

## Product Information

updated: 05/2018  
replace vers. 07/2017

# LIPOXOL MED

## Polyethylene glycols for the pharmaceutical and cosmetic industry

LIPOXOL MED grades are in compliance with the current requirements of the Pharmacopoeias from Europe, Japan and USA and they are listed under US-DMF type IV (No. 19165).  
(Information regarding **GMP status** on the last page)

### Product description

- Chemical name: Polyethylene glycol
- Description: Depending of the molecular weight the LIPOXOL MED grades are liquid or solid polymers soluble in water. They are produced by the addition of ethylene oxide to ethylene glycol (under alkaline conditions and neutralized with lactic acid).
- Synonyms: PEG, Macrogol,  $\alpha$ -Hydro- $\omega$ -hydroxypoly-(oxy-1.2-ethynediyl), Polyoxyethylene glycol
- CAS-Number: [25322-68-3]
- Formula:  $\text{HO}-(\text{CH}_2\text{CH}_2\text{O})_n\text{-H}$ , n = Number of ethylene oxide units
- Grades: The LIPOXOL MED grades are available with an average molecular weight of 300-8000 g/mol. The average molecular weight is given in the product name. The following table gives an overview about the LIPOXOL MED grades.

| Product name     | Ph. Eur. Monograph | USP/NF Monograph           | Jap. Ph. Monograph         | INCI-Name |
|------------------|--------------------|----------------------------|----------------------------|-----------|
| LIPOXOL 300 MED  | Macrogol 300       | Polyethylene Glycol - 300  |                            | PEG - 6   |
| LIPOXOL 400 MED  | Macrogol 400       | Polyethylene Glycol - 400  | Macrogol 400               | PEG - 8   |
| LIPOXOL 600 MED  | Macrogol 600       | Polyethylene Glycol - 600  |                            | PEG - 12  |
| LIPOXOL 1000 MED | Macrogol 1000      | Polyethylene Glycol - 1000 |                            | PEG - 20  |
| LIPOXOL 1500 MED | Macrogol 1500      | Polyethylene Glycol - 1500 |                            | PEG - 32  |
| LIPOXOL 3000 MED | Macrogol 3000      | Polyethylene Glycol - 3000 |                            | PEG - 60  |
| LIPOXOL 3350 MED | Macrogol 3350      | Polyethylene Glycol - 3350 | Macrogol 4000 <sup>1</sup> | PEG - 75  |
| LIPOXOL 4000 MED | Macrogol 4000      | Polyethylene Glycol - 4000 |                            | PEG - 90  |
| LIPOXOL 6000 MED | Macrogol 6000      | Polyethylene Glycol - 6000 |                            | PEG - 150 |
| LIPOXOL 8000 MED | Macrogol 8000      | Polyethylene Glycol - 8000 | Macrogol 6000 <sup>1</sup> | PEG - 180 |

<sup>1</sup> Different denomination according to the Jap. Pharmacopeia

The products LIPOXOL 3350 MED and LIPOXOL 4000 MED are also available as **Spray Powder**, please refer to the product information "**LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP**".

