

## Regulatory Product Information

### ELASTOSIL AUX 4K-I

#### RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2015/863/EU (RoHS) 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)

Product does not contain SVHC in amounts > 0.1 %.

#### 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**

Based on our knowledge of the raw material and processes used in the manufacture of this product, we have no reason to expect that animal/human derived materials are present in this product. Therefore, the risk of contamination with TSE/BSE (Transmissible Spongiform Encephalopathies/ Bovine Spongiform Encephalopathy) is considered being highly unlikely.

## **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 this product are in compliance. Limitation(s): Volatiles max. 0.5%. Extractable substances: max. 0.5%.

### **France**

- ▶ Arrêté du 25 novembre 1992

The ingredients of this product 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 this product are in compliance. Limitation(s): Overall migration from the final article may not exceed 10 mg/dm<sup>2</sup> or 60 mg/kg.

### **Switzerland**

- ▶ Swiss Ordinance SR 817.023.21  
The ingredients of the product are listed in annex 9.

**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 9685-2016

With the exception of the platinum catalyst, the ingredients are in compliance for use as additives in rubber and/or silicone rubber.

- ▶ Standard GB 4806.11-2016

The siloxane based starting substances are listed in Table A.2

**Please note:**

- ▶ The product must be appropriately cured under observance of the limits for platinum (see Regulatory Product information for the particular platinum catalyst).
- ▶ This product is for use as an additive in addition curing silicone elastomers.

Maximum Use Level: 5%.

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 71-3:2013, 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
- PFOS (Perfluorooctane sulfonate), PFOA (Perfluorooctanoic acid)
- POP (Persistent organic pollutants) as defined in Regulation (EC) 850/2004 (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 (EC) No 1005/2009
- SCCP (Short-chain chlorinated paraffins)

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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For questions relating to this data sheet, please contact:  
PS.Silicone@wacker.com

Wacker Chemie AG  
Hanns-Seidel-Platz 4  
81737 München, Germany

## Regulatory Product Information

### ELASTOSIL AUX 4K-X

#### RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2015/863/EU (RoHS) 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)

Product does not contain SVHC in amounts > 0.1 %.

#### 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**

Based on our knowledge of the raw material and processes used in the manufacture of this product, we have no reason to expect that animal/human derived materials are present in this product. Therefore, the risk of contamination with TSE/BSE (Transmissible Spongiform Encephalopathies/ Bovine Spongiform Encephalopathy) is considered being highly unlikely.

## **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 this product are in compliance. Limitation(s): Volatiles max. 0.5%. Extractable substances: max. 0.5%.

### **France**

- ▶ Arrêté du 25 novembre 1992

The ingredients of this product 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 this product are in compliance. Limitation(s): Overall migration from the final article may not exceed 10 mg/dm<sup>2</sup> or 60 mg/kg.

### **Switzerland**

- ▶ Swiss Ordinance SR 817.023.21  
The ingredients of the product are listed in annex 9.

**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 9685-2016  
With the exception of the platinum catalyst, the ingredients are in compliance for use as additives in rubber and/or silicone rubber.

- ▶ Standard GB 4806.11-2016  
The siloxane based starting substances are listed in Table A.2

**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 71-3:2013, 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
- PFOS (Perfluorooctane sulfonate), PFOA (Perfluorooctanoic acid)
- POP (Persistent organic pollutants) as defined in Regulation (EC) 850/2004 (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 (EC) No 1005/2009
- SCCP (Short-chain chlorinated paraffins)

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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**WACKER**

## Regulatory Product Information

### ELASTOSIL AUX BATCH PT 1

#### RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2015/863/EU (RoHS) 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)

Product does not contain SVHC in amounts > 0.1 %.

#### 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**

Based on our knowledge of the raw material and processes used in the manufacture of this product, we have no reason to expect that animal/human derived materials are present in this product. Therefore, the risk of contamination with TSE/BSE (Transmissible Spongiform Encephalopathies/ Bovine Spongiform Encephalopathy) is considered being highly unlikely.

## **Food Contact Regulations**

This platinum catalyst batch is suitable for use as an aid to production (AP) in silicone elastomers intended to come into contact with food provided that the limits for platinum are met.

