Product Documentation

# LIPEX® Cellect™

8539

Version
Date 2024-01-25

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® Cellect™ |
| Art. No: | 8539 |
| 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** | Phytosteryl Canola Glycerides | 68990-51-2 | 273-605-2 |
| US | Phytosteryl Canola Glycerides | 68990-51-2 | 273-605-2 |
| China* | Phytosteryl Canola Glycerides<br>植物甾醇低芥酸菜油甘油酯类 | 68990-51-2 | 273-605-2 |
| Alternative INCI | | | |
| | | | |
| | | | |
| | | | |

*) 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. | | | |
| | . | | |
| | | | |
| | | | |

Margrét Viborg
Global Regulatory Affairs Manager

## 2.1 Specifications

For specification see Product Data Sheet (PDS)

Download latest version at www.aakpersonalcare.com/

## 2.2 Typical values

For typical values see Product Data Sheet (PDS)

Download latest version at www.aakpersonalcare.com/

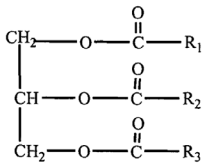
## 2.3 Certificate of Analysis

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)

Download latest version at www.aakpersonalcare.com/

## 3.1 Biological data

**Botanical origin**

| **INCI** | Botanical origin | *)Geographical origin | Part used | Content % | Wild grown or cultivated |
|---|---|---|---|---|---|
| Phytosteryl Canola Glycerides | Brassica Napus | EU | Seeds | 100 | Cultivated |
| | | | | | |

*)**Geographical origin may change**

## 3.2 Composition breakdown

| INCI name (EU) | CAS | EINECS | Average Content % |
|---|---|---|---|
| Phytosteryl Canola Glycerides | 68990-51-2 | 273-605-2 | 99,85 |
| Ascorbyl Palmitate | 137-66-6 | 205-305-4 | 0,15 |

Palm content

☒Containing palm

☒RSPO SG: 99051

☐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 | | |
| Refining | X | |
| Deodorising | X | |
| Hydrogenation | X | |
| Interesterification | X | |
| Esterification | | |
| Winterisation | X | |
| 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 @ 110C 80 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 Cellect™

### 7.01 General read-across consideration and justification

**Test name:**

CIR Safety report

**Method and laboratory:**

Review and safety assessment of phytosterols as used in cosmetics

**Test material:**

26 phytosterols and phytosterol esters used in cosmetics, including canola sterols and phytosteryl canolate

**Results:**

Phytosterols and phytosterol esters are safe in the present practices of use in cosmetics.

**Read across**

Statement

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

**Test name:**

Scientific opinion on the safety of soybean sterols

**Method and laboratory:**

EFSA summary and opinion on the safety of new stigmasterol ester rich plant sterol preparations

**Test material:**

Stigmasterol esters >=85%

**Results:**

Phytosterols and phytostanols (saturated phytosterols) are approved for use in foods up to a daily intake of 3 g/day.

**Read across**

Statement

**Reference ID:**

S-219 - Scientific opinion on the safety of stigmasterol-rich plant sterols as food additive, Aguilar, F et al, EFSA Journal, 10(5), (2012), 2659 (39 pages)

**Test name:**

CIR Safety Report

**Method and laboratory:**

Review and safety assessment of PEG-derivatives of soybean sterols, including discussions on the safety of free sterols.

**Test material:**

PEG-n soybean sterols (n=5,10,16,25, 30 and 40).

**Results:**

CIR panel concluded that PEG derivatives of phytosterols are safe for use in cosmetics.

**Comments:**

This CIR safety assessment also gives information on the safety of free sterols, especially soybean sterols.

**Read across**

Statement

**Reference ID:**

S-261 Final report of the amended safety assessment of PEG-5, -10, -16, -25, -30 and -40 soy sterol. Anon. Int J Toxicol, 23(Suppl 2), 23-47, (2004)

**Test name:**

Review and safety assessment of phytosterols as food additives

**Method and laboratory:**

Expert panel evaluation of food safety (JECFA) aspects of phytosterols.

**Test material:**

Phytosterols, phytostanols and their esters

**Results:**

The panel concluded that a dietary Allowed Daily Intake (ADI) of up to 40 mg/kg bw/day of phytosterols is acceptable in humans.

