

Croda Pharma

FDA IID listed products

Injectable

Nasal and Auricular

Ophthalmic

Oral

Topical

Transdermal

Vaginal and Rectal

Smart science to improve lives™

CRODA

Injectable



| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/daily exposure | Product description |
|---|------------|---|------------------|-------|--------------------------------------|---|--|---|
| 1,2-distearoyl-sn-glycero-3-phosphocholine | 043PI2M0K | DSPC | Solid | - | - | IV | 2.8% or 50mg | Among the main components of biological membranes, drives the formation of encapsulation and provides structure to LNPs, and prevents premature breakdown of LNPs |
| Benzyl Alcohol | LKG8494WBH | Super Refined™ Benzyl Alcohol | Liquid | 12.9 | USP-NF, Ph. Eur., JP/JPE | ENDO EP IM IS IV ST SUB | 0.9% 1% 0.9 - 2% 0.92% 0.9 - 10.3% or 144 - 180mg 0.92 - 1% 0.9 - 0.95% or 469.8mg | High purity aromatic alcohol can be used as a preservative, solvent, and viscosity reducing agent for injectable dosage forms. |
| Castor Oil | D5340Y2I9G | Super Refined™ Castor Oil | Liquid | 14.0* | USP, Ph. Eur., JP/JPE, ChP | IM | 30% - None listed, 274mg** | Highly purified castor oil, used as an emulsifying and solubilising agent. |
| Cholesterol | 97C5T2UQ7J | Cholesterol (synthetic) | Solid | - | USP-NF, Ph. Eur., JP/JPE | IF IV EP | 0.47% 0.32% or 52 - 437mg 0.33% | Cholesterol is currently the only sterol used in Commercial production of LNPs, and provides stability to the particle. |
| Corn Oil | 8470G57WFM | Super Refined™ Corn Oil Super Refined™ Corn Oil NP | Liquid Liquid | 7.9* | USP-NF USP-NF, Ph. Eur. | IM | None listed | Highly purified, corn-derived solvent for IM injections. |
| Cottonseed Oil | H3E878020N | Super Refined™ Cottonseed Super Refined™ Cottonseed NP | Liquid Liquid | 7.9* | USP-NF USP-NF | IM | 56 - 87.46% | Highly purified, cottonseed-derived solvent and vehicle for injections. |
| Medium-Chain Triglycerides | C9H2L21V7U | Super Refined™ GTCC | Liquid | 10.0* | USP-NF, Ph. Eur., JP/JPE, ChP | IV SUB | 1.1% 990.3mg | Solubiliser and carrier for oil soluble actives. Proven in parenteral applications. |
| Oleic Acid | 2UMI9U37CP | Super Refined™ Oleic Acid | Liquid | - | USP-NF, Ph. Eur., JP/JPE | IV | 0.03% | Highly purified oleic acid that acts as an emulsifier. |
| Peanut Oil | 5TL50QU0W4 | Super Refined™ Peanut Oil Super Refined™ Peanut NP | Liquid Liquid | 7.8* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | IM | None listed | Highly purified peanut oil ideal for sustained-release and controlled-release IM injections. |
| PEG-15 Hydroxystearates (Polyoxyl 15 Hydroxystearate) | 71YMM1X75O | Crodasol™ HS HP | Solid | - | USP-NF, Ph. Eur. | IV | 4.4% | A high purity nonionic surfactant which provides excellent solubilisation properties. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------|------------|--|----------------------------|-------|---|--|---|---|
| Polyethylene Glycol 300 | 5655G9Y8AQ | Super Refined™ PEG 300 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | IM IV | 50 - 56.4% 44.22 - 65% | Highly purified PEG 300 that is used as a solvent, suspending agent and viscosity modifier. |
| Polyethylene Glycol 400 | B697894SGQ | Super Refined™ PEG 400 Super Refined™ PEG 400 LTG | Liquid Liquid | - | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE, ChP | IM IV | 18% v/v - 20.3% w/v 75.58% or 7470mg | Highly purified PEG 400 used as a solvent, suspending agent and viscosity modifier. Offers enhanced API and formulation stability. |
| Polyethylene Glycol 600 | NL4J9F21N9 | Super Refined™ PEG 600 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | IV | 5% | Highly purified PEG 600 used as a stabiliser. |
| Polyoxyl 35 Castor Oil | 6D4M1DAL6O | Super Refined™ P35 Castor Oil | Liquid | 14.0 | USP-NF, Ph. Eur., JP/JPE | IM IV | 7% 7 - 52.75% or 24945mg** | High purity castor oil derivative can be used as a nonionic solubiliser and emulsifier. |
| Polysorbate 20 | 7T1F30V5YH | Tween™ 20 HP Super Refined™ Polysorbate 20 | Liquid Liquid | 16.7 | USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | SUB IM IV SUB | 7% 0.16 - 1.62% or 18mg 1% - None listed None listed | O/W emulsifier, solubiliser, wetting and dispersing agent. Effective solubilising agent for oil soluble vitamins and essential oils. Minimises drug interaction with the excipient. |
| Polysorbate 80 | 6OZP39ZG8H | Tween™ 80 HP Super Refined™ Polysorbate 80 Super Refined™ Polysorbate 80 POA | Liquid Liquid Liquid | 15.0 | USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | IA IB IL IM IS IV IVIT | 0.19 - 0.2% or 5mg 0.04% 0.19% 0.1 - 5% or 2mg 0.19 - 0.2% 0.5 - 96.3% or 53 - 125mg 0.02% | Low moisture, low peroxide, O/W emulsifier, solubiliser and wetting agent. Recommended when formulating with highly sensitive and unstable APIs. Super Refining removes polar impurities, preventing reactions with APIs and enhancing stability. |
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP, JP/JPE, ChP | IM IV | 41.6 - 82.04% 5 - 82.04% | Highly purified propylene glycol for use as a solvent and preservative. Dissolves a wide variety of materials and is similar to ethanol as an antiseptic. |
| Sesame Oil | QX10HYY4QV | Super Refined™ Sesame Oil Super Refined™ Sesame Oil NP | Liquid Liquid | 7.8* | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE | IM | 70% v/v | High purity sesame-derived triglyceride, used as a solvent for sustained-release IM injections. |
| Sorbitan Monolaurate | 6W9PS8B71J | Span™ 20 HP | Liquid | 8.6 | USP-NF, Ph. Eur., JP/JPE, ChP | IM | 0.38% | O/W co-emulsifier soluble in fatty compositions and solvents and dispersible in water, acids and alkalis useful in oral preparations. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|---|------------|---|------------------|------|--------------------------------------|--------------|--------------------------------|--|
| Sodium N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine | 3L6NN8ZZKU | DSPE PEG 2000 | Liquid | - | - | IV | 1 - 129mg | Functional lipid that forms the exterior shell and stabilises the LNP, drives the size of the particles and shields the LNP from the immune system until entry into cells is achieved. |
| Soybean Oil | 241ATL177A | Super Refined™ Soybean Oil Super Refined™ Soybean Oil NP | Liquid Liquid | 7.7* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | IV | 2.75 -20% | High purity soy-derived triglyceride used as vehicle and fat source for IV applications. |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|------|---|
| ENDO | ENDOTRACHEAL; INJECTION |
| EP | EPIDURAL; INJECTION, SUSPENSION, LIPOSOMAL |
| IA | INTRA-ARTICULAR; INJECTION, SUSPENSION INTRA-ARTICULAR; INJECTION, SUSPENSION, EXTENDED RELEASE |
| IB | INTRABURSAL; INJECTION |
| IC | INTRACAVITARY; INJECTION INTRACAVITARY; INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION |
| IF | IUSP-NFILTRATION; INJECTABLE, LIPOSOMAL |
| IL | INTRALESIONAL; INJECTION INTRALESIONAL; INJECTION, SUSPENSION |

| Key | Route/Dosage form |
|------|--|
| IVIT | INTRAVITREAL; INJECTION, SUSPENSION |
| ST | SOFT TISSUE; INJECTION |
| SUB | SUBCUTANEOUS; INJECTION SUBCUTANEOUS; INJECTION, SOLUTION |

| Key | Route/Dosage form |
|-----|---|
| IM | INTRAMUSCULAR; INJECTION INTRAMUSCULAR; INJECTION, SUSPENSION, EXTENDED RELEASE INTRAMUSCULAR; INJECTION, POWDER, FOR SUSPENSION INTRAMUSCULAR; INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION INTRAMUSCULAR; SOLUTION |
| IS | INTRASYNOVIAL; INJECTION INTRASYNOVIAL; SUSPENSION, INJECTION |
| ITY | INTRATYMPANIC; SUSPENSION |
| IV | INTRAVENOUS; SOLUTION INTRAVENOUS; INJECTION, POWDER, FOR SOLUTION INTRAVENOUS; CONCENTRATE INTRAVENOUS; LIQUID INTRAVENOUS; SOLUTION, CONCENTRATE INTRAVENOUS; INJECTABLE, LIPOSOMAL INTRAVENOUS; INJECTION, POWDER, FOR SUSPENSION INTRAVENOUS; INJECTION, SUSPENSION, LIPOSOMAL INTRAVENOUS; INJECTION, SUSPENSION |

