Product Documentation

LIPEX® SheaSoft TR™

7601

Valid from
Date: 2023-09-20

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

Contents

1.1 Identification

Producer:	AAK Sweden AB, Västra kajen SE-374 82 Karlshamn, Sweden
Tradename:	LIPEX® SheaSoft TR™
Art. No:	7601
Country of Origin	Sweden

This product is used globally. As the product may fit in the definition of several CAS numbers, AAK give examples of alternative CAS number to be used for instance in inventory lists search.

	INCI	**CAS Number**	**EC number**
EU /AAK first choice	**BUTYROSPERMUM PARKII BUTTER**	**194043-92-0**	**293-515-7**
US	Butyrospermum Parkii (Shea) Butter	194043-92-0	293-515-7
China*	牛油果树（BUTYROSPERMUM PARKII）果脂	194043-92-0	293-515-7
Alternative INCI	Butyrospermum Parkii Oil	91080-23-8	293-515-7
	Vegetable Oil	68956-68-3	279-313-5
	Hydrogenated Vegetable Oil	68334-28-1	269-820-6
	Hydrogenated Shea Butter**	N/A	N/A

	Chemical name	**CAS Number**	**EC number**
Other relevant CAS numbers which not used as INCI.	Glycerides, C16-18 and C18-unsatd.	67701-30-8	266-948-4

*) For NMPA information see section 9.2.2 China – NMPA

**) INCI name to be used for NATRUE certified finished cosmetic products

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

2.1 Specifications

For specification see Product Data Sheet (PDS)

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2.2 Typical values

For typical values see Product Data Sheet (PDS)

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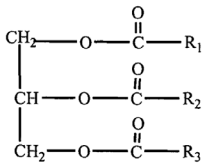
2.3 Certificate of Analysis

For example of COA, see Appendix.

2.4 Auxiliary chemical and physical data

Molecular weight ~880 g/mol

Stucture



R_1, R_2, R_3: C_{15}-, C_{17}- saturated, C_{17}- unsaturated alkyl chains

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

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3.1 Biological data

Botanical origin

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

*)**Geographical origin may change**

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
Butyrospermum Parkii Butter	194043-92-0	293-515-7	100	Emollient

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	X	
Interesterification	X	
Esterification		
Winterization		
Solvent Fractionation	X	Hexane
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.

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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 General statements AAK Cosmetic Ingredients 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 20 hours

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® SheaSoft TR™

7.01 General read-across consideration and justification

Cosmetic ingredients based on vegetable oils and fats are composed mainly of triglycerides containing a glycerol backbone esterified to linear saturated fatty acids with a carbon chain length of C8-C18 as well as unsaturated C18 fatty acids. The toxicology and toxicokinetics of glycerides and fatty acids are well known as a result of their widespread and long-term use in nutritional (food and feed), personal care and industrial applications.
For human health hazard assessment and read-across purposes a system based on the fatty acid composition is used by REACH as a method to systematise the classification of vegetable oils and fats, in order to minimise the number of individual registrations and Chemical Safety Reports needed for an accurate safety assessment. The chemical, physical and metabolic behaviour of vegetable oils and fats from different sources are sufficiently similar to allow for such a simplification (Appendix S001). This system is based on the “Soaps and Detergents Association” nomenclature which gives a category description for different types of lipids, with varying chain lengths and functional groups (Appendix S002). In this report the following “Glycerides, C16-C18 saturated, C18 unsaturated” with the SDA Reporting Number 11-001-00 (“SDA-11) is frequently used for read-across purpose. In a few cases, “Glycerides, C8-C18, C18 unsaturated”, SDA reporting number 01-001-00, and “Glycerides, C16-C18”, SDA reporting number 19-001-00, are referenced if appropriate information has not been found for the SDA-11 category.

7.02 Acute toxicity

7.02.1 Acute oral toxicity

Test name:

Acute oral toxicity

Method and laboratory:

Species: rat
Oral administration by gavage
Palm oil was administered at a single dose of 5,000 mg/kg bw to 5 rats

Test material

Palm oil

Results:

LD50: > 5,000 mg/kg bw

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S003 – CIR Safety assessment of palm oil and derivatives, Int J Toxicol 19 (Suppl 2), 7-28, (2000)

Several vegetable oils have been tested for acute toxicity in rats and found to have an LD50 > 5,000 mg/kg bw/day. They are widely used as food ingredients and have a very long history of safe use, so that no acute oral toxicity is expected.

7.02.2 Acute inhalation toxicity

Based on the physical state (semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C), the probability of inhalation exposure to 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other vegetable fats will be extremely limited. Acute inhalation exposure is therefore not expected to pose an issue for human health under normal and foreseeable handling and use conditions (Annex VIII, Section 8.5, column 2 of the REACH regulation).

7.02.3 Acute dermal toxicity

Test name:

Acute dermal toxicity

Method and laboratory:

Species: guinea pig
Vehicle: no vehicle
Single dose 3,000 mg/kg bw applied dermally to guinea pigs and the animals observed for 7d.

Test material

Fully hydrogenated coconut oil

Results:

LD50: > 3,000 mg/kg bw;
LD0: = 3,000 mg/kg bw

Read across

Read across	Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S004 – CIR Safety assessment of coconut oil and derivatives, J Amer Coll Toxicol, 5(3), 103-121, (1986)

Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other vegetable fats are not toxic via the oral route and have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications, so that acute dermal toxicity is not expected.

7.02.4 Acute toxicity by other exposure routes

There are no other relevant exposure routes for shea butter, 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' or other vegetable fats and oils.

7.02.5 Summary and discussion of acute toxicity

Substances identified as 'Glycerides, C16-18 saturated and C18-unsatd. (SDA Reporting Number: 11-001-00)', including shea butter and other vegetable oils and fats, have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Acute oral, inhalation or dermal toxicity is 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:

Skin irritation and sensitization potential in vivo

Method and laboratory:

Several reported skin irritation studies from different sources, including HRIPT and in use studies

Test material

Shea butter in concentrations ranging from 0.1% to 60% in formulations

Results:

No adverse effects reported in the different studies

Comments:

Table 8a in the CIR report

Read across

Read across Review of shea butters in CIR report

Reference ID:

S-007 - Final report: Plant derived fatty acid oils as used in cosmetics, CIR Expert Panel, March 4, 2011

Test name:

Skin irritation and sensitization potential in vivo

Method and laboratory:

50 subject human repeat insult patch test (HRIPT), BioScreen Testing, US, 2010

Test material

Lipex Shea, 100 %

Results:

No adverse effects were reported during the study. No identifiable signs or symptoms for primary irritation or sensitization were noted

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S005 - BCS 10-116A / 678587

Test name:

Primary skin irritation

Method and laboratory:

50 subject human single application closed patch test. Institute Dr Schrader, DE, 2004

Test material

Lipex Shea, 100% and 50% in High Oleic Sunflower Seed Oil

Results:

No adverse effects were reported during the study. Very good skin compatibility concluded at both tested concentrations

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S006 - CC-04-018

Test name:

Human repeated insult patch test (HRIPT)

Method and laboratory:

50 subject human repeat insult patch test, 10 male/40 female, 9 exposures
BioScreen Testing Services, Inc, Torrance, CA, US
BCS: 10-116A / 678585
2010

Test material

Lipex 102™, 100%

Results:

Under the conditions of this study, there were no identifiable signs or symptoms of primary irritation or sensitization (contact allergy) noted for the material.

