



Product Documentation

Akocare Coconut Oil™

7716

Version

Date 2024-01-12

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.

A handwritten signature in blue ink, appearing to read 'Staffan Norberg', followed by a large, stylized blue checkmark or 'L' shape.

Head of Development AAK-PC

Staffan Norberg

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1.1 Identification

Producer: AAK Sweden AB, Västra kajen SE-374 82 Karlshamn, Sweden
Tradename: Akocare Coconut Oil™
Art. No: 7716
Country of Origin: Sweden

This product is used globally. As the product may fit in the definition of several CAS numbers, AAK give examples of alternative CAS number to be used for instance in inventory lists search.

	INCI	CAS Number	EC number
EU /AAK first choice	Cocos Nucifera	8001-31-8	232-282-8
US	Cocos Nucifera (Coconut) Oil	8001-31-8	232-282-8
China*	椰子 (COCOS NUCIFERA) 油	8001-31-8	232-282-8
Alternative INCI	Glycerides, C8-18 and C18- unsatd.	67701-28-4	266-946-3

*) For NMPA information see section 9.2.2 China – NMPA

	Chemical name	CAS Number	EC number
Other relevant CAS numbers which not used as INCI.	Glycerides, C16-18 and C18-unsatd.	67701-28-4	266-946-3

Margrét Viborg
Global Regulatory Affairs Manager

2.1 Specifications

For specification see Product Data Sheet

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2.2 Typical values

For typical values see Product information

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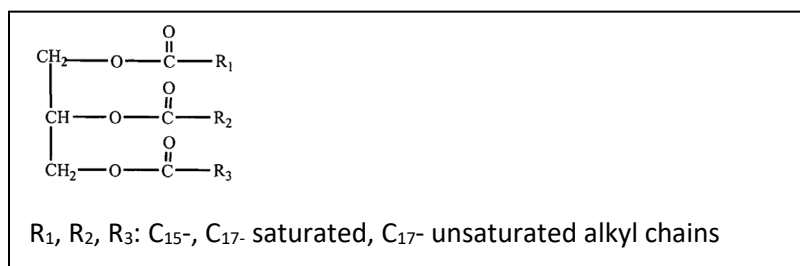
2.3 Certificate of Analysis

For example, of COA, Not available

2.4 Auxiliary chemical and physical data

Molecular weight ~880 g/mol

Structure



For other Chemical and Physical data,

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3.1 Biological data

Botanical origin

INCI	Botanical origin	^{*)} Geographical origin	Part used	Content %	Wild grown or cultivated
<i>Cocos Nucifera</i>	Copra	Phillipines	Fruit flesh	100	Cultivated

^{*)}Geographical origin may change

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
Cocos Nucifera Oil (EU)	8001-31-8	232-282-8	100	Emollient

Palm content

☐ Containing palm

☐ RSPO SG:

☐ RSPO MB:

☒ Do not contain Palm



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

4.1 Production data

For flowchart, see Appendix.

The following operations are used in the processing of this ingredient

Process		Comment
Mechanical extraction	X	
Solvent extraction		
Refining	X	
Deodorizing	X	
Hydrogenation		
Interesterification		
Esterification		
Winterization		
Solvent Fractionation		
Dry Fractionation		
Ethoxylation		
Molecular distillation		
Other processing		

5. BY-PRODUCTS AND OTHER IMPURITIES

5.1 AAK Contaminant standard

AAK utilizes HACCP/CCP methodology to identify relevant hazardous substances for vegetable oils and the critical points throughout 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 maximum 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 71 hours

Storage @ 20C

Peroxide value 12 month: 0,3 24 month: 0,5

Storage @ 40C

Peroxide value 12 month: 1,8 24 month: 3,8

7 Human Health and Environmental Hazard Assessment

Akocare Coconut Oil

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, 2008

Test material

Coconut oil
Hydrogenated coconut oil
Coco-glycerides
Hydrogenated coco-glycerides

Results:

Coconut oil and related ingredients are safe as cosmetic ingredients in the practices of use and concentrations described in this safety assessment.

Comments:

The Expert Panel stresses that pesticide residues and heavy metals should be minimised and that aflatoxin may not be present in coconut oil and its' derivatives.

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S182 - CIR Final report on coconut oil 2008

Test name:

CIR Safety Report

Method and laboratory:

Toxicological summary and conclusion by the CIR expert panel, 2011

Test material

Coconut oil
Hydrogenated coconut oil
Hydrogenated coco-glycerides

Results:

Coconut oil and related ingredients are safe as cosmetic ingredients in the practices of use and concentrations described in this safety assessment

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S181 - CIR Final report on coconut oil 2011

Cosmetic ingredients based on vegetable oils and fats are composed mainly of triglycerides containing a glycerol backbone esterified to linear saturated fatty acids with a carbon chain length of C8-C18 as well as unsaturated C18 fatty acids. The toxicology and toxicokinetics of glycerides and fatty acids are well known as a result of their widespread and long-term use in nutritional (food and feed), personal care and industrial applications.

