

**LIPOXOL 400 MED**

Version: 1.03

Revision Date 17.02.2017

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**Company/Undertaking Identification**

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**Identification of the product / Product identifiers**

<b>Trade name:</b>	<b>LIPOXOL 400 MED</b>
<b>CAS-No.:</b>	25322-68-3
<b>CAS Name:</b>	Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -hydroxy-
<b>INCI-Name</b>	PEG-8

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**Regulatory Information (REACH and Chemical Inventories)****Registration number / Substance name (REACH):**

<b>REACH No.:</b>	Not available (polymer).
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**Information about monomers**

All monomers of this polymer have been registered according to Regulation (EC) No. 1907/2006 (REACH).

All starting molecules and further reactants of this polymer have been registered or are exempt from the obligation to register according to Regulation (EC) No 1907/2006 (REACH).

**Notification status**

Switzerland. Consolidated Inventory - <b>CH INV</b>	listed (product or constituents are listed)
US. Toxic Substances Control Act - <b>TSCA</b>	listed (product or constituents are listed)
Canada. Canadian Environmental Protection Act (CEPA). Domestic Substances List (DSL) - <b>DSL</b>	listed (product or constituents are listed)
New Zealand. Inventory of Chemicals (NZIoC), as published by ERMA New Zealand - <b>NZIOC</b>	listed (product or constituents are listed)
Australia. Industrial Chemical (Notification and Assessment) Act - <b>AICS</b>	listed (product or constituents are listed)
Japan. Kashin-Hou Law List - <b>ENCS (JP)</b>	listed (product or constituents are listed)
Japan. Industrial Safety & Health Law (ISHL) List - <b>ISHL (JP)</b>	listed (product or constituents are listed)

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Korea. Existing Chemicals Inventory (KECI) - <b>KECI (KR)</b>	listed (product or constituents are listed)
Philippines. The Toxic Substances and Hazardous and Nuclear Waste Control Act - <b>PICCS (PH)</b>	listed (product or constituents are listed)
China. Inventory of Existing Chemical Substances - <b>INV (CN)</b>	listed (product or constituents are listed)

**Information about origin of the product**

<b>Country of manufacture:</b>	Germany
<b>Source:</b>	The ingredients of this product are synthetic based. The product meets therefore the criteria to be classified as vegan.
<b>Genetically Modified Organisms (GMO):</b>	Assuming the use of the raw materials and manufacturing process currently employed this product does not intentionally contain genetically modified organisms (GMOs) or substances made of GMOs.
<b>BSE / TSE:</b>	Assuming the use of the raw materials and manufacturing process currently employed the product does not contain any BSE/TSE contamination.

**Information about Food and Food Contact****Kosher / Halal information**

<b>Kosher status:</b>	Product is produced under rabbinical supervision, a Kosher Certificate is available.
<b>Halal status:</b>	Product is not produced under muslimic supervision. Intermediates and starting material are of non-animal origin. Product is made by a process in which only auxiliaries of non-animal origin have been used. Processing equipment is only used for products of non-animal origin. We permit in case of request a muslimic inspection of the production plant. Product is made by a process in which only auxiliaries of non-ethanol origin have been used.

**Food contact information****CFR; Title 21 Food and Drugs; Part 172 Food additives permitted for direct addition to food for human consumption**

§ 172.820 Polyethylene glycol (mean molecular weight 200-9,500)

Listed as: Polyethylene glycol (molecular weight 200-9,500)

**CFR; Title 21 Food and Drugs; Part 173 Secondary direct food additives permitted in food for human consumption**

§ 173.340 Defoaming agents

Listed as: Polyethylene glycol

as defined in § 172.820

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**CFR; Title 21 Food and Drugs; Part 175 Indirect food additives: Adhesives and components of coatings**  
§ 175.105 Adhesives

Listed as: Polyethylene glycol (molecular weight 200-6,000)

**CFR; Title 21 Food and Drugs; Part 175 Indirect food additives: Adhesives and components of coatings**  
§ 175.320 Resinous and polymeric coatings for polyolefin films

Listed as: (b) The coatings are formulated from optional substances which are: (2) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, by prior sanctions, or approvals.

