Product Documentation

Akoline MCM™

8515

Version
Date 2024-01-05

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 MCM™
Art. No:	8515
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	Caprylic/capric glycerides	85409-09-2	287-075-5
US	Caprylic/capric glycerides	85409-09-2	287-075-5
China*	辛酸/癸酸甘油酯类 (Caprylic/capric glycerides)	85409-09-2	287-075-5
Alternative INCI	Glycerides, C8-10 mono- and di-	85536-07-8	287-488-0

*) 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)

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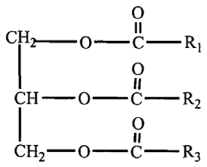
2.3 Certificate of Analysis

For example of COA, see Appendix.

2.4 Auxiliary chemical and physical data

Molecular weight ~880 g/mol

Stucture



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

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

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3.1 Biological data

Botanical origin

INCI	Botanical origin	*)Geographical origin	Part used	Content %	Wild grown or cultivated
Caprylic / capric glyceride	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
Caprylic / capric glyceride	85409-09-2	287-075-5	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	X	
Deodorising	X	
Hydrogenation		
Interesterification		
Esterification	X	
Winterisation		
Solvent Fractionation		
Dry Fractionation		
Ethoxylation		
Molecular distillation		
Other processing	X	

5. BY-PRODUCTS AND OTHER IMPURITIES

5.1 AAK Contaminant standard

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

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

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

5.2 Other Impurities specific substances

Download latest version of "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 > 150 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

Akoline MCM

7.01 General read-across consideration and justification

Test name:
CIR Safety report

Method and laboratory:
Toxicological summary and conclusion by the CIR expert panel, 2004

Test material:
43 glyceryl monoesters including glyceryl caprylate and glyceryl caprylate/caprate

Results:
It is concluded that the glyceryl monoesters are safe as cosmetic ingredients in the present practices of use

Read across
Read across General information on mono- and diglyceride used in cosmetics

Reference ID:
S240 - Final report on the amended safety assessment of glyceryl laurate, glyceryl laurate SE (and others), Int J Toxicol, 23 (Supplement 2), 55-94, (2004)

Test name:
Toxicological and registration summary (ECHA, REACH)

Method and laboratory:
Public summary of results in ECHA database

Test material
Glycerides, C8-10, mono- and di- (CAS No. 85536-07-8)

Results:
See ECHA website

Read across
Read across Same fatty acid and glyceride composition

Reference ID:
S239 - https://echa.europa.eu/registration-dossier/-/registered-dossier/5620/1 Accessed 2019-09-07

Test name:
EFSA safety report

Method and laboratory:
Summary of safety data made by European Food Safety Authority

Test material
Mono- and diglycerides of fatty acids, including caprylic and capric acids

Results:
Mono/diglycerides are considered to be safe for human consumption without limitations

Read across
Read across General information on mono- and diglycerides used in foods

Reference ID:
S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

Mono- and diglycerides, including ‘caprylic/capric glycerides’ are composed mainly of esters containing glycerol esterified to linear saturated or unsaturated fatty acids with a carbon chain length of C8-C18. For safety assessment various fatty acid glyceryl mono- and diesters can be used for read-across. Such glyceryl esters are described for example in “Final Report of Amended Safety Assessment of Glyceryl Laurate (…)" (Cosmetic Ingredient Review, 2004, reference S240). Relevant read-across substances are saturated and unsaturated fatty acid glycerides with chain lengths from C8-C22.

‘Caprylic/capric glycerides’ are mixtures of glyceryl mono- and di-esters with C8 and C10 fatty acids. The dominating chemical species are glyceryl caprylate, glyceryl caprate, glyceryl dicaprylate, glyceryl dicaprate and glyceryl caprylocaprate. The concentrations of the individual species depend on fatty acid composition and processing conditions.

For read-across purposes data from longer chain saturated and unsaturated mono- and diglycerides can be used for systemic effects. Local effects on skin and mucosa may differ due to the higher surface activity of caprylic/capric glycerides.

7.02 Acute toxicity
7.02.1 Acute oral toxicity

Test name:

Acute oral toxicity

Method and laboratory:

Species: Rat (Fischer, 20 male / 20 female), single administration of 20-30 ml/kg by gastric tube

Species: Mouse (RFVL, 20 male / 20 female), single administration of 20-57 ml/kg bw by gastric tube.

Clinical observation for 14 days.