For human health hazard assessment and read-across purposes a system based on the fatty acid composition is used by REACH as a method to systematize the classification of vegetable oils and fats, in order to minimize the number of individual registrations and Chemical Safety Reports needed for an accurate safety assessment. The chemical, physical and metabolic behavior of vegetable oils and fats from different sources are sufficiently similar to allow for such a simplification (Appendix S001) This system is based on the "Soaps and Detergents Association" nomenclature which gives a category description for different types of lipids, with varying chain lengths and functional groups (Appendix S002). In this report the following "Glycerides, C16-C18 saturated, C18 unsaturated" with the SDA Reporting Number 11-001-00 ("SDA-11") is frequently used for read-across purpose. In a few cases, "Glycerides, C8-C18, C18 unsaturated", SDA reporting number 01-001-00, and "Glycerides, C16-C18", SDA reporting number 19-001-00, are referenced if appropriate information has not been found for the SDA-11 category.

7.02 Acute toxicity

7.02.1 Acute oral toxicity

Test name:

Acute oral toxicity

Method and laboratory:

Species: rat

Oral administration by gavage

Palm oil was administered at a single dose of 5,000 mg/kg bw to 5 rats

Test material

Palm oil

Results:

LD50: > 5,000 mg/kg bw

Read across

Read across Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Reference ID:

S003 – safety assessment of palm oil and derivatives, CIR 2000

Several vegetable oils have been tested for acute toxicity in rats and found to have an LD50 > 5,000 mg/kg bw/day. They are widely used as food ingredients and have a very long history of safe use, so that no acute oral toxicity is expected.

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 20°C), the probability of inhalation exposure to 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)' and other vegetable fats will be extremely limited. Acute inhalation exposure is therefore not expected to pose an issue

for human health under normal and foreseeable handling and use conditions (Annex VIII, Section 8.5, column 2 of the REACH regulation).

7.02.3 Acute dermal toxicity

Test name:

Acute dermal toxicity

Method and laboratory:

Species: guinea pig

Vehicle: no vehicle

Single dose 3,000 mg/kg bw applied dermally to guinea pigs and the animals observed for 7 d.

Test material

Fully hydrogenated coconut oil

Results:

LD50: > 3,000 mg/kg bw;

LD0: = 3,000 mg/kg bw

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S004 – Safety assessment of coconut oil and derivatives, CIR 1986

‘Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)’ and other vegetable fats are not toxic via the oral route and have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications, so that acute dermal toxicity is not expected.

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

Substances identified as ‘Glycerides, C8-18 saturated and C18-unsatd. (SDA Reporting Number: 01-001-00)’, including coconut oil and other 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. 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 repeated insult patch test (HRIPT)

Method and laboratory:

48 subjects (male/female), Induction: 9 consecutive applications on the back over 3 weeks, Challenge: 2 weeks after final application, scoring 24 and 72 hours post-application (Protocol 1.01S).

Consumer Product Testing Co., Fairfield, NJ, US, 2011

Test material

Kristal (Refined Coconut Oil) 50% in High Oleic Sunflower seed oil (Akosun).

Results:

Under the conditions of this study, the test material did not indicate a potential for dermal irritation or allergic contact sensitization.

Read across

Original

Reference ID:

S106 - C11-3035.01

Test name:

Human repeated insult patch test (HRIPT)

Method and laboratory:

109 subjects (male/female), Induction: 9 consecutive applications on the back over 3 weeks, Challenge: 2 weeks after final application, scoring 24 and 72 hours post-application (Protocol 1.01).

Consumer Product Testing Co., Fairfield, NJ, US, 2008

Test material

Lipex Palmkernel 38, 100%

Results:

Under the conditions of this study, the test material did not indicate a potential for dermal irritation or allergic contact sensitization.

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S115 - C08-3807.03

Test name:

Human Repeat Insult Patch Test

Method and laboratory:

50 subject human repeat insult patch test, 5 male/43 female, 9 exposures
BioScreen Testing Services, Inc, Torrance, CA, US
BCS: 15-617A/907101

Test material

Akosoft 36 100%

Results:

Under the conditions of this study, there were no identifiable signs or symptoms of primary irritation or sensitization (contact allergy) noted for the material.

