MICROLEX®
molecules

MICROLEX®

m o l e c u l e s

2013.2014

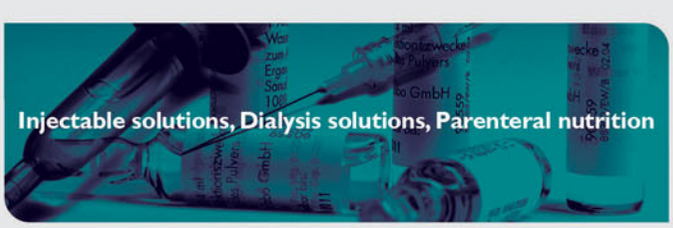
MICROLEX® molecules

www.microlex.at

Application areas

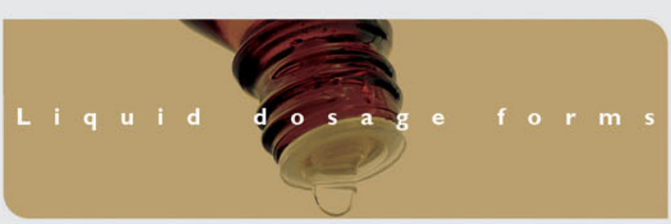
Solid dosage forms

Compared with wet granulation, direct compression requires less industrial equipment and allows productivity to be improved with good flowability, excellent compressibility and a specific particle size distribution to ensure uniform mixing.



Injectable solutions, Dialysis solutions, Parenteral nutrition

Pyrogen-free nutrients and osmotic agents guaranteed critical preparations of Injectable and dialysis solutions requiring high purity and reliable raw materials.



Liquid dosage forms

High quality polyols and ethoxylated Sorbitan esters suitable for production of Syrups, Solutions, Liquid ampoules, Dispersions, Semi-solids, and Softgels

Microlex® at a Glance

Microlex® is specialized in developing and manufacturing products for the Pharmaceutical industry. An experienced team provides its customers with rapid and goal-oriented solutions to their product ideas, thereby shortening time to market. The technical capability and Know How help to provide its customers with solutions tailored to their individual requests and product innovations.

Our innovative active pharmaceutical ingredients, and excipients are manufactured with the same high standards as for pharmaceutical products and comply with current Good Manufacturing Practices (cGMP), which help the group continuously expands its range of new products to meet customer needs and guaranty the safety of our materials and their compliance with the quality requirements defined by international pharmacopoeias (BP, EP, JP, USP, NF).

Microlex® with a wide range of services as:

.Micronization
.Micro-encapsulation
.Spray Drying
.Granulation
.Freeze Drying
.Emulsifying

and via its quality control system in collaboration with european science Institute, organized a periodically GMP audit of our sources and process a complete Qualification according to FDA General Formulation assistance for Micronization and provide our customers worldwide with a full service of Documentation for Pharmaceutical API and Excipients as:

-Toxicology study
-Classification process
-Indication study
-Mechanism of action
-Side effects studies
-Stability report
-Residue studies
-Certifying results
-DMF in CTD format
-Sales History
-Free sales certificate

