

# Pharmaceutical Solubilizers & Emulsifiers

*Innovative Products for Oral  
and Topical Applications*

**SEPPIC**

Ingredients that inspire

# Pharmaceutical Solubilizers & Emulsifiers

1




For solids, liquids and semi-solids drug dosage forms

## Product description

- Non-ionic surfactants to obtain water-in-oil (W/O), oil-in-water (O/W) emulsions or to solubilize active ingredients.
- High-quality products: PHA PREMIUM grade.
- Good compatibility with other surfactants & different technologies (HME, encapsulation, etc.).
- For oral & topical pharmaceutical applications.

## MONTANE™ PHA PREMIUM range




Sorbitan esters

Trade name	Chemical name	Physical form	HLB	Regulatory
MONTANE™ 20 PHA PREMIUM	Sorbitan laurate	Liquid	9	[Ph. Eur.] [USP-NF] [ChP] 
MONTANE™ 60 PHA PREMIUM	Sorbitan stearate	Pellets	5	[Ph. Eur.] [USP-NF] [ChP] 
MONTANE™ 80 PHA PREMIUM	Sorbitan oleate	Liquid	4.5	[Ph. Eur.] [USP-NF] [ChP] 
MONTANE™ 83 PHA PREMIUM	Sorbitan sesquioleate	Liquid	4	[Ph. Eur.] [USP-NF]

NEW

## MONTANOX™ PHA PREMIUM range

Polysorbates

Trade name	Chemical name	Physical form	EO	HLB	Regulatory
MONTANOX™ 20 PHA PREMIUM	Polysorbate 20	Liquid	20	17	[Ph. Eur.] [USP-NF] [ChP] 
MONTANOX™ 60 PHA PREMIUM	Polysorbate 60	Liquid/ Gel	20	15	[Ph. Eur.] [USP-NF] [ChP] 
MONTANOX™ 80 PHA PREMIUM	Polysorbate 80	Liquid	20	15	[Ph. Eur.] [USP-NF] [ChP] 

## SIMULSOL™ PHA range

Macrogols

Trade name	Chemical name	Physical form	EO	HLB	Regulatory
SIMULSOL™ M 45 PHA PREMIUM	Polyoxyl 8 Stearate (or) Polyethylene Glycol 400 Stearate (or) Macrogol Stearate	Waxy solid	8	11	[Ph. Eur.] [USP-NF]
SIMULSOL™ M 52 PHA	Polyoxyl 40 stearate (or) Polyethylene Glycol 2000 Stearate (or) Macrogol Stearate	Solid	40	17	[Ph. Eur.] [USP-NF]
SIMULSOL™ 58 PHA	Ceteareth-20 (or) Macrogol Cetostearyl Ether	Solid	20	16	[Ph. Eur.]
SIMULSOL™ 68 PHA	Ceteareth-22 (or) Macrogol Cetostearyl Ether	Solid	22	16	[Ph. Eur.]
SIMULSOL™ P23 PHA	Polyoxyl 23 Lauryl Ether (or) Macrogol Lauryl Ether	Solid	23	17	[Ph. Eur.]

At Seppic we propose a full range of **surfactants**. We have developed a multi-compendial range of **emulsifiers & solubilizers** intended for your oral & topical formulation developments. **MONTANOX™ & SIMULSOL™** can also be used to improve the solubility of poorly-soluble API & increase bioavailability.

- Lipophilic non-ionic surfactants, soluble & dispersible in oil
- Emulsifier, used to form W/O emulsions
- Stable in slightly acidic & slightly alkaline media

- Polyethoxylated sorbitan esters: ethoxylated MONTANE™
- Hydrophilic non-ionic surfactants soluble & dispersible in water
- Solubilizer for poorly-soluble active ingredients & Emulsifier & to obtain O/W emulsions
- Stable in acidic & basic media & in the presence of electrolytes

- Ethoxylated fatty acids & fatty alcohols
- Hydrophilic non-ionic surfactants used as solubilizing or emulsifying agents
- SIMULSOL™ PHA products are used to form O/W or W/O emulsions. By combining them with each other or with other emulsifiers from MONTANE™ or MONTANOX™ PHA PREMIUM ranges, it is possible to obtain extremely stable emulsions
- Stable in a wide range of pH & in the presence of electrolytes