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S120 - BCS 10-116A/678585

Test name:

Human repeated insult patch test (HRIPT)

Method and laboratory:

50 subject human repeat insult patch test, 10 male/40 female, 9 exposures
BioScreen Testing Services, Inc, Torrance, CA, US
BCS: 10-116A / 678590
2010

Test material

Lipex SheaSoft™, 100%

Results:

Under the conditions of this study, there were no identifiable signs or symptoms of primary irritation or sensitization (contact allergy) noted for the material.

Read across

Read across — Same origin, same fatty acid composition and unsaponifiable profile

Reference ID:
S116 - BCS 10-116A/678590

Test name:

Skin corrosivity

Results:

In view of the results from the HRIPT testing (above) and literature data no corrosivity to the skin is expected.

7.03.2 Eye & mucous membrane irritation and corrosivity

Test name:

Eye and mucous membrane irritation by HET-CAM test

Method and laboratory:

In vitro assessment of the acute irritation potential to mucous membranes with the Hen's egg Chorioallantoic Membrane Test.
Test amount 300 microliter/cm2.
Institute Dr Schrader, DE, 2005

Test material

Lipex Shea™,
Lipex CocoaSoft™, Lipex Shea-U™, Lipex PreAct™ tested as Akorex L), diluted to 50% in Akosun (High Oleic Sunflowerseed oil)

Results:

Irritation scores 0.00-0.30
Estimated irritation potential in vivo: “slightly irritant” (irritation score <=0.8)

Comments:

Diluent, Akosun, had 0.0 in Irritation score

Read across

Read across — Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:
S008 - CCT-05-009

Test name:

Eye and mucous membrane irritation by HET-CAM test

Method and laboratory:

Evaluation of the irritancy potential utilising the HET-CAM test.
0.3 ml/o.3 mg of test article is administered to 4 chorioallantoic membranes from hen's eggs. The reactions are scored according to a fixed scale and the total score (max 32) is reported.
Consumer Products Testing Co, Fairfield, NJ, USA, 2011

Test material

Lipex SheaSoft™, 50% in high oleic sunflower seed oil

Results:

Under the conditions of this test, the test article has practically no ocular irritation potential in vivo

Read across

Read across	Same origin, same fatty acid composition and unsaponifiable profile

Reference ID:

S140 - CP V11-3043-5

Test name:

Eye corrosivity

Results: In

In view of the results from the in vitro testing (above) no corrosivity to the eye or mucous membranes is expected

7.03.3 Summary and discussion on irritation and corrosivity

Substances identified as 'Glycerides, C16-18 saturated and C18-unsatd. (SDA Reporting Number: 11-001-00)', including shea butter and other vegetable oils and fats, have a very long history of safe use in a wide range of nutritional (food and feed), 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:

Literature search

Method and laboratory:

PubMed, PubMed Central & Google Scholar search performed in February 2015

Test material

Search on "Shea butter" (and equivalents) AND "sensitisation"/"allergy" (and equivalents)

Results:

No case reports or other publications found associating shea butter with sensitisation or Allergies

Test name:

Protein content and immunological assay

Method and laboratory:

Read across from literature
Coomassie protein assay, IgE binding via Western blot and ELISA assay

Test material

Fat and kernel extracts from raw shea kernels

Results:

Protein content in butter 6-12 microgram/ml. No IgE-binding detected in sera from tree nut allergic subjects

Comments:

Read-across justification: The main allergenic constituents in vegetable oils are proteins. If the protein content is low enough and if the associated proteins are nonallergenic, an assessment of the allergenic potential can be done using the protein content.

Read across

Read across See comment

Reference ID:

S009 – Shea butter proteins, Chawla, J Allerg Clin Immunol, March 2011, 680-682, (2011)

Test name:

Protein assays

Method and laboratory:

Hoffman extraction method and micro BCA protein assay. Leatherhead Food International, UK, 2009.

Test material

Lipex Shea™, Lipex 205™, Akogreen O, Organic extra Virgin Olive Oil, RBD Organic EV Olive Oil, all 100%

Results:

Estimated concentration of proteins in microgram/ml:

Organic EV Olive oil: 414
Akogreen O: 54
RBD EV Olive oil: 21
Lipex Shea™: 12
Lipex 205™: 12

Read across

Read across Representative data for read-across

Reference ID:

S010 - Project Report, LFI 29 April 2009

Test name:

Protein content

Method and laboratory:

Proteins extracted from the oils and protein content of extracts determined using the Perbio Science Micro BCA protein assay kit.
Leatherhead Food Research, Leatherhead, Surrey, UK
2010

Test material

Lipex 106™, Lipex sheaSoft™ (3 batches), Lipex 102™ (3 batches)

Results:

Protein content in microgram/ml:
Lipex 106™: 12
Lipex SheaSoft™: <5, 12, 13

Lipex 102™: <5, 7, 9

Read across

Read across Representative data for read-across

Reference ID:

S144 - LFR report, 2010

Test name:

Protein content

Method and laboratory:

Protein content calculated from nitrogen analysis using a chemiluminescence method (Butterworth Laboratories SOP IM 003A, issue 4)
Butterworth Laboratories Ltd, Teddington, UK, 2013

Test material

Akosun (2 batches), Lipex Shea™, Lipex Bassol C™, Lipex 205™,

Results:

Protein content in mg/l:

Akosun: <9.4/<9.4
Lipex Shea™: 33.8
Lipex 205™: 11.3
Lipex Bassol C™: <9.4

Read across

Read across Representative data for read-across

Reference ID:

S146 - 1212-0121/RN-00072-13

Test name:

Assay of fragrance allergens in oils (EU Directive 2003/15 CE)

Method and laboratory:

Eurofins Analytik GmbH, Hamburg, DE
2005

Test material

Lipex Shea-U™, Lipex 205™, Lipex Shea™,

Results:

None of the 26 listed allergens were detected above the detection limit in the test articles

Read across

Read across Representative data for read-across

Reference ID:

S147 - AR-05-JJ-041876-01, AR-05-JJ-041878-01, AR-05-JJ-041879-01

Test name:
Presence of known food allergens

Results:
Known food allergens are not present in refined vegetable oils

Read across
Statement
Reference ID:
S011 - AAK statement on food allergens

Test name:
Presence of allergens according to EC 1223/2009 Annex III

Results:
Known fragrance allergens are not present in refined vegetable oils

Read across
Statement
Reference ID:
S012 - AAK statement on fragrance allergens

7.04.1 Summary and discussion of sensitisation

Substances identified as 'Glycerides, C16-18 saturated and C18-unsatd. (SDA Reporting Number: 11- 001-00)', including shea butter and other vegetable oils and fats, have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the tests and references reported above, sensitisation and allergenicity are not considered to pose an issue for human health under normal and foreseeable handling and use conditions, provided that the substances are adequately purified to remove proteins.

7.05 Repeated dose, sub-chronic and chronic toxicity

7.05.1 Oral administration

Test name:

13 week feeding study

Method and laboratory:

Species: rat (Colworth-Wistar) 15 male/15 female
Duration: 13 weeks
Dosage: 20% of diet

Test material

Hydrogenated shea olein
Unhydrogenated shea olein
Palm oil
Soybean oil
Hydrogenated palm oil
Hydrogenated soybean oil

Results:

No adverse effects were observed in any of the tested diets.

Comments:

Read-across justification: The product contains similar types of C16 and C18 saturated and unsaturated fatty acids and similar level of unsaponifiable matter content and composition to the tested products.

Read across

Read across See comment

Reference ID:

S013 – Studies to investigate the absorption and excretion of shea oleine sterols in rat and man, Earl LK et al, Int J toxicol, 21, (2002), 353-359

Test name:

47 week feeding study

Method and laboratory:

Species: rat (Wistar) male/female
Dosage: 18.5% (nominal in diet)
Vehicle: no vehicle
Duration: 47 wks (daily ad libitum)

A 47 wk repeated dose study was conducted to compare the effects of various sources of dietary fat. Bodyweight gain and food intake, fat absorption, cholesterol levels and other parameters were measured during the course of the study. At termination, various organs were weighed, and liver and intestine were examined histologically.

