Product Information

updated: 11/2024
replace vers. 12/2022

LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

Polyethylene glycols for the pharmaceutical industry

LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP satisfy the current requirements of the Pharmacopoeias from Europe, Japan and USA and are produced and filled according to **Good Manufacturing Practices (GMP)** standard relating to Article 47 Directive 2001/83/EC.

CEP for both types is available: R1-CEP 2009-392-Rev 01, issued 6th July 2022

Product description

Chemical name:	Polyethylene glycol
Description:	LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are solid polymers soluble in water. They are produced by the addition of ethylene oxide to ethylene glycol with **sodium hydroxide** as catalyst.
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 average molecular weight is given in the product name.

Product name	Ph. Eur. Monograph	USP/NF Monograph	Jap. Ph. Monograph	INCI-Name
LIPOXOL 3350 MED SP	Macrogol 3350	Polyethylene Glycol - 3350	Macrogol 4000 [1]	PEG - 75
LIPOXOL 4000 MED SP	Macrogol 4000	Polyethylene Glycol - 4000		PEG - 90

[1] Different denomination according to the Jap. Pharmacopeia

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

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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

LIPOXOL (specification)	3350 MED SP	Unit	Method
Appearance at 20°C	powder	-	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 13926
Apparent weight-average molecular mass	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 (231)
Ethylene and Diethylene glycol	≤ 1000 [1]	mg/kg	AB 039 010 [2]
Ethylene glycol	≤ 620	mg/kg	AB 039 010 [2]
Acid/alkaline react. substances	≤ 0.1	ml 0,1 n 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/NF
1,4-Dioxane	≤ 1	mg/kg	USP
Ethylene oxide	≤ 1.0	mg/kg	USP
Potassium	≤ 5	mg/kg	Ph. Eur. 2.4.12 mod.
Bulk density	≥ 550	g/l	Ph. Eur. 2.9.34
Identification A, B, C	complies with the requirements		Ph. Eur.
Identification A, B	complies with the requirements		USP
Particle size [µm]			
< 90	≤ 10	%	DIN EN ISO 4610
90 – 150	10 - 25	%	
150 – 355	50 - 80	%	
355 - 500	≤ 20	%	
500 – 800	≤ 5	%	
> 800	≤ 1	%	

1 limit acc. to regulation No. (EC) 1223/2009 (Annex III: DEG ≤ 1000 mg/kg) (details please refer to page 7 “cosmetic”)
2 internal method

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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

LIPOXOL (specification)	**4000 MED SP**	**Unit**	**Method**
Appearance at 20°C	powder	-	visual
Appearance of solution (10% in water)	clear	-	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	26 - 31	mg KOH/g	DIN EN 13926
Average molar mass	3600 - 4400	g/mol	calc. from OH no.
Assay	90.0 – 110.0	%	USP/NF
Acid number	≤ 0.2	mg KOH/g	EN ISO 2114
Freezing point	53 - 59	°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)	110 - 170	mPa s	Ph. Eur.
kinem. Viscosity at 98.9°C	110 - 158	mm^2/s	USP/NF
Heavy metals as Pb	≤ 5	mg/kg	USP (231)
Ethylene and Diethylene glycol (not required for LIPOXOL > 1000 g/mol)	- [1]	-	-
Ethylene glycol (part of ICH Q3C residual solvent)	- [3]	-	-
Acid/alkaline react. substances	≤ 0.1	ml 0,1 n NaOH	Ph. Eur.
Red. substances	≥ 3	R	Ph. Eur.
Formaldehyde	≤ 15	mg/kg	Ph. Eur.
Sulphated ash	≤ 0.1	% by mass	USP/NF
Dioxane	≤ 1	mg/kg	USP
Ethylene oxide	≤ 1.0	mg/kg	USP
Potassium	≤ 5	mg/kg	Ph. Eur. 2.4.12 mod.
Bulk density	≥ 520	g/l	Ph. Eur. 2.9.34
Identification A, B, C	complies with the requirements		Ph. Eur.
Particle size [µm]			
< 90	≤ 10	%	DIN EN ISO 4610
90 – 150	10 - 25	%	
150 – 355	50 - 80	%	
355 - 500	≤ 20	%	
500 – 800	≤ 5	%	
> 800	≤ 1	%	

1 limit acc. to regulation No. (EC) 1223/2009 (Annex III: DEG ≤ 1000 mg/kg) can be ensured (details please refer to page 7 “cosmetic”)