Cross reading to § 172.820  
Cross reading to § 173.340  
Cross reading to § 175.105  
Cross reading to § 178.3750  
Cross reading to § 178.3910

**CFR; Title 21 Food and Drugs; Part 176 Indirect food additives: Paper and paperboard components**  
§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods

Listed as: (a) (4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

Cross reading to § 172.820  
Cross reading to § 173.340  
Cross reading to § 175.105  
Cross reading to § 178.3750  
Cross reading to § 178.3910

**CFR; Title 21 Food and Drugs; Part 176 Indirect food additives: Paper and paperboard components**  
§ 176.180 Components of paper and paperboard in contact with dry food

Listed as: (b) (1) Substances that by § 176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

Cross reading to § 172.820  
Cross reading to § 173.340  
Cross reading to § 175.105  
Cross reading to § 178.3750  
Cross reading to § 178.3910

**CFR; Title 21 Food and Drugs; Part 176 Indirect food additives: Paper and paperboard components**  
§ 176.200 Defoaming agents used in coatings

Listed as: (c) Any substance employed in the production of defoaming agents and which is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

Cross reading to § 172.820  
Cross reading to § 173.340  
Cross reading to § 175.105  
Cross reading to § 178.3750  
Cross reading to § 178.3910

**CFR; Title 21 Food and Drugs; Part 176 Indirect food additives: Paper and paperboard components**  
§ 176.300 Slimicides

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Listed as: (d) Adjuvant substances permitted to be used in the preparation of slimicides include substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, substances permitted to be used in paper and paperboard by other regulations in this chapter (...).

Cross reading to § 176.170

Cross reading to § 176.180

Cross reading to § 176.200

**CFR; Title 21 Food and Drugs; Part 178 Indirect food additives: Adjuvants, production aids, and sanitizers**  
§ 178.3570 Lubricants with incidental food contact

Listed as: (c) Any substance employed in the production of the lubricants described in this section that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

Cross reading to § 172.820

Cross reading to § 173.340

Cross reading to § 175.105

Cross reading to § 178.3750

Cross reading to § 178.3910

**CFR; Title 21 Food and Drugs; Part 178 Indirect food additives: Adjuvants, production aids, and sanitizers**  
§ 178.3750 Polyethylene glycol (mean molecular weight 200–9,500)

Listed as: Polyethylene glycol (molecular weight 200-9,500)

**CFR; Title 21 Food and Drugs; Part 178 Indirect food additives: Adjuvants, production aids, and sanitizers**  
§ 178.3910 Surface lubricants used in the manufacture of metallic articles

Listed as: Polyethylene glycol (molecular weight 300 or greater)

Mono- and diethylene glycol content not to exceed a total of 0.2%.

**CFR; Title 21 Food and Drugs; Part 181 Prior-sanctioned food ingredients**  
§ 181.30 Substances used in the manufacture of paper and paperboard products used in food packaging

Listed as: Polyethylene glycol 400

**Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food**

Listed as: Polyethyleneglycol, CAS 25322-68-3

Reference number: PM/REF 23590/76960

Use as additive or polymer production aid: yes

Use as monomer or other starting substance or macromolecule obtained from microbial fermentation: yes

Restrictions and specifications: nothing mentioned

**Council of Europe. List of FCMs for Paper and Board (Tech Doc No. 1), Resolution AP (2002)1 on Paper and Board Materials and Articles Intended to Come into Contact with Foodstuffs**  
LIST 1 OF ADDITIVES: list of additives assessed

Listed as: polyethyleneglycol

Reference number: PM/REF 76960

The number of the list in which the substance is classified by the Scientific Committee for food / EFSA (SCF-L): 2

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### BfR Recommendations on Food Contact Materials (Germany)

XXI. Commodities based on Natural and Synthetic Rubber (as of 01.10.2014)

Listed as: 2.1.3.1.2.4. Processing aids:....Polyethylene glycols and their fatty alkyl ethers, max. 2.0 % (no more than 0.2 % monoethylene glycol)  
2.1.3.1.2.5 Slip agents and mould release agents: ... Polyethylene glycol  
2.1.3.2.2.5 Slip and mould release agents: Polyethyleneglycol and/or polypropyleneglycol

In any case: Polyethylene glycol may contain no more than 0.2 % monoethylene glycol. For method of determination see Communication 28 on the testing of plastics in Bundesgesundheitsblatt, 16 (1973) 362.