Test material

Coconut oil
Oleo oil
Butter fat
Corn Oil
Safflower oil

Results:

NOAEL: 18.5% in diet (i.e. Ca. 9,250 mg/kg bw/day)
No effects on bodyweight gain, caloric efficiency, mortality, organ weights and histopathology of liver and intestine. The plasma cholesterol and liver lipid, phospholipids and cholesterol level were also not markedly different between the groups

Comments:

Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)
Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Read across

Read across See comment

Reference ID:

S014 – Nutritional evaluation of fats, Harkins, JAOCS, 45, 26-30, (1968)

Test name:

90 days feeding study

Method and laboratory:

Species: Wistar rat male/female
Dosage: 10% (nominal in diet)
Vehicle: no vehicle
Exposure: 90 days (daily)

Groups of 30 weanling rats were fed diets containing 10% of crude palm oil, groundnut oil or refined palm olein oil and adequate amounts of all other nutrients for 90 days. Food intake and bodyweight were monitored weekly. At the end of the experiment, cholesterol and triglycerides of serum, liver and heart of all animals were analysed.

Test material

Palm oil

Results:

NOAEL: 10% in diet (i.e. ca. 5,000 mg/kg bw/day)
No effects on growth rate, feed efficiency ratio, protein efficiency ratio, net protein utilization, digestibility, fat absorption, nitrogen balance, phosphorous and calcium retention, lipid profiles, serum enzymes and blood hematology

Read across

Read across Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S015 – Nutritional evaluation Palm oil, Manorama, Am J Clin Nutr, 53, 1031S-1033S, (1991)

Test name:

13 week combined repeated dose and reproduction study

Method and laboratory:

Species: rat (Sprague-Dawley), male/female
Combined repeated dose and reproduction/developmental screening
Dosage: 15% (nominal in diet)
Vehicle: no vehicle
Exposure: 13 weeks (Daily)

Groups of 10 male and 30 female rats were fed during 13 weeks with diets containing 15% crude palm oil. Other groups received diets with heated palm oil, crude/heated soy oil, crude/heated peanut oil or crude/heated sunflower oil at the same concentration. Clinical signs and bodyweight were recorded

Test material

Palm oil, Soybean oil, Sunflower seed oil, Peanut oil

Results:

NOAEL: 15% in diet (male/female) (i.e. from 17,000 - 7,000 mg/kg bw/day, as the bodyweight of animals increased regularly over the course of the study.)

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S016 – Toxicology and nutrition of heated oils, Coquet, Rev Fr Corps Gras, 24(19), 484-492, (1977)

Test name:

Repeated dose 90 day oral toxicity

Method and laboratory:

Species: rat (Wistar) male/female
Dosage: 0, 1, 5 and 15% (nominal in diet)
Vehicle: no vehicle
Exposure: 98 and 100 days for female and male rats, respectively (Daily)
OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Test material

Pine nut oil

Results:

NOAEL: 15% in diet (i.e. ca. 8,866 mg/kg bw/day in males and 10,242 mg/kg bw/day in females) (nominal)
No toxicologically significant effects observed

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S017 - Subchronic and genotoxicity study Korean pine oil, Speijers, Regul Toxicol Pharmacol, 55, 158-165, (2009)

Test name:

Repeated dose 90 day oral toxicity

Method and laboratory:

Species: rat (Sprague-Dawley) male/female
Dosage: 19% (nominal in diet)
Vehicle: no vehicle
Exposure: 91 d (Daily ad libitum)

Equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Test material

Fully hydrogenated soybean oil
Fully hydrogenated rapeseed oil (C22:0 44%)

Results:

NOAEL: 7.5% in diet (i.e. ca. 3,750 mg/kg bw/day)

Increased haemoglobin level in males and ovary weights in females without histopathological findings. Slightly increased feed consumption after 4 wks attributed to lower absorbability of fully hydrogenated soybean oil

Comments:

Glycerides, C16-18 (SDA Reporting Number: 19-001-00)
Glycerides, C16-C22 (SDA Reporting number: 21-001-00)

Read across

Read across Glycerides, C16-18 (SDA Reporting Number: 19-001- 00)

Reference ID:

S018 – Biological evaluation of hydrogenated rapeseed oil, Nolen, GA, JAOCS, (1981), 31-37

Test name:

Repeated dose 90 day oral toxicity

Method and laboratory:

Species: rat (Sprague-Dawley) male/female
Dosage: 19% (nominal in diet)
Vehicle: no vehicle
Exposure: 91 d (Daily ad libitum)

Equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Test material

Soybean oil

Results:

NOAEL: 19% in diet (i.e. ca. 9,500 mg/kg bw/day)
No treatment-related effects on any of the parameters recorded

Read across

Read across Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S018 – Biological evaluation of hydrogenated rapeseed oil, Nolen, GA, JAOCS, (1981), 31-37

A large number of repeated dose oral toxicity studies have been conducted with various vegetable oils and/or animal fats at different degrees of hydrogenation and/or interesterification, particularly in the context of nutritional research. For practical reasons, only a limited number of studies are reported here.

Vegetable oils and fats, including shea butter, are a component of a normal diet. Although differences may be observed on bodyweight gain, food consumption and certain measured parameters depending on the chain length distribution of the fatty acids associated to the glycerides and their degree of unsaturation, research overall indicates that, when consumed at nutritionally relevant concentrations (i.e. typically up to the equivalent of 35% of calories in food), there are no adverse effects on health and longevity.
Across all studies, tested doses ranged from 7.5 to 19% in diet. No significant toxicity was seen at any of the tested dose rates. For risk assessment purposes, the relevant oral NOAEL could therefore be considered to be 18.5% in diet, which is equivalent to an estimated 9,250 mg/kg bw/day.

7.05.2 Inhalation studies

No studies could be located on the repeated dose inhalation toxicity of vegetable oils and fats. However, given their physical state (solid to semi-solid to liquid under environmental conditions), low vapour pressure (< 0.001 Pa at 20°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, in accordance with Annex VIII, column 2 of the REACH regulation (1907/2006/EC).

7.05.3 Dermal administration

No studies have been located on the repeated dose dermal toxicity of vegetable oils and fats. However, this substance and others from the same read-across category present low systemic toxicity upon repeated dose oral exposure for which absorption is higher (96%) than via the dermal route (default 10%, see also section 7.9.2), 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 nutritional (food and feed), 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.

7.05.4 Other routes of administration

There are no other relevant routes of exposure for ‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ or for shea butter and other vegetable oils and fats

7.05.5 Human studies

Test name:

Dietary intervention study

Method and laboratory:

Test group: 100 healthy volunteers aged 45 +/- 13 years
Duration: 24-25 days
Administration: oral Dosage: 30 g/day of margarine, corresponding to a fat intake of 21 g/day

Test material

Margarines with approximately 70% fat from different sources, including shea butter

Results:

No adverse effects of the tested margarines in a normal dietary context were observed.

Comments:

Read-across justification: The product contains same types of C16 and C18 saturated and unsaturated fatty acids and similar level of unsaponifiable matter content and composition to the tested products.