## For liquids and semi-solids drug dosage forms <sup>2</sup>

### Applications

- MONTANE™, MONTANOX™ & SIMULSOL™ are non-ionic emulsifiers & co-emulsifiers, used to create W/O & O/W emulsions, as solubilizers and wetting agents as well as co-surfactant in most foaming products.
- To improve the solubility of poorly-soluble API & increase bioavailability.
- They are highly compatible with electrolytes and with other surfactants while not being sensitive to pH variation.
- They can be used in many oral (syrups, suspensions, etc.) or topical (creams, emulsions, gels, etc.) formulations.

Liquids & semi-solids pharmaceutical dosage forms						
Trade name	Ointment	O/W cream	W/O cream	Aqueous solution / Suspension	Shampoo	Liquid Soap
	Administration routes					
MONTANE™ 20 PHA PREMIUM		••	••	•		
MONTANE™ 60 PHA PREMIUM	••	••	••	•		
MONTANE™ 80 PHA PREMIUM	••	••	••	•		
MONTANE™ 83 PHA PREMIUM	••	•	•			
MONTANOX™ 20 PHA PREMIUM		•	•	••	•	
MONTANOX™ 60 PHA PREMIUM	•	••	•		•	
MONTANOX™ 80 PHA PREMIUM	•	•	•	••		
SIMULSOL™ M 45 PHA PREMIUM	•	••	•	•		
SIMULSOL™ M 52 PHA	•	••	•	•		
SIMULSOL™ P23 PHA	•	••	•	•		
SIMULSOL™ 58 PHA	•	••	•	•		
SIMULSOL™ 68 PHA	•	••	•	•		

#### Source

Data from Inactive Ingredient Search for Approved Drug Products (chemical name), FDA/CDE.  
Data Through: January 2, 2022.

FDA: Food and Drug Administration Inactive Ingredient Database  
CDE: Center for Drug Evaluation & Research

#### Legends

API → Active Pharmaceutical Ingredient  
EO → Number of Oxyethylene units.  
HLB → Hydrophilic-Lipophilic Balance.  
[Ph. Eur.] → European Pharmacopoeia.  
[USP-NF] → United States Pharmacopoeia (USP) and the National Formulary (NF).  
[ChP] → Ongoing: Chinese Pharmacopoeia



→ #Emulsifiers & Solubilizers

→ #Oral & topical use

#Pharmacopoeia Compliance:  
→ [USP-NF] & [Ph.Eur.],  
[FDA-IID] listed

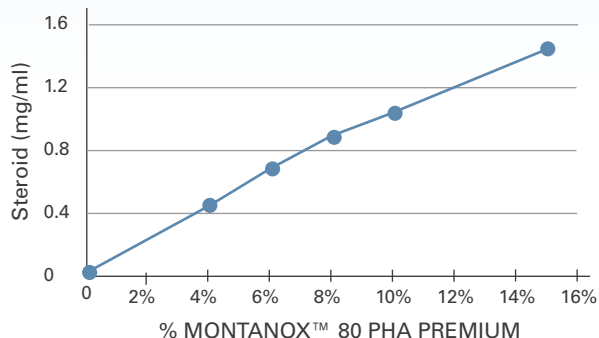
→ #Manufactured according to  
IPEC-PQG GMP guidelines

→ #High-quality grade

→ #Low residual solvents

**Solubilizers** for API such as Fenofibrate with MONTANOX™ 20 PHA PREMIUM; other examples of API solubilisation with MONTANOX™ 80 PHA PREMIUM include Ibuprofen, Carbamazepine, Verapamil, Diclofenac... Those can also be used for dispersion or solubilization of essential oils & vitamins.

#### Solubilization of steroid in solution with MONTANOX™ 80 PHA PREMIUM



#### Other Particular Applications

##### Biological Applications:

MONTANOX™ 80 PHA PREMIUM -  
Biomanufacturing applications,  
cell-culture media, reagent for diagnostic kits

##### Encapsulation:

MONTANE™ 60 PHA PREMIUM &  
MONTANOX™ 80 PHA PREMIUM -  
Taste-masking & slow release properties.

##### Hot Melt Extrusion:

MONTANE™ 20 PHA PREMIUM.

