Product Documentation

# Akoline LC™

**8049**

Version
Date 2024-01-10

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: | Akoline LC™ |
| Art. No: | 8049 |
| Country of Origin | EU |

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** | Glyceryl Stearate Citrate | 55840-13-6 | 259-855-5 |
| US | Glyceryl Stearate Citrate | 55840-13-6 | 259-855-5 |
| China* | 甘油硬脂酸酯柠檬酸酯 | 55840-13-6 | 259-855-5 |
| Alternative INCI | | | |
| | | | |

*) For NMPA information see section 9.2.2 China – NMPA

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 |

## 3.1 Biological data

**Botanical origin**

| **INCI** | Botanical origin | *)Geographical origin | Part used | Content % | Wild grown or cultivated |
|---|---|---|---|---|---|
| Glyceryl Stearate Citrate | Elaeis Guineensis | Malaysia or Indonesia | Fruit flesh | 100 | Cultivated |
| | | | | | |

*)**Geographical origin may change**

## 3.2 Composition breakdown

| INCI name (EU) | CAS | EINECS | Average Content % | Function |
|---|---|---|---|---|
| Glyceryl Stearate Citrate | 55840-13-6 | 259-855-5 | 100 | Emulsifier |
| | | | | |

**Palm content:**

☒Containing palm

☐RSPO SG:

☒RSPO MB: CU-RSPO SCC-817671

☐Do not contain Palm

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

## 4.1 Production data

The following operations are used in the processing of this ingredient

| Process | | Comment |
|---|---|---|
| Mechanical extraction | | |
| Solvent extraction | | |
| Refining | | |
| Deodorising | | |
| Hydrogenation | | |
| Interesterification | | |
| Esterification | X | |
| Winterisation | | |
| Solvent Fractionation | | |
| Dry Fractionation | | |
| Ethoxylation | | |
| Molecular distillation | | |
| Other processing | X | See attached flowchart |
| | | |
| | | |
| | | |

# 5. BY-PRODUCTS AND OTHER IMPURITIES

## 5.1 AAK Contaminant standard

Not available, for more information please contact AAK.

## 5.2 Other Impurities specific substances

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

## 5.3 Impurities AAK Cosmetic Products

### 5.3.1 Allergens

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

### 5.3.2 Proteins

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

### 5.3.3 VOC – Volatile Organic Compounds

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

### 5.3.4 Sulphonates

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

### 5.3.5 Parabens

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

### 5.3.6 Phthalates

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

### 5.3.7 Silicones

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

## 6.1 Stability data

OSI Value @ 120C No data

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

## Akoline LC

### 7.01 General read-across consideration and justification

**Test name:**

CIR safety report

**Method and laboratory:**

Safety assessment and review of various glyceryl ester based cosmetic ingredients

**Test material:**

Glyceryl stearate citrate and other similar substances

**Results:**

The panel concludes that existing and available data do not support the safety of glyceryl diesters and their derivatives for use in cosmetic products, mainly due to suspected tumor promoting effect of 1,2-diacylglycerol.

**Comments:**

See also Amended CIR safety evaluation (S-323).

**Read across**

Statement

**Reference ID:**

S-322 Safety assessment of glyceryl dilaurate, glyceryl diarachidate… Final Report of the Cosmetic Ingredient Review Expert Panel, 2002 (available on-line at https://www.cir-safety.org/ )

**Test name:**

Amended CIR safety report

**Method and laboratory:**

Safety assessment and review of various glyceryl ester based cosmetic ingredients

**Test material:**

Glyceryl stearate citrate and other similar substances

**Results:**

The panel concluded that glyceryl dilaurate, glyceryl diarachidate, glyceryl stearate citrate and other substances covered in the amended review are safe for use in cosmetics, provided that the level of 1,2-diesters of glycerol is not high enough to induce epidermal hyperplasia.

**Comments:**

The permitted level of 1,2-diesters is not explicitly stated. In view of the rapid hydrolysis by lipases and the higher stability of 1,3-diesters versus 1,2-diesters it is unlikely that the level of 1,2-diesters in actual applications will be high enough to be of concern.

**Read across**

Statement

**Reference ID:**

S-323 Amended final report on the safety assessment of glyceryl dilaurate, glyceryl diarachidate…, Johnson, W, Int J Toxicol, 26 (Suppl 3), 1-30, (2007)

**Test name:**

EFSA Safety assessment of several polar derivatives of mono- and diglycerides

**Method and laboratory:**

Opinion and statement from EFSA on the safety of use of citric acid esters of mono- and diglycerides as food emulsifiers. The report also comprises a summary of existing toxicological studies on other derivatives of mono- and diglycerides (E472a-f).

**Test material:**

Citric acid esters of mono- and diglycerides (CITREM, E472c)

**Results:**

There are very few relevant studies for E472c in the EFSA safety assessment. However, due to the hydrolysis of the citric acid ester to citric acid and mono- and diglycerides (which are further metabolized to fatty acids and glycerol), it is concluded that E472c is safe for use as a food additive and no limit on intake (ADI) is necessary.

