



## Product Documentation

**LIPEX® SheaSolve™**  
5046

Valid from  
Date: 2024-01-30



To whom it may concern

Dear valued customer:

The purpose of this document is to provide you with the information required to evaluate the safety of this product to fulfil the legal requirements. The second purpose of the document is to provide you with all information required during the coding process. AAK has gathered the questions received throughout the years and collected the answers within this document. The document is strictly addressing the cosmetic and personal care applications, thus having no intention to cover, pharmaceutical, food or other applications. As the regulatory requirements increases on the answers given as well as the number of questionnaires increases, AAK has chosen to focus on quality and to give you an answer within a reasonable time. This document represents the answer to your questionnaire. AAK has tried to be as complete and accurate as possible in providing the information and feels comfortable it covers the needs for you. In the case AAK does not possess data or information for a particular subject it is stated in the document.

A handwritten signature in blue ink, followed by a large, stylized blue checkmark or 'L' shape.

Head of Development AAK-PC

Staffan Norberg



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## 1.1 Identification

Producer: AAK Sweden AB, Västra kajen SE-374 82 Karlshamn, Sweden  
 Tradename: LIPEX® SheaSolve™  
 Art. No: 5046  
 Country of Origin: Sweden

This product is used globally. The product may fit various CAS, EC and INCI names. For instance LIPEX®SheaSolve contains Ethyl Oleate, Ethyl Stearate, Ethyl Linoleate, Ethyl Palmitate and Butyrospermum Parkii (Shea) Butter Unsaponifiable, thus if preferable to keep a global INCI these can be used in EU and US. Also in countries where the inventory list and other regular requirements do not confirm the first choice CAS number, the alternative CAS numbers can be used. This is not a legally binding document and the end user are required to check the actual status for each relevant legislation.

	INCI	CAS Number	EC number
<b>EU /AAK first choice</b>	<b>Shea Butter Ethyl Esters</b>	<b>1456887-14-1</b>	<b>N/A</b>
US	Shea Butter Ethyl Esters	1456887-14-1	N/A
China*	Ethyl Oleate (and) Ethyl Stearate (and) Ethyl Linoleate (and) Ethyl Palmitate (and) Butyrospermum Parkii (Shea) Butter Unsaponifiables  油酸乙酯 (and) 硬脂酸乙酯 (and) 亚油酸乙酯 (and) 棕榈酸乙酯 (and) 牛油果树 (BUTYROSPERMUM PARKII) 脂不皂化物	111-62-6 (and) 111-61-5 (and) 544-35-4 (and) 628-97-7 (and) 225234-14-0	203-889-5 (and) 203-887-4 (and) 208-868-4 (and) 211-064-6 (and) 607-097-4
Alternative INCI	Ethyl Oleate (and) Ethyl Stearate (and) Ethyl Linoleate (and) Ethyl Palmitate (and) Butyrospermum Parkii (Shea) Butter Unsaponifiables	111-62-6 (and) 111-61-5 (and) 544-35-4 (and) 628-97-7 (and) 225234-14-0	203-889-5 (and) 203-887-4 (and) 208-868-4 (and) 211-064-6 (and) 607-097-4
	Ethyl Oleate (and) Ethyl Stearate (and) Ethyl Linoleate (and) Ethyl Palmitate (and) Butyrospermum Parkii (Shea) Butter Extract	111-62-6 (and) 111-61-5 (and) 544-35-4 (and) 628-97-7 and 91080-23-8	203-889-5 (and) 203-887-4 (and) 208-868-4 (and) 211-064-6 (and) 293-515-7

\*) For NMPA information see section 9.2.2 China – NMPA

	Chemical name	CAS Number	EC number
Other relevant CAS numbers which not used as INCI.	Fatty acids, C18 (saturated and unsaturated) ethyl esters	N/A	940-683-0
	Fatty acids, C16-C18 and C18 unsaturated, Ethyl esters	85049-36-1	285-206-0

\*) For NMPA information see section 9.2.2 China – NMPA



Margrét Viborg  
 Global Regulatory Affairs Manager  
 Personal Care, AAK Sweden AB



## 2.1 Specifications

For specification see Product Data Sheet (PDS)

Download latest version at [www.aakpersonalcare.com/](http://www.aakpersonalcare.com/)

## 2.2 Typical values

For typical values see Product Data Sheet (PDS)

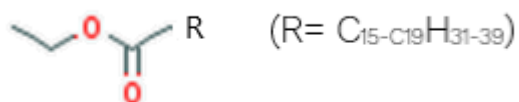
Download latest version at [www.aakpersonalcare.com/](http://www.aakpersonalcare.com/)

## 2.3 Certificate of Analysis

See appendix

## 2.4 Auxiliary chemical and physical data

Molecular weight ~310 g/mol



For other Chemical and Physical data, see Product Data Sheet (PDS)

Download latest version at [www.aakpersonalcare.com/](http://www.aakpersonalcare.com/)

### 3.1 Biological data

#### Botanical origin

INCI	Botanical origin	<sup>*)</sup> Geographical origin	Part used	Content %	Wild grown or cultivated
Shea Butter Ethyl Esters	Vitellaria Paradoxa	West Africa	Kernels	100	Wild grown

<sup>\*)</sup>Geographical origin may change

### 3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
Shea Butter Ethyl Esters	1456887-14-1		100	Emollient Ester

#### Palm content

☐ Containing palm

☐ RSPO SG:

☐ RSPO MB:

☒ Do not contain Palm



Margrét Viborg  
Global Regulatory Affairs Manager  
Personal Care, AAK Sweden AB



## 4.1 Production data

For flowchart, see Appendix.

The following operations are used in the processing of this ingredient

Process		Comment
Mechanical extraction	X	
Solvent extraction	X	Hexane
Refining	X	
Deodorizing	X	
Hydrogenation		
Interesterification		
Esterification	X	
Winterization		
Solvent Fractionation	X	Acethone
Dry Fractionation		
Ethoxylation		
Molecular distillation		
Other processing		



## **5. BY-PRODUCTS AND OTHER IMPURITIES**

### **5.1 AAK Contaminant standard**

Not available, for more information contact AAK.

