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# Technical Information

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# Kolliwax<sup>®</sup> SSF

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® = Registered trademark of BASF in many countries.

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## 1. Introduction

Kolliwax® SSF (Sodium Stearyl Fumarate) is a highly effective lubricant that is widely used for high-quality pharmaceutical tablet and capsule production. Kolliwax® SSF is compatible with a wide range of APIs and excipients, giving formulators a versatile and reliable design space for product development.

During tableting, Kolliwax® SSF reduces friction between the formulation and processing equipment, enabling efficient and consistent manufacturing while minimizing defects. Compared to magnesium stearate, it shows a lower risk of over-lubrication and can improve the flow properties of powders and granules, making it a preferred choice for many formulations.

In addition, Kolliwax® SSF provides excellent lubrication without significantly affecting the dissolution of active pharmaceutical ingredients. Owing to its hydrophilicity, it supports a favorable dissolution profile.

## 2. Chemical & Physical Properties

Kolliwax® SSF is the monosodium salt of the ester of fumaric acid with stearic alcohol. Its chemical structure is shown in Figure 1.

### Chemical names

Sodium stearyl fumarate (Ph.Eur., USP, JPE), Sodium monostearyl fumarate, Sodium octadecyl fumarate, Sodium octadecyl (E)-butenedioate, (E)-2-Butenedioic acid mono-octadecyl ester sodium salt

### Chemical Structure

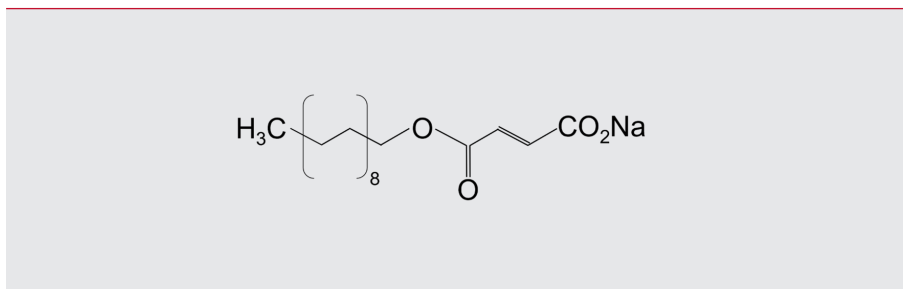


Fig. 1: Chemical structure of sodium stearyl fumarate, Kolliwax® SSF, with the molecular formula C<sub>22</sub>H<sub>39</sub>NaO<sub>4</sub> and a molar mass of 390.54 g/mol.

### CAS number

4070-80-8

### Chemical formula

C<sub>22</sub>H<sub>39</sub>NaO<sub>4</sub>

### Molecular weight

390.54 g/mol

### Melting Point

220°C (decomposes without melting)

Kolliwax® SSF is a white or almost white, fine powder. Isolated Kolliwax® SSF particles are flat and show the typical sharp edges (Figure 2). Particle size distribution is narrow and tailored to the targeted application as lubricant (Table 1, Figure 3).

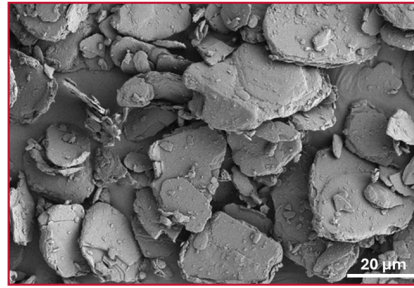


Fig. 2: Scanning Electron Microscope (SEM) image of a typical sample of Kolliwax® SSF.

	Unit of measure	Typical values
$d_{10}$	$\mu\text{m}$	1 to 2.5
$d_{50}$	$\mu\text{m}$	5 to 12
$d_{90}$	$\mu\text{m}$	9 to 30
Specific surface area	$\text{m}^2/\text{g}$	1.2 to 2.0

Table 1: Exemplary volume-based particle size distribution (PSD) by Laser Diffraction and specific surface area of Kolliwax® SSF ( $n = 9$  batches), measured by Laser diffraction (Malvern Mastersizer 3000, powder dispersed at 2.5 bar).

