Product Documentation

LIPEX® SheaLuxe TR™

5127

Valid from
Date: 2024-11-18

Contents

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.

Head of Development AAK-PC

Staffan Norberg

1.1 Identification

Producer:	AAK Sweden AB, Västra kajen SE-374 82 Karlshamn, Sweden
Tradename:	LIPEX® SheaLuxe TR™
Art. No:	5127
Country of Origin	EU

This product is used globally. The product may fit various CAS, EC and INCI names. For instance LIPEX®SheaLuxe TR™ contains Ethyl Oleate and Ethyl Stearate, 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
EU /AAK first choice	**Ethyl Oleate (and) Ethyl Stearate**	**111-62-6 (and) 111-61-5 (and)**	**203-889-5 (and) 203-887-4 (and)**
US	Ethyl Oleate (and) Ethyl Stearate	111-62-6 (and) 111-61-5 (and)	203-889-5 (and) 203-887-4 (and)
US	Shea Butter Ethyl Esters	1456887-14-1	N/A
China*	Ethyl Oleate (and) Ethyl Stearate (油酸乙酯 (and) 硬脂酸乙酯)	111-62-6 (and) 111-61-5 (and)	203-889-5 (and) 203-887-4 (and)
Alternative INCI	Shea Butter Ethyl Esters	1456887-14-1	N/A

*) 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 Information

Download latest version at http://www.aakpersonalcare.com/

2.2 Typical values

For typical values see Product Information

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2.3 Certificate of Analysis

CoA not available

2.4 Auxiliary chemical and physical data

Molecular weight ~310 g/mol

For other Chemical and Physical data, see Product Information

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3.1 Biological data

Botanical origin

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

*)**Geographical origin may change**

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
Ethyl Oleate	11-62-6		45-70	Emollient Ester
Ethyl Stearate	111-61-5		23-35	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	Acetone
Dry Fractionation		
Ethoxylation		
Molecular distillation		
Other processing		

5. BY-PRODUCTS AND OTHER IMPURITIES

5.1 AAK Contaminant standard

AAK utilizes HACCP/CCP methodology to identify relvant hazardous substances for vegetable oils and the critical points thoughout the handling in order to minimize and control risk.

The relevant contaminants to control in products based vegetable oils and butters are listed in our Contaminant Standard. AAK's process ensure that the product fulfil the contaminant statement.

Download latest version at aakpersonalcare.com

The contaminant represent the maxium levels that can be found and not the actual levels. These contaminant are considered as technically unavoidable.

5.2 Other Impurities specific substances

Download latest version of "AAK personal Care position on impurities" at aakpersonalcare.com

5.3 Impurities AAK Cosmetic Products

5.3.1 Allergens

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.2 Proteins

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.3 VOC – Volatile Organic Compounds

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.4 Sulphonates

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.5 Parabens

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.6 Phthalates

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.7 Silicones

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

6.1 Stability data

OSI Value @ 120C 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® SheaLuxe TR™

Read-across category
Fatty acid esters / Short chain alcohol / Unsaponifiables: Low: <1%

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
Ethyl esters of C16-18, C18-unsaturated fatty acids

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 Similar 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 Similar 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 Similar 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 Similar 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 givento 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 subcutanous 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 increases 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 inhalatory 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 CO2 (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 Po/w and water solubility.
Test material:
Isopropyl myristate
Results:
QSAR estimation is estimated to 0.0002 mg/cm2/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/cm2). 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 Similar 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 Similar 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. Therefor 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. Pseudokircheniella 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 Pseudokirchneliella subcapitata in the test conditions used in this study.
72h EL50>100 mg/l
72h NOEC 50 mg/l

Comments:

Read across:

Read across Similar 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".

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.

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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

9.1.2 EU Cosmetic Regulation EC 1223/2009, Annex II and III
Latest statement, download “Statement on EU Cosmetic Regulation” at aakpersonalcare.com

9.1.3 EU REACH 1907/2006
Latest statement, download “REACH Statement” at aakpersonalcare.com

9.1.4 EU SVHC (Substance of Very High Concern)
Latest statement, download “General Statement AAK Ingredients” at 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

9.2.2 China – NMPA
Latest statement, download “NMPA Statement” at aakpersonalcare.com

9.2.3 UK REACH
Latest statement, download “UK REACH Statements” at aakpersonalcare.com

9.2.4 Turkey - KKDIK
Latest statement, download “Turkey-KKDIK and SEA Statement” at aakpersonalcare.com

9.2.5 Australia - TGA
Latest statement, download “AAK PC Products and TGA status” at 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

9.3.2 Nano particles
Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

9.3.3 Nagoya Protocol / Biodiversity and Access Benefit Sharing regulation
Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

9.3.4 CITES
Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

9.3.5 CMR
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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, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
DSL (Canada)	Domestic Substances List	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
AICS (Australia)	The Australian Inventory of Chemical Substances	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
IECIC (China)	Inventory of Existing Cosmetic Ingredients in China	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 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, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
Japan	Japan Pharmacopoeia	No data.
KECI (South Korea)	Korea Existing Chemicals Inventory	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 is listed and valid to be used.
NECI (Taiwan)	National Existing Chemical Inventory	Not listed, Not listed, but CAS. No CAS. No 111-62-6, 111-61-5 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

Not available, please contact AAK for further information

10.2.2 Vegan and Vegetariam claim

Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

10.2.3 Other

10.3 Other Statements

10.3.1 BSE/TSE statements:

Not available, please contact AAK for further information.