Microlex® General List

Product Name	Chemical Description(Synonyms)	Physical Form	Application			Monograph				Certification				
			Topical	Oral	Parenteral	Ph.Eur	USP/NF	JP/JPE	FDA IIG	GMP	CEP	Halal	Kosher	FSC
Microlex® MS-101	MAGNESIUM STEARATE	Milled/Sieved		*		*	*						*	*
Microlex® MS-102	MAGNESIUM STEARATE	Milled/Sieved		*		*	*						*	*
Microlex® MS-103	MAGNESIUM STEARATE	Milled/Sieved		*		*	*						*	*
Microlex® MS-104	MAGNESIUM STEARATE	Milled/Sieved		*		*	*						*	*
Microlex® MS-105	MAGNESIUM STEARATE	Micronized		*		*	*			*			*	*
Microlex® SA-121	CALCIUM STEARATE	Milled/Sieved	*	*		*	*	*				*		*
Microlex® SA-122	CALCIUM STEARATE	Micronized	*	*		*	*	*		*		*		*
Microlex® CS-141	STEARIC ACID	Milled/Sieved	*	*		*	*	*				*	*	*
Microlex® CS-142	STEARIC ACID	Micronized	*	*		*	*	*		*		*	*	*
Microlex® CMC L	Carboxymethyl Cellulose low Viscosity	Milled/Sieved		*			*	*		*			*	*
Microlex® CMC M	Carboxymethyl Cellulose medium Viscosity	Milled/Sieved		*			*	*		*			*	*
Microlex® CMC H	Carboxymethyl Cellulose high Viscosity	Milled/Sieved		*			*	*		*			*	*
Microlex® MCC 101	Microcrystalline Cellulose	Milled/Sieved		*			*	*		*			*	*
Microlex® MCC 102	Microcrystalline Cellulose	Milled/Sieved		*			*	*		*			*	*
Microlex® MLP 520 25.µ	MANNITOL	Milled/Sieved	*	*		*	*			*		*		*
Microlex® MLP 520 50.µ	MANNITOL	Milled/Sieved	*	*		*	*			*		*		*
Microlex® MLP 520 180.µ	MANNITOL	Milled/Sieved	*	*		*	*			*		*		*
Microlex® LCM 80.m	LACTOSE MONOHYDRATE	Milled/Sieved		*			*	*		*			*	*
Microlex® LCM 180.m	LACTOSE MONOHYDRATE	Milled/Sieved		*			*	*		*			*	*
Microlex® LCM 200.m	LACTOSE MONOHYDRATE	Milled/Sieved		*			*	*		*			*	*
Microlex® LCM 120.s	LACTOSE MONOHYDRATE	Milled/Sieved		*			*	*		*			*	*
Microlex® LCM 180 .s	LACTOSE MONOHYDRATE	Milled/Sieved		*			*	*		*			*	*
Microlex® LCM 220.s	LACTOSE MONOHYDRATE	Milled/Sieved		*			*	*		*			*	*
Microlex® LCA 60.m	LACTOSE ANHYDROUS	Milled/Sieved		*			*	*		*			*	*
Microlex® LCA 120.m	LACTOSE ANHYDROUS	Milled/Sieved		*			*	*		*			*	*
Microlex® LCA 200.m	LACTOSE ANHYDROUS	Micronized		*			*	*		*			*	*
Microlex® HML C2910	HYPROMELLOSE	Milled/Sieved		*		*	*	*		*		*		*
Microlex® HML C2906	HYPROMELLOSE	Milled/Sieved		*		*	*	*		*		*		*
Microlex® HML C2208	HYPROMELLOSE	Milled/Sieved		*		*	*	*		*		*		*
Microlex® HML P200	HYPROMELLOSE-PHTHALAT	Milled/Sieved		*		*	*	*		*		*		*
Microlex® HML P220	HYPROMELLOSE-PHTHALAT	Milled/Sieved		*		*	*	*		*		*		*

			Application			Monograph				Certification				
Product Name	**Chemical Description(Synonyms)**	**Physical Form**	Topical	Oral	Parenteral	Ph.Eur	USP/NF	JP/JPE	FDA IIG	GMP	CEP	Halal	Kosher	FSC
Microlex® PVD K30	POVIDONE PVP	Milled/Sieved		*			*	*		*		*	*	*
Microlex® PVD K90	POVIDONE PVP	Milled/Sieved		*			*	*		*		*	*	*
Microlex® C.PVD S600	COPOVIDONE	Milled/Sieved		*			*	*		*		*	*	*
Microlex® Cr.PVD CL-110	CROSPOVIDONE	Milled/Sieved		*			*	*		*		*	*	*
Microlex® Cr.PVD CL-25	CROSPOVIDONE	Milled/Sieved		*			*	*		*		*	*	*
Microlex® Cr.PVD UCL-25	CROSPOVIDONE	Milled/Sieved		*			*	*		*		*	*	*
Microlex® Cr.PVD UCL-110	CROSPOVIDONE	Milled/Sieved		*			*	*		*		*	*	*
Microlex® SE 20	Sorbitan Laurate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 40	Sorbitan Palmitate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 60	Sorbitan Stearate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 65	Sorbitan Tristearate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 70	Sorbitan Isostearate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 80	Sorbitan Oleate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 83	Sorbitan Sesquioleate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® SE 85	Sorbitan Trioleate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® PSE 20	Polyoxyethylene sorbitan monolaurate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® PSE 40	Polyoxyethylene sorbitan monopalmitate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® PSE 60	Polyoxyethylene sorbitan monostearate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® PSE 80	Polyoxyethylene sorbitan monooleate	Stabilized Liquid	*	*		*	*		*			*		*
Microlex® HF W35P	Hard fat - Glycerides, C12-C18	Stabilized Hard-fat	*	*		*	*		*			*		*
Microlex® HF W35	Hard fat - Glycerides, C12-C18	Stabilized Hard-fat	*	*		*	*		*			*		*
Microlex® HF H15P	Hard fat - Glycerides, C12-C18	Stabilized Hard-fat	*	*		*	*		*			*		*
Microlex® HF H15	Hard fat - Glycerides, C12-C18	Stabilized Hard-fat	*	*		*	*		*			*		*
Microlex® ML-Inj 500	MANNITOL INJECTABLE	Micronized			*	*	*	*	*	*	*	*	*	*
Microlex® DX-Inj 500	DEXTROSE INJECTABLE	Micronized			*	*	*	*	*	*	*	*	*	*
Microlex® PCL-Inj 500	POTASSIUM CHLORIDE INJECTABLE	Micronized			*	*	*	*	*	*	*	*	*	*
Microlex® CAL-Inj 500	CALCIUM CHLORIDE INJECTABLE	Micronized			*	*	*	*	*	*	*	*	*	*
Microlex® MGS-Inj 500	MAGNESIUM SULFATE INJECTABLE	Micronized			*	*	*	*	*	*	*	*	*	*