**Read across**

Statement

**Reference ID:**

S-262 Joint Expert Committee on Food Additives 69th Report, WHO Technical Report Series 952, 3.1.6 Phytosterols, 39-46, (2009)

**Test name:**

REACH dossier

**Method and laboratory:**

REACH registration of the substance class Phytosterols, CAS 949109-75-5

**Test material:**

Several phytosterol preparations with varying composition and different origins

**Results:**

No short term or long-term hazards have been identified for Phytosterols CAS 949109-75-5

**Comments:**

The dossier is relevant as a background material for phytosterol ester safety assessment.

**Read across**

Statement

**Reference ID:**

S-263 ECHA. Online access, accessed 2020-01-17. Phytosterols CAS 949109-75-5

Phytosterols are structurally related to cholesterol found in mammalian cell membranes and represent similar functionalities in plants. Vegetable oils contain normally between 100-3000 mg/kg of phytosterols, either esterified to fatty acids or in the free alcohol form. The phytosterols can be concentrated by different extraction and distillation methods and re-esterified to different fatty acid sources. The main commercial sources for phytosterols are soybean oil and tall oil from wood pulping but numerous other sources such as canola, avocado and olive sterols are also available.

The chemistry of phytosterols from different vegetable sources is very similar, the main differences being the relative proportions of different phytosterol species and the total content found in the plant. The main phytosterol in plants is beta-sitosterol but campesterol, stigmasterol and brassicasterol are also frequently present. They all share the basic steroidal 4-membered ring, with a hydroxyl group in position 3 and a side chain attached to carbon 17. The different phytosterol species are mainly identified by the structure of the side chain.

There is no evidence in the referenced literature of differentiated toxicological properties for the main phytosterols so this safety assessment is valid for all phytosterols and their esters as a generic description, even if the composition may differ between ingredients from different sources. This review also includes references to the saturated versions of the phytosterols, the phytostanols.

Phytosterols and especially their fully hydrogenated versions (phytostanols) are used as dietary interventions to reduce plasma cholesterol (especially in the form of LDL). In cosmetics the uses are given as skin- and hair conditioning agents, skin protectants and viscosity modifiers.

## 7.02 Acute toxicity
## 7.02.1 Acute oral toxicity

**Test name:**

Acute oral toxicity

**Method and laboratory:**

Summary of literature data given in CIR report

**Test material:**

Phytosterol and phytostanol esters of different origins

**Results:**

Oral administration in rats of a diet containing 8% phytosterol esters showed no adverse effects.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

**Test name:**

Acute Oral Toxicity in mouse

**Method and laboratory:**

Species: Mouse, male
n=3, 3 doses
n=1, 4 doses
Observation for 7 days

**Test material:**

beta-sitosterol, 97% purity

**Results:**

LD50 (mouse, oral): 1250 mg/kg bw

**Read across**

| | |
|---|---|
| Read across | Beta-sitosterol is the main phytosterol in typical phytosterol esters. |

**Reference ID:**

S-259 Genotoxic and cytotoxic studies of beta-sitosterol and pteropodine in mouse. Panigua-Perez et al, Journal of Biomedicine and Biotechnology, 2005:3, 242-247, (2005)

No reliable LD50 values for phytosterols, phytostanols and/or their esters have been identified. However, based on sub-chronic and chronic exposure date, as well as the normal dietary exposure to phytosterols and their esters, acute oral toxicity is not considered to be relevant in the evaluation of the safety of these substances.

## 7.02.2 Acute inhalation toxicity

Based on the semi-solid to solid character and low volatility of phytosterol esters, the probability of inhalation exposure will be 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:**

Summary of literature data given in CIR report

**Test material:**

Phytosterol and phytostanol esters of different origins

**Results:**

Acute dermal toxicity was given as >2000 mg/kg bw in one referenced study. Species: rat, n=5/sex, duration 14 days. No deaths or clinical signs of toxicity were observed.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

Phytosterol esters do not show acute toxicity 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. Acute dermal toxicity is therefore not expected to pose an issue for human health under normal and foreseeable handling and use conditions.

## 7.02.4 Acute toxicity by other exposure routes

There are no other administration routes identified for this substance category.

