Product Documentation

Akofine R™

Version
Date 2025-07-15

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:	Akofine R™
Art. No:	7169
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	**Hydrogenated Vegetable Oil**	**68334-28-1**	**269-820-6**
US	Hydrogenated Vegetable Oil	68334-28-1	269-820-6
China*	氢化植物油 Hydrogenated Vegetable Oil	68334-28-1	269-820-6
Alternative INCI	HYDROGENATED RAPESEED OIL	84681-71-0	283-532-8

*) 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, C16-22	68002-70-0	268-083-8

Margrét Viborg
Global Regulatory Affairs Manager

2.1 Specifications

For specification see Product information

Download latest version at http://customer.aakpersonalcare.com/

2.2 Typical values

For typical values see Product information

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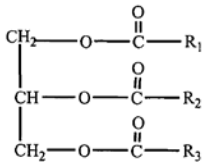
2.3 Certificate of Analysis

For example of COA, see Appendix . C0039

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,

Download latest version at http://customer.aakpersonalcare.com/

3.1 Biological data

Botanical origin

INCI	Botanical origin	*)Geographical origin	Part used	Content %	Wild grown or cultivated
HYDROGENATED VEGETABLE OIL	Brassica Napus	EU	Seeds	100	Cultivated

*)**Geographical origin may change**

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
HYDROGENATED VEGETABLE OIL	68334-28-1	269-820-6	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	X	Hexane
Refining	X	
Deodorizing	X	
Hydrogenation	X	
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 relvant hazardous substances for vegetable oils and the critical points thoughout the handling in order to minimize and control risk.

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

Download latest version at aakpersonalcare.com

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

5.2 Other Impurities specific substances

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

5.3 Impurities AAK Cosmetic Products

5.3.1 Allergens

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.2 Proteins

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.3 VOC – Volatile Organic Compounds

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.4 Sulphonates

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.5 Parabens

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.6 Phthalates

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

5.3.7 Silicones

Download "General statements AAK Cosmetic Ingredients" at aakpersonalcare.com

6.1 Stability Data

OSI Value @ 110C min 100 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

Akofine R

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, 2001

Test material

Tri-saturated triglycerides such as trilaurin, tristearin and tribehenin

Results:

Saturated glyceryl triesters are considered safe as cosmetic ingredients in the present practices of use and concentration.

Read across

Read across	CIR Report - Triglycerides based on saturated fatty acids, such as tristearin and tribehenin.

Reference ID:

S205 Final report on the safety of trilaurin, triarachidin, tribehenin…., Johnson, W., Int J Toxicol, 20(Suppl 4) (2001), 61-94

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-C22 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 systematise the classification of vegetable oils and fats, in order to minimise the number of individual registrations and Chemical Safety Reports needed for an accurate safety assessment. The chemical, physical and metabolic behaviour of vegetable oils and fats from different sources are sufficiently similar to allow for such a simplification. 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.

This report uses the following SDA categories for read across purposes where the chemical and toxicological properties are considered to be sufficiently similar:
“Glycerides, C16-C18 saturated, C18 unsaturated” with the SDA Reporting Number 11-001-00 (“SDA-11”)
“Glycerides, C8-C18, C18 unsaturated”, SDA reporting number 01-001-00 ("SDA-01")
"Glycerides, C16-C18 saturated", SDA reporting number 19-001-00 ("SDA-19")
"Glycerides, C16-C22 saturated", SDA Reporting number 21-001-00 ("SDA-21")

Read-across is also made from studies on saturated triglycerides based on long chain fatty acids, such as tripalmitin, tristearin, tribehenin etc. They share the basic chemical structure with the other categories of triglycerides and are mainly differentiated by their high melting points.

7.02 Acute toxicity

7.02.1 Acute oral toxicity

Test name:

Acute Oral Toxicity

Method and laboratory:

Data reported in CIR Safety Assessment

Test material

Tribehenin
Tristearin

Results:

Tribehenin: LD50 (mice) 5 g/kg bw
Tristearin: LD50 > 20 g/kg bw (rats)

Read across

Read across	Akofine R & Akofine P have similar chemical and physical characteristics as the test substances

Reference ID:

S205 Final report on the safety of trilaurin, triarachidin, tribehenin…., Johnson, W., Int J Toxicol, 20(Suppl 4) (2001), 61-94

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

Test name:

Particle size in powdered fats

Method and laboratory:

The particle size in Akofine powdered fats has been estimated by sieving and microscopy

Test material

Akofine R
Akofine P

Results:

The average particle size in Akofine powdered fats is estimated to be 100 micrometers.

