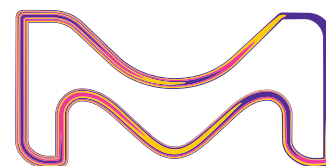


Chinese regulation for Excipients and Active Pharmaceutical Ingredients (APIs)

List of Registration dossiers

Registration No.	Cat. No.	Usage as	Administration Route	ChP Compliance	Product Description
F20220000530	ARK2140	Excipient	Parenteral		Squalene
F20220000157	100013	Excipient	Topical and sublingual/ Transdermal/Oral		Acetone EMPROVE® ESSENTIAL Ph Eur,BP,JPE,NF
F20210000471	100056	Excipient	Injection/Ophthalmic/topical and sublingual/Transdermal/ Oral administration/Other		Acetic acid (glacial) 100% EMPROVE® ESSENTIAL Ph Eur,BP,JP,USP,E 260
F20200000569	100193	Excipient	Parenteral		Caprylic acid (Octanoic acid) EMPROVE® EXPERT Ph Eur,NF
F20170000260	100201	Excipient	Parenteral	✓	Phenol EMPROVE® ESSENTIAL Ph Eur,ChP,JP,USP
F20180001333	100419	Excipient	Oral	✓	Parteck® M 200 (Mannitol) EMPROVE® ESSENTIAL Ph Eur, ChP,BP,JP,USP,E 421
F20180001333	100494	Excipient	Oral	✓	Parteck® M 100 (Mannitol) EMPROVE® ESSENTIAL Ph Eur,ChP,BP,JP,USP,E 421
F20200000037	100590	Excipient	Injection/Oral/Ophthalmic	✓	Glycine cryst. EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20220000164	100661	Excipient	Topical and sublingual/ Transdermal/Oral		Parteck® LUB STA 50 (Stearic acid 50 vegetable grade) EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF
F20200000380	100681	Excipient	Oral/Parenteral	✓	Succinic Acid cryst. EMPROVE® ESSENTIAL ChP, NF, JPE, ACS
F20170000066	100805	Excipient	Oral	✓	Titanium(IV) oxide EMPROVE® ESSENTIAL Ph Eur, ChP,BP,USP,JP,E 171
F20170000107	100892	Excipient	Parenteral	✓	Sucrose EMPROVE® EXPERT Ph Eur,BP,ChP,JP,NF (upgrade in July 2023)
F20200000375	100967	Excipient	Injection/Inhalation/ Ophthalmic/topical and sublingual/Transdermal/Oral	✓	Ethanol 96% EMPROVE® EXPERT Ph Eur,ChP, JP,USP
F20200000378	100986	Excipient	Oral/Injection/Ophthalmic preparation/Topical and sublingual/Transdermal	✓	Ethanol absolute EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20220000158	100995	Excipient	Topical and sublingual/ Transdermal/Oral	✓	2-Propanol EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP
F20200000340	101544	Excipient	Injection/Oral/Other	✓	L-Arginine monohydrochloride EMPROVE® EXPERT Ph Eur, BP,ChP,JP, USP
F20210000066	101587	Excipient	Oral/Parenteral		L-Arginine EMPROVE® EXPERT Ph Eur,JP,USP