Comments:

INCI: Hydrogenated Coco-glycerides

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S100 - BCS 15-617A/907101

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:

Eye and mucous membrane irritation by HET-CAM test

Method and laboratory:

Evaluation of the irritancy potential utilising the HET-CAM test.

0.3 ml/o.3 mg of test article is administered to 4 chorioallantoic membranes from hen's eggs.

The reactions are scored according to a fixed scale and the total score (max 32) is reported.

Consumer Products Testing Co, Fairfield, NJ, USA, 2011

Test material

Kristal (refined and deodorised coconut oil), 25% in corn oil (50%)+ high oleic sunflowerseed oil (25%)

Results:

Under the conditions of this test, the test article has practically no ocular irritation potential in vivo

Read across

Original

Reference ID:

S142 - CP V11-3043-1

In view of the results from HET-CAM testing and available literature data, no corrosivity to the eye or mucous membranes is expected for this substance category.

7.03.3 Summary and discussion on irritation and corrosivity

Substances identified as 'Glycerides, C8-18 saturated and C18-unsatd. (SDA Reporting Number: 01-001-00)', including coconut oil and other vegetable oils and fats of similar composition, 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 and eye irritation and/or corrosiveness are not considered to pose an issue for human health under normal and foreseeable handling and use conditions.

7.04 Skin sensitization

Test name:

Presence of known food allergens

Results:

Known food allergens are not present in refined vegetable oils

Read across

Statement

Reference ID:

S011 - AAK statement on food allergens

Test name:

Presence of allergens according to EC 1223/2009 Annex III

Results:

Known fragrance allergens are not present in refined vegetable oils

Read across

Statement

Reference ID:

S012 - AAK statement on fragrance allergens

Test name:

Allergenicity and sensitization

Method and laboratory:

Human study, 12 subjects, double blind randomized pilot study. Participants had known allergies to cocamidopropylbetain.

Test material

Coconut oil, 100%

Results:

Coconut oil is not an allergen at 100% concentration

Comments:

Cited in CIR Report on the safety assessment of Cocos nucifera (coconut oil) 2011.

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S180 - Shaffer et al (2006)

7.04.1 Summary and discussion of sensitisation

Substances identified as 'Glycerides, C8-18 saturated and C18-unsatd. (SDA Reporting Number: 01-001-00)', including coconut and palmkernel oil and other vegetable oils and fats 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:

47 week feeding study

Method and laboratory:

Species: rat (Wistar) male/female

Dosage: 18.5% (nominal in diet)

Vehicle: no vehicle

Duration: 47 wks (daily ad libitum)

A 47 wk repeated dose study was conducted to compare the effects of various sources of dietary fat. Bodyweight gain and food intake, fat absorption, cholesterol levels and other parameters were measured during the course of the study. At termination, various organs were weighed, and liver and intestine were examined histologically.

Test material

Coconut oil

Oleo oil

Butter fat

Corn Oil

Safflower oil

Results:

NOAEL: 18.5% in diet (i.e. Ca. 9,250 mg/kg bw/day)

No effects on bodyweight gain, caloric efficiency, mortality, organ weights and histopathology of liver and intestine. The plasma cholesterol and liver lipid, phospholipids and cholesterol level were also not markedly different between the groups

Comments:

Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001- 00)

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S014 – Nutritional evaluation of fats, Harkins 1968

Test name:

90 days feeding study

Method and laboratory:

Species: Wistar rat male/female

Dosage: 10% (nominal in diet)

Vehicle: no vehicle

Exposure: 90 days (daily)

Groups of 30 weanling rats were fed diets containing 10% of crude palm oil, groundnut oil or refined palm olein oil and adequate amounts of all other nutrients for 90 days. Food intake and bodyweight were monitored weekly. At the end of the experiment, cholesterol and triglycerides of serum, liver and heart of all animals were analysed.

Test material

Palm oil

Results:

NOAEL: 10% in diet (i.e. ca. 5,000 mg/kg bw/day)

No effects on growth rate, feed efficiency ratio, protein efficiency ratio, net protein utilization, digestibility, fat absorption, nitrogen balance, phosphorous and calcium retention, lipid profiles, serum enzymes and blood hematology

Read across

Read across Read across from typical food grade vegetable oils (palm oil, SDA11)

Reference ID:

S015 – Nutritional evaluation Palm oil, Manorama 1991

Test name:

Repeated dose 90 day oral toxicity

Method and laboratory:

Species: rat (Sprague-Dawley) male/female

Dosage: 19% (nominal in diet)

Vehicle: no vehicle

Exposure: 91 d (Daily ad libitum)

Equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Test material

Soybean oil

Results:

NOAEL: 19% in diet (i.e. ca. 9,500 mg/kg bw/day)

No treatment-related effects on any of the parameters recorded

Read across

Read across Read across from typical food grade vegetable oils (soybean oil, SDA11)

Reference ID:

S018 – Biological evaluation hydrogenated rapeseed oil, Nolen 1981

7.05.2 Inhalation studies

No studies could be located on the repeated dose inhalation toxicity of vegetable oils and fats. However, given their physical state (solid to semi-solid to liquid under environmental conditions), low vapour pressure (< 0.001 Pa at 20°C) and the fact that they are not handled or marketed as a powder, 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).