### BfR Recommendations on Food Contact Materials (Germany)

XXXVI. Paper and board for food contact (as of 01.10.2014)

Listed as: Polyethyleneglycols which contain no more than 0.2% monoethyleneglycol

Listed under: C. Special Paper refining agents: II. Humectants

### BfR Recommendations on Food Contact Materials (Germany)

XLIV. Artificial Sausage Casings (as of 01.10.2014)

Listed as: I. Artificial casings of cellulose hydrate (cellophane); A. Base film; 2. Moisturisers; b) Tri- and polyethyleneglycol with a monoethyleneglycol content of no more than 0.2%; however, only in association with a coating after Section B, No. 1, in total, max. 27.5%

### BfR Recommendations on Food Contact Materials (Germany)

XLVIII. Materials for Coating the Outside of Hollow Glassware (as of 01.03.1975)

Listed as: Polyethyleneglycols which contain no more than 0.2% monoethyleneglycol

### BfR Recommendations on Food Contact Materials (Germany)

Following BfR recommendations generally state that „Additives permitted by the Commission Regulation (EU) No 10/2011 may be used in compliance with the restrictions stipulated therein“:

- III. Polyethylene
- V. Polystyrene Produced Exclusively from the Polymerisation of Styrene
- VI. Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers
- VII. Polypropylene
- X. Polyamides
- XI. Polycarbonates and Mixtures of Polycarbonates with other Polymers or Copolymers
- XII. Unsaturated Polyester Resins
- XIV. Polymer Dispersions
- XVI. Polyvinyl Ethers
- XVII. Poly(terephthalic acid diol esters)
- XX. Polyisobutylene, Isobutylene Copolymers and Mixtures of Polyisobutylene with other Polymers
- XXII. Polymers Based on Esters of Acrylic and Methacrylic Acids, their Copolymers, and Mixtures of these with other Polymers
- XXXIII. Acetal Resins
- XXXIV. Vinylidene Chloride Copolymers with a Predominant Content of Polyvinylidene Chloride
- XXXV. Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and Unsaturated Aliphatic Acids, and their Salts and Esters (A.2.)
- XXXV. Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and Unsaturated Aliphatic Acids, and their Salts and Esters (B.2.)
- XXXVII. Polybutene-(1) - (2.)
- XXXIX. Commodities Based on Polyurethanes
- XLII. Plasticizer-Free Chlorinated Polyvinyl Chloride, Plasticizer-Free Chlorinated Copolymers of Vinyl Chloride and Mixtures of these Polymers with other Copolymers - 2.
- XLIII. Poly(4-methylpentene-1)
- XLVI. Cross-linked Polyethylene - A. Peroxide cross-linked Polyethylene - 2.
- XLVI. Cross-linked Polyethylene - B. Physically (electron-beam irradiation) cross-linked polyethylene -
- L. Copolymers and Graft Polymers of Acrylonitrile

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This is an unofficial translation of the BfR recommendation. Only the German version is binding (published: <http://bfr.zadi.de/kse/>).

### **D.M. 21/03/1973 and following amendments (Positive list of allowed substance for food contact application) - (Italy)**

Listed as: Polyethyleneglycol, CAS 25322-68-3

Reference number: PM/REF 76960

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 1 (Monomers and Additives Permitted in Plastics Intended for Food Contact): List 1, Part A Permitted monomers and other starting substances

Listed as: Polyethyleneglycol, CAS 25322-68-3

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 1 (Monomers and Additives Permitted in Plastics Intended for Food Contact): List 2 Permitted Additives

Listed as: Polyethyleneglycol, CAS 25322-68-3

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 2 & 3 (permitted substances and restrictions on the manufacture of cellulose film): Additive group: Moisture retention material, Usage allowed in varnishes for cellulose films

Listed as: Polyethyleneglycol, CAS 25322-68-3

Average molecular weight between 250-1,200.