Non-warranty

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Nasal and Auricular



| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------|------------|--|----------------------------------|-------|--|--------------|--------------------------------|--|
| Benzyl Alcohol | LKG8494WBH | Super Refined™ Benzyl Alcohol | Liquid | 12.9 | USP-NF, Ph. Eur., JP/JPE | AO NS | 0.9% 5mg/ml or 1.08mg/0.2ml | High purity aromatic alcohol can be used as a preservative, solvent, and viscosity reducing agent. |
| Castor Oil | D5340Y2I9G | Super Refined™ Castor Oil | Liquid | 14.0* | USP-NF, Ph. Eur., JP/JPE | NS | 214.4mg - None listed | Highly purified castor oil, used as an emulsifying and solubilising agent. |
| Cetyl Alcohol | 936JST6JCN | Crodacol™ C70 Crodacol™ C95 | Pastille Pastille | - | USP-NF, Ph. Eur. | AO | 1% | Natural, saturated fatty alcohol that acts as an emulsion thickener and stabiliser. |
| Cottonseed Oil | H3E878020N | Super Refined™ Cottonseed Super Refined™ Cottonseed NP | Liquid Liquid | 7.9* | USP-NF USP-NF | NS | 50.5mg | Cotton-derived triglyceride used as a solvent |
| Glyceryl Monostearate | 230OU9XXE4 | Cithrol™ GMS 40 pharma | Solid | 13.4 | USP-NF | AO | 0.5% | Nonionic, O/W and W/O emulsifier and emulsion stabiliser dispersant and emollient. Forms sustained release matrices. |
| Isopropyl Myristate | 0RE8K4LNJS | Crodamol™ IPM pharma Super Refined™ IPM | Liquid Liquid | 10.0* | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE | AO | 3.85% w/v or 0.02% w/w | Solvent used to encourage rapid absorption into skin. |
| Lanolin | 7EV65EAW6H | Medilan™ Medilan™ Super Medilan™ Ultra Pharmalan™ | Solid Solid Solid Solid | - | USP, Ph. Eur. USP-NF USP-NF USP-NF | NS | None listed | Purified medical grade lanolin, serves as a long lasting emollient and moisturiser with exceptional aesthetic properties. |
| Oleic Acid | 2UMI9U37CP | Super Refined™ Oleic Acid | Liquid | - | USP-NF, Ph. Eur., JP/JPE | NS | 0.01% w/w | Highly purified oleic acid that acts as an emulsifier. |
| Oleth-O2 | 7L6R1SQ6M0 | Super Refined™ Brij O2 | Liquid | 4.9 | - | AO | 33mg** | Brij O2 is a naturally derived alcohol ethoxylate. It can be utilised as a solubiliser or in emulsifier systems where a low HLB value is required. |
| Peanut Oil | 5TL50QU0W4 | Super Refined™ Peanut Oil Super Refined™ Peanut Oil NP | Liquid Liquid | 7.8 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | AO | 48.3% | High purity topical vehicle and solvent. |
| Petrolatum | 4T6H12BN9U | Super Refined™ Petrolatum | Solid | - | USP, Ph. Eur., JP/JPE, ChP | AO | None listed | Versatile, high-performance petrolatum with improved stability against oil- water separation and excellent oxidative stability. |
| Polyethylene Glycol 300 | 5655G9Y8AQ | Super Refined™ PEG 300 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | AO | 97.43% | Highly purified PEG 300 used as a solvent and stabiliser. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------|------------|--|--------------------------------------|-------|---|--------------|--|--|
| Polyethylene Glycol 400 | B697894SGQ | Super Refined™ PEG 400 Super Refined™ PEG 400 LTG | Liquid Liquid | - | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE, ChP | NS | 200mg | Highly purified PEG 400 that enhances active and formulation stability. |
| Polyoxyl 40 Stearate | 13A4J4NH9I | Myrj™ S40 pharma | Solid | 16.7 | USP-NF, Ph. Eur., ChP | AO | 1% | Nonionic, versatile O/W emulsifier giving systems optimum stability. |
| Polysorbate 20 | 7T1F30V5YH | Tween™ 20 pharma Tween™ 20 HP Super Refined™ Polysorbate 20 | Liquid Liquid Liquid | 16.7 | USP-NF USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | AO NS | 0.1% 25 - 27mg | O/W emulsifier, solubiliser, wetting and dispersing agent. |
| Polysorbate 80 | 6OZP39ZG8H | Tween™ 80 pharma Tween™ 80 HP Super Refined™ Polysorbate 80 Super Refined™ Polysorbate 80 POA | Liquid Liquid Liquid Liquid | 15.0 | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | AO NS | 0.02 - 2.5% 0.05mg - None listed | Low moisture, low peroxide, O/W emulsifier, solubiliser and wetting agent. Recommended when formulating with highly sensitive APIs. |
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP, JP/JPE, ChP | AO NS | 10 - 56.55% or ADJ PH 50mg or 12000mg/100ml | Highly purified propylene glycol ideal for use as a solvent and preservative. Dissolves a wide variety of materials and useful as an antiseptic. |
| Sorbitan Monolaurate | 6W9PS8B71J | Span™ 20 pharma Span™ 20 HP | Liquid Liquid | 8.6 | Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP | NS | 22.9mg | O/W co-emulsifier; dispersible in water, acids and alkalis. |
| Sorbitan Trioleate | QE6F49RPJ1 | Span™ 85 pharma | Liquid | 1.8 | Ph. Eur. | NS | 0.86%w/w - None listed | W/O emulsifier and stabiliser in nasal dose forms. |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|-----|--------------------------------------|
| AO | AURICULAR (OTIC); OIL |
| | AURICULAR (OTIC); DROPS |
| | AURICULAR (OTIC); SOLUTION |
| | AURICULAR (OTIC); SOLUTION, DROPS |
| | AURICULAR (OTIC); SUSPENSION |
| NS | NASAL; AEROSOL, METERED |
| | NASAL; AEROSOL, SPRAY |
| | NASAL; GEL |
| | NASAL; SOLUTION |
| | NASAL; SPRAY, METERED |

Non-warranty

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| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|--|------------|--|----------------------------------|-------|---|----------------------------|---------------------------------------|---|
| Castor Oil | D5340Y2I9G | Super Refined™ Castor Oil | Liquid | 14.0* | USP, Ph. Eur., JP/JPE, ChP | OE | 0.15% | Highly purified castor oil, used as an emulsifying and solubilising agent. |
| Cetyl Alcohol | 936JST6JCN | Crodacol™ C70 Crodacol™ C95 | Pastille Pastille | - | USP-NF, Ph. Eur. | OSUS | 0.5% | Natural, saturated fatty alcohol that acts as an emulsion thickener and stabiliser. |
| Glyceryl Monostearate | 230OU9XXE4 | Cithrol™ GMS 40 pharma | Solid | 3.4 | USP-NF | OSUS | 0.5% | Nonionic, O/W and W/O emulsifier and emulsion stabiliser dispersant and emollient. Forms sustained release matrices. |
| Lanolin Alcohol | 884C3FA9HE | Super Hartolan™ pharma | Pastille | - | USP-NF, Ph. Eur. | OO | 10% | Powerful emulsifier and emulsion stabiliser. |
| Lanolin | 7EV65EAW6H | Medilan™ Medilan™ Super Medilan™ Ultra Pharmalan™ | Solid Solid Solid Solid | - | USP, Ph. Eur. USP-NF USP-NF USP-NF | OO | 3% w/w | Purified medical grade lanolin that serves as a long lasting emollient and moisturiser with exceptional aesthetic properties. |
| Peanut Oil | 5TL50QU0W4 | Super Refined™ Peanut Oil Super Refined™ Peanut Oil NP | Liquid Liquid | 7.8* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | OSOL | None listed | High purity peanut-derived triglyceride used as a solvent. |
| PEG-15 Hydroxystearate (Polyoxyl 15 Hydroxystearate) | 71YMM1X75O | Crodasol™ HS HP | Solid | - | USP-NF, Ph. Eur. | OE | 0.25% | A high purity nonionic surfactant which provides excellent solubilisation properties. |
| Petrolatum | 4T6H12BN9U | Super Refined™ Petrolatum | Solid | - | USP, Ph. Eur., JP/JPE, ChP | OO | 97% w/w | Versatile, high-performance petrolatum with improved stability against oil- water separation and excellent oxidative stability. |
| Poloxamer 188 | LQA7B6G8JG | Synperonic™ PE/F 68 pharma | Solid | - | USP-NF, Ph. Eur. | OSOL | 0.1% | Effective solubiliser and O/W emulsifier. |
| Poloxamer 407 | TUF2IVW3M2 | Synperonic™ PE/F 127 | Solid | - | USP-NF, Ph. Eur. | OG OSOL OSUS-D OO | 2% w/w 0.2% 0.1% None listed | Solubiliser used in contact solutions and eyedrops. |
| Polyethylene Glycol 300 | 5655G9Y8AQ | Super Refined™ PEG 300 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | OSOL | None listed | High purity solvent and suspending agent. |
| Polyethylene Glycol 400 | B697894SGQ | Super Refined™ PEG 400 Super Refined™ PEG 400 LTG | Liquid Liquid | - | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE, ChP | OSOL OSOL-DP | 4% w/w 1% | Highly purified PEG 400 that enhances active and formulation stability. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------------------|------------|---|--------------------------------------|-------|---|---|--|--|
| Polyoxyl 35 Castor Oil | 6D4M1DAL6O | Super Refined™ P35 Castor Oil | Liquid | 14.0 | USP-NF, Ph. Eur., JP/JPE | OSOL OSOL-D | 5% 4.86% | High purity castor oil derivative can be used as a nonionic solubiliser and emulsifier. |
| Polyoxyl 40 Hydrogenated Castor Oil | 7YC686GQ8F | Croduret™ 40 pharma | Solid | 13.0 | USP-NF, Ph. Eur. | OSOL OSOL-D | 1% 0.53% | Nonionic surfactant, emollient and stabiliser. |
| Polyoxyl 40 Stearate | 13A4J4NH9I | Myrj™ S40 pharma | Solid | 16.7 | USP-NF, Ph. Eur., ChP | OO OSOL OSUS | None listed 7% w/w 0.5% | Nonionic, versatile O/W emulsifier giving systems optimum stability. |
| Polysorbate 20 | 7T1F30V5YH | Tween™ 20 pharma Tween™ 20 HP Super Refined™ Polysorbate 20 | Liquid Liquid Liquid | 16.7 | USP-NF USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | OSUS | 0.05% | O/W emulsifier, solubiliser, wetting and dispersing agent. |
| Polysorbate 80 | 6OZP39ZG8H | Tween™ 80 pharma Tween™ 80 HP Super Refined™ Polysorbate 80 Super Refined™ Polysorbate 80 POA | Liquid Liquid Liquid Liquid | 15.0 | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | OD OE OSOL OSOL-D OSOL-GE OSUS OSUS-D | 0.05% w/w 4% 0.25% 0.15% 0.05% w/w 0.1% w/w 0.1% w/w | Low moisture, low peroxide, O/W emulsifier, solubiliser and wetting agent. Recommended when formulating with highly sensitive APIs. |
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP-NF, JP/JPE, ChP | OE OG OSOL OSOL-D OSUS OSUS-DP | 1.5% 4.4% w/w 1% 0.75% 0.75% 1% v/v | Highly purified propylene glycol ideal for use as a solvent and preservative. Dissolves a wide variety of materials and useful as an antiseptic. |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|---------|--|
| OD | OPHTHALMIC, DROPS |
| OE | OPHTHALMIC, EMULSION |
| OG | OPHTHALMIC, GEL |
| OO | OPHTHALMIC, OINTMENT |
| OS-DR | OPHTHALMIC, DROPS |
| OSOL | OPHTHALMIC, SOLUTION |
| OSOL-D | OPHTHALMIC, SOLUTION, DROPS |
| OSOL-GE | OPHTHALMIC SOLUTION, GEL FORMING, EXTENDED RELEASE |
| OSUS | OPHTHALMIC, SUSPENSION |
| OSUS-D | OPHTHALMIC SUSPENSION, DROPS |

