

 **BASF**

We create chemistry

L-Menthol

Topical analgesic



Delivering what matters

We produce excipients and active ingredients of high quality and performance. Our team of experienced industry specialists supports you in developing effective formulations – giving you a vital advantage in a highly demanding market.

L-menthol is an active pharmaceutical ingredient with a fresh, minty scent that produces a cooling sensation. Widely used in topical and oral applications, L-menthol is a versatile active ingredient that can be formulated into various dosage forms for symptomatic relief of various conditions. L-menthol is utilized by pharmaceutical companies to develop Rx and OTC cough suppressants, topical analgesics, and oral anesthetics. Formulate L-menthol in conjunction with BASF's broad portfolio of functional excipients to develop innovative topical and oral dosage forms.



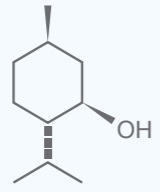
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1 Introduction

BASF's pharmaceutical grade L-menthol is a synthetically produced organic compound. This active ingredient can be obtained in the form of white flakes that are solid at room temperature. In addition to smelling characteristically fresh like peppermint, BASF's synthetic L-menthol is nature-identical.

Chemical information

Name	L-menthol
Structural formula	
Empirical formula	C ₁₀ H ₂₀ O
Molecular weight	156.27 g/mol
Solubility	<ul style="list-style-type: none"> ■ Practically insoluble in water ■ Soluble at concentrations of at least 1 g per mL solvent in acetone, acetonitrile, dimethylformamide (DMF), ethanol, heptane, isopropanol, methanol, propane-1,2-diol (propylene glycol), tetrahydrofuran (THF), and toluol ■ Soluble at concentrations of at least 0.3 g per mL solvent in polyethylene glycol 400 (PEG 400)

Product details

Generic name	Levomenthol, L-menthol, 3-p-menthanol, hexahydrothymol, menthomenthol	
CAS number	2216-51-5	
Manufacturing site	BASF SE, Germany	
Manufacturing process	Synthetic	
Regulatory	<ul style="list-style-type: none"> ■ USP, Ph. Eur., JP, and IP monographs ■ US-DMF and CEP available 	<ul style="list-style-type: none"> ■ GMP for APIs (ICH Q7 Guideline) ■ Complete pharma documentation available

L-Menthol Flakes Pharma

PRD number	30573640
Appearance	White flakes
Packaging and article number	20 kg card box with liner (50308668)
Sample and article number	0.5 kg aluminium bottle (50308669)
Retest period	60 months
Storage and transport	Store in original packaging. Protect from frost (above 5°C) and store below 25°C and against humidity.

Additional quality and regulatory information is available through RegXcellence®.

The following formulations are exemplary. Formulating procedures are recommendations based on established laboratory conditions and may require alterations dependent on the final application. NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE MADE REGARDING PRODUCTS DESCRIBED OR DESIGNS, DATA OR INFORMATION SET FORTH, OR THAT THE PRODUCTS, DESCRIPTIONS, DESIGNS, DATA OR INFORMATION MAY BE USED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS.

2 Topical Menthol Formulations

Selection of lipidic fluid

It is important to choose the right lipidic fluid to not only achieve the desired sensory properties, but to maintain critical qualities for solubilization and delivery of the active ingredient. Kollicream® OD is among one of many multifunctional emollients supplied by BASF that can be used to solubilize L-menthol.

Emollient	Chemical Name	mPa·s	MW	mm ² /10min	Class	Emollience
Kollicream® IPM	Isopropyl myristate	5–6	270	1200	Fast	Dry, light
Kollicream® 3C	Cocoyl caprylocaprate	11	335	800	Medium	Medium
Kollicream® OA	Oleyl alcohol	33	270	700		
Kollicream® DO	Decyl oleate	15.9	415	700		
Kollicream® OD	Octyldodecanol	58–64	300	600	Slow (molten)	Rich
Kollisolv® MCT 70	Medium-chain triglycerides	25–33	500	550		
Kollicream® CP 15	Cetyl palmitate	Solid	480	Solid		

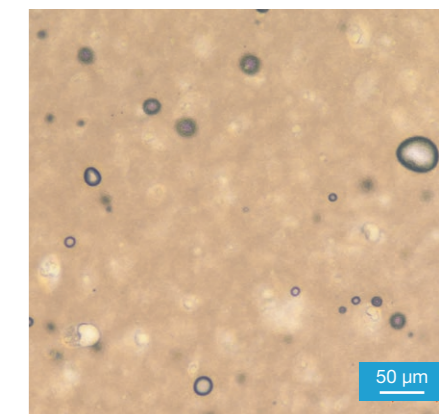
Menthol rich cream

A rich cream formulation offering a slow spread and cushioned feeling when applied to the skin