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# LIPOXOL MED

| LIPOXOL (specification)               | 300 MED                        | 400 MED             | 600 MED              | 1000 MED             | Unit               | Method                  |
|---------------------------------------|--------------------------------|---------------------|----------------------|----------------------|--------------------|-------------------------|
| Appearance at 20°C                    | liquid, clear                  | liquid, clear       | liquid, solid        | solid                | -                  | visual                  |
| Appearance of solution (10% in water) | clear                          | clear               | clear                | clear                | -                  | visual                  |
| Appearance of solution (25% in water) | clear                          | clear               | clear                | clear                | -                  | visual                  |
| Colour number (APHA) (25 % in water)  | ≤ 15                           | ≤ 15                | ≤ 15                 | ≤ 15                 | mg Pt/l            | DIN EN 1557             |
| Colour number (BY) (25 % in water)    | ≥ 6                            | ≥ 6                 | ≥ 6                  | ≥ 6                  | BY                 | Ph. Eur.                |
| Hydroxyl number                       | 356 - 394                      | 267 - 295           | 178 - 197            | 107 - 118            | mg KOH/g           | DIN EN 13296            |
| Average molar mass                    | 285 - 315                      | 380 - 420           | 570 - 630            | 950 - 1050           | g/mol              | calc. from OH no        |
| Assay                                 | 95 - 105                       | 95 - 105            | 95 - 105             | 95 - 105             | %                  | USP/NF                  |
| Acid number                           | ≤ 0.2                          | ≤ 0.2               | ≤ 0.2                | ≤ 0.2                | mg KOH/g           | EN ISO 2114             |
| Freezing point                        | -                              | -                   | 15 - 25              | 35 - 40              | °C                 | Ph. Eur.                |
| pH (5 % in demin. water)              | 4.5 - 7.5                      | 4.5 - 7.5           | 4.5 - 7.5            | 4.5 - 7.5            | -                  | USP/NF                  |
| Water                                 | ≤ 1.0                          | ≤ 1.0               | ≤ 1.0                | ≤ 1.0                | % by mass          | Ph. Eur.                |
| dyn. Viscosity at 20°C                | 80 - 105                       | 105 - 130           | 15 - 20 <sup>2</sup> | 22 - 30 <sup>2</sup> | mPa s              | Ph. Eur.                |
| kinem. Viscosity at 98.9°C            | 5.4 - 6.4                      | 6.8 - 8.0           | 9.9 - 11.3           | 16.0 - 19.0          | mm <sup>2</sup> /s | USP/NF                  |
| Heavy metals as Pb                    | ≤ 5                            | ≤ 5                 | ≤ 5                  | ≤ 5                  | mg/kg              | USP/NF                  |
| Ethylene and Diethylene glycol        | ≤ 2500                         | ≤ 1000 <sup>4</sup> | ≤ 1000 <sup>4</sup>  | ≤ 1000 <sup>4</sup>  | mg/kg              | AB 039 010 <sup>3</sup> |
| Ethylene glycol                       | ≤ 620                          | ≤ 620               | ≤ 620                | ≤ 620                | mg/kg              | AB 039 010 <sup>3</sup> |
| Acid/alkaline react. substances       | ≤ 0.1                          | ≤ 0.1               | ≤ 0.1                | ≤ 0.1                | ml 0.1 M NaOH      | Ph. Eur.                |
| Red. substances                       | ≥ 3                            | ≥ 3                 | ≥ 3                  | ≥ 3                  | R                  | Ph. Eur.                |
| Formaldehyde                          | ≤ 30                           | ≤ 30                | ≤ 30                 | ≤ 30                 | mg/kg              | Ph. Eur.                |
| Sulphate ash                          | ≤ 0.1                          | ≤ 0.1               | ≤ 0.1                | ≤ 0.1                | % by mass          | USP/NF                  |
| 1,4-Dioxane                           | ≤ 1                            | ≤ 1                 | ≤ 1                  | ≤ 1                  | mg/kg              | Ph. Eur.                |
| Ethylene oxide                        | ≤ 1                            | ≤ 1                 | ≤ 1                  | ≤ 1                  | mg/kg              | Ph. Eur.                |
| Identification A, B, C                | complies with the requirements |                     |                      |                      |                    | Ph. Eur.                |

<sup>2</sup> 50 % in water

<sup>3</sup> internal method

<sup>4</sup> acc. to the requirements of regulation No. (EC) 1223/2009 (Annex III)

| LIPOXOL<br>General product description | 300 MED    | 400 MED    | 600 MED                 | 1000 MED                | Unit              | Method |
|--|------------|------------|-------------------------|-------------------------|-------------------|--------|
| Density at 20°C                        | appr. 1.12 | appr. 1.12 | appr. 1.08 <sup>2</sup> | appr. 1.08 <sup>2</sup> | g/cm <sup>3</sup> | --     |
| Solubility in water (at 20°C)          | unlimited  | unlimited  | unlimited               | appr. 750               | g/l               | --     |
| Surface tension (at 20°C)              | 48         | 48         | 54 - 57 <sup>2</sup>    | 54 - 57 <sup>2</sup>    | mN/m              | --     |
| Freezing point                         | -20 - -10  | 4 - 8      | -                       | -                       | °C                | --     |
| Flash point                            | appr. 220  | appr. 240  | appr. 270               | appr. 260               | °C                | --     |
| Ignition temperature                   | appr. 370  | appr. 370  | appr. 380               | appr. 420               | °C                | --     |

