

## Regulatory Product Information

### ELASTOSIL® R 401/50 S

#### RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2011/65/EU (RoHS 2) are intentionally introduced during manufacture. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

#### WEEE (Waste of Electrical and Electronic Equipment)

None of the substances mentioned in Directive 2012/19/EU (WEEE) are intentionally introduced during manufacture. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

#### Heavy Metals

- ▶ Directive 94/62/EC (Packaging and packaging waste)
- ▶ CONEG (Coalition of Northeastern Governors)
- ▶ Directive 2000/53/EC (End-of life vehicles)

None of the substances concerned (lead, chromium VI, cadmium, mercury) are intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

#### REACH SVHC (Substances of Very High Concern)

Product does not contain SVHC in amounts > 0.1 %.

#### ODS (Ozone Depleting Substances)

Substances mentioned in "The Montreal Protocol on Substances that Deplete the Ozone Layer" are not contained as intentionally added ingredients.

#### Allergens

- ▶ Regulation (EU) No 1169/2011, substances listed in Annex II
- ▶ Substances listed in the Food Allergen Labeling and Consumer Protection Act (FALCPA)

- ▶ Latex
- ▶ Fragrances

The substance(s) mentioned above are not used in the manufacture or the formulation of this product.

## **GMO (Genetically Modified Organisms)**

Product is not derived from genetically modified organisms and for its manufacture no intermediates and/or auxiliary agents which are genetically modified are used.

## **BSE/TSE**

Product is not derived from human or animal origin and for its manufacture no intermediates and/or auxiliary agents which are of human or animal origin are used.

## **Food Contact Regulations**

### **Europe**

- ▶ Regulation (EC) No 1935/2004

Provided appropriate processing, the product is suitable for the manufacture of food contact materials and articles according to this Regulation. 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 on the market.

- ▶ Regulation (EU) No 10/2011

Not applicable. Silicones are exempted from this Regulation.

- ▶ Regulation (EC) No 2023/2006

Not applicable. This product is considered as a starting material and therefore out of the scope of this Regulation.

### **Germany**

- ▶ Recommendation of the BfR XV. Silicones

The ingredients of the product and its curing agents Crosslinker C1, C6 and E are in compliance. Limitation(s): Volatiles max. 0.5%. Extractable substances: max. 0.5%.

If Bis(2,4-dichlorobenzoyl)peroxide (Crosslinker E) is used as curing catalyst, a SML (specific migration limit) of 5 mg/kg food or food simulant relating to the decomposition product 2,4-dichlorobenzoic acid, has to be met.

### **France**

- ▶ Arrêté du 25 novembre 1992

The ingredients of the product and its curing agents Crosslinker C1, C6 and E are in compliance. Limitation(s): Overall migration from the final article may not exceed 10 mg/dm<sup>2</sup> or 60 mg/kg. Volatiles max. 0.5%.

### **Spain**

- ▶ Royal Decree 847 of July 2011

The ingredients of the product and its curing agents Crosslinker C1, C6 and E are in compliance. Limitation(s): Overall migration from the final article may not exceed 10 mg/dm<sup>2</sup> or 60 mg/kg.

**USA**

The product is suitable for use under the following section(s) of Title 21 of the Code of Federal Regulations and those which refer to these:

- ▶ §177.2600 RUBBER ARTICLES INTENDED FOR REPEATED USE; Extraction limits must be met on the finished article per 177.2600 (e) & (f).

**China**

- ▶ Standard GB 9685-2008

The ingredients of this product and its curing agents C1, C6 and E are in compliance for use in rubber.

Regulatory sanctioning of the ingredients in a product does not imply that the finished product manufactured from those ingredients is considered safe for contact with food by regulatory bodies. The responsibility for compliance of the finished article and any testing requirements relating to migration, extraction or volatile limits resides with the manufacturer of the finished product.

**Pharmaceutical Regulations****European Regulations**

Provided appropriate processing this product successfully passed the following tests according to the European Pharmacopoeia section 3.1.9 Silicon Elastomer for Closures and Tubing:

- ▶ Reducing substances
- ▶ Substances soluble in hexane
- ▶ Volatile matter

This information must not be considered a specification as it is not part of our regular quality control.

**Residual solvents**

None of the solvents either mentioned in Guideline for residual solvents (CPMP/ICH/283/95) of the current edition of European Pharmacopoeia or in US Pharmacopoeia Section 467 are intentionally introduced.

**Toy Regulations**

- ▶ DIN EN 71-3

Substances mentioned in DIN EN 71-3:2013, table 2 are not intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

- ▶ DIN EN 71-9

Substances mentioned in DIN EN 71-9:2007, tables 2A – 2I are not intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

- ▶ CPSIA (Consumer Product Safety Improvement Act) of 2008

None of the substances concerned (lead, phthalates) are intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

## Substances

- ▶ PAH (Polycyclic aromatic hydrocarbons)
- ▶ DMF (Dimethylfumarate)
- ▶ APEO (Alkylphenol ethoxylates)
- ▶ Phthalates
- ▶ Azo compounds
- ▶ PCDD/PCDF (Polychlorinated dibenzodioxins and dibenzofurans)
- ▶ Asbestos
- ▶ Melamine
- ▶ BPA (Bisphenol A), BPS (Bisphenol S)
- ▶ Radioactive substances

The substances mentioned above are not intentionally introduced. Therefore they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available.

## Irradiation

Product does not undergo any form of radiation treatment.

## Chemical Inventory Status

See Safety Data Sheet.

## Certificates

Available ISO Certificates can be downloaded via  
[http://www.wacker.com/cms/en/wacker\\_group/wacker\\_facts/ims/certificates/certificates.jsp](http://www.wacker.com/cms/en/wacker_group/wacker_facts/ims/certificates/certificates.jsp)

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