Comments:

There is no data on the respirable fraction in the fat powders but in view of the powdering method used, this is estimated to be low.

Read across

Read across	The respirable fraction of the product is estimated to be low and pose no acute inhalatory toxicity risk

Reference ID:

S192 - AAK internal memo

Based on the physical state (high melting solids under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C), the probability of inhalation exposure to ‘Glycerides,

C16-18 (SDA Reporting Number: 19-001-00)' and 'Glycerides, C16-22 (SDA Reporting number: 21-001-00)' will be limited. The average particle sizes of the powdered versions are large (approx 100-150 micrometer) reducing the inhalation exposure of the powders. 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:

No data available for this test

Read across

No data	High melting triglyceride is not absorbed so acute dermal toxicity is not a concern

'Glycerides, C16-18 (SDA Reporting Number: 19-001-00)' and 'Glycerides, C16-22 (SDA Reporting number: 21-001-00)' 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. They are also high melting limiting their solubility and absorption through the skin, further limiting their dermal toxicity.

7.02.4 Acute toxicity by other exposure routes

There are no other relevant exposure routes for 'Glycerides, C16-18 (SDA Reporting Number: 19-001-00)' or 'Glycerides, C16-22 (SDA Reporting number: 21-001-00)'

7.02.5 Summary and discussion of acute toxicity

Substances identified as 'Glycerides, C16-18 (SDA Reporting Number: 19-001-00)' and 'Glycerides, C16-22 (SDA Reporting number: 21-001-00)' , have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic, pharmaceutical 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:

88 subject human repeat insult patch test, Inveresk Research International, Tranent, Scotland
Report no 12771, 1996

Test material

Cremeol HF-52 (SDA-11)
Cremeol HF-62 (SDA-21)
Cremeol GPO (SDA-11)
Cremeol PS-17 (SDA-11)
Cremeol PS-6 (SDA-11)
tested at 50% in liquid paraffin

Results:

The tested materials produced very low or no irritation during induction. None of the tested materials elicited reactions during the challenge phase.

Comments:

The tested materials are liquid to high melting vegetable oil based triglycerides, conforming to the SDA reporting classes SDA-11 and SDA-21.

Read across

Read across Read-across category: SDA-21 (Cremeol HF-62)

Reference ID:

S207 Inveresk Research International, Report 12771, Project number IRI 588393, "Five vegetable triglycerides and liquid paraffin oil, A human Repeat Insult Patch Test"

Test name:

Skin corrosivity

Results:

In view of the results from the HRIPT testing (above) and literature data no corrosivity to the skin is expected.

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/0.3 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

Akofine R, 5% in high oleic sunflowerseed oil

Results:

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

Read across

Original

Reference ID:

S135 - CP V11-3043-6

Test name:

Eye corrosivity

Results:

In view of the results from the HET-CAM testing (above) no corrosivity to the eye or mucous membranes is expected

7.03.3 Summary and discussion on irritation and corrosivity

Substances identified as ‘Glycerides, C16-18 saturated (SDA Reporting Number: 19-001-00)’, and 'Glycerides, C16-C22 saturated (SDA Reporting number: 21-001-00)' and other similar vegetable oils and fats, have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the tests reported above, skin 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:

No data available for this test

Read across

No data

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

7.04.1 Summary and discussion of sensitisation

Substances identified as ‘Glycerides, C16-18 saturated (SDA Reporting Number: 19- 001-00)’, and 'Glycerides C16-C22 saturated (SDA Reporting number 21-001-00)' and other similar vegetable oils and fats, have a very long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the tests 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

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

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

Fully hydrogenated soybean oil
Fully hydrogenated rapeseed oil (C22:0 44%)

Results:

NOAEL: 7.5% in diet (i.e. ca. 3,750 mg/kg bw/day)

Increased haemoglobin level in males and ovary weights in females without histopathological findings. Slightly increased feed consumption after 4 wks attributed to lower absorbability of fully hydrogenated soybean oil