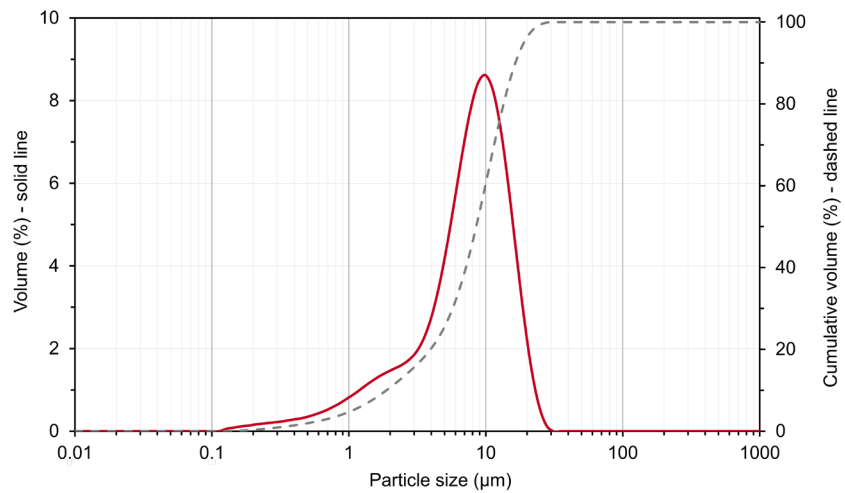


Fig. 3: Typical average particle size distribution (PSD) curve of Kolliwax® SSF. The solid line shows the volume fraction values, while the cumulative distribution values are given by the dashed line.

### Powder characteristics

Typical powder properties are listed in the following table (Table 2).

Parameter	Unit of measure	Typical value
Bulk density	g/mL	0.35
Tapped density	g/mL	0.44
True density	g/mL	1.14
Angle of repose	°	49

Table 2: Typical powder characteristics of Kolliwax®.

### Solubility

At room temperature, Kolliwax® SSF is practically insoluble in water, slightly soluble in methanol, practically insoluble in acetone and in anhydrous ethanol. The solubility in water significantly increases with temperature.

### Dynamic Vapor Sorption (DVS)

The water uptake of Kolliwax® SSF is very low and remains below 0.2% even at a relatively high humidity of 90%. When opened and exposed to typical 40 – 50 % relative humidity, Kolliwax® SSF has a moisture absorption of less than 0.05% (Figure 4).

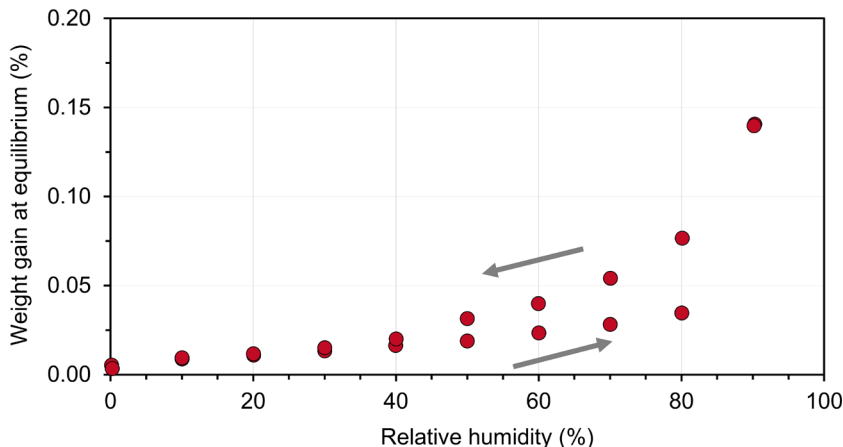


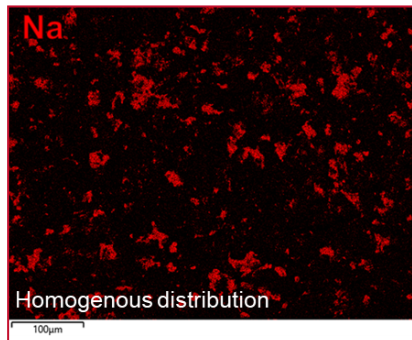
Fig. 4: Typical equilibrium water sorption of Kolliwax® SSF at 25°C.