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# LIPOXOL MED

| LIPOXOL (specification)               | 1500 MED                       | 3000 MED            | 4000 MED            | 6000 MED            | 8000 MED      | Unit               | Method                  |
|---------------------------------------|--------------------------------|---------------------|---------------------|---------------------|---------------|--------------------|-------------------------|
| Appearance at 20°C                    | flakes                         | flakes/powder       | flakes/powder       | flakes/powder       | flakes/powder | -                  | visual                  |
| Appearance of solution (10% in water) | clear                          | clear               | clear               | clear               | clear         | -                  | visual                  |
| Appearance of solution (25% in water) | clear                          | clear               | clear               | clear               | clear         | -                  | visual                  |
| Colour number (APHA) (25% in water)   | ≤ 15                           | ≤ 15                | ≤ 15                | ≤ 15                | ≤ 15          | mg Pt/l            | DIN EN 1557             |
| Colour number (BY) (25% in water)     | ≥ 6                            | ≥ 6                 | ≥ 6                 | ≥ 6                 | ≥ 6           | BY                 | Ph. Eur.                |
| Hydroxyl number                       | 70 - 80                        | 34 - 41.5           | 26 - 31             | 17 - 21             | 12.5 - 16     | mg KOH/g           | DIN EN 13296            |
| Average molar mass                    | 1400 - 1600                    | 2700 - 3300         | 3600 - 4400         | 5400 - 6600         | 7000 - 9000   | g/mol              | calc. from OH no        |
| Assay                                 | 90 - 110                       | 90 - 110            | 90 - 110            | 90 - 110            | 87.5 - 112.5  | %                  | USP/NF                  |
| Acid number                           | ≤ 0.2                          | ≤ 0.2               | ≤ 0.2               | ≤ 0.2               | ≤ 0.2         | mg KOH/g           | EN ISO 2114             |
| Freezing point                        | 42 - 48                        | 50 - 56             | 53 - 59             | 55 - 61             | 55 - 62       | °C                 | Ph. Eur.                |
| pH (5 % in demin. water)              | 4.5 - 7.5                      | 4.5 - 7.5           | 4.5 - 7.5           | 4.5 - 7.5           | 4.5 - 7.5     | -                  | USP/NF                  |
| Water                                 | ≤ 1.0                          | ≤ 1.0               | ≤ 1.0               | ≤ 1.0               | ≤ 1.0         | % by mass          | Ph. Eur.                |
| dyn. Viscosity at 20°C (50% in water) | 34 - 50                        | 75 - 100            | 110 - 170           | 200 - 270           | 260 - 510     | mPa s              | Ph. Eur.                |
| kinem. Viscosity at 98.9°C            | 26 - 33                        | 67 - 93             | 110 - 158           | 250 - 390           | 470 - 900     | mm <sup>2</sup> /s | USP/NF                  |
| Heavy metals as Pb                    | ≤ 5                            | ≤ 5                 | ≤ 5                 | ≤ 5                 | ≤ 5           | mg/kg              | USP/NF                  |
| Ethylene and Diethylene glycol        | ≤ 1000 <sup>4</sup>            | ≤ 1000 <sup>4</sup> | ≤ 1000 <sup>4</sup> | ≤ 1000 <sup>4</sup> | -             | mg/kg              | AB 039 010 <sup>3</sup> |
| Ethylene glycol                       | ≤ 620                          | ≤ 620               | ≤ 620               | ≤ 620               | -             | mg/kg              | AB 039 010 <sup>3</sup> |
| Acid/alkaline react. substances       | ≤ 0.1                          | ≤ 0.1               | ≤ 0.1               | ≤ 0.1               | ≤ 0.1         | ml 0.1 M NaOH      | Ph. Eur.                |
| Red. substances                       | ≥ 3                            | ≥ 3                 | ≥ 3                 | ≥ 3                 | ≥ 3           | R                  | Ph. Eur.                |
| Formaldehyde                          | ≤ 15                           | ≤ 15                | ≤ 15                | ≤ 15                | ≤ 15          | mg/kg              | Ph. Eur.                |
| Sulphate ash                          | ≤ 0.1                          | ≤ 0.1               | ≤ 0.1               | ≤ 0.1               | ≤ 0.1         | % by mass          | USP/NF                  |
| 1,4-Dioxane                           | ≤ 1                            | ≤ 1                 | ≤ 1                 | ≤ 1                 | ≤ 1           | mg/kg              | Ph. Eur.                |
| Ethylene oxide                        | ≤ 1                            | ≤ 1                 | ≤ 1                 | ≤ 1                 | ≤ 1           | mg/kg              | Ph. Eur.                |
| Identification A, B, C                | complies with the requirements |                     |                     |                     |               |                    | Ph. Eur.                |