**Read across**

Statement

**Reference ID:**

S-338 Re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and di-acetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472a-f) as food additives, EFSA Journal 18(3):6032, 1-66

**Test name:**

REACH registration dossier

**Method and laboratory:**

REACH registration dossier with toxicological and environmental data

**Test material:**

Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates, (CAS 91052-16-3)

**Results:**

See separate entries for details

**Read across**

Statement

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di- citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

REACH registration dossier

**Method and laboratory:**

REACH registration dossier with toxicological and environmental data

**Test material:**

Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts, (CAS 91744-23-9)

**Read across**

Statement

**Reference ID:**

S-340 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts', CAS number 91744-23-9
https://echa.europa.eu/registration-dossier/-/registered-dossier/24811

**Test name:**

REACH registration dossier

**Method and laboratory:**

REACH registration dossier with toxicological and environmental data

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates

**Read across**

Statement

**Reference ID:**

S-341 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates'
https://echa.europa.eu/registration-dossier/-/registered-dossier/23747

**Test name:**

REACH registration dossier

**Method and laboratory:**

REACH registration dossier with toxicological and environmental data

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts, (CAS 91744-38-6)

**Read across**

Statement

**Reference ID:**

S-342 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts', CAS 91744-38-6
https://echa.europa.eu/registration-dossier/-/registered-dossier/12022

**Test name:**

REACH registration dossier

**Method and laboratory:**

REACH registration dossier with toxicological and environmental data

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, sodium salts, (CAS 91744-39-7)

**Read across**

Statement

**Reference ID:**

S-343 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, sodium salts', CAS 91744-39-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/12131

Citric acid esters of mono- and diglycerides belong to a group of ingredients that share the mono- and diglyceride structure as a common denominator. Glycerol is esterified to one or two straight chain saturated or unsaturated fatty acids, normally a combination of palmitic and stearic acid.
The free hydroxyl groups on the mono- and diglycerides are further reacted with an acid, ranging from acetic to tartaric acid. These ingredients are usually used as food additives, as emulsifying agents or conditioning agents for prepared food. One big use area is powders for infant nutrition. This class of food additives is known as E472a-f, where (a) is the acetic acid derivative, (b) is lactic acid esters, (c) is citric acid esters and (d)-(f) are variations containing tartaric acid.

The chemistry of this group of compounds is rather similar from a toxicological point of view. The esters are usually rapidly hydrolyzed in the stomach and intestines by lipases to the corresponding acids and glycerol. The citric acid esters of mono- and diglycerides would typically release citric acid, palmitic acid and stearic acid as well as glycerol, which are all endogenous substances in normal metabolism. They are generally regarded as non-toxic functional ingredients for food applications and very few new studies have been published in the last 20 years.

The nomenclature, INCI names and CAS numbers for the citric acid esters of mono- and diglycerides vary depending on the producer of the material (See 7.11 for a summary). For saturated mono- and diglycerides both "hydrogenated vegetable glycerides citrate" and "glyceryl stearate citrate" are used. In both cases the names should be interpreted as "mixed mono- and diglycerides, comprising palmitic and stearic acid in different proportions, esterified with citric acid". From a toxicological point of view, these variations are insignificant.

The citric acid esters of mono- and diglycerides can be partially or completely neutralized by a weak alkali resulting in sodium or potassium salts. These sodium or potassium salts are easier to disperse in water than the corresponding acid form and are often preferred due to the higher functionality in the application. From a toxicological point of view the neutralised and the acid forms can be seen as equal.

The two CIR safety reports from 2002 and 2007 are mainly dealing with underivatized mono- and diglycerides of fatty acids and are of limited use for the evaluation of the citric acid esters, especially since the data reported are old and without proper references to original articles. Only data where enough details about test methodology are listed are presented in this safety report.

Several entries of citric acid esters of mono- and diglycerides are found in REACH registrations. The toxicological data and environmental toxicity data are heavily read-across and only one registration is extensively extracted in this safety review.

## 7.02 Acute toxicity
### 7.02.1 Acute oral toxicity

**Test name:**

Acute oral toxicity

**Method and laboratory:**

OECD Guideline 423, OECD Guideline 401

**Test material:**

Glycerides, C16-18 & C18-unsatd., mono- and di-, acetates, (CAS 91052-13-0)
Glyceryl citrate/lactate/linoleate/oleate

**Results:**

LD50>2000 mg/kg bw

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

### 7.02.2 Acute inhalation toxicity

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

### 7.02.3 Acute dermal toxicity

**Test name:**

Acute dermal toxicity

**Method and laboratory:**

OECD Guideline 402

**Test material:**

Glycerides, C16-18 & C18-unsatd., mono- and di-, acetates, (CAS 91052-13-0)
Glyceryl citrate/lactate/linoleate/oleate

**Results:**

LD50>2000 mg/kg bw

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

### 7.02.4 Acute toxicity by other exposure routes

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

## 7.02.5 Summary and discussion of acute toxicity

No fully verified data for the acute oral, dermal or inhalation toxicity has been identified for Akoline GC/LC. The CIR report states the LD50 (Oral) and LD50 (dermal) to be >2 g/kg bw/day but no published data are shown. It is stated in the EFSA report that although no data exist for the acute oral toxicity, absence of short term and sub-chronic toxicity indicate that acute toxicity would not be a concern. The various REACH registrations for citric acid esters of mono- and diglycerides report read-across studies, and values of LD50(Oral) / LD50(dermal) in excess of 2000 mg/kg bw are reported.