## 3. Functionality

Kolliwax® SSF reduces friction between the tablet and the manufacturing equipment. Lubricants reduce both the ejection force (i.e., interaction between tablet and die wall) and stripping force (i.e., interaction between tablet and punch tip). Without proper lubrication there is a risk for tablet defects such as edge chipping and lamination.

Suitable Functionality-Related Characteristics (FRCs) of Kolliwax® SSF are particle size and specific surface area as indicated in Ph.Eur. These parameters influence the performance as a lubricant and can also impact the manufacturing process of oral formulations. Figure 5 illustrates the uniform distribution of the fine Kolliwax® SSF particles on the tablet surface.

Kolliwax® SSF (top view tablet)



Kolliwax® SSF (side view tablet)

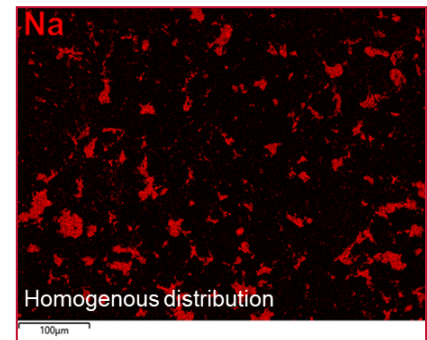


Fig. 5: Typical homogenous distribution characteristics of Kolliwax® SSF on the tablet surface (tablet formulation: 99 % (w/w) Ludipress® and 1 % (w/w) Kolliwax® SSF) by Energy Dispersive X-Ray Spectroscopy (EDXS).

## 4. Handling / Processing instructions

This product is produced in accordance with high quality standards. Owing to its inherent material characteristics, agglomeration may occur. Storage at temperatures not exceeding 25 °C is required to preserve product quality and to limit the formation of larger agglomerates. Sieving before use is recommended to ensure appropriate handling and full product performance.

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

## 5. Application examples

Kolliwax® SSF is used in a concentration range between 0.5% to 5.0% of the total tablet mass. To ensure process robustness, the ejection stress (i.e., ejection force in N divided by the band area in mm<sup>2</sup>) should be less than 3.0 MPa. However, the amount of lubricant should not significantly reduce the tensile strength or prolong the disintegration and dissolution time of tablets.

Recommended Kolliwax® SSF concentrations:

MCC-based formulations:  $\geq 0.5$  % Kolliwax® SSF

Ludipress®-based formulations:  $\geq 3.0$  % Kolliwax® SSF

DiCaFos-based formulations:  $\geq 4.0$  % Kolliwax® SSF

Lubricant effects on tableability and sensitivity of powder blends with different fillers and lubricants are displayed in ZoomLab®, BASF's virtual platform for drug product development. Figures 6 and 7 illustrate, by example, the calculated lubricant tableability and sensitivity of various powder blends containing Kolliwax® SSF.

