Pharmaceutical Excipients Index

Excipients are our Business, Health is our Commitment





Seppic, a company of Air Liquide Healthcare



Healthcare Specialty Ingredients

Seppic main focuses:

- Human health
- Animal health
- Beauty care
- Nutraceuticals
- Performance materials



Home Healthcare



Hospital Care #Quality

#Reproducibility

Seppic provides
functional excipients
& technical solutions
to assist you in your
formulation projects

Our pharmaceutical ingredients come with a full quality & regulatory package to support you in your registrations

Seppic also offers
assistance to help you
make the most
of our excipients

Excipients for Pharmaceutical Applications

- Problem-solving excipients
- Formulation expertise in solid, semi-solid & liquid form
- Technical assistance

#Performance

- Raw material information datasheets and regulatory statements
- Multicompendial excipients (Ph.Eur., USP-NF, JP/JPE and/or ChP compliant)*
- EXCiPACT™ certification (IPEC GMP guidelines) for most of our oral and topical excipients
- Manufacturing of API and injectables adjuvants & surfactants according to GMP Part II guidelines

EXCIPACT™ is a quality assurance mark which certifies compliance with Good Manufacturing Practice for pharmaceutical excipients.

IPEC: International Pharmaceutical Excipient Council.

GMP Part II: Guide to Good Manufacturing Practice for Medical Products Part II.

GMP Part II: Guide to Good Manufacturing Practice for Medical Products Part *Detailed list on pages 14-15.

#Innovation

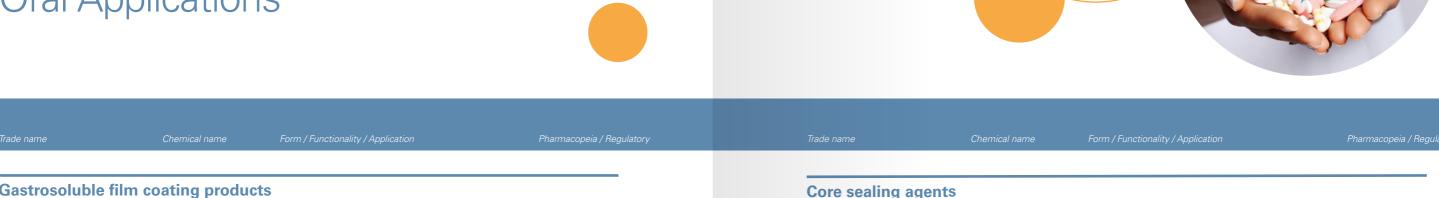
- Sepischool training for oral dosage forms
- Dermoschool training for topical dosage forms
- Formulation assistance (color-matching, placebos, on site coating support...)
- Customized ready-to-use film coating products

#Assistance

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Oral Applications



Gastrosoluble film c	oating products	6	
SEPIFILM™ Classic	Based on hypromellose	 Coloured aqueous and/or organic coating agent Available in white Available in titanium dioxide free Colorless and more than 30 colors available 	[Ph. Eur.]*
SEPIFILM™ LP (Low permeability)	Based on hypromellose and stearic acid	 Protects against moisture Available in white, colored, clear Available in titanium dioxide free Various moisture protection levels available 	[Ph. Eur.]*
SEPIFILM™ SC	Based on hypromellose and sucrose	Ready-to-use sugar coating Available in white	[Ph. Eur.]* [USP-NF]*
SEPIFILM™ PW	Based on hypromellose - in powder form	 Coloured aqueous coating agent Available in white, clear Available in titanium dioxide free More than 10 colors available 	[Ph. Eur.]*
SEPIFILM™ White TF (Titanium dioxide free)	Based on hypromellose - in powder form	White coating agent Free of titanium dioxide Patented composition with unique ingredients	[Ph. Eur.]*
Dry Solubilisers			
SEPITRAP™ 80	Magnesium aluminometasilicate / Polysorbate 80	Solubilizers in powder form for direct compression, capsule formulations and HME	[Ph. Eur.]*
SEPITRAP™ 4000	Magnesium aluminometasilicate Polyoxyl-40 hydrogenated castor oil	Solubilizers in powder form for direct compression, capsule formulations and HME	[Ph. Eur.]*
Binder / Disintegran	t		
SEPISTAB™ ST 200	Partially pregelatinised starch	Filler-binder-disintegrant Free flowing granular powder with specific partials size.	[Ph. Eur.] [USP-NF] =