3 limit acc. to ICH Q3C (MEG ≤ 620 mg/kg) can be ensured (details please refer to page 12 “residual solvents”)

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Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

LIPOXOL General product description	**3350 MED SP**	**4000 MED SP**	**Unit**	**Method**
Average molecular mass (calc. from Hydroxyl number)	3015 - 3620	3600 - 4400	g/mol	-
Acid number	≤ 0.2	< 0.2	mg KOH/g	-
kinem. viscosity 98.9°C	76 - 110	110 - 158	mm^2/s	-
Density at 20°C (50 % in water)	ca. 1.08	ca. 1.08	g/cm^3	-
Solubility in water (at 20°C)	ca. 560	ca. 500	g/l	-
Surface tension at 20°C (50 % in water)	53 - 57	54 - 57	mN/m	-
Flash point	ca. 250	ca. 250	°C	-
Ignition temperature	ca. 420	ca. 420	°C	

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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

General product description

Applications

- LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are mainly used as active ingredients in medicinal products, i.e. laxatives.
- Indications: chronic constipation, evacuation of the bowel before colonoscopy.
- Laxatives containing PEG's as API's are offered as powders.
- Laxative powders are dissolved in water before being used.
- Part of the water in the laxative solution is bounded by the PEG (hygroscopic!) resulting in a "sponge".
- Application: oral
- PEG is not taken in by the digestive tract and the "sponge" enters the colon resulting in a discharging reflex by increasing the volume.
- PEG's are not metabolised in the human body

Typical composition (of a laxative based on PEG is)

- LIPOXOL 3350 MED SP or LIPOXOL 4000 MED SP: 85-99 %
- Electrolytes (e.g. NaCl, Na_2SO_4, $NaHCO_3$ and/or KCl): 0-15 %
- Flavours: none - traces
- Dyes: none - traces
- Sweeteners: none - traces

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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

Statements and Confirmations

Aflatoxine

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain any aflatoxine.

Alkaloids

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain any alkaloids.

Allergens (Food)

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP do not contain any antibiotics.

Bisphenol A

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain any Bisphenol A.

BSE/TSE

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP 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	-

LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

Substance	CAS No.	Content	remarks
Ethylene glycol	107-21-1	max. 620 mg/kg	-
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 LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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.

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 3350 MED SP and LIPOXOL 4000 MED SP 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.

Sasol Germany GmbH
Anckelmannsplatz 1, 20537 Hamburg Postal address PO Box 26 18 05, 20508 Hamburg
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Substance	CAS No.	Content	remarks
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 3350 MED SP and LIPOXOL 4000 MED SP do not contain any Dioxin contamination.

Elemental Impurities (ICH Q3D)

LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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	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 3350 MED SP and LIPOXOL 4000 MED SP do not contain any ethanol.

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Food additive (E 1521)

LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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. 0.1 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 3350 MED SP and LIPOXOL 4000 MED SP 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.

GMO

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain any genetic modified substances.

Halal

- LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are not produced under muslimic supervision
- Intermediates, starting material and LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are of non-animal origin
- LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP are produced under rabbinical supervision, a Kosher Certificate is available
- Intermediates, starting material and LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are of non-animal origin
- LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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

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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

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 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP 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**:

MOSH / MOAH

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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.

Sasol Germany GmbH
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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

Nonylphenol ethoxylates

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP do not contain any preservatives, inhibitors, stabilizers or antioxidants.

Radioactive

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain any radioactive contamination and is not irradiated.

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LIPOXOL 3350 MED SP / LIPOXOL 4000 MED SP

REACH

Not relevant, LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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.

Registration Status

LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP: 3 years starting with the date of production

Residual solvents

LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 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

LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are stable 3 years 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.

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SVHC substances

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain substances from the SVHC list (candidate list).

Vegan status

- Intermediates, starting materials and LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are of non-animal origin
- LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP 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 3350 MED SP and LIPOXOL 4000 MED SP are free of Genetically Modified Material (GMO)
- LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP are free of sugar

WADA list

Assuming the use of the raw materials and manufacturing process currently employed the LIPOXOL 3350 MED SP and LIPOXOL 4000 MED SP do not contain any substances from the WADA list (world anti-doping association).

Packaging

Product	PE Sack (25 kg / 500kg in carton box)	Big Bag (700 kg)
LIPOXOL 3350 MED SP	X	x
LIPOXOL 4000 MED SP	X	X

Alternative packaging on demand

Safety data sheets

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

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