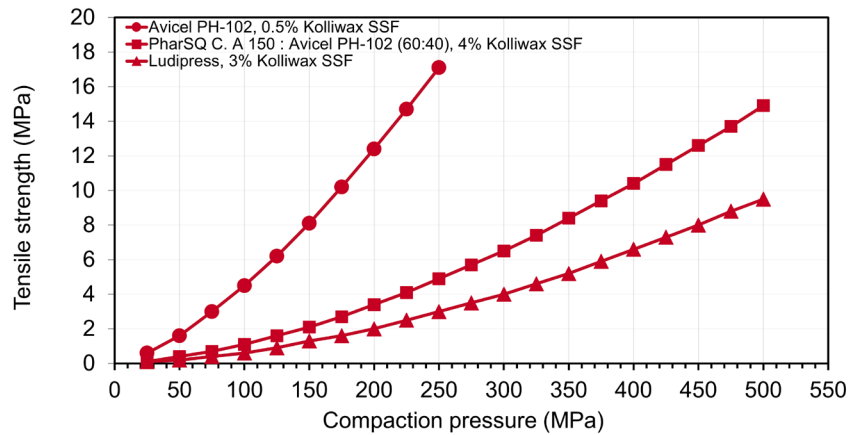


Fig. 6: Tableability of different powder blends with Kolliwax® SSF (Avicel® PH-102 with 0.5% Kolliwax® SSF, PharSQ® Coarse A 150 : Avicel® PH-102 (60:40) with 4.0% Kolliwax® SSF, and Ludipress® with 3% Kolliwax® SSF). Source: ZoomLab®, Lubricant Effect on Tableability App. Source: ZoomLab®, Lubricant Effect on Tableability App. For demonstration purposes, the compression pressure has been raised above typical values in this diagram.

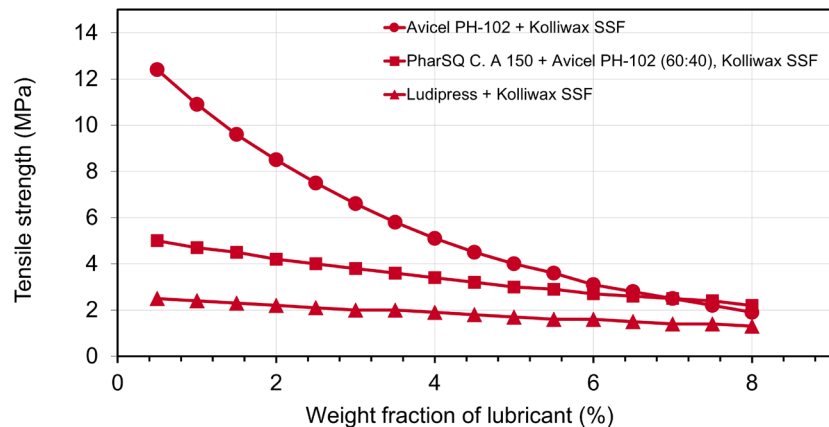


Fig. 7: Lubricant sensitivity of different powder blends with Kolliwax® SSF (Avicel® PH-102 with Kolliwax® SSF, PharSQ® Coarse A 150 : Avicel® PH-102 (60:40) with Kolliwax® SSF, and Ludipress® with Kolliwax® SSF) at 200 MPa compaction pressure. Source: ZoomLab®, Lubricant Effect on Tableability App. Source: ZoomLab®, Lubricant Effect on Tableability App. For demonstration purposes, the weight fraction of lubricant has been raised above typical values in this diagram.

## Formulation 1

Formulation: »Propranolol-HCl tablets«

Propranolol-HCl can be administered orally or by intravenous injection. It is a fine powder that impacts flowability and processability, making it a challenging drug for direct compression.

Tableting Blend	% [w/w]
Propranolol-HCl	10.0
Ludipress®	84.0
Kolliwax® SSF	6.0

### Preparation

Manual sieving of Kolliwax® SSF and Propranolol-HCl through an 800µm sieve separately. Subsequently, weigh Propranolol-HCl and Ludipress®, and blend for 8 minutes. Following this, incorporate Kolliwax® SSF and blend for an additional 2 minutes.

Tableting	
Technology	Direct Compression
Equipment	Styl'One Evo
Punch	10 mm, biplan
Compression pressure	50, 100, 150, 200, 250 MPa
Mass	500 mg

The formulation enabled successful direct compression. Good tableability was observed throughout the process, achieving ideal tensile strength at low compression pressure with an ejection stress of < 3 MPa (Figure 8 & 9).

