Technical Information

July 2012

03_120611e-02/Page 1 of 6
Last change WF-No. 119863

Kolliphor® SLS
Kolliphor® SLS Fine

This technical information gives an overview on the use of Kolliphor SLS and Kolliphor SLS Fine as excipients for solid oral dosage forms.

BASF
We create chemistry

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.

Table 1: New Tradenames-and former Tradenames

Tradename	Former Tradename	Chemistry
Kolliphor SLS	Texapon K 12 G PH	Sodium Lauryl Sulfate
Kolliphor SLS Fine	Texapon K 12 P PH	Sodium Lauryl Sulfate

CAS-No.

Kolliphor SLS	151-21-3
Kolliphor SLS Fine	151-21-3

PRD-No. and Article-No.

Table 2: PRD and article numbers of Kolliphor SLS and Kolliphor SLS Fine

	PRD	Article-No.	Packaging
Kolliphor SLS	30569546	50253852 50253851	25 kg 600 kg
Kolliphor SLS Fine	30554762	50253853	15 kg

Specifications

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

Regulatory Status

Table 3 lists all monographs Kolliphor SLS and Kolliphor SLS Fine are meeting.

Table 3: Compendial names

Tradename	Monographic Names
Kolliphor SLS	Ph.Eur.: Sodium Laurilsulfate USP/NF: Sodium Lauryl Sulfate JP: Sodium Lauryl Sulfate
Kolliphor SLS Fine	Ph.Eur.: Sodium Laurilsulfate USP/NF: Sodium Lauryl Sulfate JP: Sodium Lauryl Sulfate

Kolliphor SLS Fine has a self-affirmed GRAS status. A kosher certificate is available upon request for both grades.

Typical properties

Production

Spray-dried sodium alkyl sulfate, based on a natural saturated straight-chain primary fatty alcohol.

Physical Form

Free flowable powder (Kolliphor SLS Fine) or granules (Kolliphor SLS).

Appearance

White to off-white. Faint characteristic odor.

Melting point

204 – 207 °C

CMC

2.365 g/l (8.2 mmol/l) at 20 °C

Solubility information

Soluble in hot and cold water, sparingly soluble in ethanol.

Incompatibilities

In high concentrations corrosive to steel. Dust may irritate eyes and respiratory system.

Particle size distribution

Figure 1 shows the typical particle size distribution of Kolliphor SLS Fine measured by laser diffraction with a powder module.

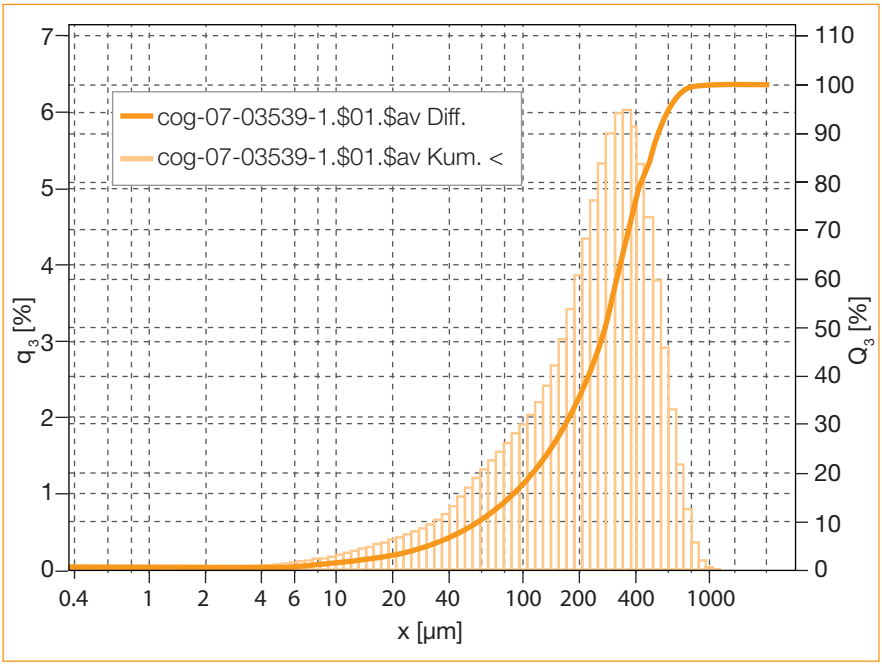


Figure 1: Typical Particle size distribution of Kolliphor SLS Fine measured by laser diffraction.

