

Regulatory Product Information

WACKER® AK 350 SILICONE FLUID

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 (EC) No 2023/2006

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

- ▶ Regulation (EU) No 10/2011

The product is listed as an additive in the positive list of Regulation (EU) No 10/2011 and amendments (superseding Directive 2002/72/EC). The product is listed under its chemical name Polydimethylsiloxane (ref.-No. 76721) and complies with the specifications under column (4) and (10). It is not subject to a specific migration limit (SML). Dimethylpolysiloxane is approved as food additive under E 900, therefore the product formally meets the definition of a dual use substance. However, the product is not recommended for this use and should not be used as food additive. In addition, Dimethylpolysiloxane is mainly used as a processing aid and does not have a technological effect in food. NIAS are not contained at levels which could endanger human health.

Germany

The product complies with the positive lists of the following Recommendation(s) of the BfR:

- ▶ XIV. Plastic Dispersions
- ▶ XV. Silicones
- ▶ XXXVI. Paper and Board
- ▶ XXXVI/2. Paper and Board for baking purposes

Switzerland

- ▶ Swiss Ordinance SR 817.023.21

The product is listed under its chemical name in annexes 2, 9 and 10 as a fully evaluated substance.

USA

A food contact statement can be provided separately upon request.

Japan

- ▶ Food Sanitation Act Article 18(3), Positive List System

The ingredient is listed in the Positive List Table 2 Additives with serial No. 108(2). The use limit by polymer group is given as the amount of the substance that a business operator specifies, on its own responsibility, for substance(s) classified in the corresponding polymer group in Table 1 (Base materials) when producing a synthetic resin. The amount should be the minimum level required to exhibit the intended effect.

China

- ▶ Standard GB 4806.1-2016 General safety requirements

The product meets all applicable requirements of this Standard insofar as it is not classified as hazardous to human health according to the European classification and labelling requirements.

- ▶ Standard GB 4806.16-2025

The product is listed in Table A.2 under its chemical name and complies with the specifications. It is not subject to a specific migration limit (SML).

China

- ▶ Standard GB 9685-2016

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|--------------------------------------|----------------------|-------|------------------------------------|
| Annex 1 - Plastics | Dosage as necessary: | | PE, PP, PS, AS, ABS, PC, PVC, PVDC |
| Annex 1 - Plastics | Maximum level | 2.0 % | POM, PA |
| Annex 1 - Plastics | Maximum level | 0.3 % | PET |
| Annex 2 - Coatings | Dosage as necessary | | |
| Annex 3 - Rubber | Dosage as necessary | | |
| Annex 4 - Inks | Maximum level | 1.0 % | |
| Annex 5 - Adhesives | Dosage as necessary | | |
| Annex 6 - Paper and Paperboard | Dosage as necessary | | |

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.

Agricultural Use Regulations**USA**

The ingredient(s) of the product are exempted from the requirement of a tolerance under the following Act(s) of Title 40 of the Code of Federal Regulations:

- ▶ §180.960 Polymers
- ▶ §180.910 Inert Ingredients used pre- and post-harvest
- ▶ §180.920 Inert Ingredients used pre-harvest

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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