

June 28, 2023

# AEROSIL® R 972

## Food Contact Information

### **EU: Regulation 10/2011**

AEROSIL® R 972 is in compliance with Regulation (EU) 10/2011 with the FCM No. 87; Ref. 86285–Silicone dioxide, silanated.

### **BfR Recommendation XIV**

AEROSIL® R 972 is in compliance with BfR–XIV.

### **BfR Recommendation XXXVI**

AEROSIL® R 972 is not in compliance with BfR–XXXVI.

### **Switzerland: SR 817.023.21 (latest published version)**

AEROSIL® R 972 is a FCM substance with the No. 5080; Ref. No. 86285 – Silicone dioxide, silanated. In compliance with Annex 10, List for evaluated (A) substances of the “Ordinance of the FDHA on Materials and Articles (SR 817.023.21)”

The components of AEROSIL® R 972 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)**

AEROSIL® R 972 complies with the compositional requirements for printing inks for direct and indirect food contact.

### **China: GB 9685 – 2016**

AEROSIL® R 972 is in compliance with GB 9685–2016 for the usage in plastic with max. use in PET of 0.1% and in PP of 0.5%. The use temperature of materias produced from it should be less than 100°C.

Adhesives and inks with this substance shall not be used in the production of food contact materials and articles for infants and young children. The above restrictions should be marked according to GB 4806.1.

Maximum dosage: Adhesive: 0.002% (dry weight); Ink: 4% (dry weight)

NHFPC Year 2017 No. 9:

Application in plastic: PVDF – 50%; Used as processing agent only. For PVDF materials produced by this substance, the maximum food contact temperature is 100°C.

NHFPC Year 2018 No. 11:

Application in plastic: PP: 0.02%, coating and coating layer: 0.5% For PP materials and coating, coating layer produced by this substance, the maximum food contact temperature is 121°C.

#### **FDA: FDA**

AEROSIL® R 972 may be used in compliance with the following FDA regulations:

##### 175.105 – Adhesives

It is listed as Silicone dioxide with the limitation not to exceed 2% by weight. It also must be separated from the food by a functional barrier and assumed that cannot be otherwise be reasonably expected to become a component of the food in significant amounts.

##### 175.300 – Resinous & Polymeric coatings

Based on an Opinion Letter by Keller and Heckman LLP AEROSIL® R 972 is fully in compliance with 21 CFR incl. 175.300 up to a usage level of 5% in coatings.

AEROSIL® R 972 is not in compliance with 21 CFR 176.170 and 176.180.

#### **Mercosur:**

AEROSIL® R 972 is in compliance with MERCOSUR/GMC/RES. No. 39/19 Mercosur technical regulation on "positive list of additives for plastic materials intended for the manufacture of food contact packages and equipment" List of authorized Additives for plastic materials and polymeric coatings, Appendix I: Mercosur substance number: 87, European reference-number: 86285. The particle size specification for silicon dioxide, silanated will be fulfilled.

#### **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 AEROSIL® R 972.

*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.*

## Substances

Pigments and substances based on:

- Antimony
- Arsenic
- Cadmium
- Chromium (VI)
- Lead
- Mercury
- Selenium

Pigment colourants:

- 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-Ethoxyethanol 110-80-5
- 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 (latest published version)

We would like to confirm that during the production process of AEROSIL® R 972 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

**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

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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](http://www.evonik.de)  
[www.coating-additives.com](http://www.coating-additives.com)

Please contact for region Europe, Middle East, Russia and Afrika  
[regulatory-coating-additives-europe@evonik.com](mailto:regulatory-coating-additives-europe@evonik.com)

Please contact for region Americas  
[regulatory-coating-additives-americas@evonik.com](mailto:regulatory-coating-additives-americas@evonik.com)

Please contact for region Asia, Australia and New Zealand  
[regulatory-coating-additives-asia@evonik.com](mailto:regulatory-coating-additives-asia@evonik.com)