particle size

and capsule filling

• Perfectly adapted for direct compression

Core sealing agents			
SEPIFILM™ LP (Low permeability)	Based on hypromellose (or) hydroxypropyl cellulose	 Aqueous and/or organic ready-to-use film coating agents for core sealing Protector for sensitive and friable tablets Alternative to organic coatings 	[Ph. Eur.] ²
Colouring agents			
SEPISPERSE™ DRY	Colouring agent in granule form	• Film color • More than 30 colors available	[Ph. Eur.] ¹ [USP-NF]
SEPISPERSE™ AP	Colouring agent in liquid form water-based	 Film color Available in white More than 10 colors available 	[Ph. Eur.] ¹
SEPISPERSE™ AS	Colouring agent for sugar - Coating in liquid form	Sugar coating colouration 8 colors available	[Ph. Eur.] [‡]
Finishing coating			
SEPIFILM™ GLOSS	Film coating agent	Gloss effect for tablet	[Ph. Eur.]

Legends

[Ph. Eur.] → European Pharmacopoeia

[Ph. Eur.]* \rightarrow Raw materials are compliant to European Pharmacopoeia

[USP-NF] → United States Pharmacopeia (USP) and the National Formulary (NF)

[USP-NF]* → Raw materials are compliant to United States Pharmacopeia

Oral, Topical & Mucosal Applications







Trade name	Chemical name	Form / Functionality / Application	EO/HLB	Pharmacopeia / Reg
паце пате	Chemical hame	топп т инспонансу / Аррисалоп	LOTTLD	т паппасорета у пед
Polysorbates - Non ion	nic hydrophil	ic surfactants		
MONTANOX™ 20 PHA PREMIUM	Polysorbate 20	Physical form: Liquid Performant API solubilizer for all types of oral formulations O/W emulsifier for topical formulations	EO: 20 HLB: 17	[Ph. Eur.] [USP-NF] [ChP]
MONTANOX™ 60 PHA PREMIUM	Polysorbate 60	Physical form: Liquid/Gel O/W emulsifier, widely used to form very stable topical O/W emulsion alone /or in combination with MONTANE™ 60 PHA PREMIUM	EO: 20 HLB: 15	[Ph. Eur.] [USP-NF] [ChP]
MONTANOX™ 80 PHA PREMIUM	Polysorbate 80	Physical form: Liquid Performant API solubilizer for all types of oral formulations O/W emulsifier for topical formulations	EO: 20 HLB: 15	[Ph. Eur.] [USP-NF] [ChP]
Sorbitan esters - Non	ionic lipophi	lic surfactants		
MONTANE™ 20 PHA PREMIUM	Sorbitan laurate	Physical form: Liquid • Performant API solubilizer for all types of oral formulations • Well suited for HME applications	HLB: 9	[Ph. Eur.] [USP-NF] [ChP]
MONTANE™ 60 PHA PREMIUM	Sorbitan stearate	Physical form: Pellets • W/O emulsifier, widely used to form very stable topical O/W emulsion alone /or in combination with MONTANOX™ 60 PHA PREMIUM	HLB: 5	[Ph. Eur.] [USP-NF] [ChP]
MONTANE™ 80 PHA PREMIUM	Sorbitan oleate	Physical form: Liquid • W/O emulsifier, widely used to form very stable O/W topical emulsion in combination with MONTANOX™ 80 PHA PREMIUM	HLB: 4.5	[Ph. Eur.] [USP-NF] [ChP]
MONTANE™ 83 PHA PREMIUM	Sorbitan sesquioleate	Physical form: Liquid • W/O emulsifier used in cream & ointment formulations for topical and rectal applications	HLB: 4	[Ph. Eur.] [USP-NF]

