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

Table 1: New Tradenames-and former Tradenames

<table>
<thead>
<tr>
<th>Tradename</th>
<th>Former Tradename</th>
<th>Chemistry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kolliphor SLS</td>
<td>Texapon K 12 G PH</td>
<td>Sodium Lauryl Sulfate</td>
</tr>
<tr>
<td>Kolliphor SLS Fine</td>
<td>Texapon K 12 P PH</td>
<td>Sodium Lauryl Sulfate</td>
</tr>
</tbody>
</table>

CAS-No.

<table>
<thead>
<tr>
<th>Tradename</th>
<th>CAS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kolliphor SLS</td>
<td>151-21-3</td>
</tr>
<tr>
<td>Kolliphor SLS Fine</td>
<td>151-21-3</td>
</tr>
</tbody>
</table>

PRD-No. and Article-No.

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

<table>
<thead>
<tr>
<th>PRD</th>
<th>Article-No.</th>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kolliphor SLS</td>
<td>30569546</td>
<td>50253852</td>
</tr>
<tr>
<td></td>
<td>50253851</td>
<td>600 kg</td>
</tr>
<tr>
<td>Kolliphor SLS Fine</td>
<td>30554762</td>
<td>50253853</td>
</tr>
<tr>
<td></td>
<td>15 kg</td>
<td></td>
</tr>
</tbody>
</table>

Specifications


Regulatory Status

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

Table 3: Compendial names

<table>
<thead>
<tr>
<th>Tradename</th>
<th>Monographic Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kolliphor SLS</td>
<td>Ph.Eur.: Sodium Laurilsulfate</td>
</tr>
<tr>
<td></td>
<td>USP/NF: Sodium Lauryl Sulfate</td>
</tr>
<tr>
<td></td>
<td>JP: Sodium Lauryl Sulfate</td>
</tr>
<tr>
<td>Kolliphor SLS Fine</td>
<td>Ph.Eur.: Sodium Laurilsulfate</td>
</tr>
<tr>
<td></td>
<td>USP/NF: Sodium Lauryl Sulfate</td>
</tr>
<tr>
<td></td>
<td>JP: Sodium Lauryl Sulfate</td>
</tr>
</tbody>
</table>

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.

![Graph showing particle size distribution](image)

**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.

![SEM Image](image)

**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**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Name</th>
<th>mg per tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>Ibuprofen</td>
<td>400</td>
</tr>
<tr>
<td>Tablettose® 80</td>
<td>Lactose monohydrate</td>
<td>350</td>
</tr>
<tr>
<td>Vivapur® 102</td>
<td>Microcrystalline cellulose</td>
<td>175</td>
</tr>
<tr>
<td>Kollidon® 30</td>
<td>Polyvinylpyrrolidone K 30</td>
<td>50</td>
</tr>
<tr>
<td>Kolliphor™ SLS Fine</td>
<td>Sodium lauryl sulfate</td>
<td>20</td>
</tr>
<tr>
<td>Aerosil®</td>
<td>Fumed silica</td>
<td>5</td>
</tr>
</tbody>
</table>

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

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