It is concluded that acute toxicity is not a health hazard or concern for this substance group.

## 7.03 Irritation & corrosivity

### 7.03.1 Skin irritation and corrosivity

**Test name:**

Summary of several skin irritation studies in REACH registration

**Method and laboratory:**

OECD Guideline 404. Rabbits, semi-occlusive patch, duration of exposure 4h, observation up to 7-14 days.

**Test material:**

Glyceryl citrate/lactate/linoleate/oleate

**Results:**

Not irritating

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

Skin irritation (24h human closed patch test)

**Method and laboratory:**

No guideline followed. N=40. Dilution 1:10 in water. Application of closed patch for 24 h, evaluation at 24, 48 and 72 h after removal of patch.

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts, (CAS 91744-38-6)

**Results:**

Not irritating

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-342 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts', CAS 91744-38-6
https://echa.europa.eu/registration-dossier/-/registered-dossier/12022

### 7.03.2 Eye & mucous membrane irritation and corrosivity

**Test name:**

Summary of eye irritation in REACH registration

**Method and laboratory:**

OECD Guideline 405. Rabbits, exposure 24 hours, observations up to 72 hours.

**Test material:**

Glyceryl citrate/lactate/linoleate/oleate

**Results:**

Not irritating

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

### 7.03.3 Summary and discussion on irritation and corrosivity

No actual skin irritation or eye irritation studies have been performed on Akoline GC/LC. The CIR safety reports mention old unpublished studies from Huls America Inc, with slight indication of skin irritation and no eye irritation but study details are not available. From the read-across data for structurally similar substances in the REACH registrations, it can be concluded that skin or eye irritation is not likely to occur.

It is therefor concluded that citric acid esters of mono- and diglycerides are not irritating to the skin or the eye and mucous membranes.

In the absence of skin/eye irritation, it is concluded that citric acid esters of mono- and diglycerides are not likely to cause skin or eye corrosion.

## 7.04 Skin sensitization

**Test name:**

Summary of skin sensitization data in REACH registration

**Method and laboratory:**

Several in vivo tests (OECD 406, Magnusson Kligman Maximization Test) are reported. The test substances are typically diluted in mineral oil for induction tests and petrolatum for challenge tests.

**Test material:**

Glycerides, C16-18 and C18-hydroxy mono- and di-, (CAS 91845-19-1)
Glycerides C16-18 mono-, di-and tri-, hydrogenated, citrates, potassium salts, (CAS 91744-38-5)

**Results:**

Not sensitizing

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

In vivo skin sensitization test

**Method and laboratory:**

Magnusson-Kligman guinea pig sensitization test. N=10.Challenge by intradermal injection of 5% glyceryl stearate citrate in paraffin oil, challenge after 14 days by topical application of 25% glyceryl stearate citrate in petrolatum.
Laboratory: Safepharm Laboratories, 1981.

**Test material:**

Glyceryl stearate citrate

**Results:**

Not sensitizing

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-323 Amended final report on the safety assessment of glyceryl dilaurate, glyceryl diarachidate…, Johnson, W, Int J Toxicol, 26 (Suppl 3), 1-30, (2007)

**Test name:**

Skin sensitization

**Method and laboratory:**

OECD 406 (Buehler/Magnusson-Kligman). Induction and challenge 2, 25, 50 and 100% in corn oil. Challenge with undiluted test substance on day 28.

**Test material:**

Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts, (CAS 91744-23-9)

**Results:**

Not sensitizing

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-340 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts', CAS number 91744-23-9
https://echa.europa.eu/registration-dossier/-/registered-dossier/24811

## 7.04.1 Summary and discussion of sensitization

According to read-across studies, presented in the CIR safety report and in REACH registration dossiers, citric acid esters of mono- and diglycerides are not sensitizing.

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

### 7.05.1 Oral administration

**Test name:**

Summary of repeated dose toxicity studies

**Method and laboratory:**

6 separate studies are presented in the document. Only one study was performed with citric acid esters of mono- and diglycerides (1966). This 10 day study comprises two treatment levels (23100 and 37500 mg/kg bw/day), with lard as reference substance. Mortalities, organ weights, gross pathologies and histopathologies were investigated. The NOAEL based on this study was set to >= 37500 mg/kg bw/day.

**Test material:**

Castor oil, (CAS 8001-79-4)
Glycerides, C8-18 and C18-unsatd., mono- and di-, acetates, (CAS 92052-13-0)
Glycerides, C16-18 and C18-hydroxy, mono- and di-, (CAS 91845-19-1)
Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates (CAS 91052-16-3)

**Results:**

It is concluded on the basis of the studies on the read-across substances and the citric acid esters, that there are no observed adverse effects and no repeated dose toxicity hazards are identified.

