

Kolliphor[®] SML 20

Pharmaceutical grade sorbitan laurate for topical and oral applications





Inspiring Medicines for Better Lives

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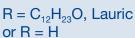
Pharmaceutical grade sorbitan laurate for topical and oral applications

Kolliphor® SML 20 (sorbitan laurate) is a non-ionic, lipophilic surfactant and emulsifier for pharmaceutical applications, derived from the dehydration and esterification of sorbitol and lauric acid.

As a non-ethoxylated surfactant and emulsifier, Kolliphor® SML 20 can be used in a range of oral and topical dosage forms including capsules, tablets, suspensions, aerosols, foams, creams, gels, and more. While often acting as a solubilizing agent, this excipient can also act as an emulsifier for semi-solid products. Kolliphor® SML 20 has a long history of use in topical applications as an oil-in-water emulsifier for steric stabilized systems, but can also be used to formulate water-in-oil emulsions due to its low HLB value of 8.6.*

Figure 1. The represented formula is simplified showing the structure of sorbitan laurate, only.

RO RO RC ٦R





Kolliphor[®] SML 20

Product details

Generic name	Sorbitan laurate
CAS number	1338-39-2
Manufacturing site	Duesseldorf, Germany
Manufacturing process	Semi-synthetic
Regulatory	Ph. Eur.IPEC-PQG GMP for excipientsComplete pharma documentation available
Appearance	Brownish-yellow, viscous liquid
Certified	Kosher, Halal
PRD number	30776707
Packaging and article numbers	190 kg lacquered steel drum (ART 50728982)
Sample and article number	0.5 kg glass bottle (ART 50728983)
Retest period	24 months
Storage and transport	Store in the original packaging and below 30°C

Key customer benefits

Supply reliability	Product is globally available in 190 kg drums
Consistent quality	Ph. Eur. monograph compliance (Sorbitan Laurate)
Sustainability	Roundtable on Sustainable Palm Oil (RSPO) certification available
Technical service	 Deep understanding of excipient science Formulation guidance with ZoomLab[™]
BASF Virtual Pharma Assistants	 Regulatory documentation available in RegXcellence[®] Product details available in MyProductWorld

Full pharma regulatory documentation and submission support



Example cream formulation

A lightweight, quick-spreading cream for even skin application.

Phase	Ingredient	Chemical name	% (w/w)
	Kolliwax® CSA 50	Cetostearyl alcohol	7.00
	Kollisolv® MCT 70	Triglycerides, medium-chain	10.00
A	Kolliwax [®] GMS II	Glycerol monostearate 40-55 (type II)	2.00
	Kolliphor [®] SML 20	Sorbitan laurate	1.94
	Kolliphor [®] CS 20	Macrogol cetostearyl ether 20	1.56
	Water	Water	73.5
З	Glycerin	Glycerin	3.00
	Xanthan gum	Xanthan gum	0.30
C	EuxyI™ PE 9010	Phenoxyethanol-ethylhexylglycerin	0.70

Procedure

- 1. Weigh out phase A into an appropriately sized beaker. Place the mixture under an overhead mixer and set to 50 rpm. Heat the mixture to 70 – 80°C.
- 2. In a separate beaker, weigh out the water for phase B and heat to 70 80°C.
- 3. Add phase A to phase B under shear.
- 4. Homogenize mixture at 5000 rpm for 10 minutes.
- 5. Place the mixture under an overhead mixer and allow to cool under mild shear.
- 6. When the formulation has cooled to 45°C, add in the preservative (phase C).

Example lotion formulation

An easy-to-apply lotion offering a balance between gentleness and skin absorption.

Phase	Ingredient	Chemical name	% (w/w)
	Kolliwax [®] CSA 50	Cetostearyl alcohol	5.00
	Kollicream [®] IPM	Isopropyl myristate	10.00
A	Kolliwax [®] GMS II	Glycerol monostearate 40-55 (type II)	2.00
	Kolliphor [®] SML 20	Sorbitan laurate	1.00
	Kolliphor [®] CS 20	Macrogol cetostearyl ether 20	1.00
В	Water	Water	77.00
	Glycerin	Glycerin	3.00
	Xanthan gum	Xanthan gum	0.30
С	EuxyI™ PE 9010	Phenoxyethanol-ethylhexylglycerin	0.70

Procedure

- Weigh out phase A into an appropriately sized beaker. Place the mixture under an overhead mixer and set to 50 rpm. Heat the mixture to 70 – 80°C.
- 2. In a separate beaker, weigh out the water for phase B and heat to 70 80°C.
- 3. Add phase A to phase B under shear.
- 4. Homogenize mixture at 5000 rpm for 10 minutes.
- 5. Place the mixture under an overhead mixer and allow to cool under mild shear.
- 6. When the formulation has cooled to 45°C, add in the preservative (phase C).

Example gel formulation

A simple gel that offers a cooling sensation upon application.

Phase	Ingredient	Chemical name	% (w/w)
	Ethanol	Ethanol	10.00
	Glycerin	Glycerin	5.00
Ą	Kollisolv® PEG 400	Polyethylene glycol	12.00
	Kolliphor [®] SML 20	Sorbitan laurate	2.00
	Euxyl™ PE 9010	Phenoxyethanol-ethylhexylglycerin	1.00
	Kolliphor [®] P 407	Poloxamer 407	18.00
В	Water	Water	52.00

Procedure

- 1. Leave phase B refrigerated at 5 °C for 24 hours, or until all of the Kolliphor[®] P 407 has dissolved in the water.
- 2. Add phase A to phase B. Stir slowly until the poloxamer has gelled, being careful not to mix in excess air.

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