



Statement on Suitability for use under food contact Regulations REPLISIL 25 LE

It is herewith confirmed that the ingredients of REPLISIL 25 LE Comp. A/B comply with the positive lists of the below mentioned regulations.

Provided appropriate processing, the product is therefore suitable for the manufacture of food contact materials and articles in compliance with Regulation (EC) No. 1935/2004. Compliance with the requirements of Regulation (EC) No. 1935/2004, especially the suitability of the material or article for the intended use, the observance of any given limitations, the effect on taste and smell of the food has to be ensured by the producer of the finished food contact material or article as it is placed onto the market.

1. Germany: BfR XV. Silicones:
Extractables and volatiles may not exceed 0,5%.
2. France: Arrêté du 25 novembre 1992:
Volatile components may not exceed 0,5%. Total migration is limited to 60mg/Kg.
3. Switzerland: Ordinance 817.21.23, Annex 5:
Total migration is limited to 60 mg/Kg
4. USA: FDA 21 CFR
- 4.1 §177.2600 Rubber articles intended for repeated use:
Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives no to exceed 20 milligrams per square inch during the first 7 hours of extraction, not to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n-hexane at reflux temperature, shall yield total extractives no to exceed 175 milligrams per square inch during the first 7 hours of extraction not to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.



Product: **REPLISIL 25 LE**
RTV-2 silicone



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4.2 § 175.300 Resinous and Polymeric Coatings:

Extractive limits under § 175.300 © to € have to be observed.

Regulatory sanctioning of the ingredients in a product does not imply that the finished product manufactured from those ingredients is considered safe by regulatory bodies. Responsibility for compliance with specific limits on migration/extraction or volatiles resides with the manufacturer of the finished product.

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