Test material

Caprylic/capric mono/diglyceride (Nikkol MGK)

Results:

LD50 (rat): 26-27 ml/kg bw (about 27000 mg/kg bw)

LD50 (mouse): 27-28 ml/kg bw (about 28000 mg/kg bw)

Read across

Read across	Same fatty acid and glyceride composition

Reference ID:

S227 - Improvement of bioavailability of poorly absorbed drugs: III. Oral acute toxicity and local irritation of medium chain glyceride. Sekine M. et al, J Pharmacobio-Dyn., 8, 633-644, (1985)

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

7.02.2 Acute inhalation toxicity

Based on the physical state (semi-solid to solid under environmental conditions) and low vapour pressure (0.001 Pa at 25C), the probability of inhalation exposure to 'Caprylic/capric glycerides' and other similar substances 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.

7.02.3 Acute dermal toxicity

Test name:

Acute dermal toxicity

Method and laboratory:

Species: Rat

Test material

Mono/diglycerides of coconut fatty acids

Results:

LD50 > 2000 mg/kg bw

Comments:

Fatty acid composition and monoglyceride/diglyceride distribution not quantified.

Read across

Read across Similar fatty acid and glyceride composition

Reference ID:

S226 - Physikochemische und toxikologische Aspekte von Partialglyceriden als Wirkstoffträger für Transdermalsysteme. Heers, W., Arzneim.- Forsch. - Drug Res., 39(11), 1491-1494, (1989)

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

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

Mono- and diglycerides of fatty acids, including 'caprylic/capric glycerides' and 'glyceryl monostearate', have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Acute oral, inhalation or dermal toxicity is therefore not considered to pose an issue for human health under normal and foreseeable handling and use conditions.

7.03 Irritation & corrosivity
7.03.1 Skin irritation and corrosivity

Test name:

Human Repeat Insult Patch Test with challenge

Method and laboratory:

52 subjects (male/female), age 18-70 years, Fitzpatrick phototype II and III. Induction: 9 consequtive applications on the back over 3 weeks, Challenge: 2 weeks after final application.

Test material:

Mix of Akoline MCM 10%, Akosun (high oleic sunflowerseed oil) 90%

Results:

During the induction period, the test item induced no reaction or irritation. During the challenge phase a single application of the test item induced no allergic reaction. Based on these results, the test item has a very good skin compatibility and does not show a sensitizing effect.

Comments:

The test item was dissolved in oil due to the high surface activity of the test substance.

Read across

Original

Reference ID:

S225 - Eurofins EVIC Romania, ER 19/028-29/19-0186, 2019

In view of the results from HRIPT testing and available literature data, no corrosivity to the skin is expected for this substance category.

7.03.2 Eye & mucous membrane irritation and corrosivity

Test name:

In Vitro Eye Irritation: Ocular Irritation Assay using the EpiOcular Human Tissue Model

Method and laboratory:

EpiOcular reconstructed human cornea-line epithelium model, according to standard procedure. Test dose 50 microliter, spread directly on the EpiOcular tissue using distilled water as negative control and methyl acetate as positive control.

Test material:

Mix of Akoline MCM 10%, Akosun (high oleic sunflowerseed oil) 90%

Results:

In this study under the given conditions, the test item showed irritant effects. No prediction of the ocular irritation potential of the test item can be made using the EpiOcular test under current conditions, requiring additional testing.

Comments:

The test item was dissolved in oil due to the high surface activity of the test substance.

Read across

Original

Reference ID:

S224 - Eurofins Munich Study No.: 191205, 2019

Test name:

Eye irritation - summary of test results

Method and laboratory:

1) Rabbit, n=3, scoring 24, 48, 72 hours, up to 7 days
2) Rabbit, n=6, scoring 24, 48 and 72 h

Test material:

1) Glyceryl laurate (neat)
2) 20% emulsion in water

Results:

1) Neat glyceryl laurate: mean irritation score 0.17 of max 80 (corneal lesions) and 1.33 of max 20 (conjunctival lesions), indicating no eye irritation potential.
2) Glyceryl laurate emulsion: The glyceryl laurate emulsion was classified as "non-irritant". Mean irritation score 0 (corneal opacity, inflammation of iris) and 3.7 (of 110) for conjunctival irritation.

Read across

Read across	Glyceryl laurate is structurally similar to caprylic/capric glycerides with slightly longer chain-length.

Reference ID:
S240 - Final report on the amended safety assessment of glyceryl laurate, glyceryl laurate SE (and others), Int J Toxicol, 23 (Supplement 2), 55-94, (2004)

In view of the results from in vitro testing and available literature data, corrosivity to the eye or mucous membranes is not expected for this substance category. However, due to the results from the in vitro irritation testing (EpiOcular), eye irritation cannot be excluded and further investigations are necessary.