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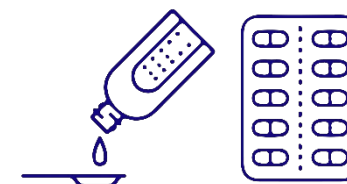
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Croda Pharma

Oral



| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|--------------------------------------|------------|---|----------------------|-------|--------------------------------------|-----------------------------|--|---|
| Beeswax (White Wax) | 7G1J5DA97F | Super Refined™ Beeswax | Solid | - | USP-NF, Ph. Eur., JP/JPE | OCAP OT | 15.3 - 18.36 mg 0.08 - 14 mg | Highly purified beeswax, used in sustained release oral dosage forms. |
| Benzyl Alcohol | LKG8494WBH | Super Refined™ Benzyl Alcohol | Liquid | 12.9 | USP-NF, Ph. Eur., JP/JPE | OCAP OSOLN OSUS OT | 1.23 - 50 mg 50mg/ml 100mg** 1.06 - 2.31 mg | High purity aromatic alcohol can be used as a preservative, solvent, and viscosity reducing agent. |
| Caprylocaproyl Polyoxyl-glycerides 8 | 00BT03FSO2 | Crodasol™ CCMG 400 pharma Super Refined™ CCMG 400 | Liquid | 12.0 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | OCAP OSOLN | 274.7MG or 3623 mg** 61.2 mg/ml | Mixture of caprylocaproyl macroglycerides that demonstrates amphiphilic characteristics and is primarily used in oral pharmaceutical applications. |
| Castor Oil | D5340Y2I9G | Super Refined™ Castor Oil | Liquid | 14.0* | USP, Ph. Eur., JP/JPE, ChP | OCAP OG OT SUB | 1.04 - 1.76 mg 32.1 mg/5 ml 0.01 - 23.27mg or None Listed 1.60 mg | Highly purified fatty acid triglyceride, ideal for solubilising and emulsifying applications. |
| Cetostearyl Alcohol | 2DMT128M1S | Crodacol™ CS50 Crodacol™ CS90 | Pastille Pastille | - | USP-NF USP-NF, Ph. Eur. | OT OCAP | 62mg or 800mg** 9.43mg | Stabiliser, co-emulsifier and thickener. |
| Cetyl Alcohol | 936JST6JCN | Crodacol™ C70 Crodacol™ C95 | Pastille Pastille | - | USP-NF, Ph. Eur. | OCAP OT | 0.96 - 12.5mg 0.25 - 59mg or 9mg** | Natural, saturated, vegetable-derived fatty alcohol used in delayed release applications. |
| Cetyl Esters Wax | D072FFP9GU | Crodamol™ SS pharma | Pastille | 7.0* | USP-NF | OP | None Listed | Vegetable derived bodying agent |
| Corn Oil | 8470G57WFM | Super Refined™ Corn Oil Super Refined™ Corn Oil NP | Liquid Liquid | 7.9* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | OCAP OSUS OT SUB | 918mg 2.5ml/5ml or 2.56mg/5ml 0.03 - 20mg or None Listed 1.7mg | Highly purified corn-derived triglyceride, used in tablets or capsules for oral dosage. |
| Cottonseed Oil | H3E878020N | Super Refined™ Cottonseed Super Refined™ Cottonseed NP | Liquid Liquid | 7.9* | USP-NF USP-NF | OCAP OT | None Listed 0.16mg | Highly purified tablet binder and mild cathartic |
| Glyceryl Monocapryl-ocaprate | G7515SW10N | Crodamol™ GMCC pharma | Solid | - | USP-NF, Ph. Eur. | OCAP | 375 - 502mg** | A mixture of monoglycerides and diglycerides of caprylic and capric acids. It functions as a skin-conditioning agent/ emollient, and as a surfactant/emulsifying agent. It can be prepared by esterification of glycerin with specific fatty acids. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|--|------------|---|------------------|-------|---|-----------------------------------|---|--|
| Glyceryl Monostearate | 230OU9XXE4 | Cithrol™ GMS 40 pharma | Solid | 3.4 | USP-NF, Ph. Eur. | OE OT | None listed 0.25 - 264.3mg or 272mg** | Nonionic emulsifier, W/O and O/W emulsion stabiliser and dispersant, used to form sustained release matrices. |
| Glyceryl Oleate | 4PC054V79P | Cithrol™ GMO HP | Solid | 3.0 | USP-NF, Ph. Eur. | OCAP OG SUB | 2.5 - 32.4mg 1.9mg 1.23mg | |
| Glyceryl Stearate/ PEG-100 Stearate | RD25J5V947 | Arlacel™ 165 pharma | Solid | 11.0 | Ph. Eur. | OT | 1.8mg | W/O emulsifier and O/W emulsion stabiliser, offering controlled drug release and enhances active bioavailability. |
| Medium-Chain Triglycerides | C9H2L21V7U | Crodamol™ GTCC Super Refined™ GTCC | Liquid Liquid | 10.0* | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP | OCAP OP OSOLN OSUS OT | 3.08 - 250mg 3390mg/5ml 946mg/ml 3390mg/5ml 0.34 - 0.87mg | Versatile nonionic O/W emulsifier mainly used in non-polar oil phases |
| Oleic Acid | 2UMI9U37CP | Super Refined™ Oleic Acid | Liquid | - | USP-NF, Ph. Eur., JP/JPE | OCAP OT | 619.67mg 0.72mg - None Listed | Solubiliser and carrier for oil soluble actives. Also used as a capsule and tablet filler and lubricant. |
| Olive Oil | 6UYK2W1W1E | Super Refined™ Olive Oil | Liquid Liquid | 7.7* | - | OCAP OSOLN | None Listed 425mg/ml | Highly purified oleic acid, used to improve active bioavailability in tablet formulations and soft gel-caps. |
| Peanut Oil | 5TL50QU0W4 | Super Refined™ Peanut Oil Super Refined™ Peanut Oil NP | Liquid Liquid | 7.8* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | OCAP OT | 313.8mg None Listed | Olive-derived triglyceride used as oral capsule lubricant. |
| Peg-7 Linoleoyl Glycerides | 993L8OB0ER | Super Refined™ L18 POG | Liquid | - | USP-NF, Ph. Eur. | OCAP | 300mg | Peanut-derived triglyceride used as a solvent. |
| PEG 8 Stearate | 2P9L47VI5E | Myrj™ S8 pharma | Solid | 10.8 | USP-NF, Ph. Eur. | OCON OSUS | 25mg/5ml 51mg** | Low HLB emulsifier and solubiliser of poorly water-soluble API's. It also exhibits emolliency, humectancy, and skin penetration enhancement properties. O/W emulsifier for oral suspension. Additionally, it can be used as a primary or secondary emulsifier in SEDDS or SMEDDs formulations. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|----------------------------------|------------|--|------------------|-----|---|--|--|--|
| Petrolatum | 4T6H12BN9U | Super Refined™ Petrolatum | Solid | - | USP, Ph. Eur., JP/JPE, ChP | OCAP OT | 0.07mg 0.18 - 3.5mg | Versatile, high-performance petrolatum with improved stability against oil-water separation and excellent oxidative stability. |
| Poloxamer 124 | 1S66E28KXA | Synperonic™ PE/L 44 | Liquid | - | - | OSUS | 0.09mg/ml | O/W emulsifier, cleansing and dispersing agent. |
| Poloxamer 188 | LQA7B6G8JG | Synperonic™ PE/F 68 pharma | Solid | - | USP-NF, Ph. Eur., JP/JPE | OCAP OCON OG OL OP OSOLN OSUS OT PERIO | 3 - 25.1mg 0.25mg/ml 26mg/5ml 0.5mg/ml 25mg/5ml or 30mg** 100mg/ml 100mg/5ml 3 - 66.9mg 55mg | Effective solubiliser and O/W emulsifier, used in toothpaste and mouthwash applications because of its great foaming properties. |
| Poloxamer 331 | IS93EQR73R | Synperonic™ PE/L 101 | Liquid | - | - | OP OSUS | 26.43 - 1000mg/5ml 12.5mg/5ml | W/O emulsifier used as a wetting agent and effective defoamer. |
| Poloxamer 407 | TUF2IVW3M2 | Synperonic™ PE/F 127 | Solid | - | - | OCAP OP OSOLN OSUS OT PERIO OT | 5 - 117.1mg 0.01mg/mg 50mg/5ml 2.5mg/5ml 106.7 - 110mg 155mg 9mg or 2mg** | O/W emulsifier with superior thermo-reversible gelling properties, ideal for drug delivery systems increasing contact of active at target site. Lacks bitter taste making it suitable for toothpaste. Highly purified PEG 300 used as a stabiliser |
| Polyethylene Glycol 300 | 5655G9Y8AQ | Super Refined™ PEG 300 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | OCAP | 4.4 - 324.5mg or 1378mg** | Highly purified PEG 400 used as a solvent, suspending agent and viscosity modifier. Offers enhanced API and formulation stability. |
| Polyethylene Glycol 400 | B697894SGQ | Super Refined™ PEG 400 Super Refined™ PEG 400 LTG | Liquid Liquid | - | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE, ChP | OCON OF OSOLN OSUS OSY OT | 600mg/ml 4.76mg 562.5mg/ml or 24000mg** 250mg/5ml 74mg/ml 0.8 - 45mg or 2 - 135mg** | Highly purified PEG 400 used as a solvent, suspending agent and viscosity modifier. Offers enhanced API and formulation stability. |
| Polyethylene Glycol 600 | NL4J9F21N9 | Super Refined™ PEG 600 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | OCAP OSOLN OT | 580.6mg or 658mg** 650mg/5ml 2.5mg - None Listed | Highly purified PEG 600 enhances active and formulation stability. |
| Polyoxyl 20 Cetostearyl Ether | YRC528SWUY | Cetomacrogol™ 1000 pharma | Solid | - | USP-NF, Ph. Eur. | OSUS | 20mg** | O/W emulsifier for oral suspension. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------------------|------------|---|----------------------------|-------|---|---|---|---|
| Polyoxyl 35 Castor Oil | 6D4M1DAL6O | Super Refined™ P35 Castor Oil | Liquid | 14.0 | USP-NF, Ph. Eur., JP/JPE | OCAP OSOLN OSUS OT SUB | 599.4mg 50 - 515mg/ml 0.4mg/ml 2 - 5.2mg 2mg | High purity castor oil derivative can be used as a nonionic solubiliser and emulsifier. |
| Polyoxyl 40 Hydrogenated Castor Oil | 7YC686GQ8F | Croduret™ 40 pharma | Liquid | 13.0* | USP-NF, Ph. Eur. | DSOLN OCAP OL OSOLN OT | 1% w/w 101.25mg or 3319mg** 102mg/ml 450mg/ml 50mg or 120mg** | Vegetable-derived nonionic O/W emulsifier and stabiliser that is a tasteless solubiliser for vitamins, mouthwashes, essential oils and drug actives. |
| Polyoxyl 40 Stearate | 13A4J4NH9I | Myrj™ S40 pharma | Solid | 16.7 | USP-NF, Ph. Eur., ChP | OCAP OG OT | 7mg None Listed 2 - 8.48mg | Nonionic, hydrophilic, water soluble, O/W emulsifier used in combination with other emulsifiers to give optimum stability, opacity and texture |
| Polysorbate 20 | 7T1F30V5YH | Tween™ 20 pharma Tween™ 20 HP Super Refined™ Polysorbate 20 | Liquid Liquid Liquid | 16.7 | USP-NF USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | OCAP OP OSUS OT | 56.25mg 1.3mg/5ml 5mg/ml 0.35mg -None listed or 17mg** | O/W emulsifier, solubiliser, wetting and dispersing agent. Effective solubilising agent for oil soluble vitamins, essential oils and flavours in mouthwashes. |
| Polysorbate 40 | ST111B5A2X | Tween™ 40 pharma Tween™ 40 HP | Liquid | 15.6 | USP-NF, Ph. Eur. | ODPS OELX OSUS | 0.02ml 0.05mg/5ml None Listed | O/W emulsifier, co-solvent and wetting agent. |
| Polysorbate 60 | CAL22UVI4M | Tween™ 60 pharma Tween™ 60 HP Super Refined™ Polysorbate 60 | Liquid Liquid Liquid | 14.9 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE | BU OE OSUS OT | 0.23mg 20mg/ml 25mg/5ml None Listed | O/W emulsifier and solubiliser. Super Refined Polysorbate 60 is extremely mild and enhances stability of formulations. |
| Polysorbate 80 | 6OZP39ZG8H | Tween™ 80 Tween™ 80 HP Super Refined™ Polysorbate 80 Super Refined™ Polysorbate 80 POA | Liquid | - | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | OCAP OCON OLEX OG OP OPST OSOLN OSUS OT OTRCH SUB | 0.04 - 418.37mg 1mg/ml 2.5mg/15ml 5mg 66mg or 15mg/5ml 0.92mg/ml 126mg/ml 10-250mg/5ml or 7.5mg/2.5ml 0.3 - 24mg or 350mg** None Listed 0.08mg | Low moisture, low peroxide, O/W emulsifier, solubiliser and wetting agent. Recommend when formulating with highly sensitive and unstable APIs. Super Refining removes polar impurities that prevent reactions with APIs and enhances stability. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|------------------------------|------------|---|------------|-------|---|--------------------------|--|---|
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP, JP/JPE | BU | 1.02 -1.48mg | Highly purified propylene glycol for use as a solvent and preservative. Dissolves a wide variety of materials and is similar to ethanol as an antiseptic. |
| | | | | | | DP | 0.5% w/w | |
| | | | | | | DON | None Listed | |
| | | | | | | DSOLN | 2% w/w | |
| | | | | | | OCAP | 1.7 - 148.31mg or None Listed | |
| | | | | | | OCON | 7000mg** | |
| | | | | | | ODPS | 200mg/ml | |
| | | | | | | OELX | 3108mg/15ml | |
| | | | | | | OL | 540mg/ml | |
| | | | | | | OP | 55mg | |
| | | | | | | OSOLN | 518mg/ml or 3500mg** | |
| | | | | | | OSUS | 1.25mg/ml, 250mg/ml or 3000mg** 5700mg** | |
| | | | | | | OSY | 1.5 - 14.62mg or 25 - 64mg** | |
| Propylene Glycol Monolaurate | 668Z5835Z3 | Super Refined™ PGML | Liquid | 4.5 | USP-NF, Ph. Eur. | OT | 4.5mg/ml | High purity mixture of propylene glycol and esters of lauric (C12) acid used for formulating poorly water-soluble API's into oral and topical formulations. |
| | | | | | | OCAP | 235mg | |
| Sesame Oil | QX10HYY4QV | Super Refined™ Sesame Oil Super Refined™ Sesame Oil NP | Liquid | 7.8* | USP-NF, Ph. Eur., JP/JPE | OCAP | 162.5mg | Highly purified sesame-derived triglyceride, used as a solvent for oil soluble actives in oral capsules, tablets and emulsions |
| | | | Liquid | | | USP-NF, Ph. Eur., JP/JPE | OT | |
| Sorbitan Monolaurate | 6W9PS8B71J | Span™ 20 pharma Span™ 20 HP | Liquid | 8.6 | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP | OCAP | 0.08mg | O/W co-emulsifier which is soluble in fatty compositions and solvents. It is dispersible in water, acids and alkalis and useful in oral preparations. |
| | | | Liquid | | | OE | None listed | |
| | | | | | | OP | 66.7mg | |
| | | | | | | OSUS | 2.5mg/ml | |
| Sorbitan Monooleate | 06XEA2VD56 | Span™ 80 pharma Span™ 80 HP | Liquid | 4.3 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | OCAP | 1.7 - 153.9mg | W/O emulsifier and O/W emulsion stabiliser used as a wetting agent and dispersant. HP grade offers lower moisture, peroxide and acid levels. |
| | | | Liquid | | | OSOLN | 150mg/ml | |
| | | | | | | OT | 0.13 - 7.8mg | |

