Product Information

updated: 11/2024
replace vers. 12/2022

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. (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, α-Hydro-ω-hydroxypoly-(oxy-1.2-ethynediyl), Polyoxyethylene glycol

CAS-Number: [25322-68-3]

Formula: $HO-(CH_2CH_2O)_n-H$, 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 2000 MED	--	Polyethylene Glycol – 2000	--	PEG - 40
LIPOXOL 3000 MED	Macrogol 3000	Polyethylene Glycol - 3000	--	PEG - 60
LIPOXOL 3350 MED	Macrogol 3350	Polyethylene Glycol - 3350	Macrogol 4000 [1]	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 [1]	PEG - 180

[1] 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".**

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

Product Information

updated: 11/2024
replace vers. 12/2022

LIPOXOL MED

LIPOXOL (specification)	**300 MED**	**400 MED**	**600 MED**	**1000 MED**	**1500 MED**	**Unit**	**Method**
Appearance at 20°C	liquid, clear	liquid, clear	liquid, solid	solid	flakes	-	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	356 - 394	267 - 295	178 - 197	107 - 118	70 - 80	mg KOH/g	DIN EN 13926
Average molar mass	285 - 315	380 - 420	570 - 630	950 - 1050	1400 - 1600	g/mol	calc. from OH no
Assay	95.0 – 105.0	95.0 – 105.0	95.0 – 105.0	95.0 – 105.0	90.0 – 110.0	%	USP/NF
Acid number	≤ 0.2	≤ 0.2	≤ 0.2	≤ 0.2	≤ 0.2	mg KOH/g	EN ISO 2114
Freezing point	-	-	15 - 25	35 - 40	42 - 48	°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	80 - 105	105 - 130	15 - 20 [2]	22 - 30 [2]	34 – 50	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	26 - 33	mm^2/s	USP/NF
Heavy metals as Pb	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5	mg/kg	USP (231)
Ethylene and Diethylene glycol	≤ 2500	≤ 1000 [4]	≤ 1000 [4]	≤ 1000 [4]	≤ 1000 [4]	mg/kg	AB 039 010 [3]
Ethylene glycol	≤ 620	≤ 620	≤ 620	≤ 620	≤ 620	mg/kg	AB 039 010 [3]
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	≤ 30	≤ 30	≤ 30	≤ 30	≤ 15	mg/kg	Ph. Eur.
Sulphated 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	USP
Ethylene oxide	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	mg/kg	USP
Identification A, B, C	complies with the requirements						Ph. Eur.

2 50 % in water
3 Internal method
4 limit acc. to regulation No. (EC) 1223/2009 (Annex III: DEG ≤ 1000 mg/kg) can be ensured (details please refer to page 7 “cosmetic”)

LIPOXOL **General product description**	**300 MED**	**400 MED**	**600 MED**	**1000 MED**	**1500 MED**	**Unit**	**Method**
Density at 20°C	appr. 1.12	appr. 1.12	appr. 1.08 [2]	appr. 1.08 [2]	appr. 1.08	g/cm^3	--
Solubility in water (at 20°C)	unlimited	unlimited	unlimited	appr. 750	appr. 630	g/l	--
Surface tension (at 20°C)	48	48	54 - 57 [2]	54 - 57 [2]	54 - 57 [2]	mN/m	--
Freezing point	-20 - -10	4 – 8	-	-		°C	--
Flash point	appr. 220	appr. 240	appr. 270	appr. 260	appr. 260	°C	--
Ignition temperature	appr. 370	appr. 370	appr. 380	appr. 420	appr. 420	°C	--

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

Product Information

updated: 11/2024
replace vers. 12/2022

LIPOXOL MED

LIPOXOL (specification)	2000 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	51 - 62	34 – 42	26 - 31	17 - 21	12 – 16	mg KOH/g	DIN EN 13926
Average molar mass	1800 - 2200	2700 - 3300	3600 - 4400	5400 - 6600	7000 - 9000	g/mol	calc. from OH no
Assay	90.0 – 110.0	90.0 – 110.0	90.0 – 110.0	90.0 – 110.0	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	47 - 52	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)	47 – 60	75 – 100	110 – 170	200 – 270	260 – 510	mPa s	Ph. Eur.
kinem. Viscosity at 98.9°C	38 - 49	67 – 93	110 – 158	250 – 390	470 – 900	mm^2/s	USP/NF
Heavy metals as Pb	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5	mg/kg	USP (231)
Ethylene and Diethylene glycol (not required for LIPOXOL > 1000 g/mol)	- [4]	- [4]	- [4]	- [4]	- [4]	-	-
Ethylene glycol (part of ICH Q3C residual solvent)	- [5]	- [5]	- [5]	- [5]	- [5]	-	-
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.
Sulphated 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	USP
Ethylene oxide	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	≤ 1.0	mg/kg	USP
Identification A, B, C	complies with the requirements						Ph. Eur.
Identification A	complies with the requirements						USP

