WACKER

Regulatory Product Information

ELASTOSIL® VARIO 40

RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2011/65/EU (RoHS), including subsequent amendments e.g. Directive 2015/863/EU, are intentionally introduced. Therefore they are not expected to be present in amounts exceeding the defined limit values.

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)

Please see Safety Data Sheet.

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

The 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

- XV. Silicones

The ingredient(s) of this product are in compliance. Limitation(s): Volatiles max. 0.5%. Extractable substances: max. 0.5%.

France

- Arrêté du 25 novembre 1992

The ingredient(s) of this product are in compliance. Limitation(s): Volatiles max. 0.5%. Overall migration from the final article must not exceed 10 mg/dm² or 60 mg/kg.

Switzerland

- Swiss Ordinance SR 817.023.21

The ingredients of the product are listed in Annex 9. Limitation(s): Overall migration from the final article must not exceed 10 mg/dm² 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:

- §175.300 RESINOUS AND POLYMERIC COATINGS; Extractive limits under (c) - (e) on finished article
- §177.2600 RUBBER ARTICLES INTENDED FOR REPEATED USE; Extraction limits must be met on the finished article per 177.2600 (e) & (f).

Please note:
The product must be appropriately cured under observance of the limits for platinum (see Regulatory Product information for the particular platinum catalyst).

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.

Toy Regulations

- DIN EN 71-3

Substances mentioned in DIN EN 71-3:2019, 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
- Bisphenols, their derivatives and salts according to Regulation (EU) 2024/3190
- Radioactive substances
- POP (Persistent organic pollutants) as defined in Regulation (EU) 2019/1021 (Stockholm Convention)
- Conflict minerals as defined in section 1502(e)(4) of H.R. 4173, of the Wall Street Reform and Consumer Protection Act
- ODS (Ozone Depleting Substances) as mentioned in Regulation (EU) 2024/590
- SCCP (Short-chain chlorinated paraffins)
- PVC (Polyvinyl chloride)
- PFAS (Fluorinated compounds including per- or polyfluorinated 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 Certificates can be downloaded via
https://www.wacker.com/cms/de/wacker_group/wacker_facts/ims/certificates/certificates.jsp

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