Read across

Read across See comment

Reference ID:

S020 – Plant sterol-enriched margarines and reduction of plasma total and LDL-cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects, Weststrate & Meijer, Eur J Clin Nutr, 52 (1998), 334-343

Test name:

Dietary intervention study

Method and laboratory:

Test group: 76 volunteers (39 male/37 female) aged 44 +/- 11 years
Duration: 9 weeks
Administration: oral
Dosage: 25 g of margarine per day, corresponding to a fat intake of 17,5 g fat per day

Test material

Margarines with approximately 70 % fat from different sources, including shea butter

Results:

No adverse effects of the tested margarines in a normal dietary context were observed.

Comments:

Read-across justification: The product contains similar types of C16 and C18 saturated and Unsaturated fatty acids and similar level of unsaponifiable matter content and composition to the tested products

Read across

Read across See comment

Reference ID:

S021 – Plant sterols in diet, Sierksma, Br J Nutrition, 82, 273-282, (1999)

Substances identified as ‘Glycerides, C16-18 saturated and C18-unsatd. (SDA Reporting Number: 11-001-00)’, and other substances of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. These substances (in the form of olive oil, corn oil, sunflower oil etc.) are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects.

Based on these above facts, 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

A large number of repeated dose oral toxicity and dietary intervention studies have been conducted with vegetable oils and fats of different origins and at different degrees of hydrogenation and/or esterification in the context of nutritional research as well as in toxicological investigations. Although differences may be observed on bodyweight gain, food consumption and certain measured parameters depending on the chain length distribution of the fatty acids associated to the glycerides and their degree of unsaturation, research overall indicates that, when consumed at nutritionally relevant concentrations (i.e. up to the equivalent of ca. 35% of total calorie intake, there are no adverse effects on health and longevity. Similar results were obtained for the other substances of the same read-across category. Across all studies, the highest oral NOAEL could be considered to be 18.5% in feed, equivalent to an estimated 9,250 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.

Shea butters, and other refined vegetable oils from the same read-across category present low systemic toxicity upon repeated dose oral exposure for which absorption is higher than via the dermal route, so that repeated dose dermal toxicity is also expected to be minimal. Furthermore, given its physical state (solid to semi-solid under environmental conditions), low vapour 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:

13 week combined repeated dose and reproduction study

Method and laboratory:

Species: rat (Sprague-Dawley), male/female
Combined repeated dose and reproduction/developmental screening
Dosage: 15% (nominal in diet)
Vehicle: no vehicle
Exposure: 13 weeks (Daily)

Groups of 10 male and 30 female rats were fed during 13 weeks with diets containing 15% crude palm oil. Other groups received diets with heated palm oil, crude/heated soy oil, crude/heated peanut oil or crude/heated sunflower oil at the same concentration. Clinical signs and bodyweight were recorded

Test material

Palm oil, Soybean oil, Sunflower seed oil, Peanut oil

Results:

NOAEL: 15% in diet (male/female) (i.e. from 17,000 - 7,000 mg/kg bw/day, as the bodyweight of animals increased regularly over the course of the study.)

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S016 – Toxicology and nutrition of heated oils, Coquet, Rev Fr Corps Gras, 24(19), 484-492, (1977)

Test name:

Reproduction study in rats

Method and laboratory:

Species: Colworth-Wistar rats
(Study 1: 20M+20F, Study 2:50M+50F)
Dosage: Diets with 7-15% of shea oleins, corresponding to an intake of 3.5 - 7.5 g/kg bw/day of hydrogenated shea olein.

Test material

Study 1: Shea olein, hydrogenated shea olein & cocoa butter

Study 2: Shea butter, shea olein, hydrogenated shea olein, palm oil and hydrogenated palm oil

Results:

None of the two individual studies reported in the article indicate any reproduction toxicity for shea butter, cocoa butter, shea olein, hydrogenated shea olein, palm oil or hydrogenated palm oil.

Comments:

Read-across justification:
The product contains similar types of C16 and C18 saturated and unsaturated fatty acid and similar level of unsaponifiable matter content and composition to the tested products

Read across

Read across See comment

Reference ID:

S026 Reproduction studies in the rat with shea oleine and hardened shea oleine, Baldrick P, Robinson JA and Hepburn PA, Food Chem Toxicol. 2001, 39(9), 923-30.

Test name:

Multigeneration reproduction study

Method and laboratory:

Species: rat (Wistar) male/female
Dosage: 10% (nominal in diet)
Vehicle: no vehicle
Exposure: 3 generations (Daily)
Groups of 24 (12 male and 12 female) inbred weanling albino rats were given a diet containing 10% of the tested fats and oils. Bodyweight and food intake were recorded weekly for 15 weeks. Fertility index or conception rate, sex ratio, mean weaning weight, pre-weaning mortality, number of days from introduction of mating, behaviour of pups and adults were recorded for generation F0 to F3.

Test material

Red palm oil, Groundnut oil, Palm oleins, Hydrogenated vegetable oil

Results:

NOAEL (all generations): 10% in diet (male/female), (i.e. ca. 5,000 mg/kg bw/day)

No significant adverse effects were observed on any of the reproductive or toxicological parameters

Read across

Read across See comment

Reference ID:

S-027 Multigeneration study vegetable oils, Manorama, Fd Chem Toxic, 31(5), 369-375, (1993)

Taken together, the above weight of evidence suggests that ‘glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’, including shea butter and other vegetable oils and fats, are not toxic for reproduction on oral exposure. Because absorption and therefore systemic exposure via the dermal route is lower than via the oral route, reproductive toxicity from dermal contact is also not expected. Finally, given the physical state (semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C) of the substance, as well as the fact that it is not handled or marketed as a powder, reproductive toxicity as a result of inhalatory exposure is not likely. Across all studies, tested doses ranged from 8.75 to 15% in diet. No significant toxicity was seen at any of the doses rates. For risk assessment purposes, the highest oral NOAEL could be considered to be 15% in diet which is equivalent to an estimated 7,000 mg/kg bw/day, on the basis of a 13-week combined repeated dose and reproduction / developmental screening (feeding) study.

7.06.2 Human studies

'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other substances of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. Moreover, in the form of olive oil, corn oil, sunflower oil, etc., they are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of the repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects.

Based on the above facts, 'glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)', including shea butter and other vegetable oils and fats, are not assessed to be reproductive toxicants and no further consideration for this endpoint is required.

7.06.3 Developmental toxicity/teratogenicity

7.06.3.1 Non-human studies

Test name:

Two generation reproduction toxicity study

Method and laboratory:

Species: rat (Sprague-Dawley)
Dosage: 15% (nominal in diet),daily ad libitum
Vehicle: no vehicle
Exposure: F0 generation: from weaning
F1 generation: from conception

Developmental toxicity/teratogenicity potential was observed in groups of 25 pairs of two generations of male and female rats. The first two litters of each generation were permitted to be born naturally. During the third pregnancy of each generation, one half of the females were sacrificed on Day 13 of gestation and inspected for early embryonic death. The remaining females were sacrificed on Day 21 of gestation, and the fetuses were examined for either skeletal or soft tissue abnormalities.

Test material

Partially hydrogenated soybean oil

Results:

NOAEL (maternal toxicity): 15% in diet (i.e. ca. 7,500 mg/kg bw/day).
No effects on following parameters: Growth and food consumption, gross pathology, organ weights, histopathology, average conception rate, number of corpora lutea, implantations and resorptions.
NOAEL (developmental toxicity): 15 % in diet.
No effects on following parameters: Sizes of litters at birth, stillbirths, live births, postnatal mortality, weight gain, skeletal variations / defects and soft-tissue abnormalities

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S-028 Effects of fresh and used hydrogenated soybean oil on reproduction and teratology in rats, Nolen, GA, JAOCS, 49(12), (1972), 688-693

Across all studies, tested doses ranged from 8.75 to 15% in diet. No significant toxicity was seen at any of the doses rates. For risk assessment purposes, the highest oral NOAEL could be considered to be 15% in diet, on the basis of a two-generation study conducted in rats, which is equivalent to an estimated 7,500 mg/kg bw/day.