## 7.02.5 Summary and discussion of acute toxicity

Phytosterols and their esters have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic, pharmaceutical 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:**

Summary of skin irritation

**Method and laboratory:**

A summary and review of skin irritation and sensitization studies for phytosterols and phytosterol esters given in the CIR report. In vivo and in vitro studies are reported

**Test material:**

Phytosterols

**Results:**

Phytosterols are not irritating to the skin

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

Based on the safety assessments and reviews, it can be concluded that phytosterols and phytosterol esters are not irritating or corrosive to the skin at use concentrations.

### 7.03.2 Eye & mucous membrane irritation and corrosivity

**Test name:**

Summary of eye irritation

**Method and laboratory:**

A summary and review of eye irritation studies for phytosterols and phytosterol esters given in the CIR report. In vivo and in vitro studies are reported in the summary.

**Test material:**

Phytosterols

**Results:**

Phytosterols are not irritating to the eyes

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

Based on the safety assessments and reviews, it can be concluded that phytosterols and phytosterol esters are not irritating or corrosive to the eye or mucous membranes at use concentrations.

### 7.03.3 Summary and discussion on irritation and corrosivity

Based on the safety assessments and review it is concluded that phytosterols and phytosterol esters pose a minimal risk to cause skin or eye irritation in use concentrations. It is also concluded that the phytosterols and phytosterol esters are not corrosive to skin, eyes or mucous membranes.

## 7.04 Skin sensitization

**Test name:**

Skin sensitization

**Method and laboratory:**

1. Analysis of residual hydrophilic and hydrophobic/denatured proteins by ELISA
2. Clinical test on 32 soybean allergic subjects.

**Test material:**

1 phytosterol ester and 5 phytostanol esters prepared from soybean sterols as starting material.

**Results:**

Phytosterols and -stanols derived from soybean oil do not contain soybean proteins and do not elicit allergic reactions in soybean allergic subjects.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-257 EFSA Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies, EFSA-Q-2006-162. EFSA Journal, 486, 1-8, (2007)

**Test name:**

Skin sensitization

**Method and laboratory:**

1. Analysis of residual proteins after hydrolysis and extraction of amino acids.
2. Clinical test on 36 soybean allergic subjects.

**Test material:**

1 phytosterol ester and 5 phytostanol esters prepared from soybean sterols as starting material.

**Results:**

Phytosterols and -stanols derived from soybean oil do not contain soybean proteins and do not elicit allergic reactions in soybean allergic subjects.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-256 EFSA Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies, EFSA-Q-2007-082. EFSA Journal, 571, 1-6, (2007)

**Test name:**

Summary of sensitization

**Method and laboratory:**

A summary and review of sensitization studies for phytosterols and phytosterol esters given in the CIR report. Animal and human studies are reported in the summary.

**Test material:**

Phytosterols and phytosterol esters

**Results:**

Phytosterols and phytosterol esters are not sensitizing

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

**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 sensitization

No actual studies on the sensitization potential have been performed by AAK on Lipex Cellect.

Phytosterols and phytosterol esters have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications.

Supported by the references reported above, sensitization 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:**

Summary of short term and sub-chronic toxicity

**Method and laboratory:**

A summary and review of short term and sub-chronic toxicity of phytosterol esters is given in the EFSA report. Two 13-week animal studies are summarized and reviewed.

**Test material:**

Soybean sterol esters

**Results:**

No significant adverse effects were observed in the studies. The NOAEL is given as 3.0-6.6 g/kg bw/day of the phytosterol esters.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-219 - Scientific opinion on the safety of stigmasterol-rich plant sterols as food additive, Aguilar, F et al, EFSA Journal, 10(5), (2012), 2659 (39 pages)

### 7.05.2 Inhalation studies

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

### 7.05.3 Dermal administration

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

### 7.05.4 Other routes of administration

There are no other identified relevant routes of exposure for this substance category

### 7.05.5 Human studies

**Test name:**

Dietary study

**Method and laboratory:**

Human dietary study (randomized, double-blind placebo controlled parallel trial)
185 volunteers (35-64 years)
Duration: 1 year
Dosage: Daily intake of 1.6g of plant sterol esters in margarine

**Test material:**

Plant sterol esters (48% beta-sitosterol, 27 % campesterol, 19% stigmasterol)

**Results:**

4-6% decrease of serum LDL and total cholesterol
Clinical chemistry and hematological parameters were not affected. No adverse effects were attributed to the intake of plant sterol esters for 1 year.
Plant sterol intake is considered to be a safe and effective way to decrease serum cholesterol levels in humans.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-218 - Safety of long-term consumption of plant sterol esters-enriched spreads, Hendriks, HFJ, Brink, EJ, Meijer, GW, Princen, HMG, Ntanios, FY. Eur J Clin Nutr, 57, (2003), 681-692

## 7.05.6 Summary and discussion

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.

