Product Documentation

Akoline PGPR™

8516

Version
Date 2024 02 06

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 PGPR™
Art. No:	8616
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	Polyglyceryl-3 Ricinoleate	29894-35-7	
US	Polyglyceryl-3 Ricinoleate	29894-35-7	
China*	聚甘油-3 蓖麻醇酸酯 Polyglyceryl-3 Ricinoleate	29894-35-7	
Alternative INCI	POLYGLYCERYL-3 POLYRICINOLEATE	235783-76-3	

*) 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/

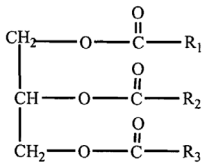
2.3 Certificate of Analysis

For example of COA, see Appendix.

2.4 Auxiliary chemical and physical data

Molecular weight ~880 g/mol

Stucture



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

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

Download latest version at www.aakpersonalcare.com/

3.1 Biological data

Botanical origin

INCI	Botanical origin	*)Geographical origin	Part used	Content %	Wild grown or cultivated
Polyglyceryl-3 Ricinoleate	*Ricinus communis*	India or Brazil	Seeds	100	Cultivated

*)**Geographical origin may change**

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
Polyglyceryl-3 Ricinoleate	29894-35-7		99,955	Emulsifier
Alpha Tocopherol	10191-41-0	233-466-0	0,02	Preservative
Citric Acid	77-92-9	201-069-1	0,02	Preservative
Propylene Glycol	57-55-6		0,005	

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 @ 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 PGPR

7.01 General read-across consideration and justification

Test name:

CIR Safety assessment

Method and laboratory:

Safety assessment and review of various polyglycerol ester based cosmetic ingredients

Test material:

274 polyglycerol esters with 2 to 20 glycerol units and a variety of fatty acids

Results:

The CIR panel concludes that the polyglycerol esters are safe in cosmetics in the current practices and when formulated to be non-irritating.

Read across

Statement

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

Test name:

EFSA scientific opinion and safety review

Method and laboratory:

EFSA scientific opinion and safety review on polyglycerol polyricinoleate (E 476)

Test material:

Polyglycerol polyricinoleate

Results:

EFSA concludes that polyglycerol polyricinoleate is not of concern for acute or long-term toxicity, including reproductive toxicity, genotoxicity and carcinogenicity. The oral/systemic ADI (acceptable daily intake) is set to 25 mg/kg bw.

Read across

Statement

Reference ID:

S-346 Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive. EFSA Journal 15(3): 4743, 54pp, (2017)

Test name:

EFSA scientific opinion and safety review

Method and laboratory:

EFSA scientific opinion and safety review on polyglycerol esters of fatty acids (E 475)

Test material:

Polyglycerol esters of fatty acids

Results:

EFSA concludes that polyglycerol esters of fatty acids are not of concern for acute or long-term toxicity, including reproductive toxicity, genotoxicity and carcinogenicity. There is no need to set an ADI (acceptable daily intake) for food applications.

Read across

Statement

Reference ID:

S-347 Re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive. EFSA Journal 15(12): 5089, 32pp, (2017)

Test name:

Summary and review of polyglyceryl polyricinoleate

Method and laboratory:

Review and summary of studies on polyglycerol polyricinoleate

Test material:

Polyglycerol polyricinoleate

Results:

Review of preparation, use and biological studies on polyglycerol polyricinoleate

Comments:

General background information

Read across

Statement

Reference ID:

S-348 Overview of the preparation, use and biological studies on polyglycerol polyricinoleate (PGPR). Wilson, R., van Schie, B.J. & Howes, D., Food Chemical Toxicology, 36, 711-718, (1998)

Test name:

REACH registration dossier

Method and laboratory:

REACH registration dossier with toxicological and environmental data

Test material:

Polyglycerol-3

Read across

Statement

Reference ID:

S-352 ECHA, REACH registration 'Reaction mass of 3-[3-(2,3-dihydroxypropoxy)-2-hydroxypropoxylpropane-1,2-diol...', https://echa.europa.eu/registration-dossier/-/registered-dossier/13319 Accessed 2020-08-18

Test name:

REACH registration dossier

Method and laboratory:

REACH registration dossier with toxicological and environmental data

Test material:

Polyglycerol-3 caprate/laurate

Read across

Statement

Reference ID:

S-353 ECHA, REACH registration 'Reaction products of decanoic acid and lauric acid with glycerol and polyglycerol',
https://echa.europa.eu/registration-dossier/-/registered-dossier/25834
Accessed 2020-08-18

Test name:

REACH registration dossier

Method and laboratory:

REACH registration dossier with toxicological and environmental data

Test material:

Polyglycerol-3 caprate

Read across

Statement

Reference ID:

S-354 ECHA, REACH registration '1,2,3-propantriol, homopolymer, decanoate', CAS 74504-65-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/23621
Accessed 2020-08-18

Test name:

REACH registration dossier

Method and laboratory:

REACH registration dossier with toxicological and environmental data

Test material:

Polyglycerol-3

Read across

Statement

Reference ID:

S-355 ECHA, REACH registration '1,2,3-propantriol, homopolymer', CAS 25618-55-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/14285
Accessed 2020-08-18

Polyglycerol esters are a large group of emulsifiers and viscosity regulating substances that comprise a polar group made from polyglycerol and a non-polar group consisting of fatty acids. The majority of the polyglycerol esters are based on polyglycerol-3, which are mixtures of di-, tri-, and tetraglycerol with varying amounts of glycerol and higher oligomers. A typical composition is quoted in the EFSA review (S-347) as 1.3% glycol, 26.2% glycerol, 4.9% cyclic diglycerol, 22.7% diglycerol, 15.6% triglycerol, 9.1% tetraglycerol, 6.0% pentaglycerol, 3.8% hexaglycerol and 3.6% higher polyglycerols. Another group of common polyglyceryl esters are based on polyglycerol-10, with a distribution of oligomers centering on 10 glycerol units.

The polyglycerol may be esterified to one or more fatty acids or mixtures of fatty acids. The saturated fatty acids range from caprylic (C8) to behenic (C22), and unsaturated esters are normally based on oleic and/or linoleic acids (C18:1, C18:2). Iso-esters with branched fatty acids are also available (mainly isostearates). Hydroxy acids such as ricinoleic acid and dihydroxystearate are also used, the ricinoleic acid normally as a polymer of ricinoleic acid ("polyricinoleates"). Many commercial ingredients are named after the starting raw material, for example "coconut oil polyglyceryl-6 esters". Such ingredients are characterized by the fatty acids found in the starting materials so for the coconut based material mainly lauric/myristic/palmitic/stearic acids.

The polyglycerols are esterified with one or more fatty acids. For example, polyglyceryl-3 stearate has on average one fatty acid per polyglycerol but the actual composition will be a mixture of mono-esters, di-esters, tri-esters etc and unreacted polyglycerol.

The toxicology and environmental properties of the polyglyceryl esters depend on the properties of the substances themselves but also on the metabolites (polyglycerols and fatty acids). For this reason, read-across can be made over a wide range of different polyglyceryl esters. In this review both saturated, unsaturated, branched and hydroxy-acid based materials are considered equal from a toxicology and environmental point of view and extensive read-across is applied. The main point for caution is the skin and eye irritation potential of the shorter chain (C8-C12) esters, due to their high surface activity, which will differ from the longer chain alternatives.

7.02 Acute toxicity
7.02.1 Acute oral toxicity

Test name:

Summary of acute toxicity of polyglycerol esters

Method and laboratory:

Review and summary of several studies on the acute toxicity of polyglyceryl esters

Test material:

Polyglycerol esters of various saturated, unsaturated and branched fatty acids

Results:

LD50(oral): >5g/kg bw (rat)
LD50(dermal): >5g/kg bw (rat)

Comments:

(Table 12 in report).

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

Test name:

Acute oral toxicity

Method and laboratory:

Summary of acute oral toxicity data in EFSA review on polyglycerol polyricinoleate (PGPR).

Test material:

Polyglycerol polyricinoleate
Ricinoleic acid
Castor oil
Polyglycerols

Results:

LD50(rat, PGPR): >20000 mg/kg bw
LD50(mouse, PGPR): >100000 mg/kg bw
LD50(rat, polyglycerols): >2000 mg/kg bw

Comments:

Castor oil and ricinoleic acid cause diarrhoea and potential disturbance of the intestinal mucosa.

