Product Documentation

Akoline SL™

8690

Version
Date 2025 03 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:	Akoline SL™
Art. No:	8690
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	Sodium Stearoyl Lactylate	25383-99-7	246-929-7
US	Sodium Stearoyl Lactylate	25383-99-7	246-929-7
China*	硬脂酰乳酰乳酸钠 Sodium Stearoyl Lactylate	25383-99-7	246-929-7
Alternative INCI	Sodium Stearoyl Lactylate	18200-72-1	242-090-6

*) 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
Sodium Stearoyl Lactylate	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
Sodium Stearoyl Lactylate	25383-99-7	246-929-7	100	Emulsifier

Palm content:

☒Containing palm

☒RSPO SG: CU-RSPO SCC-817671

☐RSPO MB:

☐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 SL

7.01 General read-across consideration and justification

Test name:

CIR Safety Report

Method and laboratory:

Safety assessment of sodium stearoyl lactylates and other alkyl lactylates in cosmetics

Test material:

Sodium stearoyl lactylate and other alkyl lactylates

Results:

It is concluded that sodium stearoyl lactylate is considered safe for cosmetic use in present practices when formulated to be non-irritating and non-sensitizing.

Read across

Read across

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

Test name:

EFSA Safety assessment of sodium stearoyl lactylate as food additive

Method and laboratory:

Opinion and statement from EFSA on the safety of use of sodium and calcium salts of stearoyl lactylates as food additives. The report also comprises a summary of existing toxicological studies.

Test material:

Sodium and calcium stearoyl-2-lactylate

Results:

Based on the existing data, a ADI (Acceptable Daily Intake) by dietary sources was determined to be 22 mg/kg bw/day.

Comments:

The main source for SSL in the diet is processed foods and bakery products. No consideration of personal care uses is given in the EFSA Scientific Opinion.

Read across

Read across

Reference ID:

S-319 EFSA Scientific Opinion on the re-evaluation of sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) as food additives. EFSA Journal, 11(5), 3144-(2013)

Sodium Stearoyl Lactylate (SSL) is a typical representative of the ingredient group called 'salts of alkanoyl lactyl lactylates'. These substances are composed of a medium to long chain fatty acid (caproyl to behenoyl, most commonly stearoyl), esterified to an oligomer of lactic acid. The most typical lactic acid moiety comprises two to three units. The alkanoyl lactyl lactylate is usually found as the sodium or calcium salt, depending on the desired properties and the intended use.

SSL and other alkanoyl lactylates are commonly used as emulsifiers in food and personal care preparations. SSL has the European registry number E481 and the corresponding calcium salt is E482.

Sodium and calcium salts of lactyl lactylates were reviewed by JECFA (WHO) in the 1970'ies, based on studies ranging back to the 1950'ies (referenced extensively in the EFSA Scientific Opinion and the CIR safety assessment). Many of the referenced studies are based on unpublished data and therefor not explicitly reviewed in this safety assessment. Due to the lack of recent toxicological studies, read-across in this safety assessment is done over all existing variants found in the literature. Data on sodium and calcium salts as well as differing chain lengths in the alkyl and lactylate chains are used. This is justified by the rapid hydrolysis of the alkanoyl lactyl lactylate into the correponding fatty acids and lactic acid which are both constituents of typical foods and part of the endogenous metabolism.

For this safety assessment, a search has been done on CAS numbers 2538-99-7 (Sodium stearoyl lactylate) and 5793-94-2 (Calcium stearoyl lactylate) in the ECHA (REACH) database on-line. No useful toxicological or ecological information was found at this moment but should appear in the future.

7.02 Acute toxicity
7.02.1 Acute oral toxicity

Test name:

Acute Oral Toxicity

Method and laboratory:

Referenced in CIR Safety Report.

Test material:

See "Results"

Results:

25 g/kg bw (Calcium stearoyl lactylate, rats)
>6.1 g/kg bw (Sodium Isostearoyl lactylate, rats)
6.81 mg/kg bw (Sodium stearoyl lactylate, rats)
4.88 g/kg bw (Sodium stearoyl lactylate, rats)
25 g/kg bw (Sodium stearoyl lactylate, rats)

Comments:

The acute oral toxicity of sodium and calcium salts of alkanoyl lactylates is very low based on the presented studies.