Comments:

Glycerides, C16-18 (SDA Reporting Number: 19-001-00)
Glycerides, C16-C22 (SDA Reporting number: 21-001-00)

Read across

Read across	Tested substances are fully hydrogenated fats, similar to Akofine R and Akofine P

Reference ID:

S018 – Biological evaluation of hydrogenated rapeseed oil, Nolen, GA, JAOCS, (1981), 31-37

Test name:

91 day feeding study in rats

Method and laboratory:

Species: rat (Sprague-Dawley)
Dosage: 5-15% in diet
Duration: 91 days

A 91 day feeding study in rats was conducted to investigate the safety of a synthetic triglyceride with high content of behenic acid (Caprenin). Survival, clinical signs, body weight, feed consumption etc were evalued as well as histopathology of selected organs.

Test material

Caprenin, a synthetic triglyceride comprising 45% C22, 27% C10 and 23% C8

Results:

No adverse effects were detected, and C22 was not deposited in the fat deposits. The study has determined the NOAEL for the synthetic, high-behenic acid triglyceride, to more than 13.2 g/kg bw/day for male rats and more than 14.6 g/kg bw/day for female rats.

Read across

Read across Tested substance has high level of C22, similar to Akofine R

Reference ID:

S208 A 91 day feeding study in rats with Caprenin, Webb, DR, Wood, FE, Bertram, TA and Fortier, NE, Fd Chem Toxic, 31(12) (1993), 935-946

Due to their high melting points and poor palatability, very few studies on 'Glycerides, C16-C18 saturated (SDA-19)' or 'Glycerides, C16-C22 saturated (SDA-21)' have been carried out. However, a large number of repeated dose oral toxicity studies have been conducted with various vegetable oils and/or animal fats at different degrees of hydrogenation and/or interesterification, particularly in the context of nutritional research. For practical reasons, only a limited number of studies are reported here. Some of these studies have been carried out at elevated levels of the saturated long-chain fatty acids and are consequently also applicable to the SDA-19 and SDA-21 type of materials.

Vegetable oils and fats are a component of a normal human 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 to 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.
Across all studies, tested doses ranged from 7.5 to 19% in diet. No significant toxicity has been observed at any of the tested dose rates. For risk assessment purposes, the relevant oral NOAEL for oils and fats could therefore be considered to be 19% in diet, which is equivalent to an estimated 9,250 mg/kg bw/day.

7.05.2 Inhalation studies

Test name:

No data available for this test

Read across

No data

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), respiratory exposure is not likely to occur. For high-melting saturated fats, that are frequently delivered in powder or flake form, particle size distributions must be considered (see above, Section 7.02.2). Coarse powders, such as the Akofine P and Akofine R, have median particle size of 100 micrometer which is well above the respirable particle sizes (<5 micrometers).

Repeated inhalation exposure is 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

Test name:

No data available for this test

Read across

No data

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, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ or for shea butter and other vegetable oils and fats

7.05.5 Human studies

Test name:

No data available for this test

Read across

No data

Substances identified as 'Glycerides, C16-C18 saturated', 'Glycerides, C16-C22 saturated' and ‘Glycerides, C16-18 saturated and C18-unsatd' (SDA-19, SDA-21 and SDA-11) 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 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

A large number of repeated dose oral toxicity and dietary intervention studies have been conducted with vegetable oils and fats of different origins and at different degrees of hydrogenation and/or esterification in the context of nutritional research as well as in toxicological investigations. 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. up to the equivalent of ca. 35% of total calorie intake, there are no adverse effects on health and longevity. Similar results were obtained for the other substances of the same read-across categories. Across all studies, the highest oral NOAEL could be considered to be 18.5% in feed, equivalent to an estimated 9,250 mg/kg bw/day. This value is considered relevant for risk assessment purposes, although it is only a reflection of the study setup and

not of effects observed at higher doses.

Refined vegetable oils from the relevant read-across categories present low systemic toxicity upon repeated dose oral exposure for which absorption is higher than via the dermal route, so that repeated dose dermal toxicity is also expected to be minimal. Furthermore, given its physical state (solid to semi-solid under environmental conditions) and low vapour pressures, 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:

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 SDA-11. Similar chemical structures but differing in saturation.