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kollicream® OD	Octyldodecanol	Emollient	10.00
	Kolliphor® CS 20	Polyoxyl cetostearyl ether 20	Emulsifier	4.00
	Kolliwax® CSA 50	Cetostearyl alcohol	Structuring agent	12.00
	Kolliwax® GMS II	Mono- and di-glycerides	Structuring agent	6.00
	L-Menthol Pharma flakes	L-menthol	API	10.00
B	Water	Water	Solvent	52.30
	Glycerin	Glycerin	Emollient	5.00
C	Euxyl® PE 9010	Phenoxyethanol-ethylhexylglycerin	Preservative	0.70

Procedure

1. Weigh out phases A and B into appropriately sized beakers. Place mixtures under overhead mixers and set to 50 rpm. Heat the mixtures to 90°C.
2. Add phase A to phase B. Homogenize at 5000 rpm for 10 minutes.
3. Place the mixture under an overhead mixer and set to 200 rpm for 15 minutes.
4. Decrease mixing speed to 125 rpm. When the formulation has cooled to 45°C, add in phase C (preservative).
5. Continue mixing until formulation has cooled to room temperature.



Menthol rich cream – light microscopy (200x magnification)

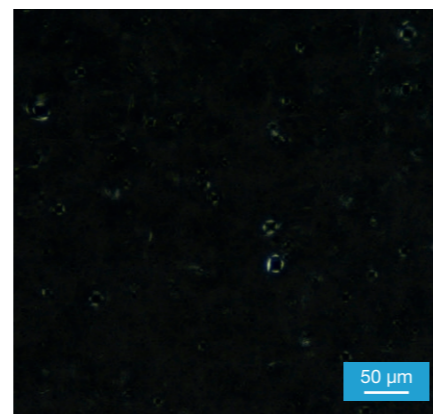
Menthol medium cream

A medium-weight cream formulation offering a balance between spreadability and skin absorption

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kollicream® OD	Octyldodecanol	Emollient	12.00
	Kolliphor® CS 20	Polyoxyl cetostearyl ether 20	Emulsifier	3.40
	Kolliwax® CSA 50	Cetostearyl alcohol	Structuring agent	10.00
	Kolliwax® GMS II	Mono- and di-glycerides	Structuring agent	4.50
	L-Menthol Pharma flakes	L-menthol	API	10.00
B	Water	Water	Solvent	54.40
	Glycerin	Glycerin	Emollient	5.00
C	Euxyl® PE 9010	Phenoxyethanol-ethylhexylglycerin	Preservative	0.70

Procedure

1. Weigh out phases A and B into appropriately sized beakers. Place mixtures under overhead mixers and set to 50 rpm. Heat the mixtures to 90°C.
2. Add phase A to phase B. Homogenize at 5000 rpm for 10 minutes.
3. Place the mixture under an overhead mixer and set to 200 rpm for 15 minutes.
4. Decrease mixing speed to 125 rpm. When the formulation has cooled to 45°C, add in phase C (preservative).
5. Continue mixing until formulation has cooled to room temperature.

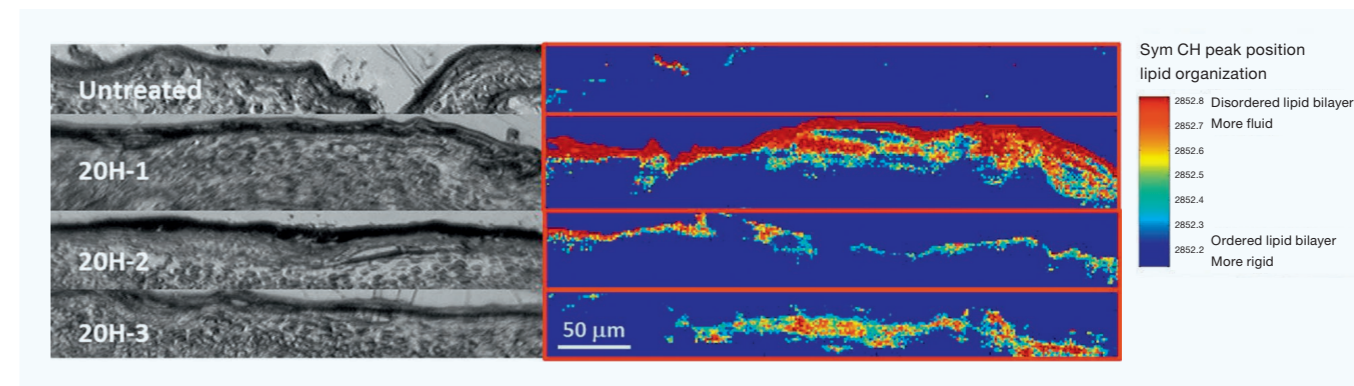


Menthol medium cream – polarized microscopy (200x magnification)

Fluidization of stratum corneum lipids with skin penetration enhancers

In addition to functioning as solvents, oleochemical lipidic emollients such as Kollicream® OD also serve as skin penetration enhancers. When formulated in conjunction with L-menthol, lipidic emollients can be used to synergistically promote the skin permeation of some APIs. To evaluate stratum corneum lipid behavior upon exposure to penetration enhancers, spectroscopic evaluations have been used.

