Technical Information

Kolliwax® HCO

Hydrogenated castor oil powder for pharmaceutical use.

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1. Introduction

Kolliwax® HCO consists of Hydrogenated Castor Oil in powder form intended for pharmaceutical use. At room temperature it is a hard wax with a high melting point (85 – 88 °C). The primary function of Kolliwax® HCO is its use as an excipient in both oral and topical pharmaceuticals. For example,in solid oral dose formulations, Kolliwax® HCO is a highly effective lubricant, as well as a matrix lipid for the preparation of sustained release formulations. In topical preparations, Kolliwax® HCO is a structure-building consistency factor that can provide stiffness, viscosity and various sensorial properties.

2. Technical properties

Description

Kolliwax® HCO is obtained by hydrogenation of castor oil. It mainly consists of the triglceride of 12-hydrostearic acid.

Hydrogenated castor oil is vegetable origin (castor oil) and is compatible with most natural vegetable and animal waxes.

Structural formula

The chemical structure of Kolliwax® HCO is represented in Figure 1.

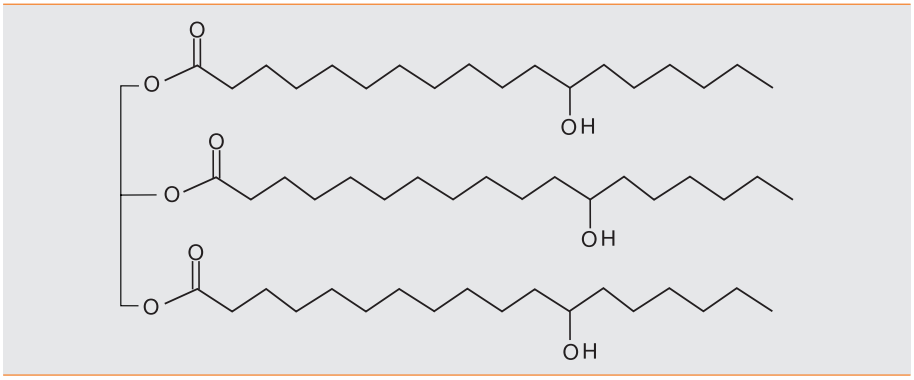


Figure 1: Chemical structure of hydrogenated castor oil

CAS number

8001-78-3

Particle size distribution

Kolliwax® HCO is milled to its final particle size distribution; an example of a typical lot of Kolliwax® HCO is shown in Figure 2.

Typical Particle size distribution	D (10)	D (50)	D (90)	D (4,3)
Kolliwax® HCO	3.8 µm	26.1 µm	72.9 µm	33.0 µm

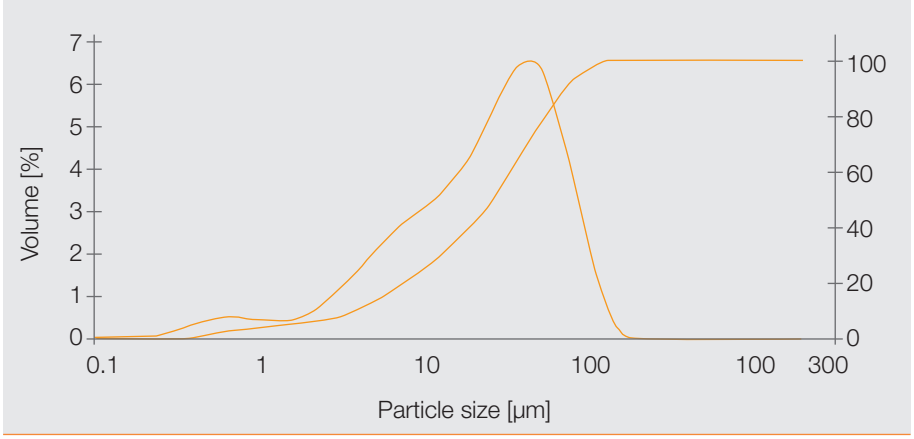


Figure 2: Typical Particle size distribution of hydrogenated castor oil

Dynamic vapor sorption

DVS was measured for Kolliwax® HCO under the following conditions:
Time between cycles 20 min, Min. time per cycle 50 min, Max. time per cycle 36 h
Equilibrium condition 0.05 % per 15 minutes.

The maximal water uptake at 90% rel humidity was at 0.1%. Therefore the material is considered to be not hygroscopic.

Solubility

As per the Ph. Eur. Monograph. Castor oil, hydrogenated Kolliwax® HCO is practically insoluble in water, slightly soluble in methylene chloride, very slightly soluble in anhydrous ethanol and practically insoluble in petroleum.