<sup>3</sup> internal method

<sup>4</sup> acc. to the requirements of regulation No. (EC) 1223/2009 (Annex III)

| LIPOXOL (General product description)  | 1500 MED   | 3000 MED   | 4000 MED   | 6000 MED   | 8000 MED   | Unit              | Method |
|--|------------|------------|------------|------------|------------|-------------------|--------|
| Bulk density (flakes)                  | appr. 0.5  | appr. 0.5  | appr. 0.5  | appr. 0.5  | appr. 0.5  | g/cm <sup>3</sup> | --     |
| Bulk density (powder)                  | appr. 0.6  | appr. 0.6  | appr. 0.6  | appr. 0.6  | appr. 0.6  | g/cm <sup>3</sup> | --     |
| Density at 20°C (50 % in water)        | appr. 1.08 | appr. 1.08 | appr. 1.08 | appr. 1.08 | appr. 1.08 | g/cm <sup>3</sup> | --     |
| Solubility in water (at 20°C)          | appr. 630  | appr. 560  | appr. 500  | appr. 500  | appr. 500  | g/l               | --     |
| Surface tension at 20°C (50% in water) | 54 - 57    | 53 - 57    | 54 - 57    | 54 - 57    | 53 - 57    | mN/m              | --     |
| Flash point                            | appr. 260  | appr. 250  | appr. 250  | appr. 250  | appr. 250  | °C                | --     |
| Ignition temperature                   | appr. 420  | appr. 420  | appr. 420  | appr. 420  | appr. 420  | °C                | --     |

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# LIPOXOL MED

| LIPOXOL (specification)                  | 3350 MED                       | Unit          | Method                  |
|--|--------------------------------|---------------|-------------------------|
| Appearance at 20°C                       | flakes/powder                  | -             | visual                  |
| Appearance of solution (25% in water)    | clear                          | -             | visual                  |
| Colour number (APHA) (25 % in water)     | ≤ 15                           | mg Pt/l       | DIN EN 1557             |
| Colour number (BY) (25 % in water)       | ≥ 6                            | BY            | Ph. Eur.                |
| Hydroxyl number                          | 31 - 37                        | mg KOH/g      | DIN EN 13296            |
| Apparent weight-average molecular weight | 3015 - 3685                    | g/mol         | USP                     |
| Assay                                    | 97.0 - 103.0                   | % by mass     | USP                     |
| Polydispersity                           | 1.0 - 1.2                      | -             | USP                     |
| Freezing point                           | 53 - 57                        | °C            | Ph. Eur.                |
| pH (5 % in demin. water)                 | 4.5 - 7.5                      | -             | USP/NF                  |
| Water                                    | ≤ 1.0                          | % by mass     | Ph. Eur.                |
| dyn. Viscosity at 20°C (50% in water)    | 83 - 120                       | mPa s         | Ph. Eur.                |
| Heavy metals as Pb                       | ≤ 5                            | mg/kg         | USP                     |
| Ethylene glycol                          | ≤ 620                          | mg/kg         | AB 039 010 <sup>3</sup> |
| Ethylene and Diethylene glycol           | ≤ 1000                         | mg/kg         | AB 039 010 <sup>3</sup> |
| Acid/alkaline react. substances          | ≤ 0.1                          | ml 0.1 M NaOH | Ph. Eur.                |
| Red. substances                          | ≥ 3                            | R             | Ph. Eur.                |
| Formaldehyde                             | ≤ 15                           | mg/kg         | USP                     |
| Sum of formaldehyde and acetaldehyde     | ≤ 200                          | mg/kg         | USP                     |
| Sulphate ash                             | ≤ 0.1                          | % by mass     | USP/NF                  |
| 1,4-Dioxane                              | ≤ 1                            | mg/kg         | Ph. Eur.                |
| Ethylene oxide                           | ≤ 1                            | mg/kg         | Ph. Eur.                |
| Identification Tests                     | complies with the requirements |               | Ph. Eur. / USP          |