### **5.2 Other Impurities specific substances**

Download latest version of “AAK personal Care position on impurities” at [aakpersonalcare.com](https://aakpersonalcare.com)

### **5.3 Impurities AAK Cosmetic Products**

#### **5.3.1 Allergens**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

#### **5.3.2 Proteins**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

#### **5.3.3 VOC – Volatile Organic Compounds**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

#### **5.3.4 Sulphonates**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

#### **5.3.5 Parabens**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

#### **5.3.6 Phthalates**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

#### **5.3.7 Silicones**

Download “General statements AAK Cosmetic Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)



## 6.1 Stability Data

OSI Value @ 110C                      Not applicable

Storage @ 20C

Peroxide value 12 month: No data                      24 month: No data

Storage @ 40C

Peroxide value 12 month: No data                      24 month: No data



## 7 Human Health and Environmental Hazard Assessment

### Lipex® SheaSolve™

Read-across category

Fatty acid esters / Short chain alcohol / Unsaponifiables: Medium: 2-10 %

#### 7.01 General read-across consideration and justification

**Test name:**

CIR Safety report

**Method and laboratory:**

Toxicological summary and conclusion by the CIR expert panel, 2015

**Test material:**

Alkyl esters

**Results:**

The CIR Expert Panel assessed the safety of 237 alkyl esters for use in cosmetics, concluding that these ingredients are safe in cosmetic formulations in the present practices of use and concentration when formulated to be non-irritating.

**Comments:**

**Read across:**

Read across General safety information on esters used in cosmetics

**Reference: S-049**

---

**Test name:**

CIR Safety report

**Method and laboratory:**

Toxicological summary and conclusion by the CIR expert panel, 2010

**Test material:**

Myristic acid and its salts and esters

**Results:**

Isopropyl myristate and other derivatives of myristic acid are safe as cosmetic ingredients in the current practices of use and concentration.

**Comments:**

**Read across:**

Read across General safety information on esters used in cosmetics

**Reference: S-187**

---

**Test name:**

CIR Safety report

**Method and laboratory:**

Toxicological summary and conclusion by the CIR expert panel, 1982

**Test material:**

Esters of palmitic acid

**Results:**

From the available information, it is concluded that Octyl Palmitate, Cetyl



Palmitate, and Isopropyl Palmitate are safe as cosmetic ingredients in the present practices of use and concentration.

**Comments:****Read across:**

Read across General safety information on esters used in cosmetics

**Reference: S-188**

---

**Test name:**

REACH registration dossiers (public)

**Method and laboratory:**

REACH registration dossiers with toxicological and environmental data

**Test material:**

Isopropyl myristate  
Isopropyl oleate  
Methyl stearate  
Ethyl palmitate

**Results:**

See separate entries for details. Links to individual dossiers:

<https://echa.europa.eu/registration-dossier/-/registered-dossier/16077> (isopropyl myristate)  
<https://echa.europa.eu/registration-dossier/-/registered-dossier/13373> (isopropyl oleate)  
<https://echa.europa.eu/registration-dossier/-/registered-dossier/21230> (methyl stearate)  
<https://echa.europa.eu/registration-dossier/-/registered-dossier/23690> (ethyl palmitate)  
<https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/10992/1/1> (Ethyl esters of C16-18 and C18 unsaturated fatty acids)

**Comments:**

A large number of REACH dossiers for simple esters of fatty acids are available. This listing comprises a few representative examples only.

**Read across:**

Read across General safety information on alkyl esters from REACH dossiers

**Reference: S-373**

---

**Test name:**

Scientific Opinion on ethyl oleate and other chemicals as previous cargo for edible oils and fats

**Method and laboratory:**

European Food Safety Authority: review of toxicity of chemicals that are allowed as previous cargoes when transporting edible oils and fats

**Test material:**

Ethyl oleate and other alkyl esters of fatty acids

**Results:**

Ethyl esters of fatty acids are hydrolyzed in the gut and metabolized as fatty acid and ethanol. No concerns regarding mutagenicity, genotoxicity, acute, sub-chronic or chronic toxicity are expressed.

**Comments:**

Absence of contaminants must be ensured

**Read across:**

Read across Ethyl oleate is the main component in the ingredient

**Reference: S-412**

---

**Test name:**



Scientific Opinion on the safety of feed additives

**Method and laboratory:**

European Food Safety Authority: review of 37 substances used as flavouring agents in animal feeds

**Test material:**

Ethyl oleate

**Results:**

Ethyl oleate is considered to be safe as added to animal feeds at a concentration of up to 5 mg/kg feed, based on a NOAEL value of 1370 mg/kg bw/day. The NOAEL is based on the ethanol content in ethyl oleate (approximately 14%).

**Comments:**

Ethyl oleate is rapidly metabolized into ethanol and oleic acid.

**Read across:**

Read across Ethyl oleate is the main component in the ingredient

**Reference: S-411**

---

Fatty acid ethyl esters belong to the group of generic alkyl esters of fatty acids, which are frequently used in cosmetics as emollients. This category is extensively reviewed by CIR and several safety reports have been published. Further data can be obtained from the numerous dossiers published by ECHA (EU-REACH registrations).

Alkyl esters of fatty acids are reaction products of a short chain (<C8) saturated, linear or branched alcohol with linear saturated or unsaturated fatty acids with a carbon chain length of C8-C18. Longer alcohols are also found in the wax esters that belong to the same chemical category.

Alkyl esters that are used for read-across in this review are described for example in "Amended Safety Assessment of Alkyl Esters as Used in Cosmetics" (Cosmetic Ingredient Review, 2013, reference S-049). Relevant read-across substances are saturated and unsaturated fatty acid esters with chain lengths from C14-C22, esterified to branched or straight-chain alcohols of chain lengths between C2-C8.

Most fatty acid alkyl esters are derived from vegetable oils. Such esters are frequently named based on the origin of the fatty acid, for example 'shea butter ethyl esters' that are produced from ethanol and shea butter. In such cases a read-across is made from the major components in the ingredient, for example ethyl oleate and ethyl stearate which are the main components in 'shea butter ethyl esters'.