Solid dosage forms

Microlex® expertise turns nature to advantage in a multitude of pharmaceutical applications.
Simplifies direct-compression processes and reduces production costs for a wide range of oral dosage forms using the range of Microlex® pharmaceutical performance excipients. Our products are focused on performance that can give you a competitive edge. We offer process intermediates, buffers, nutrients and inorganic excipients to maximize efficiency and productivity, plus high-functioning co-processed excipients for formulation flexibility that increases consumer appeal.

Functional properties

-Binder for wet granulation
-Carriers for spray drying or freeze drying
-Disintegrants & superdisintegrants
-Encapsulation
-Fillers or diluents
-Film coating
-Hard-pan coating

Applications
-Coated tablets
-Effervescent tablets
-Chewable/Oral dispersible tablets
-Capsules, Powders, Granules, Sachets
-Non Direct-Compression tablets

Product families
-Cyclodextrins
-Maltodextrins
-Dextroses
-Glucoses
-Pharma compounded excipients
-Polyols
-Starches

Excipients are proven effective in helping manufacturers worldwide create high-quality pharmaceutical products in the most commonly used dosage forms. Microlex® processed pharmaceutical performance excipients support the kind of formulation flexibility that helps pharmaceutical manufacturers the world over bring products to market faster.

Microlex® Stearic & Stearates cover an extensive range of applications in the pharmaceutical industry

. Tableting agent
. Lubricant
. Flowability agent
. Separating agent
. Water repellent

. MAGNESIUM STEARATE

Magnesium Stearate is the most widely used excipient in the pharmaceutical industry, it ranks as number one in the list of the Top Ten excipients used in solid oral dosage forms. In the middle east alone, more than 2500 pharmaceutical products include Magnesium Stearate.
The crystal structure of high quality Magnesium Stearate is often pictured as a deck of cards.
Due to the lamella structure Magnesium Stearate offers a very high specific surface area.
During the blending process with active ingredients, carriers or fillers,
the "plates" of Magnesium Stearate dismantle from the decks,
piece by piece, to coat other particles.

. Microlex® MS-101
.Specific surface area: 6-10 m2/g
.Median particle size (D50): 7-11 µm
.Most popular excipient for the production of tablets and capsules
.Typical quantity used during formulation: 0,2 to 1 by tablet weight
.Flowability agent for powder preblends
.Offering an efficient and low dosage in capsules

. Microlex® MS-102
.Specific surface area: 8-12m2/g
.Median particle size (D50): 5-9 µm
.Higher specific surface area and a smaller median partide size
.This product is preferred for more critical and very fine herbal formulations

. Microlex® MS-103
.Specific surface area: 6-8m2/g
.Median particle size (D50):7-11 µm
.Suitable for combination with the favourable crystalline
.Supports a lower dissolution profile
.Designed for special formulations, as low and stable viscosity is required for tablet coatings

. Microlex® MS-104
.Developed for highly complex pharmaceutical applications (e.g. inhalation medicine)
.Very tight specification with additional tests of fatty acid profile, particle size characterization and microbial count

