Product Documentation

LIPEX® SheaTris™

8649

Version
Date 2024-02-08

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

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1.1 Identification

Producer:	AAK Sweden AB, Västra kajen SE-374 82 Karlshamn, Sweden
Tradename:	LIPEX® SheaTris™
Art. No:	8649
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	**Butyrospermum Parkii Extract**	**91080-23-8**	**293-515-7**
US	Butyrospermum Parkii (Shea) Butter Extract	91080-23-8	293-515-7
China*	牛油果树（BUTYROSPERMUM PARKII）提取物	91080-23-8	293-515-7
Alternative INCI	OLUS OIL	68956-68-3	273-313-5
	BUTYROSPERMUM PARKII BUTTER UNSAPONIFIABLES	225234-14-0	607-097-4

*) 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.			

Margrét Viborg
Global Regulatory Affairs Manager

2.1 Specifications

For specification see Product Data Sheet (PDS)

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2.2 Typical values

For typical values see Product Data Sheet (PDS)

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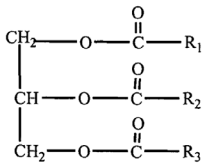
2.3 Certificate of Analysis

For example of COA, see Appendix.

2.4 Auxiliary chemical and physical data

Molecular weight ~880 g/mol

Stucture



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

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

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3.1 Biological data

Botanical origin

INCI	Botanical origin	*)Geographical origin	Part used	Content %	Wild grown or cultivated
Butyrospermum Parkii Butter extractl	Vitellaria Paradoxa	West Africa	Kernels	100	Wild

*)**Geographical origin may change**

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %
Butyrospermum Parkii Butter Extract	91080-23-8	293-515-7	100

Palm content

☐Containing palm

☐RSPO SG: 99051

☐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	
Deodorising	X	
Hydrogenation		
Interesterification		
Esterification		
Winterisation		
Solvent Fractionation	X	Hexane
Dry Fractionation		
Ethoxylation		
Molecular distillation	X	
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.

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

5.2 Other Impurities specific substances

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

5.3 Impurities AAK Cosmetic Products

5.3.1 Allergens

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

5.3.2 Proteins

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

5.3.3 VOC – Volatile Organic Compounds

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

5.3.4 Sulphonates

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

5.3.5 Parabens

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

5.3.6 Phthalates

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

5.3.7 Silicones

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

6.1 Stability Data

OSI Value @ 120C 12 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

Lipex SheaTris™

7.01 General read-across consideration and justification

Test name:

Toxicology summary

Method and laboratory:

Summary submitted to FDA on a shea concentrate used in dietary supplements

Test material

"Shea Nature"

Results:

Internal un-published test results and literature review indicate that the shea concentrate "Shea Nature" is safe for use in dietary supplements

Read across

Read across	Same origin, similar fatty acid profile and similar unsaponifiable content and profile

Reference ID:

S-193: FDA Docket number 95S-0316-rpt0179-vol132 (2003)

Test name:

Toxicology summary

Method and laboratory:

Summary submitted to FDA on two shea concentrates used in dietary supplements

Test material

"Shea Nature"
"BSP-201"

Results:

Internal un-published test results and literature review indicate that the shea concentrates "Shea Nature" and "BSP-201" are safe for use in dietary supplements

Read across

Read across	Same origin, similar fatty acid profile and similar unsaponifiable content and profile

Reference ID:

S-194: FDA Docket number 95S-0316-rpt0233-01-vol161 (2004)

Cosmetic ingredients based on shea butter share a common origin but depending on the processing conditions, the compositions vary. A common denominator is the simultaneous presence of glycerides and unsaponifiable matter. The glycerides are normally triglycerides and diglycerides, comprising saturated fatty acids (stearic and palmitic) as well as unsaturated fatty acids (oleic and linoleic), covered by the SDA Reporting Number 11-001-00 ("Glycerides, C16-C18 saturated, C18 unsaturated", "SDA-11"). The other part of the composition is frequently summarised under the umbrella name of "Shea butter unsaponifiables", comprising a complex mixture of triterpene esters, desmethyl sterols and hydrocarbons. While the toxicology and toxicokinetics of the glyceride part of the composition is well known, the existing data on the unsaponifiable part is scarce.

This report is based on studies made on ingredients derived from shea butter where the content of the unsaponifiable fraction varies from about 8% ("shea olein") to 75-80% ("shea butter concentrate"). The glyceride composition in these ingredients is dominated by tri- and diglycerides of oleic and stearic acid, with less than 15% of linoleic acid and palmitic acid. The unsaponifiable components are dominated by triterpene alcohols such as alpha- and beta-amyrin, lupeol and butyrospermol, in the form of their acetates and cinnamates. The composition of the triterpene esters is similar in all the ingredients covered by this report, it is mainly the concentration that varies.