## 7.06 Reproduction toxicity
## 7.06.1 Non-human studies

**Test name:**

Summary of reproductive toxicity

**Method and laboratory:**

A summary and review of the reproductive and developmental toxicity studies for phytosterols and phytosterol esters in Wistar rats is given in the CIR report.

**Test material:**

Phytosterol esters with beta-sitosterol, campesterol and stigmasterol as dominating phytosterols

**Results:**

No adverse effects were found in the study up to the highest tested concentration (8.1% in diet). It was concluded that the NOAEL is >=8.1% in diet, corresponding to a NOAEL of 1.54-9.1 g/kg bw/day, depending on the phase of the study.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

**Test name:**

In vivo and in vitro estrogenicity assessment

**Method and laboratory:**

Species: Rat (n=10)
Dosage: 0, 5, 50 & 500 mg/kg bw/day plant sterol esters orally by gavage
Duration: 3 days
Assay: Uterine wet weight
In vitro: competitive binding to rat uterine estrogen receptor (ER)

**Test material:**

Phytosterol esters (48% beta-sitosterol, 29% campesterol, 23 % stigmasterol)

**Results:**

Phytosterol esters do not bind to the ER receptor in vitro
Phytosterols are not estrogenic in the rat

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-221 - Safety evaluation of phytosterol esters. Part 1. Assessment of estrogenicity using a combination of in vivo and in vitro assays, Baker, VA, Hepburn, PA et al, Food Chemical Toxicol, 37, (1999), 13-22

## 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

**Test name:**

Developmental toxicity study in rat

**Method and laboratory:**

Species: Wistar rat (28 mated female rats)
Duration: 21 days
Dosage: 0, 1.75, 4.38 and 8.76 % plant stanol esters in diet

**Test material:**

Plant stanol esters (68% sitostanol, 30% campestanol)

**Results:**

No adverse maternal or fetal development effects were seen up to a dosage of 8.76% plant stanol esters in the diet. The dosages tested correspond to 2.4-3.5 g stanols/kg bw and day.

**Comments:**

Plant stanols are saturated versions of the corresponding unsaturated sterols.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-220 - Developmental toxicity study of vegetable oil-derived stanol fatty acid esters, Slesinski, RS, Turnbull, D, Frankos, VH, Wolterbeck, APM & DH Waalkens-Berendsen, Regul Toxicol Pharmacol, 29, (199), 227-233

### 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

Phytosterols and phytosterol esters have a long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the references reported above, phytosterols and phytosterol esters are not considered to pose an issue for reproductive and developmental toxicity under normal and foreseeable handling and use conditions.

## 7.07 Mutagenicity/genotoxicity

### 7.07.1 In vitro data

**Test name:**

Summary of genotoxicity

**Method and laboratory:**

A summary and review of genotoxicity and mutagenicity studies for phytosterols and phytosterol esters given in the CIR report. Multiple in vitro and in vivo studies are reported and summarized.

**Test material:**

Phytosterols and phytosterol esters

**Results:**

Phytosterols and phytosterol esters are not mutagenic or genotoxic.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

**Test name:**

Genotoxicity study

**Method and laboratory:**

Species: Mouse, male, 5 per test group
Study on induction of sister chromatid changes (SCE), cellular proliferation kinetics (CPK) and mitotic index (MI) in bone marrow cells.

**Test material:**

beta-sitosterol, 97% purity, dosage 200-1000 mg/kg bw, administered intraperitonially dissolved in mineral oil

**Results:**

No genotoxic effects were observed for beta-sitosterol in the study

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-259 Genotoxic and cytotoxic studies of beta-sitosterol and pteropodine in mouse. Panigua-Perez et al, Journal of Biomedicine and Biotechnology, 2005:3, 242-247, (2005)

### 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

Phytosterols and phytosterol esters and other structurally similar substances from the same read-across category did not exhibit any genotoxic activity in multiple in vitro genotoxicity and mutagenicity assays. This evidence, added to the long history of safe use of these substances in dietary, cosmetic and industrial uses, suggests that phytosterols and phytosterol esters 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

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

### 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

Phytosterols and phytosterol esters 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, without any apparent long-term 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.