Read across

Read across Similar chemical structures

Reference ID:

S-346 Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive. EFSA Journal 15(3): 4743, 54pp, (2017)

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:

Summary of acute toxicity of polyglycerol esters

Method and laboratory:

Review and summary of several studies on the acute toxicity of polyglyceryl esters

Test material:

Polyglycerol esters of various saturated, unsaturated and branched fatty acids

Results:

LD50(oral): >5g/kg bw (rat)
LD50(dermal): >5g/kg bw (rat)

Comments:

(Table 12 in report).

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

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

Polyglycerol esters of fatty acids, including 'polyglycerol-3 stearate' and 'polyglycerol-3 polyricinoleate', have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. The acute oral, inhalation or dermal toxicity is low and therefore not considered to pose an issue for human health under normal and foreseeable handling and use conditions. There is no Acceptable Daily Intake (ADI) assigned to polyglycerol esters of saturated fatty acids. The ADI for polyglycerol polyricinoleate is set to 25 mg/kg bw/day.

7.03 Irritation & corrosivity

7.03.1 Skin irritation and corrosivity

Test name:

Skin irritation and sensitization

Method and laboratory:

Review and summary of skin irritation and sensitization for polyglycerol esters (Table 14 in CIR report). 7 alternative studies, 36 animal studies and 24 human studies are reported.

Test material:

Saturated, unsaturated and branched polyglycerol esters

Results:

Polyglycerol esters are not irritating to the skin
Polyglycerol esters are not sensitizing

Comments:

A small number of reports indicate slight to moderate irritation (5-6 out of 67 reports)

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

7.03.2 Eye & mucous membrane irritation and corrosivity

Test name:

Eye irritation

Method and laboratory:

Review and summary of eye irritation for polyglycerol esters (Table 15 in CIR report). 23 alternative studies and animal studies and 1 human study are reported.

Test material:

Saturated, unsaturated and branched polyglycerol esters

Results:

Polyglycerol esters are not irritating to minimally irritating to the eye.

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

7.03.3 Summary and discussion on irritation and corrosivity

Based on the safety assessments and reviews it is concluded that polyglycerol esters of saturated, unsaturated, branched and hydroxy fatty acids pose a minimal risk to cause skin or eye irritation in normal use concentrations. It is also concluded that the polyglycerol esters of fatty acids are not corrosive to skin, eyes or mucous membranes.

7.04 Skin sensitization

Test name:

Skin irritation and sensitization

Method and laboratory:

Review and summary of skin irritation and sensitization for polyglycerol esters (Table 14 in CIR report). 7 alternative studies, 36 animal studies and 24 human studies are reported.

Test material:

Saturated, unsaturated and branched polyglycerol esters

Results:

Polyglycerol esters are not irritating to the skin
Polyglycerol esters are not sensitizing

Comments:

A small number of reports indicate slight to moderate irritation (5-6 out of 67 reports)

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

7.04.1 Summary and discussion of sensitization

According to read-across studies, presented in the CIR safety report and in REACH registration dossiers, polyglycerol esters such as 'polyglycerol-3 stearate' and 'polyglycerol-3 polyricinoleate' are not sensitizing.

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

Test name:

Summary of sub-chronic toxicity of polyglycerol esters

Method and laboratory:

Review and summary of the sub-chronic toxicity of polyglyceryl esters in rat (10M/10F Sprague-Dawley rats, duration 90 days, dosage 2.5, 5.0 and 10.0% in diet)

Test material:

Polyglycerol-10 decaoleate

Results:

No treatment related adverse effects were detected.

Comments:

Also cited in EFSA review (S-347)

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

Test name:

Summary of chronic toxicity of polyglycerol esters

Method and laboratory:

Review and summary of the chronic toxicity of polyglyceryl esters in mice (25M/25F mice, duration 80 weeks, dosage 5% in diet) and rats (28M/28F rats, duration 2 years, dosage 5% in diet).

Test material:

Polyglycerol esters

Results:

No treatment related adverse effects were detected. Liver and kidney weights in female mice were higher than in control group (5% groundnut oil).