## 7.02 Acute toxicity

### 7.02.1 Acute oral toxicity

**Test name:**

Acute oral, inhalation and dermal toxicity

**Method and laboratory:**

Summary of acute oral, dermal and inhalation toxicity

**Test material:**

Isopropyl myristate

**Results:**

Acute oral toxicity LD50 >2000 mg/kg bw

Acute dermal toxicity LD50 >2000 mg/kg bw

Acute inhalation toxicity LC50 >5.3 mg/l air

**Comments:**

Similar values published for other short chain alkyl esters of fatty acids in the REACH dossiers

**Read across:**

Read across Summary of acute toxicity for alkyl esters of fatty acids

**Reference: S-373a**

---

### 7.02.2 Acute inhalation toxicity

See above

### 7.02.3 Acute dermal toxicity

See above

### 7.02.4 Acute toxicity by other exposure routes

There are no other relevant exposure routes identified for fatty acid alkyl esters used in cosmetics

---

### 7.02.5 Summary and discussion of acute toxicity

Substances identified as fatty acid alkyl esters have a very long history of safe use in a wide range of cosmetic and industrial applications. Acute oral, inhalation or dermal toxicity are therefore not considered to pose an issue for human health under normal and foreseeable handling and use conditions.



## 7.03 Irritation & corrosivity

### 7.03.1 Skin irritation and corrosivity

**Test name:**

Human repeated insult patch test (HRIPT)

**Method and laboratory:**

50 subjects (male/female), Induction: 9 consecutive applications on the back over 3 weeks, Challenge: 2 weeks after final application, scoring 24 and 72 hours post-application (Protocol CP-01.01S).

Consumer Product Testing Co., Fairfield, NJ, US  
2012

**Test material:**

Lipex SheaLight™, 100% (Tested as XP3511)

**Results:**

Under the conditions of this study, the test material did not indicate a clinically significant potential for dermal irritation or allergic contact sensitization.

**Comments:****Read across:**

Read across Same composition as test substance

**Reference: S-126**

---

### 7.03.2 Eye & mucous membrane irritation and corrosivity

**Test name:**

In Vitro Eye Irritation: Ocular Irritation Assay using the EpiOcular Human Tissue Model

**Method and laboratory:**

EpiOcular reconstructed human cornea-line epithelium model, according to standard procedure. Test dose 50 microliter, spread directly on the EpiOcular tissue using distilled water as negative control and methyl acetate as positive control.

**Test material:**

Lipex SheaLight, 100%

**Results:**

In this study, under the given conditions, the test item showed no irritant effects. The test item is classified as "non-irritant" in accordance with UN GHS "No Category".

**Comments:****Read across:**

Read across Same composition as test substance

**Reference: S-363**

---

### 7.03.3 Summary and discussion on irritation and corrosivity

Substances identified as fatty acid alkyl esters have a long history of safe use in a wide range of cosmetic and industrial applications. Supported by the tests reported above, skin and eye irritation and/or corrosiveness are not considered to pose an issue for human health under normal and foreseeable handling and use conditions.

---



## 7.04 Skin sensitization

**Test name:**

Allergenicity Lipex SheaLight

**Method and laboratory:**

GARD Prediction Signature (GPS) assay, predicting of sensitizing potential by assessing the response of a set of genomic predictors from human immune cells treated with the test substance. Senzagen AB, Lund, SE, 2016

**Test material:**

Lipex SheaLight, 100%, tested as XP3634

**Results:**

Lipex SheaLight is not a sensitizer as assessed by the GARD Prediction method.

**Comments:****Read across:**

Read across Same composition as test substance

**Reference: S-190**

---

**Test name:**

Presence of known food allergens

**Method and laboratory:****Test material:****Results:**

Known food allergens are not present in refined vegetable oils

**Comments:****Read across:**

Statement

**Reference: S-011**

---

**Test name:**

Presence of allergens according to EC 1223/2009 Annex III

**Method and laboratory:****Test material:****Results:**

Known fragrance allergens are not present in refined vegetable oils

**Comments:****Read across:**

Statement

**Reference: S-400**

---

### 7.04.1 Summary and discussion of sensitization

Substances identified as fatty acid alkyl esters have a very long history of safe use in a wide range of cosmetic and industrial applications. Supported by the tests and references reported above, sensitization and allergenicity are not considered to pose an issue for human health under normal and foreseeable handling and use conditions.



## **7.05** Repeated dose, sub-chronic and chronic toxicity

### **7.05.1** Oral administration

**Test name:**

91 day feeding study in rodents

**Method and laboratory:**

Species: rat (Sprague-Dawley) 20 male/20 female

Duration: 91 days

Dosage: 0, 3.3, 6.6 and 10% of diet, High Oleic Sunflower oil used as control fat

**Test material:**

Ethyl oleate

**Results:**

Ethyl oleate in the diet was well tolerated. No toxicologically significant adverse effects were observed. NOAEL was determined to be 6000 mg/kg bw/day

**Comments:**

**Read across:**

Read across Ethyl oleate is the main component in the ingredient

**Reference: S-045**

---

### **7.05.2** Inhalation studies

No studies could be located on the repeated dose inhalation toxicity of fatty acid alkyl esters from the relevant read-across categories. However, given their low vapor pressure (< 0.011 Pa at 25°C) and the fact that they are not handled or marketed as a powder, respiratory exposure is not likely to occur. Repeated inhalation exposure is therefore not expected to pose an issue for human health and no further consideration is required for this endpoint.

---

### **7.05.3** Dermal administration

No studies have been located on the repeated dose dermal toxicity of fatty acid alkyl esters from the relevant read-across categories. However, these substances and others from the same read-across category present low systemic toxicity upon repeated dose oral exposure, so that repeated dose dermal toxicity is not expected to be higher than via the oral route. This is further supported by very long history of safe use of these types of substances in cosmetic and industrial applications.

Taken together the above facts suggest that repeated dose dermal toxicity will not pose an issue for human health under normal and foreseeable handling and use conditions. See also Chapter 7.09.2 for discussion on dermal absorption.

---

### **7.05.4** Other routes of administration

There are no other relevant exposure routes identified for fatty acid alkyl esters used in cosmetics

---



### 7.05.5 Human studies

**Test name:**

Clinical safety test in humans

**Method and laboratory:**

Test group: 235 healthy volunteers

Duration: 12 weeks

Administration: oral

Dosage: 8 g/day or 16 g/day of ethyl oleate in milk based product corresponding to 100-200 mg/kg bw/day

**Test material:**

Ethyl oleate, triolein used as control

**Results:**

No difference in adverse effects between ethyl oleate and triolein were observed. No adverse clinical effects related to ethyl oleate were observed.

**Comments:****Read across:**

Read across Ethyl oleate is the main component in the ingredient

**Reference: S-046**

---

Based on these above studies, toxicity via repeated exposure is not expected to pose an issue for human health under normal and foreseeable handling and use conditions, and no further testing for this endpoint is required.