**Emulsifiers:** combination of two surfactants, hydrophilic (high HLB) & lipophilic (low HLB), are often more effective than a single emulsifier & form very stable emulsions.

Examples of emulsions type:

- O/W emulsion:  
A blend of MONTANE™ 60 PHA PREMIUM +  
MONTANOX™ 60 PHA PREMIUM
- W/O emulsion:  
With MONTANE™ 80 PHA PREMIUM
- Other examples:

#### EU07505P | Sprayable Diclofenac Emulsion

MONTANE™ 80 PHA PREMIUM	1.50%
MONTANOX™ 80 PHA PREMIUM	1.50%
Diclofenac Sodium	1.00%
Propylene Glycol	10.00%
Isopropyl Myristate	8.00%
SEPINEO™ P 600	1.00%
Water	Qs 100%
Preservatives	1.00%

#### EU07496P | Fluid Dimethicone Emulsion

Glycerin	2.00%
Mineral Oil	4.00%
LANOL 2681	4.00%
Dimethicone 100	4.00%
SIMULSOL™ 58 PHA	0.90%
SEPINEO™ SE 68	2.10%
Parabens - Phenoxyethanol	0.50%
Water	Qs 100%

# Innovative Excipients from Compendial Raw Materials

*Delivering new technical solutions  
through well-known chemistries*

Seppic also offers **powder-form solubilizers** compatible with direct granulation process for OSD as well as a **liquid-form polymeric emulsifier** for innovative topical emulsions.

## SEPITRAP™

*Solubilizers in powder form*

SEPITRAP™ are micro-encapsulated solubilizers in powder form designed to simplify the manufacturing of solid oral form drugs.

Trade name	Surfactant	Porous Mineral Carrier	Regulatory
SEPITRAP™ 80	Polysorbate 80	Magnesium aluminometasilicate	[USP-NF]* [Ph. Eur.]*
SEPITRAP™ 4000	Polyoxyl 40 hydrogenated castor oil	Magnesium aluminometasilicate	[USP-NF]* [Ph. Eur.]*

SEPITRAP™ are used for oral dosage forms such as tablets, capsules or dry syrups for:

- Solubility enhancement of insoluble actives
- Bioavailability enhancement
- Compatibility with direct compression process.

## SIMALINE™ L80

*Liquid W/O emulsifier for Gel-in-oil emulsions*

SIMALINE™ is a polymeric, high molecular weight emulsifier used in traditional W/O emulsions or associated with SEPINEO™ pharmaceutical polymers to formulate innovative Gel-in-oil emulsions Geltrap™.

Trade name	Lipophilic surfactants		Regulatory
SIMALINE™ L80	Sorbitan oleate	PEG-30 dipolyhydroxystearate	[Ph.Eur.]*

A Gel-in-oil emulsion Geltrap™ brings benefits to both formulation scientists & patients:

- An hydrophilic internal phase (> 80%) capable of stabilizing high concentrations of polar solvents
- Unique, patient-friendly texture: fresh & cushion effect, non-greasy, non-sticky
- Additional benefits: emollient, moisturizing, water-resistance.

### Legends

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

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

**Seppic is committed to support your developments with our excipients & unique expertise**

*Seppic Teams have a large experience and are available to assist you and help you*



#### Analytical support

- To help you in our products characterisation
- Development of new analytical techniques

#### Drug development

- Chemicals synthesis
- Formulation

#### Regulatory assistance

- Regulatory Statements (BSE/TSE, GMO, Allergens,...)
- Raw Material Identification Data sheet
- Regulatory package available ([ChP] & [CDE] ongoing)

## PHA PREMIUM Grade

SEPPIC has developed a range of high-quality grade surfactants that meet the requirements of the pharmaceutical industry: **PHA PREMIUM grade**.

SEPPIC follows the **IPEC<sup>(1)</sup>-PQG Good Manufacturing Practices guidelines** for its MONTANE™ & MONTANOX™ manufacturing, from raw material supply to release of the commercial batches.

SEPPIC was successfully audited & granted the **EXCiPACT™<sup>(2)</sup> certification**.

SEPPIC is ISO 9001 & ISO 14000 certified.

