

July 31, 2019

Minivalve International B.V  
Oldenzaal  
Netherlands

### **EU food contact statement LSR2650 RSH (A&B)**

Dear Customer,

Thank you for your interest in Momentive Performance Materials and the products and services we provide.

Please find listed below the requested information on the above mentioned products.

### **EU Regulation 1935/2004**

Currently all food contact materials are regulated by the Food Contact Framework Regulation 1935/2004 of which the purpose is to "ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interest of consumers". The article 3 of this regulation is "key" as providing general but essential requirements.

This regulation stipulated that specific measures may be developed by the Commission for various groups of materials and articles for food contact as stipulated in the annex 1 of this regulation.

Currently such specific measures exist for ceramics, regenerated cellulose and plastics; for other groups of food contact materials, no EU regulations have been developed so far.

Specific measures for silicone rubbers are not foreseen to be developed yet at the Community level as this represents a very low priority for the European Commission. This means that silicone rubbers are and will remain subject to national provisions until a harmonized process is completed.

Members of the silicone industry place strong emphasis on protecting health, safety and the environment and produce silicone materials that can be used in the manufacturing of articles intended for food contact applications such as the well-known household baking moulds but not only.

For this purpose, and in addition to their usual procedures for quality assurance, Silicone manufacturers also ensure all components are compliant to any binding texts from the EU Member States, which deals with silicone resins/elastomers intended to be used in contact with

food. In this prospect, the following are examples of existing legislation/recommendations that are frequently referred to:

**- French Arrêté of 25 Novembre 1992**

(Relating to materials and objects of silicone elastomers put, or destined to be put in contact with foodstuffs, food products and drinks)

**- German BfR Recommendation XV "Silicones"**

**- Italian Decreto Ministeriale del 21/03/1973 Chapter 2 "Rubbers"**

**- Spanish Real Decreto 847/2011**

(Establishing a positive list of permitted substances for the manufacture of polymeric materials intended to come into contact with food)

Compliance to one of these texts automatically implies compliance to the EU framework Regulation 1935/2004, as laid down by its Article 6.

The ingredients of the Momentive Performance Materials' products listed above are in compliance with the positive lists of all three national legislations/recommendations.

**Council of Europe resolution ResAP (2004)5**

The ingredients of the Momentive Performance Materials' products mentioned above are in compliance with the Council of Europe Resolution AP (2004) 5 on silicones to be used for food contact applications.

**Switzerland (RS 817.023.21)**

The ingredients of the above-mentioned Momentive Performance Materials' products are in compliance with the "Ordinance of the FDA on articles and materials (RS 817.023.21) of 16 December 2016 (Status on May 1st 2017) paragraph 11 commodities of silicone. (annex 9)

On the basis of this information Momentive Performance Materials is of the opinion that the food contact article produced with the above mentioned products may safely be used in producing, manufacturing, packing, processing, treating or holding food when manufactured and formulated as prescribed by Momentive Performance Materials.

***The article must be allowed to cure fully and post cured at elevated temperatures to meet the volatile limits of the German BfR and the French Arrêté. Recommendation from Momentive is 4 hours at 200 °C in an oven with fresh air supply. The surfaces should be thoroughly cleansed prior to its first use.***

It has to be noticed however that the ultimate responsibility resides with the rubber manufacturer and that it is his role to take every reasonable action to ensure their products are suitable for use with food, will not pose a health hazard, and are safe within the spirit of the legislation. In making this determination, the applicability of specific regulatory clearances may be considered, as well as the potential for migration of impurities – e.g. byproducts, breakdown products, or residual starting materials – to food from the use of the product.

We hope this information is helpful to you. If you have any further questions please feel free to contact us.

With kind regards,



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