

March 9, 2023

SPHERILEX® DP-0111

Food Contact Information

EU: Regulation 10/2011

SPHERILEX® DP-0111 is in compliance with the specifications and standards of the Regulation (EU) 10/2011 (FCM No. 504; Ref. 86240–Silicon dioxide). The production process is under the hygienic conditions of Regulation (EU) 852/2004 (HACCP). This product is also a dual use additive with regard to the simultaneous suitability as a food additive and food contact additive: The chemical identity of this product corresponds to the chemical identity of E 551 (Silicon dioxide). However, this product is not qualified according requirements for E 551.

BfR Recommendation XIV

SPHERILEX® DP-0111 is in compliance with BfR-XIV.

BfR Recommendation XXXVI

SPHERILEX® DP-0111 is in compliance with XXXVI, XXXVI/1 and XXXVI/2.

Switzerland: SR 817.023.21 (latest published version)

SPHERILEX® DP-0111 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) substances.

The components of SPHERILEX® DP-0111 do not have any SML or restriction and are in line with the specifications and standards of Regulation (CH) 817.023.21.

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

SPHERILEX® DP-0111 is in compliance with § 4(5) German BedGgstV "German Ink Ordinance" (Annex 14 Table 1 Ref.-No. 86240 Silicon dioxide) and so it complies with the compositional requirements for printing inks for direct and indirect food contact.

China: GB 9685 – 2016

SPHERILEX® DP-0111 is in compliance with GB 9685-2016 (FCA 0782, CAS#112926-00-8) for the usage in plastics (PE, PP, PS, AS, ABS, PA, PET,

PC, PVC, PVDC, UP), paints & coatings, rubber materials, ink, paper, cardboard materials and products with dosage as necessary.

USA: FDA

SPHERILEX® DP-0111 may be used in compliance with the following FDA regulations:

175.105 – Adhesives

175.300 – Resinous & Polymeric coatings

176.170 – Components of paper & paperboard in contact with aqueous and fatty food

176.180 – Components of paper and paperboard in contact with dry food

The substance is generally recognized as safe in food (GRAS) – Agency response letter GRAS Notice No. 000554 – synthetic amorphous silica (SAS)

Mercosur:

SPHERILEX® DP-0111 is in compliance with MERCOSUR/GMC/RES. N° 32/07 – Technical Regulation on the Positive List of Additives for Plastics Materials intended for the manufacture of food contact packages and equipment. It is listed in the authorized Additives list for plastic materials Appendix 1, CAS#7631-86-9 – Silica.

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 during the production process of this product we do not intentionally use or add any 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 SPHERILEX® DP-0111.

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)

<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 would like to confirm that during the production process of SPHERILEX® DP-0111 we do not intentionally use or add any substances listed in the Nestlé Guidance Note:

Since testing of these substances is not part of our standard routine quality control and production testing procedures, we cannot warrant or guarantee the absence of these substances in this product.

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
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
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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
Ethandiol	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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