rectal applications

Trade name	Chemical name	Form / Functionality / Application	EO/HLB	Pharmacopeia / Re
Ethoxylated fatty acids				
SIMULSOL™ M 45 PHA PREMIUM	Polyoxyl 8 Stearate (or) Polyethylene Glycol 400 Stearate (or) Macrogol Stearate	Physical form: Waxy solid O/W emulsifier Stable emulsions in presence of electrolytes and at acidic or slightly alkaline pH	EO: 8 HLB: 11	[Ph. Eur.] [USP-NF]
SIMULSOL™ M 52 PHA	Polyoxyl 40 stearate (or) Polyethylene Glycol 2000 Stearate (or) Macrogol Stearate	Physical form: Solid OW emulsifier Stable emulsions in presence of electrolytes and at acidic or slightly alkaline pH	EO: 40 HLB: 17	[Ph. Eur.] [USP-NF]

Legends

→ Ongoing

EO → Number of Oxyethylene units.

HLB → Hydrophilic-Lipophilic Balance

[Ph. Eur.] → European Pharmacopoeia

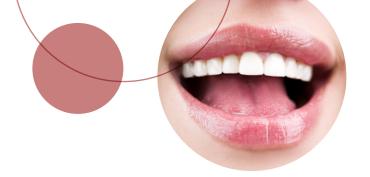
[USP-NF] → United States Pharmacopeia (USP) and the National Formulary (NF)

[ChP] → Chinese Pharmacopoeia

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Topical & Mucosal Applications





Trade name	Chemical name	Form / Functionality / Application	EO/HLB	Pharmacopeia / Regulatory
Thickeners,	Stabilizers & T	exturing agents		
SEPINEO™ P 600	Acrylamide / Sodium Acryloyldimethyl Taurate Copolymer / Isohexadecane - Polysorbate 80	Physical form: Liquid • Ready-to-use liquid polymer, it thickens over a wide range of pH (3-12) • Strong thickener of polar solvents (PEG 400, diethylene glycol monoethyl ether, propylene glycol, ethanol,) • Stabilises all types of oils without surfactant addition • Texture improvement of all dosage form from 0.5% use Gels, O/W emulsions, Cream-gels, Gel-in-oil emulsions Geltrap™, Ointments.		[FDA IID] [US DMF Type IV] [CDE]
SEPINEO™ D.E.R.M.	Hydroxyethyl Acrylate / Sodium Acryloyl Dimethyl Taurate Copolymer	Physical form: Powder Concentrated polymer in powder form, pre-neutralized and easy to use, in wide pH range (3- Strong oil-stabilizing properties even at low visco ideal for lotions Sprayable applications Texture-improvement of anhydrous formulas Gels, O/W emulsions, Cream-gels, Gel-in-oil emulsions Geltrap™, Ointments, Sprays, Powders, Foaming solutions	sities,	[US DMF Type IV]
SEPINEO™ PHD 100	Polyacrylate Crosspolymer-6	Physical form: Powder Pre-neutralized powder polymer Thickens over a wide range of pH (3-8) Robust polymer network for high API loads, ionic APIs, API combinations additions High resistance to electrolytes (> 10% NaCI) Gels, OW emulsions, Cream-gels, Gel-in-oil emulsions Ointments, Sprays, Powders, Foaming solutions	s Geltrap™,	[US DMF Type IV]
Emulsifiers				
SEPINEO™ SE 68	Cetearyl Alcohol / Cetearyl Glucoside	Physical form: Pellets • Self-Emulsifying surfactant of vegetable origin for oil-in-water emulsion • Non ionic glucolipidic structure, very stable in wide range of pH (3-12) and with various API's (anionic, cationic) • Excellent liquid crystal promoter: plays a role in maintaining skin moisturization over time and stability of O/W emulsions O/W emulsions, Gel-in-oil emulsions Geltrap™.		[US DMF Type IV]
SIMALINE L80	Sorbitan Oleate - PEG-30 Dipolyhydroxystearate	Physical form: Liquid Liquid form for easy handling Polymeric W/O surfactant with strong stabilizing properties, even at low % of use Emulsifier for innovative Gel-in-oil emulsions with strong polar solvents stabilization and texture improvement properties W/O emulsions, Gel-in-oil emulsions Geltrap™.	HLB: 4.6	[Ph. Eur.]*
SIMALINE WO	PEG 30 Dipolyhydroxystearate	Physical form: Solid paste Polymeric W/O surfactant with strong stabilizing properties, even at low % of use Co-emulsifier for innovative Gel-in-oil emulsions with strong polar solvents stabilization and texture improvement properties W/O emulsions, Gel-in-oil emulsions Geltrap TM .	HLB: 5.5	[Ph. Eur.]