Differential scanning calorimetry (DSC)

Test conditions:

Heating range	10 K/min
Sample amount	6 – 7 mg
First heating cycle	-20 – 120 °C
Cooling cycle	120 – -20 °C
Second heating cycle	-20 – 120 °C

Cycle	T Onset (°C)	T max 1 (°C)	T max 2 (°C)	T max 3 (°C)	T Offset (°C)	ΔH J/g
1. Heating	59 (±0.6)*	79 (±0.2)*	87 (±0,0)*	/	91 (±0.2)*	142 (±1)*
2. Heating	51 (±0.3)*	60 (±0.4)*	80 (±0.2)*	86 (±0.1)*	89 (±0.1)*	135 (±1)*
3. Cooling	51 (±0.3)*	60 (±0.4)*	80 (±0.2)*	86 (±0.1)*	89 (±0.1)*	135 (±1)*

Table 2: DSC Summary

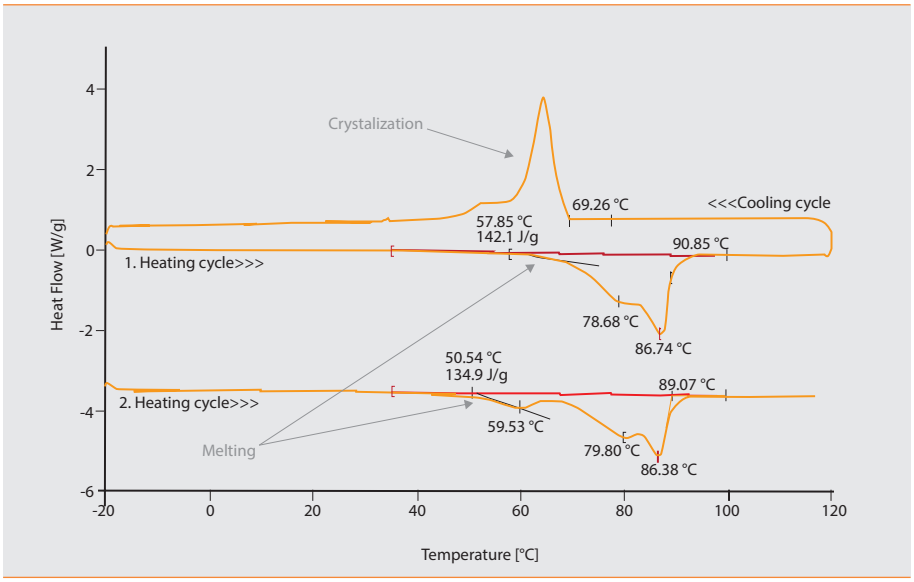


Figure 2: Typical DSC curve of Kolliwax® HCO

Flowability data

Kolliwax® HCO is a finely milled powder and exhibits flowability consistent with fine powders. Typical powder properties are listed in the following table.

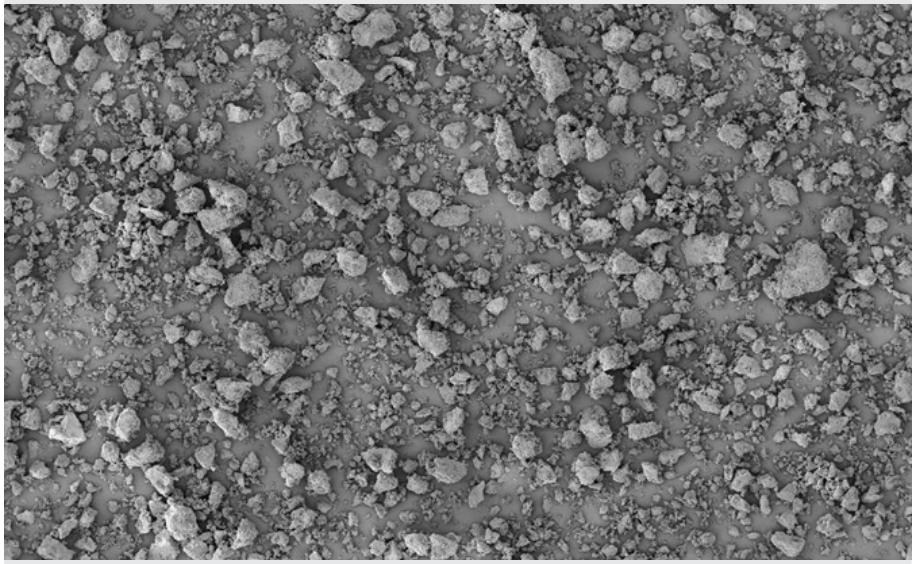
Typical powder properties	Value	Unit
Angle of repose		blocked