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

### 7.09.1 Oral administration

**Test name:**

Absorption, distribution, metabolism and excretion summary

**Method and laboratory:**

Summary of literature data given in CIR report

**Test material:**

Phytosterol and phytostanol esters of different origins

**Results:**

Less than 5% of dietary phytosterols and -stanols are absorbed in the gastrointestinal tract and the rest is excreted in the feces. The absorbed phytosterols are transported in HDL/LDL primarily to the liver where they are converted to bile acids and excreted in the feces. No major differences have been observed between different phytosterol species.

**Comments:**

The average dietary intake of phytosterols is estimated to 160-360 mg/day in the Western diet.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-251 Safety assessment of phytosterols as used in cosmetics, Final report January 27, 2014, CIR

### 7.09.2 Dermal administration

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

### 7.09.3 Inhalation route

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

## 7.10 Photoinduced toxicity

### 7.10.1 Phototoxicity: photoirritation / photosensitisation

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

### 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 85 mg/kg bw/day for systemic exposure for phytosterol esters as well as other substances of the same read-across category. This is based on the ADI (Allowed Daily Intake) in food applications which is 3 g phytosterols per day, corrected for body weight (60 kg) and phytosterol content in phytosterol esters (approximately 60%).

## 8 Ecological data
## 8.01 Degradability

**Test name:**

Biodegradation in water: screening tests

**Method and laboratory:**

BODIS (Biochemical Oxygen Demand of Insoluble Chemicals) (Scher, 2005)

**Test material:**

Phytosterols CAS 949109-75-5, soybean sterols were used in the study

**Results:**

90-92 % biodegradation in 28 days was observed in this study. It was concluded that the Phytosterols CAS 949109-75-5 were readily biodegradable

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-264 ECHA. Online access, accessed 2020-01-17. Phytosterols CAS 949109-75-5, Biodegradation in water: screening tests + Endpoint summary

**Test name:**

Biodegradation Phytosterols

**Method and laboratory:**

Scientific study on biodegradation of beta-sitosterol in simulated pulp-mill effluent treatment conditions

**Test material:**

Phytosterols from pulp mill waste water

**Results:**

High removal (>90%) of phytosterols was achieved and of which about 80% were biodegraded. The relative roles of biodegradation and bio-adsorption shifted from biodegradation in the early process to bio-adsorption later.

**Comments:**

The results indicate that biodegradation of the phytosterols are dependent on the conditions and that the relative importance for adsorption on dissolved organic solids is high.**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-265 Biological removal of phyto-sterols in pulp mill effluents. Mahmoud-Khan Z. & Hall E.R., J Environmental Management, 131, 407-414, (2013)

**Test name:**

Biodegradation Phytosterols

**Method and laboratory:**

Scientific study on biodegradation of beta-sitosterol, campesterol and stigmasterol in real pulp-mill effluent treatment conditions

**Test material:**

Phytosterols in waste water from a pulp mill (beta-sitosterol, campesterol and stigmasterol).

**Results:**

The biodegradation of the phytosterols is estimated to be about 56% in the actual waste treatment process. Another 23% is removed in the solid activated sludge and removed from the final effluent.

**Read across**

| | |
|---|---|
| Read across | See discussion on read-across justification for phytosterols and phytosterol esters |

**Reference ID:**

S-266 Removal of individual sterols during secondary treatment of pulp mill effluents. Mahmood-Khan, z. & Hall, E.R., Water Quality Research Journal of Canada, 47(1), 56-65, (2012)

Lipex Cellect has not been tested for biodegradability. The studies cited gives an indication of the biodegradability and environmental fate of phytosterols such as beta-sitosterol, campesterol and stigmasterol, which are representative for the composition of Lipex Cellect.