Actual test data in this report are taken from studies on three different AAK ingredients: Lipex 205 ("shea olein", unsaponifiable content about 8%), Lipex Shea-U (unsaponifiable content about 20%) and Lipex SheaTris ("shea concentrate", unsaponifiable content 60-65%). Read-across is done between these ingredients in cases where it has been considered possible, from chemical and toxicological points of view.

When literature data is cited, it is assumed that the unsaponifiable content and composition matches the data available for Lipex 205 ("shea olein", 8% unsaponifiables) and that the glyceride composition is covered by SDA-11.

7.02 Acute toxicity
7.02.1 Acute oral toxicity

Test name:

Acute Oral Toxicity

Method and laboratory:

Species: Wistar rat, 5 male/ 5 female
Oral administration by gavage
Dose: single administration, 2000 mg/kg bw
Duration: observation at 1, 3 and 6 hours and consecutively for 14 days

Test material

"BSP-201", shea butter concentrate with 50% unsaponifiables

Results:

No adversed effects were found at the given dose. Minimal lethal dose is >2000 mg/kg bw of the test substance

Comments:

Unpublished study, sponsored by BSP Pharma A/S, quoted in FDA submission

Read across

Read across Same origin, similar processing and similar chemical composition

Reference ID:

S-194: FDA Docket number 95S-0316-rpt0233-01-vol161 (2004)

Shea olein with an unsaponifiable content of 8% has been used for a long time as an ingredient in foods and as a cooking oil, without reports of adverse effects. Shea concentrates with an unsaponifiable content up to 80% have been used as dietary supplements, with a daily intake of unsaponifiable material up to 3 g/day, without reports of adverse effects. It is therefor concluded, that ingredients based on shea butter concentrates with unsaponifiable content up to 80% do not pose an issue an acute toxicity concern via the oral route.

7.02.2 Acute inhalation toxicity

Test name:

No data available for this test

Read across

No data

Based on the physical state (semi-liquid to solid under environmental conditions) and low vapour pressure (< 0.001 Pa at 20°C), the probability of inhalation exposure to this substance category is 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:

No data available for this test

Read across

No data

This substance and other similar mixtures of glycerides and unsaponifiables are not toxic via the oral route and have a 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 which comprise natural mixtures of glycerides with unsaponifiable components in concentrations varying from about 8% to 80%, including shea butter concentrates, have a 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:

50 subject human repeat insult patch test, 10 male/40 female, 9 exposures
BioScreen Testing Services, Inc, Torrance, CA, US
BCS: 10-116A / 678588
2010

Test material

Lipex SheaTris™, 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.

Read across
Original
Reference ID:
S118 - BCS 10-116A/678588

Test name:
Human repeated insult patch test (HRIPT)
Method and laboratory:
51 subject human repeat insult patch test, 8 male/43 female, 9 exposures
BioScreen Testing Services, Inc, Torrance, CA, US
BCS: 11-104A / 708042, 2011
Test material
Lipex 205™, 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.

Read across

Read across	Same origin, similar processing. Unsaponifiable content 8%, similar fatty acid profile.

Reference ID:
S109 - BCS 11-104A/708042

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:
In vitro assessment of the acute irritation potential to mucous membranes with the Hen's egg Chorioallantoic Membrane Test.
Test amount 300 microliter/cm2.
Institute Dr Schrader, DE, 2005
Test material
Lipex Shea™,
Lipex CocoaSoft™, Lipex Shea-U™, Lipex PreAct™ tested as Akorex L), diluted to 50% in Akosun (High Oleic Sunflowerseed oil)
Results:
Irritation scores 0.00-0.30
Estimated irritation potential in vivo: “slightly irritant” (irritation score <=0.8)

Comments:

Diluent, Akosun, had 0.0 in Irritation score

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S008 - CCT-05-009

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, 2010

Test material

Lipex SheaTris™, 50% in high oleic sunflower seed oil

Results:

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

Read across

Original

Reference ID:

S139 - CP V10-3701-1

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 which comprise natural mixtures of glycerides with unsaponifiable components in concentrations varying from about 8% to 80%, including shea butter concentrates, have a long history of safe use in a wide range of nutritional (food and feed), cosmetic and industrial applications. Supported by the test results presented in this chapter, skin and/or eye irritation/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:

Literature search

Method and laboratory:

PubMed, PubMed Central & Google Scholar search performed in February 2015

Test material

Search on “Shea butter” (and equivalents) AND “sensitisation”/”allergy” (and equivalents)

Results:

No case reports or other publications found associating shea butter with sensitisation or allergies

Test name:

Protein content

Method and laboratory:

Proteins extracted from the oils and protein content of extracts determined using the Perbio Science Micro BCA protein assay kit.
Leatherhead Food Research, Leatherhead, Surrey, UK, 2011

Test material

Lipex SheaSoft™, Lipex SheaTris™, Lipex L'sens™, all at 100%

Results:

Protein content in microgram/ml:

Lipex SheaTris: 9
Lipex L'sens: 24
Lipex SheaSoft: 41

Read across

Original

Reference ID:

S143 - LFR 125497, July 2011

Test name:

Protein assays

Method and laboratory:

Hoffman extraction method and micro BCA protein assay. Leatherhead Food International, UK, 2009.

Test material

Lipex Shea™, Lipex 205™, Akogreen O, Organic extra Virgin Olive Oil, RBD Organic EV Olive Oil, all 100%

Results:

Estimated concentration of proteins in microgram/ml:

Organic EV Olive oil: 414
Akogreen O: 54
RBD EV Olive oil: 21
Lipex Shea™: 12

Lipex 205™: 12

Read across

Read across — Same origin and similar processing. Protein content strongly dependent on degree of processing.

Reference ID:
S010 - Project Report, LFI 29 April 2009

Test name:

Assay of fragrance allergens in oils (EU Directive 2003/15 CE)

Method and laboratory:

Eurofins Analytik GmbH, Hamburg, DE, 2005

Test material

Lipex Shea-U™, Lipex 205™, Lipex Shea™,

Results:

None of the 26 listed allergens were detected above the detection limit in the test articles

Read across

Read across — Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:
S147 - AR-05-JJ-041876-01, AR-05-JJ-041878-01, AR-05-JJ-041879-01

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 which comprise natural mixtures of glycerides with unsaponifiable components in concentrations varying from about 8% to 80%, including shea butter concentrates, have a 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:

13 week feeding study

Method and laboratory:

Species: rat (Colworth-Wistar) 15 male/15 female
Duration: 13 weeks
Dosage: 20% fat in the diet, including shea olein, corresponding to 700-1100 mg/day of unsaponifiable material from shea butter

Test material

Hydrogenated shea olein
Unhydrogenated shea olein
Palm oil
Soybean oil
Hydrogenated palm oil
Hydrogenated soybean oil

Results:

Shea olein was well tolerated and had no adverse effects on the growing rats. The maximal dose in this study was 1100 mg/kg bw/day of shea butter unsaponifiables.

Read across

Read across	Same origin and similar processing, unsaponifiable content in test product about 8%.

Reference ID:

S013 – Studies to investigate the absorption and excretion of shea oleine sterols in rat and man, Earl LK et al, Int J toxicol, 21, (2002), 353-359

7.05.2 Inhalation studies

Test name:

No data available for this test

Read across

No data

7.05.3 Dermal administration

Test name:

No data available for this test

Read across

No data

7.05.4 Other routes of administration

Test name:

No data available for this test

Read across

No data

7.05.5 Human studies

Test name:

Dietary intervention study in human volunteers

Method and laboratory:

Test group: 100 healthy volunteers aged 45 +/- 13 years
Duration: 24-25 days
Administration: oral
Dosage: 30 g/day of margarine, corresponding to a fat intake of 21 g/day and an approximative intake of 1500-3300 mg/kg bw/day of shea butter unsaponifiables

Test material

Margarines with approximately 70% fat from different sources, including shea butter

Results:

No adverse effects of the tested margarines in a normal dietary context were observed

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:

S020 – Plant sterol-enriched margarines and reduction of plasma totaland LDL-cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects, Eur J Clin Nutr, 52 (1998), 334-343

Test name:

Dietary intervention study in human volunteers

Method and laboratory:

Test group: 60 healthy volunteers (28 male, 32 female)
Duration: 3 * 21 days, crossover double-blind study
Administration: oral
Dosage: 29 g/day of margarine, corresponding to a fat intake of 20 g/day and an approximative intake of 2100 mg/kg bw/day of shea butter unsaponifiables

Test material

Shea butter unsaponifiables
Rice bran unsaponifiables
Sunflower seed oil (reference)

Results:

No adverse effects of the three different diets were observed during the test period.