Trade name	Chemical name	Form / Functionality / Application	EO/HLB	Pharmacopeia / Regulat
Ethoxylated :	fatty alcohols	<u> </u>		
SIMULSOL™ 58 PHA	Ceteareth-20 (or) Macrogol Cetostearyl Ether	Physical form: Solid • W/O emulsifier • Stable emulsions in a wide pH range and in presence of electrolytes	EO: 20 HLB: 16	[Ph. Eur.]
SIMULSOL™ 68 PHA	Ceteareth-22 (or) Macrogol Cetostearyl Ether	Physical form: Solid • W/O emulsifier • Stable emulsions in a wide pH range and in presence of electrolytes	EO: 22 HLB: 16	[Ph. Eur.]
SIMULSOL™ P23 PHA	Polyoxyl 23 Lauryl Ether (or) Macrogol Lauryl Ether	Physical form: Solid API solubilizer O/W emulsifier	EO: 23 HLB: 17	[Ph. Eur.]
Foaming age	ent (preservative	free)		
AMONYL™ 380 BA C	Cocamidopropyl Betaine	Physical form: Liquid Amphoteric surfactant (dry extract 35%) compatible with cationic, non ionics, anionics and various actives Cleansing effect and stability over a wide pH range.		[COSMETIC grade] [Precedence of use in drugs
AMONYL™ 675 SB	Cocamidopropyl Hydroxysultaine	Physical form: Liquid Sulfobetaine (dry extract 48-52%) providing a stable and abundant foam, even in hard water Strong thickening synergies, with good substantivity for a conditioning effect and antistatic properties Possibility of sulfate-free hygiene products.		[COSMETIC grade]
ORAMIX™ NS 10	Decyl glucoside	Physical form: Liquid Non ionic surfactant from vegetable origin (dry extract 53-57%), with abundant & stable foam in acid and alkaline mediums Good tolerance and good compatibility with various actives (including cationics) Easy thickening		[COSMETIC grade] [Precedence of use in drugs
ORAMIDE™ DL 215	Cocamide DEA	Physical form: Liquid • Multifunctional surfactant: boost foaming power, foam stabilizer and thickener		[COSMETIC grade] [Precedence of use in drugs

Legends

→ Ongoing

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[FDA IID] → Registered in Food and Drug Administration Inactive Ingredient Database.

[CDE] → Registered in Center for Drug Evaluation.

Dermo formulas

EU07736PS | PEG-400 Rich Geltrap™

Gel-in-oil emulsion

 Water
 Qs 100%

 PEG 400
 50.00%

 SEPINEO™ P 600
 2.00%

 SIMALINE L80
 1.50%

 LANOL 2681
 5.00%

 Phenoxyethanol
 1.00%

pH = NA - Viscosity = 112,000 mPa.s. Brookfield S7 S5

- A vehicle for high quantites of polar solvents
- Texture improvement: fresh and cushion effect, non greasy, non sticky