[4] limit acc. to regulation No. (EC) 1223/2009 (Annex III: DEG ≤ 1000 mg/kg) can be ensured (details please refer to page 7/8 “cosmetic”)
[5] limit acc. to ICH Q3C (MEG ≤ 620 mg/kg) can be ensured (details please refer to page 12 “residual solvents”)

LIPOXOL (General product description)	2000 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^3	--
Bulk density (powder)	appr. 0.6	appr. 0.6	appr. 0.6	appr. 0.6	appr. 0.6	g/cm^3	--
Density at 20°C (50 % in water)	appr. 1.08	appr. 1.08	appr. 1.08	appr. 1.08	appr. 1.08	g/cm^3	--
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	--

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

Product Information

updated: 11/2024
replace vers. 12/2022

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
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 (231)
Ethylene glycol	≤ 620	mg/kg	AB 039 010 [3]
Ethylene and Diethylene glycol	≤ 1000	mg/kg	AB 039 010 [3]
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
Sulphated ash	≤ 0.1	% by mass	USP
1,4-Dioxane	≤ 1	mg/kg	USP.
Ethylene oxide	≤ 1.0	mg/kg	USP.
Identification A, B, C	complies with the requirements		Ph. Eur.
Identification A, B	complies with the requirements		USP

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^2/s	-
Density at 20°C (50 % in water)	appr. 1.08	g/cm^3	-
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	

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

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.

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 Regulation (EU) No. 2011/1169 (Annex 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

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades contain the following chemicals found on the California Proposition 65 list of chemicals published by the Governor of California:

Substance	CAS No.	Content	remarks
1,4-Dioxane	123-91-1	Please refer to limits given in specification	-
Ethylene oxide	75-21-8	Please refer to limits given in specification	-
Ethylene glycol	107-21-1	max. 620 mg/kg	-

LIPOXOL MED

Substance	CAS No.	Content	remarks
Formaldehyde	50-00-0	Please refer to limits given in specification	determined according to Ph. Eur.
Acetaldehyde	75-07-0	≤ 20 ppm	determined as free acetaldehyde by HS -GC method without considering acetals or semi-acetals

Cosmetic

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

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL MED grades fulfil the requirements regarding the annexes of the regulation No. (EC) 1223/2009 with the exception of very small amounts of the following substances:

Substance	CAS No.	Content	remarks
1,4-Dioxane	123-91-1	Please refer to limits given in specification	-
Ethylene oxide	75-21-8	Please refer to limits given in specification	-
Formaldehyde	50-00-0	Please refer to limits given in specification	determined according to Ph. Eur.
Acetaldehyde	75-07-0	≤ 20 ppm	determined as free acetaldehyde by HS -GC method without considering acetals or semi-acetals

which are characteristic for this type of product. The presence of the above listed substances is technically unavoidable and thus in compliance with Article 17 of Regulation (EC) No. 1223/2009.

With regard to the Diethylene glycol (CAS 111-46-6) 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).

Chinese Cosmetics Supervision and Administration Regulation (CSAR)

Sasol has submitted all relevant information for this product to the Chinese NMPA Cosmetic Ingredient Safety Submission Platform. Please find below the China Cosmetic Ingredient Safety Information submission code

Product name	IECIC name	Submission Code
LIPOXOL 300 MED	聚乙二醇-6 (PEG-6)	004027-03592-7001
LIPOXOL 400 MED	聚乙二醇-8 (PEG-8)	004033-03592-4531
LIPOXOL 600 MED	聚乙二醇-12 (PEG-12)	004003-03592-5933
LIPOXOL 1000 MED	聚乙二醇-20 (PEG-20)	004010-03592-2336
LIPOXOL 1500 MED	聚乙二醇-32 (PEG-32)	004017-03592-9271
LIPOXOL 3000 MED	聚乙二醇-60 (PEG-60)	004028-03592-6246