---

### 7.05.6 Summary and discussion

The highest oral NOAEL based on the studies reported above, could be considered to be 10% in feed, equivalent to an estimated 6000 mg/kg bw/day. This value is considered relevant for risk assessment purposes, although it is only a reflection of the study setup and not of effects observed at higher doses.

Fatty acid alkyl esters present low systemic toxicity upon repeated dose oral exposure, and the repeated dose dermal toxicity is also expected to be minimal. Furthermore, given its low vapor pressure and the fact that it is not handled or marketed as a powder, repeated inhalation exposure is not considered to pose an issue for human health under normal and foreseeable handling and use conditions.

Based on the above information, the substance does not qualify for repeated dose toxicity classification according to Directive 67/548/EC or Regulation 1272/2008/EC.



## 7.06 Reproduction toxicity

### 7.06.1 Non-human studies

**Test name:**

Reproduction toxicity test in rats

**Method and laboratory:**

91-day feeding study

Sprague-Dawley rats (m/f, n=20 in each treatment group)

0, 3.3, 6.7 and 10% in feed

Spermatocyte assessment for male rats

Estrous cycle assessment for female rats

Organ weights (testes, ovaries)

**Test material:**

Ethyl oleate

High oleic safflower oil

**Results:**

No treatment related effects on reproductive capacity were seen in the study.

**Comments:****Read across:**

Read across

Ethyl oleate is the main component in the ingredient

**Reference: S-045**

---

### 7.06.2 Human studies

No actual tests have been carried out and literature data has not been found for this chapter.

---

### 7.06.3 Developmental toxicity/teratogenicity

#### 7.06.3.1 Non-human studies

No actual tests have been carried out and literature data has not been found for this chapter.

---

#### 7.06.3.2 Human studies

No actual tests have been carried out and literature data has not been found for this chapter.

---

### 7.06.4 Summary and discussion of reproductive toxicity

The available data on reproductive toxicity does not indicate any adverse effects on the reproductive processes for fatty acid alkyl esters.

---



## **7.07** Mutagenicity/genotoxicity

### **7.07.1** In vitro data

**Test name:**

Bacterial Reverse Mutation Assay, Ames Test (OECD 471)

**Method and laboratory:**

Salmonella typhimurium standard plate incorporation study, with and without S9 metabolic activation. Study strains: TA97a, TA98, TA100, TA102 and TA 1535.

0.08, 0.16, 0.31, 0.63 and 1.25 mg/plate.

Bioscreen Testing, Inc, Torrance, CA, USA  
2013

**Test material:**

Lipex SheaLight™, 100%

**Results:**

Under the conditions of this assay, the test article is considered to be non-mutagenic to S. typhimurium.

**Comments:**

**Read across:**

Read across                      Same composition as test substance

**Reference: S-130**

---

The above evidence, added to the very long history of safe use of this type of substance in cosmetic and industrial uses, suggests that fatty acid alkyl esters do not have a mutagenic potential.

---

### **7.07.2** In vivo data

No actual tests have been carried out and literature data has not been found for this chapter.

---

### **7.07.3** Human studies

No actual tests have been carried out and literature data has not been found for this chapter.

---

### **7.07.4** Summary and discussion of mutagenicity

Fatty acid alkyl esters did not exhibit any genotoxic activity in bacterial reverse mutation (Ames) assays. This evidence, added to the very long history of safe use of these substances in cosmetic and industrial uses, suggests that alkyl esters of long chain fatty acids do not have a mutagenic potential.

Based on the above information, these substances do not qualify for mutagenicity classification according to Directive 67/548/EC or Regulation 1272/2008/EC.



## 7.08 Carcinogenicity

### 7.08.1 Non-human studies

**Test name:**

104 week feeding study

**Method and laboratory:**

Species: Rat (Colworth-Wistar) 50 male/50 female

Administration: oral

Duration: 104 weeks (daily)

Dosage: 15 % of diet

**Test material:**

Shea olein, shea butter and palm oil

**Results:**

The test substances showed no adverse effects and no tumorigenic potential at a daily intake of 7500 mg/kg bw /day.

**Comments:****Read across:**

Read across                      Shea butter is used in the preparation of the ingredient

**Reference: S-029**

---

**Test name:**

Carcinogenicity of fatty acid esters

**Method and laboratory:**

Study of carcinogenicity and promoter effect on skin application in mice (ST/a, m/f).

Test substances (20% in acetone) were applied to the skin, three times weekly for one year.

Animals were observed for another year or until spontaneous death or development of tumors.

**Test material:**

Methyl oleate (MO)

Methyl 12-oxo-oleate (MOO)

Methyl hydroxy-linoleate (MHO)

Croton oil (positive control)

DMBA (initiator)

**Results:**

It was found that methyl oleate is not a complete carcinogen and that the promoter effects were inconclusive in this test.

**Comments:****Read across:**

Read across                      Methyl oleate is structurally similar to ethyl oleate

**Reference: S-421**

---



**Test name:**

Carcinogenicity of fatty acid esters

**Method and laboratory:**

Study of the carcinogenicity of fatty acid methyl esters by subcutaneous and oral application.

A) In the oral study, the test substances were given to ST/a mice (m/f n=15/15) at 3.75 mg/g feed, corresponding to 15 mg/day intake per mouse. The test was continued for 84 weeks.

B) In the subcutaneous study, the test substances were given at 0.185 ml/mouse (high dose) and 0.025 ml/mouse (low dose), once a week for 26 weeks. The mice were followed for two years

**Test material:**

Methyl oleate (MO)

Methyl 12-oxo-oleate (MOO)

4-nitroquinoline-1-oxide (initiator, oral study)

DMBA (initiator, subcutaneous study)

**Results:**

No promoter effect was found for the methyl oleate in either study.

**Comments:****Read across:**

Read across Methyl oleate is structurally similar to ethyl oleate

**Reference: S-417**

---

**Test name:**

Carcinogenicity of fatty acid esters

**Method and laboratory:**

A summary of studies on fatty acid ester carcinogenicity performed between 1964-1968. 29 fatty acid derivatives were tested in BALB/c or Swiss-Webster mice (n=16, female only), by subcutaneous injections at 0.5 mg/dose or 5 mg/dose. The test substances were given once weekly for 26 weeks and the animals were followed for 18-14 months.

**Test material:**

29 fatty acid derivatives, including methyl stearate

**Results:**

Methyl stearate did not show any carcinogenic effect in the test conditions used.

