

October 29, 2024

SPHERILEX® DP-0112

Food Contact Information

Food Contact legislation pertains to the end product, such as food packaging and kitchen utensils. While information on raw materials can aid in compliance, ultimate legal adherence can only be confirmed upon completion of the finished product. The following conformities are contingent upon the product being utilized in accordance with technical data sheet specifications, such as its use as an additive or co-binder, and at the designated usage level.

EU: Regulation 10/2011

SPHERILEX® DP-0112 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-0112 is in compliance with BfR-XIV.

BfR Recommendation XXXVI

SPHERILEX® DP-0112 is in compliance with XXXVI, XXXVI/1 and XXXVI/2.

Switzerland: SR 817.023.21 (Amended on 8. Dec. 2023; in force since 1. Feb. 2024)

SPHERILEX® DP-0112 may be used for the manufacturing of printing inks for packaging according to Swiss Ordinance 817.023.21. All components are either listed in ANNEX 10 or 2 without SML 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-0112 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-0112 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.

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

SPHERILEX® DP-0112 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-0112 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*
(6th Edition of March 2024)

For 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 in SPHERILEX® DP-0112.

Detailed information of the guidance can be found under the following Link:

EUPIA Exclusion List for Printing Inks

Nestlé Guidance Note on Packaging Inks*
(Version October 2018)

We would like to confirm that we do not expect the presence of substances listed in the ***Nestlé Guidance Note on Packaging Inks*** in SPHERILEX® DP-0112.

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 given information 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:

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