. Microlex® MS-105
.Produced in accordance with strict Kosher and Halal regulations
.Offers the respective required certifications for OTC pharmaceuticals
.Meets Kosher and Halal preparations in Jewish and Arab cultures
.Qualified in high specification standards requested by European formulators

. STEARIC ACID

Some formulations in the pharmaceutical industry are incompatible with Magnesium Stearate. For such for mulations, Magnesium Stearate may be substituted by a high quality Stearic Acid.
We are pleased to offer you our range of carefully engineered Stearic Acids:

. Microlex® SA-121
.Very fine quality of a vegetable Stearic Acid
.Designed for tableting and flowability agent in specific pharmaceutical formulations
.Developed to support the high demands of the pharmaceutical industry
.Complies with Ph.Eur & USP /NF regulations
.Produced by an innovative and complex production process

. Microlex® SA -122
In addition to the characteristics offered in Microlex® MS-121, this material offers particularly low levels of impurities. This high purity level is achieved through use of special selected raw materials.

. CALCIUM STEARATE

Calcium Stearate possesses characteristics assimilable to Magnesium Stearate, likewise it is physiologically safe and is used as a:
.lubricant
.Flowability agent
.Water repellent

. Microlex® CS-141
.Specific surface area: 5-9 m2/g
.Median particle size (D50): 5-9 µm
.A perfect choice for vegetable formulations
.A water repellent agent in the production of effervescent tablets
.Preventing premature reaction of the effervescent tablets
.Preventing unwanted absorption of moisture

. Microlex® CS-142
.Produced in accordance with strict Kosher and Halal regulations
.Offers the respective required certifications for OTC pharmaceuticals
.Meets Kosher and Halal preparations in Jewish and Arab cultures
.Qualified in high specification standards requested by European formulators

Microlex® CMC L, M, and H types

Microlex® provides pharmaceutical carboxymethylcelluloses under the trade names Microlex CMC L, M, and H types,

Microlex® carboxymethylcellulose (CMC) is made by reacting sodium monochloroacetate with alkalicellulose under rigidly controlled conditions. The resultant anionic polymer is purified and dried.

L-type provides smooth solutions, based on uniform substitution with low viscosity.

M-type provides solubility and viscosity stability on medium viscosity.

H-type provides solubility and viscosity stability on strong high viscosity. Microlex CMC grades designated L, M, and H are compliant with the monograph requirements of the EP, USP/NF and Japanese Pharmacopoeia.

Microlex® MCC 101 & 102 types

Microlex® MCC provides pharmaceutical microcrystalline cellulose 101 and 102 grades primarily intended for wet granulation and direct compression applications respectively.

Microlex® MCC 101 is a fine particle size material. When used at about 20% in a wet granulation formulation it confers a range of benefits. The granulation becomes "robust" as the Microlex® MCC allows superior distribution of the water through the granulation. This promotes even granule growth and light granules for easy fluidization. Tablets made from these granules are typically easily disintegrated using conventional superdisintegrants even when hard tablets are compressed.

In direct compression Microlex® MCC 102 is a highly compactable material. The plastic defamation characteristics of MCC 102 type mean that very hard tablets can be produced at light compaction forces, extending tooling lifetime and solving problems with poorly compressible actives. In high dose direct compression applications, Microlex® MCC 102 should be included in your formulation trials.

Microlex® Mannitols cover a range of demands in the pharmaceutical industry

. Mannitols
Developed and designed for the formulation of medicines

. Microlex® MLP 520 series

. Microlex®MLP 520 25.µ
. Microlex®MLP 520 50.µ
. Microlex®MLP 520 180.µ

.A unique blend of exceptional physical and chemical stability
.Great organoleptic, non-cariogenic, sugar-free properties
.The key to a wide range of oral applications
.Use in different processes wet or dry granulation
.Direct compression, compaction or freeze-drying

. Description
White crystalline powder

. Compliance
.European Pharmacopoeia
.USP / NF
.Japanese Pharmacopoeia

. Applications
.Diluent for tablets, capsules and sachets
.Excipient for chemically unstable or moisture-sensitive actives
.Freeze-drying carrier
.Excipient of choice for flash release forms
.Sweetener for pharmaceutical chewing gum

Microlex® Lactoses cover a range of demands in the pharmaceutical industry

. LACTOSES

Lactose clearly meets the criteria for an ideal excipient. It is chemically and physically inert to other excipients and active ingredients. It is also suitable for both wet granulation and direct compression methods of tablet production.
Microlex® crystalline grades are used in wet granulation and the spray dried forms are used in direct compression.
In the direct compression method of tablet production, dry ingredients are thoroughly mixed and then compressed into tablets. This eliminates the drying steps associated with the wet granulator method. It also reduces the higher costs involved in wet granulation including increased equipment, labor, time, process validation and energy expenditure.