Registration No.	Cat. No.	Usage as	Administration Route	ChP Compliance	Product Description
F20230000212	101791	Excipient	Parenteral, Inhalation, Ophthalmic, Topical and sublingual, Transdermal, Oral		L-Glutamic acid EMPROVE® EXPERT Ph Eur,JP,USP
F20200000061	101806	Excipient	Injection/Oral		Benzyl benzoate EMPROVE® EXPERT Ph Eur,BP,USP
F20220000348	102440	Excipient	topical and sublingual/ Transdermal/Oral		Parteck® Mg DC (Magnesium hydroxide carbonate) heavy EMPROVE® ESSENTIAL Ph Eur,BP,USP,JP,E 504
F20190000622	102776	Excipient		√	Trehalose dihydrate EMPROVE® EXPERT Ph Eur,ChP,NF,JP
F20210000294	102994	Excipient	Oral		Sorbitol liquid(sorbitol syrup, crystallizing) EMPROVE® ESSENTIAL Ph Eur,BP,USP,E 420
F20200000036	103669	Excipient	Injection/Oral/Ophthalmic	√	Glycine granulated EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20190000564	103789	Excipient	Injection	√	Sucrose EMPROVE®EXPERT Ph Eur, ChP, JP, NF
F20220000177	104161	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ topical and sublingual/ Transdermal/Oral	√	Ammonium sulfate granulated EMPROVE® EXPERT ACS,ChP,NF
F20220000099	104162	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ topical and sublingual/ Transdermal/Oral	√	Sodium acetate trihydrate granulated EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20200000384	104352	Excipient	Injection, oral	√	L-Histidine EMPROVE® EXPERT Ph Eur, ChP, USP, JP
F20200000399	104354	Excipient	Injection/Ophthalmic preparation/Oral administration	√	L-Histidine monohydrochloride monohydrate EMPROVE® EXPERT Ph Eur, BP,JP
F20210000496	104672	Excipient	Parenteral/Ophthalmic preparation/topical and sublingual/ Transdermal/Oral administration/Other		Synthechol® Synthetic Cholesterol EMPROVE® EXPERT Ph Eur,BP,JP,NF
F20220000171	105980	Excipient	Topical and sublingual/ Transdermal/Oral	√	D(-)-Mannitol EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP,FCC,E 421
F20220000345	106008	Excipient	topical and sublingual/ Transdermal/Oral		Methanol EMPROVE® ESSENTIAL Ph Eur,BP,JPE,NF
F20180000400	106143	Excipient	Parenteral	√	Meglumine low in endotoxins EMPROVE® API Ph Eur,ChP,JP,USP (warning) We only hold China Dossier for Mollet (Spain) site, not Gernsheim (Germany) site
F20180000401	106143	Excipient	Oral	√	Meglumine low in endotoxins EMPROVE® API Ph Eur,ChP,JP,USP (warning) We only hold China Dossier for Mollet (Spain) site, not Gernsheim (Germany) site
F20220000350	106345	Excipient	Topical and sublingual/ Transdermal/Oral	√	Sodium dihydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur,BP,ChP,USP,JPE,E 339
F20220000351	106349	Excipient	Topical and sublingual/ Transdermal/Oral	√	Sodium dihydrogen phosphate monohydrate EMPROVE® ESSENTIAL BP,ChP,USP
F20220000363	106482	Excipient	Topical and sublingual/ Transdermal/Oral		Sodium hydroxide pellets EMPROVE® ESSENTIAL Ph Eur,BP,FCC,JP,NF,E 524
F20220000358	106576	Excipient	Topical and sublingual/ Transdermal/Oral		di-Sodium hydrogen phosphate dihydrate EMPROVE® ESSENTIAL Ph Eur,BP,USP
F20230000225	107071	Excipient	Topical and Sublingual, oral		Neotame EMPROVE® ESSENTIAL NF
F20230000213	107267	Excipient	Parenteral, Inhalation, Ophthalmic, Topical and sublingual, Transdermal, Oral		L-Phenylalanine EMPROVE® EXPERT Ph Eur,USP
F20230000231	107430	Excipient	Parenteral, Inhalation, Ophthalmic, Topical and sublingual, Transdermal, Oral		L-Proline EMPROVE® EXPERT Ph Eur,JP,USP
F20190000122	107583	Excipient	Oral	√	Parteck® SI 150 (Sorbitol) EMPROVE® ESSENTIAL Ph Eur,ChP,BP,JP,NF,JSFA,E 420