7.03.3 Summary and discussion on irritation and corrosivity

Glyceryl mono- and di-glycerides of fatty acids derived from vegetable oils and fats, have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the tests reported above, skin irritation and corrosiveness are not considered to pose an issue for human health under normal and foreseeable handling and use conditions. For medium chain fatty acid (caprylic, capric and lauric) mono-and diglycerides, eye corrosiveness is not expected, however, eye irritation cannot be excluded based on available data and further studies are needed.

7.04 Skin sensitization

Test name:
Presence of known food allergens

Results:
Known food allergens are not present in ingredients derived from 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 ingredients derived rom refined vegetable oils

Read across
Statement

Reference ID:
S012 - AAK statement on fragrance allergens

Test name:
Human Repeat Insult Patch Test with challenge

Method and laboratory:
52 subjects (male/female), age 18-70 years, Fitzpatrick phototype II and III. Induction: 9 consequtive applications on the back over 3 weeks, Challenge: 2 weeks after final application.

Test material
Mix of Akoline MCM 10%, Akosun (high oleic sunflowerseed oil) 90%

Results:
During the induction period, the test item induced no reaction or irritation. During the challenge phase a single application of the test item induced no allergic reaction. Based on these results, the test item has a very good skin compatibility and does not show a sensitizing effect.

Comments:
The test item was dissolved in oil due to the high surface activity of the test substance.

Read across
Original

Reference ID:
S225 - Eurofins EVIC Romania, ER 19/028-29/19-0186, 2019

7.04.1 Summary and discussion of sensitisation

Mono- and diglycerides of saturated and unsaturated fatty acids, including 'caprylic/capric glycerides' and 'glyceryl monostearate' and other substances in the same read-across category, have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the tests and references reported above, sensitisation and allergenicity are not considered to pose an issue for human health under normal and foreseeable handling and use conditions, provided that the substances are adequately purified to remove proteins and other contaminants.

7.05 Repeated dose, sub-chronic and chronic toxicity
7.05.1 Oral administration

Test name:

Summary of short-term and chronic oral toxicity

Method and laboratory:

Species: Rats (Sprague-Dawley, 10/sex per group)
Diet: up to 5.5% of heated/unheated dioleate in feed (3178-4210 mg/kg bw/day), 6 different treatment groups
Duration: 90 days

Species: Hamsters (Golden Syrian, male, 15 animals per group)
Duration: 8 weeks
Diet: 0 or 5 % glyceryl stearate (0 or 2500 mg/kg bw/day). 1 group treated with 15% (7500 mg/kg bw/day).

Test material

Diglycerides of oleic acid
Glyceryl monostearate

Results:

No evidence of adverse effects were reported short-term and subchronic studies in rats and hamsters up to 2500 mg/kg bw/day of diglycerides and 7500 mg/kg bw/day of glyceryl monostearate.

Comments:

See reference for details

Read across

Read across General information on mono- and diglycerides used in foods

Reference ID:

S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

Test name:

Summary of chronic toxicity and carcinogenicity

Method and laboratory:

Species: mice (50/group, male+female)
Duration: 24 months
Diet: up to 6% diglyceride in feed (7800-10020 mg/kg bw/day)

Species: Rats (60/group, male+female)
Duration: 105 weeks
Diet: up to 5.3% of diglyceride in feed (1170-2350 mg/kg bw/day)

Species: Rat (50/group, male+female)
Duration: 24 months
Diet: up to 5,5% diglyceride (1982-2507 mg/kg bw/day)

Test material

Unsaturated diglycerides

Results:

No systemic toxicity or carcinogenic effects attributed to the test substance was observed in any of the studies. The highest NOAEL for systemic toxicity was established to 2645 mg/kg bw/day.

Comments:

See reference for details

Read across

Read across	General information on mono- and diglycerides used in foods

Reference ID:

S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).www.efsa.europe.eu/efsajournal

7.05.2 Inhalation studies

No studies could be located on the repeated dose inhalation toxicity of glyceryl mono- and diesters of fatty acids. However, given their physical state (solid to semi-solid to liquid under environmental conditions), low vapour pressure (< 0.001 Pa at 20°C) and as long as they are not handled or marketed as powders, respiratory exposure is not likely to occur. Repeated inhalation exposure is therefore not expected to pose an issue for human health and no further consideration is required for this endpoint, in accordance with Annex VIII, column 2 of the REACH regulation (1907/2006/EC). Long-chain saturated mono/diglycerides are available as powders and specific safety assessment of the powder form must be considered.