Crystalline Monohydrate		Anhydrous
Milled	Sieved	Milled
Microlex® LCM 80.m	Microlex® LCM 120.s	Microlex® LCA 60.m
Microlex® LCM 180.m	Microlex® LCM 180 .s	Microlex® LCA 120.m
Microlex® LCM 200.m	Microlex® LCM 220.s	Microlex® LCA 200.m

Lactose monohydrate is typically used for wet or dry granulation. During wet granulation, liquid binders or adhesives are added to the lactose and active mixture, usually by blending. The mixture is then dried and sized, and compressed into tablets. During dry grarulation, the particle size is enhanced by aggregating the particle by roller compaction and then milling to the desired size.
Lactose has many desirable characteristics for use as a pharmceutical excipient. It is both chemically and physically stable, an highly compatible with other excipients and ingredients. In addtion, it is an all-natural product, which is available in a variety of physical forms.

Film Coating Microlex®
Cellulose esters HPMC & HPMCP developed and designed for the formulation of medicines

. Microlex® HML C2910
. Microlex® HML C2906
. Microlex® HML C2208
. Microlex® HML P200
. Microlex® HML P220

. Properties:
.Controlled by changing the phthalyl content.
.Suitable grade for particular purposes
.Selected in accordance with the properties and formulations of the product
.Higher molecular weight and higher resistance to simulated gastric fluid
.High degree of polymerisation
.Higher viscosity solution for more mechanical strenght of film
.Higher resistance of the coating formulation to simulated gastric fluid
.Effective in reducing the amount of coating

. Applications:
.Film coating of tablets
.Enteric coating of tablets
.Sustained release
.Delayed release
.Palate coating material

. Advantages of film coating:
.Enhancement of palatability by masking unpleasant tastes or objectionable odours
.Ease of ingestion/swallowing
.Improvement of product appearance
.Protection of tablets from light, oxidation & moisture
.Increasing the perception of superior product efficacy

. Compliance
.European Pharmacopoeia
.USP / NF
.Japanese Pharmacopoeia

Microlex® povidone familys designed for the formulation of medicines

. Microlex® PVD series
Povidone, Copovidone, Crospovidone
Developed and designed for a very smooth tablet surface

. Microlex® PVD (Drug Solublization)

. Microlex® PVD K30
. Microlex® PVD K90

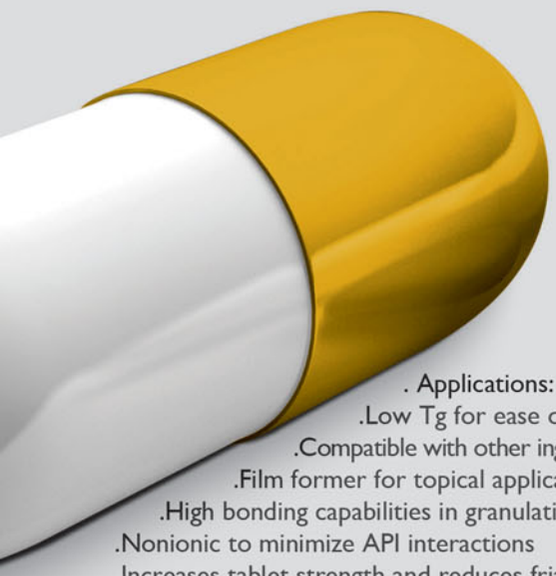
. Properties:
It is among the most commonly used solid dispersion carrires to solubilize poorly soluble drugs. It can stabilize amorphous drugs in polymer dispersions and maintain supersaturation of API aqueous solutions by preventing precipitation/crystallization

. Applications:
.Low Tg for ease of processing in hot-melt extrusion
.Solubility in wider range of solvents adds processing flexibility in spray drying
.Compatible with other ingredients to allow optimization of solid dispersion formulations for stability and delivery
.Physiologically inert for good safety profile
.Inhibits crystallization