Reference ID:

S027 Multigeneration study vegetable oils, Manorama 1993

Taken together, the above weight of evidence suggests that ‘Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21), including many types of vegetable oils and fats, 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 (semi-solid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C) of the substance, reproductive toxicity as a result of inhalatory exposure is not likely. Across all studies, tested doses ranged from 8.75 to 15% in diet. No significant toxicity was seen at any of the doses rates. 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

Test name:

No data available for this test

Read across

No data

'Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21) 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. Moreover, 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 facts, 'Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21), are not assessed to be reproductive toxicants and no further consideration for this endpoint is required.

7.06.3 Developmental toxicity/teratogenicity

7.06.3.1 Non-human studies

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 SDA-11. Similar chemical structures but differing in saturation

Reference ID:
S028 Effects of fresh and used hydrogenated soybean oil on reproduction and teratology in rats, Nolen, GA, JAOCS, 49(12), (1972), 688-693

Across all studies, tested doses ranged from 8.75 to 15% in diet. No significant toxicity was seen at any of the doses rates. For risk assessment purposes, the highest oral NOAEL could be considered to be 15% in diet, on the basis of a two generation study conducted in rats, which is equivalent to an estimated 7,500 mg/kg bw/day.

7.06.3.2 Human studies

Test name:

No data available for this test

Read across

No data

'Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21) 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. 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 repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, without any apparent adverse effects. Based on the above facts, 'Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21), and other vegetable oils and fats, are not assessed to be developmental toxicants and no further consideration for this endpoint is required

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

Lipex Bassol C™, 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	Read-across from SDA-11. Similar chemical structures but differing in saturation

Reference ID:
S148 - CiToxLab 15/251-007M

The above evidence, collected from in vitro tests on materials from the similar read-across categories, 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, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21), 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

Test name:

No data available for this test

Read across

No data

7.07.4 Summary and discussion of mutagenicity

‘Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21), and other structurally similar substances from the similar read-across categories 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, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21), and other vegetable oils and fats, do not have a mutagenic potential.

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 SDA-11. Similar chemical structures but differing in saturation

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

Reference ID:
S031 Effect of palm oil on mammary tumorigenesis, Sundram 1989

‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ and other substances of the same read-across category have been tested for carcinogenicity in rodents and found to have no effect after oral exposure. The substance also does 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 substance, carcinogenicity as a result of inhalatory exposure is not likely.

‘Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21) are sufficiently similar in structure and chemistry to each other to justify a read-across of the animal data on carcinogenicity.

7.08.2 Human studies

‘Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21) and other substances of similar read-across categories 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 repeated dose toxicity, carcinogenicity or reproductive/developmental toxicity of chemical substances, 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

‘Glycerides, C16-18 and C18-unsatd. (SDA Reporting Number: 11-001-00)’ and other substances of the same read-across category have been tested for carcinogenicity in rodents and found to have no effect after oral exposure. The substance also does 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 substance, carcinogenicity as a result of inhalatory exposure is not likely. Furthermore, ‘Glycerides, C16-18 and C18-unsatd.', 'Glycerides, C16-C18 saturated', and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-19 and SDA-21) and other substances of similar read-across categories 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:

Dietary absorption study in rat

Method and laboratory:

Species: rats
Duration: 16h
Administration: oral, free feeding
Dosage: 25-200 mg fat in a bran pellet

Absorption of radiolabelled tristearin, with or without dilution in triolein was measured by analysis of feces and remaining feed. Similar experiments were carried out with tripalmitin.

Test material

Tristearin
Tripalmitin
Triolein

Results:

Absorption of tristearin in free feeding rats was 22-34 %, depending on dose. Absorption of tripalmitin was 66%. Addition of triolein increased absorption of the trisaturated triglycerides.

The mechanism of absorption and rate limiting steps is discussed in length.

Comments:

Absorption and digestability in the gut is limited by the solubility of the saturated triglycerides. Longer chains decrease solubility and consequently the digestability.