Maximum Level 27%

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 5 (Consumer Goods Made of Silicon that Come in Contact with Food): Evaluated substance; Substance type: Additive

Listed as: Polyethyleneglycol, CAS 25322-68-3

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 6, 1A, Substances permitted for manufacture of packaging inks, Binders (monomers), evaluated

Listed as: Polyethyleneglycol, CAS 25322-68-3

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 6, 3A, Substances permitted for manufacture of packaging inks, Solvents, evaluated

Listed as: Polyethyleneglycol, CAS 25322-68-3

### **Ordinance of the FDHA on articles and materials (RS 817.023.21) (Swiss Confederation)**

Annex 6, 4A, Substances permitted for manufacture of packaging inks, Additives (except pigments), evaluated

Listed as: Polyethyleneglycol, CAS 25322-68-3

**Hygienic standards for uses of additives in food containers and packaging materials (GB 9685-2008, Sep 9, 2008, amended through MOH No. 2014-14, July 8, 2014) (China)**

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Listed as: Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, CAS 25322-68-3

Specific Migration Limit (SML): 30 mg/kg

use for Adhesives

use for Plastics

Types of plastics

PA

PET

SML/QM/DL expressed as: Ethylene glycol

Dosage as necessary.

### **Hygienic standards for uses of additives in food containers and packaging materials (GB 9685-2008, Sep 9, 2008, amended through MOH No. 2014-14, July 8, 2014) (China)**

Listed as: Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, CAS 25322-68-3

Specific Migration Limit (SML): 30 mg/kg

use for Plastics

Types of plastics

PE

PP

PS

AS

ABS

Maximum Level 3%

Dosage as necessary.

### **Hygienic standards for uses of additives in food containers and packaging materials (GB 9685-2008, Sep 9, 2008, amended through MOH No. 2014-14, July 8, 2014) (China)**

Listed as: Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, CAS 25322-68-3

Specific Migration Limit (SML): 30 mg/kg

use for Plastics

Types of plastics

PC

Maximum Level 0.2 %

Dosage as necessary.

### **Hygienic standards for uses of additives in food containers and packaging materials (GB 9685-2008, Sep 9, 2008, amended through MOH No. 2014-14, July 8, 2014) (China)**

Listed as: Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, CAS 25322-68-3

Specific Migration Limit (SML): 30 mg/kg

use for Paper

use for Coating

Maximum Level 15,0

Dosage as necessary.

### **Hygienic standards for uses of additives in food containers and packaging materials (GB 9685-2008, Sep 9, 2008, amended through MOH No. 2014-14, July 8, 2014) (China)**

Listed as: Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, CAS 25322-68-3

use for Ink

SML/QM/DL expressed as: Ethylene glycol

Maximum Quantity of Residue: 0.1%

Dosage as necessary.

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Hygienic standards for uses of additives in food containers and packaging materials (GB 9685-2008, Sep 9, 2008, amended through MOH No. 2014-14, July 8, 2014) (China)

Listed as: Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, CAS 25322-68-3

Specific Migration Limit (SML): 30 mg/kg

use for Rubber

use for Plastics

Types of plastics

POM

PBT

SML/QM/DL expressed as: Ethylene glycol

Maximum Quantity of Residue: 0.1%

Dosage as necessary.

## Pharmacological information / Pharmacopeia

### EU-Pharmacopeia (Ph.Eur.)

The product is in line with this pharmacopeia.

### US-Pharmacopeia (USP/NF)

The product is in line with this pharmacopeia.

### Japanese Pharmacopeia (JP)

The product is in line with this pharmacopeia.

## Cosmetic regulations / Use in cosmetic products

### Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

General statement: The product does not contain any of the substances listed in the below mentioned annexes of the current version of the Regulation (EC) No. 1223/2009, with the exception of very small amounts of the following substances, which are characteristic for this type of product.

