

Good Manufacturing Practices for Organosilicon materials intended to come into contact with food

Purpose

This factsheet is designed to help Member Companies respond to questions related to Good Manufacturing Practices for organosilicon materials intended to come into contact with food and that may arise in the context of meetings, contacts with customers etc.

Regulatory Background

[Article 3.1 of Regulation 1935/2004/EC](#) on materials and articles intended to come into contact with food stipulates that these should be manufactured in accordance with good manufacturing practice so that their components do not migrate into food, in quantities that could;

1. Endanger human health;
2. Bring an unacceptable change in the composition of the food;
3. Deteriorate organoleptic properties of the food.

[Regulation 2023/2006/EC](#) on good manufacturing practice for materials and articles intended to come into contact with food stipulates general considerations required for the implementation of article 3.1. of Regulation 1935/2004.

Silicone materials compliance with Regulation 2023/2006/EC

Responsibilities of Silicone producers

CES members' typical product ranges do not constitute "Materials or Articles" as they should be understood under the terms of Regulation 2023/2006/EC. Instead they are considered "Starting Materials".

As such, they fall outside the scope of this Regulation. However some "article-type" products (i.e. cured silicone rubbers or resins) could end up being used in food-contact applications when products are supplied indirectly through distribution channels. In this case the Articles are subject to stringent quality control procedures already in place such as those for medical or healthcare applications clearance.

If products are indeed intended for food contact applications, their compliance with applicable European, Member States or FDA regulations is systematically checked.

As part of their commitment to Responsible Care, CES member companies have implemented strict product stewardship practices. Furthermore, these products are certified under ISO 9001 Standard.

Responsibilities of Silicone processors

Good Manufacturing Practice principles have to be applied by the processor of raw silicone materials. These can be either additives or precursor compounds for the manufacture of silicone rubbers or resins.

Good Manufacturing Practice for silicone processors

Important aspects, which the silicone starting substances processor has to take care of are the following:

1. Appropriate processing

In the case of silicone elastomers, one of the most essential criteria to determine suitability for food contact is the limit for volatile substances of 0.5% as required by the Recommendation XV. Silicones of the BfR and the French Decree of November 25, 1992. To achieve this, it may not be sufficient to cure the starting material, post-curing may be necessary to remove or reduce volatile impurities or by-products. The instructions of the silicone supplier should be strictly followed.

2. Contamination prevention in production, storage, packaging and transport

As silicones are prone to take up lipophilic substances, silicone elastomers intended to come into contact with food should be produced on dedicated equipment to avoid any transfer of substances from materials not made of silicones.

Manufacturing equipment and packaging materials should be carefully evaluated on their ability of potential substance migration.

3. Documentation and traceability

Appropriate documentation on quality critical items must be maintained. A procedure for incoming starting substances to outgoing food contact materials shall be in place.

4. Hygiene policy

Adequate and appropriate hygiene measures for personnel, factories, warehouses and transport should be established. Staff should be trained on their obligations and responsibilities in the context of current legislation requirements and GMP principles.

5. Quality Assurance System and Quality Policies

A Quality Assurance System should be developed and maintained to ensure product conformity to the specified requirements for use in food contact applications. In the case of silicone elastomers, one of the most essential criteria to determine suitability for food contact is the limit for volatile substances of 0.5% as required by the Recommendation XV. Silicones of the BfR and the French Decree of November 25, 1992.

Health and Safety Commitment

CES and its members place strong emphasis on protecting health, safety and the environment in accordance with their commitment to the Responsible Care programme of the chemicals industry. They are confident that silicone products are safe when used as intended.

For more information about silicones, their uses or our industry, please visit our website, www.silicones.eu and follow us on Twitter, [@SiliconesEU](https://twitter.com/SiliconesEU).

In case of more specific questions, please write to **Dr. Pierre Germain**, CES Secretary General at pge@cefic.be or +32 2 676 73 77.