Comments:

Also cited in EFSA review (S-347)

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

Test name:

Sub-chronic and short-term oral toxicity

Method and laboratory:

Summary of short-term oral toxicity data in EFSA review on polyglycerol polyricinoleate (PGPR).

1) Mouse 100M/100F, duration 14 days, dosage 0.5-8% PGPR in diet (450-7200 mg/kg bw/day).

2) Mouse 140M/140F, duration 14 days, dosage 0, 5,10 & 15% in diet (0, 4500, 9000 and 13500 mg/kg bw/day).

3) Rat 6M/6F, duration 5 days, dosage 10 ml/kg bw/day by gavage (10000 mg/kg bw/day).

4) Rat 24M/24F, duration 14 days, dosage 18% in diet (16200 mg/kg bw/day).

Test material:

Polyglycerol polyricinoleate

Results:

1) No adverse effects observed up to 1800 mg/kg bw/day. Increased liver weights observed at higher dosages.

2) Comparable growth rates between treatment and control groups. Increased liver weights in PGPR groups.

3) No adverse effects observed.

4) Increased liver weights seen in PGPR groups

The EFSA panel concludes that the increased liver weight is reversible and due to high levels of the test substance.

Comments:

2 more studies with similar conditions and outcomes reported in the EFSA review (S-346).

Read across

Read across Similar chemical structures

Reference ID:

S-346 Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive. EFSA Journal 15(3): 4743, 54pp, (2017)

Test name:

Chronic and carcinogenicity toxicity

Method and laboratory:

Summary of long-term and carcinogenicity toxicity data in EFSA review on polyglycerol polyricinoleate (PGPR).

1) Mice 100M/100F in four treatment groups, duration 80 weeks, dosage 5% in diet (7500 mg/kg bw/day).

2) Rats 48M/48F, duration 30 and 45 weeks (2 studies), dosage 9% in diet (4500 mg/kg bw/day).

3) Rats 30M/30F, duration 2 years, dosage 5% (2500 mg/kg bw/day).

Test material:

Polyglycerol polyricinoleate

Results:

1) No treatment related adverse effects observed. No increased incidence of tumors observed. NOAEL (mice) = 7500 mg/kg bw/day.

2) No treatment related adverse effects were observed. NOAEL (rat) = 4500 mg/kg bw/day.

3) No treatment related adverse effects observed. No increased incidence of tumors observed. NOAEL (rat) = 2500 mg/kg bw/day.

Read across

Read across Similar chemical structures

Reference ID:

S-346 Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive. EFSA Journal 15(3): 4743, 54pp, (2017)

Test name:

Chronic toxicity and carcinogenicity

Method and laboratory:

Summary of chronic toxicity and carcinogenicity studies in EFSA review on polyglycerol esters

1) mIce, 25M/25F, duration 80 weeks, dosage 5% in diet (7500 mg/kg bw/day).

2) rats, 28M/28F per dosage group, duration 2 years, dosage 5% in diet (2500 mg/kg bw/day)

Test material:

Polyglycerol esters of fatty acids

Results:

1) No treatment related adverse effects were observed. No increased incidence of tumors. NOAEL (mice) = 7500 mg/kg bw/day.

2. No treatment related adverse effects were observed. No increasedincidence of tumors. NOAEL (rat) = 2500 mg/kg bw/day.

Read across

Read across Similar chemical structures

Reference ID:

S-347 Re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive. EFSA Journal 15(12): 5089, 32pp, (2017)

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

7.05.6 Summary and discussion

The highest oral NOAEL for polyglycerol esters of fatty acids based on the studies reported above, could be considered to be 5% in feed, equivalent to an estimated 2500 mg/kg bw/day.

Polyglycerol-3 stearate, polyglycerol-3 ricinoleate 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 glycerol, polyglycerols and fatty acids. The glycerol and the fatty acids are metabolized according to well established pathways. Polyglycerol is excreted without metabolization in the urine or faeces. 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

Test name:

Reproduction study PGPR

Method and laboratory:

Three-generation reproduction study in rats.

Test material:

Polyglycerol polyricinoleate (ADMUL WOL), 1.5% in diet

Results:

No adverse, treatment related, effects on the reproductive function were observed in this study.

Comments:

Also cited in EFSA review (S-346). Study of limited value due to methodological problems.