*Required HLB

**Maximum Daily Exposure

Croda Pharma

Oral

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-----------------------|------------|---|------------------|------|--------------------------------------|------------------|--|--|
| Sorbitan Monostearate | NVZ410H58X | Span™ 60 pharma | Solid | 4.7 | USP-NF, Ph. Eur. | OSUS | 62.5mg/ml | Stable O/W emulsifier with low odour and colour. W/O emulsifier and O/W emulsion stabiliser used in metered dose forms. |
| | | | Solid | | USP-NF, Ph. Eur., JP/JPE | OT | 3.5mg | |
| Sorbitan Trioleate | QE6F49RPJ1 | Span™ 85 pharma | Liquid | 1.8 | Ph. Eur. | OCAP OP OT | None listed 1.5mg/ml None listed | |
| Soybean Oil | 241ATL177A | Super Refined™ Soybean Oil Super Refined™ Soybean Oil NP | Liquid Liquid | 7.7* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | OCAP OT | 129.87 - 283.53mg 0.14mg | Soybean-derived triglyceride used as a vehicle in drug administration. |
| Squalane | GW89575KF9 | Pripure™ 3759 | Liquid | - | - | OP | 0.02mg | Biomimetic skin lipid with excellent spreading and moisturizing properties. Imparts a soft, silky, velvety feel. |
| Stearyl Alcohol | 2KR89I4H1Y | Crodacol™ S95 | Pastille | - | USP-NF, Ph. Eur. | OCAP OP OT | 72mg 0.11mg 20 - 244mg or 120mg** | Natural, vegetable-derived, saturated fatty alcohol. Insoluble in water and soluble in ethanol. |
| Sucrose Stearate | 274KW0050M | Crodesta™ F160 | Solid | - | - | OCAP OT | 44.57mg 10.89 - 44.56mg | Mild O/W emulsifier that reduces irritation in non-alkaline and non-soap emulsions. |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|-------|---|
| BU | BUCCAL; FILM BUCCAL; FILM, SOLUBLE BUCCAL; GUM, CHEWING |
| DP | DENTAL; PASTE |
| DON | DENTAL; OINTMENT |
| DSOLN | DENTAL; SOLUTION |
| PERIO | PERIDONTAL; GEL |
| OCAP | ORAL; CAPSULE ORAL; CAPSULE, COATED ORAL; CAPSULE, COATED, EXTENDED RELEASE ORAL; CAPSULE, COATED PELLETS ORAL; CAPSULE, DELAYED RELEASE ORAL; CAPSULE, EXTENDED RELEASE ORAL; CAPSULE, FOR SUSPENSION ORAL; CAPSULE, LIQUID FILLED |
| OCON | ORAL; CONCENTRATE |

| Key | Route/Dosage form |
|-------|---|
| ODPS | ORAL; DROPS |
| OE | ORAL; EMULSION |
| OLEX | ORAL; ELIXIR |
| OF | ORAL; FILM, SOLUBLE |
| OG | ORAL; GRANULE ORAL; GRANULE, FOR SOLUTION ORAL; GRANULE, FOR SUSPENSION |
| OL | ORAL; LIQUID ORAL; LIQUID, EXTENDED RELEASE |
| OP | ORAL; POWDER ORAL; POWDER, FOR SOLUTION ORAL; POWDER, FOR SUSPENSION |
| OPST | ORAL; PASTE |
| OSOLN | ORAL; SOLUTION ORAL; SOLUTION CONCENTRATE |

| Key | Route/Dosage form |
|-------|---|
| OSUS | ORAL; SUSPENSION ORAL; SUSPENSION, DROPS ORAL; SUSPENSION, EXTENDED RELEASE |
| OSY | ORAL; SYRUP |
| OT | ORAL; TABLET ORAL; TABLET, CHEWABLE ORAL; TABLET, COATED ORAL; TABLET, COATED PARTICLES ORAL; TABLET, EXTENDED RELEASE ORAL; TABLET, FILM COATED ORAL; TABLET, FILM COATED, EXTENDED RELEASE ORAL; TABLET, ORALLY DISINTEGRATING ORAL; TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE |
| OTRCH | ORAL; TRIOCHE |
| SUB | SUBLINGUAL; SPRAY SUBLINGUAL; TABLET |