. Microlex® C.PVD (Drug Solublization, Tablet Binding, Tablet Film Coating)

. Microlex® C.PVD S600

. Properties:
.Drug Solublization, Tablet Binding, Tablet Film Coating
.Provides a matrix to solubilize poorly soluble drugs in melt-extruded or spray-dried solid dispersions
.Applied in a wide variety of dosage forms including oral solid, liquid, and topical formulations
.A linear random water-soluble copolymer of N-vinylpyrrolidone and vinyl acetate that combines a unique set of properties for application in a wide variety of dosage forms
.A key ingredient in high-solids film coating formulations



. Applications:
.Low Tg for ease of processing in hot-melt extrusion and spray drying
.Compatible with other ingredients to allow optimization of solid dispersion formulations for stability and delivery
.Film former for topical applications
.High bonding capabilities in granulations
.Nonionic to minimize API interactions
.Increases tablet strength and reduces friability due to high compressibility and excellent adhesive properties
.Physiologically inert for good safety profile
.Solubility in aqueous and polar organic solvents adds processing flexibility
.Improved film adhesion
.Increased processing efficiencies

. Microlex® Cr.PVD (Drug Solublization, Tablet Disintegration)

. Microlex® Cr.PVD CL-110
. Microlex® Cr.PVD CL-25
. Microlex® Cr.PVD UCL-25
. Microlex® Cr.PVD UCL-110

. Properties:
A solid dispersion carrier for drug solubilization incorporated into conventional formulations to facilitate the dissolution of poorly API due to porous surface morphology, large surface area and N-methyl vinylpyrrolidone-like unit molecular structure. Combines rapid swelling wicking (due to porosity and capillary action) and particle recovery on wetting releasing energy that facilitates disin tegration High interfacial activity enhances dissolution.

. Applications:
.Enhances solubility/dissolution of poorly soluble drugs, especially at higher use levels.
.Two key particle sizes (small particle size especially suitable for orally disintegrating tablet dosage forms)
.High compressibility for use with poorly compressible drugs
.Intragranular or extragranular application
.Nonionic for superior cationic drug dissolution
.Does not gel, so will not retard release of drug

. Compliance
.European Pharmacopoeia
.USP / NF
.Japanese Pharmacopoeia

Liquid dosage forms

This range of excipients is composed of monoesters and triesters of fatty acids like lauric, stearate and oleic which differ in terms of their hydrophilic/lipophilic balance value and are used to form water-in-oil or oil-in-water emulsions, also may be used alone as lipophilic emulsifiers to formulate water-in-oil emulsions.

This range may be used practically in all emulsion formulations, in particular in pharmaceutical products such as: creams, ointments, lotions, syrups, solutions, liquid ampoules, dispersions, semi-solids, softgels.

Sorbitan esters and their ethoxylates are a range of mild nonionic surfactants with multifunctional benefits in a number of healthcare applications. Entirely vegetable-derived have long-standing pharmacopoeia approvals and are ideal in topical preparations.

Functional benefits

-Nonionic emulsifiers
-Excipients
-Dispersants
-Solubilisers
-Very low peroxide value
-Low moisture content
-Pyrogen-free sorbitol starting material
-Packaged under nitrogen

. Sorbitan esters and their ethoxylates

. Microlex® SE–PSE

. Description

Sorbitan esters and their ethoxylates are a range of mild nonionic surfactants with multifunctional benefits in a number of healthcare applications. Entirely vegetable-derived, have long-standing pharmacopoeia approvals and are ideal in topical preparations.

Sorbitan Esters		
Trade Name	INCI Name	Pharmacopoeia Monograph
Microlex® SE 20	Sorbitan Laurate	BP, PhEur
Microlex® SE 40	Sorbitan Palmitate	----,----
Microlex® SE 60	Sorbitan Stearate	BP, PhEur
Microlex® SE 65	Sorbitan Tristearate	BP, PhEur, USP/NF
Microlex® SE 70	Sorbitan Isostearate	----,----
Microlex® SE 80	Sorbitan Oleate	BP, PhEur, USP/NF
Microlex® SE 83	Sorbitan Sesquioleate	BP, PhEur, USP/NF
Microlex® SE 85	Sorbitan Trioleate	BP, PhEur, USP/NF
Ethoxylated Sorbitan Esters		
Trade Name	INCI Name	PharmacopoeiaMonograph
Microlex® PSE 20	Polyoxyethylene sorbitan monolaurate	BP, PhEur, USP/NF
Microlex® PSE 40	Polyoxyethylene sorbitan monopalmitate	BP, PhEur, USP/NF
Microlex® PSE 60	Polyoxyethylene sorbitan monostearate	BP, PhEur, USP/NF
Microlex® PSE 80	Polyoxyethylene sorbitan monooleate	BP, PhEur, USP/NF