7.05.3 Dermal administration

No studies have been located on the repeated dose dermal toxicity for this category. However, this substance and others from the same read-across category present low systemic toxicity upon repeated dose oral exposure for which absorption is higher (96%) than via the dermal route (default 10%, see also section 7.9.2), so that repeated dose dermal toxicity is not expected to be higher than via the oral route. This is further supported by very long history of safe use of these types of substances in nutritional (food and feed), cosmetic and industrial applications. Taken together the above facts suggest that repeated dose dermal toxicity will not pose an issue for human health under normal and foreseeable handling and use conditions.

7.05.4 Other routes of administration

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

7.05.5 Human studies

Mono- and di-glycerides of fatty acids 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. Based on these above facts, toxicity via repeated exposure is not expected to pose an issue for human health under normal and foreseeable handling and use conditions, and no further testing for this endpoint is required.

7.05.6 Summary and discussion

Glyceryl mono- and diesters of fatty acids derived from vegetable oils and fats, are frequently used as emulsifiers in foods consumed as part of a normal diet. While minor differences may be observed in safety parameters depending on the chain length distribution of the fatty acids associated to the glycerides and their degree of unsaturation, research overall indicates that, when consumed at nutritionally relevant concentrations, there are no adverse systemic effects on health and longevity.

For risk assessment purposes, the relevant systemic NOAEL is considered to be up to 7% in diet, which is equivalent to an estimated 4630 mg/kg bw/day (EFSA 2017).

7.06 Reproduction toxicity
7.06.1 Non-human studies

Test name:

Summary of reproductive and developmental toxicity

Method and laboratory:

An oral two-generation reproduction test in rats (30/sex per group). Dose levels up to 5 ml diglyceride by day (up to 4630 mg/kg bw/day)

Developmental toxicity was investigated in a separate study (25 animals/group). Dose up to 5 ml/kg bw/day of unsaturated diglyceride.

Test material

Unsaturated diglycerides

Results:

No effects on reproductive or developmental effects were observed. NOAEL was established to be 4630 mg/kg bw/day.

Comments:

See reference for details

Read across

Read across General information on mono- and diglycerides used in foods

Reference ID:

S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

The above weight of evidence suggests that mono- and di-glycerides of fatty acids, including ‘caprylic/capric glycerides' and 'glyceryl monostearate' as well as other substances in the same read-across category, are not toxic for reproduction on oral exposure. Because absorption and therefore systemic exposure via the dermal route is lower than via the oral route, reproductive toxicity from dermal contact is also not expected. Finally, given the physical state (liquid, semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C) of the substances, reproductive toxicity as a result of inhalatory exposure is not likely. No significant reproduction and development toxicity was seen in the reported studies. For risk assessment purposes, the highest oral NOAEL could be considered to be 4630 mg/kg bw/day, on the basis of a two-generation reproduction / developmental feeding study.

7.06.2 Human studies

Mono- and di-glycerides of fatty acids 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. Based on these above facts, toxicity via repeated exposure is not expected to pose an issue for human health under normal and foreseeable handling and use conditions, and no further testing for this endpoint is required.

7.06.3 Developmental toxicity/teratogenicity
7.06.3.1 Non-human studies

Test name:

Summary of reproductive and developmental toxicity

Method and laboratory:

An oral two-generation reproduction test in rats (30/sex per group). Dose levels up to 5 ml diglyceride by day (up to 4630 mg/kg bw/day)

Developmental toxicity was investigated in a separate study (25 animals/group). Dose up to 5 ml/kg bw/day of unsaturated diglyceride.

Test material

Unsaturated diglycerides

Results:

No effects on reproductive or developmental effects were observed. NOAEL was established to be 4630 mg/kg bw/day.

Comments:

See reference for details

Read across

Read across General information on mono- and diglycerides used in foods

Reference ID:

S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

The above weight of evidence suggests that mono- and di-glycerides of fatty acids, including 'caprylic/capric glycerides' and 'glyceryl monostearate' as well as other substances in the same read-across category, are not toxic for reproduction on oral exposure. Because absorption and therefore systemic exposure via the dermal route is lower than via the oral route, reproductive toxicity from dermal contact is also not expected. Finally, given the physical state (liquid, semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C) of the substances, reproductive toxicity as a result of inhalatory exposure is not likely. No significant reproduction and development toxicity was seen in the reported studies. For risk assessment purposes, the highest oral NOAEL could be considered to be 4630 mg/kg bw/day, on the basis of a two-generation reproduction / developmental feeding study.