**Comments:**

Also referenced in the EFSA evaluation (S-338)

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di- citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

### 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

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

### 7.05.5 Human studies

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

### 7.05.6 Summary and discussion

The EFSA evaluation of citric acid esters of mono- and diglycerides conclude that the short term and sub-chronic toxicity is very low and no ADI (Acceptable Daily Intake) value is required in food applications. Only one actual study from 1966 on citric acid esters of mono- and diglycerides, stating a NOAEL (oral, systemic) to be as high as 37500 mg/kg bw/day. The available REACH registrations refer to read-across from similar substances.

It is concluded that the citric acid esters of mono- and diglycerides have very low short term and sub-chronic toxicity.

## 7.06 Reproduction toxicity

### 7.06.1 Non-human studies

**Test name:**

Summary of reproductive and developmental toxicity

**Method and laboratory:**

4 different studies on the reproductive toxicity and 8 studies on developmental toxicity are presented in the summary. No data on citric acid esters of mono- and diglycerides were found so read-across from structurally similar substances is used as the base for the evaluation.

**Test material:**

Glycerides, castor-oil, mono-, hydrogenated, acetates, (CAS 736150-63-3)
Glycerides, C8-18 and C18-unsatd., mono- and di-, acetates, (CAS 91052-13-0)

**Results:**

No adverse effects on the reproductive health or fertility were observed.
No adverse effects on the developmental toxicity were observed.

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

### 7.06.2 Human studies

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

### 7.06.3 Developmental toxicity/teratogenicity

### 7.06.3.1 Non-human studies

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

### 7.06.3.2 Human studies

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

### 7.06.4 Summary and discussion of reproductive toxicity

No published studies on citric acid esters of mono- and diglycerides regarding reproductive and developmental toxicity have been identified. The read-across studies presented in REACH registration documents and in the EFSA evaluation state that no treatment related adverse effects on reproduction or off-spring development have been identified, up to the highest tested levels. As the highest tested levels vary from about 1000 mg/kg bw/day to about 8600 mg/kg bw/day in the different studies, a NOAEL is difficult to assign to the citric acid esters of mono- and diglycerides. The relevance of the the read-across substances also need to be considered.

The studies presented in the EFSA evaluation and in the REACH registrations conclude that reproductive and developmental toxicity is low for citric acid esters of mono- and diglycerides, based on read-across data from related substance classes. Acetic acid esters of castor oil glycerides showed NOAEL values of 1159-2200 mg/kg bw/day (M/F) for fertility and 1342-2260 mg/kg bw/day (generation F1) for fetal development. Acetic acid esters of C8-18 & C18-unsaturated mono/diglycerides showed a NOAEL of 1000 mg/kg bw/day for both fertility and developmental toxicity. In both cases the NOAEL represented the highest tested dose.

It is concluded that citric acid esters of mono- and diglycerides can be considered non-toxic for reproduction and development and a conservative estimation of the NOAEL can be set to 2200 mg/kg bw/day.

## 7.07 Mutagenicity/genotoxicity
## 7.07.1 In vitro data

**Test name:**

Summary of mutagenicity and genotoxicity tests

**Method and laboratory:**

9 different studies are presented for different citric acid esters of mono- and diglycerides and from structurally similar substances. The tests comprise in vitro mammalian chromosome aberration tests, in vitro gene mutation study in bacteria (Ames' test, with and without metabolic activation) and in vitro gene mutation tests in mammalian cells.

**Test material:**

Glycerides, C8-18 and C18-unsatd., mono- and di-, acetates, (CAS 92052-13-0)
Glyceryl citrate/lactate/linoleate/oleate
Glycerides, C16-18 mono- di- and tri-, hydrogenated, citrates, potassium salts, (CAS 91744-38-6)

**Results:**

All the tested substances are found to be non-mutagenic.

**Comments:**

See reference for additional tested substances.

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di- citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

In vitro genotoxicity

**Method and laboratory:**

OECD 476 (In vitro Mammalian Cell Gene Mutation Test). Chinese hamster lung fibroblasts, with and without metabolic activation. Dosage 4.7-150 microgram/l in THF.

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates

**Results:**

Not genotoxic

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-341 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates'
https://echa.europa.eu/registration-dossier/-/registered-dossier/23747

### 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

Based on in vitro studies on gene mutation tests in bacteria and mammalian cells as well as mammalian chromosome aberration tests on substances that are structurally relevant, it is concluded that citric acid esters of mono- and diglycerides do not present any concern for mutagenicity and genotoxicity.

## 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

No published studies have been found for carcinogenic effects of citric acid esters of mono- and diglycerides or relevant structurally similar substances.

The CIR safety assessments from 2002 and 2007 (amended) refer to potential risks involved in diglycerides causing or promoting epidermal hyperplasia (abnormal increase in number of cells). The effect is said to be linked to 1,2-diglycerides, especially with short chain fatty acids (C10, C12) or mixed saturated/unsaturated fatty acids. The citric acid esters of mono- and diglycerides that are reviewed in this safety assessment are based on C16 and C18 saturated fatty acids and do not contain appreciable amounts of unreacted 1,2-diglycerides of either short chain or mixed saturated/unsaturated fatty acids.