**Comments:****Read across:**

Read across Methyl stearate is structurally similar to ethyl steare

**Reference: S-416**

---

**Test name:**

Carcinogenicity of fatty acid esters

**Method and laboratory:**

Carcinogenicity study on Swiss mice (female, n=50 per treatment group). The test substance at 10, 50 (dissolved in acetone) and 100% were applied to the skin of the mice, twice a week for up to 120 weeks.

**Test material:**

Isopropyl myristate

**Results:**

No statistically significant increase in tumors were detected in this study

**Comments:****Read across:**

Read across Isopropyl myristate is a representative of fatty acid alkyl esters

**Reference: S-418**

---

**7.08.2 Human studies**

No actual tests have been carried out and literature data has not been found for this chapter.

---

**7.08.3 Summary and discussion of carcinogenicity**

The available oral and dermal studies show neither carcinogenic nor promoter effect from fatty acid alkyl esters used in cosmetics. The substances do not contain any functional groups suggesting carcinogenic activity. Given the physical state, low vapor pressure of the substances and the fact that they are not handled or marketed as a powder, carcinogenicity as a result of inhalation exposure is not likely.

Based on the above information, the substance does not qualify for carcinogenicity classification according to Directive 67/548/EC or Regulation 1272/2008/EC.



## 7.09 Toxicokinetics: absorption, metabolism, distribution and elimination (ADME)

Alkyl esters of fatty acids are composed mainly of reaction products of saturated, linear or branched alcohols with chain length 2-22, esterified to linear saturated or unsaturated fatty acids with a carbon chain length of C8-C18. Such alkyl esters are described for example in "Amended Safety Assessment of Alkyl Esters as Used in Cosmetics" (Cosmetic Ingredient Review, 2013, reference S-049).

Typical ester based cosmetic emollients are mixtures of esters derived from vegetable oils with predominantly unsaturated and saturated C12-C18 fatty acids esterified to short chain alcohols such as ethanol or isopropanol.

The metabolism and toxicokinetic behaviour of fatty acid alkyl esters are expected to reflect the behaviour of the parent alcohol and fatty acid respectively as the esters are readily hydrolyzed to the corresponding alcohol and fatty acid in the body.

---

### 7.09.1 Oral administration

**Test name:**

Absorption, distribution and excretion study

**Method and laboratory:**

Species: Rat (Sprague-Dawley)

Dosage: single, peroral dose, 1700 or 3400 mg/kg bw

Duration: 72 hours

**Test material:**

Radio-labeled ethyl oleate

Control: radiolabeled triolein

**Results:**

Ethyl oleate showed 70-90% absorption, compared to 90-100% for the triolein. Tissue distribution of radioactivity was similar in both cases, with the highest concentration in the mesenteric fat. Both test materials were excreted as CO<sub>2</sub> (40-70%). Fecal excretion of ethyl oleate was dose dependent (7-20%). The results show that ethyl oleate is metabolised in a manner similar to that of oleic acid ingested as triolein.

**Comments:****Read across:**

Read across Ethyl oleate is the main component in the ingredient

**Reference: S-046**

---

**Test name:**

ADME

**Method and laboratory:**

Radiolabelled ethyl esters of fatty acids (ethyl oleate, ethyl eicosapentaenoate) were administered into the stomachs of rats. Blood samples were taken at intervals up to 2 hours. The rats were killed and the internal organs were extracted. Total radioactivity in the different organs was measured.

**Test material:**

Ethyl oleate

Ethyl eicosapentanoate

**Results:**

Fatty acid ethyl esters are rapidly hydrolyzed in the gastrointestinal tract.

**Comments:**

**Read across:**

Read across Ethyl oleate is the main component in the ingredient

**Reference: S-374**

---

**7.09.2 Dermal administration****Test name:**

Skin penetration of cosmetic emollients

**Method and laboratory:**

QSAR modelling of dermal absorption for REACH dossier, based on molecular weight, log  $P_{o/w}$  and water solubility.

**Test material:**

Isopropyl myristate

**Results:**

QSAR estimation is estimated to 0.0002 mg/cm<sup>2</sup>/event. A dermal absorption coefficient of 10% can be used for margin-of-safety assessments.

**Comments:****Read across:**

Read across Similar behavior is expected for the ingredient

**Reference: S-373a**

---

**Test name:**

Skin penetration of cosmetic emollients

**Method and laboratory:**

Radiolabelled emollients were applied on the skin of hairless mice, guinea pigs and angora rabbits and the presence of the emollients was observed by radiography at different treatment times.

**Test material:**

Isopropyl myristate

Triolein

n-octadecane

decane decyl ether

2-hexyldecane decyl ether

**Results:**

Isopropyl myristate was absorbed via the hair follicles and sebaceous glands and was distributed in the epidermis after 24 hours. Slight dermal penetration was observed but systemic effects were not found.

**Comments:****Read across:**

Read across Similar behavior is expected for the ingredient

**Reference: S-410**

---

**7.09.3 Inhalation route**

No significant inhalatory exposure to alkyl esters of fatty acids is expected as the substances have a negligible vapor pressure at relevant temperatures.



## **7.10** Photoinduced toxicity

### **7.10.1** Phototoxicity: photoirritation / photosensitisation

#### **Test name:**

In vivo phototoxicity test

#### **Method and laboratory:**

The test material was applied to the skin on the back for 24 hours, followed by consecutive irradiation with UV-A (5 J/cm<sup>2</sup>). Scoring after 1, 24, 48 and 72 hours after irradiation.

28 subjects (3 male/25 female).

proDERM standard protocol V04 (71-UV-Tox), approximating the principles of GCP.

proDerm Study 14.0300-71/B

proDERM Institute for Applied Dermatological Research, Schenefeld/Hamburg, DE  
2014

#### **Test material:**

Lipex SheaLight™, 100%

#### **Results:**

The test product did not invoke photo-toxic reactions under the test conditions applied in this study.

#### **Comments:**

#### **Read across:**

Read across                      Same composition as test substance

#### **Reference: S-122**

---

### **7.10.2** Phototoxicity: photomutagenicity / photoclastogenicity

No actual tests have been carried out and literature data has not been found for this chapter.

---

### **7.10.3** Other relevant human studies (clinical)

No actual tests have been carried out and literature data has not been found for this chapter.

