Pharmaceutical Excipients Index

Excipients are our Business,
Health is our Commitment

SEPPIC

Ingredients that inspire

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**

#Assistance

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.
*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

Oral Applications

Gastrosoluble film coating products

Trade name	Chemical name	Form / Functionality / Application	Pharmacopeia / Regulatory
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.]* [USP-NF]*
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.]* [USP-NF]*
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.]* [USP-NF]*
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.]* [USP-NF]*

Dry Solubilisers

Trade name	Chemical name	Form / Functionality / Application	Pharmacopeia / Regulatory
SEPITRAP™ 80	*Magnesium aluminometasilicate / Polysorbate 80*	• **Solubilizers in powder form for direct compression, capsule formulations and HME**	[Ph. Eur.]* [USP-NF]*
SEPITRAP™ 4000	*Magnesium aluminometasilicate Polyoxyl-40 hydrogenated castor oil*	• **Solubilizers in powder form for direct compression, capsule formulations and HME**	[Ph. Eur.]* [USP-NF]*

Binder / Disintegrant

Trade name	Chemical name	Form / Functionality / Application	Pharmacopeia / Regulatory
SEPISTAB™ ST 200	*Partially pregelatinised starch*	• **Filler-binder-disintegrant** • Free flowing granular powder with specific particle size • Perfectly adapted for direct compression and capsule filling	[Ph. Eur.] [USP-NF]

Core sealing agents

Trade name	Chemical name	Form / Functionality / Application	Pharmacopeia / Regulatory
SEPIFILM™ SN	*Based on shellac gum*	• **Organic film coating agent for seal coating**	[Ph. Eur.]* [USP-NF]*
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.]* [USP-NF]*

Colouring agents

Trade name	Chemical name	Form / Functionality / Application	Pharmacopeia / Regulatory
SEPISPERSE™ DRY	*Colouring agent in granule form*	• **Film color** • More than 30 colors available	[Ph. Eur.]* [USP-NF]*
SEPISPERSE™ K	*Colouring agent in liquid form ethanol-based*	• **Film color** • White and Blue film colors available	[Ph. Eur.]* [USP-NF]*
SEPISPERSE™ M	*Colouring agent in liquid form water and ethanol-based*	• **Film color** • Pink film color	[Ph. Eur.]* [USP-NF]*
SEPISPERSE™ AP	*Colouring agent in liquid form water-based*	• **Film color** • Available in white • More than 10 colors available	[Ph. Eur.]* [USP-NF]*
SEPISPERSE™ AS	*Colouring agent for sugar - Coating in liquid form*	• **Sugar coating colouration** • 8 colors available	[Ph. Eur.]* [USP-NF]*

Finishing coating

Trade name	Chemical name	Form / Functionality / Application	Pharmacopeia / Regulatory
SEPIFILM™ GLOSS	*Film coating agent*	• **Gloss effect for tablet**	[Ph. Eur.]* [USP-NF]*

Legends

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- [Ph. Eur.] → European Pharmacopoeia
- [Ph. Eur.]* → 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

Polysorbates - Non ionic hydrophilic surfactants

Trade name	Chemical name	Form / Functionality / Application	EO / HLB	Pharmacopeia / Regulatory
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: **Pearls** • 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 lipophilic surfactants

Trade name	Chemical name	Form / Functionality / Application	EO / HLB	Pharmacopeia / Regulatory
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 NEW	*Sorbitan sesquioleate*	Physical form: **Liquid** • W/O emulsifier used in cream & ointment formulations for topical and rectal applications	HLB: 4	[Ph. Eur.] [USP-NF]

Ethoxylated fatty acids

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

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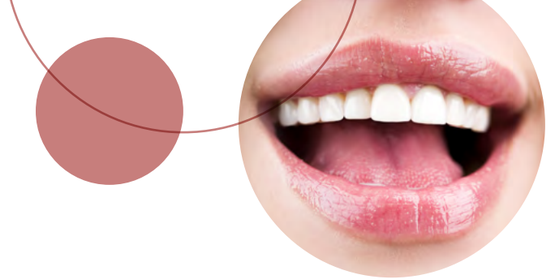
[ChP] → Chinese Pharmacopoeia

Topical & Mucosal Applications



Thickeners, Stabilizers & Texturing agents

Trade name	Chemical name	Form / Functionality / Application	EO / HLB	Pharmacopeia / Regulatory
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 (3-12) • Strong oil-stabilizing properties even at low viscosities, 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*		[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% NaCl) *Gels, O/W emulsions, Cream-gels, Gel-in-oil emulsions Geltrap™, Ointments, Sprays, Powders, Foaming solutions*		[US DMF Type IV]

Emulsifiers

Trade name	Chemical name	Form / Functionality / Application	EO / HLB	Pharmacopeia / Regulatory
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™ .*	HLB: 5.5	[Ph. Eur.]