EU07565P | High Oil & Solvent Content Cream-gel

Cream-gel

 Water
 Qs 100%

 Diethylene Glycol Monoethyl
 25.00%

 Ether
 25.00%

 SEPINEO™ P 600
 2.00%

 Mineral Oil
 30.00%

 Parabens - Phenoxyethanol
 1.00%

pH = 5.9 - Viscosity = 140,000 mPa.s. Brookfield S7 S5

- Stabilizing high quantities of solvents and oils
- Without additional emulsifyer
- A unique feat of SEPINEO[™] polymers

EU07717P | Diclofenac Cream-gel with Enhanced Skin Delivery

Cream-gel

 Water
 Qs 100%

 Diclofenac Sodium
 1.00%

 LANOL 2681
 8.00%

 SEPINEO™ P 600
 4.00%

 Parabens - Phenoxyethanol
 1.00%

pH = 8 - Viscosity = 47,500 mPa.s. Brookfield S4 S6

- Significantly higher epidermis and dermis permeation of Diclofenac Sodium vs. benchmark
- Easy skin spreading
- Fresh, non-greasy texture

EU07694P | 5% Lidocaine HCl Cream-gel

Cream-gel

 Water
 Os 100%

 Lidocaine Hydrochloride
 5.00%

 Isopropyl Myristate
 10.00%

 LANOL 2681
 20.00%

 SEPINEO™ P 600
 5.00%

 Parabens - Phenoxyethanol
 1.00%

pH = 3.8 - Viscosity = 69,900 mPa.s. Brookfield S7 S5

- Stabilization of 5% of ionic API Lidocaine Hydrochloride
- Oil-stabilizing polymer
- Performant even at acid pH

EU07710P | 10% Lidocaine HCI Cream-gel

Cream-gel

 Water
 Qs 100%

 Lidocaine Hydrochloride
 10.00%

 SEPINEO™ PHD 100
 3.00%

 SEPINEO™ P 600
 1.00%

 LANOL 2681
 10.00%

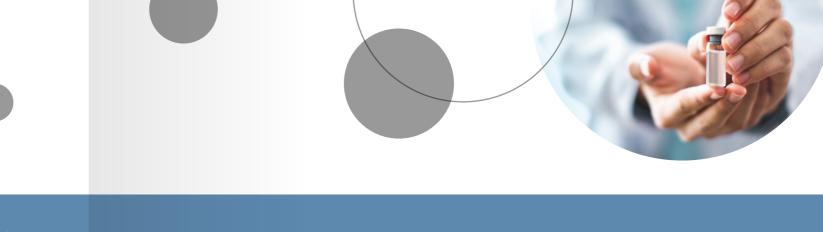
 Parabens - Phenoxyethanol
 1.00%

pH = 5.1 - Viscosity = 25,100 mPa.s. Brookfield S4 S6

- Robust polymeric network of SEPINEO™ PHD 100
- Combined with SEPINEO™ P 600 for better performance & texture

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Parenteral Applications



Trade name	Chemical name	Functionality / Application	Pharmacopeia / Regul
Injectable surfactants			
MONTANOX™ 20 PPI	Polysorbate 20	 Emulsifying, solubilizing surfactant complying with the current pharmacopoeias Injectable quality for human applications 	[Ph. Eur.] [USP-NF] [JP/JPE] [ChP]
MONTANOX™ 80 PPI	Polysorbate 80	 Emulsifying, solubilizing surfactant complying with the current pharmacopoeias Injectable quality for human applications Oleic acid of vegetable origin 	[Ph. Eur.] [USP-NF] [JP] [ChP]
MONTANOX™ 80 API	Polysorbate 80 Very low water content	 Emulsifying, solubilizing surfactant complying with the current pharmacopoeias Injectable quality for human applications Oleic acid of vegetable origin 	[Ph. Eur.] [USP-NF] [JP] [ChP]
MONTANOX™ 80 LPI	Polysorbate 80 Low pH	 Emulsifying, solubilizing surfactant complying with the current pharmacopoeias (EP/USP/JP) Injectable quality for human applications Oleic acid of vegetable origin 	[Ph. Eur.] [USP-NF] [JP]
MONTANE™ 80 PPI	Sorbitan oleate	 Emulsifying surfactant complying with the current pharmacopoeias (EP/USP) Injectable quality for human applications Oleic acid of vegetable origin 	[Ph. Eur.] [USP-NF] [ChP]
MONTANE™ 20 PPI	Sorbitan laurate	 Emulsifying surfactant complying with the current pharmacopoeias Injectable quality for human applications 	[Ph. Eur.] [USP-NF] [ChP]