Based on the cited literature it can be concluded that:
- the ester bonds are hydrolyzed in aqueous environments to fatty acids and phytosterol
- the fatty acids are metabolized by microorganisms by beta-oxidation to smaller fragments and eventually to carbon dioxide
- phytosterols have low water solubility and may adsorb to organic matter in aquatic environments, leading to inclusion in sediment or in solid waste treatment sludges
- phytosterols can also be degraded by bio-oxidation by activated sludge in aerobic conditions

## 8.02 Accumulation

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

## 8.03 Aquatic toxicity

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

## 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 | Listed |
| DSL (Canada) | Domestic Substances List | Not listed but at NDSL and ICL ”Fatty acids, vegetable-oil, esters with sterols, mixed with vegetable-oil glycerides” is listed and valid to be used. |
| AICS (Australia) | The Australian Inventory of Chemical Substances | No data |
| 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. | No data |
| Japan | Japan Pharmacopoeia | No |
| KECI (South Korea) | Korea Existing Chemicals Inventory | KE-no: KE-16844 |
| PICCS (Philippines) | Philippine Inventory of Chemicals and Chemical Substances | No data |
| NZIoC (New Zealand) | New Zealand Inventory of Chemicals | Listed |
| NECI (Taiwan) | National Existing Chemical Inventory | Listed |
| 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

### 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 www.aakpersonalcare.com

## 11.2 Kosher

The product is produced according to Kosher.

Download latest version at www.aakpersonalcare.com

## 11.3 ISO 9001

The product is produced according to ISO 9001.

ISO certificate latest version available for downloading at www.aak.com/

## 11.4 EFFCI GMP

The product is produced according to EFFCI GMP.

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

## 11.6 Other

No other available

# 12. PATENTS

## 12.1 Patents

No data.

# TRANSPORTS AND HANDLING - LIPEX® Cellect™

## 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.

Buckets: Melt the whole content until fluid or approx. 60C

During processing need to be heated to 65C to remove crystal memory.

### 13.3.2 Use of full package for partly use

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

Buckets: Melt the whole content until at least 60C

**Buckets remaining part is left to crystallize in 20C or below and repack if possible to smaller packaging.**

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.

**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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S018 Nolen, GA (1981), 'Biological evaluation of hydrogenated rapeseed oil', *Journal of the American Oil Chemists' Society*, 58 (1), 31-37.

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S029 Carthew, P., P. Baldrick, and P.A. Hepburn (2001), 'An assessment of the carcinogenic potential of shea oleine in the rat', *Food and Chemical Toxicology Food Chem.Toxicol.*, 39 (0278-6915), 807-15.

S030 Sylvester, PW, et al. (1986), 'Comparative effects of different animal and vegetable fats fed before and during carcinogen administration on mammary tumorigenesis, sexual maturation, and endocrine function in rats.', *Cancer Res*, 46 (2), 757-62.

S031 Sundram, K, et al. (1989), 'Effect of dietary palm oils on mammary carcinogenesis in female rats induced by 7,12-dimethylbenz(a)anthracene.', *Cancer Res*, 49 (6), 1447-51.

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# 15. DISCLAIMER

## 15.1 Disclaimer

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**Ship-to -**

# Analytical Certificate

| | |
|---|---|
| **Delivery** | **81412309 - 20** |
| **Print date** | 2023-12-28 |
| **Your reference** | |
| **Our reference** | Benjamin Sales |
| **Material** | 8539-373 LIPEX® Cellect™ |
| **Your material no.** | |
| **Date of shipment** | 2023-12-20 |

**Batch** 0002596259 / **Quantity** 9 KG / **Prod. date** 2022-10-26
**Inspection lot** 3049576

| Characteristic | Result | | Lower Limit | Target | Upper Limit |
|---|---|---|---|---|---|
| **Acid value(IUPAC 2.201(m))** | | | | | |
| Acid value | 0.50 | mg KOH/g | | | 1.00 |
| **Peroxide value(AOCS Cd 8-53)** | | | | | |
| Peroxide value | < 0.1 | meq/kg | | | 1.0 |
| **Free sterol in sterolesters(AAK CR-001-01)** | | | | | |
| Free sterol in sterolesters | 4 | % | | | 4 |

Lipex Cellect is frozen directly after production,
and taken out of frozen storage prior to delivery.
Shelf life: 24 months from out of frozen storage
"i.e. 24 months from ""Date of dispatch from AAK Sweden AB""above.