7.05.3 Dermal administration

No studies have been located on the repeated dose dermal toxicity of vegetable oils and fats. 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 relevant routes of exposure for 'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' or for coconut oil, palmkernel oil or other vegetable oils and fats in the same read-across category.

7.05.5 Human studies

Substances identified as 'Glycerides, C8-18 saturated and C18-unsatd. (SDA Reporting Number: 01-001-00)', 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

Vegetable oils and fats, including coconut and palmkernel oil, are a component of a normal diet. Although differences may be observed on bodyweight gain, food consumption and certain measured 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 (i.e. typically up to the equivalent of 35% of calories in food), there are no adverse effects on health and longevity.

For risk assessment purposes, the relevant oral NOAEL is considered to be 18.5% in diet, which is equivalent to an estimated 9,250 mg/kg bw/day.

7.06 Reproduction toxicity

7.06.1 Non-human studies

Test name:

13 week combined repeated dose and reproduction study

Method and laboratory:

Species: rat (Sprague-Dawley), male/female

Combined repeated dose and reproduction/developmental screening

Dosage: 15% (nominal in diet)

Vehicle: no vehicle
Exposure: 13 weeks (Daily)

Groups of 10 male and 30 female rats were fed during 13 weeks with diets containing 15% crude palm oil. Other groups received diets with heated palm oil, crude/heated soy oil, crude/heated peanut oil or crude/heated sunflower oil at the same concentration. Clinical signs and bodyweight were recorded

Test material

Palm oil, Soybean oil, Sunflower seed oil, Peanut oil

Results:

NOAEL: 15% in diet (male/female) (i.e. from 17,000 - 7,000 mg/kg bw/day, as the bodyweight of animals increased regularly over the course of the study.)

Read across

Read across Read across from typical food grade vegetable oils (SDA11)

Reference ID:

S016 – Toxicology and nutrition of heated oils, Coquet 1977

Test name:

Multigeneration reproduction study

Method and laboratory:

Species: rat (Wistar) male/female

Dosage: 10% (nominal in diet)

Vehicle: no vehicle

Exposure: 3 generations (Daily)

Groups of 24 (12 male and 12 female) inbred weanling albino rats were given a diet containing 10% of the tested fats and oils. Bodyweight and food intake were recorded weekly for 15 weeks. Fertility index or conception rate, sex ratio, mean weaning weight, pre-weaning mortality, number of days from introduction of mating, behaviour of pups and adults were recorded for generation F0 to F3.

Test material

Red palm oil, Groundnut oil, Palm oleins, Hydrogenated vegetable oil

Results:

NOAEL (all generations): 10% in diet (male/female), (i.e. ca. 5,000 mg/kg bw/day)

No significant adverse effect were observed on any of the reproductive or toxicological parameters

Read across

Read across Read-across from typical food grade vegetable oils (SDA11)

Reference ID:

S027 Multigeneration study vegetable oils, Manorama 1993

Test name:

Two generation reproduction toxicity study

Method and laboratory:

Species: rat (Sprague-Dawley)

Dosage: 15% (nominal in diet), daily ad libitum

Vehicle: no vehicle

Exposure: F0 generation: from weaning
F1 generation: from conception

Developmental toxicity/teratogenicity potential was observed in groups of 25 pairs of two generations of male and female rats. The first two litters of each generation were permitted to be born naturally. During the third pregnancy of each generation, one half of the females were sacrificed on Day 13 of gestation and inspected for early embryonic death. The remaining females were sacrificed on Day 21 of gestation, and the fetuses were examined for either skeletal or soft tissue abnormalities.

Test material

Partially hydrogenated soybean oil

Results:

NOAEL (maternal toxicity): 15% in diet (i.e. ca. 7,500 mg/kg bw/day).

No effects on following parameters: Growth and food consumption, gross pathology, organ weights, histopathology, average conception rate, number of corpora lutea, implantations and resorptions.

NOAEL (developmental toxicity): 15 % in diet.