---

## **7.11** Special investigations

No actual tests have been carried out and literature data has not been found for this chapter.

---

## **7.12** Summary and NOAEL statement

Based on the data presented in Chapter 7.1 to 7.11, the NOAEL is set to 6000 mg/kg bw/day for systemic exposure for fatty acid ethyl esters and other substances of the same read-across category.

---

## 8 Ecological data

### 8.01 Degradability

**Test name:**

Biodegradability OECD 301F

**Method and laboratory:**

OECD 301F Manometric Respirometry Test 1992

Aerobic biodegradability of organic compounds. 28 day study by determination of oxygen demand in a closed respirometer.

Anox-Kaldnes AB, Lund, SE, 2012

**Test material:**

Lipex SheaLight™, 100%, tested as XP3511

**Results:**

The test article is "readily biodegradable" according to the criteria specified in OECD guidelines for degradability testing.

**Comments:****Read across:**

Read across Same composition as test substance

**Reference: S-164**

---

**Test name:**

Biodegradability

**Method and laboratory:**

CEC L-33-T-82

**Test material:**

Ethyl esters of rapeseed oil

Methyl esters of rapeseed oil, linseed oil, lard and tallow.

**Results:**

Ethyl esters of rapeseed oil were found to be 94% degraded after 21 days in the conditions used in the standard. Similar degradation was found for the methyl esters (90-98%).

**Comments:**

The biodegradability of all the tested esters was good, irrespective of fatty acid composition or alcohol (methanol/ethanol).

**Read across:**

Read across Similar fatty acid composition

**Reference: S-369**

---

Vegetable oil based esters are made from alcohols and unbranched, even numbered fatty acids with normally 0-3 double bonds. The ester bonds are hydrolyzed in aqueous environments to fatty acids and the corresponding alcohol. Both alcohol and the fatty acids are metabolized by microorganisms by beta-oxidation to smaller fragments and eventually to carbon dioxide. The hydrolysis of the esters is catalysed by acids, alkalies as well as lipases exuded by the microorganisms. The rate of breakdown is faster for shorter chain and more unsaturated esters due to higher solubility in water.

Esters are in general readily biodegradable in OECD 301 based tests.

---

### 8.02 Accumulation



Esters are generally easily hydrolyzed to free fatty acids and corresponding alcohols by aquatic and soil microorganisms. The fatty acids and the alcohols are easily metabolized by aquatic and soil microorganisms. Therefore the risk of environmental accumulation is regarded as minimal.

---

### 8.03 Aquatic toxicity

**Test name:**

Freshwater alga and cyanobacteria growth inhibition test

**Method and laboratory:**

OECD TG 201 (2006)

The growth inhibition test was carried out according to the standard on Water Accommodated Fractions (WAFs) of the test substance. No Effect Concentration (NOEC) and Effect Loading Rate (EL) was determined after 72 hours of exposure to the WAFs. *Pseudokirchneriella subcapitata* (green alga) was used for the test.

Toxicon AB, Härslöv, SE, 2015

**Test material:**

Lipex SheaLight™, 100%

**Results:**

The test article is non-toxic towards the green alga *Pseudokirchneriella subcapitata* in the test conditions used in this study.

72h EL50 > 100 mg/l

72h NOEC 50 mg/l

**Comments:****Read across:**

Read across Same composition as test substance

**Reference: S-178**

---

**Test name:**

Acute aqueous toxicity

**Method and laboratory:**

Daphnia magna Test Method

The products were assayed for 48 hours with *Daphnia magna* neonates that were less than 24 hours old with no renewal of the water. The test protocol closely followed the Environment Canada test method "Biological Test Method: Acute Lethality Test Using *Daphnia* spp" (Environment Canada 1990).

**Test material:**

Water soluble fraction of vegetable oil based biodiesels (methyl esters of soybean and/or canola oil).

**Results:**

LC50 (48h) for *Daphnia magna* was found to be 24650 mg/l for the water soluble fraction of a biodiesel based on canola oil and 7500 mg/l for a soybean oil based product.

**Comments:****Read across:**

Read across C16-C18 saturated, C18-unsaturated fatty acid esters

**Reference: S-189**

---

Based on the available information, fatty acid alkyl esters and other substances belonging to the same read-across category, can in general be regarded as non-toxic to freshwater algae and show low acute aquatic toxicity.



## 9.1 EU

### 9.1.1 Statement on EU Cosmetic Regulation EC 1223/2009

Latest statement, download “Statement on EU Cosmetic Regulation” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.1.2 EU Cosmetic Regulation EC 1223/2009, Annex II and III

Latest statement, download “Statement on EU Cosmetic Regulation” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.1.3 EU REACH 1907/2006

Latest statement, download “REACH Statement” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.1.4 EU SVHC (Substance of Very High Concern)

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

## 9.2 Other country specific regulations:

### 9.2.1 US (California) Proposition 65

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.2.2 China – NMPA

Latest statement, download “NMPA Statement” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.2.3 UK REACH

Latest statement, download “UK REACH Statements” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.2.4 Turkey - KKDIK

Latest statement, download “Turkey-KKDIK and SEA Statement” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.2.5 Australia - TGA

Latest statement, download “AAK PC Products and TGA status” at [aakpersonalcare.com](https://aakpersonalcare.com)

## 9.3 Other non-Country specific regulatory issues

### 9.3.1 Animal testing

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.3.2 Nano particles

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.3.3 Nagoya Protocol / Biodiversity and Access Benefit Sharing regulation

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.3.4 CITES

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 9.3.5 CMR

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)





## 9.4 Inventory lists

Inventory lists relates to substances already existing in a specific market. The inventory list to the chemical legislation of the country or region. INCI labeling is not related to the chemical legislation. The nomenclature may differ between these two types of regulations hence the wording may change.

In the Table below, column 3:

- 1) Listed means:
  - a. The substance name and CAS number described as “AAK first choice name”, in section “1.1 Identification” is listed and not prohibited in the inventory list of the country.
- 2) Not listed, however CAS. No XXXXX-XX-X is listed and valid to be used.
  - a. The substance name and CAS number described as “AAK first choice name”, section “1.1 identification” is not found but instead the Cas XXXXX-XX-X mentions is listed as well as fits with the chemical description of the product, hence can be used instead.
- 3) No data:
  - a. AAK has not been able to find the substance in the inventory list.