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:

S202: Effect of plant sterols from rice bran and triterpene alcohols from sheanut oil on serum lipoprotein concentrations in humans. Vissers MN et al, Am J Clin Nutr, 72, (2000), 1510-1515

7.05.6 Summary and discussion

A small number of repeated dose oral toxicity and dietary intervention studies have been conducted with shea butters with varying levels of unsaponifiable matter. Although differences may be observed on bodyweight gain, food consumption and certain measured parameters depending on the test conditions, 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. Across all studies, the highest oral NOAEL could be considered to be 3300 mg/kg bw/day of shea butter unsaponifiables. 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.

Shea butters with various levels of unsaponifiable matter, 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), low vapour pressure and the fact that it is not handled or marketed as a powder, repeated inhalation exposure is not considered to pose an issue for human health under normal and foreseeable handling and use conditions.

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

7.06 Reproduction toxicity

7.06.1 Non-human studies

Test name:

Reproduction study in rats

Method and laboratory:

Species: Colworth-Wistar rats
(Study 1: 20M+20F, Study 2:50M+50F)
Dosage: Diets with 7-15% of shea oleins, equal to 3.5-7.5 g/kg/day. This corresponds to 480 mg/kg/day of shea butter unsaponifiables at the highest dosage.

Test material

Study 1: Shea olein, hydrogenated shea olein &cocoa butter

Study 2: Shea butter, shea olein, hydrogenated shea olein, palm oil and hydrogenated palm oil

Results:

None of the two individual studies reported in the article indicate any reproduction toxicity for shea butter, cocoa butter, shea olein, hydrogenated shea olein, palm oil or hydrogenated palm oil.

Comments:

It can be concluded that up to 480 mg/kg bw/day of shea butter unsaponifiables is safe from a reproduction toxicity point of view

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:

S026 Reproduction studies in the rat with shea oleine and hardened shea oleine, Baldrick P, Robinson JA and Hepburn PA, Food Chem Toxicol. 2001, 39(9), 923-30.

7.06.2 Human studies

Test name:

No data available for this test

Read across

No data

7.06.3 Developmental toxicity/teratogenicity

7.06.3.1 Non-human studies

Test name:

No data available for this test

Read across

No data

7.06.3.2 Human studies

Test name:

No data available for this test

Read across

No data

7.06.4 Summary and discussion of reproductive toxicity

Substances which comprise natural mixtures of glycerides with unsaponifiable components in concentrations varying from about 8% to 80%, including shea butter concentrates, have a 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, shea butter unsaponifiables and shea butter concentrates, are not considered to pose an issue for reproductive toxicity under normal and foreseeable handling and use conditions.

7.07 Mutagenicity/genotoxicity

7.07.1 In vitro data

Test name:

Bacterial Reverse Mutation Assay, Ames Test

Method and laboratory:

Salmonella typhimurium standard plate incorporation study, with and without S9 metabolic activation. Study strains: TA 1535, TA1537, TA98 and TA100.
0,8, 40, 200, 1000 and 5000 microgram/plate
Quintiles Ltd, Ledbury, UK, 1998

Test material

Lipex Shea-U™, 100 % tested as "Shea butter FP 98-017"

Results:

The test article was not mutagenic under the conditions of this test.

Read across

Read across	Same origin and similar fatty acid and unsaponifiable composition.

Reference ID:
S131 - THI/001

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

Substances which comprise natural mixtures of glycerides with unsaponifiable components in concentrations varying from about 8% to 80%, did not exhibit any genotoxic activity in bacterial reverse mutation (Ames) assays. This evidence, added to the long history of safe use of these substances in nutritional (food and feed), cosmetic and industrial uses, suggests that this category of substances does 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:

104 week feeding study

Method and laboratory:

Species: Rat (Colworth-Wistar) 50 male/50 female
Administration: oral
Duration: 104 weeks (daily)
Dosage: 15 % of diet

Test material

Shea olein, shea butter and palm oil

Results:

The test substances showed no adverse effects and no tumorigenic potential at a daily intake of 7500 mg/kg bw /day of shea olein or shea butter. This corresponds to a daily intake of 480 mg/kg bw of shea butter unsaponifiables.

The study concluded that there is no tumorigenic potential in shea olein, corresponding to a daily intake of 480 mg/kg bw/day of shea butter unsaponifiables.

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:

S029 An assessment of the carcinogenic potential of shea oleine in the rat, Carthew P, Baldrick P, and Hepburn PA, Food Chem
Toxicol. 39 (2001), 807-815

7.08.2 Human studies

Test name:

No data available for this test

Read across

No data

7.08.3 Summary and discussion of carcinogenicity

Substances which comprise natural mixtures of glycerides with unsaponifiable components in concentrations varying from about 8% to 80%, 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 and the fact that it is not handled or marketed as a powder, carcinogenicity as a result of inhalatory exposure is not likely. Furthermore, these substances have a long history of safe use in nutritional (food and feed), cosmetic and industrial applications.