Legends

 \longrightarrow Ongoing

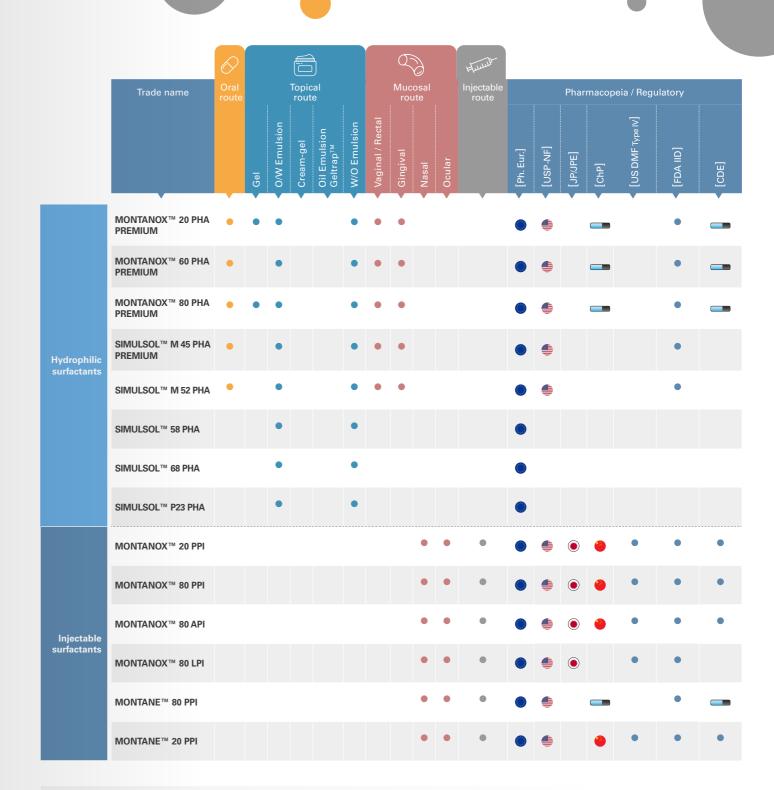
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Quick Guide





Legends

→ Ongoing

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[CDE] → Registered in Center for Drug Evaluation.

A wide spectrum of disciplines

to support you

Chemistry

Synthesis of molecules, design of processes. Fields: polymers, surfactants, green chemistry, alkoxylation.

Applications

Physical properties & prototyping.

Forms

Solid, liquid & semi-solid forms. Oral, Topical, Injectable & Mucosal routes.



Intellectual Property

Regulatory affairs

Pharmacopoeia compliance. Registration (DMF), regulatory package.

Quality

GMP manufacturing (EXCIPACT™, GMP Part II) validated procedures, audit

Analytical

Chemical stability, trace analysis, safety, method validation.

Toxicology

Safety of products.

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Notes:

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Air Liquide Healthcare is a world leader in medical gases, home healthcare and healthcare specialty ingredients. Thanks to the 16,300 men and women from our Healthcare activities, we are an expert in chronic diseases following up 1,8 Million patients at home and in new places of care, and supplier of medical gases solutions and associated services for 15,000 hospitals and clinics. We are engaged alongside patients, healthcare professionals and hospitals to make the healthcare system efficient and virtuous for all, with one imperative: create value for the patient. Our claim 'Changing Care.With You' encapsulates this new perspective.

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