In skin samples treated with Kollicream® OD for 20 hours and then imaged by ATR-FTIR, Kollicream® OD was detected up to 40 µm deep into the skin. Kollicream® OD allowed for a significant change in the skin barrier integrity including the fluidization of lipids. This fluidization of the lipids in the stratum corneum can be used to promote API permeation enhancement of some drugs.



ATR-FTIR images showing the CH₂ (~2850 cm⁻¹) peak position.



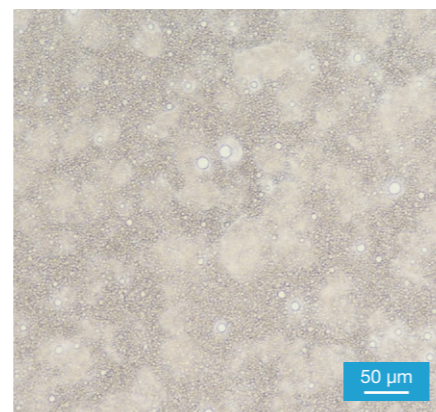
Menthol light cream

A quick spreading cream formulation boasting a light-weight texture complemented by a glossy finish

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kollicream® 3C	Cocoyl caprylocaprata	Emollient	2.50
	Kollicream® IPM	Isopropyl myristate	Emollient	9.50
	Kolliphor® CS 12	Macrogol cetostearyl ether 12	Emulsifier	2.50
	Koliwax® CA	Cetyl alcohol	Structuring agent	3.50
	Koliwax® SA	Stearyl alcohol	Structuring agent	1.50
	Koliwax® GMS II	Mono- and di-glycerides	Structuring agent	2.00
	L-Menthol Pharma flakes	L-menthol	API	2.50
B	Water	Water	Solvent	70.30
	Glycerin	Glycerin	Emollient	5.00
C	Euxyl® PE 9010	Phenoxyethanol-ethylhexylglycerin	Preservative	0.70

Procedure

1. Weigh out phases A and B into appropriately sized beakers. Place mixtures under overhead mixers and set to 50 rpm. Heat the mixtures to 90°C.
2. Add phase A to phase B. Homogenize at 5000 rpm for 10 minutes.
3. Place the mixture under an overhead mixer and set to 200 rpm for 15 minutes.
4. Decrease mixing speed to 125 rpm. When the formulation has cooled to 45°C, add in phase C (preservative).
5. Continue mixing until formulation has cooled to room temperature.



Menthol light cream – light microscopy (200x magnification)

Optimization of critical quality attributes with Koliwax® fatty alcohols

Koliwax® fatty alcohols and emulsifiers such as Kolliphor® CS 12 (macrogol cetostearyl ether 12) and CS 20 (macrogol cetostearyl ether 20) synergistically promote the formation of the viscoelastic lamellar gel network to stabilize oil droplets. Functioning as both structuring agents and skin permeation modifiers, Koliwax® fatty alcohols exhibit excipient multifunctionality.

When higher melting range fatty alcohol Koliwax® SA (stearyl alcohol) is formulated in combination with lower melting range fatty alcohols Koliwax® CA (cetyl alcohol) or MA (myristyl alcohol), topical formulations experience enhanced stability and rheological performance. Use pre-mixed Koliwax® fatty alcohol blends or create customized mixtures with individual Koliwax® fatty alcohols to enhance formulation stability of menthol creams.

Koliwax® fatty alcohol blends – microstructure and globule size distribution

	Koliwax® CSA 50	Koliwax® CSA 70
Microstructure		
D10 (μm)	2.61 ± 0.00	2.50 ± 0.14
D50 (μm)	4.05 ± 0.07	3.90 ± 0.42
D90 (μm)	5.45 ± 0.21	5.20 ± 0.57

Yield stress of variable fatty alcohol-based creams composed of singular fatty alcohols

Fatty Alcohol	Yield Stress (Pa)
Koliwax® CSA 50	16
Koliwax® CSA 70	13
Koliwax® MA	12
Koliwax® CA	9
Koliwax® SA	1

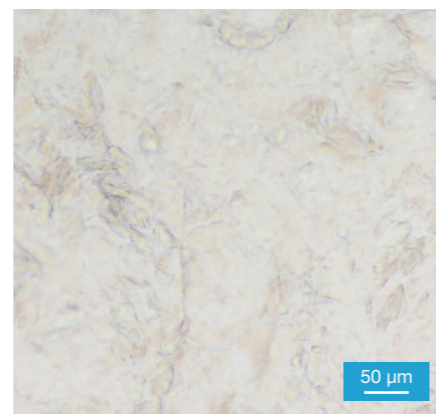
Menthol ointment

A tunable alternative to traditional petrolatum-based ointment formulations

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kollisolv® PEG 3350*	Polyethylene glycol 3350	Structuring agent	30.00
	Kollisolv® PEG 300	Polyethylene glycol 300	Solvent	45.00
	Kollisolv® PG	Propylene glycol	Solvent	20.00
	L-Menthol Pharma flakes	L-menthol	API	5.00

Procedure

1. Weigh out phase A into an appropriately sized beaker.
2. Place mixture under an overhead mixer and set to 85 rpm. Heat mixture to 60°C.
3. Once ingredients have completely melted, remove heat.
4. Mix at 50 rpm until the formulation has cooled to room temperature.



