

January 28, 2021

SURFYNOL® 104 PA

Food Contact Information

EU: Regulation 10/2011

SURFYNOL® 104 PA 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 XXXVI

The components of SURFYNOL® 104 PA are in compliance with BfR-Recommendation XXXVI when used as additive.

Switzerland: SR 817.023.21

SURFYNOL® 104 PA is in compliance with the "Ordinance of the FDHA on Materials and Articles (SR817.023.21)" –status 1 December 2019. All components (additives and / or monomers) are listed in Annex 10 in the lists for evaluated (A) with SML of 0.05 mg/kg.

China: GB 9685

The components of SURFYNOL® 104 PA are in compliance with GB 9685–2016.

USA: FDA

SURFYNOL® 104 PA maybe used in compliance with the following sections and is subject to applicable limitations:

21 CFR 175.105

Limitations: separated from food by a functional barrier, or has only trace exposure of the adhesive to aqueous or fatty foods at seams or edges of the laminate.

21 CFR 175.300

Limitations: If a coating prepared with SURFYNOL® 104 PA surfactant undergoes the same curing treatment used for SURFYNOL® 104 surfactant, and applicable extractions with food-simulating solvents do not yield detectable amounts of isopropyl alcohol, then isopropyl alcohol would not be expected to become a component of contacted food and it therefore could be said that the treated coating complies with 21 CFR 175.300 as well as with 21 CFR 175.105 (assuming all other components of the coating, in addition to SURFYNOL® 104 PA surfactant can be used in compliance with 21CFR175.300). The coating manufacturer is responsible for determining whether isopropyl alcohol is removed from the coating during the curing treatment.

Mercosur:

SURFYNOL® 104 PA has not yet been evaluated regarding Mercosur Regulations.

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

All components of SURFYNOL® 104 PA 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.

EUPIA 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 SURFYNOL® 104 PA.

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 SURFYNOL® 104 PA:

General exclusions

Titanium Acetyl Acetate (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
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

Please note that SURFYNOL® 104 PA contains < 0.005% Methylisobutylketone (MiBK) CAS#108-10-1 as impurity.

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