Due to the rapid metabolism in the skin by microbial or endogenous lipases, the citric acid esters of mono- and diglycerides are hydrolyzed into free fatty acids (palmitic & stearic acid), citric acid and glycerol. All of these substances are part of a normal mammalian metabolism and do not constitute known risks for carcinogenicity.

It is concluded that citric acid esters of mono- and diglycerides are unlikely to be a health hazard from a carcinogenicity point of view.

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

**Test name:**

Toxicokinetics (ADME)

**Method and laboratory:**

Summary of toxicokinetic data (absorption, distribution, metabolism and excretion) for citric acid esters of mono- and diglycerides and other structurally similar glycerides.

**Test material:**

None

**Results:**

No actual data on the ADME have been identified. It is postulated that citric acid esters of mono- and diglycerides undergo the same type of absorption and metabolism as normal triglycerides, ie hydrolysis aided by lipases into free fatty acids, citric acid and glycerol, which are further metabolized and excreted.

**Comments:**

Uptake via the dermal route is indicated to be low, on grounds of the molecular weight and polarity of the substance.
Uptake via the inhalation route can occur if the substance is present in aerosol particles with a diameter <15 micrometers.

**Read across**

| | |
|---|---|
| Read across | Generic discussion of ADME of glycerides, including citrates and other similar derivatives of mono- and diglycerides |

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

In vitro digestion study

**Method and laboratory:**

In vitro investigation on the metabolism of citric acid esters of mono- and diglycerides in simulated infant food application. The citric acid esters are studied both alone and in a simulated infant food emulsion.

**Test material:**

Citric acid ester of mono- and diglycerides, (Grindsted CITREM LR10, Danisco A/S)

**Results:**

The citric acid ester is rapidly hydrolyzed to free fatty acids and a glyceryl citrate. The water-soluble glyceryl citrate can be persistent in some conditions in the in vitro study.

**Read across**

| | |
|---|---|
| Read across | Read across from structurally similar substances |

**Reference ID:**

S-325 In vitro digestion of citric acid esters of mono- and diglycerides (CITREM) and CITREM-containing infant formula/emulsions, Amara, S. et al, Food&Function, 5(7), 1409-1421 (2014)

### 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

No published studies on the phototoxicity, photoirritation, photosensitization or other photo-induced effects for citric acid esters of mono- and diglycerides or relevant read-across substances have been found.

The chemical structure of citric acid esters of mono- and diglycerides and the absence of photo-induced toxicity for the constituents makes it unlikely that any health hazards linked to photo-toxicity would occur at normal use conditions.

### 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

The citric acid esters of mono- and diglycerides are common emulsifiers and food additives, as well as functional ingredients in personal care products. Due to the different origins and backgrounds, the nomenclature is complicated. This section is listing the different names and identification numbers for the citrates covered by this safety report.

INCI name: CAS number(s):
Glyceryl stearate citrate: 55840-13-6, 86418-55-5, 39175-7-9
Hydrogenated palm glycerides citrate: 91744-68-2
Hydrogenated vegetable glycerides citrate: 97593-31-2
Hydrogenated tallow glyceride citrate: 68990-59-0
Hydrogenated tallow glycerides citrate: 91723-33-0
Glyceryl citrate/lactate/linoleate/oleate: No CAS found

REACH nomenclature:

Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates: 91052-16-3
Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates, calcium salts: 91052-18-5
Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates, potassium salts: 91052-20-9
Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates, sodium salts: 91052-22-1
Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts: 91744-23-9
Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, sodium salts: 91744-24-0
Glycerides, C16-18 and C18-unsatd., mono-, dicitrates: 91052-30-1
Glycerides, C16-18 and C18-unsatd., mono-, dicitrates, calcium salts: 91052-32-3
Glycerides, C16-18 and C18-unsatd., mono-, dicitrates, potassium salts: 91052-34-5
Glycerides, C16-18 and C18-unsatd., mono-, dicitrates, sodium salts: 91052-36-7
Glycerides, C16-18 mono-, di- and tri-, citrates: 91744-36-4
Glycerides, C16-18 mono-, di- and tri-, hydrogenated, citrates: No CAS found
Glycerides, C16-18 mono-, di- and tri-, hydrogenated, citrates, potassium salts: 91744-38-6
Glycerides, C16-18 mono-, di- and tri-, hydrogenated, citrates, sodium salts: 91744-39-7

## 7.12 Summary and NOAEL statement

Based on the data presented in chapter 7.1-7.11 a NOAEL value of 2200 mg/kg bw/day for systemic exposure is given for citric acid esters of mono- and diglycerides.

This value is based on data presented in Chapter 7.06 (Reproduction and developmental toxicity).