<sup>3</sup> internal method

| LIPOXOL General product description      | 3350 MED              | Unit               | Method |
|--|-----------------------|--------------------|--------|
| Bulk density (flakes/powder)             | appr. 0.5 / appr. 0.6 | g/l                | -      |
| Average molecular mass (calc.)           | 3015 - 3620           | g/mol              | -      |
| Acid number                              | ≤ 0.2                 | mg KOH/g           | -      |
| kinem. viscosity 98.9°C                  | 76 - 110              | mm <sup>2</sup> /s | -      |
| Density at 20°C (50 % in water)          | appr. 1.08            | g/cm <sup>3</sup>  | -      |
| Solubility in water (at 20°C)            | appr. 560             | g/l                | -      |
| Surface tension at 20°C (50 % in water ) | 53 - 57               | mN/m               | -      |
| Flash point                              | appr. 250             | °C                 | -      |
| Ignition temperature                     | appr. 420             | °C                 | -      |

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**LIPOXOL MED**

**General product description**

**Applications**

LIPOXOL MED grades are widely used excipients in a variety of pharmaceutical preparations. The liquid LIPOXOL MED grades are used as solvent, solubilizer and viscosity regulator in liquid pharmaceutical formulations. Mixtures of liquid and solid LIPOXOL MED grades are used as ointment bases. Solid LIPOXOL MED grades are used as suppository bases and act as binders and plasticizers for tablets (Handbook of Pharmaceutical Excipients, 2nd edition, p. 355 ff.). LIPOXOL 3350 MED and LIPOXOL 4000 MED are used as active ingredients in medicinal products, i.e. laxatives.

The liquid LIPOXOL MED grades are readily soluble in water and miscible in all portions with other grades. With increasing molecular weight the solubility in water is slightly lowered. However, even the solubility of LIPOXOL 8000 MED in water is more than 500 g/l. The LIPOXOL MED grades are (according to their molecular weight) soluble in polar organic solvents like alcohols, benzene, glycerine glycol and chloroform. No or slight solubility is given in aliphatic hydrocarbons, ethers and fats. LIPOXOL MED grades can be used to enhance the aqueous solubility or dissolution characteristics of poorly soluble compounds.

Due to their hygroscopicity the LIPOXOL MED grades are used as moisturizers which provide soft and readily dispersible ointment bases causing a liquid flow opposed to the resorption. On skin they show a cleansing and drying effect. Therefore LIPOXOL MED containing ointments can be used to treat wet and inflamed wounds.

Liquid LIPOXOL MED grades are used as water miscible solvents dedicated for dissolution of actives in soft gelatine capsules. Aqueous solutions of LIPOXOL MED grades can be either used as suspending agents or to adjust the viscosity and consistency of pharmaceutical products. When used in combination with emulsifiers LIPOXOL MED grades can act as emulsion stabilizers.

In solid dosage forms LIPOXOL 3350 MED, 4000 MED, 6000 MED and 8000 MED enhance the effectiveness of tablet binders and provide plasticity to granules. There are a number of techniques producing tablets containing LIPOXOL MED grades. When used for thermoplastic granulation a mixture of powdered components with 10-15 % LIPOXOL 6000 MED is heated to 70-75°C resulting in a paste. Whilst cooling and stirring granules are formed. Solid LIPOXOL MED grades can be used for film coating of tablets or as polishing or softener materials for film tablets.

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**LIPOXOL MED**

**Statements and Confirmations**

**Aflatoxine**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any aflatoxine.

**Alkaloids**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any alkaloids.

**Allergens (Food)**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any food allergens according to Directive No. 2011/1169/EC (appendix II).