Read across

Read across See generic read-across justification

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

Acute oral toxicity is not expected to pose an issue for human health for this substance.

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

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

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

Sodium stearoyl lactylate and other substances in the same read-across category, have a long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. The acute oral toxicity in published studies is very low and although specific studies on acute dermal and inhalation toxicity are lacking, it can be concluded that acute oral, inhalation or dermal toxicity is 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:

In vitro investigation and modelling of skin toxicity

Method and laboratory:

Skin irritation/toxicity was investigated using in vitro assays (MTT and LDH test of cell viability and detection of IL-8 and IL-1alpha). A model for predicting skin toxicity was developed based on physicochemical and structural parameters.

Test material:

4 ionic surfactants, including Sodium stearoyl lactylate (SSL), and 14 non-ionic surfactants

Results:

SSL was found to exhibit low skin toxicity in the assays and a low probability of skin irritation can be expected. However, it is predicted to be a potential skin sensitizer in this test.

Read across

Read across	Sodium stearoyl lactylate (Dermofeel SL) is used as model compound in the investigation.

Reference ID:

S-321 Skin toxicity of surfactants: Structure/toxicity relationships, Colloids Surfaces A: Physicochemical and Engineering Aspects, 469, 166-179 (2015)

Test name:

Summary of dermal irritation tests in CIR report (S-318, table 6).

Method and laboratory:

Different skin irritation tests (in vitro, animal and human) are presented in Table 6 of the CIR safety report (S-318).

Test material:

Sodium caproyl/lauroyl lactylate
Calcium stearoyl lactylate
Sodium stearoyl lactylate

Results:

Sodium and calcium alkanoyl lactylates show a variety of skin irritation results in the studies presented, ranging from non-irritants to severe irritants. It can be concluded that concentrations over 2% (in anhydrous systems) or above 25% in aqueous systems may increase the risk of skin irritation.

Read across

Read across	See generic read-across justification

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

7.03.2 Eye & mucous membrane irritation and corrosivity

Test name:

Summary of eye irritation in CIR safety assessment

Method and laboratory:

1) Bovine Corneal Opacity test (OECD TG 437)
2) Rabbit eye irritation test (n=6)

Test material:

1) Sodium caproyl/lauroyl lactylate, 10% in 0.9% sodium chloride solution
2) Calcium stearoyl lactylate (100%)
Sodium lauroyl lactylate (10%)
Sodium stearoyl lactylate (100%)
Sodium isostearoyl lactylate (15%, 100%)

Results:

1) Non-corrosive
2) Undiluted sodium isostearoyl lactylate was irritating to the rabbit eye, whereas the other tested ingredients were non-irritating.

Read across

Read across See generic read-across justification

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

7.03.3 Summary and discussion on irritation and corrosivity

Skin irritation tests reported in the CIR safety assessment (S-318) show skin irritation potential for sodium alkanoyl lactylates when tested at high concentrations (2% - undiluted). Tests done with 2 and 5% sodium stearoyl lactylate dissolved in petrolatum show significant skin irritation effects. Tests in actual formulations containing up to 7% sodium stearoyl lactylate were found non-irritating.

Sodium and calcium alkanoyl lactylates, when diluted at 10-15% in water, showed no eye irritation potential.

The CIR safety report states that sodium stearoyl lactylate is safe for cosmetic use under current practices, provided that it is formulated to be non-irritating and non-sensitizing. Based on data presented in the CIR safety assessment (table 3 on frequency of use), it can be concluded that use levels up to 1.1% in leave on skin care products, and 0.45% in baby care products can be considered acceptable (as a guideline).

7.04 Skin sensitization

Test name:

Summary of dermal sensitization tests in CIR report (S-318, table 6).

Method and laboratory:

Different skin sensitization tests (in vitro, animal and human) are presented in Table 6 of the CIR safety report (S-318).