Complying with the current edition of the **European & US Pharmacopeias** ([Ph.Eur.] & [USP-NF]).

SEPPIC takes additional steps to guarantee: **Reproducibility, Quality, Traceability.**

As an excipient supplier SEPPIC declares itself yearly to the ANSM (French Health Authorities).

<sup>(1)</sup> IPEC: International Pharmaceutical Excipient Council

<sup>(2)</sup> EXCiPACT™ is a quality assurance mark which certifies compliance with Good Manufacturing Practice for pharmaceutical excipients.

#### Nota:

The analytical specifications warranted are only those mentioned on the certificate of analysis supplied with each delivery of the product.

Except as set forth above, Seppic\* makes no warranties, whether express, implied of statutory, as to the product which is the subject of this document. Without limiting the generality, of the foregoing, Seppic\* makes no warranty of merchantability of the product or of the fitness of the product for any particular purpose. Buyer assumes all risk and liability resulting from the use or sale of the product, whether singly or in combination with other goods. The information set forth herein is furnished free of charge and is based on technical data that Seppic\* believes to be reliable. It is intended for use by persons having technical skill and their own discretion and risk. Since conditions of use are outside Seppic\*'s control, Seppic\* makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Nothing herein is to be taken as a license to operate under or a recommendation to infringe any patents.

*Air Liquide Healthcare is a world leader in medical gases, home healthcare, hygiene products and healthcare specialty ingredients. It aims to provide customers in the continuum of care from hospital to home with medical products, specialty ingredients and services that contribute to protecting vulnerable lives.*

\*Seppic being

#### Seppic S.A. - Paris

FRANCE  
Tel: +33 (0)1 42 91 40 00  
info.seppic@airliquide.com

#### Seppic S.A. - Castres

FRANCE  
Tel: +33 (0)5 63 72 69 69  
Fax : +33 (0)5 63 72 69 70

#### Seppic S.A. - Pontreux

FRANCE  
Tel: +33 (0)2 96 95 31 32  
contact.biotechmarine@airliquide.com

#### Seppic S.A. - Lons

FRANCE  
Tel: + 33 (0)5 59 13 04 20  
contact-serdex@airliquide.com

#### Seppic S.A. - Villers-sur-Fère

FRANCE  
Tel: +33 (0)1 42 91 40 00  
info.seppic@airliquide.com

#### UNITED STATES- Seppic Inc.

UNITED STATES  
Tel: +1 973 882 5597  
us.seppic@airliquide.com

#### UNITED STATES - Polykon Manufacturing LLC

UNITED STATES  
Tel: +1 804 624 9057  
sharon.harper@airliquide.com

#### BRASIL - Seppic Brasil EQCI Ltda

BRASIL  
Tel: +55 11 3252 3911  
brasil.seppic@airliquide.com

#### COLOMBIA - Seppic Colombia SAS

COLOMBIA  
Tel: +571 702 44 48  
colombia.seppic@airliquide.com

#### GERMANY - Seppic GmbH

GERMANY  
Tel: +49 (0)221 888824 0  
germany.seppic@airliquide.com

#### ITALY - Seppic Italia Srl

ITALY  
Tel: +39 02 38009110  
italy.seppic@airliquide.com

#### POLAND - Seppic Office

POLAND  
Tel: +48 22 11 60 759  
poland.seppic@airliquide.com

#### CHINA - Seppic Shanghai Chemical Specialities Co.

CHINA  
Tel: +86 (21) 64 66 01 49  
china.seppic@airliquide.com

#### INDIA - Air Liquide India Holding Pvt Ltd

INDIA  
Tel: + 91 22 61046464  
india.seppic@airliquide.com

#### SINGAPORE - Seppic Office

SINGAPORE  
Tel: +65 6378 5213  
singapore.seppic@airliquide.com

#### JAPAN - Seppic Office

JAPAN  
Tel: +81 3 6414 6725  
japan.seppic@airliquide.com

#### KOREA - Seppic Office

Seoul, KOREA 06168  
Tel: +82-2-3019-2569  
korea.seppic@airliquide.com

© 2023 Seppic - Seppic is a subsidiary of the AIR LIQUIDE group

**SEPPIC**

A company  
**Air Liquide**  
HEALTHCARE

seppic.com