

Kolliwax[®] grades

® = Registered trademark of BASF

Consistency factors for topical pharmaceutical application and excipients for oral solid dosage forms.

This technical information gives an overview on the use of the Kolliwax grades in topical pharmaceutical applications and oral solid dosage forms.

Rebranding

As a result of the integration of former Cognis excipients in the BASF portfolio a rebranding was conducted. The rebranding should increase the reliability and compliance for the supply of pharmaceutical excipients. The following table shows a comparison of old versus new trade names.

Tradename	Former Tradename	Chemistry
Kolliwax GMS I	Speziol MD Pharma	Glyceryl Monostearate
Kolliwax GMS II	Cutina GMS V PH	Glyceryl Monostearate
Kolliwax HCO	Cutina HR PH	Hydrogenated castor oil
Kolliwax MA	Speziol C 14 Pharma	Myristyl Alcohol
Kolliwax CA	Speziol C 16 Pharma	Cetyl Alcohol
Kolliwax CSA 50	Speziol C 16-18 Pharma	Cetostearyl Alcohol
Kolliwax CSA 70	Speziol D Pharma	Cetostearyl Alcohol
Kolliwax SA	Speziol C 18 Pharma	Stearyl Alcohol
Kolliwax SA Fine	New product	Stearyl Alcohol
Kolliwax S	Speziol L2SM GS Pharma	Stearic Acid Palmitic Acid
Kolliwax S Fine	Speziol L2SM GF Pharma	Stearic Acid Palmitic Acid

Table 1: New Tradenames- and former Tradenames

	PRD-No.	Article-No.	CAS-No.
Kolliwax GMS I	30554753	50253531	67701-33-1
Kolliwax GMS II	30554444	50253254	85251-77-0
Kolliwax HCO	30554455	50253255	8001-78-3
Kolliwax MA	30554492	50253415	112-72-1
Kolliwax CA	30554718	50253459	36653-82-4
Kolliwax CSA 50	30554719	50253501	67762-27-0
Kolliwax CSA 70	30554721	50253504	67762-27-0
Kolliwax SA	30554720	50253503	112-92-5
Kolliwax SA Fine	30563963	50284249	112-92-5
Kolliwax S	30554752	50253532	67701-03-5
Kolliwax S Fine	30554750	50253810	67701-03-5

Table 2: PRD-, Article- and CAS-Numbers.

Specifications

See separate documents: „Standard Specification (not for regulatory purposes)“ available via BASF's WorldAccount: <https://worldaccount.basf.com> (registered access).

Regulatory Status

In table 2 you can find an overview of all the monographs for the Kolliwax grades.

Tradename	Compendial Name
Kolliwax GMS I	Ph. Eur.: Glycerol Monostearate 40-55 (type I)
Kolliwax GMS II	Ph. Eur.: Glycerol Monostearate 40-55 (type II) USP/NF: Mono- and Di-glycerides
Kolliwax HCO	Ph. Eur.: Castor Oil Hydrogenated USP/NF: Hydrogenated Castor Oil JP: Hydrogenated Oil
Kolliwax MA	NF: Myristyl Alcohol
Kolliwax CA	Ph. Eur.: Cetyl Alcohol USP/NF: Cetyl Alcohol JP: Cetanol
Kolliwax CSA 50	Ph. Eur.: Cetostearyl Alcohol USP/NF: Cetostearyl Alcohol JP: Cetostearyl Alcohol
Kolliwax CSA 70	Ph. Eur.: Cetostearyl Alcohol
Kolliwax SA	Ph. Eur.: Stearyl Alcohol USP/NF: Stearyl Alcohol JP: Stearyl Alcohol
Kolliwax SA Fine	Ph. Eur.: Stearyl Alcohol USP/NF: Stearyl Alcohol JP: Stearyl Alcohol
Kolliwax S	Ph. Eur.: Stearic Acid 50 USP/NF: Stearic Acid 50 JP: Stearic Acid
Kolliwax S Fine	Ph. Eur.: Stearic Acid 50 USP/NF: Stearic Acid 50 JP: Stearic Acid

Table 3: Compendial names

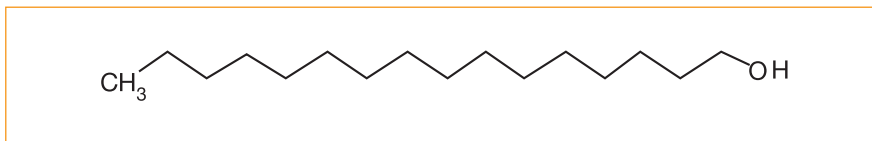
A Kosher certificate for all Kolliwax grades is available upon request.
All Kolliwax grades are produced under IPEC GMP guidelines.

Product groups

In the Kolliwax portfolio you can find consistency factors from different chemical classes like, fatty alcohols, glycerides, fatty acids and hydrogenated castor oil.