7.06.3.2 Human studies

‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ and other substances of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. In the form of olive oil, corn oil, sunflower oil, etc., they are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects. Based on the above facts, ‘Glycerides, C16-18 and C18 unsaturated (SDA Reporting Number: 11-001-00)’, shea butters and other vegetable oils and fats, are not assessed to be developmental toxicants and no further consideration for this endpoint is required

7.06.4 Summary and discussion of reproductive toxicity

It can be concluded from the data presented in Section 7.6.1 and 7.6.2 that vegetable oils and fats do not present any reproduction toxicity at daily intakes of less than 7500 mg/kg bw. This value is considered relevant for risk assessment purposes, although it is only a reflection of study setups and not of effects observed at higher doses.

7.07 Mutagenicity/genotoxicity

7.07.1 In vitro data

Test name:

OECD Guideline 471 (Bacterial Reverse Mutation Assay) (Ames test)

Method and laboratory:

S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (with and without metabolic activation)

E. coli WP2 uvr A (with and without metabolic activation)

Doses: 10, 33, 100, 333 and 1000 µg/plate

Test material

Pine nut oil

Results:

Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (all strains/cell types tested)

Cytotoxicity: negative for E. coli WP2 uvr A (all strains/cell types tested)

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S017 - Subchronic and genotoxicity study Korean pine oil, Speijers, Regul Toxicol Pharmacol, 55, 158-165, (2009)

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.
0.05, 0.1, 0.5, 1.0 and 5.0 mg/plate.
Consumer Products Testing Co, Fairfield, NJ, USA
2008

Test material

Lipex Genova™, Lipex Omega 3/6™, Lipex Palmkernel 38, Lipex Shea Betaine™, Lipex Shea Q, all at 100%

Results:

There is no detectable genotoxic activity associated with any of the test articles at non-cytotoxic test concentrations.

Comments:

Cytotoxic concentrations vary with the test material (Lipex Shea Q> 0.05 mg/plate, Lipex Shea Betaine > 0.1 mg/plate, Lipex Omega 3/6 >1.0 mg/plate, Lipex Palmkernel 38 and Lipex Genova >5.0 mg/plate))

Read across

Read across — Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S132 - CP M08-3813

Test name:

Bacterial Reverse Mutation Assay, Ames Test

Method and laboratory:

Salmonella typhimurium standard plate incorporation study, with and without S9 metabolic activation. Study strains: TA 1535, TA1537, TA98 and TA100.
0,8, 40, 200, 1000 and 5000 microgram/plate
Quintiles Ltd, Ledbury, UK, 1998

Test material

Lipex Shea-U™, 100 % tested as "Shea butter FP 98-017"

Results:

The test article was not mutagenic under the conditions of this test.

Read across

Read across — Same origin and similar fatty acid and unsaponifiable composition.

Reference ID:

S131 - Quintiles report THI/001, 1998

Test name:

Bacterial reverse Mutation Assay (OECD 471)

Method and laboratory:

Salmonella typhimurium standard plate incorporation study, with and without S9 metabolic activation. Study strains: TA98, TA100, TA 1535 and TA1537.
Test concentrations were 1.581, 5, 15,81, 50, 158.1, 500, 1581 and 5000 microgram/plate.

CiToxLab Hungary, Szabadsagpuszta, Hungary

Test material

Lipex L'sens™, 100%

Results:

The test item had no mutagenic effect in the examined bacterial strains under the test conditions of this study.

Read across

Read across — Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00). Unsaponifiables from shea butter.

Reference ID:

S150 - CiToxLab 15/252-007M

The above evidence, collected from in vitro tests on materials from the same read-across category, added to the very long history of safe use of these types of substances in nutritional (food and feed), cosmetic and industrial uses, suggests that ‘Glycerides, C16-18

and C18-unsatd. (SDA Reporting Number: 11-001-00)', including shea butter and other vegetable oils and fats 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

'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other structurally similar substances from the same read-across category 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 nutritional (food and feed), cosmetic and industrial uses, suggests that 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)', including shea butter and other vegetable oils and fats, do not have a mutagenic potential.

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

7.07.4 Summary and discussion of mutagenicity

'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other structurally similar substances from the same read-across category 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 nutritional (food and feed), cosmetic and industrial uses suggests that 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)', including shea butter and other vegetable oils and fats, do not have a mutagenic potential.

Based on the above information, the substance does 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 justification: The product contains similar types of C16 and C18 saturated and Unsaturated fatty acid and similar level of unsaponifiable matter content and composition to the tested products.

Read across

Read across See comment

Reference ID:

S029 An assessment of the carcinogenic potential of shea oleine in the rat, Carthew P, Baldrick P, and Hepburn PA, Food Chem
Toxicol. 39 (2001), 807-815

Test name:

6 month feeding study

Method and laboratory:

Species: rat (Sprague-Dawley) female
Dosage: oral, 20% (nominal in diet)
Vehicle: No vehicle
Exposure: Approximately 6 months (Daily)

A study was conducted to investigate whether palm oil, as a dietary fat, has an impact on mammary carcinogenesis in female rats induced by DMBA.
Groups of 32 female rats were given one single dose DMBA (7.5 mg p.o.) and after 1 wk the rats were switched to a 5% corn oil control diet for the rest of the experiment.

Test material

Palm oil

Results:

NOAEL = 20% in diet (i.e. ca. 10,000 mg/kg bw/day)
Non-promoting effect on chemically induced mammary carcinogenesis in female rats

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:
S-030 Tumorigenic effect of vegetable oils, Sylvester, Cancer Res, 46. 757-762, (1986)

Test name:

5 months feeding study

Method and laboratory:

Species: rat (Sprague-Dawley) female
Dosage: oral, 20% by weight (nominal in diet)
Vehicle: no vehicle
Exposure: 6 months (daily)

A study was conducted to investigate whether palm oil has an impact on mammary carcinogenesis in female rats induced by DMBA. Groups of 20 female rats were given one single dose DMBA and after three days were fed with semi-synthetic diets containing 20% various fats and oils, for a duration of 5 months. At autopsy, blood was collected from the tumor-bearing rats. The tumors were examined and lipid extractions were made for analysis of fatty acid profile, as well as tocopherols, tocotrienols and carotenes content.

Test material

Palm oil, Corn oil, Soybean oil

Results:

NOAEL = 20% in diet (i.e. ca. 10,000 mg/kg bw/day)
Non-promoting effect on chemically induced mammary carcinogenesis in female rats

Read across

Read across	Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:
S031 Effect of palm oil on mammary tumorigenesis, Sundram, Cancer Res, 49, 1447-1451, (1989)

'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other substances of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. In the form of olive oil, corn oil, sunflower oil, etc., they are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of the repeated dose toxicity, carcinogenicity or reproductive / developmental toxicity of chemical substances, without any apparent adverse effects. As dermal absorption is lower than absorption via the oral route (see Section 7.9.2), carcinogenicity following dermal systemic uptake is not expected. Finally, given the physical state (semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C) of the substance, as well as the fact that it is not handled or marketed as a powder, carcinogenicity as a result of inhalatory exposure is not likely.

7.08.2 Human studies

‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ and other substances of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. In the form of olive oil, corn oil, sunflower oil, etc., they are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects. Based on the above facts, carcinogenicity 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.