Menthol ointment – light microscopy
(200x magnification)

*Kollisolv® PEG 3350 is commercially available only in the USA and Canada.

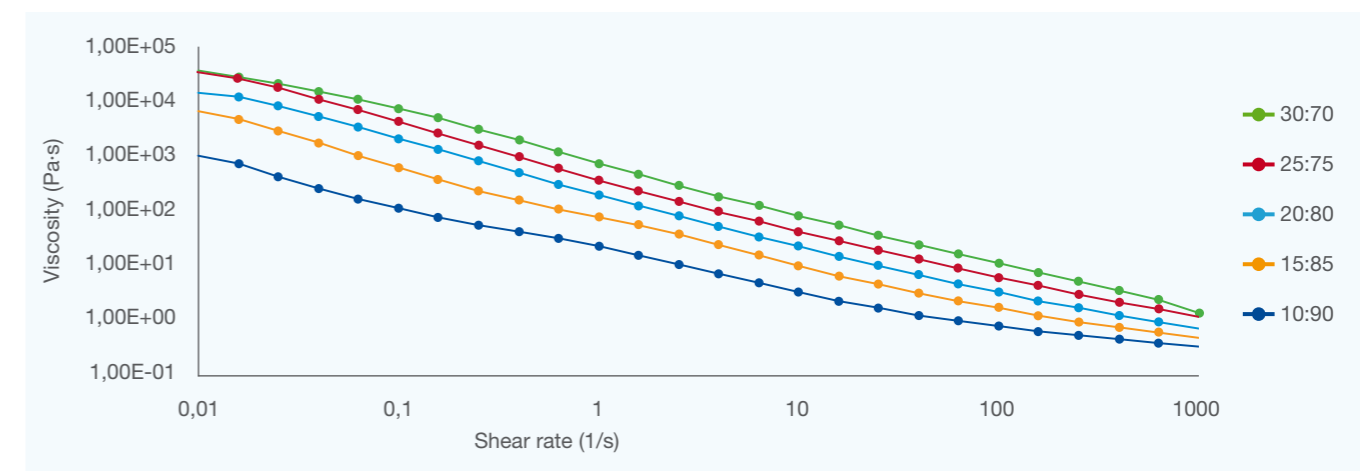
Influence of PEG ratios on rheological performance

BASF offers an array of high and low-molecular weight Kollisolv® PEGs to address various topical formulation needs.

BASF Trade Name	Chemical Name	Physical State at Room Temperature
Kollisolv® PEG 300	Polyethylene glycol 300	Liquid
Kollisolv® PEG 400	Polyethylene glycol 400	
Kollisolv® PEG 1000	Polyethylene glycol 1000	Solid
Kollisolv® PEG 1450	Polyethylene glycol 1450	
Kollisolv® PEG 3350	Polyethylene glycol 3350	
Kollisolv® PEG 8000	Polyethylene glycol 8000	

High and low-molecular weight PEGs exhibit distinct functionalities. While high-molecular weight PEGs serve to reliably build viscosity and enhance formulation stability, low-molecular weight PEGs function as excellent solvents and solubilizing agents for numerous substances that do not readily dissolve in water. When formulated together, these versatile, water-miscible excipients can be used to create ointments and suppositories with customizable rheological properties. Combine high and low-molecular weight PEGs to develop water-washable menthol ointments that can be tuned to achieve target sensory profiles.

PEG ointment rheology



PEG ointment rheology of Kollisolv® PEG 3350:Kollisolv® PEG 400 ointments.

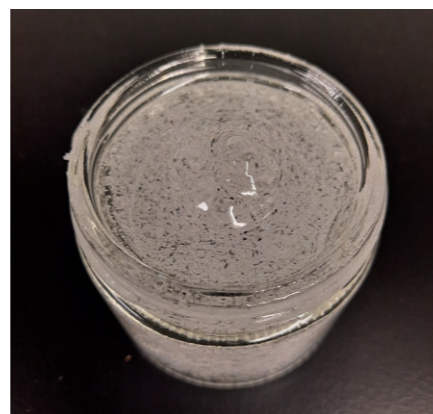
Menthol gel

A cool, refreshing gel that thickens upon skin contact

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kollisol [®] PG	Propylene glycol	Solvent	20.00
	Kollisol [®] PEG 400	Polyethylene glycol 400	Solvent	5.00
	Ibuprofen	Ibuprofen	API	5.00
	L-Menthol Pharma flakes	L-menthol	API	3.00
B	Kolliphor [®] P 407	Poloxamer 407	Gelling agent	13.00
	Ethanol	Ethanol	Solvent	15.00
C	Water	Water	Solvent	38.30
D	Euxyl [®] PE 9010	Phenoxyethanol-ethylhexylglycerin	Preservative	0.70