Fatty Alcohols

Chemical Structure



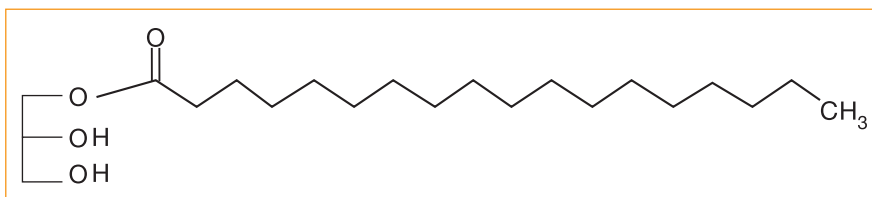
Picture 1: Chemical structure of Kolliwax SA

	Structure	Melting Point [°C]	Acid Value	Hydroxyl value
Kolliwax MA	$C_{14}H_{30}O$	36 – 42	max. 2	250 – 267
Kolliwax CA	$C_{16}H_{34}O$	46 – 52	max. 1.0	218 – 238
Kolliwax CSA 50	$C_{16}H_{34}O$ / $C_{18}H_{38}O$	49 – 56	max. 1.0	208 – 228
Kolliwax CSA 70	$C_{16}H_{34}O$ / $C_{18}H_{38}O$	49 – 56	max. 1.0	208 – 228
Kolliwax SA	$C_{18}H_{38}O$	57 – 60	max. 1.0	197 – 217

Table 4: Typical properties of the fatty alcohols

Glycerides

Chemical Structure



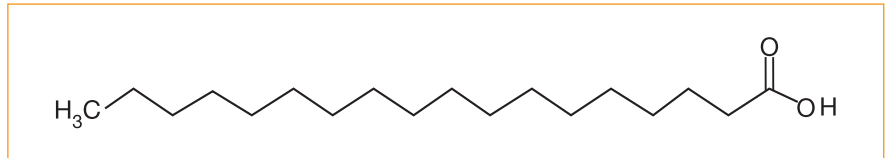
Picture 2: Chemical Structure of the main component of Kolliwax GMS I (Glycerol Monostearate 40-55 (typ I))

	Melting Point [°C]	Acid Value	Saponification value	HLB value
Kolliwax GMS I	54 – 64	max. 3.0	158 – 177	3.8
Kolliwax GMS II	54 – 64	max. 3.0	158 – 177	3.8
Kolliwax GDB	65 – 77	max. 4.0	145 – 165	2.0

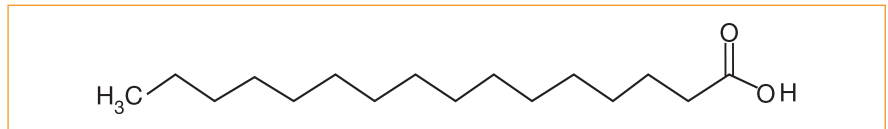
Table 5: Typical properties of the glycerides

Fatty Acids

Chemical Structure



Picture 3: Stearic acid



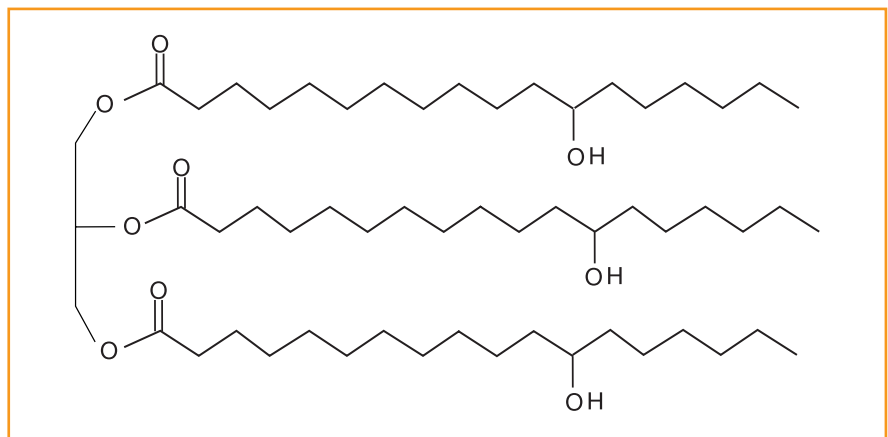
Picture 4: Palmitic acid

	Melting Point [°C]	Acid Value	Iodine value
Kolliwax S	56 – 72	194 – 212	max. 4.0
Kolliwax S Fine	56 – 72	194 – 212	max. 4.0

Table 6: Typical properties of the fatty acids

Hydrogenated Castor Oil

Chemical Structure



Picture 5: Chemical Structure of the main component of Kolliwax HCO

	Melting Point [C]	Acid Value	Hydroxyl value	Saponification value	Iodine value
Kolliwax HCO	83 – 88	max. 4.0	145 – 165	176 – 182	max. 5

Table 7: Typical properties of hydrogenated castor oil

Application

The following table 8 gives an overview on the most important applications and functions of all Kolliwax grades.