Density

Typical powder properties	Value	Unit
Bulk density	g/mL	0.38
Tap density	g/mL	0.52
Hausner factor	°	1,3743.2

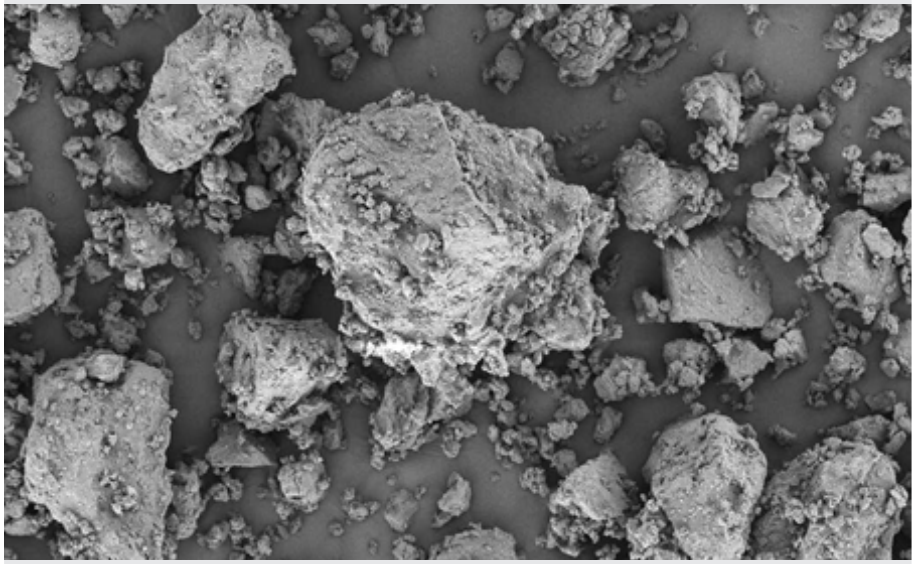
Scanning Electron Microscopy Pictures (SEM)

Images of a typical lot of Kolliwax® HCO are shown in the following SEM images at various magnifications.