# 8 Ecological data
## 8.01 Degradability

**Test name:**

Biodegradability in water

**Method and laboratory:**

OECD 301F

**Test material:**

Glycerides, C16-18 and C18-unsatd., mono- and di-, citrates, (CAS 91052-16-3)

**Results:**

Readily biodegradable

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

Biodegradability

**Method and laboratory:**

OECD 301D (Closed bottle test)

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, sodium salts, (CAS 91744-39-7)

**Results:**

Readily biodegradable

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-343 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, sodium salts', CAS 91744-39-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/12131

**Test name:**

Biodegradability

**Method and laboratory:**

OECD 301D

**Test material:**

Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts, (CAS 91744-23-9)

**Results:**

Readily biodegradable

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**
S-340 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts', CAS number 91744-23-9
https://echa.europa.eu/registration-dossier/-/registered-dossier/24811

**Test name:**

Biodegradability

**Method and laboratory:**

OECD 301D (Closed bottle test)

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts, (CAS 91744-38-6)

**Results:**

Readily biodegradable

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**
S-342 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts', CAS 91744-38-6
https://echa.europa.eu/registration-dossier/-/registered-dossier/12022

## 8.02 Accumulation

Citric acid esters of mono- and diglycerides as well as relevant read-across substances are readily biodegradable. They are generally easily hydrolyzed to free fatty acids, citric acid and glycerol by aquatic and soil microorganisms. The fatty acids, citric acid and glycerol are easily metabolized by aquatic and soil microorganisms. Therefor the risk of environmental accumulation is regarded as minimal.

## 8.03 Aquatic toxicity

**Test name:**

Summary of aquatic toxicity

**Method and laboratory:**

One long-term study on aquatic invertebrates (daphnia), and two short-term studies (fish & algae) are summarized (OECD 203).

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, potassium salts, (CAS 91744-38-6)

**Results:**

NOEL(21d) = 60 mg/l (daphnia)
LL50(96h) > 100 mg/l (fish)
NOELR(72h) > 100 mg/l (algae)

**Comments:**

Conclusion: no aquatic toxicity observed up to solubility limit (about 1.3 mg/l)

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-339 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono- and di-citrates', CAS number 91052-16-3
https://echa.europa.eu/registration-dossier/-/registered-dossier/18167

**Test name:**

Summary of aquatic toxicity tests

**Method and laboratory:**

OECD 203 (Danio rerio, 96h, WAF, 100 mg/l)
OECD 202 (Daphnia magna, 48h, WAF, 100 mg/l)
OECD 201 (Pseudokirchneriella subcapitata, 72h, WAF,6.25-100 mg/l)

**Test material:**

Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts, (CAS 91744-23-9)

**Results:**

NOELR(fish) 100 mg/l
NOELR(Daphnia) 100 mg/l WAF
NOELR(algae) 100 mg/l WAF

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-340 ECHA, REACH registration 'Glycerides, C16-18 and C18-unsatd., mono-, di- and tri-, citrates, potassium salts', CAS number 91744-23-9
https://echa.europa.eu/registration-dossier/-/registered-dossier/24811

**Test name:**

Aquatic toxicity

**Method and laboratory:**

OECD 203 (Danio rerio, 96h, WAF, 100 mg/l)

OECD 202 (Daphnia magna, 48h, WAF, 100 mg/l)
OECD 201 (Pseudokirchneriella subcapitata, 72h, WAF,6.25-100 mg/l)

**Test material:**

Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts, (CAS 91744-38-6)

**Results:**

NOELR(fish) 100 mg/l
NOELR(Daphnia) 100 mg/l WAF
NOELR(algae) 100 mg/l WAF

**Read across**

Read across Read across from structurally similar substances

**Reference ID:**

S-342 ECHA, REACH registration 'Glycerides, C16-18, mono-, di- and tri-, hydrogenated, citrates, potassium salts', CAS 91744-38-6
https://echa.europa.eu/registration-dossier/-/registered-dossier/12022

## 8.04 Summary of ecotoxicity

The citric acid esters of mono- and diglycerides are readily biodegraded, do not accumulate in the environment and show low toxicity to aquatic organisms (fish, invertebrates and algae). It is therefor concluded that they pose minimal risk to the environment.

## 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 | No |
| DSL (Canada) | Domestic Substances List | No but on the ICL list CAS 55840-13-6 is found. |
| AICS (Australia) | The Australian Inventory of Chemical Substances | No data |
| IECSC (China) | Inventory of Existing Chemical Substances Produced or Imported in China | No data |
| 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 | Not found |
| KECI (South Korea) | Korea Existing Chemicals Inventory | No data |
| PICCS (Philippines) | Philippine Inventory of Chemicals and Chemical Substances | No data |
| NZIoC (New Zealand) | New Zealand Inventory of Chemicals | No data |
| NECI (Taiwan) | National Existing Chemical Inventory | CAS 55840-13-6 is found and valid to be used. |
| Saudia Arabia | The Saudi Arabian Standards Organisation | No data |
| Malaysia | Chemicals Information Management System | No data |
| Mexico | Inventario Nacional de Sustancias Químicas | No data |
| Turkey | | No data |

## 10.1 Official standards

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

## 10.2 Private standards

### 10.2.1 Ecocert, Cosmos or Natrue

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

### 10.2.2 Vegan and Vegetariam claim

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

### 10.2.3 Other

## 10.3 Other Statements

### 10.3.1 BSE/TSE statements:

Not available, please contact AAK for more information.

### 10.3.2 GMO statement

Not available, please contact AAK for more information.