Non-warranty

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Croda Pharma

Topical



| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/daily exposure | Product description |
|---------------------|-------------|----------------------------------|----------------------|-------|-------------------------------|--|---|---|
| Beeswax (White Wax) | 7G1J5DA97F | Super Refined™ Beeswax | Solid | - | USP-NF, Ph. Eur., JP/JPE | TON TC TL | 7.3% 10% 1% | Highly purified beeswax used to increase viscosity of creams & ointments. |
| Beeswax (Synthetic) | None Listed | Syncrowax™ BB4 | Pastille | - | - | TC | 3.5% | Beeswax alternative to build viscosity. |
| Benzyl Alcohol | LKG8494WBH | Super Refined™ Benzyl Alcohol | Liquid | 12.9 | USP-NF, Ph. Eur., JP/JPE | TC TG TL TON TSH TSOLN TSUS TT | 1 - 2.7% 2% 2% 2.2% 1.25% 2% 1% None listed | High purity aromatic alcohol can be used as a preservative, solvent, and viscosity reducing agent. |
| Castor Oil | D5340Y2I9G | Super Refined™ Castor Oil | Liquid | 14.0* | USP-NF, Ph. Eur., JP/JPE, ChP | TON TSOLN | 14.9% None listed | Highly purified fatty acid triglyceride, ideal for solubilising and emulsifying applications. |
| Ceteth-10 | LF9X1PN3XJ | Brij™ C10 | Solid | - | - | TL | 2.5% | Waxy O/W emulsifier stable over wide pH range. |
| Ceteth-20 | I835H2IHHX | Brij™ C20 | Solid | - | - | TC TL TSOL | 6% 2% 2% | Versatile, biodegradable O/W emulsifier compatible with nonionic surfactants, most anionic and cationic surfactants, and stable over a wide pH range. |
| Cetostearyl Alcohol | 2DMT128M1S | Crodacol™ CS50 Crodacol™ CS90 | Pastille Pastille | - | USP-NF USP-NF, Ph. Eur. | TA TC TL TSPY TON TSUS TT | 1.09% 12% 5% 1% 1.2% 2.5% None listed | Stabiliser, co-emulsifier, thickener used in cream bases. |
| Cetyl Alcohol | 936JST6JCN | Crodacol™ C70 Crodacol™ C95 | Pastille Pastille | - | USP-NF, Ph. Eur. | TA TC TE TL TON TSOLN TSUS TSUP | 3.2% 45% None listed 1% 7% None listed 2.01% 0.03mg/mg | Natural, saturated fatty alcohol of non-animal origin is a wax-like emollient and viscosity builder in creams and lotions. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-----------------------------------|------------|---|------------------|-------|--------------------------------------|---------------------------------------|---|---|
| Cetyl Esters Wax | D072FFP9GU | Crodamol™ SS pharma | Pastille | 7.0* | USP-NF | TC TL TSUP TT | 10.3% 1% None listed None listed | Vegetable derived emollient and bodying agent for creams and ointments. |
| Cetyl Palmitate | 5ZA2S6B08X | Crodamol™ CP pharma | Solid | 10.0* | USP-NF, Ph. Eur. | TC TON TSOLN | 0.32% None listed 0.05% | Dry emollient which Improves emulsion texture and stability. |
| Cholesterol | 97C5T2UQ7J | Cholesterol | Solid | - | USP-NF, Ph. Eur. | TC TL TON | 1% 1.5% 5% | Excellent moisturiser with skin conditioning benefits, powerful W/O emulsifier and emulsion stabiliser. |
| Coco-Betaine | 03DH2IZ3FY | Crodateric™ CAB 30 | Liquid | - | - | TSH | 6% | Mild surfactant with gentle cleansing properties. |
| Cocoyl Caprylocaprate | 8D9H4QU99H | Crodamol™ CCC pharma | Liquid | - | Ph. Eur. | TG | 2.5% | A non-irritating liquid ideal for sensitive site applications. |
| Corn Oil | 8470G57WFM | Super Refined™ Corn Oil Super Refined™ Corn Oil NP | Liquid Liquid | 7.9* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | TC | None listed | High purity corn derived triglyceride used as a solubiliser for poorly water soluble API's. |
| Diethylene Glycol Monoethyl Ether | A1A1I8X02B | Super Refined™ DEGEE | Liquid | 16.0 | USP-NF, Ph. Eur. | TC TG TL TON | 15% 49.91% 10% 5% | High purity glycol ether that can enhance the permeation of poorly water- soluble APIs through various layers of the skin. |
| Diethyl Sebacate | I41B9FJK6V | Crodamol™ SE | Liquid | - | USP-NF, JP/JPE | TL TSOLN | 2.97% 24% | Excellent solubiliser and emulsifier; may be applied as a solvent or dissolution agent. |
| Diisopropyl Adipate | P7E6YFV72X | Crodamol™ DA pharma | Liquid | 9.0* | JP/JPE | TA TC TG TL TSOLN TSPY | 5% 7% 1.5% 20% 10.88% 12% | Low viscosity ester with excellent solvency and spreading properties. |
| Dimethyl Isosorbide | SA6A6V432S | Super Refined™ DMI | Liquid | - | - | TA TC | 5.44% 15% | Enhances transdermal delivery of actives. |
| Emulsifying Wax | Multiple | Polawax™ USP-NF pharma | Pastille | | USP-NF | TA TC TL | 1.05% 24.8% 4% | Emulsifying wax stable in presence of ions, heat and over a wide pH range. Produce liquid crystal emulsions that promote 'time release' hydration with excellent texture and stability. |
| Ethyl Oleate | Z2Z439864Y | Crodamol™ EO pharma | Liquid | 11.0* | USP-NF, Ph. Eur. | TP | 14mg | Low viscosity solvent for lipophilic actives. |
| Ethylhexyl Hydroxystearate | B7180BVV5E | Crodamol™ OHS | Solid | 12.0* | - | TC | 12% | Rich high viscosity branched chain emollient. |
| Glyceryl Isostearate | HYE7O27HAO | Cithrol™ GMIS 40 | Liquid | - | - | TC | 2.7% | Low HLB emulsifier and rich emollient. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|------------------------------------|------------|--|------------------|----------------|---|---|---|--|
| Glyceryl Monostearate | 230OU9XXE4 | Cithrol™ GMS 40 pharma | Solid | 3.4 | USP-NF, Ph. Eur. | TA TC TLIQ TON TL TSUS | 3.27% 20% 1% 5% 9% 1.25% | Nonionic, O/W and W/O emulsifier, emulsion stabiliser, dispersant and emollient. Forms sustained release matrices. |
| Glyceryl Oleate | 4PC054V79P | Cithrol™ GMO HP | Solid | 3.0 | USP-NF, Ph. Eur. | TC TG TSPY | 3.5% 1% 0.95% | High purity oleic acid grade enhances active bioavailability. Membrane penetration enhancer. |
| Glyceryl Stearate/PEG-100 Stearate | RD25J5V947 | Arlacel™ 165 pharma | Solid | - | Ph. Eur. | TC | 7.5% | Versatile nonionic O/W emulsifier mainly used in non-polar oil phases. Tolerates the addition of mildly acidic actives and salts. |
| Isopropyl Isostearate | C67IXB9Y7T | Crodamol™ IPIS pharma | Liquid | 10.5* | USP-NF, Ph. Eur. | TC | 3% | Light, easy spreading emollient offers superb moisturisation and moderate water resistance. |
| Isopropyl Myristate | 0RE8K4LNJS | Crodamol™ IPM pharma Super Refined™ IPM | Liquid Liquid | 10.0* 10.0* | USP-NF, Ph. Eur., JP/JPEE USP-NF, Ph. Eur., JP/JPE | TA TC TG TL TOIL TON TP TSPY TSUP | 9.3% 15% 0.88% w/v 5% 3.12% w/v 35% 7mg 41.3% w/v 0.01mg/mg | Solvent used to encourage rapid absorption into skin. |
| Isopropyl Palmitate | 8CRQ2TH63M | Crodamol™ IPP pharma Super Refined™ IPP | Liquid Liquid | 10.0* | USP-NF, Ph. Eur. USP-NF, JP/JPE | TA TC TG TL TON TSPY | 7.3% 5% None listed 5% None listed 7.3% | Easy spreading non-occlusive dry emollient. |
| Isostearic Acid | X33R8U0062 | Prisorine™ 3505 | Liquid | - | - | TC TG TON | 25% 0.2% None listed | An exceptionally mild liquid fatty acid that offers a light lubricious feel. It offers film forming properties, making it ideal for use in soaps and liquid cleansers. |
| Isostearyl Alcohol | Q613OCQ44Y | Super Refined™ Isostearic Acid | Liquid | - | - | TC TL TON TSUS | 3% 2.5% None listed 2.5% | Easy spreading, liquid fatty alcohol with superior moisturising properties and very light, silky dry skin feel. |
| Lanolin Alcohols | 884C3FA9HE | Super Hartolan™ pharma | Pastille | - | USP-NF, Ph. Eur. | TC TL TON | 6% 8% | Hydrophobic vehicle with excellent emollient and moisturising properties. Powerful emulsifier and emulsion stabiliser. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|----------------------------|------------|--|----------------------------------|-------|---|-------------------------------------|--|--|
| Laureth-23 | N72LMW566G | Brij™ L23 pharma | Liquid | 16.9 | USP-NF, Ph. Eur. | TA TC TE TL | 1.08% None listed 0.45% None listed | High HLB nonionic O/W emulsifier. Spreading, wetting, solubilising, cleansing and foaming agent. |
| Laureth-4 | 6HQ855798J | Brij™ L4 | Liquid | 9.7 | Ph. Eur. | TC TG TL TSOLN | 1.1% 3% 1.3% 5.22% | Nonionic O/W emulsifier used as solubiliser, wetting agent or dispersant. |
| Lanolin | 7EV65EAW6H | Medilan™ Medilan™ Super Medilan™ Ultra Pharmalan™ | Solid Solid Solid Solid | - | USP-NF, Ph. Eur. USP-NF USP-NF USP-NF | TC TE TL TON TSH | 3% 0.25% 1.5% 10% 2% | Purified medical grade lanolin serves as long lasting emollient and moisturiser with exceptional aesthetic properties |
| Medium-Chain Triglycerides | C9H2L21V7U | Crodamol™ GTCC pharma Super Refined™ GTCC | Liquid | 10.0* | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP | TA TON TL TSPY TG TC | 10.87% 20% 7% 18% 10% 15% | Solubiliser for oil soluble actives, good emollient with excellent oxidative stability |
| Oleic Acid | 2UMI9U37CP | Super Refined™ Oleic Acid | Liquid | - | USP-NF, Ph. Eur., JP/JPE | TC TG TSOLN | 25% 2.5% 7.4% | Highly purified oleic acid used as an emulsifier. Can improve bioavailability of poorly water soluble actives. |
| Oleth-10/Oleth-5 | Multiple | Brij™ O5 pharma Brij™ O10 pharma | Liquid Liquid | 12.4 | USP-NF, Ph. Eur. Ph. Eur. | TC TSOLN | None listed None listed | Primary O/W emulsifier suitable for forming microemulsion gels. Forms clear gels. |
| Oleth-20 | YTH167I2AG | Brij™ O20 pharma | Solid | 15.5 | Ph. Eur. Ph. Eur. | TSH | 0.6% | Extremely effective lipophilic solubiliser. |
| Oleth-O2 | 7L6R1SQ6M0 | Super Refined™ Brij™ O2 | Liquid Liquid | 4.9 | - | TOIL | 163mg** | Brij O2 is a naturally derived alcohol ethoxylate. It can be utilised as a solubiliser or in emulsifier systems where a low HLB value is required. |
| Oleyl Alcohol | 172F2WN8DV | Super Refined™ Oleyl Alcohol | Liquid | - | USP-NF, Ph. Eur. | TC TG TL TON | 10% 1.5% 10% 5% | Highly purified lipid based solubiliser and skin penetration enhancer. Ideal for transdermal delivery systems. |
| Oleyl Oleate | 3X3L452Y85 | Super Refined™ Oleyl Oleate | Liquid | 7.0* | USP-NF, JP/JPE | TON | 2.55% | High purity plant-derived oleate ester that imparts a light skin feel, due to its excellent compatibility with oils and fats. |
| Olive Oil | 6UYK2W1W1E | Super Refined™ Olive Oil | Liquid | 7.7* | - | TL TSOAP TSOLN | 27.75% None listed 0.6% | High purity emollient and lubricant. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|----------------------------------|------------|----------------------------|------------|-------|--------------------------|--|--|--|
| Peanut Oil | 5TL50QU0W4 | Super Refined™ Peanut Oil | Liquid | 7.8* | USP-NF, Ph. Eur. | TC | 10% | High purity topical vehicle and solvent. |
| | | | Liquid | | | TOIL | 44.00% w/v | |
| PEG-8 Stearate | 2P9L47VI5E | Myrj™ S8 pharma | Solid | 10.8 | USP/USP-NF, Ph. Eur. | TC TSP | 6.66% None listed | Nonionic hydrophilic O/W emulsifier. Stable in presence of electrolytes, acids and alkalis. |
| PEG-25 Propylene Glycol Stearate | X21KPH4633 | Myrj™ S25/1 | Solid | 16.0 | - | TC | 2.5% | Mild but powerful nonionic emulsifier. |