Section: Annex II: List of substances prohibited in cosmetic products  
Listed as: Ethylene oxide, CAS 75-21-8  
Concentration:  $\leq 1$  ppm  
Reference number: 182

Section: Annex II: List of substances prohibited in cosmetic products  
Listed as: 1,4-Dioxane, CAS 123-91-1  
Concentration:  $\leq 1$  ppm  
Reference number: 343

Section: Annex II: List of substances prohibited in cosmetic products



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Listed as:	2,2'-oxydiethanol, Diethylene glycol (DEG), CAS 111-46-6
Concentration:	<= 0.1 %
Reference number:	1370

Section:	Annex III: List of substances which cosmetic products must not contain except subject to the restrictions laid down
Listed as:	2,2'-oxydiethanol, Diethylene glycol (DEG), CAS 111-46-6
Concentration:	<= 0.1 %
Reference number:	186
Restrictions/Conditions:	As traces in ingredients Maximum concentration in ready for use preparation 0.1%

Section:	Annex III: List of substances which cosmetic products must not contain except subject to the restrictions laid down
Listed as:	Formaldehyde, CAS 50-00-0
Concentration:	<= 30 ppm
Reference number:	13
Restrictions/Conditions:	Product type, body parts: Nail hardening products Maximum concentration in ready for use preparation: 5 % (as formaldehyde) For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.

Based on the production process and the raw materials currently employed, the presence of the above listed substances is technically unavoidable and thus in compliance with Article 17 of Regulation (EC) No. 1223/2009.

## Other regulations

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### Detergents regulations

#### REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents

Not applicable, the product is not a detergent.

### EU Ecolabel / DID list

Version:	2014
Listed as:	2539: Polyethylene glycol, MW<4100

The product is biodegradable under anaerobic conditions.  
This information is based on the current DID-list.

### Volatile organic compounds

#### Swiss VOC Ordinance 814.018

According to Article 2 of the SR 814.018 VOCs are liable for tax if they are listed on the positive list of substances (Annex 1) or contained in products mentioned in the positive list of products (Annex 2). According to Article 8(a) of the SR 814.018, those mixtures and products are exempted from tax in which the VOC content does not exceed 3 per cent (% by weight).

We hereby confirm that, to the best of our present knowledge, assuming the use of the raw materials and manufacturing

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process currently employed, the product does not contain > 3% of the substances on the positive list of substances (Annex 1) of the SR 814.018.

### Directive EU 2010/75 and its amendments

The VOC Directive 2010/75/EU of the European Community is a complex regulation. Only based on the properties of a substance it is not possible to make a decision whether this regulation applies to the substance or not. A statement can be made only in connection with the application and the conditions of use.

As a producer of raw materials we do not have information on actual usage and conditions of use. Therefore, we can only make a statement about the volatility and the boiling point under standard conditions. You will find this information in chapter 9 of our material safety data sheet.

### Directive 2004/42/EC

The VOC Directive 2004/42/EC of the European Community is a complex regulation. Only based on the properties of a substance it is not possible to make a decision whether this regulation applies to the substance or not. A statement can be made only in connection with the application and the conditions of use.

As a producer of raw materials we do not have information on actual usage and conditions of use. Therefore, we can only make a statement about the volatility and the boiling point under standard conditions. You will find this information in chapter 9 of our material safety data sheet.

### Directive 1999/13/EC

Directive 1999/13/EG was repealed by Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010; Official Journal No L 334, page 17, 17.12.2010.

## Other regulations about special uses

Directive 2000/53/EC on end-of life vehicles (ELV)

Directive 94/62/EC on packaging and packaging waste (Packaging Waste Directive)

2009/48/EC; EN71-3; EN 71-9 (Toys)

USA CONEG (Coalition of Northeastern Governors) Regulation

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Directive 2012/19/EC on waste of electrical and electronic equipment (WEEE).

This product meets the relevant requirements of this/these Directive(s) or Regulation(s).

## Disposal considerations

A waste code in accordance with the European Waste Catalogue (EWC) may not be assigned to this product since it admits of a classification only when the consumer uses it for some purpose.

The waste code must be determined in agreement with the regional waste disposal authority or company.