Quality Control Manager
AAK Sweden AB

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

ZAO S11879 1



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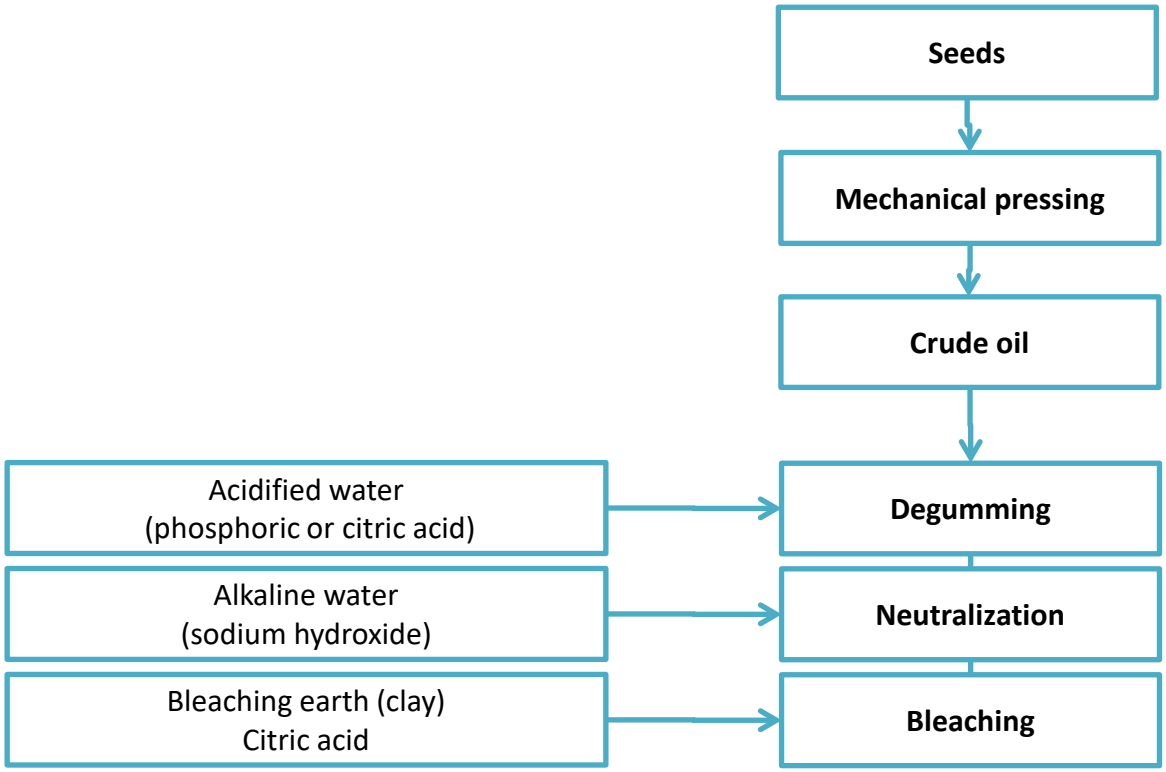
Org. no. : 556478-1796
VAT no. : SE556478179601
Approved for Swedish F-tax
Registered Office: Karlshamn

