



FOOD CONTACT STATUS DOCUMENT - EUROPE

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We hereby confirm the following for our product, as supplied:

DOWSIL™ 732 MULTI-PURPOSE SEALANT, CLEAR

Chemical nature: Silicone elastomer

Regulatory background

In the area of food contact materials, plastic materials and articles are regulated by a specific measure harmonized at EU level and that provides lists of authorized substances, i.e. the Regulation (EC) 10/2011.^[1]

Coatings, printing inks, adhesives and silicone rubbers are not covered by Commission Regulation (EU) No 10/2011 and do not have such specific EU harmonized legislation. These groups of materials are subject to the general requirements of EU framework Regulation (EC) 1935/2004 and where existing, to the relevant member state legislations.^[2]

European Union

Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended (latest amendment: Regulation (EU) No 2020/1245)

- Coatings, printing inks, adhesives and silicone rubbers are not covered by Regulation (EU) 10/2011 but can be used under the condition the finished food contact material(s) or article(s) meet any requirement provided in below table.

The product contains the following substances with a restriction and/or specification in Annex I and II of Regulation (EU) No 10/2011. We like to draw your attention to the fact that this regulation also includes a limit of 10 mg/dm² on the overall migration from finished plastic articles in contact with food (Article 12). Please note that it is the responsibility of both the manufacturers of finished food contact articles as well as the industrial packers to make sure that these articles in their actual use are in compliance with the imposed restrictions.

FCM No	Ref. No	Substance	CAS #	Limits	Restrictions, Specifications where applicable
504	86240	Silicon dioxide	7631-86-9		When used in this product, following specification for synthetic amorphous silicon dioxide is met: primary particles of 1 – 100 nm which are aggregated to a size of

					0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size.
575	76721	Polydimethylsiloxane (Mw > 6 800 Da)	63148-62-9		when present in this product, viscosity at 25 °C is not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)
-	-	Methyl-tin compounds (Group Restriction No 9)	-	SML(T)= 0.18mg/kg	expressed as tin.

Dual Use Additives

With reference to article 11(3) of the Regulation (EU) 10/2011 as amended, our product contains the following substance(s) which is/are also authorized as food additives by Regulation (EC) 1333/2008 as amended:

FCM No	E-number	Substance
504	E 551	Silicon dioxide
575	E 900	Polydimethylsiloxane

Regulation (EC) 1935/2004 (framework)

Article 3 (safety clause)^[2]

It is the responsibility of the end-use manufacturer to verify the compliance of the finished materials or articles at the specific real and/or foreseeable conditions of use, based on the information provided. Dow does not on a routine basis perform organoleptic tests on articles produced from this product. To the best of our current knowledge, when used according to Dow's recommendations and/or under normal or foreseeable conditions of use, the product should meet the relevant requirements of Article 3 of regulation (EC) No 1935/2004. Those requirements are available in the Union Guidance on Regulation (EU) 10/2011 as regards information in supply chain.

Article 17 (traceability)

The product is manufactured under a Quality Management System certified to be in compliance with ISO 9001:2015. The requirements of article 17 of Regulation (EC) 1935/2004 on traceability are fulfilled by the adherence to the clause 8.5.2 (Identification and traceability) of ISO 9001:2015 standard.

Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, as amended

The mentioned products do not constitute "Materials or Articles" as they should be understood under the terms of Regulation (EC) No 2023/2006. Instead they are considered "Starting Materials". However, this product is produced according to our quality management systems, and certified under ISO 9001 Standard. Please visit CES – Silicones Europe website (www.silicones.eu/silicones-uses/silicones-in-food) for further information.

European countries

Note: substances with restrictions under the Regulation (EU) 10/2011 are not reproduced again (see appropriate section above). Only substances with additional restriction under the specific national legislation are reported here below.

German BfR Recommendation XV on Silicones (BfR-Empfehlungen XV zu Silicone)

The product is manufactured with:

- starting material(s) listed in Section III;
- one or several component(s) not listed Section III;

French Arrêté of 25 November 1992 on silicone elastomers intended to come into contact with foodstuffs (Arrêté Ministériel du 25 novembre 1992 relatif aux matériaux et objets en élastomères de silicone mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires)

The product is manufactured with:

- one or several component(s) not listed;

[1] The Regulation (EC) 10/2011 provides in Annex I a list of authorized monomers, starting substances and additives for the manufacture of plastics materials and articles. Substances not included in the Union list (polymer production aids, aids to polymerization...) shall be assessed in accordance with internationally recognized scientific principles on risk assessment (article 19).

[2] The framework Regulation (EC) 1935/2004 sets general rules applicable to all food contact materials. One of the key provision is article 3, which states that materials and articles intended to come into contact with food shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

Legenda: FCM No = the unique identification number of the substance; Ref. No = the EEC packaging material reference number; SML = the specific migration limit applicable to the substance and expressed in mg/kg food or food simulant; SML(T) = the total specific migration limit for the sum of substances for which the group restriction applies and expressed in mg/kg food or food simulant; QM = the maximum quantity in the final product; QM(T) = the total maximum quantity in the final product for the sum of substances for which the group restriction applies; ND = not-detectable, with a limit of detection of 0,01 mg/kg food or food simulant.

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