
Technical Information

Kolliwax® Grades

Fatty acids and alcohols:

Consistency factors for topical formulations, and excipients for solid oral dosage forms.

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® = Registered trademark of BASF in many countries.

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1. Introduction

Our Kolliwax® portfolio includes fatty acids and alcohols that can be used as (co-) emulsifiers and consistency factors in topical pharmaceutical applications, but may also function as excipients in solid oral dosage forms, e.g., as matrix formers and lubricants.

This document focuses on fatty acids and alcohols of the Kolliwax® family. Please refer to the individual technical information sheet for specific information on our two glyceride based grades Kolliwax® GMS II and Kolliwax® HCO (Glycerol Monostearate, and Hydrogenated Castor Oil, respectively).

Trade name	Compendial Name
Kolliwax® CA	Ph.Eur.: Cetyl Alcohol USP/NF: Cetyl Alcohol
Kolliwax® CSA 50	Ph.Eur.: Cetostearyl Alcohol USP/NF: Cetostearyl Alcohol JP: Cetostearyl Alcohol
Kolliwax® CSA 70	Ph.Eur.: Cetostearyl Alcohol
Kolliwax® MA	USP/NF: Myristyl Alcohol
Kolliwax® SA Kolliwax® SA Fine	Ph.Eur.: Stearyl Alcohol USP/NF: Stearyl Alcohol JP: Stearyl Alcohol
Kolliwax® S Kolliwax® S Fine	Ph.Eur.: Stearic Acid 50 USP/NF: Stearic Acid 50 JP: Stearic Acid 50

Table 1: Compendial names for fatty alcohols and acids of the Kolliwax® family.

2. Technical properties

Description

Kolliwax® grades are white to slightly yellowish, waxy substances derived from natural resources, namely coconut oil, palm kernel oil, and/or palm stearine. With melting points above room temperature, these products are either supplied as powder, pearls, or pellets (see table 1 and table 2 for details). The numeric part of the name of the two grades of Kolliwax® CSA represents the approximate weight percentage of stearyl alcohol.

Trade name	Chemical nature	CAS-No.	Melting ranges [°C]*
Kolliwax® CA	Cetyl Alcohol (C ₁₆)	36653-82-4	46 – 52
Kolliwax® CSA 50 Kolliwax® CSA 70	Cetyl/Stearyl Alcohol (C ₁₆ /C ₁₈)	67762-27-0	49 – 56
Kolliwax® MA	Myristyl Alcohol (C ₁₄)	112-72-1	36 – 42
Kolliwax® SA Kolliwax® SA Fine	Stearyl Alcohol (C ₁₈)	112-92-5	57 – 60
Kolliwax® S Kolliwax® S Fine	Stearic/Palmitic Acid (C ₁₈ /C ₁₆)	67701-03-05	56 – 72

* Values given for guidance only, see specification sheets for detailed information on melting and/or freezing temperatures.

Table 2: Properties of fatty alcohols and acids of the Kolliwax® family.

Typical appearance



Figure 1: Typical appearance of the Koliwax® grades. The scale in the back is metric, with 1 mm per mark. For detailed information on particle size distributions, please refer to the individual product specification sheets.

Scanning electron microscopy (SEM)