## Restrictions on Use and on Import/Export

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### Substances of very high concern (SVHC) - Candidate List and REACH Annex XVII

#### REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

This product does not contain substances of very high concern (SVHC) as mentioned in the current SVHC-list with >0.1 % (w/w).

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### Information about special compounds/ingredients

#### Residual solvents

According to "Impurities Guideline for Residual Solvents (CPMP/ICH/283/95)" only class 2 solvents ethylene glycol and 1,4-dioxane are likely to be present. Both are below the option 1 limit.

#### Allergens

We hereby confirm that, to the best of our present knowledge, assuming the use of the raw materials and manufacturing process currently employed, our product does not contain allergens listed in Directive No. 2011/1169/EC (appendix II) and its amendments.

We hereby confirm that, to the best of our present knowledge, assuming the use of the raw materials and manufacturing process currently employed, our product does not contain allergens listed in Regulation No. (EU) 1223/2009 (annex III) and its amendments, except small amounts of the following technically unavoidable substances:

Substance name	CAS-No. EC-No.	content
formaldehyde	50-00-0 200-001-8	<= 30 PPM
2,2'-oxydiethanol (DEG)	111-46-6 203-872-2	<= 0.1 %

### Information on nano materials/nano particles

We herewith confirm that to the best of our present knowledge this product is neither defined as such nor contains nano particles. This evaluation is based on the physical chemical properties of the material.

### Microbiological quality

We hereby confirm that, to the best of our present knowledge, assuming the use of the raw materials and manufacturing process currently employed, the total viable count in this product is is < 100 cfu/g with no recovery during total count of S.aureus, C.albicans and Gram negative rods.

The content of

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Yeast / Candida albicans

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is less than 1 cfu/g

### Information about CMR substances

We hereby confirm that, to the best of our present knowledge, assuming the use of the raw materials and manufacturing process currently employed, our product does not contain any CMR-substances classified as CMR category 1A, 1B and 2 in accordance with Regulation 1272/2008 (EC) and its adaptations, with the exception of very small amounts of the following technically unavoidable substances:

Substance name	CAS-No. EC-No.	content
ethylene oxide	75-21-8 200-849-9	<= 1 PPM
1,4-dioxane	123-91-1 204-661-8	<= 1 PPM
formaldehyde	50-00-0 200-001-8	<= 30 PPM

### Preservatives

This product does not contain any preservatives.

### Information about other special components

None of the following substances are used in the process or are expected to be part of the raw materials used to manufacture this product:

- Acrylamide
- Aflatoxines
- Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Allergens, such as tree nuts, peanuts, eggs, milk, wheat, soybeans, fish, and crustaceans
- Aromatic amines
- Asbestos
- Azo compounds
- Bisphenol A
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Dioxins
- Epoxy derivatives listed in EU Directive 2002/16/EC
- Gluten
- Melamine
- Methyl bromide
- Natural rubber latex and dry natural rubber
- Ozone-depleting chemicals
- Pesticides
- Phthalates
- Polyaromatic Hydrocarbons
- Polybrominated Diphenyl Ethers (PBDEs)
- Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)
- Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)
- Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonates (PFOS)
- Radioactive Substances
- Organo-Tin Compounds

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- Vinyl Chloride Monomer (VCM) and Polyvinyl Chloride (PVC)

We hereby confirm that, to the best of our present knowledge, assuming the raw materials and the manufacturing process currently employed, the product contains < 1 ppm of heavy metals calculated as lead.

We hereby confirm that, to the best of our present knowledge, assuming the raw materials and the manufacturing process currently employed, our product does not contain any endocrine disruptors.

We hereby confirm that, to the best of our present knowledge, assuming the raw materials and the manufacturing process currently employed, our product does not contain any adsorbable/extractable organic halides (AOX/EOX).

## Other statements / Disclaimer

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### Toxicological and ecotoxicological properties

For more information about toxicological and ecotoxicological properties and information please refer to the MSDS of this product.

### Legal statement

The information provided in this document is correct to the best of our knowledge, information and belief at the date of its publication. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

This information is based on our present knowledge and experience.

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