10.3.2 GMO statement

Not available, please contact AAK for further information.

10.3.3 Other:

No data

11. CERTIFICATES

11.1 Halal

The product is produced according to Halal.

Download latest version at aakpersonalcare.com

11.2 Kosher

The product is produced according to Kosher.

Download latest version at aakpersonalcare.com

11.3 ISO 9001

The product is produced according to ISO 9001.

ISO certificate latest version available for downloading at aak.com

11.4 EFFCI GMP

Not available

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 ® SheaLuxe TR™

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.

14. REFERENCES

14.1 References

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15. DISCLAIMER

15.1 Disclaimer

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Ship-to -

Analytical Certificate

Delivery	**81510959 - 10**
Print date	2024-10-30
Your reference	
Our reference	Femke den Hartog
Material	5127-300 LIPEX® SheaLuxe TR
Your material no.	
Date of shipment	2024-09-11
Trailer No	

Batch 0002866035 / **Quantity** 9 KG / **Prod. date** 2024-08-06
Inspection lot 3477280

Characteristic	Result		Lower Limit	Target	Upper Limit
Acid value(IUPAC 2.201(m))					
Acid value	0,46	mg KOH/g			1,00
Colour Lovibond(Lovibond Tintometer)					
Colour 5 1/4" Red	0,0				1,0
Iodine value Wijs(IUPAC 2.205)					
Iodine value Wijs	74,5		65,0		85,0
Peroxide value(AOCS Cd 8b-90(m))					
Peroxide value	1,9	meq/kg			5,0

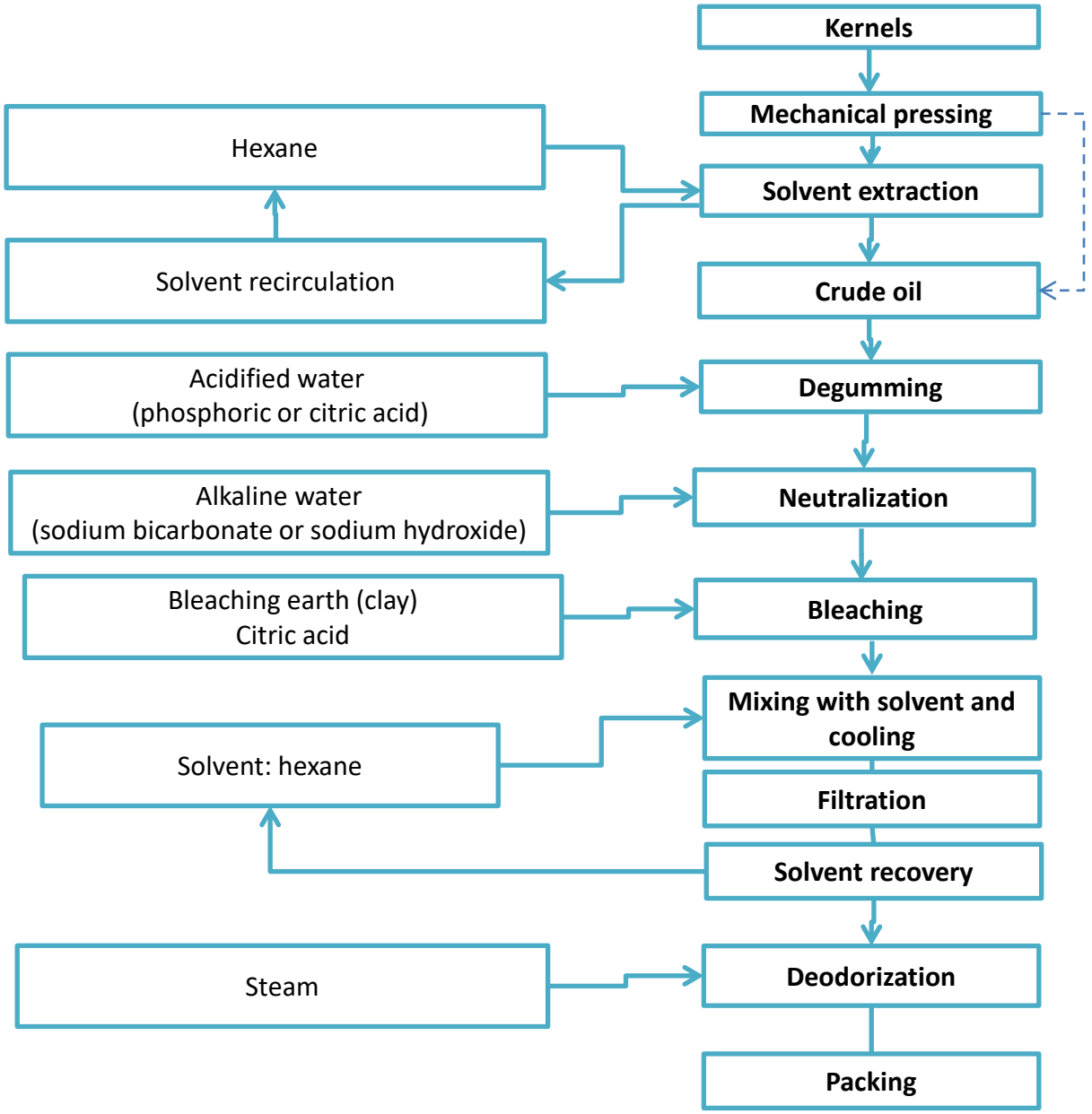
LIPEX® SheaLuxe TR is frozen directly after production,
and taken out of frozen storage prior to delivery.
Shelf life: For pails 12 months from out of frozen storage, for drums 18 months from out of frozen storage.
"i.e. 12/ 18 months from ""Date of shipment from AAK Sweden AB"" above."