Read across

Read across	Tristearin and tripalmitin are similar in structure and chemistry to Akofine R and Akofine P

Reference ID:

S204 The absorption of tristearin and stearic acid and tripalmitin and palmitic acid. Studies on the rate limiting step in rats. Hamilton, JD, Webb, PJW and Dawson, AM, Biochim Biophis Acta, 176 (1969), 27-36

Test name:

Feeding study

Method and laboratory:

Species: rat (Sprague-Dawley) male/female
Dosage: oral, 15 or 7.5% in diet
Exposure regime: daily, 15 d at 15% or 91 d at 7.5%; ad libitum
Absorption measured by analysis of unabsorbed fecal fat.

Test material

Fully hydrogenated soybean oil
Fully hydrogenated rapeseed oil (C22:0 44%)

Results:

Absorption:
FH Soybean oil
- 6±4% at 15% (15 d)
- 17% at 7.5% (91 d)

FH Rapeseed oil
- 8+/-6% at 15% (15d)
- 18% at 7.5% (91d)

Comments:

Glycerides, C16-18 (SDA Reporting Number: 19-001-00)
Glycerides, C16-C22 (SDA Reporting number: 21-001-00)

Read across

Read across	Akofine R and Akofine P have similar chemical and physical characteristics as the test substances

Reference ID:

S018 – Biological evaluation of hydrogenated rapeseed oil, Nolen, GA, JAOCS, (1981), 31-37

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 gastro-intestinal 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

Test name:

No data available for this test

Read across

No data

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:

No data available for this test

Read across

No data

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, C16-18 (SDA Reporting Number: 19-001-00)' and 'Glycerides, C16-C22 (SDA Reprting number 21-001-00)' as well as other substances of the same read-across category.

8 Ecological data

8.01 Degradability

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
2010

Test material

Akofine P, 100%

Results:

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

Comments:

The degradability exceeds 100% indicating that the COD analysis is underestimated.

Read across

Read across	The product has similar chemical and physical characteristics as the test substances

Reference ID:

S163 - AnoxKaldnes 10-224-1

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. The above facts and the tests performed indicate that 'Glycerides, C16-18 saturated and C18 unsaturated (SDA Reporting number 11-001-00)' can be considered as readily biodegradable.

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. Therefor the risk of environmental accumulation is regarded as minimal.

8.03 Aquatic toxicity

Test name:

No data available for this test

Read across

No data

8.04 Summary of ecotoxicity

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. Based on the fact that triglyceride based oils are easily hydrolysed to free fatty acids and glycerol by aquatic and soil microorganisms, accumulation is not expected.

Toxicity to aquatic organisms is expected to be low, based on read-across from studies on toxicity towards freshwater algae, made on substances from relevant read-across categories (mainly triglycerides from the SDA-11 category (Glycerides, C16-C18 saturated, C18 unsaturated).

Based on the available information, long-chained vegetable oils and similar substances belonging to the read-across categories 'Glycerides C16-C18 and C18 unsaturated', 'Glycerides C8-C18, C18-unsaturated', 'Glycerides C16-C18 saturated' and 'Glycerides, C16-C22 saturated' (SDA-11, SDA-01, SDA-19 and SDA-21) can in general be regarded as biodegradable, non-accumulating and non-toxic to freshwater algae and show low acute environmental 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
AICIS (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.	Listed
Japan	Japan Pharmacopoeia	Hydrogenated oil
KECI (South Korea)	Korea Existing Chemicals Inventory	KE-20177 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	Not listed, but Fats and Glyceridic oils, vegetable, hydrogenated (68334-28-1) is listed and valid to be used.
TCSI (Taiwan)	National Existing Chemical Inventory	Oils, vegetable, hydrogenated
Saudia Arabia	The Saudi Arabian Standards Organisation	No data
Malaysia	Chemicals Information Management System	No data
Mexico	Inventario Nacional de Sustancias Químicas	Not listed but Grasas y aceites glicerídicos, vegetales
Turkey		Yes. Local name: Yağlar, bitkisel, hidrojenlenmiş; English name: Oils, vegetable, hydrogenated

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

No data

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 – Akofine R™

13.1 Transports

No data available

13.2 storage unopen package

Storage to fulfill shelf life:

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

Retest of batch:

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

13.3 Handling of product for use

13.3.1 Use of full package

Recommended melting temperature.

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

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

13.3.2 Use of full package for partly use

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

Reseal packaging and store in 20C or below

If Akofine R™ is repeatedly heated make sure that the material is heated properly to at least 60C 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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S015 Manorama, R and C Rukmini (1991), 'Nutritional evaluation of crude palm oil in rats.', *Am J Clin Nutr*, 53 (4 Suppl), 1031S-3S.