Product	PH. Eur.	W/O Emulsifier	O/W Emulsifier	W/O CoEmulsifier	O/W CoEmulsifier	Consistency factor	Lubricant	Matrix Former	Suppository masses
Kolliwax MA	Myristyl Alcohol				■	■			■
Kolliwax CA	Cetyl Alcohol				■	■			■
Kolliwax CSA 50	Cetostearyl Alcohol				■	■			■
Kolliwax SA	Stearyl Alcohol				■	■			■
Kolliwax SA Fine	Stearyl Alcohol						■	■	■
Kolliwax CSA 70	Cetostearyl Alcohol				■	■			■
Kolliwax GMS I	Glycerol Monostearate 40-55 (typ I)	■			■	■			■
Kolliwax GMS II	Glycerol Monostearate 40-55 (typ II)	■			■	■			■
Kolliwax HCO	Castor Oil Hydrogenated					■	■	■	■
Kolliwax S	Stearic Acid 50		■		■	■		■	■
Kolliwax S Fine	Stearic Acid 50						■	■	■

Table 8: Application of the Kolliwax grades

Emulsion

The Kolliwax grades can be used for all kinds of topical pharmaceutical applications such as gel creams, lotions and creams: The typical usage concentration in emulsions and creams is about 1 – 5%.

All Kolliwax grades will act as consistency factors and co-emulsifier at the same time. With their amphiphilic structure they will stabilize the surface between oil and water and will help to enhance the viscosity with building up a liquid crystalline network in the water-phase (lamellar structure).

They are able to stabilize W/O and O/W emulsion and they will help to create a unique softness and creaminess in the end application.

Lubricants

Lubricants prevent ingredients from clumping together and from sticking to the tablet punches or capsule filling machine. Lubricants also ensure that tablet formation and ejection can occur with low friction.

Common minerals like talc or silica, and fats, e.g. vegetable stearin, magnesium stearate or stearic acid are the most frequently used lubricants in tablets or hard gelatin capsules. Lubricants are added in small quantities to tablet and capsule formulations to improve certain processing characteristics.

Suppository masses

Suppository formulation can be hardened and adjusted in their melting point by the addition of a Kolliwax grade.

Effect of consistency factors on viscosity

Formulation	Consistency factor	5%
	Kollicream 3C	16.0%
	Kolliphor CS 20	1.0
	Water dem.	78%

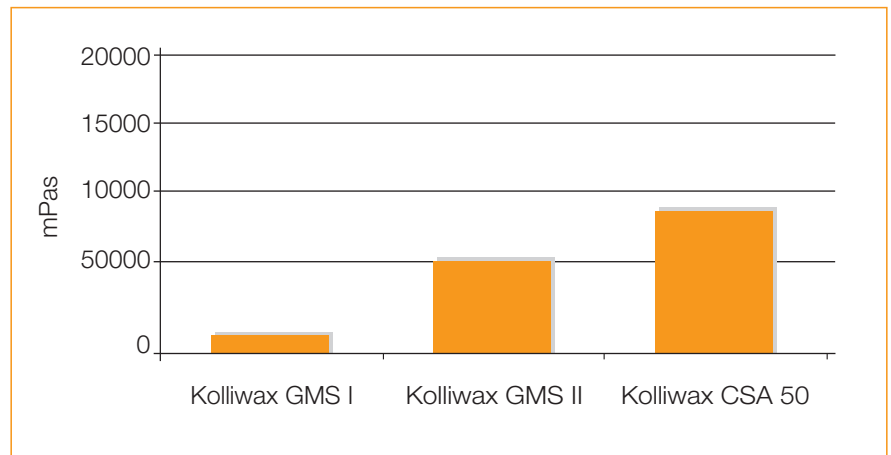


Figure 1: Viscosity of a basic formulation with different consistency factors

In the above mentioned formulation Kolliwax CSA 50 shows the best effect on the viscosity enhancement.

Skin Tolerance

All Kolliwax types have a good skin tolerance.

Raw material origin

All Kolliwax grades are based on vegetable and synthetic raw materials.

Toxicology

The toxicological abstracts are available on request.
Individual reports can be shared under secrecy agreement.

Stability and storage

In originally sealed containers all the Kolliwax types can be stored for at least two years. It is important that they are protected from moisture and stored at less than 30 °C.

Handling and Disposal

Please refer to the individual Material Safety Data Sheet (MSDS) for instructions on safe and proper handling and disposal.

Formulation Example**Oil in Water emulsion**

	Ingredient	Name	Amount
I	Kolliwax GMS II	Glyceryl Monostearate 40-55 Type II	4.0%
	Kolliwax CSA 50	Cetostearyl Alcohol	2.8%
	Kolliphor CS 20	Macrogol Cetostearyl Ether 20	1.6%
	Kolliphor CS 12	Macrogol Cetostearyl Ether 20	0.8%
	Kollicream CP 15	Cetyl Palmitate 15	0.8%
	Kollicream IPM	Isopropylmyristate	5.0%
	Kollicream 3C	Cocoyl Caprylocaprate	5.0%
	Kollicream OD	Octyldodecanol	5.0%
	II	Kollisolv G 99	Glycerin
Preservative			q.s.
Water			70.0%

Note

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