. Suppository base hard fats

. Microlex® HF

. Description

HF W35 hard fat suppository base with a high mono- and diglyceride content. High elasticity and polarity. Hydroxyl value of 40-50 mg KOH/g, saponification value of 230-240 mg KOH/g.

. Description

HF H15 hard fat suppository base with a low content of mono- and diglycerides. Hydroxyl value of 5-15 mg KOH/g, saponification value of 230-240 mg KOH/g.

. Functions

.Stiffening agent

.Suppository base

Suppository base Hard Fats		
Trade Name	INCI Name	Pharmacopoeia Monograph
Microlex® HF W35P	Glycerides, C12-C18	PhEur, USP/NF
Microlex® HF W35	Glycerides, C12-C18	PhEur, USP/NF
Microlex® HF H15P	Glycerides, C12-C18	PhEur, USP/NF
Microlex® HF H15	Glycerides, C12-C18	PhEur, USP/NF

Injectable solutions
Dialysis solutions
Parenteral nutrition

Injectable and dialysis solutions are critical preparations requiring high purity and reliable raw materials. Microlex® is a leading world wide supplier of pyrogen-free nutrients and osmotic agents.

These Microlex® pyrogen-free raw materials comply with the world's most stringent pharmacopoeia specifications with comprehensive quality checking, purity and filterability taking place to ensure the high standards required for dialysis and infusion therapies.

Advantage

-European qualification
-High purity
-Particularly low content of secondary salts
-Complies with EP and USP pharmacopoeias
-Special packaging
-Formulation assistance

Certification

-GMP certificate
-EDQM CEP certificate
-Halal certificate

Microlex® Injectable grades, Dialysis solutions, Parenteral nutrition

Developed and designed for the formulation of medicines

. Microlex® ML-Inj (Mannitol)
. Microlex® DX-Inj (Dextrose)
. Microlex® PCL-Inj (Potassium Chloride)
. Microlex® CAL-Inj (Calcium Chloride)
. Microlex® MGS-Inj (Magnesium Sulfate)

Injectable and dialysis solutions are critical preparations requiring high purity and reliable raw materials. Microlex® is a leading world wider supplier of pyrogen-free nutrients and osmotic agents.
These Microlex® pyrogen-free raw materials comply with the world's most stringent pharmacopoeia specifications. Comprehensive quality check, purity and filterability ensures the highest standards required for dialysis and infusion therapies.

. Applications
.Diuretic-osmotic for injectable solutions
.Dialysis solution
.Injectible solution
.Parenteral nutrition

. Compliance
.European Pharmacopoeia
.USP / NF
.Japanese Pharmacopoeia

. Advantage
.European qualification
.High purity
.Particularly low content of secondary salts
.Complies with EP and USP pharmacopoeias
.Special packaging
.Formulation assistance

. Certification
.cGMP and FDA approved
. Regulatory Documentation
.GMP certification
.FDA inspection
.DMF in CTD format
.CEP from EDQM