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

It can be concluded from the data presented in Section 7.6.1 and 7.6.2 that mono- and di-glycerides of fatty acids derived from vegetable oils and fats do not present any reproduction toxicity at daily intakes of less than 4630 mg/kg bw. This value is considered relevant for risk assessment purposes, although it is only a reflection of study setups and not of effects observed at higher doses.

7.07 Mutagenicity/genotoxicity
7.07.1 In vitro data

Test name:

Reverse Mutation Assay using Bacteria (Salmonella typhimurium)

Method and laboratory:

Salmonella typhimurium standard plate incorporation study, with and without metabolic activation. Study strains: TA98, TA100, TA 1535, TA1537 and T102.
Test concentrations were 1.00, 3.16, 10,0, 31.6, 100, 316, 1000, 2500 and 5000 microgram/plate.
Eurofins Biopharma Products Testing Munich GmbH.

Test material

Akoline MCM, 100%

Results:

Akoline MCM is considered to be non-mutagenic in this bacterial reverse mutation assay

Read across

Original

Reference ID:

S223 - Eurofins Munich Study No.: 191209, 2019

Test name:

Summary of genotoxicity

Method and laboratory:

In vitro: Ames test
In vivo: micronucleus test (mice)

Test material

Unsaturated diglycerides

Results:

No genotoxic effects were observed in the reported tests.

Comments:

See reference for details

Read across

Read across General information on mono- and diglycerides used in foods

Reference ID:
S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

The above evidence, collected from in vitro tests and literature, added to the very long history of safe use of these types of substances in nutritional (food and feed), cosmetic and industrial uses, suggests that glyceryl mono- and di-esters of fatty acids derived from vegetable oils and fats, including 'glyceryl caprylate/caprate' and 'glyceryl monostearate', do not have a mutagenic potential.

7.07.2 In vivo data

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

7.07.3 Human studies

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

7.07.4 Summary and discussion of mutagenicity

The above evidence, collected from in vitro tests and literature, added to the very long history of safe use of these types of substances in nutritional (food and feed), cosmetic and industrial uses, suggests that glyceryl mono- and di-esters of fatty acids derived from vegetable oils and fats, including 'glyceryl caprylate/caprate' and 'glyceryl monostearate', do not have a mutagenic potential.

7.08 Carcinogenicity
7.08.1 Non-human studies

Test name:

Summary of chronic toxicity and carcinogenicity

Method and laboratory:

Species: mice (50/group, male+female)
Duration: 24 months
Diet: up to 6% diglyceride in feed (7800-10020 mg/kg bw/day)

Species: Rats (60/group, male+female)
Duration: 105 weeks
Diet: up to 5.3% of diglyceride in feed (1170-2350 mg/kg bw/day)

Species: Rat (50/group, male+female)
Duration: 24 months
Diet: up to 5,5% diglyceride (1982-2507 mg/kg bw/day)

Test material

Unsaturated diglycerides

Results:

No systemic toxicity or carcinogenic effects attributed to the test substance was observed in any of the studies. The highest NOAEL for systemic toxicity was established to 2645 mg/kg bw/day.

Comments:

See reference for details

Read across

Read across General information on mono- and diglycerides used in foods

Reference ID:

S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

Test name:

Summary of carcinogenic effects

Method and laboratory:

Two initiation-promotion studies referenced in publication (1: mammary gland tumorigenesis, Sprague-Dawley rats. 2: multiorgan carcinogenesis bioassay, F344 rats)

Test material

Unsaturated diglycerides

Results:
No enhancing/promotion effect on tumorigenesis was observed in the 2 studies.

Comments:
See reference for details

Read across
Read across General information on mono- and diglycerides used in foods

Reference ID:
S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

Glyceryl mono- and di-esters of fatty acids derived from vegetable fats and oils 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 adverse effects. As dermal absorption is lower than absorption via the oral route (see Section 7.9.2), carcinogenicity following dermal systemic uptake is not expected. Finally, given the physical state (liquid, semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C) of the substances, carcinogenicity as a result of inhalatory exposure is not likely.

7.08.2 Human studies

Glyceryl mono- and di-esters of fatty acids derived from vegetable fats and oils 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 adverse effects. Based on the above facts, carcinogenicity is not expected to pose an issue for human health under normal and foreseeable handling and use conditions and no further testing for this endpoint is required.