7.08.3 Summary and discussion of carcinogenicity

‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ and other substances of the same read-across category have been tested for carcinogenicity in rodents and found to have no effect after oral exposure. The substance also does not contain any functional groups suggesting carcinogenic activity. No carcinogenicity is expected from dermal exposure as systemic uptake will be lower than from the oral route. Finally, given the physical state, low vapour pressure of the substance and the fact that it is not handled or marketed as a powder, carcinogenicity as a result of inhalatory exposure is not likely. Furthermore, ‘glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ and other substances of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. In the form of olive oil, corn oil, sunflower oil, etc., they are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of the repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects

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)

Vegetable oils and fats are composed mainly of triglycerides containing a glycerol backbone esterified to linear saturated fatty acids with a carbon chain length of C8-C18 as well as unsaturated C18 fatty acids. The toxicokinetics of glycerides and fatty acids are well known as a result of their widespread use in nutritional (food and feed) applications

7.09.1 Oral administration

Test name:

Feeding study

Method and laboratory:

Species: rat (Wistar), male/female
Dosage: oral, 18.5% in diet
Exposure regime: daily, 47 wks; ad libitum

At intervals during the study, feces were collected, pooled and analysed for fat content. Net fat absorption was calculated from dietary intake and fecal excretion.

Test material

Coconut oil

Results:

Absorption: 96%

Read across

Read across	Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S014 – Nutrional evaluation of fats, Harkins, JAOCS, 45, 26-30, (1968)

Test name:

Repeated dose 90 day oral toxicity

Method and laboratory:

Species: rat (Sprague-Dawley) male/female
Dosage: 19% (nominal in diet)
Vehicle: no vehicle
Exposure: 91 d (Daily ad libitum)
Equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Test material

Fully hydrogenated soybean oil

Fully hydrogenated rapeseed oil (C22:0 44%)

Results:

NOAEL: 7.5% in diet (i.e. ca. 3,750 mg/kg bw/day)

Increased haemoglobin level in males and ovary weights in females without histopathological findings. Slightly increased feed consumption after 4 wks attributed to

lower absorbability of fully hydrogenated soybean oil

Comments:

Glycerides, C16-18 (SDA Reporting Number: 19-001-00)
Glycerides, C16-C22 (SDA Reporting number: 21-001-00)

Read across

Read across Glycerides, C16-18 (SDA Reporting Number: 19-001- 00)

Reference ID:

S018 – Biological evaluation of hydrogenated rapeseed oil, Nolen, GA, JAOCS, (1981), 31-37

Test name:

Repeated dose 90 day oral toxicity

Method and laboratory:

Species: rat (Sprague-Dawley) male/female
Dosage: 19% (nominal in diet)
Vehicle: no vehicle
Exposure: 91 d (Daily ad libitum)

Equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Test material

Soybean oil

Results:

NOAEL: 19% in diet (i.e. ca. 9,500 mg/kg bw/day)
No treatment-related effects on any of the parameters recorded

Read across

Read across Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S018 – Biological evaluation of hydrogenated rapeseed oil, Nolen, GA, JAOCS, (1981), 31-37

When taken up orally, triglycerides are split in the intestinal lumen into glycerol and fatty acids with the help of lipases and bile secretions (in a process called lipolysis), then move into the cells lining the intestines (absorptive enterocytes). The triglycerides are rebuilt in the enterocytes from their fragments and packaged together with cholesterol and proteins to form chylomicrons. These are excreted from the cells, collected by the lymph system and transported to the large vessels near the heart before entering the blood. Various tissues can capture the chylomicrons, releasing the triglycerides to be used as a source of energy. When the body requires fatty acids as a source of energy, the hormone glucagon signals the breakdown of the triglycerides by hormone-sensitive lipases to release free fatty acids from the adipose cells (fat cells), the major site of triglyceride accumulation. The fatty acids are then broken down by stepwise elimination of C2-units in the mitochondrial β-oxidation. The C2-units are esterified to acetyl-coenzyme A which directly enters the citric acid cycle where it is converted to carbon dioxide and energy. The extent of absorption in the gastro-intestinal system varies depending on the chain length of the fatty acids and their degree of saturation. Generally, short-chain fatty acids are better absorbed than the long chain counterparts. Also, absorption decreases with increasing saturation (S032 MacDonald, 1973; S033 Robinson, 1973).

7.09.2 Dermal administration

No experimental studies have been located for absorption through the dermal route. However, as per Section R.7.12.2 of REACH guidance document R7.C (2014), the extent of dermal absorption may be predicted based on physico-chemical properties, including:
− Water solubility
− Partition coefficient
− Molecular weight / fatty acid chain length (inversely proportional)

Long chain triglycerides (exemplified by 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)', shea butters and other vegetable oils and fats) are poorly water soluble (< 10 mg/L), have an estimated log Pow > 6 and a molecular weight of approximately 900 D. As such, uptake into the stratum corneum of skin and further transfer into the epidermis are likely to be low. A default dermal penetration value of 10% can be assumed (REACH guidance document R7.C). However, triglycerides can also be hydrolysed in the skin to free fatty acids and glycerol which are easily absorbed. Thus, for the purpose of safety assessment, the dermal absorption has been assumed to be 100%.

7.09.3 Inhalation route

No significant inhalatory exposure to typical vegetable oils and fats will occur as the substances are either semi-solid to solid under environmental conditions or have a negligible vapour pressure at relevant temperatures.

7.10 Photoinduced toxicity

7.10.1 Phototoxicity: photoirritation / photosensitisation

Test name:

Phototoxicity test - in vivo

Method and laboratory:

28 subject human photo-toxicity test according to proDERM Standard Protocol-V04
UVA 5 J/ cm2
ProDERM, DE, 2014

Test material

Lipex Shea, 100%

Results:

No photo-toxic reaction from Lipex Shea under applied test conditions or any skin reaction on un-radiated skin

Read across

Read across — Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S036 - PD 14.0300-71/E

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

Test name:

Comedogenicity

Method and laboratory:

11 subjects, 4 weeks
Daily application in the facial area
BioScreen Clinical Services, 2011

Test material

Lipex SheaSoft

Results:

Total comedone number post treatment was 188 versus baseline 179. This difference is not statistically significant (p-value 0.577). Under the conditions of the study it was concluded that the claim "non-comedogenic" can be substantiated for this product.

Read across

Read across — Same origin, same fatty acid composition and unsaponifiable profile

Reference ID:

S037 - BCS 11-013/708185

Test name:

Comedogenicity

Method and laboratory:

Clinical assessment of facial comedones
11 subjects, 4 weeks
Daily application of test material in the facial area
BioScreen Clinical Services, Torrance, CA, US, 2011

Test material

Lipex 205™, 100%

Results:

Under the conditions of the study, there was no statistically significant difference between the comedone counts at baseline and 4 weeks post-treatment with test product. The claim 'non-comedogenic' can thus be substantiated for the test product.

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S102 - BCS 11-013/708185

Based on the studies that have been carried out it can be concluded that solid and liquid shea butters have no comedogenic effect.

7.12 Summary and NOAEL statement

Based on the data presented in Chapter 7.1 to 7.11, the NOAEL is set to 9250 mg/kg bw/day for systemic exposure for ‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ 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, 2010

Test material

Lipex Shea™, 100%

Results:

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

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S160 - AnoxKaldnes 10-224-4

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, 2009

Test material

Lipex 205™, 100%

Results:

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

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S169 - AnoxKaldnes 09-290-3

Based on the available information, shea butters can in general be regarded as readily biodegradable according to the OECD testing guidelines.