# Flowchart Lipex Cellect




Explanations what each step contribute with

Separates crude oil from seed

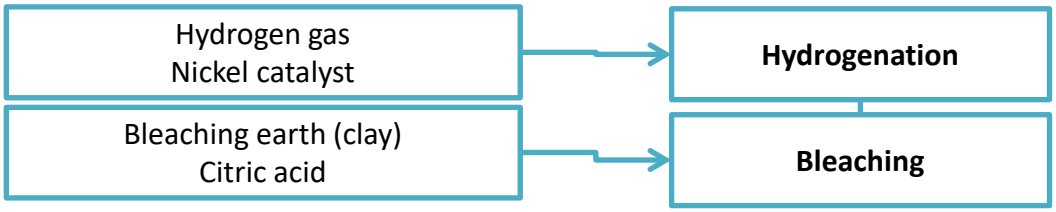
Separates crude oil from seed

Removes phospholipids, metals and proteins

Removes free fatty acids, metals and proteins

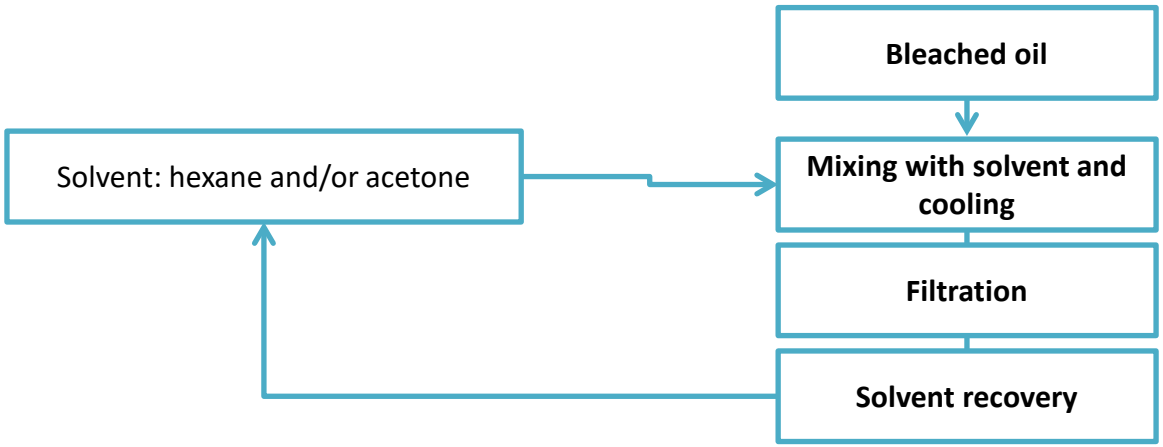
Removes pigments, metals and proteins

# Flowchart Lipex Cellect




Removes unsaturation by reduing double bonds

Removes pigments, metals, proteins and catalyst traces

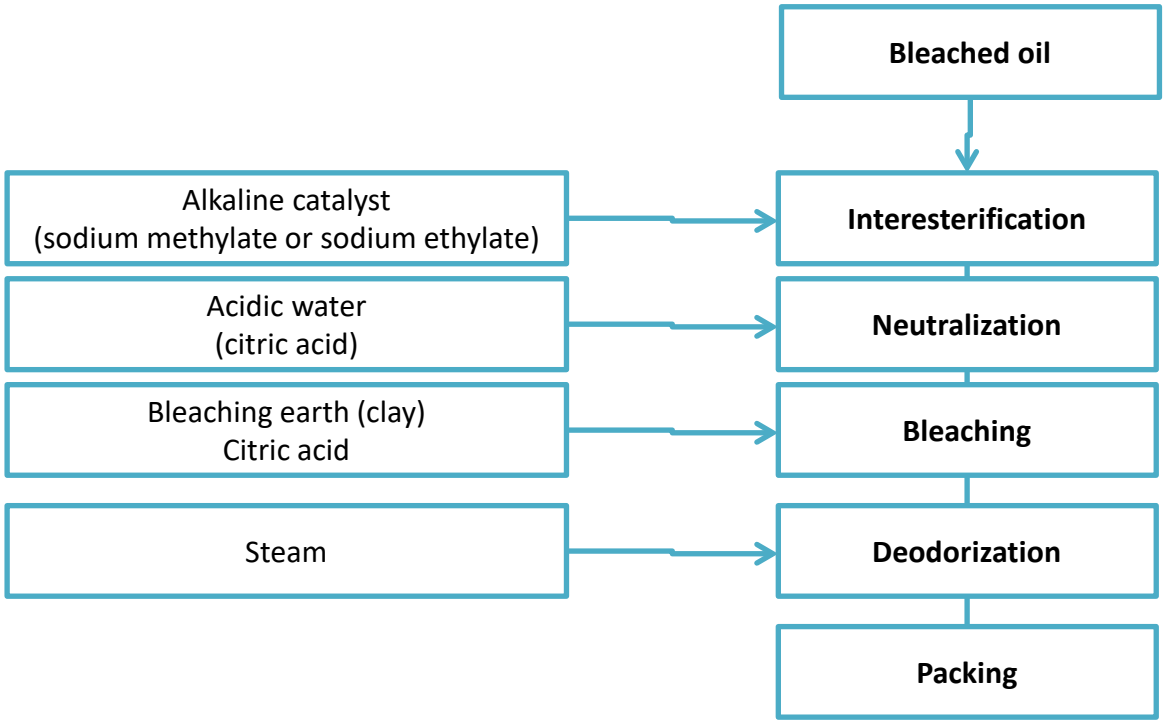



Explanations what each step contribute with

Separates solid and liquid constituents

See Disclaimer

# Flowchart Lipex Cellect




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

See Disclaimer