Test material:

Sodium caproyl/lauroyl lactylate
Calcium stearoyl lactylate
Sodium stearoyl lactylate

Concentrations range from 0.5% to 50% in different vehicles.

Results:

Sodium stearoyl lactylate is predicted to be a skin sensitizer (S-321).
Animal models (LLNA) indicate Sodium caproyl/lauroyl lactylate, SSL and sodium lauroyl lactylate to be weak-moderate sensitizers.

Comments:

It is concluded in the CIR safety report that the alkanoyl lactylates present a weak to moderate risk for sensitization.

Read across

Read across See generic read-across justification

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

7.04.1 Summary and discussion of sensitization

Sodium stearoyl lactylate as well as shorter chain alkanoyl lactylates have been identified in animal models and predictive modelling as potential weak to moderate skin sensitizers. One case report referenced in the CIR safety assessment further strengthens the conclusion. The lack of more case reports as well as conclusive in vivo studies, on the other hand, indicates that sodium stearoyl lactylate cannot be considered as a confirmed skin sensitizer.

The CIR safety report states that sodium stearoyl lactylate is safe for cosmetic use under current practices, provided that it is formulated to be non-irritating and non-sensitizing. Based on data presented in the CIR safety assessment (table 3 on frequency of use), it can be concluded that use levels up to 1.1% in leave on skin care products, and 0.45% in baby care products can be considered acceptable (as a guideline).

7.05 Repeated dose, sub-chronic and chronic toxicity

7.05.1 Oral administration

Test name:

One-year oral toxicity in rats

Method and laboratory:

Feeding study in Wistar rats (30 male/30 female per test group) with different levels of sodium stearoyl lactylate incorporated in the diet. Mean intake was 558-2214 mg/kg bw/day in males and 670-2641 mg/kg bw/day in females.

Test material:

Sodium stearoyl lactylate, 0, 1.25, 2.5 and 5.0% in standard diet.

Results:

SSL was well tolerated evidenced by absence of toxicologically significant changes in all investigated parameters. The NOAEL is reported as 2214/2641 mg/kg bw/day for male/female rats respectively.

Read across

Read across	Test done with food grade sodium stearoyl lactylate (Emplex) similar to Akoline SL.

Reference ID:

S-320 A one-year oral toxicity study of sodium stearoyl lactylate (SSL) in rats, Lamb et al, Food Chem Toxicol, 48, 2663-2669 (2010)

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 sodium and calcium salts of alkanoyl lactylates is given in the CIR safety report. Several oral feeding studies are presented with exposures between 0.5 - 22% (in diet).

Test material:

Sodium caproyl/lauroyl lactylate
Calcium stearoyl lactylate
Sodium stearoyl lactylate

Results:

No treatment specific adverse effects were seen at concentrations up to 12.5%. At 22% the mortality in the test animals was high (data not given).

Read across

Read across	See generic read-across justification

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

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

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

7.05.6 Summary and discussion

The highest oral NOAEL for sodium and calcium stearoyl lactylate based on the studies reported above, could be considered to be 5% in feed, equivalent to an estimated 2500 mg/kg bw/day.

Sodium and calcium stearoyl lactylate and other substances from the same read-across category present low systemic toxicity upon repeated dose oral exposure, and the repeated dose dermal toxicity is also expected to be minimal. The substances are metabolized into lactic acid and a fatty acid, both of which are normally occurring endogenic metabolites in mammals. Furthermore, being non-volatile, repeated inhalation exposure is not considered to pose an issue for human health under normal and foreseeable handling and use conditions.

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

7.06 Reproduction toxicity

7.06.1 Non-human studies

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

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

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

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 reproductive and developmental toxicity for sodium stearoyl lactylate or other substances in the same read-across category have been found.

7.07 Mutagenicity/genotoxicity

7.07.1 In vitro data

Test name:

Summary of genotoxicity studies

Method and laboratory:

A summary and review of genotoxicity studies of sodium and calcium salts of alkanoyl lactylates is given in the CIR safety report. The studies include Ames' test data and chromosome aberration tests in hamster fibroblasts.