Procedure

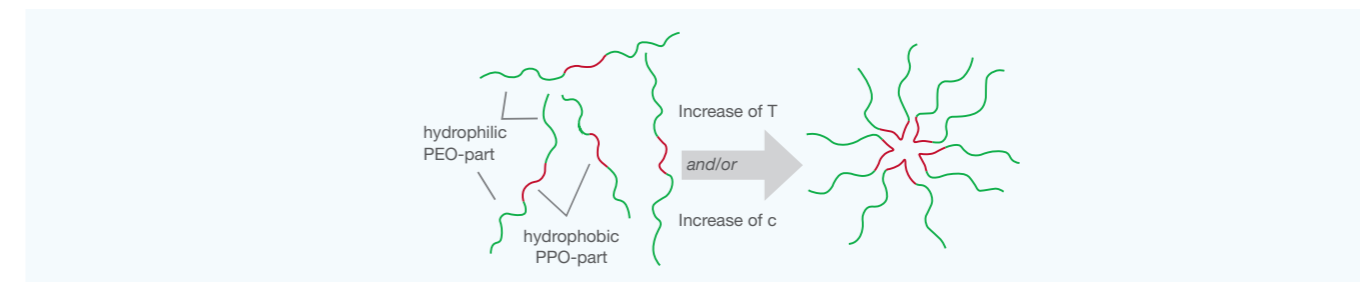
1. Weigh out phase A and phase B in separate appropriately sized beakers.
2. Mix phase A at room temperature with an overhead mixer at 350 rpm until complete dissolution.
3. Mix phase B at room temperature with an overhead mixer at 300 rpm until a viscous, white solution should form.
4. Add phase A to phase B and mix at 300 rpm until complete homogenization.
5. Reduce mixer speed to 100–120 rpm and slowly add water in five parts.
6. Once the last part of water has been added, mix for 5 minutes. Add phase D (preservative) and mix for 5 minutes. Allow the gel to rest for 45 minutes to achieve the finalized properties.



Menthol gel – macrostructure

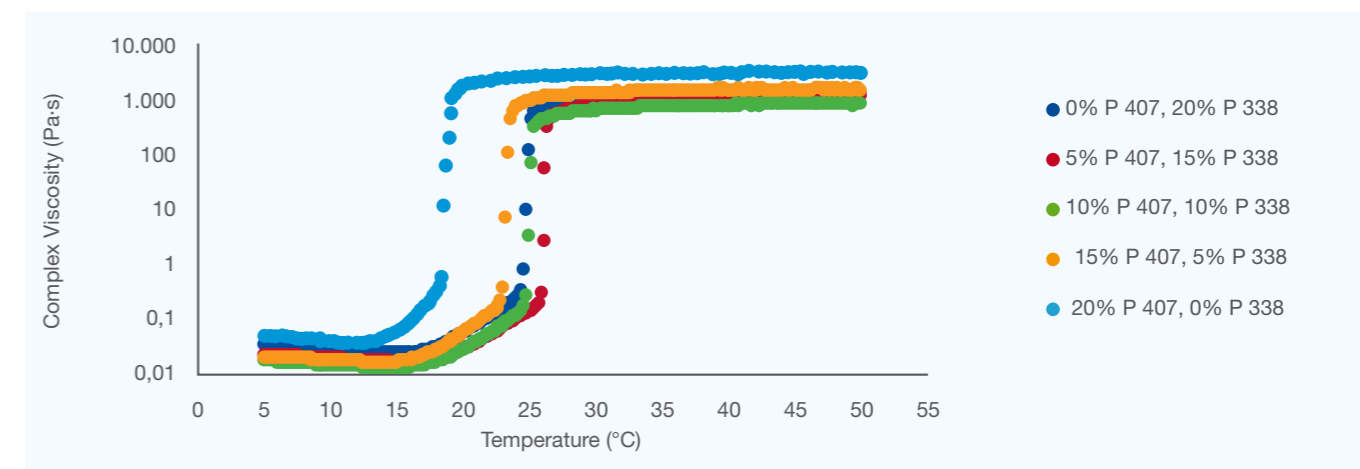
Formulation of thermo-reversible gels

Poloxamers are synthetic block copolymers of ethylene oxide and propylene oxide that can be processed either hot or cold. Kolliphor[®] poloxamers can be used to make gels and viscous emulsions by both emulsifying and forming phases and networks via the hydrophobic and hydrophilic interactions; these hydrophobic and hydrophilic interactions are driven by the PPO and PEO segments of the polymer, respectively.



BASF's Kolliphor[®] P 407 (poloxamer 407), P 338 (poloxamer 338), and P 188 (poloxamer 188) can be combined to form thermo-reversible menthol gels with tunable properties. The ratio of Kolliphor[®] P 407 to Kolliphor[®] P 338 was adjusted incrementally by 5% (wt/wt%) to tune formulation gel point and rheological performance as shown in the graph below.