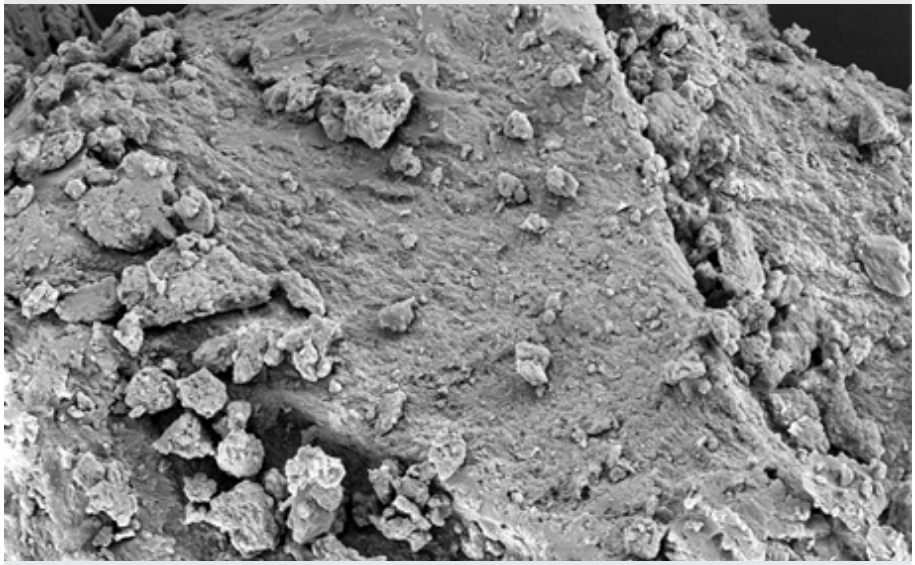


60 : 1

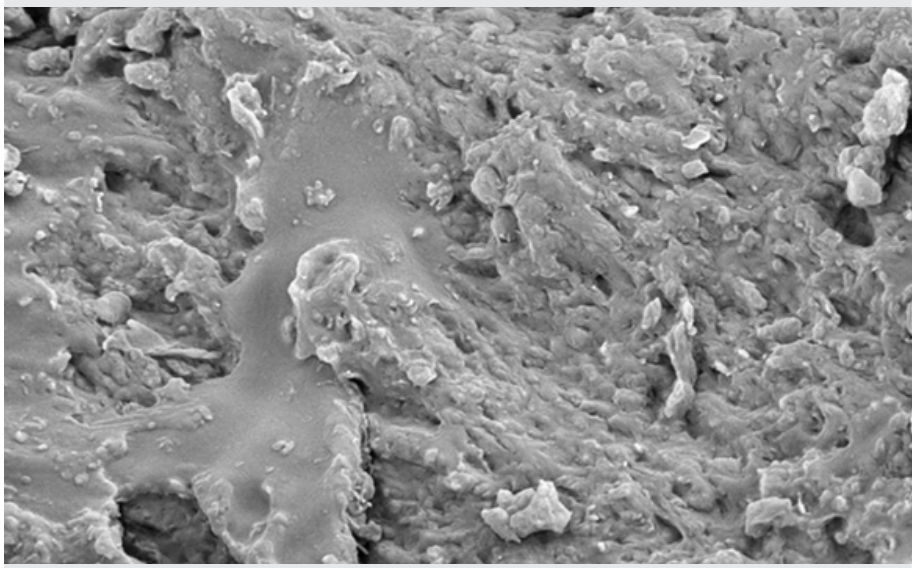
500 µm



300 : 1 — 100 µm



1500 : 1 — 20 µm



1500 : 1 — 2 µm

3. Handling

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

4. Example Application

Lubrication

Lubrication is an essential part of solid oral dose preparation, where specifically, 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. Consequently, lubricants are added in small quantities to tablet and capsule formulations to improve certain processing characteristics. In solid oral dose formulations Kolliwax® HCO can be used as an effective alternative lubricant to magnesium stearate. Furthermore, it is compatible with a large number of actives, and does not provide a metallic taste.

The following study elaborates the optimal working concentration of Kolliwax® HCO as a lubricant. This study was performed on direct compressible placebo formulations using Ludipress®. The “Sweet Spot” diagram shows the optimal working concentration balancing the lubrication effectiveness with the ejection force and the tablet characteristics (e.g. disintegration and hardness).

Study design

Formulation	1	2	3
Ludipress®	99.5%	99.0%	97.0%
Kolliwax® HCO	0.5%	1.0%	3.0%

Blending time: Turbula blender with 2 / 5 / 10 minutes mixing time

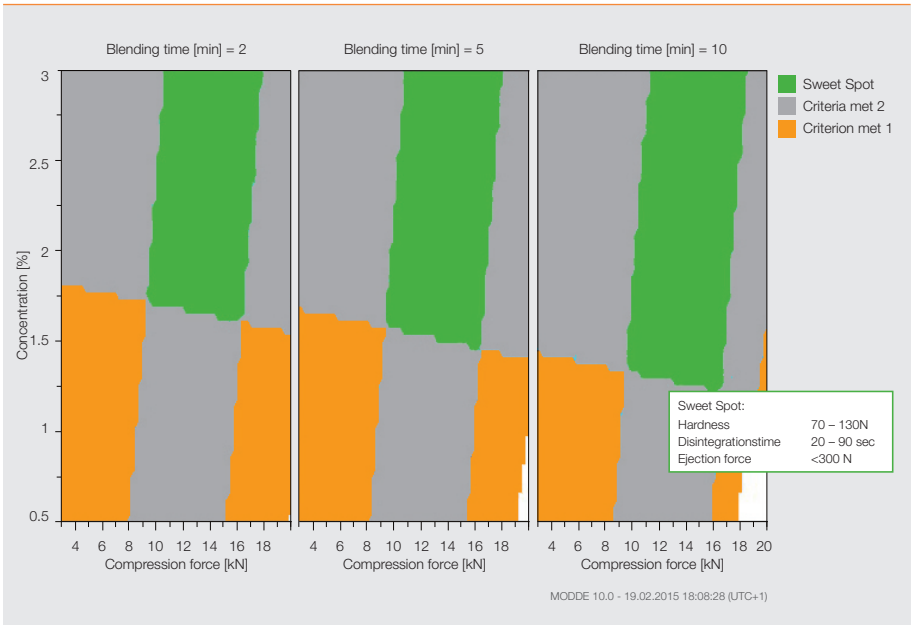
Compression: Korsch XL 100 rotary press, 10 mm flat, 300 mg tablet mass
3 kN / 5 kN / 10 kN / 15 kN / 20 Kn

Evaluation parameter

Compression behavior:
Compression force upper punch, Compression force lower punch, Ejection force.