| PEG-60 Hydrogenated Castor Oil | 02NG325BQG | Croduret™ 60 | Solid | 14.7* | Ph. Eur., JP/JPE | TC TG | 1.9% 1.9% | Nonionic surfactant, emollient and stabiliser. |
| PEG-75 Lanolin | 09179OX7TB | Solan™ 75/50 | Liquid | - | - | TA TE TSOLN | 1.5% 1.5% 1% | Water soluble lanolin used as solubiliser and emollient. |
| PEG-100 Stearate | YD01N1999R | Myrj™ S100 pharma | Solid | 18.8 | USP-NF, Ph. Eur. | TC TL | 2.1% 1% | Nonionic O/W emulsifier useful as auxiliary surfactant to optimise HLB requirements. |
| Petrolatum | 4T6H12BN9U | Super Refined™ Petrolatum | Solid | - | USP-NF, Ph. Eur., JP/JPE | TA TC TE TL TN TSOAP TSP | 7.9% 66.4% 7.8% 25% 99.98% 0.85% None listed | Versatile, high-performance petrolatum with improved stability against oil-water separation and excellent oxidative stability. |
| Poloxamer 124 | 1S66E28KXA | Synperonic™ PE/L 44 | Liquid | - | USP-NF, Ph. Eur. | TG TL | 0.2% 0.2% | O/W emulsifier with effective cleansing and dispersing properties. |
| Poloxamer 182 | JX0HIX6OAG | Synperonic™ PE/L 62 | Liquid | - | - | TG | 0.2% | Wetting, dispersing and cleansing agent. |
| Poloxamer 188 | LQA7B6G8JG | Synperonic™ PE/F 68 pharma | Solid | - | USP-NF, Ph. Eur., JP/JPE | TC | 1% | Effective emulsifier, solubiliser and foamer. |
| Poloxamer 407 | TUF2IVW3M2 | Synperonic™ PE/F 127 | Solid | - | USP-NF, Ph. Eur., JP/JPE | TC TG TL TSOLN TSUS | 1% 0.2% 1% 0.2% 0.5% w/v | High molecular weight emulsifier and solubiliser. Very effective thermo-reversible gelling agent. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------------------|------------|---|----------------------------|-------|--|--|--|--|
| Polyethylene Glycol 300 | 5655G9Y8AQ | Super Refined™ PEG 300 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | TC TON TL TDOLN | 4% 57% 2% 29.7% | Highly purified PEG 300 that enhances active and formulation stability. |
| Polyethylene Glycol 400 | B697894SGQ | Super Refined™ PEG 400 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | TA TC TE TG TL TLIQ TON TSOLN TSP TSW | None listed 7.5% 1.2% 45% 5% 1% 65% 99% None listed 70% | Highly purified PEG 400 used as a solvent, suspending agent and viscosity modifier. Offers enhanced API and formulation stability. |
| Polyethylene Glycol 600 | NL4J9F21N9 | Super Refined™ PEG 600 | Liquid | - | USP-NF, Ph. Eur., JP/JPE | TSOLN | 0.3% | Highly purified PEG 600 enhances active and formulation stability. |
| Polyoxyl 20 Cetostearyl Ether | YRC528SWUY | Cetomacrogol™ 1000 pharma | Pastille | 15.7 | USP-NF, Ph. Eur. | TA TC TG TL TSP | 5.5% 6% 2% 1% 2.42% | O/W emulsifier for creams and lotions. Solubiliser of essential oils, vitamins and API's with low water solubility |
| Polyoxyl 40 Hydrogenated Castor Oil | 7YC686GQ8F | Croduret™ 40 pharma | Liquid | 13.0* | USP-NF, Ph. Eur. | TC | 1% | Nonionic surfactant, emollient and stabiliser. |
| Polyoxyl 40 Stearate | 13A4J4NH9I | Myrj™ S40 pharma | Solid | 16.7 | USP-NF, Ph. Eur., ChP | TA TC TL TON TSP | 2.83% 8.8% 3% None listed None listed | Nonionic, hydrophilic O/W emulsifier suitable for creams and lotions when used in combination with other emulsifiers to give optimum stability, opacity and texture. |
| Polysorbate 20 | 7T1F30V5YH | Tween™ 20 pharma Tween™ 20 HP Super Refined™ Polysorbate 20 | Liquid Liquid Liquid | 6.7 | USP-NF USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | TA TC TE TG TL TSH TSOAP TSOLN | 3.7% 0.8% 2% 5% 7.8% 8% 0.02% 15% | O/W emulsifier, solubliser, wetting and dispersing agent for actives such as calamine, menthol and phenol. |
| Polysorbate 40 | ST111B5A2X | Tween™ 40 pharma | Liquid | 15.6 | USP-NF, Ph. Eur. | TC TG TL TLIQ | 3% 0.2% 2% 2% | O/W emulsifier, co-solvent and wetting agent. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/daily exposure | Product description |
|-----------------------------------|-------------|--|--------------------------------------|-------|---|--------------|----------------------------|--|
| Polysorbate 60 | CAL22UVI4M | Tween™ 60 pharma Tween™ 60 HP Super Refined™ Polysorbate 60 | Liquid Liquid Liquid | 14.9 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. USP-NF, Ph.Eur., JP/JPE | TA | 0.43% | O/W emulsifier used in combination with other surfactants to achieve desired HLB value. An extremely mild emulsifier and solubiliser. |
| | | | | | | TC | 6.1% | |
| | | | | | | TL | 5% | |
| | | | | | | TON | 2% | |
| | | | | | | TSH | 14.55% | |
| | | | | | | TSUP | 0.03mg/mg | |
| | | | | | | TSUS | 2.85% | |
| TT | None listed | | | | | | | |
| Polysorbate 80 | 6OZP39ZG8H | Tween™ 80 pharma Tween™ 80 HP Super Refined™ Polysorbate 80 Super Refined™ Polysorbate 80 POA | Liquid Liquid Liquid Liquid | 15.0 | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | TA | 0.98% | Low moisture, low peroxide, O/W emulsifier, solubiliser and wetting agent. Recommend when formulating with highly sensitive and unstable APIs. |
| | | | | | | TC | 5% | |
| | | | | | | TE | 2.5% | |
| | | | | | | TG | 8.5% | |
| | | | | | | TL | 15% | |
| | | | | | | TON | 0.1% | |
| | | | | | | TP | None listed | |
| PPG-15 Stearyl Ether | 1II18XLS1L | Arlamol™ PS15E | Liquid | 10.0* | - | TG | 2% | Exceptional emollient brings velvety skin feel, moisturisation and elasticity. |
| | | | | | | TON | 15% | |
| | | | | | | TSUS | 16% | |
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP, JP/JPE, ChP | TA | 21.5% | Highly purified propylene glycol for use as a solvent and preservative. Dissolves a wide variety of materials and is similar to ethanol as an antiseptic. |
| | | | | | | TC | 71.08% | |
| | | | | | | TCL | 0.02mg/mg | |
| | | | | | | TE | 8% | |
| | | | | | | TG | 98.09% | |
| | | | | | | TJ | 20% | |
| | | | | | | TL | 30% | |
| | | | | | | TON | 65% | |
| | | | | | | TP | 700mg | |
| | | | | | | TSH | 8% | |
| | | | | | | TSOLN | 99.98% | |
| | | | | | | TSP | 40% | |
| | | | | | | TSUS | 0.75% w/v | |
| | | | | | | TSUP | 0.2mg/mg | |
| TSW | 34.6% | | | | | | | |
| Propylene Glycol 11 Stearyl Ether | S4G2J0Y0LG | Arlamol™ PS11E pharma | Liquid | - | USP-NF, Ph. Eur. | TA | 5% | Non-occlusive emollient and excellent solvent for a wide range of actives. Acts as a coupling agent to enable compatibility of polar and non-polar oils. Excellent spreader and lubricant. |
| | | | | | | TSUS | 16% | |
| Propylene Glycol Monolaurate | 668Z5835Z3 | Super Refined™ PGML | Liquid | 4.5 | USP-NF, Ph. Eur. | TG | 3% | High purity mixture of propylene glycol and esters of lauric (C12) acid used for formulating poorly water soluble API's into oral and topical formulations. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|----------------------------|------------|---|------------------|--------|-----------------------------------|-------------------|--------------------------------|---|
| Sodium Lauroyl Sarcosinate | 632GS99618 | Crodasinic™ LS30 Crodasinic™ LS95 pharma | Liquid | - | - | TL | 0.75% | Powerful, but mild anionic surfactants, wetting and foaming agents |
| | | | Soild | | | TSH | 12.5% | |
| | | | | | | TSUS | 0.75% | |
| Sorbitan Monolaurate | 6W9PS8B71J | Span™ 20 pharma Span™ 20 HP | Liquid | Liquid | Ph. Eur. | TA | 4.74% | O/W co-emulsifier, dispersible in water, acids and alkalis |
| | | | Liquid | Liquid | USP-NF, Ph. Eur., JP/JPE, ChP | TC | 0.5% | |
| | | | | | | TG | 1% | |
| Sorbitan Monooleate | 06XEA2VD56 | Span™ 80 pharma Span™ 80 HP | Liquid | 4.3 | USP-NF, Ph. Eur. | TC | 3.5% | Liquid W/O emulsifier and O/W emulsion stabiliser. Used as wetting agent and dispersant for zinc oxide, calamine and penicillin. |
| | | | Liquid | | USP-NF, Ph. Eur. | TE | 2.5% | |
| | | | | | | TL | 7% | |
| | | | | | | TG | 0.2% | |
| | | | | | | TON | None listed | |
| | | | | | | TSPY | 0.25% | |
| Sorbitan Monostearate | NVZ4I0H58X | Span™ 60 pharma Span™ 60 HP | Solid | 4.7 | USP-NF, Ph. Eur. | TA | 0.55% | Stable O/W emulsifier with low odour, pale colour and mild on skin. Used to emulsify fatty alcohols, esters and mineral and silicone oils. |
| | | | Solid | | USP-NF, Ph. Eur., JP/JPE | TC | 8% | |
| | | | | | | TL | 2.5% | |
| | | | | | | TON | None listed | |
| | | | | | | TSOLN | None listed | |
| | | | | | | TSPY | 4.58% | |
| | | | | | | TSUS | 2.15% | |
| Sorbitan Monopalmitate | 77K6Z421KU | Span™ 40 pharma | Pastille | 6.7 | USP-NF, Ph. Eur. | TC | 2% | Highly effective at forming O/W emulsions, particularly when used in combination with Tween 40. Possesses a wax-like structure, useful when rigidity is required in formulations. |
| | | | | | | TL | 0.08% w/v | |
| | | | | | | TLIQ | 2% | |
| | | | | | | TP | 10.5mg | |
| | | | | | | | | |
| Sorbitan Sesquioleate | 0W8RRI5W5A | Span™ 83 pharma | Liquid | 3.7 | USP-NF, Ph. Eur. | TON | 2.5% | W/O emulsifier and O/W emulsion stabiliser. |
| Soybean Oil | 241ATL177A | Super Refined™ Soybean Oil Super Refined™ Soybean Oil NP | Liquid Liquid | 7.7* | USP-NF, Ph. Eur. USP, Ph. Eur. | TSOLN | 5.82% | Highly purified oil useful as great natural emollient. |
| Squalane | GW89575KF9 | Pripure™ 3759 | Liquid | - | - | TA TC TSOLN | 2.23% 6% 1% | Biomimetic skin lipid with excellent spreading and moisturising properties. Imparts a soft, silky, velvety feel. |
| Stearth-10 | FD0913P475 | Brij™ S10 pharma | Solid | 12.4 | USP-NF, Ph. Eur. | TA | None listed | O/W emulsifier and co-emulsifier with wetting and dispersing properties. |
| Stearth-100 | 4OH5W9UM87 | Brij™ S100 | Solid | - | - | TC | 0.6% | High HLB vegetable based emulsifier stable over a wide pH range. |
| | | | | | | TON | 0.6% | |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|---------------------|------------|-----------------|------------|------|------------------|---------------------------------------|---|--|
| Steareth-2 | V56DFE46J5 | Brij™ S2 pharma | Pastille | 4.9 | USP-NF, Ph. Eur. | TA TC TL TON | 1.09% 4.5% 0.4% 5% | Produces stable O/W emulsions by forming liquid crystal oleosomes. Tolerant to high levels of electrolytes and extreme pH. Works well with Brij S721. |
| Steareth-21 | 53J3F32P58 | Brij™ S721 | Solid | 15.5 | - | TC TL | 3% 3% | Stable O/W emulsifier that forms liquid crystalline oleosomes. Works well with Brij S2. |
| Stearyl Alcohol | 2KR89I4H1Y | Crodacol™ S95 | Pastille | - | USP-NF, Ph. Eur. | TA TC TL TON TSUP TSUS | 1% 30% 1% w/v 8% 0.09mg/mg 2.01% | Natural, saturated fatty alcohol of non-animal origin are wax-like emollients and viscosity builders in creams and lotions. Insoluble in water and soluble in ethyl alcohol. |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|------|---|
| TA | TOPICAL; AEROSOL TOPICAL; AEROSOL, FOAM TOPICAL; AEROSOL, METERED TOPICAL; AEROSOL, SPRAY |
| TC | TOPICAL; CREAM TOPICAL; CREAM, AUGMENTED TOPICAL; CREAM, EMULSION, SUSTAINED RELEASE |
| TCL | TOPICAL; CLOTH |
| TD | TOPICAL; DROPS |
| TDRS | TOPICAL; DRESSING |
| TE | TOPICAL; EMULSION TOPICAL; EMULSION, AEROSOL FOAM TOPICAL; EMULSION, CREAM TOPICAL; EMULSION, LOTION |