Complex viscosity vs. temperature (poloxamer combination)



Oscillation temperature ramp of poloxamer combination solutions (20% cumulative poloxamer in water).

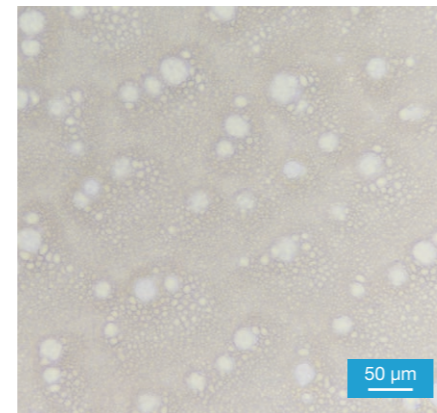
Menthol sprayable film former

An easily applied, fast drying spray that yields smooth, cohesive films on the skin

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kollicoat® SR 30 D	Polyvinyl acetate dispersion	Film former	15.00
	Ethanol	Ethanol	Solvent	78.00
	Kollicream® IPM	Isopropyl myristate	Emollient	2.00
	L-Menthol Pharma flakes	L-menthol	API	5.00

Procedure

1. Weigh out phase A into an appropriately sized beaker.
2. Place mixture under an overhead mixer and set to 150 rpm until complete solubilization of menthol.
3. Transfer to an appropriate spray pump bottle.

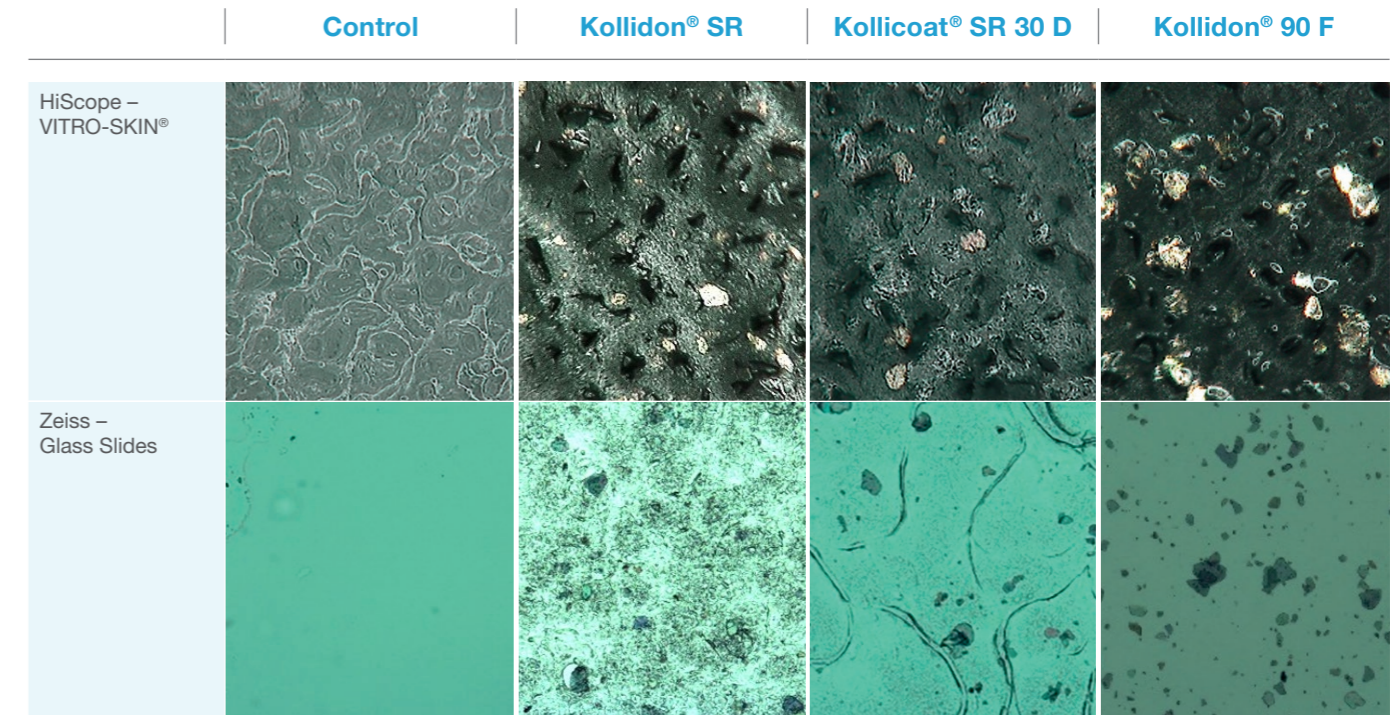


Menthol sprayable film former – light microscopy (200x magnification)

Topical film formers as innovative dosage forms

Topical film formers are formulations that yield a cohesive film on the surface of the skin. Characterized by fast drying times and good bioadhesion, film formers allow for retention or controlled delivery of the API into the skin. BASF offers an array of polymer chemistries that can be synergistically combined with its broad portfolio of excipients for the development of topical film formers.

