Technical Information

Kolliphor® SML 20

Sorbitan laurate for pharmaceutical applications

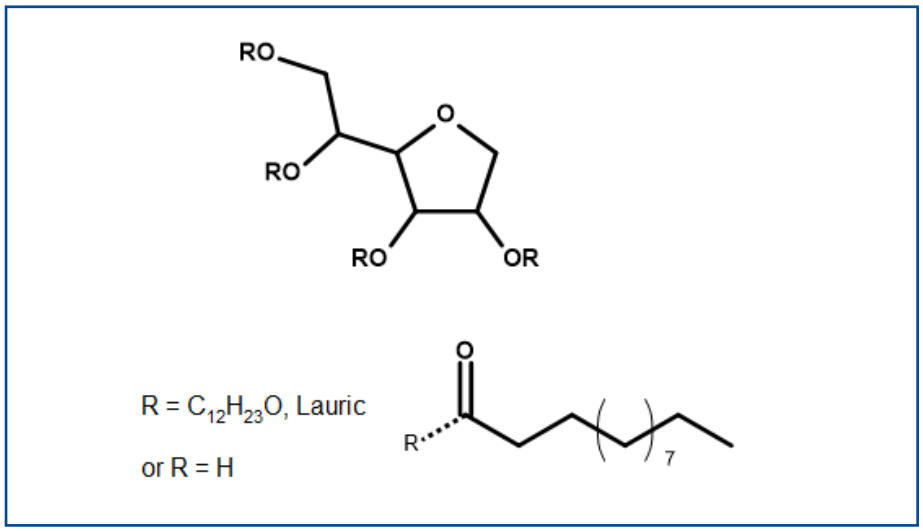
BASF
We create chemistry

Chemical information

Chemical name	Sorbitan Laurate
CAS number	1338-39-2
Regulatory Status	Kolliphor® SML 20 meets the current Ph. Eur. monograph under its compendial name “Sorbitan Laurate”. Furthermore, it meets the requirements of IPEC-PQG GMP for Excipients.
Sustainable Sourcing	Roundtable on Sustainable Palm Oil (RSPO) certification available

Sorbitan laurate is a non-ionic lipophilic surfactant and emulsifier for pharmaceutical applications, derived from dehydration and esterification of sorbitol and lauric acid.

Structural formula *



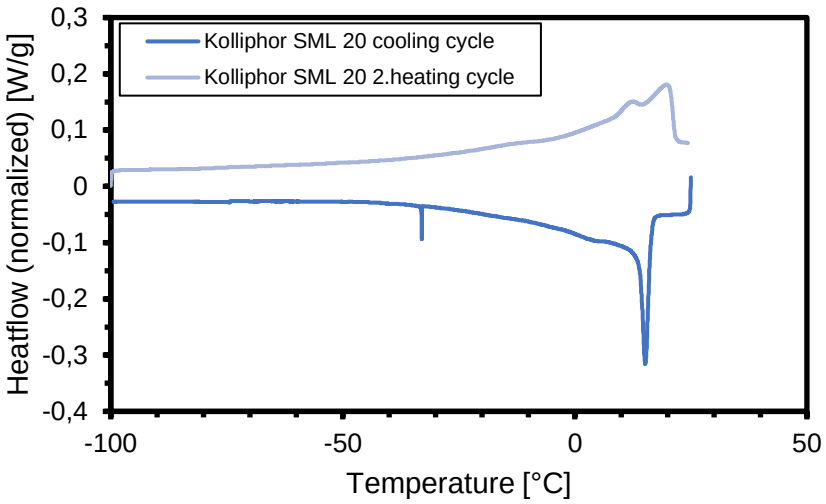
* the represented formula is simplified showing the structure of sorbitan laurate, only.