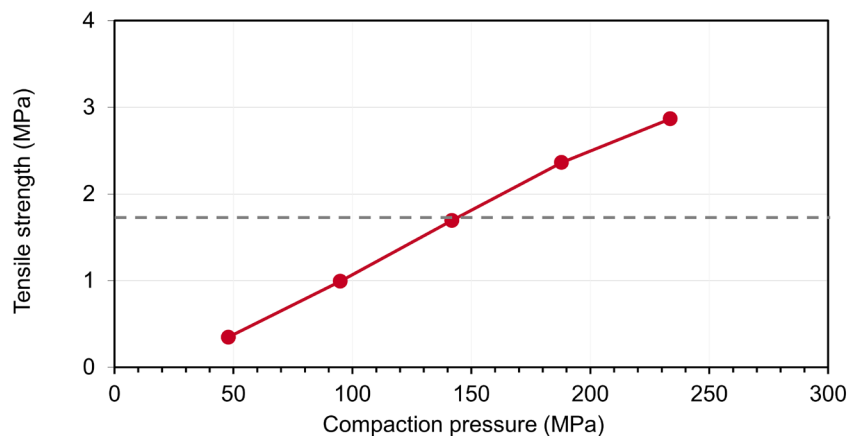


Fig. 8: Tableability profile of Propranolol-HCl tablets consisting of 10% Propranolol-HCl, 84% Ludipress®, and 6% Kolliwax® SSF. The minimum tensile strength required for product handling is given by the dashed grey line.

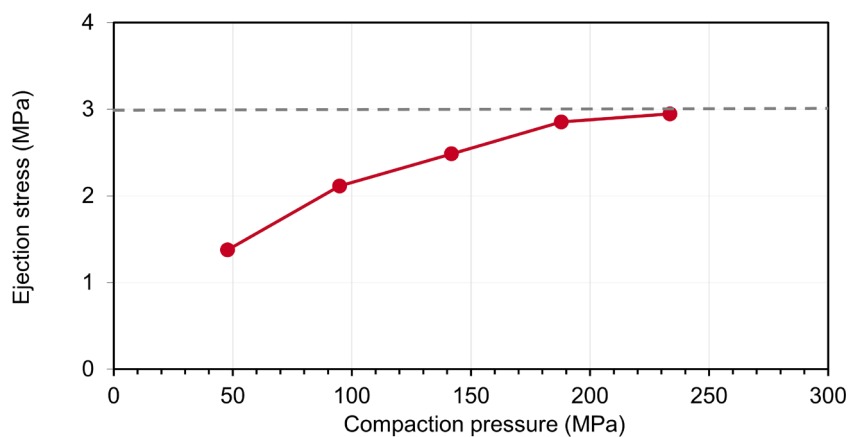


Fig. 9: Processability profile (e.g., ejection stress) of Propranolol-HCl tablets consisting of 10% Propranolol-HCl, 84% Ludipress®, and 6% Kolliwax® SSF. The dashed grey line denotes the maximum allowable ejection stress according to the tablet production parameters.

## 6. Articles and Packaging

PRD-No.*	Product name	Article numbers	Article	Packaging
30783922	Kolliwax® SSF	50752535	0.1 kg technical sample	HDPE bottle
		50809646	10 kg commercial article	Fiberboard box with PE liner

\* BASF's commercial product number.

## 7. Documents, Quality & Regulatory Information

The current versions of documents, quality and regulatory information are accessible via [MyBASFWorld](#)

## 8. ZoomLab®

ZoomLab® is BASF's digital platform designed to streamline drug product development by using advanced formulation algorithms to instantly predict and optimize pharmaceutical formulations in the key areas of tableting, solubilization, and topicals. It provides formulators access to a broad ingredient and formulation database, expert learning resources, and integrated services that eliminate lengthy trial-and-error steps in early development. Among the portfolio of over 30 apps, "[Lubricant Effect on Tableability](#)" facilitates accelerated formulations with i.e., Kolliwax® SSF by providing science-based predictive profiles.

More information & Sign-up can be found here: [zoomlab.com](https://zoomlab.com)



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