Kollidon® SR (80% polyvinyl acetate, 19% povidone, 0.8% SLS, 0.2% silica), Kollicoat® SR 30 D (polyvinyl acetate dispersion), and Kollidon® 90 F (povidone) form physical barriers that both protect the skin and enhance API retention. Gold pigment (faux API) has been found to demonstrate uniform “API” deposition onto in vitro skin models and glass slides. Menthol film formers provide patients with a new, innovative method to quickly and neatly apply product to large surface areas of the skin, allowing for symptomatic relief without the tackiness or oiliness commonly seen in more traditional topical dosage forms.



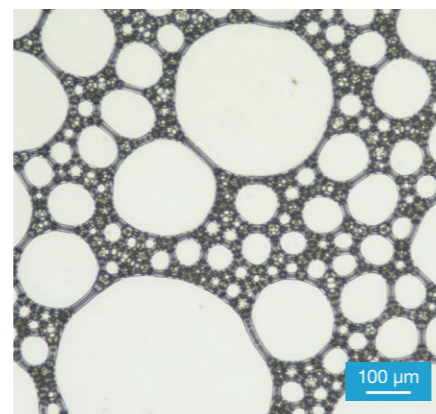
Menthol aerosol foam

A light, airy foam offering enhanced spreadability to complement desirable sensory parameters

Phase	Ingredient	Chemical Name	Functionality	wt/wt%
A	Kolliwax® CSA 50	Cetostearyl alcohol	Structuring agent	3.20
	Kolliphor® CS 12	Macrogol cetostearyl ether 12	Emulsifier	6.40
	Kollicream® 3C	Cocoyl caprylocaprates	Emollient	3.00
	L-Menthol Pharma flakes	L-menthol	API	2.00
B	Water	Water	Solvent	78.70
C	Euxyl® PE 9010	Phenoxyethanol-ethylhexylglycerin	Preservative	0.70
D	A-46	Propane/Isobutane	Propellant	6.00

Procedure

1. Weigh out phases A and B into appropriately sized beakers. Place mixtures under overhead mixers and set to 50 rpm. Heat the mixtures to 90°C.
2. Add phase A to phase B. Mix at 300 rpm for 10 minutes.
3. Decrease mixing speed to 125 rpm.
4. When the formulation has cooled to 45°C, add in phase C (preservative).
5. Continue mixing until the formulation has cooled to room temperature.
6. Transfer the formulation into an aerosol foam dispenser and charge with propellant.



Menthol aerosol foam – light microscopy
(100x magnification)

Importance of mildness

Dosage form selection and excipient mildness play essential roles in minimizing the risk of irritation and adverse reactions when developing topical products. Unlike convention topical vehicles, foam formulations offer enhanced spreadability and a unique sensory profile. When formulated with mild materials, menthol foam formulations can facilitate both improved patient compliance and acceptance.

In addition to Kollicream® 3C, several BASF materials have been evaluated for their allergy or irritation potential via clinical mildness studies. Patch testing was conducted on patients with a history of sensitive skin to study excipient mildness. The materials listed below have demonstrated minimal allergy or irritation potential.*

Trade Name	Chemical Name
Kollicream® 3C	Cocoyl caprylocaprates
Kollicream® CP 15	Cetyl palmitate 15
Kollicream® DO	Decyl oleate
Kollicream® IPM	Isopropyl myristate
Kollicream® OA	Oleyl alcohol
Kollicream® OD	Octyldodecanol
Kolliphor® CS 20	Polyoxyl 20 cetostearyl ether 20
Kolliphor® PS 60	Polysorbate 60
Kollisol® PEG 300	Polyethylene glycol 300
Soluplus®	Polyvinyl caprolactam – polyvinyl acetate – polyethylene glycol copolymer



* Patch testing is considered to be the standard methodology for evaluating contact dermatitis. In partnership with Dr. Joseph Fowler and his team at Forefront Dermatology, patch testing was conducted on patients who presented with a history of chronic dermatitis of unknown cause. Finn Chambers® were used to apply test substances to the backs of patients, per a globally standardized protocol. BASF products were applied at 35% in petrolatum or water. The patches were removed following a 48-hour contact period. The application sites were then evaluated and scored at 48, 72, and 96 hours after initial patch placement. The study was concluded after 500 patients were treated.