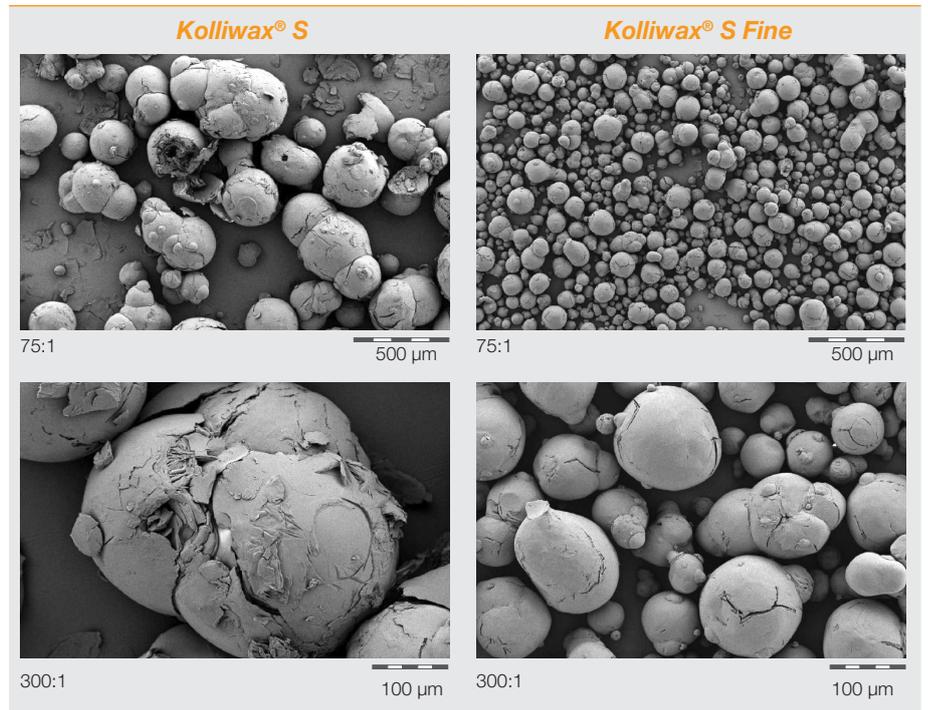


Figure 2: SEM images of Koliwax® S, and Koliwax® S Fine. Please refer to the individual specification sheets for detailed information on particle size distributions.

3. Application

Overview

The following table 3 gives an overview on the most important applications and functions of the Kolliwax® fatty alcohols and acids: while fatty acids and alcohols are generally used as consistency factors, our fine grades of stearic acid and stearyl alcohol (Kolliwax® S Fine and Kolliwax® SA Fine, respectively) allow to use these substances in the preparation of solid dosage forms, where they can aid as lubricants or matrix formers.

Product	Ph. Eur.	O/W Emulsifier	O/W Co-Emulsifier	Consistency Factor	Lubricant	Matrix Former
Kolliwax® CA	Cetyl Alcohol		■	■		■
Kolliwax® CSA 50	Cetostearyl Alcohol		■	■		■
Kolliwax® CSA 70			■	■		■
Kolliwax® MA	Myristyl Alcohol		■	■		
Kolliwax® SA	Stearyl Alcohol		■	■		■
Kolliwax® SA Fine			■	■	■	■
Kolliwax® S	Stearic Acid	■	■	■		■
Kolliwax® S Fine		■	■	■	■	■

Table 3: Application of the Kolliwax® grades.

Emulsions

Exhibiting excellent skin tolerance, the Kolliwax® grades can be used for all kinds of topical pharmaceutical applications, such as creams, gels, lotions, and ointments. The typical usage concentration in emulsions is about 1 – 5%.

All Kolliwax® grades will act as consistency factors and co-emulsifiers at the same time. With their amphiphilic structure, they will stabilize the interface between oil and water and will help to enhance the viscosity by building up a liquid crystalline network (lamellar sheet structure). Stabilizing w/o and o/w emulsions, they also aid in bringing a unique softness and creaminess to the targeted formulation.

Lubricants

In tableting processes for solid oral dosage forms, lubricants are used to prevent ingredients from clumping to undesired aggregates and from sticking to the tablet punches or capsule filling machine. In addition, lubricants hamper the friction that would hinder tablet formation and ejection.

Among inorganic materials (e.g. talc or silica), fat based substances like vegetable stearin, magnesium stearate or stearic acid are commonly used as lubricants in tablets or hard gelatin capsules. Lubricants are added in small quantities to tablet and capsule formulations to improve certain processing characteristics.

Formulation examples

Guideline for the preparation of the model formulations:

1. Heat components of phase A to 80 – 85 °C and stir until transformed into a homogeneous melt.
2. Heat components of phase B to 80 – 85 °C. Under constant stirring, slowly add phase A to phase B, homogenize for 5 min at 5000 rpm. Let cream cool to 35 °C while mixing at 200 rpm, and add preservative.