EC (EU)	EC-inventory	Listed
TSCA (U.S.)	Toxic Substances Control Act	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used. .
DSL (Canada)	Domestic Substances List	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
AICS (Australia)	The Australian Inventory of Chemical Substances	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
IECIC (China)	Inventory of Existing Cosmetic Ingredients in China	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
ENCS (Japan)	Combined list of existing and notified chemical substances as the Japanese Existing and New Chemical Substances Inventory.	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
Japan	Japan Pharmacopoeia	No data.
KECI (South Korea)	Korea Existing Chemicals Inventory	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
NECI (Taiwan)	National Existing Chemical Inventory	Not listed, but CAS. No CAS. No 111-62-6, 111-61-5, 544-35-4, 628-97-7 and 72869-74-0 is listed and valid to be used.
Saudia Arabia	The Saudi Arabian Standards Organisation	No data.
Malaysia	Chemicals Information Management System	No data.
Mexico	Inventario Nacional de Sustancias Químicas	No data.
Turkey		No data.



## 10.1 Official standards

Standard	Conform	Monograph
EUR/Ph	n.a	
USP/NF	n.a	
JP	See inventory list 9.4	

## 10.2 Private standards

### 10.2.1 Ecocert, Cosmos or Natrue

Latest statement, download at [aakpersonalcare.com](https://aakpersonalcare.com)

### 10.2.2 Vegan and Vegetarian claim

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 10.2.3 Other

## 10.3 Other Statements

### 10.3.1 BSE/TSE statements:

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 10.3.2 GMO statement

Latest statement, download “General Statement AAK Ingredients” at [aakpersonalcare.com](https://aakpersonalcare.com)

### 10.3.3 Other:

No data



## 11. CERTIFICATES

### 11.1 Halal

The product is produced according to Halal.

Download latest version at [aakpersonalcare.com](https://aakpersonalcare.com).

### 11.2 Kosher

The product is produced according to Kosher.

Download latest version at [aakpersonalcare.com](https://aakpersonalcare.com)

### 11.3 ISO 9001

The product is produced according to ISO 9001.

ISO certificate latest version available for downloading at [aak.com](https://aak.com).

### 11.4 EFFCI GMP

No data

### 11.5 Food Safety/ FSSC 22000

Not available.

### 11.6 Other

No other available



## **12. PATENTS**

### **12.1 Patents**

No data.



## **TRANSPORTS AND HANDLING - LIPEX® SheaSolve™**

### **13.1 Transports**

No data available

### **13.2 storage unopen package**

#### **Storage to fulfill shelf life:**

Store in temperature 20C or lower. Dark, dry and odor free condition in unopen packaging's.  
See Product data sheet for more information.

#### **Retest of batch:**

Retest for prolonged shelf life is only possible after agreement with sales responsible.

### **13.3 Handling of product for use**

#### **13.3.1 Use of full package**

Recommended melting temperature.

Drums: Melt the whole content until fluid or approx. 45C

Cans: Melt the whole content until fluid or approx. 45C

During processing need to be heated to 45C to remove crystal memory.

#### **13.3.2 Use of full package for partly use**

##### **Reseal packaging and store in 20C or below or repack to smaller packaging format**

Drums: Melt the whole content until at least 45C

Cans: Melt the whole content until at least 45C

From an oxidation point of view restrict the number of heating/cooling cycles, depending on the time the product is kept at high temperature. The more times it is heated/cooled, the shorter the shelf life will be.

At lower temperatures a precipitate may form on prolonged storage. If the material has been stored at low temperatures and has started to crystallize it is important to melt the whole content before use. Recommended melting temperature for product in drums, is at least 45 C. Melt the whole content and homogenize. Keep melting time as short as possible to avoid oxidation of the product.

#### **Note:**

AAK's shelf life is for ingredients that are unopened and stored according to the instructions given in the product Data sheet. This guarantee is invalidated once the packaging is opened and the ingredients reheated. It is the user's responsibility to validate that a reheated material fulfills shelf life requirements in a formulation. See Product Data Sheet.



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## 15. DISCLAIMER

### 15.1 Disclaimer

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Ship-to -

### Analytical Certificate

<b>Delivery</b>	<b>81272009 - 30</b>
<b>Print date</b>	2023-01-172
<b>Your reference</b>	
<b>Our reference</b>	Femke den Hartog
<b>Material</b>	5046-650 LIPEX SHEASOLVE
<b>Your material no.</b>	
<b>Date of shipment</b>	2023-01-10

Batch 0002544673 / Quantity 3.145 KG / Prod. date 2022-12-09

Inspection lot 3079545

/ Best before 2024-06-09

Characteristic	Result	Lower Limit	Target	Upper Limit
<b>Acid value(IUPAC 2.201(m))</b>				
Acid value	0,22 mg KOH/g			1,00
<b>Colour Lovibond(Lovibond Tintometer)</b>				
Colour 5 1/4" Red	0,6			2,0
<b>Iodine value Wijs(IUPAC 2.205)</b>				
Iodine value Wijs	70,2	63,0		75,0
<b>Peroxide value(AOCS Cd 8b-90(m))</b>				
Peroxide value	0,3 meq/kg			5,0

Quality Control Manager  
AAK Sweden AB

This document is electronically produced, and valid without an AAK signature.