Registration No.	Cat. No.	Usage as	Administration Route	ChP Compliance	Product Description
F20220000168	108212	Excipient	Topical and sublingual/ Transdermal/Oral		Parteck® PLX 188 (Poloxamer 188) (stabilized with 70ppm BHT) EMPROVE® ESSENTIAL Ph Eur,NF
F20220000347	108346	Excipient	Parenteral inhalation/ Ophthalmic/Topical and sublingual/Transdermal/Oral		D(+)-Glucose monohydrate EMPROVE® EXPERT Ph Eur,BP,JP,USP
F20170000101	108386	Excipient	Parenteral	√	Tris(hydroxymethyl)aminomethane (Trometamol) EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JPC,USP
F20190000386	108421	Excipient	Oral/Parenteral	√	Titriplex® III (ethylenedinitrilotetraacetic acid disodium salt dihydrate) EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP
F20220000165	108486	Excipient	Topical and sublingual/ Transdermal/Oral	√	Urea cryst. EMPROVE® ESSENTIAL Ph Eur,BP,ChP,USP,JP
F20190000157	108800	Excipient	Parenteral/Transdermal/Oral		Zinc acetate dihydrate EMPROVE® ESSENTIAL Ph Eur,USP
F20200000381	108846	Excipient	Oral/Parenteral/ Transdermal	√	Zinc oxide EMPROVE® ESSENTIAL Ph Eur, ChP, BP, JP, USP
F20190000538	108915	Excipient	Injection		Zinc chloride Ph Eur,BP,USP
F20220000349	112488	Excipient	Parenteral/Inhalation/ Ophthalmic/Topical and sublingual/Transdermal/Oral		N-Acetyl-DL-tryptophan EMPROVE® EXPERT Ph Eur,BP
F20180001170	112635	Excipient	Oral	√	Parteck® Delta M (Mannitol) EMPROVE® ESSENTIAL Ph Eur,BP,USP,ChP, JP,E 421
F20210000487	128201	Excipient	Topical and sublingual/ Transdermal/Oral	√	Sodium acetate anhydrous EMPROVE® ESSENTIAL ChP,USP,FCC,E 262
F20210000488	128202	Excipient	Injection/Ophthalmic preparation/Topical and sublingual/Transdermal/Oral/ Other	√	Sodium acetate anhydrous EMPROVE® EXPERT ChP,USP
F20200000498	128205	Excipient	Injection/Ophthalmic/Oral	√	Sodium acetate trihydrate EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20220000352	128209	Excipient	Topical and sublingual/ Transdermal/Oral	√	Zinc sulfate heptahydrate EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP
F20210000453	128211	Excipient	topical and sublingual/ Transdermal/Oral	√	Sodium sulfate anhydrous EMPROVE® ESSENTIAL Ph Eur,BP,ChP,USP,E 514
F20200000042	128218	Excipient	Injection/Oral	√	Ammonium sulfate EMPROVE® EXPERT ACS, ChP, NF
F20210000456	128221	Excipient	Injection/Ophthalmic preparation/ topical and sublingual/ Transdermal/ Oral administration/Other		Zinc chloride EMPROVE® EXPERT Ph Eur,BP,USP
F20220000264	128222	Excipient	Topical and sublingual/ Transdermal/Oral		Iron(III)-chloride-hexahydrate EMPROVE® ESSENTIAL Ph Eur,JPE
F20210000452	128225	Excipient	Parenteral/Inhalation/ Ophthalmic	√	Sodium sulfate anhydrous EMPROVE® EXPERT Ph Eur,BP,ChP,USP
F20190000387	137004	Excipient	Oral/Parenteral	√	Titriplex® III (ethylene dinitrilo tetraacetic acid disodium salt dihydrate) EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP,ACS
F20200000063	137017	Excipient	Oral/Injection/Ophthalmic preparation/Topical and sublingual/Transdermal	√	Sodium chloride EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20220000359	137020	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ Topical and sublingual/ Transdermal/Oral		Sodium hydroxide pellets EMPROVE® EXPERT Ph Eur,BP,JP,NF
F20220000197	137028	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ topical and sublingual/ Transdermal/Oral		Glycerol anhydrous (vegetable) EMPROVE® EXPERT Ph Eur,BP,JP,USP,ACS
F20180000870	137096	Excipient	Parenteral	√	D(-)-Mannitol EMPROVE® EXPERT Ph Eur,BP,USP,ChP,JP
F20220000167	137112	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ topical and sublingual/ Transdermal/Oral	√	Poloxamer 188 EMPROVE® EXPERT (stabilized with 70ppm BHT) Ph Eur,NF

Registration No.	Cat. No.	Usage as	Administration Route	ChP Compliance	Product Description
F20180001619	137120	Excipient	Injection	✓	Benzyl Alcohol EMPROVE® EXPERT Ph Eur,ChP,JP,NF
F20220000161	137171	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ topical and sublingual/ Transdermal/Oral	✓	Polysorbate 80 high purity EMPROVE® EXPERT Ph Eur,ChP,JP,NF
F20220000162	137172	Excipient	Parenteral/Inhalation/ Ophthalmic preparation/ topical and sublingual/ Transdermal/Oral	✓	Polysorbate 20 high purity EMPROVE® EXPERT Ph Eur,ChP,JPE,NF
F20210000254	141350	Excipient	Oral/Ophthalmic/Transdermal	✓	Polyvinyl alcohol 4-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
F20190000493	141353	Excipient	Ophthalmic/Transdermal/Oral	✓	Polyvinyl alcohol 40-88 EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
F20190000494	141355	Excipient	Ophthalmic/Transdermal/Oral	✓	Polyvinyl alcohol 18-88 EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
F20190000562	141439	Excipient	Oral	✓	Parteck® SRP 80 (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
F20210000044	141464	Excipient	Oral	✓	Parteck® MXP (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur,JPE,USP
F20200000177	171597	Excipient	Injection/Topical and sublingual/Oral	✓	Parteck® SI 400 LEX (Sorbitol) EMPROVE® EXPERT Ph Eur,BP,ChP,NF,JP
F20210000543	585807	Excipient	Parenteral		ALC-0315
F20220000145	586054	Excipient	Parenteral		ALC-0159
Y20190009001	603430	API	Oral		Urea-13C, UBT Grade
F20200000193	817059	Excipient	Topical and sublingual/ Transdermal/Oral	✓	Triethyl citrate EMPROVE® ESSENTIAL Ph Eur,ChP,JPE,NF
F20180001635	817081	Excipient	Parenteral	✓	Sodium caprylate EMPROVE® EXPERT Ph Eur,ChP,NF

If you want to raise a registration request for a API/Excipient that you don't find in that list, please contact your local representative.

Please understand that the registration requests are prioritized with respect to our final marketing decision.

To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645 Spain: 901 516 645 Option 1
Germany: 069 86798021 Switzerland: 0848 645 645
Italy: 848 845 645 United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: [MerckMillipore.com/offices](https://www.MerckMillipore.com/offices)

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Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