Test material:

Sodium caproyl/lauroyl lactylate
Calcium stearoyl lactylate

Results:

Calcium and sodium alkanoyl lactylates were found to be 'not mutagenic' in the different tests.

Comments:

Also cited in EFSA Scientific Opinion S-319.

Read across

Read across See generic read-across justification

Reference ID:

S-318 Final report - Safety assessment of alkanoyl lactyl lactate salts as used in cosmetics, Cosmetic Ingredient Review, July 17, 2019. Available at CIR website https://www.cir-safety.org/

Test name:

Mutagenicity in vitro

Method and laboratory:

Reverse mutation assay in Salmonella typhimurium
DNA-repair test in Bacillus subtilis
Chromosomal aberration tests with mammalian cells in vitro

Test material:

242 food additives used in Japan, including calcium stearoyl lactylate and lactic acid

Results:

Neither Calcium stearoyl-2 lactylate nor lactic acid were mutagenic in the tests

Read across

Read across See generic read-across justification

Reference ID:

S-336 Primary mutagenicity screening of food additives currently used in Japan, Ishidate et al, Food Chem Toxicol. 22(8), 623-636, (1984)

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

Sodium and calcium salts of stearoyl lactylate 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 sodium and calcium alkanoyl lactylates do not have a mutagenic potential.

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

7.08 Carcinogenicity

7.08.1 Non-human studies

Test name:

One-year oral toxicity in rats

Method and laboratory:

Feeding study in Wistar rats (30 male/30 female per test group) with different levels of sodium stearoyl lactylate incorporated in the diet. Mean intake was 558-2214 mg/kg bw/day in males and 670-2641 mg/kg bw/day in females.

Test material:

Sodium stearoyl lactylate, 0, 1.25, 2.5 and 5.0% in standard diet.

Results:

Histopathological examination of the female rats revealed a relatively high incidence of endometrial stromal polyps in the uterus. A control study showed this to be common for the rat strain used in the study and it was concluded that the effect was not related to the treatment.

Comments:

Also cited and commented in EFSA Scientific Opinion S-319 and in the CIR safety Report S-318.

Read across

Read across See generic read-across justification

Reference ID:

S-320 A one-year oral toxicity study of sodium stearoyl lactylate (SSL) in rats, Lamb et al, Food Chem Toxicol, 48, 2663-2669 (2010)

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

Sodium and calcium salts of alkanoyl lactylates and other substances of the same read-across category have a long history of safe use in nutritional (food and feed), cosmetic and industrial applications, without any apparent adverse effects. Based on the above facts, carcinogenicity is not expected to pose an issue for human health under normal and foreseeable handling and use conditions and no further testing for this endpoint is required.

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

7.09.1 Oral administration

Sodium and calcium salts of alkanoyl lactyl lactates are rapidly and nearly completely hydrolyzed into fatty acids and lactic acids after oral intake (EFSA, Scientific Opinion, S-319). The lactate is rapidly metabolized and exhaled as CO2 or as lactic acid in the urine. The hydrolysis products (fatty acid and lactic acid) are also endogenous substances in mammals. In this context, no specific differences between sodium or calcium salts are expected, neither between different chain lengths of the fatty acids.

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 actual tests have been carried out and literature data has not been found for this chapter.

7.10.1 Phototoxicity: photoirritation / photosensitisation

7.10.2 Phototoxicity: photomutagenicity / photoclastogenicity

7.10.3 Other relevant human studies (clinical)

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 2214 mg/kg bw/day for systemic exposure for ‘Sodium Stearoyl Lactylate' as well as other substances of the same read-across category.

The CIR safety report states that sodium stearoyl lactylate is safe for cosmetic use under current practices, provided that it is formulated to be non-irritating and non-sensitizing. Based on data presented in the CIR safety assessment (table 3 on frequency of use), it can be concluded that use levels up to 1.1% in leave on skin care products, and 0.45% in baby care products can be considered acceptable (as a guideline).