7.08.3 Summary and discussion of carcinogenicity

No studies indicating carcinogenic effects from glyceryl mono- and di-esters derived from vegetable oils and fats have been found in the literature. Given their frequent use in foods and nutrition, as well as being used as emulsifiers in personal care and industrial products, they show a very long history of safe use.

No carcinogenicity is expected from dermal exposure as systemic uptake will be lower than from the oral route. Finally, given the physical state, low vapour pressure of the substances and the fact that they are not handled or marketed as a powder, carcinogenicity as a result of inhalatory exposure is not likely.

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

7.09 Toxicokinetics: absorption, metabolism, distribution and elimination

When taken up orally, medium chain glycerides are split in the stomach by lingual lipase and in the intestinal lumen by pancreatic lipase into glycerol and fatty acids, allowing for a direct absorption via the portal vein to the liver. The medium chain fatty acids are catabolized into C2 fragments in the liver and used for building longer fatty acids or oxidized to CO2 and energy. Very little medium chain fatty acids are stored in the adipose tissue. (S183, Traul et al, 2000). Medium chain mono- and di-glycerides are predicted to metabolise in the same manner, as they are part of the hydrolytic pathway for medium chain triglycerides.

7.09.1 Oral administration

Test name:

Absorption, distribution, metabolism and excretion summary

Method and laboratory: In

In vitro and animal studies on absorption and digestion

Test material

Mono- and diglycerides of fatty acids

Results:

Several studies show that mono- and diglycerides are rapidly hydrolysed to glycerol and fatty acids which are absorbed to 98-99%.

Read across

Read across General information on mono- and diglycerides used in foods

Reference ID:

S241 - Re-evaluation of mono- and di-glycerides of fatty acids (E 471) as food additives. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal, 15(11), 5045, 1-43, (2017).
www.efsa.europe.eu/efsajournal

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

Test name:

Skin penetration enhancement

Method and laboratory:

In vitro skin permeation using 5-fluorouracil combined with different excipients. Diffusion cell with excised human abdominal skin was used for the study. Excipients of different polarities, including glyceryl caprylate/caprate were tested.

Test material

Caprylic/capric mono/diglyceride (Estol GMCC 3601)

Results:

Caprylic/capric mono/diglyceride was shown to be a moderate skin penetration enhancer for a hydrophilic test molecule.

Read across

Read across	Same fatty acid and glyceride composition

Reference ID:

S228 - Glyceryl monocaprylate/caprate as a moderate skin penetration enhancer. Cornwell, P.A. et al, Int J Pharmaceutics, 171, 243-255, (1998)

7.12 Summary and NOAEL statement

Based on the data presented in Chapter 7.1 to 7.11, the NOAEL is set to 4630 mg/kg bw/day for systemic exposure for ‘caprylic/capric glycerides' as well as other substances of the same read-across category.

8 Ecological data

8.01 Degradability

Test name:

Biodegradability (OECD 301B)

Method and laboratory:

Public summary of results in ECHA database

Test material

Glycerides, C8-10, mono- and di- (CAS No. 85536-07-8)

Results:

Glycerides, C8-10, mono- and di- (CAS No. 85536-07-8) can be considered as readily biodegradable (82.6% biodegradation in 28 days).

Read across

Read across	Same fatty acid and glyceride composition

Reference ID:

S238 - https://echa.europa.eu/registration-dossier/-/registered-dossier/5620/5/3/1
Accessed 2019-09-07

Vegetable oil based esters, including mono- and di-glycerides, are made from alcohols and unbranched, even numbered fatty acids with normally 0-3 double bonds. The ester bonds are hydrolysed in aqueous environments to fatty acids and the corresponding alcohol. Both alcohol and the fatty acids are metabolised by microorganisms by beta-oxidation to smaller fragments and eventually to carbon dioxide. The hydrolysis of the esters is catalysed by acids, alkalies as well as lipases exuded by the microorganisms. The rate of breakdown is faster for shorter chain and more unsaturated esters due to higher solubility in water. Mono- and di-glycerides are in general readily biodegradable in OECD 301 based tests.

8.02 Accumulation

Esters, such as glyceryl mono- and di-esters of fatty acids derived from vegetable fats and oils, are generally easily hydrolysed to free fatty acids and corresponding alcohols by aquatic and soil microorganisms. The fatty acids and the alcohols are easily metabolised by aquatic and soil microorganisms. Therefor the risk of environmental accumulation is regarded as minimal.