Read across

Read across Similar chemical structures

Reference ID:

S-350 A Three-generation reproduction study on polyglycerol polyricinoleate (PGPR) in Wistar rats. Wilson, R. & Smith, M., Food Chemical Toxicology, 36, 739-741, (1998)

Test name:

Reproduction and development toxicity

Method and laboratory:

Review and summary of reproduction and development toxicity of polyglyceryl esters in rats (OECD Guideline 422, dosage 0, 100, 300 and 1000 mg/kg bw/day).

Test material:

Polyglycerol-3 diisostearate

Results:

NOAEL for systemic effects was determined to be >1000mg/kg bw/day. No treatment related adverse effects were detected.

Comments:

Also cited in EFSA review (S-347)

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

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 reliable published studies on reproductive and developmental toxicity for polyglycerol esters of fatty acids or other substances in the same read-across category have been found. One study on polyglycerol polyricinoleate is available but the study is not well designed and lack important details in the documentation. A study on polyglycerol-3 diisostearate is reported in the CIR review (S-345) showing no effects on reproduction up to the highest tested concentration (1000 mg/kg bw/day). Several problems relating to the execution of the study are reported and the validity of the study is questionable.

7.07 Mutagenicity/genotoxicity

7.07.1 In vitro data

Test name:

Mutagenicity and genotoxicity

Method and laboratory:

Review and summary of mutagenicity and genotoxicity polyglycerol esters (Table 13 in CIR report). 27 in vitro tests are reported (Ames test, mammalian cell mutation assays, chromosomal aberration assays, with and without metabolic activation)

Test material:

Saturated, unsaturated and branched polyglycerol esters

Results:

The tested polyglycerol esters are not mutagenic, genotoxic or clastogenic.

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

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 polyglycerol esters of fatty acids do not present any concern for mutagenicity and genotoxicity.

7.08 Carcinogenicity
7.08.1 Non-human studies

Test name:

Carcinogenic properties

Method and laboratory:

Assessment of carcinogenic potential for PGPR in rat & mouse.
Rat: 60 M/ 60 F, duration 2 years, dosage 5% in diet
Mice: 25 M/ 25F, duration 80 weeks, dosage 5% in diet

Test material:

Polyglycerol polyricinoleate
(ADMUL WOL)

Results:

No carcinogenic effects were detected. No adverse effects on growth, food consumption, longevity or haematology. No treatment related histological changes. Increase in liver and kidney weight was observed in both mice and rats.

Read across

Read across Similar chemical structures

Reference ID:

S-349 Assessment of the carcinogenic potential of polyglycerol polyricinoleate (PGPR) in rats and mice, Smith, M.R., Wilson, R. & Hepburn, P.A., Food Chemical Toxicology, 36, 747-754, (1998)

Test name:

Chronic and carcinogenicity toxicity

Method and laboratory:

Summary of long-term and carcinogenicity toxicity data in EFSA review on polyglycerol polyricinoleate (PGPR).

1) Mice 100M/100F in four treatment groups, duration 80 weeks, dosage 5% in diet (7500 mg/kg bw/day).

2) Rats 48M/48F, duration 30 and 45 weeks (2 studies), dosage 9% in diet (4500 mg/kg bw/day).

3) Rats 30M/30F, duration 2 years, dosage 5% (2500 mg/kg bw/day).

Test material:

Polyglycerol polyricinoleate

Results:

1) No treatment related adverse effects observed. No increased incidence of tumors observed. NOAEL (mice) = 7500 mg/kg bw/day.

2) No treatment related adverse effects were observed. NOAEL (rat) = 4500 mg/kg bw/day.

3) No treatment related adverse effects observed. No increased incidence of tumors observed. NOAEL (rat) = 2500 mg/kg bw/day.

Read across

Read across Similar chemical structures

Reference ID:

S-346 Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive. EFSA Journal 15(3): 4743, 54pp, (2017)

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

Several chronic toxicity and carcinogenicity studies are summarized in the EFSA reviews on polyglyceryl esters and polyglyceryl polyricinoleate (S-346 & S-347). The studies show that no increases in tumor incidence can be seen in mice fed 7500 mg/kg bw/day or rats fed 2500 mg/kg bw/day. A NOAEL of 2500 mg/kg bw/day is derived from these studies.