No effects on following parameters: Sizes of litters at birth, stillbirths, live births, postnatal mortality, weight gain, skeletal variations / defects and soft-tissue abnormalities

Read across

Read across Read across from typical food grade vegetable oils (SDA11)

Reference ID:

S028 Reproduction study hydrogenated soybean oil, Nolen 1972

Taken together, the above weight of evidence suggests that 'glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)', including coconut oil, palmkernel oil and other vegetable oils and fats 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, as well as the fact that they are not handled or marketed as a powders, reproductive toxicity as a result of inhalatory exposure is not likely. Across the reported studies, tested doses ranged from 10 to 15% in diet. No significant toxicity was seen at any of the doses. For risk assessment purposes, the highest oral NOAEL could be considered to be 15% in diet which is equivalent to an estimated 7,000 mg/kg bw/day, on the basis of a 13-week combined repeated dose and reproduction / developmental screening (feeding) study.

7.06.2 Human studies

'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' 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, 'glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)', including coconut oil, palmkernel oil and other vegetable oils and fats in the same read-across category, are not assessed to be reproductive toxicants and no further

consideration for this endpoint is required.

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

It can be concluded from the data presented in Section 7.6.1 and 7.6.2 that vegetable oils and fats do not present any reproduction toxicity at daily intakes of less than 7500 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:

Bacterial reverse Mutation Assay (OECD 471)

Method and laboratory:

Salmonella typhimurium standard plate incorporation study, with and without S9 metabolic activation. Study strains: TA98, TA100, TA 1535 and TA1537.

Test concentrations were 1.581, 5, 15,81, 50, 158.1, 500, 1581 and 5000 microgram/plate.

CiToxLab Hungary, Szabadsagpuszta, Hungary

Test material

Akosoft 36, 100%

Results:

The test item had no mutagenic effect in the examined bacterial strains under the test conditions of this study.

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S149 - CiToxLab 15/249-007M

Test name:

Bacterial Reverse Mutation Assay, Ames Test (OECD 471)

Method and laboratory:

Salmonella typhimurium standard plate incorporation study, with and without S9 metabolic activation. Study strains: TA97a, TA98, TA100, TA102 and TA 1535.

0.05, 0.1, 0.5, 1.0 and 5.0 mg/plate.
Consumer Products Testing Co, Fairfield, NJ, USA
2008

Test material

Lipex Genova™, Lipex Omega 3/6™, Lipex Palmkernel 38, Lipex Shea Betaine™, Lipex Shea Q, all at 100%

Results:

There is no detectable genotoxic activity associated with any of the test articles at non-cytotoxic test concentrations.

Comments:

Cytotoxic concentrations vary with the test material (Lipex Shea Q > 0.05 mg/plate, Lipex Shea Betaine > 0.1 mg/plate, Lipex Omega 3/6 > 1.0 mg/plate, Lipex Palmkernel 38 and Lipex Genova > 5.0 mg/plate))

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S132 - CP M08-3813

The above evidence, collected from in vitro tests on materials from the same read-across category, 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 'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)', including coconut oil, palmkernel oil and other vegetable oils and fats, 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

'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' 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. Taken together the above facts suggests that mutagenicity is not expected to pose an issue for human health and no further consideration for this endpoint is required.

7.07.4 Summary and discussion of mutagenicity

'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' and other structurally similar substances from the same read-across category did not exhibit any genotoxic activity in bacterial reverse mutation (Ames) assays. This evidence, added to the very long history of safe use of these substances in nutritional (food and feed), cosmetic and industrial uses, suggests that 'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)', including coconut oil, palm kernel oils and other vegetable oils and fats of similar origin and composition, do not have a mutagenic potential.

Based on the above information, the substance does not qualify for mutagenicity

classification according to Directive 67/548/EC or Regulation 1272/2008/EC.

7.08 Carcinogenicity

7.08.1 Non-human studies

Test name:

6 month feeding study

Method and laboratory:

Species: rat (Sprague-Dawley) female

Dosage: oral, 20% (nominal in diet)

Vehicle: No vehicle

Exposure: Approximately 6 months (Daily)

A study was conducted to investigate whether palm oil, as a dietary fat, has an impact on mammary carcinogenesis in female rats induced by DMBA.

Groups of 32 female rats were given one single dose DMBA (7.5 mg p.o.) and after 1 wk the rats were switched to a 5% corn oil control diet for the rest of the experiment.