Ethoxylated fatty alcohols

Trade name	Chemical name	Form / Functionality / Application	EO / HLB	Pharmacopeia / Regulatory
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 agent (preservative free)

Trade name	Chemical name	Form / Functionality / Application	EO / HLB	Pharmacopeia / Regulatory
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 • Foam texturizing & emolient properties • Low free DEA content < 3%.		[COSMETIC grade] [Precedence of use in drugs]

Legends

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- [Ph. Eur.] → European Pharmacopoeia
- [Ph. Eur.]* → Raw materials are compliant to European Pharmacopoeia
- [US DMF Type IV] → Registration on Drug Master File. Seppic has registered Type IV DMFs at the Food and Drug Administration (FDA).
- [FDA IID] → Registered in Food and Drug Administration Inactive Ingredient Database.
- [CDE] → Registered in Center for Drug Evaluation.

Dermo formulas

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	Qs 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

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 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

EU07710P | 10% Lidocaine HCl 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

Parenteral Applications

Trade name	*Chemical name*	*Functionality / Application*	*Pharmacopeia / Regulatory*
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

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[JP/JPE] → Japanese Pharmacopoeia / Japanese Pharmaceutical Excipients
[ChP] → Chinese Pharmacopoeia

Quick Guide

	Trade name	Oral route	Topical route: Gel	Topical route: O/W Emulsion	Topical route: Cream-gel	Topical route: Oil Emulsion Geltrap™	Topical route: W/O Emulsion	Mucosal route: Vaginal / Rectal	Mucosal route: Gingival	Mucosal route: Nasal	Mucosal route: Ocular	Injectable route	Pharmacopeia / Regulatory: [Ph. Eur.]	[USP-NF]	[JP/JPE]	[ChP]	[US DMF Type IV]	[FDA IID]	[CDE]
Film coating	SEPIFILM™ range	●											*	*			●	●	
Solubilizers	SEPITRAP™ 80	●											*	*			●		
	SEPITRAP™ 4000	●											*	*					
Colouring agents	SEPISPERSE™ DRY	●											*	*			●		
	SEPISPERSE™ K, M, AP, AS (Liquid range)	●											*	*			●		
Binder / Disintegrant	SEPISTAB™ ST 200	●											●	▬				●	
Innovative polymers	SEPINEO™ P 600		●	●	●	●		●									●	●	●
	SEPINEO™ D.E.R.M.		●	●	●	●		●	●								●		
	SEPINEO™ PHD 100		●	●	●	●		●	●								▬		
Innovative emulsifier	SEPINEO™ SE 68			●		●		●	●								●		
Lipophilic surfactants	SIMALINE L80					●	●	●	●				*						
	MONTANE™ 20 PHA PREMIUM	●				●	●	●	●				●	●		▬		●	▬
	MONTANE™ 60 PHA PREMIUM	●				●	●	●	●				●	●		▬		●	▬
	MONTANE™ 80 PHA PREMIUM	●				●	●	●	●				●	●		▬		●	▬
	MONTANE™ 83 PHA PREMIUM	●				●	●	●					●	●				●	

	Trade name	Oral route	Topical route: Gel	Topical route: O/W Emulsion	Topical route: Cream-gel	Topical route: Oil Emulsion Geltrap™	Topical route: W/O Emulsion	Mucosal route: Vaginal / Rectal	Mucosal route: Gingival	Mucosal route: Nasal	Mucosal route: Ocular	Injectable route	Pharmacopeia / Regulatory: [Ph. Eur.]	[USP-NF]	[JP/JPE]	[ChP]	[US DMF Type IV]	[FDA IID]	[CDE]
Hydrophilic surfactants	MONTANOX™ 20 PHA PREMIUM	●	●	●			●	●	●				●	●		▬		●	▬
	MONTANOX™ 60 PHA PREMIUM	●		●			●	●	●				●	●		▬		●	▬
	MONTANOX™ 80 PHA PREMIUM	●	●	●			●	●	●				●	●		▬		●	▬
	SIMULSOL™ M 45 PHA PREMIUM	●		●			●	●	●				●	●				●	
	SIMULSOL™ M 52 PHA	●		●			●	●	●				●	●				●	
	SIMULSOL™ 58 PHA			●			●						●						
	SIMULSOL™ 68 PHA			●			●						●						
	SIMULSOL™ P23 PHA			●			●						●						
Injectable surfactants	MONTANOX™ 20 PPI							●	●	●			●	●	●	●	●	●	●
	MONTANOX™ 80 PPI							●	●	●			●	●	●	●	●	●	●
	MONTANOX™ 80 API							●	●	●			●	●	●	●	●	●	●
	MONTANOX™ 80 LPI							●	●	●			●	●	●		●	●	
	MONTANE™ 80 PPI							●	●	●			●	●		▬		●	▬
	MONTANE™ 20 PPI							●	●	●			●	●		●	●	●	●

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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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