Selected chemical and physical parameters

Property	Kolliphor® SML 20 typical values
Appearance	Brownish- yellow, viscous liquid
HLB*	8.6 ****
cmc**	69 mg/L
viscosity***	1645 mPas (40 °C) 793 mPas (50 °C) 356 mPas (60 °C) 191 mPas (70 °C) 108 mPas (80 °C)

* HLB value was calculated using Griffins method (Griffin, W.C. (1949) Classification of Surface-Active Agents by “HLB”. Journal of Cosmetic Science, 1, 311-326.)
** cmc was measured by Wilhelmy plate method (R-20220930-00036).
***Haake MARS III, shear rate of 500 1/s and at 40 - 80°C; geometry plate/plate P20 CS L – B11026 (17040L).
**** The HLB can vary depending on variations in the absolute fatty acid composition. Based on the analyzed fatty acid distribution of three batches, HLB values of 8.6, 8.6, and 8.7 were calculated. A rounded HLB of 9 will be met for all batches provided by BASF.

Differential Scanning Calorimetry (DSC)



1st heating cycle - 100 °C → + 25 °C	Cooling + 25 °C → - 100 °C	2nd heating cycle - 100 °C → + 25 °C
Tg: - 24 °C Tm: 12.3 °C 19.7°C	Crystallization start: 15.2 °C Crystallization peak: - 28 °C - 14 °C	Tg: - 20 °C Tm: 12.5 °C 19.8 °C

Differential scanning calorimetry was performed in two cooling and heating cycles applying a cooling/heating rate of two Kelvin per minute. The glass transition temperatures (Tg) and melting points (Tm) are reported for both heating cycles and the second cooling cycle (R-20220802-00040).

Water solubility & viscosity:

Kolliphor® SML 20 is soluble in organic solvents, such as ethanol, and methanol. It is insoluble in water and poorly soluble in acetone. The viscosity of the solutions is depending on the concentration of Kolliphor® SML 20 in the respective solvent:

solvent	Concentration Kolliphor® SML 20 in solvent	Viscosity* [mPas]
methanol	10 % 50 % 90 %	1.0 2.0 61.0
ethanol	10 % 50 % 90 %	0.9 3.0 106.0

* Haake RotoVisco1, shear rate of 500 1/s and at 25°C; geometry cup DG43 and Rotor Z41 (16821L).

Example Applications:

a) Light Cream

A light-weight, quick-spreading cream for even skin application.

Phase	Ingredient	Chemical name	Wt/wt%
A	Kolliwax® CSA 50	Cetostearyl alcohol	7.00
	Kollisolv® MCT 70	Medium chain triglyceride	10.00
	Kolliwax® GMS II	Mono- and di-glycerides	2.00
	Kolliphor® SML 20	Sorbitan laurate	1.93
	Kolliphor® CS 20	Cetostearyl ether	1.56
B	Water	Water	73.5
	Glycerin	Glycerin	3.00
	Xanthan gum	Xanthan gum	0.30
C	Phenoxyethanol-ethylhexylglycerin	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 – 80ºC.
2. In a separate beaker, weigh out the water for phase B and heat to 70 – 80ºC.
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 ºC, add in the preservative (phase C).

b) Easily spreadable Lotion:

A smooth application intended for easy spreadability.

Phase	Ingredient	Chemical name	Wt/wt%
A	Kolliwax® CSA 50	Cetostearyl Alcohol	5.00
	Kollisolv® MCT 70	Medium chain triglyceride	12.00
	Kolliwax® GMS II	Mono- and di- glycerides	0.50
	Kolliphor® SML 20	Sorbitan laurate	1.98
	Kolliphor® CS 20	Cetostearyl Ether	1.62
B	Water	Water	74.9
	Glycerin	Glycerin	3.00
	Xanthan Gum	Xanthan Gum	0.30
C	Phenoxyethanol ethylhexylglycerin	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 – 80ºC.

2. In a separate beaker, weigh out the water for phase B and heat to 70 – 80ºC.
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 ºC, add in the preservative (phase C).

c) Easy-to-apply Lotion

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

Phase	Ingredient	Chemical name	Wt/wt%
A	Kolliwax® CSA 50	Cetostearyl Alcohol	5.00
	Kollicream® IPM	Isopropyl Myristate	10.00
	Kolliwax® GMS II	Mono- and di-glycerides	2.00
	Kolliphor® SML 20	Sorbitan laurate	1.00
	Kolliphor® CS 20	Cetostearyl Ether	1.00
B	Water	Water	77.00
	Glycerin	Glycerin	3.00
	Xanthan Gum	Xanthan Gum	0.30
C	Phenoxyethanol	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 – 80ºC.
2. In a separate beaker, weigh out the water for phase B and heat to 70 – 80ºC.
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 ºC, add in the preservative (phase C).