Depending on the application, the maximum use level in formulation should be based on the lowest of the systemic NOAEL calculation or the CIR recommendation.

8 Ecological data

No published data for biodegradability, accumulation or aquatic toxicity have been found for sodium stearoyl lactylate or similar alkanoyl lactylates. However, the rapid breakdown under hydrolytic conditions into stearic acid and lactic acid oligomers, indicates that the sodium stearoyl lactylate should meet the criteria for ready biodegradability and for non-accumulation in the environment. The aquatic toxicity is not studied for the alkanoyl lactylates but data on lactic acid indicates a low toxicity to algae, invertebrates and fish, provided that the pH value is not extremely low. The aquatic toxicity of alkyl lactates increases with increasing lipophilicity (reference S-356), however, the sodium stearoyl lactylates are highly hydrophilic and should show minimal toxicity to aquatic organisms.

8.01 Degradability

Test name:

Biodegradability

Method and laboratory:

OECD 301D (closed bottle test, 1992)/OECD 301C (1992)

Test material:

Lactic acid
Methyl-, ethyl-, n-propyl-, i-propyl-, n-butyl-, i-butyl-, n-pentyl-, i-pentyl-, 2-ethylhexyl- and n-octyl lactate

Results:

Lactic acid and the alkyl lactates tested were all readily biodegradable

Comments:

Alkyl lactylates are easily hydrolyzed to lactic acid and fatty acids in an aqueous environment.

Read across

Read across See generic read-across justification

Reference ID:

S-356 The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts, Bowmer, C.T. et al, Chemosphere, 37(7), 1317-1333, (1998)

8.02 Accumulation

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

8.03 Aquatic toxicity

Test name:

Aquatic toxicity

Method and laboratory:

Algal growth inhibition test OECD 201 (1984)/ EPA EG-8 (1982) using Selenastrum capricornutum, 72/96 h
Acute toxicity to invertebrates OECD 202 (Daphnia magna)/EPA EG-1 (1982), 48 h
Acute toxicity to fish OECD 203 (Brachydanio rerio)/EPA EG-9 (1992) (Pimephales promelas), 96h

Test material:

Lactic acid
Methyl-, ethyl-, n-propyl-, i-propyl-, n-butyl-, i-butyl-, n-pentyl-, i-pentyl-, 2-ethylhexyl- and n-octyl lactate
Sodium lactate

Results:

NOEC (Algae, 72-96h)
- lactic acid 1900 mg/l
- n-octyl lactate 3.2 mg/l
NOEC (Daphnia, 48 h)
- lactic acid 180 mg/l
- n-octyl lactate 18-32 mg/l
NOEC (Fish, 96h)
- lactic acid 320 mg/l
- n-octyl lactate 18 mg/l
NOEC (Daphnia, 48h,fish 96 h)
- sodium lactate >=10000 mg/l

Comments:

The toxicity of lactic acid to Daphnia and fish is explained by the low pH value (3.5-4.1) of the test solutions which were not buffered. The test with sodium lactate shows no toxicity to Daphnia magna.

Toxicities to algae, daphnia and fish follow a lipophilicity scale in this study, the most lipophilic substances having the highest toxicity.

Read across

Read across See generic read-across justification

Reference ID:

S-356 The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts, Bowmer, C.T. et al, Chemosphere, 37(7), 1317-1333, (1998)

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	CAS 25383-99-7 is listed and valid to be used
DSL (Canada)	Domestic Substances List	CAS 25383-99-7 is listed and valid to be used
AICIS (Australia)	The Australian Inventory of Chemical Substances	CAS 25383-99-7 is listed and valid to be used
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	CAS 25383-99-7 is listed and valid to be used
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.	CAS 25383-99-7 is listed and valid to be used
Japan	Japan Pharmacopoeia	Not found
KECI (South Korea)	Korea Existing Chemicals Inventory	CAS 25383-99-7 KE-26348; CAS 18200-72-1 KE-26349 is lited and valid to be used.
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	CAS 25383-99-7 is listed and valid to be used
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	CAS 25383-99-7 is listed and valid to be used
TCSI (Taiwan)	National Existing Chemical Inventory	CAS 25383-99-7 is listed and valid to be used.
Saudia Arabia	The Saudi Arabian Standards Organisation	No data
Malaysia	Chemicals Information Management System	No data
Mexico	Inventario Nacional de Sustancias Químicas	Yes Ácido octadecanóico, 2-(1-carboxietoxi)-1-metil-2-oxoetil éster, sal de sodio (1:1)
Turkey		Yes for EC# 246-929-7. Local name: Sodyum 2-stearoillaktat;