### ▶ 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 limit for platinum has to be observed: 50 ppm For coating of paper and plastic films: 120 ppm

## **France**

### ▶ Arrêté du 25 novembre 1992

The limit for platinum has to be observed: 120 ppm

## **USA**

### ▶ §175.300 RESINOUS AND POLYMERIC COATINGS; Extractive limits under (c) - (e) on finished article

The limit for platinum has to be observed: 150 ppm

### ▶ §175.320 RESINOUS AND POLYMERIC COATINGS FOR POLYOLEFIN FILMS

The limit for platinum has to be observed: 100 ppm

### ▶ §176.170 COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS; Extractive limits under (c) - (d) on finished article.

The limit for platinum has to be observed: 200 ppm

Release coatings for pressure sensitive adhesives: 100 ppm

### ▶ §176.180 COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH DRY FOOD

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

No specific limitation assigned by FDA

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 71-3:2013, 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
- PFOS (Perfluorooctane sulfonate), PFOA (Perfluorooctanoic acid)
- POP (Persistent organic pollutants) as defined in Regulation (EC) 850/2004 (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 (EC) No 1005/2009
- SCCP (Short-chain chlorinated paraffins)

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

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81737 München, Germany

## Regulatory Product Information

### ELASTOSIL® R 401/60 S

#### RoHS (Restriction of Hazardous Substances)

None of the substances mentioned in Directive 2015/863/EU (RoHS) 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)

Product does not contain SVHC in amounts > 0.1 %.

#### 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

- ▶ 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.

**Switzerland**

- ▶ Swiss Ordinance SR 817.023.21  
The ingredients of the product are listed in annex 9.

**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 9685-2016  
The ingredients of this product and its curing agents C1, C6 and E are in compliance for use in rubber and/or silicone rubber.

- ▶ Standard GB 4806.11-2016  
The siloxane based starting substances are listed in Table A.2.

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
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- PCDD/PCDF (Polychlorinated dibenzodioxins and dibenzofurans)
- Asbestos
- Melamine
- BPA (Bisphenol A), BPS (Bisphenol S)
- Radioactive substances
- PFOS (Perfluorooctane sulfonate), PFOA (Perfluorooctanoic acid)
- POP (Persistent organic pollutants) as defined in Regulation (EC) 850/2004 (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 (EC) No 1005/2009
- SCCP (Short-chain chlorinated paraffins)

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](https://www.wacker.com/cms/de/wacker_group/wacker_facts/ims/certificates/certificates.jsp)

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Hanns-Seidel-Platz 4  
81737 München, Germany

# CERTIFICATE OF COMPLIANCE USP BIOLOGICAL TESTS CLASSIFICATION VI

**Material tested:** Elastosil R401/60 Control No: 34623HO  
**Manufacturer:** WACKER Chemie GmbH, Werk Burghausen  
Johannes-Hess-Str. 24, D-84489 Burghausen  
**Studies performed:**

## ACUTE SYSTEMIC TOXICITY (USP)

The saline, alcohol in saline, polyethylene glycol 400 and vegetable oil extracts of the test item injected into mice did not produce a significantly greater systemic reaction than the blank extractant.

## INTRACUTANEOUS TOXICITY (USP)

The saline, alcohol in saline, polyethylene glycol 400 and vegetable oil extracts of the test item injected intracutaneously in rabbits did not produce a significantly greater tissue reaction than the blank extractant.

## IMPLANTATION TEST (USP)

The macroscopic reaction of the test item implanted 120 hours was not significant as compared to the USP negative control plastic.

The sample of the test item extracted at a ratio of 60 cm<sup>2</sup>/20ml and at a temperature of 50 ± 1°C for 72 hours met the requirements of a USP Class VI Plastic.

**BIOSERVICE Scientific Laboratories GmbH Munich**

Behringstraße 6

D-82152 Planegg



A handwritten signature in blue ink, appearing to read "Albrecht Poth".

Dr. Albrecht Poth

Manager Biological Safety Testing

Date: July 10, 1998