Tablet characteristics:
Weight, Height, Diameter, Hardness, Tensile strength, Disintegration time

Sweet spot diagram



Diagrammm 2: Sweet spot diagram for optimal working concentration of Kolliwax® HCO as a lubricant

The optimal working concentration of Kolliwax® HCO as a lubricant is starting at 1.5% w/w.

Modified release

As either a lipid-based matrix, or a coating ingredient, Kolliwax® HCO may be used to prepare a sustained released formulation for water soluble APIs (e.g. Alfuzosin HCL, Aminophylline, Lithium Carbonate, Niacin, Sulfanilamide, Theophylline). Kolliwax® HCO can be used as a standalone matrix ingredient or in combination with other sustained release excipients. Typical concentrations for matrices and coatings can range from 5% to greater than 20% w/w.

Topical application

In topical formulations Kolliwax® HCO can be used as consistency factor to enhance the viscosity of the formulation. The typical concentration it at about 0.1 – 2%. Kolliwax® HCO is compatible with most natural vegetable and animal waxes and can therefore be used in combination with fatty alcohols and other consistency factors (e.g. Cetyl Alcohol, Stearyl Alcohol).

Waxes can also affect the sensory profile and the stability of a topical formulation. They are solid at ambient temperatures and stabilize emulsions as the viscosity is increased by formation of lamellar structures in oil-in-water formulations. Specifically, Kolliwax® HCO can be used as consistency factor in a multitude of O/W, W/O or anhydrous formulations. Kolliwax® HCO has a special advantage because of its high melting point and is able to support the formulation stability particularly at elevated temperatures. However, it is critical that the oil phase of the formulation is thoroughly melted and well mixed prior to emulsification. Below is a placebo formulation example, which can be used as a starting point for further formulation work with different types of APIs.

Cream formulation

Phase	Tradename	Chemical	Function	%
I	Di Water	Water	Solvent	70.8
	Glycerin	Glycerin	Humectant	5.0
	Kolliphor® CSS	Sodium cetostearyl sulfate	Emulsifier	1.0
II	Kollicream® IPM	Isopropyl myristate	Emollient	5.0
	Kolliwax® HCO	Hydrogenated castor oil	Consistency factor	2.0
	Kolliwax® CSA 50	Cetostearyl alcohol	Consistency factor	6.0
III	Preservative	Preservative	Preservative	0.2
IV	API	Active pharmaceutical ingredient	API	10.0

Procedure:

Heat the mixture phase I and II separately to 85 – 90 °C: Make sure that Kolliwax® HCO is molten.

Mix phase I and II, homogenize 2 minutes at about 5000 rpm, transfer to impeller mixer, 4 flat blades at 250 rpm.

At 40 °C add III, cool down to 30 °C and add to a sealed glass container. Allow to equilibrate for 24 hours prior to analytical testing and or evaluation.

Anhydrous formulation

Phase	Tradename	Chemical	Function	%
I	Novata® BC PH	Hard Fat	Consistency factor	21.6
	White wax	Cera alba	Consistency factor	4.2
	Kolliwax® GMS II	Glyceryl monostearate	Consistency factor	3.9
	Kolliwax® HCO	Hydrogenated castor oil	Consistency factor	2.6
	Kollicream® CP 15	Cetyl Palmitate	Emollient	4.9
	Kollicream® 3C	Cocoyl caprylocaprate	Emollient	18.1
II	Kollicream® OD	Octyldodecanol	Emollient/Solvent	19.7
	Kollisolv® MCT 70	Medium chain triglycerides	Solvent	23.0
	API	Active pharmaceutical ingredient	API	2.0

Procedure:

Heat phase I to 85 – 90 °C: Make sure that Kolliwax® HCO is molten. Heat phase II separately to 70 °C or until API is solubilized. Mix phase I using an impeller mixer, 4 flat blades at 500 rpm.

At 70 °C add phase II. Cool to 30 °C while stirring at 250 rpm and add to a sealed glass container. Allow to equilibrate for 24 hours prior to analytical testing and or evaluation.

5. Safety data sheet

Safety data sheets are available on request and are sent with every consignment.

6. Retest date and storage conditions

Please refer to Quality & Regulatory Product Information (QRPI).

7. Specification

For current specification, please speak to your local BASF sales or technical representative.

8. Regulatory status

Please refer to Quality & Regulatory Product Information (QRPI).

9. Toxicological data

The toxicological abstracts are available on request.

10. PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging	
30674274	Kolliwax® HCO	50487016	20 kg	Fibreboard boxes
		50520786	0.5 kg	Plastic bottle

* BASF's commercial product number.

11. Publications

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

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