3 List of BASF Topical Excipients*

Functionality	Product	Description	Monography Name*/Chemical Name
Emollients & Solvents	Kollicream® 3C	Medium spreadability. Extremely mild. Solvent for lipophilic drugs. Enhances skin penetration.	Ph. Eur.: Cocoyl caprylocaprata, Coco-caprylate/caprata
	Kollicream® IPM	Fast spreading with light and fresh feeling. Solvent for lipophilic drugs. Enhances skin penetration.	Ph. Eur., USP/NF: Isopropyl myristate
	Kollicream® OD	Medium spreadability. Solvent for lipophilic drugs. Enhances skin penetration. Effective in exceptionally wide pH range.	Ph. Eur., USP/NF: Octyldodecanol
	Kollisolv® PEG 300	Solubilizer for drugs. Form anhydrous, hydrophilic ointments in conjunction with higher mol. weight PEG.	Ph. Eur.: Macrogols, USP/NF: Polyethylene glycol, JP: Macrogol 300, FCC: Polyethylene glycols
	Kollisolv® PEG 400	Solubilizer for drugs. Form anhydrous, hydrophilic ointments in conjunction with higher mol. weight PEG.	Ph. Eur.: Macrogols, USP/NF: Polyethylene glycol, JP: Macrogol 400, FCC: Polyethylene glycols
	Kollisolv® PG	Skin penetration enhancer & solvent.	Ph. Eur., USP/NF, JP, FCC: Propylene glycol
Emulsifiers	Kolliphor® CS 12	Nonionic emulsifier for O/W emulsions.	Ph. Eur.: Macrogol cetostearyl ether 12
	Kolliphor® CS 20	Nonionic emulsifier for O/W emulsions.	Ph. Eur.: Macrogol cetostearyl ether 20, USP/NF: Polyoxyl 20 cetostearyl ether
	Kolliphor® P 407	Solid amphiphilic co-polymer drug solubilizer, emulsifier.	Ph. Eur., USP/NF, JP, FCC: Poloxamer 407, Polythylene (196) polyoxypropylene (67) glycol
Structuring Agents	Kolliwax® GMS II	Co-emulsifier and low HLB surfactant. Stabilizes surfactant phases & emulsion droplets.	Ph. Eur.: Glyceryl monostearate 40-55 (type II), USP/NF: Mono- and di-glycerides
	Kolliwax® CSA 50	Structure-building consistency factor for semi-solids. Viscosity regulator.	Ph. Eur., USP/NF, JP: Cetostearyl alcohol
	Kolliwax® CA	Structure-building consistency factor for semi-solids. Viscosity regulator.	Ph. Eur., USP/NF: Cetyl alcohol
	Kolliwax® SA	Structure-building consistency factor for semi-solids. Viscosity regulator. Higher melting point.	Ph. Eur., USP/NF, JP: Stearyl alcohol
	Kollisolv® PEG 3350 (Pluriol® E 3350)	Forms anhydrous, hydrophilic ointments in combination with low mol. weight PEG.	USP/NF: Polyethylene glycol 3350
Film Formers	Kollicoat® SR 30 D	Sprayable polymeric film former. Flexible. Wash resistant.	Ph. Eur.: Poly(vinyl acetate) dispersion 30 percent, USP/NF: Polyvinyl acetate dispersion

*This list is to serve as a brief summary of commonly utilized excipients offered in the BASF Topical portfolio. For complete list of excipients, visit www.pharma.basf.com.

*Monograph references were updated at time of printing. Please visit us online for the latest status.

RSPO-certified Oleochemicals

It's time to think about sustainable sourcing

BASF introduces the first RSPO-certified oleochemicals for the pharmaceutical industry

A key renewable raw material for numerous pharmaceutical excipients is palm kernel oil (PKO) and its respective derivatives. The ubiquitous use of these materials across industry has contributed significantly to deforestation, loss of biodiversity and climate change. As a result, there is widespread concern about these challenges among retailers, NGOs, investors and consumers. Take advantage of BASF oleochemical products certified by the Roundtable on Sustainable Palm Oil (RSPO) and align your company and products with the strong sustainability values evolving in the marketplace.

Join BASF in committing to sustainable sourcing for oleo excipients

- ✓ Contribute significantly to your own sustainable sourcing efforts
- ✓ Same high-quality, compendial oleochemical products with no physical or chemical changes
- ✓ RSPO-certified Oleochemical Products
- ✓ Certificate numbers provided with every produced and delivered batch
- ✓ Join BASF as part of RSPO to market your own products as RSPO-certified

RSPO offers the global certification of palm oil

- ✓ 4,107 members in 92 countries
- ✓ Certifies sustainability practices of palm plantations
- ✓ Certifies the integrity of the supply chain to you

Quality & Regulatory Support



The Pharma Solutions Regulatory Team has a global and regional presence with a decades-long track record of enabling our Pharma customers to register finished drug products worldwide. We do this by efficiently offering high quality expert solutions through proactive and transparent communication.

Our global Quality Team supports our customers worldwide with regards to any quality related questions.

A regional footprint secures quick and regional specific solutions in alignment with global standards for topics like audits, statements and complaints.

In close exchange with authorities and international associations we are constantly improving our quality systems to provide the best service to our customers in more and more demanding markets. For this purpose we cooperate closely with the production sites and ensure GMP-compliant production and testing in accordance with the latest requirements of the pharmaceutical authorities.

Access to standard quality and regulatory documentation is now more efficient than ever. Retrieve your documents 24/7 from your World account or sign-up for new RegXcellence®, your free online Quality & Regulatory Assistant that provides a unified platform for compliance documents, filing assistance and audit information.



Sign-up today at:
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We create chemistry

Our service offer

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