**Antibiotics**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any antibiotics.

**Bisphenol A**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any Bisphenol A.

**BSE/TSE**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any BSE/TSE contamination.

**California Prop. 65 list**

LIPOXOL MED grades contains the following chemicals found on the California Proposition 65 list of chemicals published by the Governor of California:

- 1,4-Dioxane (max. 1 mg/kg)
- Ethylene oxide (max. 1 mg/kg)
- Formaldehyde (max. 30 mg/kg)
- Ethylene glycol (max. 620 mg/kg)

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# LIPOXOL MED

## Cosmetic

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades fulfils the requirements regarding the annexes of the regulation No. (EC) 1223/2009 with the exception of very small amounts of free Ethylene oxide ( $\leq 1$  ppm), Formaldehyde ( $\leq 30$  ppm) and 1,4-Dioxane ( $\leq 1$  ppm) which are characteristic for this type of product.

With regard to the Diethylene glycol content which is limited to max. 0.1% for the ready to use cosmetic product (Annex III) please consider the Diethylene glycol content of the relevant LIPOXOL MED type (exception for LIPOXOL 300 MED).

## CMR

We hereby confirm that, to the best of our present knowledge, assuming the use of the raw materials and manufacturing process currently employed, LIPOXOL MED does not contain any CMR-substances classified as CMR category 1A, 1B and 2 in accordance with regulation No. (EC) 1272/2008 and its adaptations, with the exception of very small amounts of free Ethylene oxide ( $\leq 1$  ppm), Formaldehyde ( $\leq 30$  ppm) and 1,4-Dioxane ( $\leq 1$  ppm) which are characteristic for this type of product.

## Dioxin

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any Dioxin contamination.

## Elemental Impurities (ICH Q3D)

LIPOXOL MED grades are in line with current version of the guideline ICH Q3D "Guideline for Elemental Impurities". Metal contents which should be identified and quantified according to guidelines are listed and are in full compliance with the requirements for ICH Q3D "Guideline for Elemental Impurities". The routine monitoring is assured.

- Class 1: Metals like Cd, Pb, As, Hg are not intentionally added in the process and are with regard to Oral Concentration below the permitted limits.
- Class 2A: Metals like Co, V, Ni are not intentionally added in the process and are with regard to Oral Concentration below the permitted limits
- Class 2B: Metals are not intentionally added in the process.
- Class 3: Metals are not intentionally added in the process

According to the risk based approach the level on the relevant elemental Impurities can be confirmed as less than 30% of the PDE.

|           | Permitted concentration for oral use | Unit  | 30% of PDE |
|-----------|--------------------------------------|-------|------------|
| <b>Cd</b> | 0.5                                  | mg/kg | max. 0.15  |
| <b>Pb</b> | 0.5                                  | mg/kg | max. 0.15  |
| <b>As</b> | 1.5                                  | mg/kg | max. 0.45  |
| <b>Hg</b> | 3                                    | mg/kg | max. 0.9   |
| <b>Co</b> | 5                                    | mg/kg | max. 1.5   |
| <b>V</b>  | 10                                   | mg/kg | max. 3     |
| <b>Ni</b> | 20                                   | mg/kg | max. 6     |

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# **LIPOXOL MED**

## **Ethanol**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any ethanol.

## **Food additive (E 1521)**

LIPOXOL 400 MED, 3000 MED, 3350 MED, 4000 MED, 6000 MED and 8000 MED are approved for the use as food additives (E 1521) acc. to regulation No. (EC) 231/2012. The confirmation for a specific batch to comply with the limits for lead (Pb: max. 1 mg/kg), ethylene oxide (EO: max. 0.2 mg/kg) and Ethylene glycol/Diethylene glycol (MEG/DEG: max. 0.25% - only for LIPOXOL 8000 MED-) can only be ensured by agreeing on a special specification.

## **Food Contact Status**

Based on the chemical composition LIPOXOL MED grades are in compliance with various regulations and recommendations. For detailed information please refer to the **RIS (Regulatory Information Sheet) document**.