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	CAS 65381-09-1 is listed and valid to be used.
DSL (Canada)	Domestic Substances List	CAS 65381-09-1 is listed and valid to be used.
AICS (Australia)	The Australian Inventory of Chemical Substances	Both CAS 73398-61-5 and 85409-09-2 is listed and valid to be used.
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	Both CAS 73398-61-5 and 85409-09-2 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.	Both CAS 73398-61-5 and 85409-09-2 is listed and valid to be used.
Japan	Japan Pharmacopoeia	Not found
KECI (South Korea)	Korea Existing Chemicals Inventory	CAS 85409-09-2 KE-17787; CAS 73398-61-5 KE-17905 is listed and valid to be used.
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Both CAS 73398-61-5 and 85409-09-2 is listed and valid to be used.
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Both CAS 73398-61-5 and 85409-09-2 is listed and valid to be used.
NECI (Taiwan)	National Existing Chemical Inventory	Both CAS 73398-61-5 and 85409-09-2 is listed and valid to be used.
Saudia Arabia	The Saudi Arabian Standards Organisation	No data
Malaysia	Chemicals Information Management System	No data
Mexico	Inventario Nacional de Sustancias Químicas	No data
Turkey		EC#277-452-2. Local name: Gliserid, dekanoil ve oktanoil karışımı

10.1 Official standards

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

10.2 Private standards

10.2.1 Ecocert, Cosmos or Natrue

Latest statement, download at aakpersonalcare.com

10.2.2 Vegan and Vegetarian claim

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

10.3 Other Statements

10.3.1 BSE/TSE statements:

Latest statement, download at aakpersonalcare.com

10.3.2 GMO statement

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

Latest statement, download at aakpersonalcare.com

11. CERTIFICATES

11.1 Halal

The product is produced according to Halal.

Download latest version at aakpersonalcare.com

11.2 Kosher

The product is produced according to Kosher.

Download latest version at aakpersonalcare.com

11.3 ISO 9001

The product is produced according to ISO 9001.

ISO certificate latest version available for downloading at aak.com

11.4 EFFCI GMP

The product is produced according to EFFCI GMP.

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

11.5 Food Safety/ FSSC 22000

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

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

11.6 Other

No other available

12. PATENTS

12.1 Patents

No data.

TRANSPORTS AND HANDLING – Akoline MCM™

13.1 Transports

No data available

13.2 storage unopen package

Storage to fulfill shelf life:

Store in temperature 20C or lower. Dark, dry and odor free condition in unopen packaging's.

See Product data sheet for more information.

Retest of batch:

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

13.3 Handling of product for use

13.3.1 Use of full package

Recommended melting temperature.

Cans: Melt the whole content until fluid or approx. 35C

Drums: Melt the whole content until fluid or approx. 35C

During processing need to be heated to 35C to remove crystal memory.

13.3.2 Use of full package for partly use

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

Cans: Melt the whole content until at least 35C

Drums: Melt the whole content until at least 35C

From an oxidation point of view restrict the number of heating/cooling cycles, depending on the time the product is kept at high temperature. The more times it is heated/cooled, the shorter the shelf life will be.

At lower temperatures a precipitate may form on prolonged storage. If the material has been stored at low temperatures and has started to crystallize it is important to melt the whole content before use. Recommended melting temperature for product in drums, is at least 35 C. Melt the whole content and homogenize. Keep melting time as short as possible to avoid oxidation of the product.

Note:

AAK's shelf life is for ingredients that are unopened and stored according to the instructions given in the product Data sheet. This guarantee is invalidated once the packaging is opened and the ingredients reheated. It is the user's responsibility to validate that a reheated material fulfills shelf life requirements in a formulation. See Product Data Sheet.

14. REFERENCES

14.1 References

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	**81399755 - 20**
Print date	2023-12-08
Your reference	
Our reference	Benjamin Sales
Material	8515-640 Akoline MCM™
Your material no.	
Date of shipment	2023-11-29

Batch 0002630510 / **Quantity** 740 KG / **Prod. date** 2023-03-17
Inspection lot 3142052 / **Best before** 2026-03-17