Bulk density

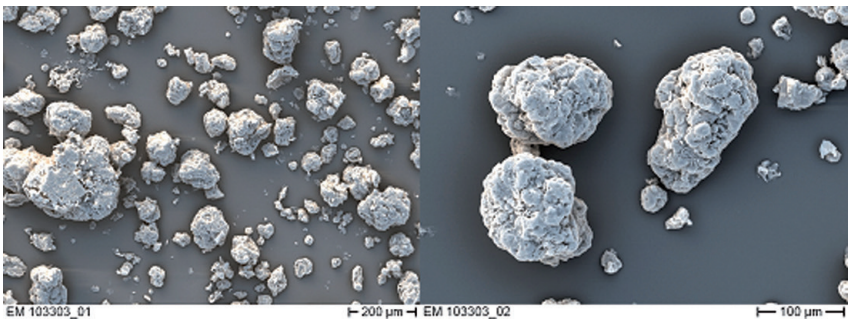
Kolliphor SLS	0.61 g/mL
Kolliphor SLS Fine	0.28 g/mL

Tapped density

Kolliphor SLS	0.70 g/mL
Kolliphor SLS Fine	0.30 g/mL

SEM Picture

Picture 1 shows a scanning electron microscopic (SEM) pictures of Kolliphor SLS Fine in two different magnitudes.



Picture 1: SEM Picture of Kolliphor SLS Fine.

Application

Solubilizer

Kolliphor SLS and Kolliphor SLS Fine can be used as solubilizers to enhance the solubility of poorly soluble APIs in both solid and liquid oral dosage forms. Kolliphor SLS grades are also suitable for semi solid dosage form like creams, lotions and gels. Sodium lauryl sulfate is also very broadly used in oral care formulations. The typical usage concentration as a solubilizer or emulsifier is 0.5–2.5 wt%.

Wetting agent in tableting

Kolliphor SLS and Kolliphor SLS Fine can reduce tablet disintegration time due to improved wettability of the tablet.

Some micronized active drugs require a wetting agent to improve drug dissolution rate if compressed into tablets or filled into hard capsules.

As wetting agent the typical usage concentration is 0.5-5 wt%.

For this application Kolliphor SLS Fine is often more suitable than Kolliphor SLS.

Lubricants

Kolliphor SLS and Kolliphor SLS Fine can be used as tablet lubricant if standard lubricants (magnesium stearate 0.5%) are incompatible with the formulation.

Since sodium lauryl sulfate can also increase drug dissolution rate, magnesium stearate cannot be replaced one to one by Kolliphor SLS fine.

Kolliphor SLS fine offers a combination of good lubrication effect together with improved tablet/capsule disintegration properties and facilitates manufacturing of modern solid dosage forms.

As lubricant the typical usage concentration of Kolliphor SLS or Kolliphor SLS Fine is 2%.

Example for use as lubricant in a direct compressible formulation

Magnesium stearate is known to form eutectics with the drug substance ibuprofen. During tableting, product can adhere on the punch tips (**Roberts et al**. 2004) and cause problems in the manufacturing process of ibuprofen tablets. The following example demonstrates how magnesium stearate can be successfully exchanged for Kolliphor SLS Fine as an alternative lubricant and tablet disintegration aid.

Table 4: Formulation of a direct compression Ibuprofen tablet

Ingredient	Name	mg per tablet
Ibuprofen	Ibuprofen	400
Tablettose® 80	Lactose monohydrate	350
Vivapur® 102	Microcrystalline cellulose	175
Kollidon® 30	Polyvinylpyrrolidone K 30	50
Kolliphor™ SLS Fine	Sodium lauryl sulfate	20
Aerosil®	Fumed silica	5

The present direct compressible tablet formulation is intended as technical example only and does not contain additional tablet disintegrants that facilitate tablet disintegration.

All components (except the lubricant) are sieved and blended in a double cone blender for 15 minutes. Kolliphor SLS Fine or alternatively magnesium stearate 0.5% (5 mg per tablet, Microcrystalline cellulose is used for mass correction) are added to the blend and blended for another 5 minutes. Tableting is carried out on an eccentric tablet press equipped with a 18 mm diameter flat faced punch.

A concentration of 2% Kolliphor SLS Fine is sufficient to obtain good lubrication results. Tablet breaking force was comparable to magnesium stearate but shows a lower standard deviation indicating homogeneous blending (Figure 2).

Tablet disintegration according to Ph. Eur. in 0.1 N HCl solution indicates shorter disintegration times for tablets lubricated with Kolliphor SLS Fine. Even the time difference between the first and the last tablet disintegrated was shorter for Kolliphor SLS Fine (Figure 3).

Ibuprofen drug dissolution experiments have been performed according to USP 33 method <711>, Kolliphor SLS Fine can improve dissolution results of the model drug substance ibuprofen. Although the tablet formulation is not optimized for high drug dissolution rates (absence of additional disintegrants in the formulation) the data can clearly demonstrate the benefit of Kolliphor SLS Fine compared to standard lubricant magnesium stearate in this application.