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S029 Carthew, P., P. Baldrick, and P.A. Hepburn (2001), 'An assessment of the carcinogenic potential of shea oleine in the rat', *Food and Chemical Toxicology Food Chem.Toxicol.*, 39 (0278-6915), 807-15.

S030 Sylvester, PW, et al. (1986), 'Comparative effects of different animal and vegetable fats fed before and during carcinogen administration on mammary tumorigenesis, sexual maturation, and endocrine function in rats.', *Cancer Res*, 46 (2), 757-62.

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15. DISCLAIMER

15.1 Disclaimer

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Ship-to -

Analytical Certificate

Delivery	**81394518 - 20**
Print date	2023-11-16
Your reference	
Our reference	Sophie Ramos
Material	7169-805 Akofine R™
Your material no.	
Date of shipment	2023-11-16

Batch 0002661662 / **Quantity** 425 KG / **Prod. date** 2023-04-25
Inspection lot 3205193 / **Best before** 2026-04-25

Characteristic	Result		Lower Limit	Target	Upper Limit
Iodine value(JT Hanus LB)					
Iodine value Hanus	2,4				5,0
Peroxide value(PV LB)					
Peroxide value	0,5	meq/kg			2,0
Acid value(Syratal LB)					
Acid value	< 0,12	mg KOH/g			0,40

Quality Control Manager
AAK Sweden AB

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ZAO K7702 1

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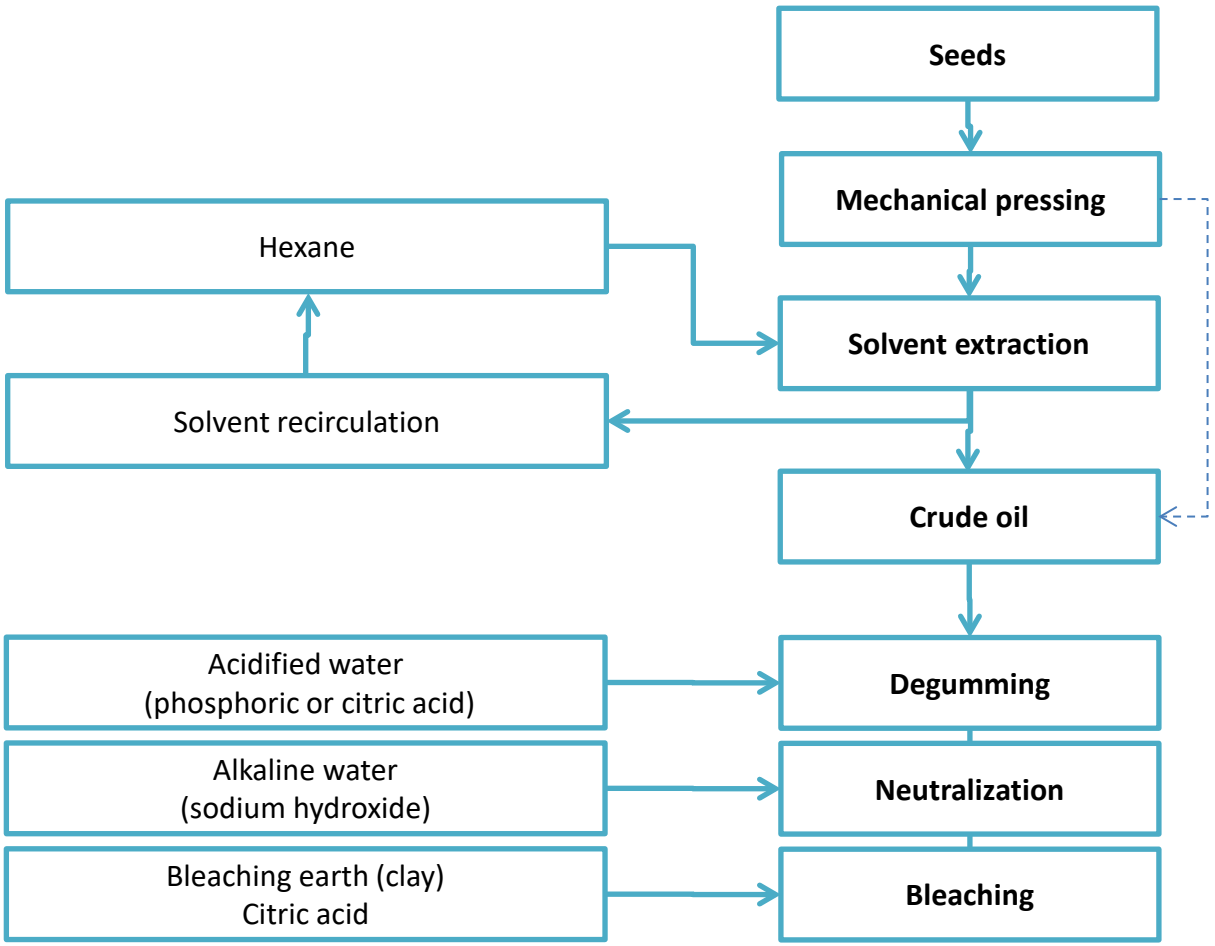
Org. no. : 556478-1796
VAT no. : SE556478179601
Approved for Swedish F-tax
Registered Office: Karlshamn