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

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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 SL™

13.1 Transports

No data available

13.2 storage unopen package

Storage to fulfill shelf life:

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

Retest of batch:

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

13.3 Handling of product for use

13.3.1 Use of full package

Recommended melting temperature.

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

During processing need to be heated to 50C to remove crystal memory.

13.3.2 Use of full package for partly use

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

Reseal packaging and store in 20C or below

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	**81374104 - 40**
Print date	2023-09-24
Your reference	
Our reference	Femke den Hartog
Material	8690-840 Akoline SL™
Your material no.	
Date of shipment	2023-09-21

Batch 4014327165 / **Quantity** 50 KG / **Prod. date** 2023-02-09
Inspection lot 3158735 / **Best before** 2025-02-08

Characteristic	Result		Lower Limit	Target	Upper Limit
Acid value(Syratal LB)					
Acid value	69.0	mg KOH/g	60.0		80.0
Ester value(Estertal LB)					
Ester value	169		150		190

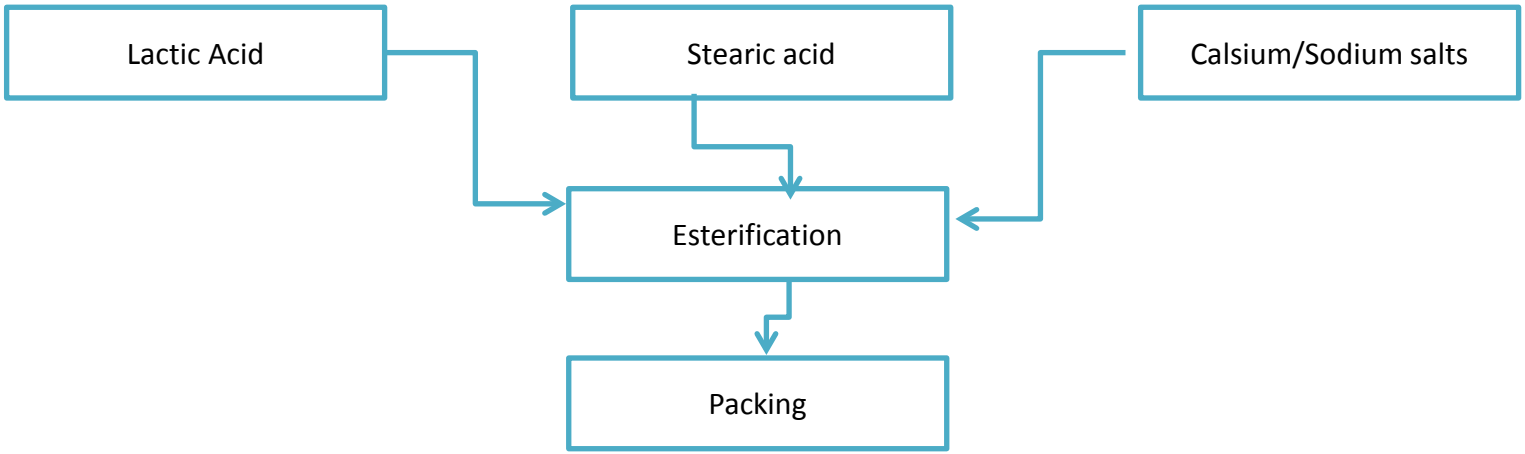
Shelf life: 24 months from production date.

Quality Control Manager
AAK Sweden AB

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

ZAO S11856 1

Flowchart Akoline Products



Flowchart
Akoline SL