## **GMO**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any genetic modified substances.

## **Halal**

- LIPOXOL MED grades are not produced under muslimic supervision
- Intermediates, starting material and LIPOXOL MED grades are of non-animal origin
- LIPOXOL MED grades are 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

## **Kosher Certificate**

- LIPOXOL MED grades are produced under rabbinical supervision, a Kosher Certificate is available
- Intermediates, starting material and LIPOXOL MED grades are of non-animal origin
- LIPOXOL MED grades are 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

## **Lactose, Latex, Gluten, Yeast, Maize, Wheat, Pork, Starch, Dyes and Nuts**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any Lactose, Latex, Gluten, Yeast, Maize, Wheat, Pork, Starch, Dyes and Nuts.

## **Sasol Germany GmbH**

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 Sitz der Gesellschaft: Hamburg Registergericht: Amtsgericht Hamburg HRB 78475



**Product Information**

**updated: 05/2018**  
replace vers. 07/2017

**LIPOXOL MED**

**Melamine**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any melamine.

**Microbiological purity**

The parameter given in chapter 5.1.4 (Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use) are regularly checked.

The determination of TAMC (total aerobic microbial count) and TYMC (total yeasts and moulds count) is done according to Ph. Eur. 2.6.12. (Microbiological examination of non-sterile products: microbial enumeration tests) and the limits of

TAMC ≤ 1000 cfu/g

TYMC ≤ 100 cfu/g

can be confirmed.

**MOSH / MOAH**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any **MOSH** - Mineral Oil Saturated Hydrocarbons and **MOAH** - Mineral Oil Aromatic Hydrocarbons.

**Nano particles**

While a definition for “nano” has recently been agreed on by the EU, official guidelines and validated analytical methods are not yet available to analyze for nano particles as described within the EU.

Nevertheless, irrespective of the above, we herewith confirm that -to the best of our knowledge- LIPOXOL MED is neither defined as such nor contains nano particles. This evaluation is based on the physical chemical properties of the material.

**Nonylphenol ethoxylates**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any nonylphenol ethoxylates (NPE).

**Nutritional value**

Sugar: free of sugar

Carbohydrate: free of carbohydrates

Nutritional value: 0 joule

**Origin of components**

The raw materials for the production of LIPOXOL MED are of synthetic origin.

The place of manufacturing is Germany.

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**LIPOXOL MED**

**Palm oil, Palm kern oil**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any palm oil or palm kern oil.

**Pesticides, biocides, hormones and residues of drug products**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any pesticides, biocides, hormones or residues of drug products.

**Phthalates (plasticizer)**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any Phthalates (such as DEHP, DINP, DIDP, DNOP, BBP and DBP) contamination.

**Preservatives**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any preservatives, inhibitors, stabilizers or antioxidants.

**Radioactive**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any radioactive contamination and is not irradiated.

**REACH**

Not relevant, LIPOXOL MED grades are polymers.

**Registration Status**

LIPOXOL MED grades have a positive listing in the following inventories:

EINECS (Europe), TSCA (USA), AICS (Australia), DSL (Canada), ENCS and IHSL (Japan), KECI (Korea), PICCS (Philippines), INV (China), CH INV (Switzerland) and NZIOC (New Zealand).

**Retest date**

LIPOXOL MED grades with an average molecular weight of < 1000 g/mol: 2 years starting with the date of production

LIPOXOL MED grades with an average molecular weight of ≥ 1000 g/mol: 3 years starting with the date of production

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## **Product Information**

**updated: 05/2018**  
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# **LIPOXOL MED**

## **Residual solvents**

LIPOXOL MED grades are manufactured without any organic solvent and comply with the requirements on residual solvents from Ph. Eur. (Chapter 5.4) and USP (Chapter 467). Residual Solvents which should be according to guidelines identified and quantified are listed and are in full compliance with the requirements for ICH Q3C "Guideline for Residual Solvents". According to "Impurities Guideline for Residual Solvents" (CPMP/ICH/283/95):

- Class 1: None of class 1 solvents are used.
- Class 2: Only ethylene glycol and 1,4-dioxane are likely to be present. Both are below the option 1 limit.
- Class 3: None of class 3 solvents are used.

## **Stability**

A stability program according to "Stability Testing of Existing Active Substances" (CPMP/QWP/122/02, rev 1 corr.) was successfully executed at long term (25°C/60% r.H) conditions.

Yearly ongoing stability tests are performed.