### 10.3.3 Other:

No data

# 11. CERTIFICATES

## 11.1 Halal

Contact AAK for more information

.

## 11.2 Kosher

Contact AAK for more information

## 11.3 ISO 9001

Contact AAK for more information

## 11.4 EFFCI GMP

No data

## 11.5 Food Safety/ FSSC 22000

Contact AAK for more information

## 11.6 Other

No other available

# 12. PATENTS

## 12.1 Patents

No data.

# TRANSPORTS AND HANDLING – Akoline LC™

## 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.

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

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

### 13.3.2 Use of full package for partly use

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

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

**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

No data

# 15. DISCLAIMER

## 15.1 Disclaimer

This document, or any answers or information provided herein by AAK, does not constitute a legally binding document of AAK. While the description designs, data and information contained herein are presented in good faith and believe to be accurate, it is provided for your guidance only. Because many factors may affect processing or application/use, we recommend that you make tests to determine the suitability of a product for your particular prior to use. It does not relieve our customers from obligation to perform a full inspection of the product upon delivery or any other obligation. No warranties of any kind either express or implied, including warranties of merchantability or fitness for a particular purpose are made regarding products described or designs, data or information set forth, or that the products design, data or information may be used without infringing the intellectual property right of others. In no case shall the descriptions, information, data or designs provided be considered a part of our terms and condition of sale.

**Ship-to -**

# Analytical Certificate

| | |
|---|---|
| **Delivery** | **81398217 - 10** |
| **Print date** | 2023-11-27 |
| **Your reference** | |
| **Our reference** | Femke den Hartog |
| **Material** | 8049-805 AKOLINE LC™ |
| **Your material no.** | |
| **Date of shipment** | 2023-11-21 |

**Batch** 4014359713 / **Quantity** 5.400 KG / **Prod. date** 2023-02-14
**Inspection lot** 3147009

| Characteristic | Result | | Lower Limit | Target | Upper Limit |
|---|---|---|---|---|---|
| **Acid value(Syratal LB)** | | | | | |
| Acid value | 11,0 | mg KOH/g | 10,0 | | 25,0 |
| **Saponification value(Försåpn Tal LB)** | | | | | |
| Saponification value | 238 | mg KOH/g | 220 | | 250 |

Shelf life: 24 months from production date.

Quality Control Manager
AAK Sweden AB

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

ZAO S17174 1



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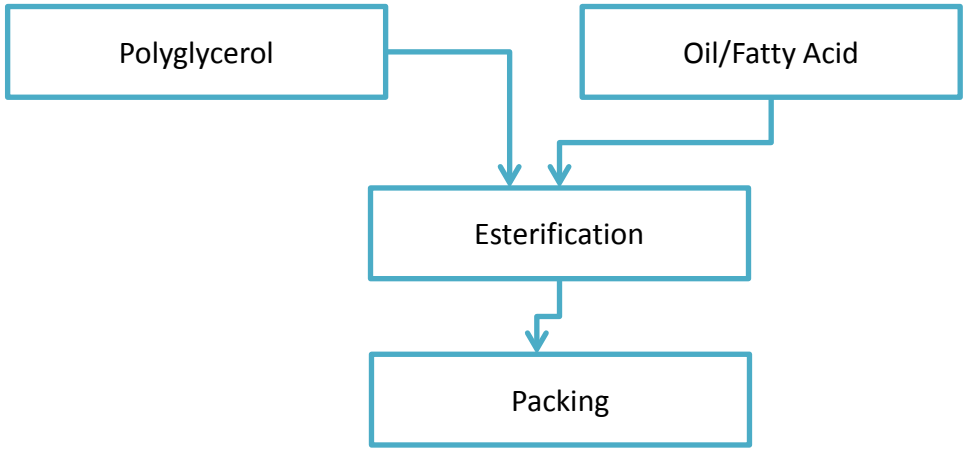
Acc. no. : 51181061768
IBAN : SE20 5000 0000 0511 8106 1768

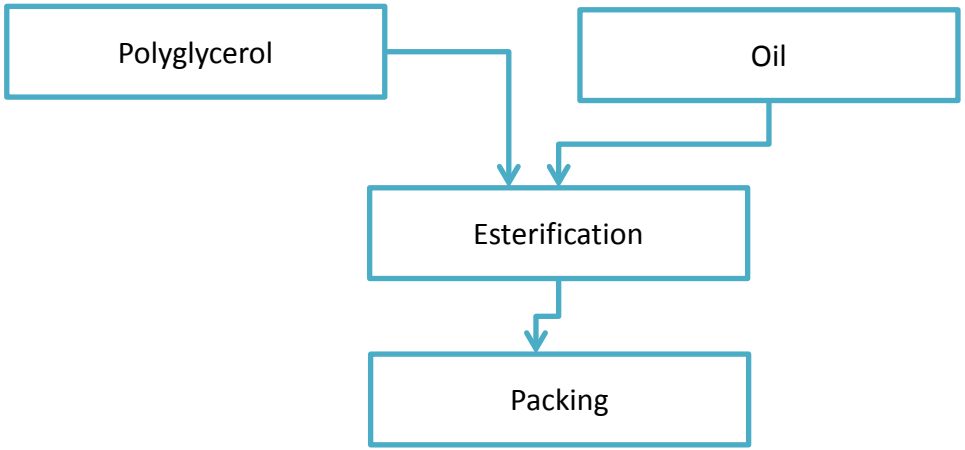
Org. no. : 556478-1796
VAT no. : SE556478179601
Approved for Swedish F-tax
Registered Office: Karlshamn