Flowchart Akofine R



Explanations what each step contribute with

Separates crude oil from seed

Separates crude oil from seed

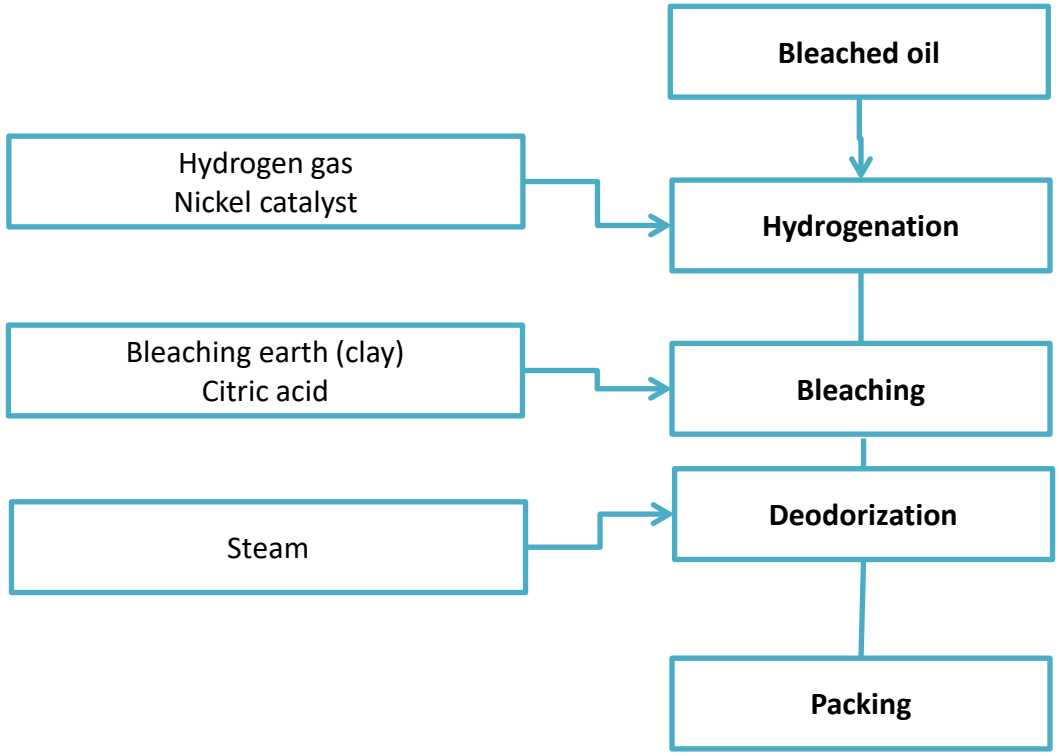
Removes phospholipids, metals and proteins

Removes free fatty acids, metals and proteins

Removes pigments, metals and proteins

See Disclaimer

Flowchart Akofine R



Explanations what each step contribute with

Removes unsaturation by reduing double bonds

Removes pigments, metals, proteins and catalyst traces

Removes flavours, free fatty acids, oxidation products and residual solvent

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