## **Storage**

The LIPOXOL MED types are stable for 2 (300-600) respectively 3 years (1000-8000) if they are stored in the original sealed and airtight packaging units. The packaging units (containers) should not be exposed to excessive heat and direct sun irradiation.

The ambient temperature for long-term storage should not exceed 25-30°C, storage at higher temperatures for a short time is acceptable but it should be assured that the solidification point is not exceeded.

A direct contact with water/moisture should be avoided.

## **SVHC substances**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any substances from the SVHC list (candidate list).

## **Vegan status**

- Intermediates, starting materials and LIPOXOL MED grades are of non-animal origin
- LIPOXOL MED grades are made by a process in which only auxiliaries of non-animal origin are used
- Processing equipment is only used for products of non-animal origin
- LIPOXOL MED is free of Genetically Modified Material (GMO)
- LIPOXOL MED is free of sugar

## **WADA list**

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades do not contain any substances from the WADA list (world anti-doping association).

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## Product Information

updated: 05/2018  
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# LIPOXOL MED

## Packaging

| Product          | Steel drum<br>(230 kg) | IBC<br>(1000 kg) | PE Sack<br>(25 kg / 1t on pallet) | Big Bag<br>(500 kg) | available as              |
|------------------|------------------------|------------------|-----------------------------------|---------------------|---------------------------|
| LIPOXOL 300 MED  | X                      | X                |                                   |                     | clear liquid              |
| LIPOXOL 400 MED  | X                      | X                |                                   |                     | clear liquid              |
| LIPOXOL 600 MED  | X                      | X                |                                   |                     | liquid - solid (at ~20°C) |
| LIPOXOL 1000 MED | X (220 kg)             |                  |                                   |                     | solid block               |
| LIPOXOL 1500 MED |                        |                  | X                                 |                     | flakes                    |
| LIPOXOL 3000 MED |                        |                  | X                                 |                     | flakes                    |
|                  |                        |                  | X                                 |                     | milled powder             |
| LIPOXOL 3350 MED |                        |                  | X                                 | X                   | flakes                    |
|                  |                        |                  | X                                 |                     | milled powder             |
| LIPOXOL 4000 MED |                        |                  | X                                 | X                   | flakes                    |
|                  |                        |                  | X                                 | X                   | milled powder             |
| LIPOXOL 6000 MED |                        |                  | X                                 | X                   | flakes                    |
|                  |                        |                  | X                                 | X                   | milled powder             |
| LIPOXOL 8000 MED |                        |                  | X                                 |                     | flakes                    |
|                  |                        |                  | X                                 |                     | milled powder             |

Alternative packaging on demand.

## GMP Status

The following products are produced and filled according to Good Manufacturing Practice (GMP) standard relating to Article 47 Directive 2001/83/EC:

- LIPOXOL 300 MED up to 8000 MED in tank cars
- LIPOXOL 1500 MED flakes up to 8000 MED flakes in 25kg PE sacks and Big Bags (different sizes)

## Safety data sheets

Data on toxicity, ecotoxicity as well as transport classes and labelling can be obtained from the material safety data sheets.

*This information is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party patent rights. In particular, no guarantee of properties in the legal sense is implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Reference to trade names used by other companies is neither a recommendation, nor is it intended to suggest that similar products could not be used. All our business transactions shall exclusively be governed by our General Sales Conditions.*

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| <b>COMPANY INFORMATION DISTRIBUTOR</b> |  |  |
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| activities                             | Distribution and export of chemicals and raw materials |  |
| VAT number                             | BE0405317567   | NL001375945B01                           |
| recall procedure available             | Yes  |  |
| emergency number (24/365)              | +32 (0)56 77 69 44                                     | +31 (0)78 6544 944                       |
| <b>QUALITY SYSTEMS</b>                 |  |  |
| ISO 9001                               | Yes  | Yes                                      |
| ISO 14001                              | Yes  | Yes                                      |
| ISO 22000                              | Yes  | Yes                                      |
| FSSC 22000                             | Yes  | Yes                                      |
| GMP+ -feed                             | Yes  | Yes                                      |
| OHSAS18001                             | -  | Yes                                      |
| ESAD                                   | Yes  | Yes                                      |
| other                                  | -  | AEO                                      |