It is concluded that polyglycerol esters 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:

The absorption, tissue distribution, metabolism and excretion of radiolabelled polyglycerol polyricinoleate was studied in rats in several ways. Both radiolabelled polyglycerol and radiolabelled fatty acids were used. The digestion of polyglycerol polyricinoleate by pancreatic lipase was also studied in vitro.

Test material:

Polyglycerol polyricinoleate

Results:

Polyglycerol esters are completely hydrolysed with the aid of lipases to the corresponding polyglycerol and fatty acids. Lower polyglycerols are excreted in the urine while higher polyglycerols are bound in the faeces. Glycerol and fatty acids are metabolized in the normal manner.

Read across

Read across Similar chemical structures

Reference ID:

S-351 The fate of ingested glyceran esters of condensed castor oil fatty acids [Polyglycerol polyricinoleate (PGPR)] in the rat. Howes, D., Wilson, R. & James, C.T., Food Chemical Toxicology, 36, 719-738, (1998)

Test name:

Summary of adsorption, distribution, metabolism and excretion of polyglycerol esters

Method and laboratory:

Review and summary of several studies on the ADME of polyglyceryl esters

Test material:

Polyglycerol esters of stearic, oleic and linoleic acids

Results:

Polyglycerol esters are hydrolyzed by lipases into polyglycerol(s) and fatty acids. The fatty acids are metabolized in the normal manner while the polyglycerols are excreted.

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

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

Test name:

Phototoxicity and photosensitization

Method and laboratory:

Review and summary of phototoxicity (guinea pigs, 10F, 0.5 ml polyglycerol-10 nonaisostearate, 150 mJ/cm2 UVB, 7000 mJ/cm2 UVA) and photosensitization (guinea pig, n=11, 7000 mJ/cm2 UVA, induction with 2 intradermal injections, challenge after 16 days, application of test substance + irradiation with 7 mJ/cm2 UVA)

Test material:

Polyglycerol-10 nonaisostearate

Results:

Polyglycerol-10 nonaisostearate is not phototoxic or a photosensitizer.

Read across

Read across Similar chemical structures

Reference ID:

S-345 Final Report: Safety assessment of polyglyceryl fatty acid esters as used in cosmetics. Cosmetic Ingredient Review, November 14, 2016. Available at https://www.cir-safety.org/

7.10.2 Phototoxicity: photomutagenicity / photoclastogenicity

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

7.10.3 Other relevant human studies (clinical)

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

7.11 Special investigations

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

7.12 Summary and NOAEL statement

Based on the data presented in chapter 7.1-7.11 a NOAEL value of 2500 mg/kg bw/day for systemic exposure is given for polyglycerol esters of fatty acids such as 'polyglycerol-3 stearate' and 'polyglycerol-3 ricinoleate'.

8 Ecological data

8.01 Degradability

Test name:

Biodegradation

Method and laboratory:

Biodegradation was followed by measuring BOD/ThOD (biological oxygen demand/theoretical oxygen demand) over 28 days in closed bottles using inoculum from a municipal sewage plant.

Test material:

Diglycerol Triglycerol
Tetraglycerol
Diglyceryl esters from caprylate to laurate
Triglyceryl esters from caprylate to laurate

Results:

All tested polyglycerols and polyglyceryl esters were readily biodegradable.

Read across

Read across Similar chemical structures

Reference ID:

S-324 Enzymatic synthesis, surface activity, antimicrobial properties and biodegradability of di- and triglycerol fatty acid esters, J Jpn Oil Soc, 48(7), 681-725, (1999)

Test name:

Biodegradability OECD 301F

Method and laboratory:

OECD 301F Manometric Respirometry Test 1992
Aerobic biodegradability of organic compounds. 28 day study by determination of oxygen demand in a closed respirometer.
Anox-Kaldnes AB, Lund, SE
2009

Test material:

Akoline PGPR, 100%

Results:

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

Read across

Original

Reference ID:

S168 - AnoxKaldnes 09-29-2

Test name:

Biodegradability

Method and laboratory:

OECD 301D

Test material:

Polyglycerol-3

Results:

Readily biodegradable

Read across

Read across Similar chemical structures

Reference ID:

S-352 ECHA, REACH registration 'Reaction mass of 3-[3-(2,3-dihydroxypropoxy)-2-hydroxypropoxylpropane-1,2-diol...',
https://echa.europa.eu/registration-dossier/-/registered-dossier/13319
Accessed 2020-08-18

Test name:

Biodegradability

Method and laboratory:

OECD 301F

Test material:

Polyglycerol-3 caprate/laurate
(read-across from polyglycerol-3 caprylate/caprinate)

Results:

Readily biodegradable

Read across

Read across Similar chemical structures

Reference ID:

S-353 ECHA, REACH registration 'Reaction products of decanoic acid and lauric acid with glycerol and polyglycerol',
https://echa.europa.eu/registration-dossier/-/registered-dossier/25834
Accessed 2020-08-18

Test name:

Biodegradability

Method and laboratory:

OECD 301F

Test material:

Polyglycerol-3 caprate

Results:

Readily biodegradable

Read across

Read across Similar chemical structures

Reference ID:

S-354 ECHA, REACH registration '1,2,3-propantriol, homopolymer, decanoate', CAS 74504-65-7

https://echa.europa.eu/registration-dossier/-/registered-dossier/23621
Accessed 2020-08-18

Test name:

Biodegradability

Method and laboratory:

OECD 301B

Test material:

Polyglycerol-3

Results:

Readily biodegradable

Read across

Read across Similar chemical structures

Reference ID:

S-355 ECHA, REACH registration '1,2,3-propantriol, homopolymer', CAS 25618-55-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/14285
Accessed 2020-08-18

8.02 Accumulation

Polyglycerol and polyglycerol esters of fatty acids as well as relevant read-across substances are readily biodegradable. They are generally easily hydrolyzed to free fatty acids, polyglycerols and glycerol by aquatic and soil microorganisms. The fatty acids, polyglycerols 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:

Aquatic toxicity

Method and laboratory:

OECD 203 (Fish)
OECD 202 (Daphnia)
OECD 201(Algae, Pseudokirchneriella subcapitata)

Test material:

Polyglycerol-3

Results:

LC50(96h, Fish): >1000 mg/l
EC50(48h, Daphnia): >1000 mg/l
NOEC(96h, Algae): 1000 mg/l

Read across

Read across Similar chemical structures

Reference ID:

S-352 ECHA, REACH registration 'Reaction mass of 3-[3-(2,3-dihydroxypropoxy)-2-hydroxypropoxylpropane-1,2-diol...',
https://echa.europa.eu/registration-dossier/-/registered-dossier/13319
Accessed 2020-08-18

Test name:

Aquatic toxicity

Method and laboratory:

OECD 203 (Fish)
OECD 202 (Daphnia)
OECD 201(Algae, Pseudokirchneriella subcapitata)

Test material:

Polyglycerol-3 caprate/laurate
(read-across from polyglycerol-3 caprylate/caprinate)

Results:

LC50(96h, Fish): 32mg/l
EC50(48h, Daphnia): 32.1 mg/l
NOEC(72h, Algae): 50 mg/l
EC50(72h, Algae): 100 mg/l

Read across

Read across Similar chemical structures

Reference ID:

S-353 ECHA, REACH registration 'Reaction products of decanoic acid and lauric acid with glycerol and polyglycerol',
https://echa.europa.eu/registration-dossier/-/registered-dossier/25834
Accessed 2020-08-18

Test name:

Aquatic toxicity

Method and laboratory:

QSAR VEGA SarPy/IFRMN 1.02 (Fish)
OECD 202 (Daphnia)
OECD 201(Algae, Pseudokirchneriella subcapitata)

Test material:

Polyglycerol-3 caprate

Results:

LC50(QSAR Fish): 1-10 mg/l
EC50(48h, Daphnia): 15.1 mg/l
NOEC(72h, Algae): 10 mg/l
EC50(72h, Algae): 56.7 mg/l

Read across

Read across Similar chemical structures

Reference ID:

S-354 ECHA, REACH registration '1,2,3-propantriol, homopolymer, decanoate', CAS 74504-65-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/23621
Accessed 2020-08-18

Test name:

Aquatic toxicity

Method and laboratory:

OECD 203 (Fish)
OECD 202 (Daphnia)
OECD 201(Algae, Pseudokirchneriella subcapitata)

Test material:

Polyglycerol-3

Results:

LC50(96h, Fish): >500 mg/l
EC50(48h, Daphnia): >1000 mg/l
EC50(72h, Algae): >1000 mg/l

Read across

Read across Similar chemical structures

Reference ID:

S-355 ECHA, REACH registration '1,2,3-propantriol, homopolymer', CAS 25618-55-7
https://echa.europa.eu/registration-dossier/-/registered-dossier/14285
Accessed 2020-08-18

8.04 Summary of ecotoxicity

The polyglycerol esters of fatty acids 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	No data
TSCA (U.S.)	Toxic Substances Control Act	No data
DSL (Canada)	Domestic Substances List	CAS number 68936-89-0 listed at NDSL, All three CAS numbers listed at ICL list and valid to be used
AICS (Australia)	The Australian Inventory of Chemical Substances	Listed (CAS 29894-35-7)
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	CAS 68936-89-0 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.	No data
Japan	Japan Pharmacopoeia	No data
KECI (South Korea)	Korea Existing Chemicals Inventory	No data
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Listed (CAS 29894-35-7)
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Listed (CAS 29894-35-7)
NECI (Taiwan)	National Existing Chemical Inventory	Listed (CAS 29894-35-7)
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 PGPR™

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.

Cans: 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

Cans: Melt the whole content until at least 35C

Reseal packaging and store in 20C or below

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 cans, 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 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

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Ship-to -

Analytical Certificate

Delivery	**81399510 - 30**
Print date	2023-11-23
Your reference	
Our reference	Angelique Mazur
Material	8616-801 Akoline PGPR™
Your material no.	
Date of shipment	2023-11-23

Batch 4014305551 / **Quantity** 25 KG / **Prod. date** 2022-11-24
Inspection lot 3107925 / **Best before** 2024-05-24

Characteristic	Result		Lower Limit	Target	Upper Limit
Iodine value(JT LB)					
Iodine value	81,0		72,0		103,0
Acid value(Syratal LB)					
Acid value	0,80	mg KOH/g			6,00
Saponification value(Försåpn Tal LB)					
Saponification value	183	mg KOH/g	170		190
Hydroxyl value(Hydroxyltal LB)					
Hydroxyl value	83,0	mg KOH/g	80,0		100,0

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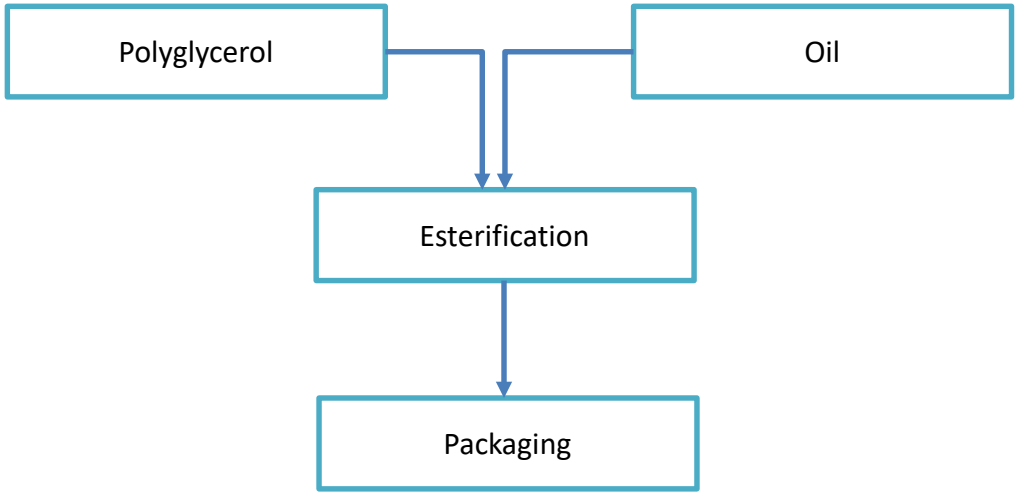
Flowchart Akoline PG7



Flowchart
Akoline PGPR