LIPOXOL MED

Product name	IECIC name	Submission Code
LIPOXOL 3350 MED Flakes	聚乙二醇-75 (PEG-75)	004031-03592-1595
LIPOXOL 3350 MED Powder	聚乙二醇-75 (PEG-75)	004031-03592-9057
LIPOXOL 4000 MED Flakes	聚乙二醇-90 (PEG-90)	004037-03592-6295
LIPOXOL 4000 MED Powder	聚乙二醇-90 (PEG-90)	004037-03592-9979
LIPOXOL 6000 MED Flakes	聚乙二醇-150 (PEG-150)	004006-03592-9783
LIPOXOL 6000 MED Powder	聚乙二醇-150 (PEG-150)	004006-03592-9934
LIPOXOL 8000 MED	聚乙二醇-180 (PEG-180)	004009-03592-4757
LIPOXOL 8000 MED Powder	聚乙二醇-180 (PEG-180)	004009-03592-7100

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 an 2 in accordance with regulation No. (EC) 1272/2008 and its adaptations, with the exception of very small amounts of the following substances which are characteristic for this type of products:

Substance	CAS No.	Content	remarks
1,4-Dioxane	123-91-1	Please refer to limits given in specification	-
Ethylene oxide	75-21-8	Please refer to limits given in specification	-
Formaldehyde	50-00-0	Please refer to limits given in specification	determined according to Ph. Eur.
Acetaldehyde	75-07-0	≤ 20 ppm	determined as free acetaldehyde by HS -GC method without considering acetals or semi-acetals

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.

LIPOXOL MED

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	Results are below Limit of detection (LOD)
Cd	0.5	mg/kg	max. 0.15	<0.05 (0.05)
Pb	0.5	mg/kg	max. 0.15	<0.05 (0.05)
As	1.5	mg/kg	max. 0.45	<0.1 (0.1)
Hg	3	mg/kg	max. 0.9	<0.1 (0.1)
Co	5	mg/kg	max. 1.5	<0.1 (0.1)
V	10	mg/kg	max. 3	<1 (1)
Ni	20	mg/kg	max. 6	<0.1 (0.1)

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 additional limits for lead (Pb: max. 1 mg/kg), ethylene oxide (EO: max. 0.1 mg/kg) and Ethylene glycol/Diethylene glycol (MEG/DEG: max. 0.25%) can only be ensured by agreeing on a special agreement on 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** (**R**egulatory **I**nformation **S**heet) **document**.

Genotoxic ICH M7

It can be concluded that the available data is sufficient for classifying LIPOXOL MED grades and all of its known and possible impurities and degradation products into one of the classes (1, 2 or 5) according to ICH M7(R2) guideline.

Furthermore, it can be concluded that based on these data and in accordance with Section 6 of ICH M7(R2) SAR predictions are necessary.

LIPOXOL MED

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.

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.

Microplastics

For detailed information please refer to the **RIS** (**R**egulatory **I**nformation **S**heet) **document**:

LIPOXOL MED

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.

Nitrosamine (EMA/189634/2019)

A specific confirmation (required by EMA) based on IPEC Risk Questionnaire is available and will be provided on demand.

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.

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.

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

LIPOXOL MED

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. 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).

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

Registration Status

LIPOXOL MED grades have a positive listing in inventories of different countries, for detailed information please refer to the **RIS** (**R**egulatory **I**nformation **S**heet) **document.**

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.

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.

LIPOXOL MED

Stability

A stability program according to “Stability of new drug substances and products” ICH Q 1 A (R2) was successfully executed. Yearly ongoing stability tests acc. EG GMP Guideline Part II are performed. A specific report is available on demand.

Storage / Transport

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 > 0,1% of 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 current WADA list (world anti-doping association).

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

LIPOXOL MED

Packaging

Product	Steel drum (230 kg)	IBC (1000 kg)	PE bag a. (25 kg / 1t on pallet) b. (25 kg / 500 kg in carton box)	Big Bag (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			a		flakes
LIPOXOL 2000 MED			a		flakes
LIPOXOL 3000 MED			a		flakes
			b		milled powder
LIPOXOL 3350 MED			a	X	flakes
			b		milled powder
LIPOXOL 4000 MED			a	X	flakes
			b	X	milled powder
LIPOXOL 6000 MED			a	X	flakes
			b	X	milled powder
LIPOXOL 8000 MED			a		flakes
			b		milled powder

Alternative packaging on demand.

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
Telephone: +49 40 63 684-1000 Telefax: +49 40 63 684-3700 info@de.sasol.com www.sasol.com
Managing Director: Dr.-Ing Thomas Tebroke Chairman des Supervisory Board Christian Schindler
Registered Office: Hamburg Register Court: Amtsgericht Hamburg HRB 78475

LIPOXOL MED

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.