8.02 Accumulation

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

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 Loading Rate (NOELR) 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, 2010

Test material

Lipex Shea™, 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 NOELR 31 mg/l

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S172 - Toxicon 025/10-6

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 Loading Rate (NOELR) 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, 2010

Test material

Lipex 205™, 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 NOELR 100 mg/l

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S177 - Toxicon 025/10-3

Summary:

Based on the available information, shea butters 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

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
Latest statement, download “General Statement AAK Ingredients” at 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, however CAS. No 68956-68-3 is listed and valid to be used.
DSL (Canada)	Domestic Substances List	Listed
AICS (Australia)	The Australian Inventory of Chemical Substances	Not listed, however refined shea butter 91080-23-8 and CAS. No 93333-83-6 is listed and valid to be used.
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	Listed
IECIC (China)	Inventory of Existing Cosmetic Ingredients in China	Listed
ENCS (Japan)	Combined list of existing and notified chemical substances as the Japanese Existing and New Chemical Substances Inventory.	Not listed, however CAS. No 67701-28-4 is listed and valid to be used.
Japan	Japan Pharmacopoeia	No (but ok ceci/JSQI monograph 253 110)
KECI (South Korea)	Korea Existing Chemicals Inventory	Not listed, however CAS. No 68956-68-3 listed, also CAS 68424-60-2 KE-17811 is listed and valid to be used.
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Not listed, however CAS. No 68956-68-3 and refined shea butter 91080-23-8 is listed and valid to be used.
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Listed but Fats and Glyceridic oils, shea butter (194043-92-0) is listed and valid to be used.
NECI (Taiwan)	National Existing Chemical Inventory	Listed
Saudia Arabia	The Saudi Arabian Standards Organisation	Not listed, however Hydrogenated vegetable oil can be used: Local name: Yağlar, bitkisel, hidrojenlenmiş; English name: Oils, vegetable, hydrogenated
Malaysia	Chemicals Information Management System	No
Mexico	Inventario Nacional de Sustancias Químicas	Not listed but Grasas y aceites glicerídicos, vegetales
Turkey		No

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

10.2.2 Vegan and Vegetarian claim

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

10.3 Other Statements

10.3.1 BSE/TSE statements:

Latest statement, download at aakpersonalcare.com

10.3.2 GMO statement

The product is not derived from GMO. Also, no GMO ingredient or raw material are used during the manufacturing process of the ingredients or raw material.

Latest statement, download at aakpersonalcare.com

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

The product is produced according to EFFCI GMP.

EFFCI GMP certificate latest version available for downloading at aak.com

11.5 Food Safety/ FSSC 22000

The product is produced according to food safety standard, FSSC 22000 (ISO 22000).

FSSC 22000 certificate latest version available for downloading at aak.com

11.6 Other

No other available

12. PATENTS

12.1 Patents

No data.

TRANSPORTS AND HANDLING - LIPEX® SheaSoft TR™

13.1 Transports

No data available

13.2 storage unopen package

Storage to fulfill shelf life:
Store in temperature below 20C or lower. Dark, dry and odour 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.

Box is possible to use amount needed directly from the box. Do not melt material directly in the box remove and melt in a vessel.

During processing need to be heated to 60C to remove crystal memory.

13.3.2 Use of full package for partly use

Box is possible to use partly directly from the box. Do not melt material directly in the box remove and melt in a vessel.

Reseal packaging and store in 20C or below to smaller packaging

If LIPEX® Sheasoft™ is repeatedly heated make sure that the material is heated properly to at least 60C every time. The remaining material left to cool may recrystallize and show inhomogeneous appearance but if the material is melted before use, it works fine. It is important that the temperature is high enough: if the material is only heated to i.e. 40C the material may separate into a solid and a liquid fraction and the composition will not be consistent between batches.
From an oxidation point of view the 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.

Note:
AAK's shelf life for ingredients that are unopened and stored according to the instructions given in the product information 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	**81094442 - 10**
Print date	2021-12-21
Your reference	
Our reference	Karina Petterson
Material	7601-510 LIPEX SHEASOFT TR
Your material no.	
Date of shipment	2021-12-13
Container no	

Batch 0002432126 / **Quantity** 10,400 KG / **Prod. date** 2021-10-14
Inspection lot 2802871 / **Best before** 2023-10-14

Characteristic	Result		Lower Limit	Target	Upper Limit
Acid value(IUPAC 2.201(m))					
Acid value	0.07	mg KOH/g			0.50
Colour Lovibond(Lovibond Tintometer)					
Colour 5 1/4" Red	1.7				2.0
Peroxide value(AOCS Cd 8b-90(m))					
Peroxide value	< 0.1	meq/kg			1.0
Iodine value Wijs(IUPAC 2.205(m))					
Iodine value Wijs	62.4		58.0		68.0

Quality Control Manager
AAK Sweden AB

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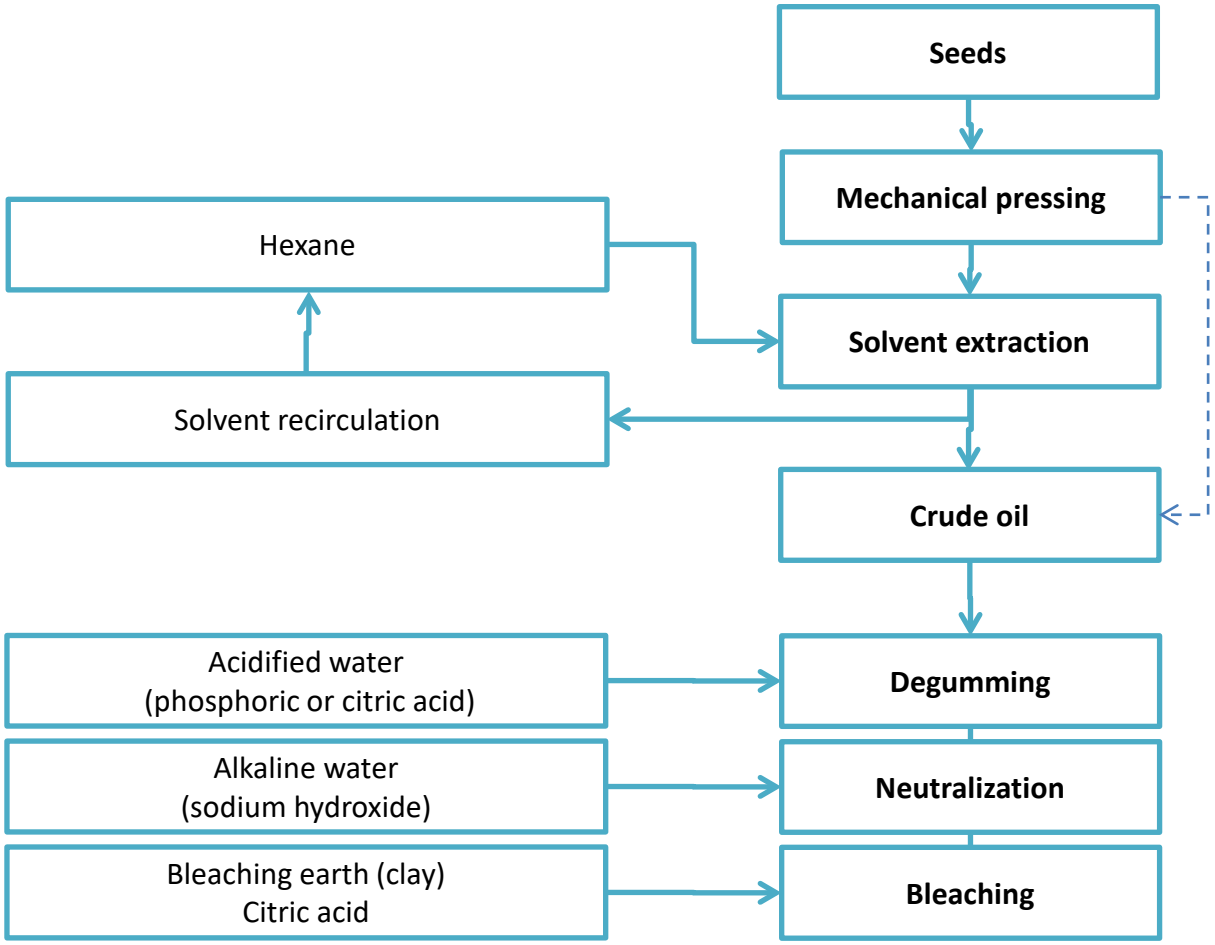
ZAO K8327 1