| Key | Route/Dosage form |
|-------|--|
| TF | TOPICAL; FILM |
| TG | TOPICAL; GEL |
| TJ | TOPICAL; JELLY |
| TL | TOPICAL; LOTION |
| TLIQ | TOPICAL; LIQUID |
| TOIL | TOPICAL; OIL |
| TON | TOPICAL; OIN™MENT |
| TP | TOPICAL; PATCH TOPICAL; PATCH, CONTROLLED RELEASE |
| TSOAP | TOPICAL; SOAP |
| TSH | TOPICAL; SHAMPOO |
| TSOLN | TOPICAL; SOLUTION TOPICAL; SOLUTION, LIQUID |

| Key | Route/Dosage Form |
|------|----------------------|
| TSP | TOPICAL; SPONGE |
| TSPY | TOPICAL; SPRAY |
| TSUP | TOPICAL; SUPPOSITORY |
| TSUS | TOPICAL; SUSPENSION |
| TSW | TOPICAL; SWAB |
| TT | TOPICAL; TABLET |

Non-warranty

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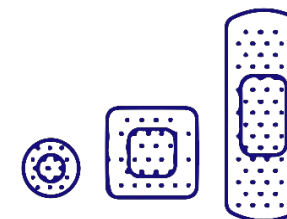
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Transdermal



| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|--------------------------------------|----------------|--|------------------|-------|---|--------------------------------|---|---|
| Diethylene Glycol Monoethyl Ether | A1A1I8X02B | Super Refined™ DEGEE | Liquid | 16.0 | USP-NF, Ph. Eur. | TG TS | 5% 430mg | High purity glycol ether that can enhance the permeation of poorly water-soluble APIs through various layers of the skin. |
| Diisopropyl Adipate | P7E6YFV72X | Crodamol™ DA pharma | Liquid | 9.0* | JP/JPE | TG | 1.5% | Low viscosity ester with excellent solvency and spreading properties. |
| Ethyl Oleate | Z2Z439864Y | Crodamol™ EO pharma | Liquid | 11.0* | USP-NF, Ph. Eur. | TF-ER | 15mg | Low viscosity solvent for lipophilic actives. |
| Glyceryl Oleate | 4PC054V79P | Cithrol™ GMO HP | Solid | 3.0 | USP-NF, Ph. Eur. | TF-ER | 18.8mg | High purity oleic acid grade enhances active bioavailability. Membrane penetration enhancer. |
| Isopropyl Myristate | 0RE8K4LNJS | Crodamol™ IPM pharma Super Refined™ IPM | Liquid Liquid | 10.0* | USP-NF USP-NF, Ph. Eur., JP/JPE | TF TF-ER TG TGM TS | 58.08mg 20.4mg 1% 1% 7.25mg | Solvent used to encourage rapid absorption into skin. |
| Isopropyl Palmitate | 8CRQ2TH63 M | Crodamol™ IPP pharma Super Refined™ IPP | Liquid | 10.0* | USP-NF, JP/JPE USP-NF, JP/JPE | TF TF-ER | 1.81mg 187.5mg | Easy spreading non-occlusive dry emollient. |
| Lauryl Lactate | G5SU0BFK7 O | Super Refined™ Lauryl Lactate | Liquid | 14.0 | None | TF-ER | 12mg | Water soluble emollient that can be used to impart non-oily lubricity to a formulation, or to reduce the tackiness of other components of topical products. |
| Medium-Chain Triglycerides | C9H2L21V7U | Crodamol™ GTCC pharma Super Refined™ GTCC | Liquid Liquid | 10.0* | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP | TF-ER | None listed | Solubiliser for oil soluble actives, good emollient with excellent oxidative stability. |
| Oleic Acid | 2UMI9U37CP | Super Refined™ Oleic Acid | Liquid | - | USP-NF, Ph. Eur., JP/JPE | TF-ER TS | 9.6mg 22mg | Highly purified oleic acid used as an emulsifier. Can improve bioavailability of poorly water-soluble actives. |
| Oleyl Alcohol | 172F2WN8DV | Super Refined™ Oleyl Alcohol | Liquid | - | USP-NF, Ph. Eur. | TF TF-ER TG TS | 6.11mg 7.45mg 1.5% 5.32mg | Highly purified lipid based solubiliser and skin penetration enhancer. Ideal for transdermal delivery systems. |
| Oleyl Oleate | 3X3L452Y85 | Super Refined™ Oleyl Oleate | Liquid | 7.0* | USP-NF, JP/JPE | TS | 30mg | High purity plant-derived oleate ester that imparts a light skin feel, due to its excellent compatibility with oils and fats. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|------------------------------|------------|---------------------------------|------------------|-------|--------------------------------------|--------------|--------------------------------|---|
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP-NF, JP/JPE, ChP | TF-ER TG | 58.13mg 20% | Highly purified propylene glycol for use as a solvent and preservative. Dissolves a wide variety of materials and is similar to ethanol as an antiseptic. |
| Propylene Glycol Monolaurate | 668Z5835Z3 | Super Refined™ PGML | Liquid | 4.5 | USP-NF, Ph. Eur. | TF | None listed | High purity mixture of propylene glycol and esters of lauric (C12) acid used for formulating poorly water soluble API's into oral and topical formulations. |
| Sorbitan Monooleate | 06XEA2VD56 | Span™ 80 pharma Span™ 80 HP | Liquid Liquid | 4.3 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | TF-ER TS | None listed 2.33mg | Liquid W/O emulsifier and O/W emulsion stabiliser. Used as wetting agent and dispersant for zinc oxide, calamine and penicillin. |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|-------|--|
| TF | TRANSDERMAL, FILM |
| TF-CR | TRANSDERMAL FILM, CONTROLLED RELEASE |
| TF-ER | TRANSDERMAL FILM, EXTENDED RELEASE |
| TG | TRANSDERMAL, GEL |
| TGM | TRANSDERMAL GEL, METERED |
| TO | TRANSDERMAL, OINTMENT |
| TP | TRANSDERMAL, PATCH |
| TP-CR | TRANSDERMAL PATCH, CONTROLLED RELEASE |
| TP-EC | TRANSDERMAL PATCH, ELECTRONICALLY CONTROLLED |
| TS | TRANSDERMAL, SYSTEM |
| TSOL | TRANSDERMAL, SOLUTION |