Model formulation Rich Cream:

This formulation utilizes Kolliwax® CSA 70 and Kolliphor® PS 60 as emulsifiers to create a very stiff cream that offers a slow spread and a cushioned feeling when rubbing into the skin. Its high immediate smoothness results from the utilization of Kollicream® IPM, a fast spreading oil with broad penetration enhancement properties that can aid as a solubilizer for lipophilic drugs.

Phase	Ingredient	Ph. Eur. name	Role	Amount [wt.-%]
A	Kolliwax® CSA 70	Cetostearyl Alcohol	Consistency Factor, Co-Emulsifier	7.0
	Kolliwax® GMS II	Glycerol Monostearate 40-55 (Type II)	Consistency Factor, Co-Emulsifier	2.5
	Kolliphor® PS 60	Polysorbate 60	Emulsifier	4.2
	Kollisolv® MCT 70	Medium Chain Triglycerides	Emollient	11.5
	Kollicream® IPM	Isopropyl Myristate	Emollient	1.3
B	Deionized Water		Solvent	69.2
	Glycerol			3.3
C	Euxyl® PE 9010		Preservative	1.0

Table 4: Model formulation for a rich Cream.

Model formulation Light Cream:

This formulation is a smooth cream with easy distribution, medium viscosity, and a glossy finish. Due to the difference in HLB values, the blending ratio of Kolliphor® CS 12 and Kolliphor® CS 20 can be used as a factor to maximize emulsion stability.

Phase	Ingredient	Ph. Eur. name	Role	Amount [wt.-%]
A	Kolliwax® CSA 50	Cetostearyl Alcohol	Consistency Factor, Co-Emulsifier	4.0
	Kolliwax® GMS II	Glycerol Monostearate 40-55 (Type II)	Consistency Factor, Co-Emulsifier	5.0
	Kolliphor® CS 20	Macrogol Cetostearyl Ether 20	Emulsifier	2.0
	Kolliphor® CS 12	Macrogol Cetostearyl Ether 12	Emollient	0.8
	Kollicream® CP 15	Cetyl Palmitate 15	Emollient	0.8
	Kollicream® IPM	Isopropyl Myristate	Emollient	7.4
B	Deionized Water		Solvent	74.0
	Glycerol			5.0
C	Euxyl® PE 9010		Preservative	1.0

Table 5: Model formulation for a light cream.

4. Handling & Safety

Please refer to the individual material safety data sheet (MSDS) for instructions on safe and proper handling and disposal. Material safety data sheets are available on request and are sent with every consignment.

5. Product specification

The current version of the product specification is available on BASF WorldAccount, or from your local BASF sales representatives.

6. Regulatory & Quality

Please refer to the individual document quality & regulatory product information (QRPI), available on BASF WorldAccount and from your local sales representative. The QRPI document covers all relevant information including retest periods and storage conditions.

7. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30554718	Kolliwax® CA	50253459	25 kg Plastic film bag
		50259499	0.5 kg Plastic bottle**
30554719	Kolliwax® CSA 50	50253501	25 kg Plastic film bag
		50259500	0.5 kg Plastic bottle**
30554721	Kolliwax® CSA 70	50253504	25 kg Plastic film bag
		50259502	0.5 kg Plastic bottle**
30554492	Kolliwax® MA	50375472	20 kg Corrugated fiberboard box with PE liner
		50259498	0.5 kg Plastic bottle**
30554720	Kolliwax® SA	50253503	25 kg Plastic film bag
		50259501	0.5 kg Plastic bottle**
30563963	Kolliwax® SA Fine	50284249	25 kg Plastic film bag
		50372378	0.5 kg Plastic bottle**
30554752	Kolliwax® S	50253532	25 kg Plastic film bag
		50259521	0.5 kg Plastic bottle**
30554750	Kolliwax® S Fine	50253810	25 kg Plastic film bag
		50259508	0.5 kg Plastic bottle**

* BASF's commercial product number.

** Free non-GMP samples (0.5 kg) for testing purposes are available on request.

8. Publications

<http://pharmaceutical.basf.com/en.html>

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