Storage recommendation:

Refer to the individual document quality and regulatory product information (QRPI), available on RegXcellence® and from your local BASF sales representative.

Product Details:

PRD number	30776707
Packaging and article number	190 kg steel drum, (ART 50728982)
Sample and article number	0.5 kg glass bottle (ART 50728983)
Handling and Safety	Refer to the safety data sheet (SDS) for instructions on safe and proper handling and disposal. SDS are available on RegXcellence® and are sent with every consignment.
Product Specification	The current version of the product specification is available on RegXcellence® and MyProductWorld or from your local BASF sales representative.
Regulatory and Quality	Refer to the individual document quality and regulatory product information (QRPI), available on RegXcellence® and from your local BASF sales representative. The QRPI document covers all relevant information including retest periods and storage conditions.
Stability and Retest Period	The product is typically stable for 3 years after date of production provided storage under recommended conditions. For the retest period and storage conditions please see “Quality & Regulatory Product Information” in RegXcellence®

ZoomLab™, RegXcellence® & MyProductWorld

ZoomLab™

Your virtual formulation assistant

- Eliminate trial and error by instantly optimizing and predicting your next
  starting formulation
- Explore a robust knowledge base of active ingredients, excipients, and
  Formulations
- Create personalized development projects while maintaining drug chemistry confidentiality

Predict your next drug's starting formulation instantly

RegXcellence®

Your virtual quality & regulatory assistant

- Instantly download standard quality and regulatory documents
- Find comprehensive compliance information and request customized documentation
- Stay in compliance with automated change notifications

Make quality and regulatory compliance a breeze

MyProductWorld

Your virtual product assistant

- Find your favorite excipient and active ingredients, browse comprehensive
  product information, request 3rd party audit reports, and more
- Request and track samples, order products, and more via your personalized
  user profile

Find pharma grade excipients and API solutions faster

Register for free at https://virtualpharmaassistants.basf.com/s/ and meet your 24/7 Virtual Pharma Assistants today!

Disclaimer

This document, or any information provided herein does not constitute a legally binding obligation of BASF and has been prepared in good faith and is believed to be accurate as of the date of issuance. Unless expressly agreed otherwise in writing in a supply contract or other written agreement between you and BASF:

(a) To the fullest extent not prohibited by the applicable laws, BASF EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY FACT OR LAW, INCLUDING ANY IMPLIED WARRANTIES, REPRESENTATIONS OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, NON-INFRINGEMENT, AND ANY REPRESENTATIONS, WARRANTIES, CONDITIONS OR GUARANTEES, ARISING FROM STATUTE, COURSE OF DEALING OR USAGE OF TRADE and BASF HEREBY EXPRESSLY EXCLUDES AND DISCLAIMS ANY LIABILITY RESULTING FROM OR IN CONNECTION WITH THIS DOCUMENT OR ANY INFORMATION PROVIDED HEREIN, including, without limitation, any liability for any direct, consequential, special, or punitive damages relating to or arising therefrom, except in cases of (i) death or personal injury to the extent caused by BASF´s sole negligence, (ii) BASF´s willful misconduct, fraud or fraudulent misrepresentation or (iii) any matter in respect of which it would be unlawful for BASF to exclude or restrict liability under the applicable laws;
(b) Any information provided herein can be changed at BASF´s sole discretion anytime and neither this document nor the
information provided herein may be relied upon to satisfy from any and all obligations you may have to undertake your own inspections and evaluations;
(c) BASF rejects any obligation to, and will not, automatically update this document and any information provided herein, unless required by applicable law; and
(d) The user is responsible for confirming that the user has retrieved the most current version of this document from BASF as appropriate