Test material

Palm oil

Results:

NOAEL = 20% in diet (i.e. ca. 10,000 mg/kg bw/day)

Non-promoting effect on chemically induced mammary carcinogenesis in female rats

Read across

Read across

Read-across from typical food grade vegetable oils (palm oil, SDA11)

Reference ID:

S030 Tumorigenic effect of vegetable oils, Sylvester 1986

Test name:

5 months feeding study

Method and laboratory:

Species: rat (Sprague-Dawley) female

Dosage: oral, 20% by weight (nominal in diet)

Vehicle: no vehicle

Exposure: 6 months (daily)

A study was conducted to investigate whether palm oil has an impact on mammary carcinogenesis in female rats induced by DMBA. Groups of 20 female rats were given one single dose DMBA and after three days were fed with semi-synthetic diets containing 20% various fats and oils, for a duration of 5 months. At autopsy, blood was collected from the tumor-bearing rats. The tumors were examined and lipid extractions were made for analysis of fatty acid profile, as well as tocopherols, tocotrienols and carotenes content.

Test material

Palm oil, Corn oil, Soybean oil

Results:

NOAEL = 20% in diet (i.e. ca. 10,000 mg/kg bw/day)

Non-promoting effect on chemically induced mammary carcinogenesis in female rats

Read across

Read across Read across from typical food grade vegetable oils (SDA11)

Reference ID:

S031 Effect of palm oil on mammary tumorigenesis, Sundram 1989

'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' 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, as well as the fact that they are not handled or marketed as a powder, carcinogenicity as a result of inhalatory exposure is not likely.

7.08.2 Human studies

'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' 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 for carcinogenicity in animal models where vegetable oils and fats belonging to the read-across category 'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' have been found. However, this category differs from 'Glycerides, C16-18 and C18-unsaturated (SDA Reporting number 11-001-00)' primarily by the chain length and unsaturation of its' constituent fatty acids and read across from this category is therefore relevant and possible. The substances also do not contain any functional groups suggesting carcinogenic activity.

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.

Furthermore, 'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)', 'Glycerides C16-C18 and C18-unsaturated, (SDA Reporting number 11-001-00)' and other vegetable oils of the same read-across category have a very long history of safe use in nutritional (food and feed), cosmetic and industrial applications. In the form of olive oil, corn oil, sunflower oil, etc., they are also frequently employed as vehicles in toxicity studies following international testing guidelines (e.g. OECD) for the evaluation of the repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects

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 (ADME)

Vegetable oils and fats are composed mainly of triglycerides containing a glycerol backbone esterified to linear saturated fatty acids with a carbon chain length of C8-C18 as well as unsaturated C18 fatty acids. The toxicokinetics of glycerides and fatty acids are well known as a result of their widespread use in nutritional (food and feed) applications

7.09.1 Oral administration

Test name:

Feeding study

Method and laboratory:

Species: rat (Wistar), male/female

Dosage: oral, 18.5% in diet

Exposure regime: daily, 47 wks; ad libitum

At intervals during the study, feces were collected, pooled and analyzed for fat content. Net fat absorption was calculated from dietary intake and fecal excretion.

Test material

Coconut oil

Results:

Absorption: 96%

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S014 – Nutritional evaluation of fats Harkins 1968

When taken up orally, triglycerides are split in the intestinal lumen into glycerol and fatty acids with the help of lipases and bile secretions (in a process called lipolysis), then move into the cells lining the intestines (absorptive enterocytes). The triglycerides are rebuilt in the enterocytes from their fragments and packaged together with cholesterol and proteins to form chylomicrons. These are excreted from the cells, collected by the lymph system and transported to the large vessels near the heart before entering the blood. Various tissues can capture the chylomicrons, releasing the triglycerides to be used as a source of energy. When the body requires fatty acids as a source of energy, the hormone glucagon signals the breakdown of the triglycerides by hormone-sensitive lipases to release free fatty acids from the adipose cells (fat cells), the major site of triglyceride accumulation. The fatty acids are then broken down by stepwise elimination of C2-units in the mitochondrial β -oxidation. The C2-units are esterified to acetyl-coenzyme A which directly enters the citric acid cycle where it is converted to carbon dioxide and energy. The extent of absorption in the gastrointestinal system varies depending on the chain length of the fatty acids and their degree of saturation. Generally, short-chain fatty acids are better absorbed than the long chain counterparts. Also, absorption decreases with increasing saturation (S032 MacDonald, 1973; S033 Robinson, 1973).

7.09.2 Dermal administration

No experimental studies have been located for absorption through the dermal route. However, as per Section R.7.12.2 of REACH guidance document R7.C (2014), the extent of dermal absorption may be predicted based on physico-chemical properties, including:

- Water solubility
- Partition coefficient
- Molecular weight / fatty acid chain length (inversely proportional)

Long chain triglycerides (exemplified by 'Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)', shea butters and other vegetable oils and fats) are poorly water soluble (< 10 mg/L), have an estimated log Pow > 6 and a molecular weight of approximately 900 D. As such, uptake into the stratum corneum of skin and further transfer into the epidermis are likely to be low. A default dermal penetration value of 10% can be assumed (REACH guidance document R7.C). However, triglycerides can also be hydrolysed in the skin to free fatty acids and glycerol which are easily absorbed. Thus, for the purpose of safety assessment, the dermal absorption has been assumed to be 100%.