ZAO K8900 1

A Company in the AAK Group

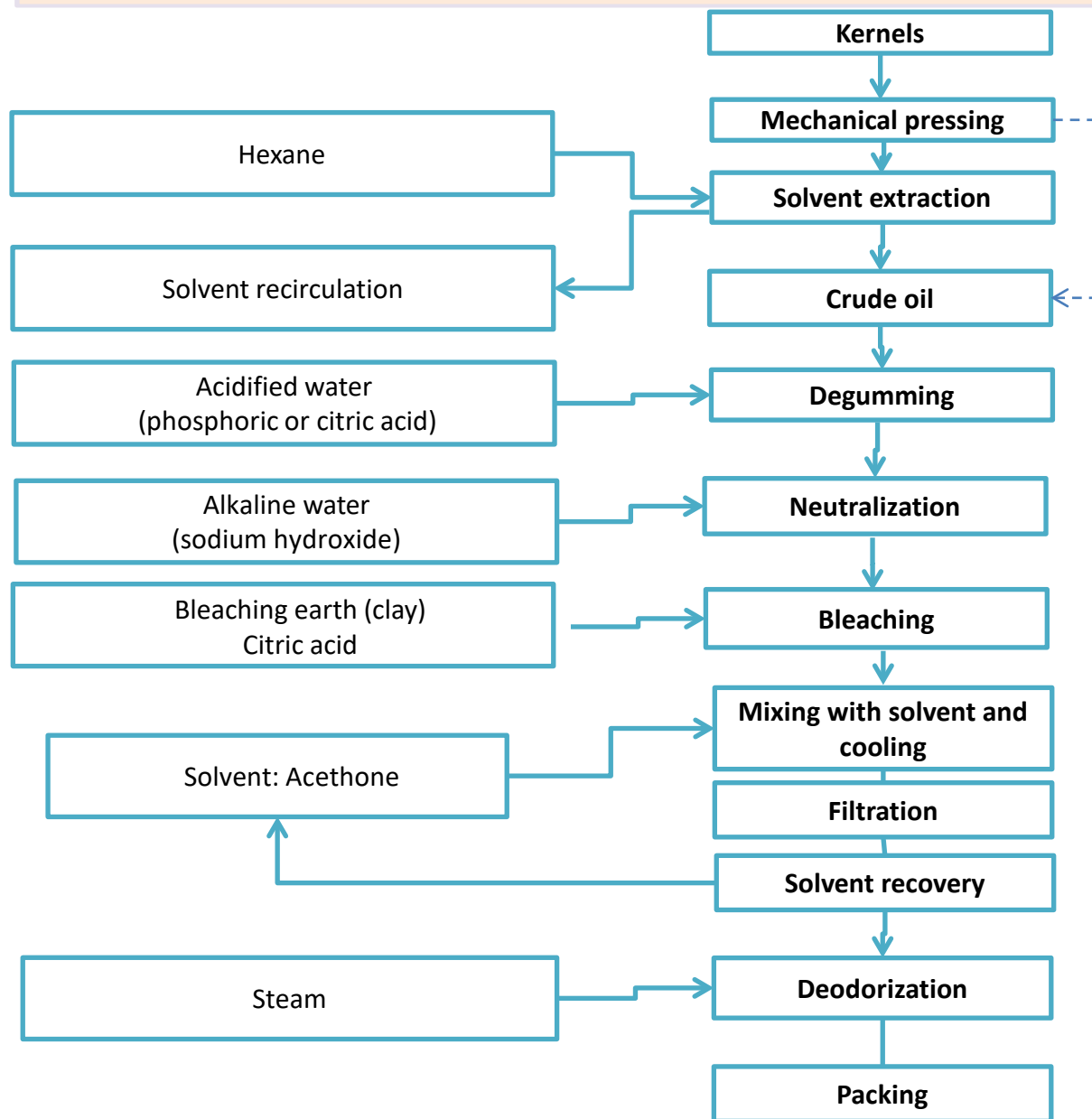
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Bic/Swift : ESSESESS  
Giro : 5430-5438  
Acc. no. : 51181061768  
IBAN : SE20 5000 0000 0511 8106 1768

Org. no. : 556478-1796  
VAT no. : SE556478179601  
Approved for Swedish F-tax  
Registered Office: Karlshamn  
See disclaimer

**Processing scheme 1: Refined and deodorised oils and fats (with solvent extraction)**

Explanations what each step contribute with

Separates crude oil from Kernels

Removes phospholipids, metals and proteins

Removes free fatty acids, metals and proteins

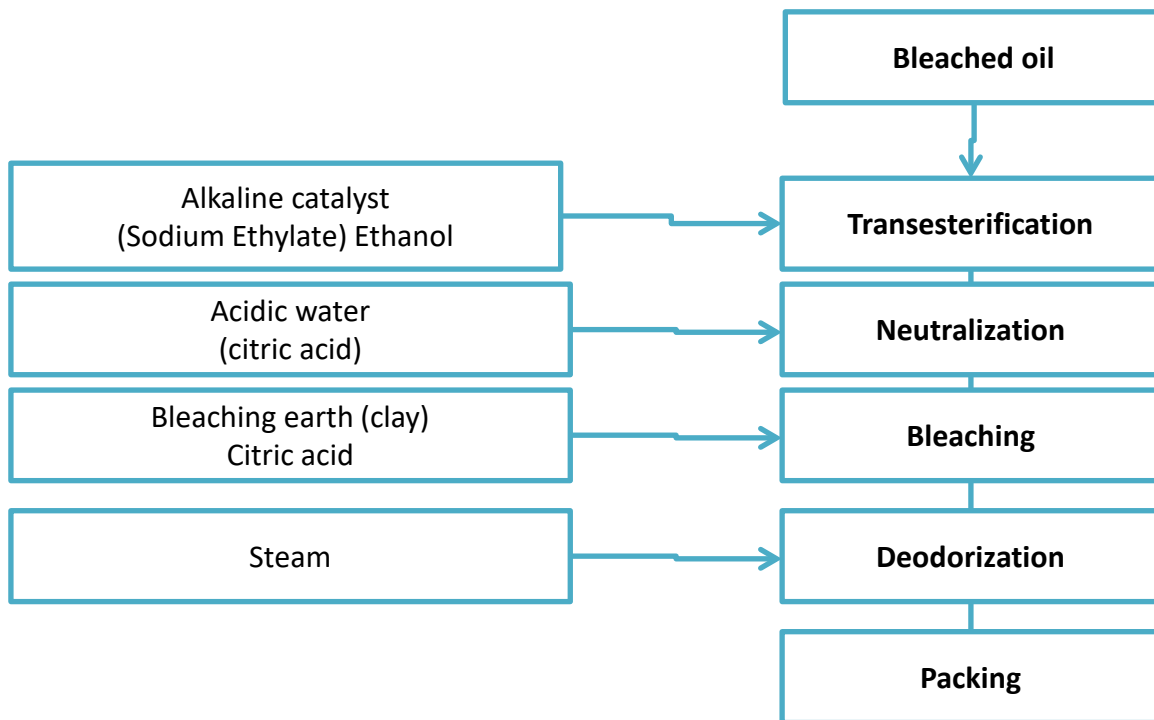
Removes pigments, metals and proteins

Separates solid and liquid constituents

Removes flavours, free fatty acids and oxidation products

See disclaimer

## Processing scheme 2: Ethylester production



Explanations what each step contribute with

Converts glycerides to ethylesters

Neutralises catalyst and stops reaction

Removes pigments, metals, proteins and catalyst traces

Removes flavours, free fatty acids and oxidation products