Quality Control Manager
AAK Sweden AB

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

ZAO K9262 1

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

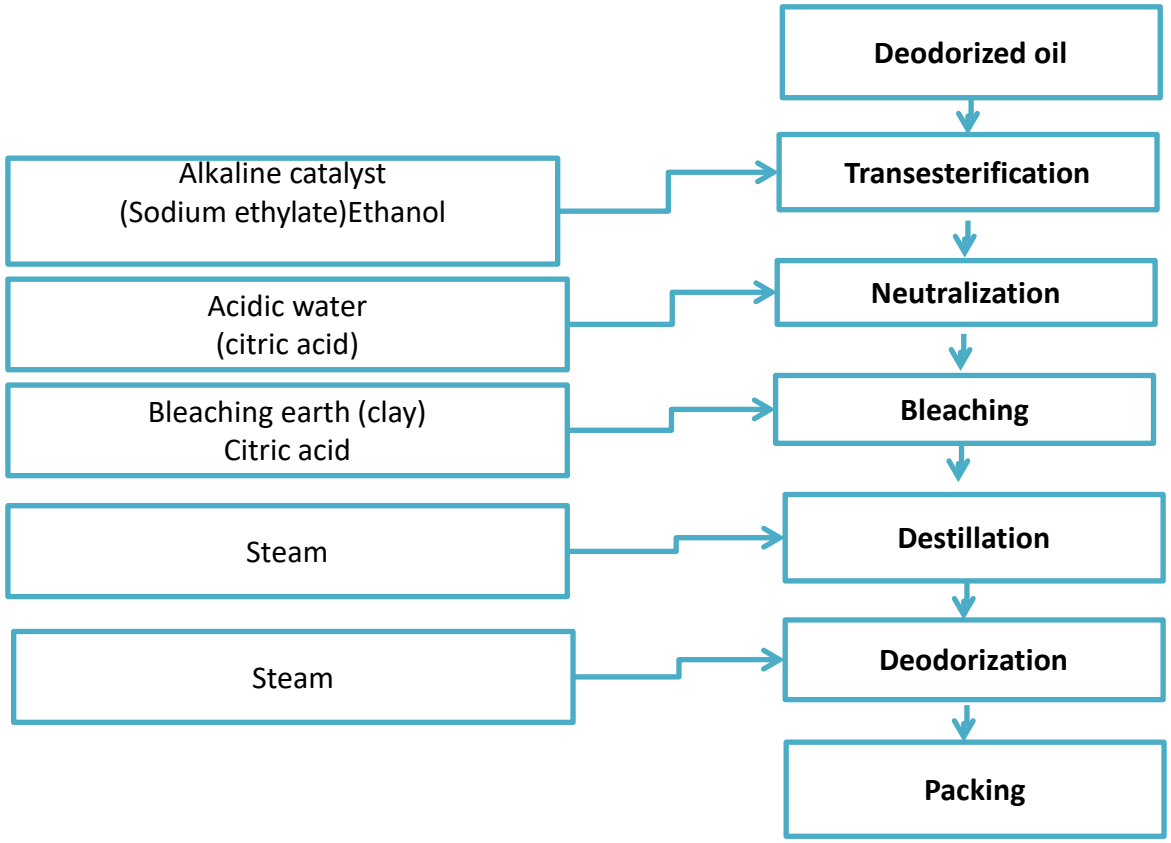
Removes pigments, metals and proteins

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

Purification to remove unsaponifiables

Removes flavours, free fatty acids and oxidation products

See disclaimer