7.09.3 Inhalation route

No significant inhalatory exposure to typical vegetable oils and fats will occur as the substances are either semi-solid to solid under environmental conditions or have a negligible vapour pressure at relevant temperatures.

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:

Comedogenicity

Method and laboratory:

12 volunteers were subjected to 11 consecutive exposures of 48 hours in closed patches. Comedones were counted after follicular biopsy using cyanoacrylate adhesive which was applied to a microscope slide and fixated. Lanolin was used as a positive control and empty patch as the negative. If there is a statistically significant difference between the test sample and the positive control, the test substance is determined to be non-comedogenic.

BioScreen Clinical Services, Inc, Torrance, CA, USA

2015

Test material

Akosoft 36, 100%

Results:

Under the conditions used for this test, the test material was determined to be non-comedogenic.

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S158 - BSC 15-311/907111

The number of studies on comedogenicity for vegetable oils and fats belonging to the read-across category "Glycerides C8-C18, C18 unsaturated (SDA Reporting number 01-001-00)" is too low to permit a generalisation. However, the performed test(s) can be seen as indicative for this category.

7.12 Summary and NOAEL statement

Based on the data presented in Chapter 7.1 to 7.11, the NOAEL is set to 9250 mg/kg bw/day for systemic exposure for 'Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)' and other substances of the same read-across category.

8 Ecological data

8.01 Degradability

Vegetable oils comprise glycerol esters of unbranched, even numbered fatty acids with normally 0-3 double bonds. The ester bonds are hydrolysed in aqueous environments to fatty acids and glycerol. The fatty acids are metabolised by microorganisms by beta-oxidation to smaller fragments and eventually to carbon dioxide. The glycerol is similarly consumed. The hydrolysis of the glycerides 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 triglycerides due to higher solubility in water.

Vegetable oils in general are readily biodegradable in OECD 301 based tests. A typical example of triglyceride biodegradation and its' mechanism is given by Fabig, Hund & Gross, Fat Sci Technol, 91(9), (1989), 357-360.

8.02 Accumulation

Based on the fact that triglyceride based oils are easily hydrolysed to free fatty acids and glycerol by aquatic and soil microorganisms. The fatty acids and the glycerol are easily metabolised by aquatic and soil microorganisms. Therefore the risk of environmental accumulation is regarded as minimal.

8.03 Aquatic toxicity

Test name:

Freshwater alga and cyanobacteria growth inhibition test

Method and laboratory:

OECD TG 201 (2006)

The growth inhibition test was carried out according to the standard on Water Accommodated Fractions (WAFs) of the test substance. No Effect Concentration (NOEC) and Effect Loading Rate (EL) was determined after 72 hours of exposure to the WAFs. *Pseudokirchneriella subcapitata* (green alga) was used for the test.

Toxicon AB, Härslov, SE
2015

Test material

Akosoft 36, 100%

Results:

The test article is non-toxic towards the green alga *Pseudokirchneriella subcapitata* in the test conditions used in this study.

72h EL50 > 100 mg/l

72h NOEC 100 mg/l

Read across

Read across Glycerides, C8-18 and C18-unsatd. (SDA Reporting Number: 01-001-00)

Reference ID:

S179 - Toxicon 041/15



Based on the available information, coconut oil, palmkernel oil and other substances belonging to the read-across category 'Glycerides C8-C18 and C18 unsaturated (SDA Reporting number 01-001-00)', can in general be regarded as non-toxic to freshwater algae and show low acute aquatic toxicity.

9.1 EU

9.1.1 Statement on EU Cosmetic Regulation EC 1223/2009

Latest statement, download "Statement on EU Cosmetic Regulation" at aakpersonalcare.com

9.1.2 EU Cosmetic Regulation EC 1223/2009, Annex II and III

Latest statement, download "Statement on EU Cosmetic Regulation" at aakpersonalcare.com

9.1.3 EU REACH 1907/2006

Latest statement, download "REACH Statement" at aakpersonalcare.com

9.1.4 EU SVHC (Substance of Very High Concern)

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

9.2 Other country specific regulations:

9.2.1 US (California) Proposition 65

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

9.2.2 China – NMPA

Latest statement, download "NMPA Statement" at aakpersonalcare.com

9.2.3 UK REACH

Latest statement, download "UK REACH Statements" at aakpersonalcare.com

9.2.4 Turkey - KKDIK

Latest statement, download "Turkey-KKDIK and SEA Statement" at aakpersonalcare.com

9.2.5 Australia - TGA

Latest statement, download "AAK PC Products and TGA status" at aakpersonalcare.com

9.3 Other non-Country specific regulatory issues

9.3.1 Animal testing

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

9.3.2 Nano particles

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

9.3.3 Nagoya Protocol / Biodiversity and Access Benefit Sharing regulation

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

9.3.4 CITES

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

9.3.5 CMR

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

9.4 Inventory lists

Inventory lists relates to substances already existing in a specific market. The inventory list to the chemical legislation of the country or region. INCI labeling is not related to the chemical legislation. The nomenclature may differ between these two types of regulations hence the wording may change.