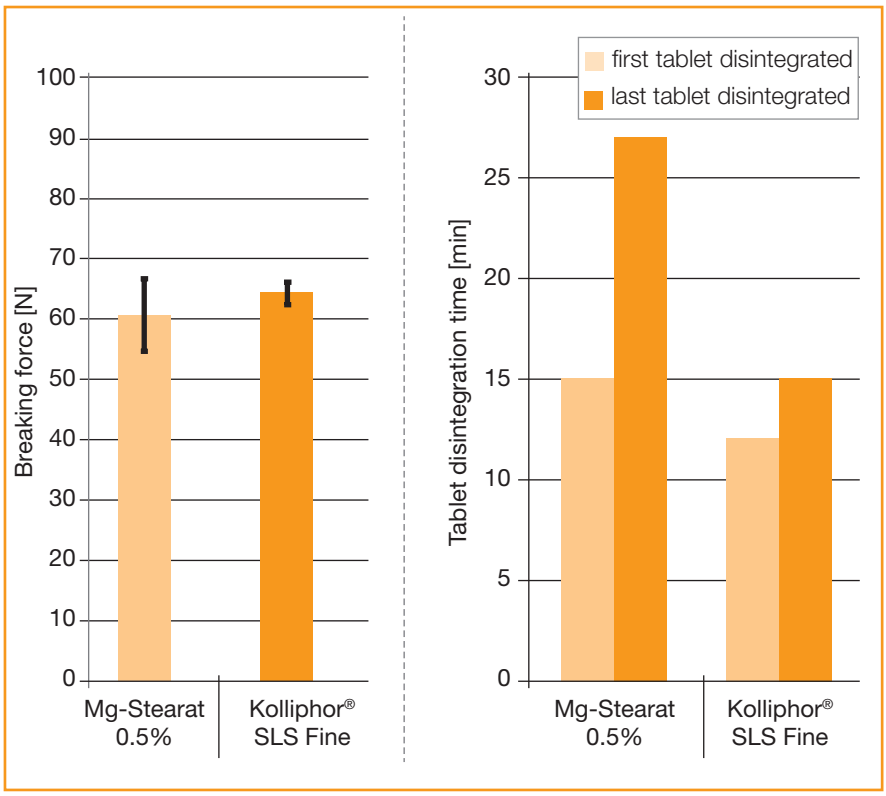


Figure 2: Breaking force and disintegration time of Ibuprofen tablets with Mg stearate compared to Kolliphor SLS Fine.

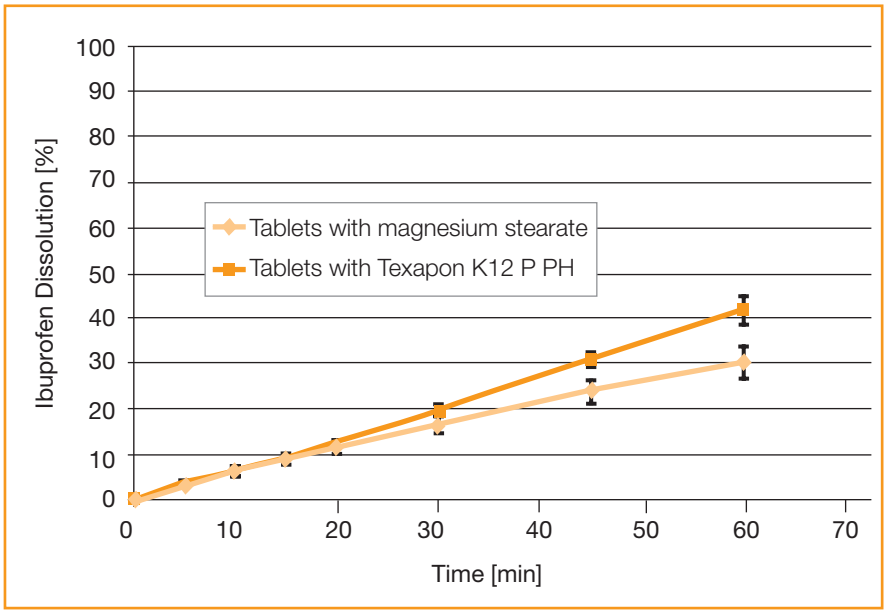


Figure 3: Dissolution of Ibuprofen tablets over time.

Raw material origin

Kolliphor SLS and Kolliphor SLS fine 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 original sealed containers Kolliphor SLS and Kolliphor SLS Fine 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.

Note

July 2012