# Flowchart Akoline Products




Flowchart
Akoline PG7

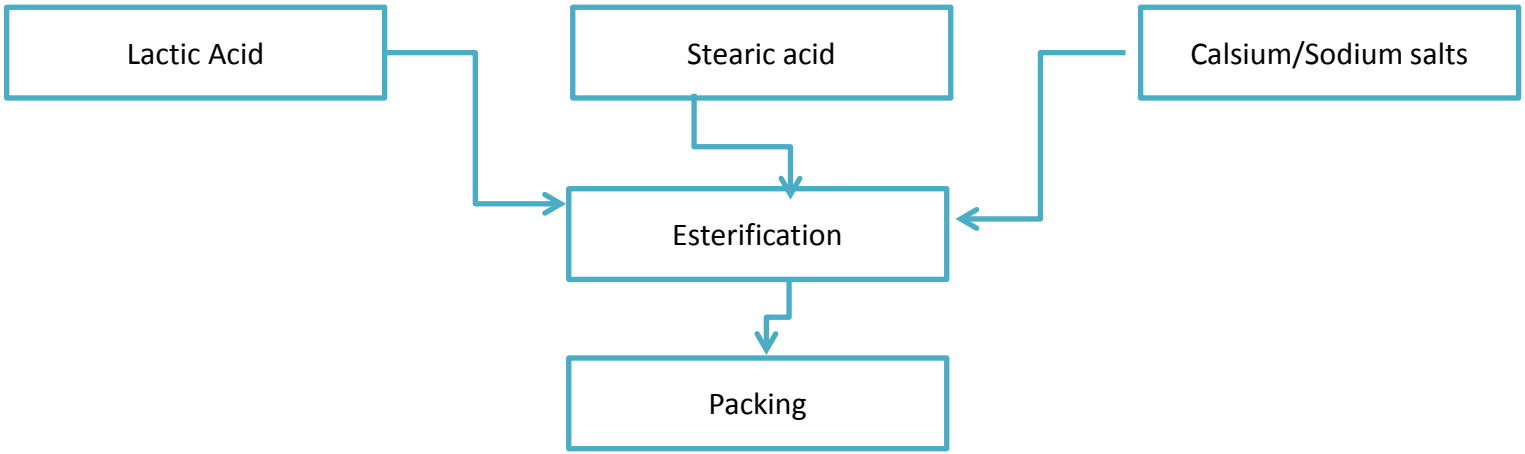
# Flowchart Akoline Products




Flowchart
Akoline PGPR

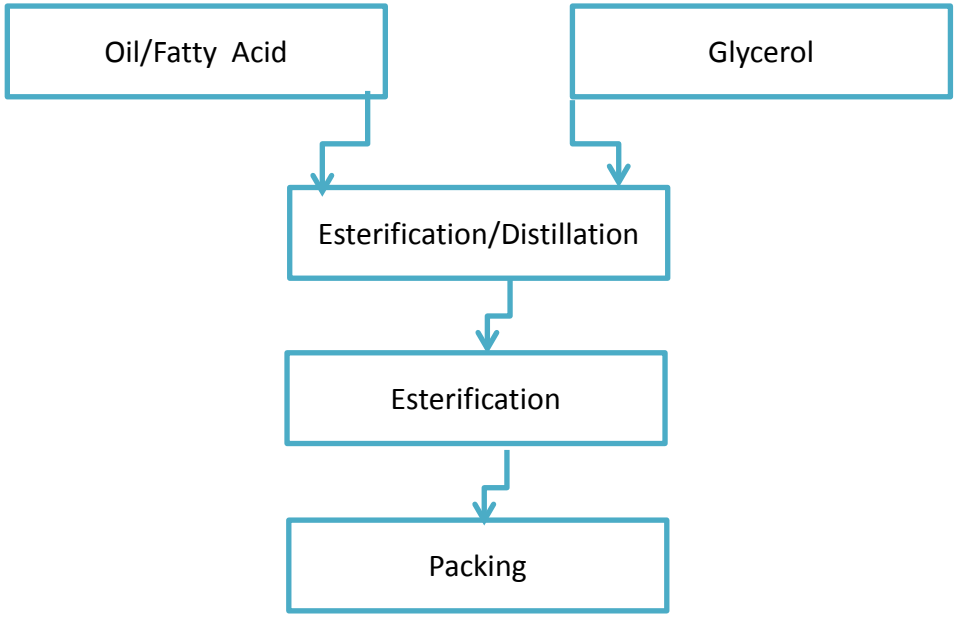
See Disclaimer

# Flowchart Akoline Products




Flowchart
Akoline SL

# Flowchart Akoline Products




Flowchart
Akoline LC
Akoline GC