In the Table below, column 3:

- 1) Listed means:
 - a. The substance name and CAS number described as “AAK first choice name”, in section “1.1 Identification” is listed and not prohibited in the inventory list of the country.
- 2) Not listed, however CAS. No XXXXX-XX-X is listed and valid to be used.
 - a. The substance name and CAS number described as “AAK first choice name”, section “1.1 identification” is not found but instead the Cas XXXXX-XX-X mentions is listed as well as fits with the chemical description of the product, hence can be used instead.
- 3) No data:
 - a. AAK has not been able to find the substance in the inventory list.

EC (EU)	EC-inventory	Listed
TSCA (U.S.)	Toxic Substances Control Act	Listed
DSL (Canada)	Domestic Substances List	Listed
AICS (Australia)	The Australian Inventory of Chemical Substances	Listed
IECSC (China)	Inventory of Existing Chemical Substances Produced or Imported in China	Listed
IECIC (China)	Inventory of Existing Cosmetic Ingredients in China	Listed
ENCS (Japan)	Combined list of existing and notified chemical substances as the Japanese Existing and New Chemical Substances Inventory.	Not listed, but CAS. No 67701-28-4 is listed and valid to be used.
Japan	Japan Pharmacopoeia	Coconut Oil
KECI (South Korea)	Korea Existing Chemicals Inventory	KE-06159 is listed and valid to be used.
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Listed
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Listed
NECI (Taiwan)	National Existing Chemical Inventory	Listed.
Saudia Arabia	The Saudi Arabian Standards Organisation	Oleum cocois
Malaysia	Chemicals Information Management System	No data
Mexico	Inventario Nacional de Sustancias Químicas	Aceite de coco.
Turkey		Yes. Local name: Hindistancevizi yağı; English name: Coconut oil

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 – Akocare Coconut Oil™

13.1 Transports

No data available

13.2 storage unopen package

Storage to fulfill shelf life:

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

Retest of batch:

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

13.3 Handling of product for use

13.3.1 Use of full package

Recommended melting temperature.

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

Drums: Melt the whole content until fluid or approx. 50C

Buckets: Melt the whole content until fluid or approx. 50C

During processing need to be heated to 60C to remove crystal memory.

13.3.2 Use of full package for partly use

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

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

Drums: Melt the whole content until at least 50C

Buckets: Melt the whole content until at least 50C

Drums and buckets remaining part is left to crystallize in 20C or below and repack if possible, to smaller packaging

If Akocare Coconut Oil™ is repeatedly heated make sure that the material is heated properly to at least 55C every time. The remaining material left to cool may recrystallize and show inhomogeneous appearance but if the material is melted before use, it works fine. It is important that the temperature is high enough: if the material is only heated to i.e. 40C the material may separate into a solid and a liquid fraction and the composition will not be consistent between batches. From an oxidation point of view the restrict the number of heating/cooling cycles, depending on the time the product is kept at high temperature. The more times it is heated/cooled, the shorter the shelf life will be.



Note:

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

14. REFERENCES

14.1 References

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15. DISCLAIMER

15.1 Disclaimer

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Ship-to -

Analytical Certificate

Delivery	81369222 - 20
Print date	2023-09-07
Your reference	
Our reference	Femke den Hartog
Material	7716-510 Akocare Coconut Oil™
Your material no.	
Date of shipment	2023-09-07

Batch 0002524252 / **Quantity** 100 KG / **Prod. date** 2022-04-22
Inspection lot 2932318 / **Best before** 2024-08-22

Characteristic	Result	Lower Limit	Target	Upper Limit
Acid value(IUPAC 2.201(m)) Acid value	< 0,0 mg KOH/g			0,5
Colour Lovibond(Lovibond Tintometer) Colour 5 1/4" Red	0,4			1,0
Peroxide value(AOCS Cd 8b-90(m)) Peroxide value	< 0,1 meq/kg			1,0
Iodine value Hanus(IUPAC 2.205(m)) Iodine value Hanus	8,7			12,0

Quality Control Manager
AAK Sweden AB

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Flowchart