Non-warranty

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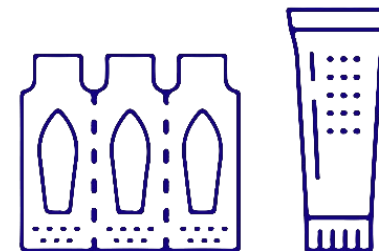
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Vaginal and Rectal



| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-----------------------|------------|----------------------------------|----------------------|-------|----------------------------|----------------------------|---|---|
| Benzyl Alcohol | LKG8494WBH | Super Refined™ Benzyl Alcohol | Liquid | 12.9 | USP-NF, Ph. Eur., JP/JPE | RG RS VC VS VT | 1.55%w/v 129mg 1% None listed None listed | High purity aromatic alcohol can be used as a preservative, solvent, and viscosity reducing agent. |
| Ceteth-20 | I835H2IHHX | Brij™ C20 | Solid | - | - | VTP | None listed | Versatile, biodegradable O/W emulsifier compatible with nonionic surfactants, most anionic and cationic surfactants, and stable over a wide pH range. |
| Cetostearyl Alcohol | 2DMT128M1S | Crodacol™ CS50 Crodacol™ CS90 | Pastille Pastille | - | USP-NF USP-NF, Ph. Eur. | VC VT VS | 12% None listed None listed | Stabiliser, co-emulsifier and thickener used in cream bases. |
| Cetyl Alcohol | 936JST6JCN | Crodacol™ C70 Crodacol™ C95 | Pastille Pastille | - | USP-NF, Ph. Eur. | RA VA VC VS | 0.66% 0.75% 4% 0.03mg/mg | Natural, saturated fatty alcohol that is a wax-like emollient and viscosity builder in creams. |
| Cetyl Esters Wax | D072FFP9GU | Crodamol™ SS pharma | Pastille | 7.0* | USP-NF | VC VS VT | 3% None listed None listed | Vegetable derived emollient and bodying agent for creams and ointments. |
| Cetyl Palmitate | 5ZA2S6B08X | Crodamol™ CP pharma | Solid | 10.0* | USP-NF, Ph. Eur. | VC | 3.30% | Dry emollient which Improves emulsion texture and stability. |
| Cholesterol | 97C5T2UQ7J | Cholesterol | Solid | - | USP-NF, Ph. Eur. | VC | 0.3% | Excellent moisturiser, emulsifier and conditioner. |
| Emulsifying Wax | Multiple | Polawax™ USP-NF pharma | Pastille | - | USP-NF | RA | 1.32 - 1.5% | Emulsifying wax that produces liquid crystal emulsions, promoting 'time release' hydration with excellent texture and stability |
| Glyceryl Isostearate | HYE7O27HAO | Cithrol™ GMIS 40 | Liquid | 3.4 | - | VC | 2.7% | Low HLB emulsifier and rich emollient. |
| Glyceryl Monostearate | 230OU9XXE4 | Cithrol™ GMS 40 pharma | Solid | 3.4 | USP-NF, Ph. Eur. | VC RS VA | 17% 35mg 3% | Nonionic, O/W and W/O emulsifier and emulsion stabiliser, dispersant and emollient |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description |
|-------------------------|------------|---|--------------------------------------|--------|---|------------------------------------|--|---|
| Hard Fat | 8334LX7S21 | Estaram™ Range (299, H15, W35) Supoweiss™ S2 | Solid Solid | - | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | RS | 2000mg | Hard fat suppository base with a low hydroxyl value, a low content of mono- and di-glycerides, and a high mono- and di-glycerides content, respectively. Semi-synthetic glycerides excipient with high plasticity. |
| Isopropyl Myristate | 0RE8K4LNJS | Crodamol™ IPM pharma Super Refined™ IPM | Liquid Liquid | 10.00* | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE | VC VS | 1% 0.01mg/mg | Solvent used to encourage rapid absorption into skin. |
| Lanolin | 7EV65EAW6H | Medilan™ Medilan™ Super Medilan™ Ultra Pharmalan™ | Solid Solid Solid Solid | - | USP, Ph. Eur. USP-NF USP-NF USP-NF | RO VC | 14% 2% | Purified medical grade lanolin, serves as a long lasting emollient and moisturiser with exceptional aesthetic properties. |
| Peanut Oil | 5TL50QU0W4 | Super Refined™ Peanut Oil Super Refined™ Peanut Oil NP | Liquid | 7.8* | USP-NF, Ph. Eur. USP-NF, Ph. Eur. | VC | 9% | High purity topical vehicle and solvent. |
| PEG-100 Stearate | YD01N1999R | Myrj™ S100 pharma | Solid | 18.8 | USP-NF, Ph. Eur. | VC | None listed | Nonionic O/W emulsifier used to optimise HLB. |
| Petrolatum | 4T6H12BN9U | Super Refined™ Petrolatum | Solid | - | USP-NF, Ph. Eur., JP/JPE | VCA VO RO | None listed 88.49% 75% | Versatile, high-performance petrolatum with improved stability against oil-water separation and excellent oxidative stability. |
| Polyethylene Glycol 400 | B697894SGQ | Super Refined™ PEG 400 Super Refined™ PEG 400 LTG | Liquid Liquid | - | USP-NF, Ph. Eur., JP/JPE USP-NF, Ph. Eur., JP/JPE, ChP | RS VS | 0.25mg/mg 30mg | High purity PEG 400 that enhances active and formulation stability. |
| Polysorbate 20 | 7T1F30V5YH | Tween™ 20 pharma Tween™ 20 HP Super Refined™ Polysorbate 20 | Liquid Liquid Liquid | 16.7 | USP-NF USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | VA VS VTP | 3% None listed 64.8mg | O/W emulsifier, solubiliser, wetting and dispersing agent for APIs like calamine, menthol and phenol. |
| Polysorbate 60 | CAL22UVI4M | Tween™ 60 pharma Tween™ 60 HP Super Refined™ Polysorbate 60 | Liquid Liquid Liquid | 14.9 | USP-NF, Ph. Eur. USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE | RS VC VS VT | 0.05mg/mg 5% 0.03mg/mg None listed | O/W emulsifier used in combination with other surfactants to achieve desired HLB value. Super Refined Polysorbate 60 is an extremely mild emulsifier and solubiliser. |
| Polysorbate 80 | 6OZP39ZG8H | Tween™ 80 pharma Tween™ 80 HP Super Refined™ Polysorbate 80 Super Refined™ Polysorbate 80 POA | Liquid Liquid Liquid Liquid | 15.0 | USP-NF, Ph. Eur. USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP USP-NF, Ph. Eur., JP/JPE, ChP | RE RS RSOL VA VC VS | 0.01% w/v 72.15mg 0.1% w/v 3% 0.4% 28mg | Low moisture, low peroxide, O/W emulsifier, solubiliser and wetting agent. Recommended when formulating with highly sensitive and unstable APIs. |

*Required HLB

**Maximum Daily Exposure

| Inactive ingredient | UNII code | Product name | Appearance | HLB | Monograph | Dosage route | Max potency/ daily exposure | Product description | | | |
|-----------------------|------------|---------------------------------|------------|-------|---------------------|--------------|--------------------------------|---|--------------------------|----|-------------|
| Propylene Glycol | 6DC9Q167V3 | Super Refined™ Propylene Glycol | Liquid | 11.6* | USP-NF, JP/JPE, ChP | RA | 47.04% - None listed | Highly purified propylene glycol for use as a solvent and preservative. Dissolves a wide variety of materials and is similar to ethanol as an antiseptic. | | | |
| | | | | | | RG | 41.44% w/v | | | | |
| | | | | | | RO | 3.6% | | | | |
| | | | | | | RSUS | 11.3% w/v | | | | |
| | | | | | | VA | 6.4% | | | | |
| | | | | | | VC | 20% | | | | |
| | | | | | | VG | 3% | | | | |
| | | | | | | VS | 252mg | | | | |
| | | | | | | VTP | 62.1mg | | | | |
| Sorbitan Monooleate | 06XEA2VD56 | Span™ 80 | Liquid | 4.3 | USP-NF, Ph. Eur. | RS | 22mg | O/W co-emulsifier, dispersible in water, acids and alkalis. | | | |
| | | | | | | Span™ 80 HP | Liquid | | USP-NF, Ph. Eur. | | |
| Sorbitan Monostearate | NVZ4I0H58X | Span™ 60 | Solid | 4.7 | USP-NF, Ph. Eur. | VC | 5% | Stable O/W emulsifier with low odour, pale colour and mild on skin. Used to emulsify fatty alcohols, esters, mineral and silicone oils. W/O emulsifier and O/W emulsion stabiliser. | | | |
| | | | | | | Span™ 60 HP | Solid | | USP-NF, Ph. Eur., JP/JPE | VT | None listed |
| | | | | | | | | | | VS | None listed |
| Sorbitan Sesquioleate | 0W8RRI5W5A | Span™ 83 | Liquid | 3.7 | USP-NF, Ph. Eur. | RO | 2% | | | | |
| Stearyl Alcohol | 2KR89I4H1Y | Codacol™ S95 | Pastille | - | USP-NF, Ph. Eur. | VC | 8.5 | Natural, saturated fatty alcohol is a wax-like emollient and viscosity builder in creams. | | | |
| | | | | | | VS | 8.5mg | | | | |

*Required HLB

**Maximum Daily Exposure

| Key | Route/Dosage form |
|------|---|
| RA | RECTAL; AEROSOL, FOAM RECTAL; AEROSOL, METERED |
| RE | RECTAL; ENEMA |
| RG | RECTAL; GEL |
| RO | RECTAL; OINTMENT |
| RSOL | RECTAL; SOLUTION |
| RS | RECTAL; SUPPOSITORY |
| RSUS | RECTAL; SUSPENSION |
| VA | VAGINAL; AEROSOL, FOAM |
| VC | VAGINAL; CREAM |
| VCAP | VAGINAL; CAPSULE |

| Key | Route/Dosage form |
|-----|----------------------|
| VG | VAGINAL; GEL |
| VS | VAGINAL; SUPPOSITORY |
| VT | VAGINAL; TABLET |
| VTP | VAGINAL; TAMPON |

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