

## 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

#### Framework Regulation (EC) 1935/2004

The Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food provides general principles to regulate any type of food contact material and is known as the Framework Regulation.

Article 3 requires that materials and articles in contact with food shall be manufactured in accordance with good manufacturing practices, so that under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- Endanger human health; or
- Bring about an unacceptable change in the composition of the food; or
- Bring about a deterioration in the organoleptic characteristics thereof.

Silicones once fully processed in finished food contact materials or articles become a component of these materials and articles which must comply the requirements of Article 3.

Article 17 requires traceability of materials and articles shall be ensured at all stages to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. As part of their commitment to Responsible Care, CES member companies have implemented strict product stewardship practices and Quality Management System certified under ISO 9001 Standard. The requirements of Article 17 are fulfilled by the adherence to the clause 7.5.3 (Identification and traceability) of ISO 9001 standard.

Articles 5 and 6 indicate that specific measures may be adopted by the European Commission or by Member States, for the groups of materials and articles listed in Annex I of Regulation (EC) No 1935/2004. A measure establishes the specific rules for materials and articles of a certain material group to comply with the requirements of the Framework Regulation. At current stage some Member States have adopted specific measures for silicones themselves or for other groups of materials while including silicones, such as rubbers.



## GMP - Regulation (EC) 2023/2006

Regulation (EC) No 2023/2006 on good manufacturing practices (GMP) for materials and articles intended to come into contact with food sets out general principles to ensure the suitability of the material or article for the intended end use. It shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances. It is focusing mainly on the principles of a quality assurance system, quality control and appropriate documentation within the manufacturing process and is not particularly aimed to cover hygiene requirements.

It is up to the individual companies to define how to fulfil these obligations considering the position in the supply chain/size of the business and integrating these requirements with complementary systems within their company, such as ISO 9001. The general intention of this regulation is to ensure that all business operators acting in the area of food contact materials are able to demonstrate the materials they place on the market are in compliance with the Framework Regulation requirements and thus do not endanger human health.

### Silicone materials compliance with Regulation (EC) 2023/2006

#### 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 (EC) 2023/2006. Instead, they are considered "Starting Materials". As such, they fall outside the scope of this Regulation.

If organosilicone starting materials are indeed intended for food contact applications, their compliance with applicable European, EU Member States or Council of Europe Members regulations is systematically checked.

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

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 similar to those applied by silicone processors.

#### Responsibilities of Silicone processors

Good Manufacturing Practice principles have to be applied by the processor of organosilicone starting materials for the manufacture of silicone rubbers or resins.

Important aspects, which the processors have 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 Order of November 25, 1992 on Silicone rubbers. 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.

## 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](http://www.silicones.eu) and follow us on Twitter, [@SiliconesEU](https://twitter.com/SiliconesEU).