LIPEX® SheaSoft TR
Refined oils and fats (with solvent extraction)



Explanations what each step contribute with

Separates crude oil from seed

Separates crude oil from seed

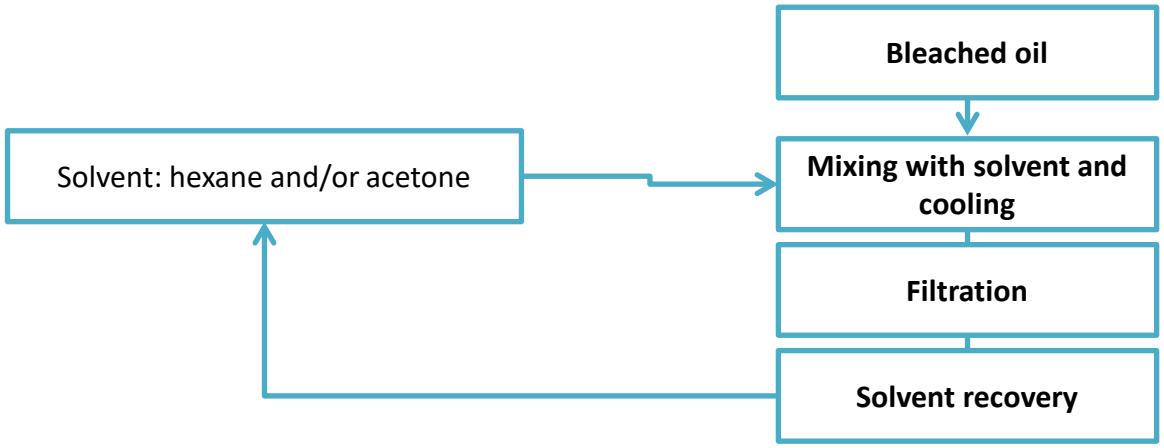
Removes phospholipids, metals and proteins

Removes free fatty acids, metals and proteins

Removes pigments, metals and proteins

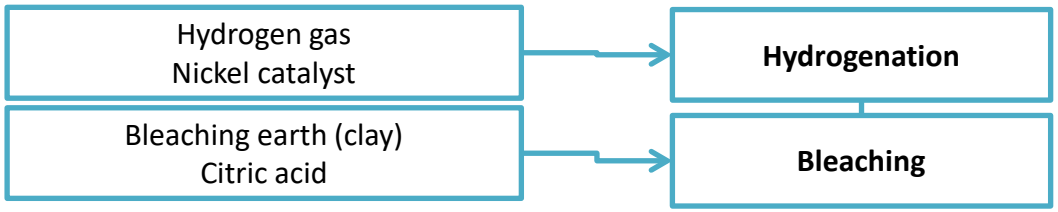
See disclaimer

LIPEX® SheaSoft TR
Solvent fractionated oils and hydrogenated oils



Explanations what each step contribute with

Separates solid and liquid constituents

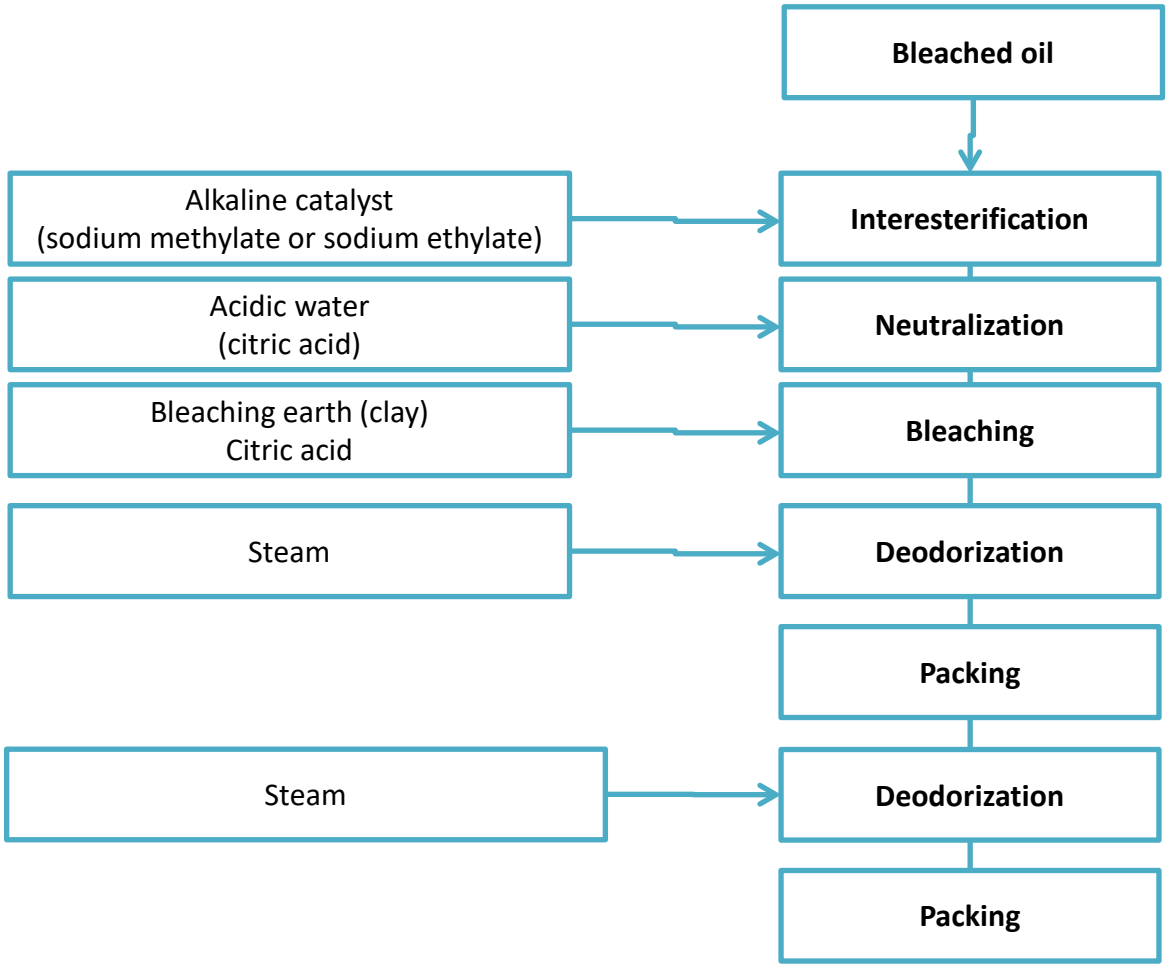


Removes unsaturation by reduing double bonds

Removes pigments, metals, proteins and catalyst traces

See disclaimer

LIPEX® SheaSoft TR
Interesterified oils and deodorised oils and fats



Explanations what each step contribute with

Randomises triglyceride composition

Neutralises catalyst and stops reaction

Removes pigments, metals, proteins and catalyst traces

Removes flavours, free fatty acids and oxidation products

Removes flavours, free fatty acids and oxidation products

See disclaimer