I. sizing agent No. 10 plastics dispersions there is no quantitative limitation but a specific migration limit (SML) of 5 mg/kg food applies.

Switzerland: SR 817.023.21 (latest published version)

SURFYNOL® 355 is in compliance with the "Ordinance of the FDHA on Materials and Articles (SR817.023.21). All components (additives and / or monomers) are listed in Annex 10 in the lists for evaluated (A) substances.

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

SURFYNOL® 355 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

The components of SURFYNOL® 355 are in compliance with GB9685 for plastics (only PE, PP, AS up to 0.5% and ABS up to 1%) and for paper (max. 1 mg /dm²)

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

SURFYNOL® 355 may be used in compliance with the following sections and may be subject to any applicable limitations:

FDA 21 CFR 173.340

FDA 21 CFR 175.105

FDA 21 CFR 175.300

FDA 21 CFR 175.320

FDA 21 CFR 176.170

FDA 21 CFR 176.180

FDA 21 CFR 176.200

FDA 21 CFR 176.210

The restrictions for 21 CFR 173.340 are (a) as a surfactant and defoaming agent, at levels not to exceed 0.05 percent weight, in scald baths for poultry defeathering, followed by potable water rinse. The temperature of the scald baths shall be not less than 125oF. (b) As a foam control and rinse adjuvant in hog dehairing machines at a use level of not more than 5 grams per hog.

The restriction for 21 CFR 176.170 is not to exceed 200 ppm in finished coated paperboard.

Mercosur:

SURFYNOL® 355 is in compliance with MERCOSUR/GMC/RES. N° 39/19 and MERCOSUR/GMC/RES.N° 02/12 for plastics in contact with food with a SML of 5 mg/kg Food.

EUPIA 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 EUPIA

“Exclusion List for Printing Inks and Related Products”, in Selection Criteria C and Substances Lists D to G (listed substances in the table) in SURFYNOL® 355.

Substances
<p>Pigments and substances based on:</p> <ul style="list-style-type: none"> • Antimony • Arsenic • Cadmium • Chromium (VI) • Lead • Mercury • Selenium
<p>Pigment colourants:</p> <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)
<p>Solvents:</p> <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
<p>Plasticisers:</p> <ul style="list-style-type: none"> • Chlorinated naphthalenes • Chlorinated paraffins • Monocresyl phosphate • Tricresyl phosphate • Monocresyl diphenyl phosphate
<p>Various Compounds:</p> <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 SURFYNOL® 355:

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 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:

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