Packaging technics

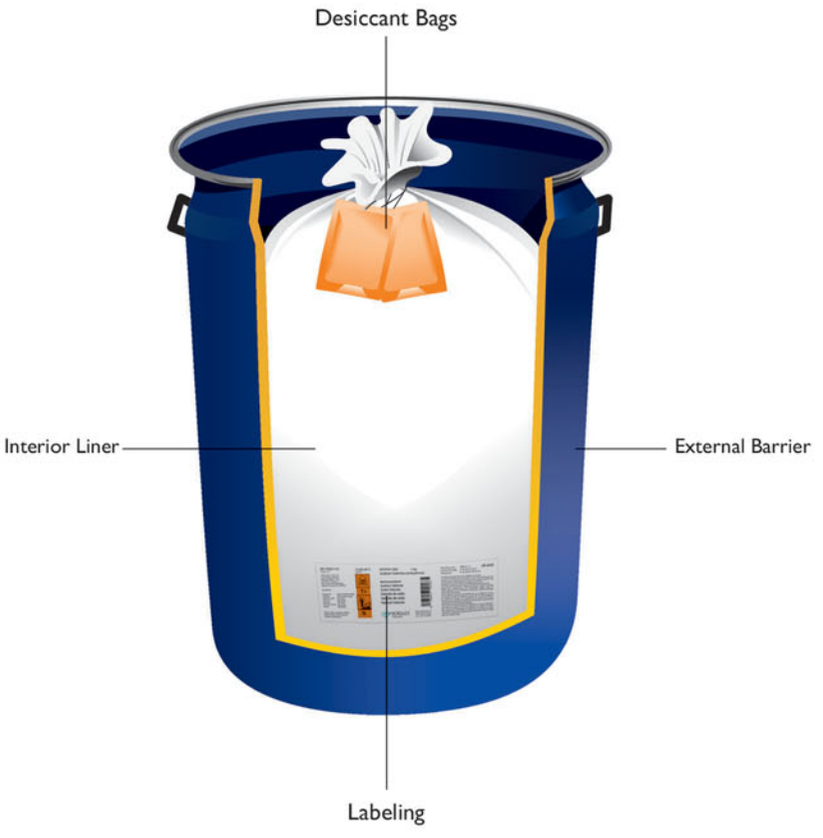
Salts Flow Freely in the Flowmor Packaging System

External Barrier—HDPE drum with gasket-sealed lid prevents moisture from entering.

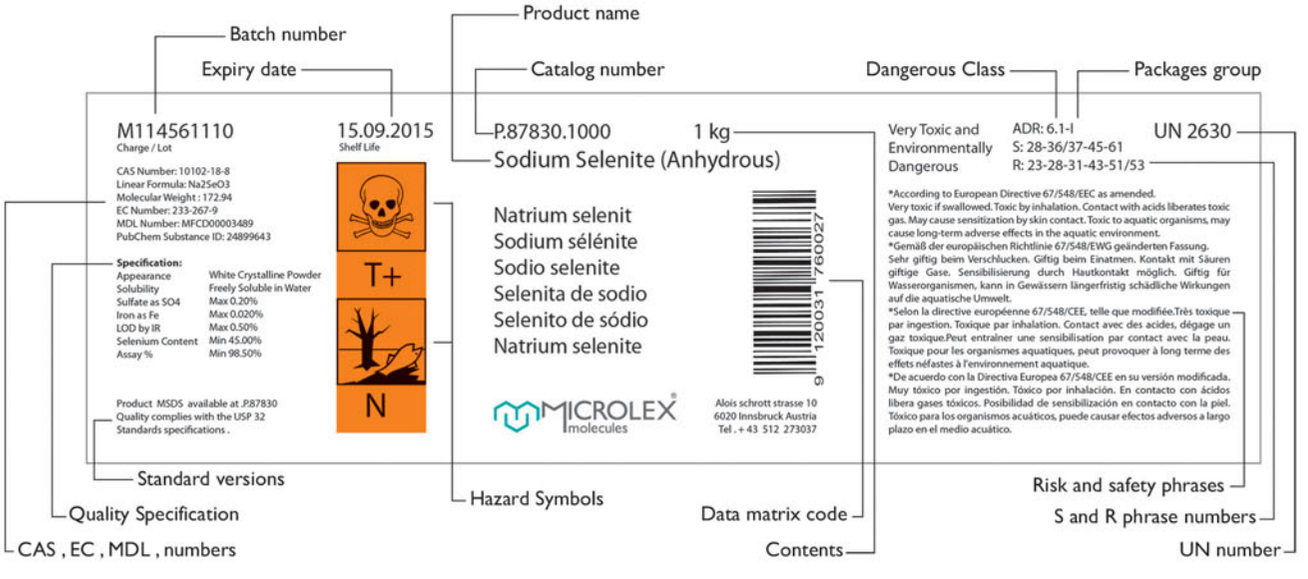
Interior Liner—Permeable liner allows moisture to migrate out of the salt.

Desiccant Bags—Absorb moisture migrating out of the salt without coming in contact with the product.

Labeling—Indicates clearly that desiccant bags are included inside the drum.



Reading our label



MICROLEX®
molecules

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