Characteristic	Result		Lower Limit	Target	Upper Limit
Total ash(EP 2.4.16)					
Total ash	< 0.05	%			0.10
Acid value(IUPAC 2.201(m))					
Acid value	0.99	mg KOH/g			2.00
Partial glycerides(AAK, LC)					
Monoglycerides Quant	60.6	%	55.0		69.0
Atomic absorption(AAK, AAS)					
Arsenic	< 0.10	mg/kg			3.00
Heavy metals (As,Pb,Cd,Ni,Fe,Cu)(AAK)					
Heavy metals (As,Pb,Cd,Ni,Fe,Cu)	< 0.50	mg/kg			10.00
Colour Lovibond(Lovibond Tintometer)					
Colour 5 1/4" Red	1.2				4.0
Iodine value Hanus(IUPAC 2.205(m))					
Iodine value Hanus	< 0.1				1.0
Saponification Value(IUPAC 2.202)					
Saponification Value	277.0	mg KOH/g	252.0		308.0
Hydroxyl value(AOCS Cd 13-60(m))					
Hydroxyl value	374	mg KOH/g		390	

ZAO S16730 1

AAK Sweden AB
SE-374 82 Karlshamn
Sweden

Phone : +46(0)454 820 00
Website : www.aak.com

Bank : Skandinaviska Enskilda Banken
Bic/Swift : ESSESESS
Giro : 5430-5438
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

Ship-to -

Analytical Certificate

Delivery	**81399755 - 20**
Print date	2023-12-08
Your reference	
Our reference	Benjamin Sales
Material	8515-640 Akoline MCM™
Your material no.	
Date of shipment	2023-11-29

Free Glycerol(Free Glycerol)

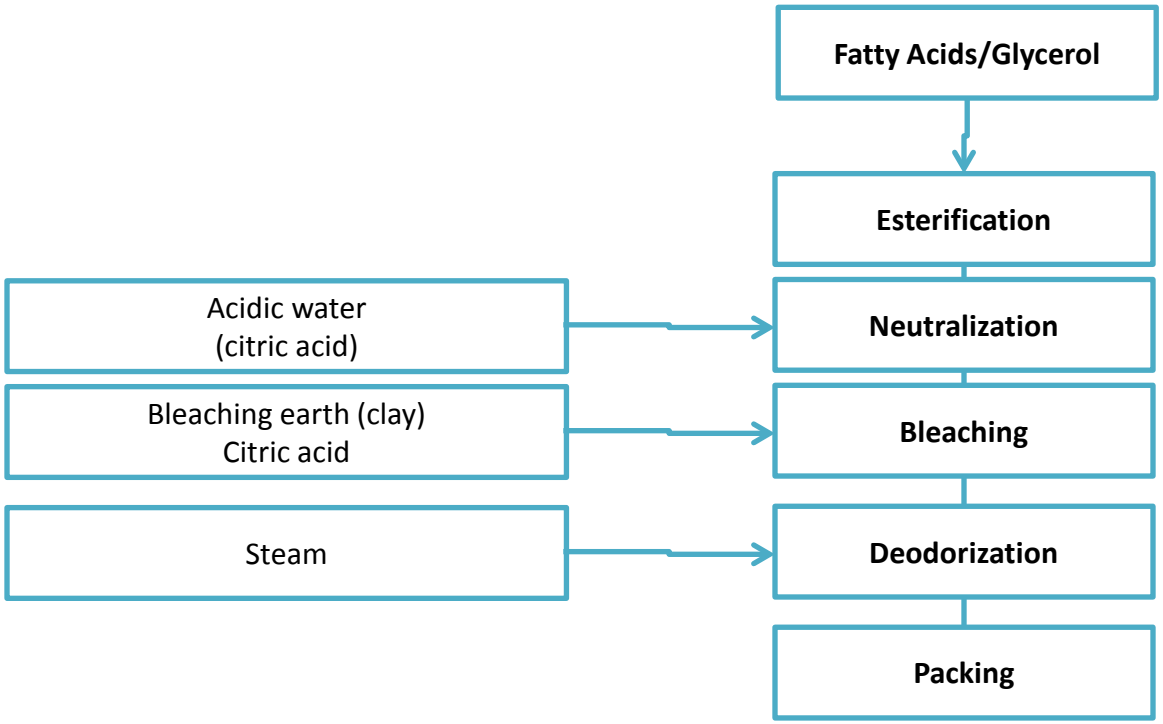
Free Glycerol EX USP2021	1.60	%	2.50

Quality Control Manager
AAK Sweden AB

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

ZAO S16730 1

Processing scheme 6: Esterified oils and fats



Explanations what each step contribute with

Randomises triglyceride composition

Neutralises catalyst and stops reaction

Removes pigments, metals, proteins and catalyst traces

Removes flavours, free fatty acids and oxidation products

See Disclaimer