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)

7.09.1 Oral administration

Test name:

Feeding study - ADME

Method and laboratory:

1. Animal study
Species: Male Colworth Wistar rats, 24 rats per group
Duration: 3 weeks
Administration: oral
Semisynthetic diet with 20% shea olein (corresponding to 10 g/kg/day of fat and about 800 mg/kg bw/day of shea butter unsaponifiables)
Collection and analysis of feces throughout week 2 and 3.
2. Human study
4 healthy, male volunteers
Duration: 8 days, 1 single administration of 25 g of shea oleine on day 3, followed by collection of feces days 3-8.

Test material

Shea oleine, approximately 8% of unsaponifiable matter

Results:

Triterpene alcohols are absorbed from the diet in a similar manner to cholesterol. Absorption rates were 27-52% in the rat, and 13-49 % in the human subjects. The triterpene alcohols were excreted metabolically unchanged and no preferential absorption was observed for any of the individual triterpene alcohols.

Read across

Read across	Same origin, similar processing and chemical composition. Unsaponifiable content 8% in the study.

Reference ID:

S203: Studies to investigate the absorption and excretion of shea oleine sterols in rat and man, Earl LK et al, Int J toxicol, 21, (2002), 353-359

7.09.2 Dermal administration

Test name:

No data available for this test

Read across

No data

7.09.3 Inhalation route

Test name:

No data available for this test

Read across

No data

7.10 Photoinduced toxicity

7.10.1 Phototoxicity: photoirritation / photosensitisation

Test name:

Phototoxic potential in vitro

Method and laboratory:

SkinEthic reconstructed epidermis
UVA 6 J/cm2
BioAlternatives, FR, 2002

Test material

25 % Lipex Shea-U, diluted in High Oleic Sunflower oil (Akosun)
25 % Lipex 205, diluted in Akosun

Results:

No effect on viability of the epidermal culture from the carrier or from Lipex Shea-U or Lipex 205 diluted with Akosun, after UV irradiation

Read across

Read across Same origin, similar fatty acid and unsaponifiable profile.

Reference ID:

S035 - AD020620

Test name:

In vivo phototoxicity test

Method and laboratory:

The test material was applied to the skin on the back for 24 hours, followed by consequtive irradiation with UV-A (5 J/cm2). Scoring after 1,24, 48 and 72 hours after irradiation.
28 subjects (3 male/25 female).
proDERM standard protocol V04 (71-UV-Tox), approximating the principles of GCP.
proDerm Study 14.0300-71/F
proDERM Institute for Applied Dermatological Research, Schenefeld/Hamburg, DE
2014

Test material

Lipex SheaTris™, 100%

Results:

The test product did not invoke photo-toxic reactions under the test conditions applied in this study.

Read across

Original

Reference ID:

S121 - PD 14.0300-71/F

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 consequtive 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

Lipex SheaTris™, 20% in Lipex Bassol C

Results:

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

Read across

Original

Reference ID:

S153 - BSC 15-311/907115

Test name:

Comedogenicity

Method and laboratory:

Clinical assessment of facial comedones
11 subjects, 4 weeks
Daily application of test material in the facial area
BioScreen Clinical Services, Torrance, CA, US, 2011

Test material

Lipex 205™, 100%

Results:

Under the conditions of the study, there was no statistically significant difference between the comedone counts at baseline and 4 weeks post-treatment with test product. The claim 'non-comedogenic' can thus be substantiated for the test product.

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:

S102 - BCS 11-013/708185

7.12 Summary and NOAEL statement

Based on the data presented in Chapter 7.1 to 7.11, the NOAEL is set to 3300 mg/kg bw/day for systemic exposure for ‘Shea butter unsaponifiables’ and other substances of the same read-across category. The corresponding NOAEL for individual ingredients should be calculated from the actual unsaponifable content of that ingredient. For an ingredient with 60-65% of the shea butter unsaponifables, the NOAEL would corerspond to a daily intake of 5000-5500 mg/kg bw, which can be considered as the lowest NOAEL based on existing evidence.

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, 2012

Test material

Lipex SheaTris™, 100%

Results:

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

Read across

Original

Reference ID:

S166 - AnoxKaldnes 12-762-2

Test name:

Biodegradability OECD 301F

Method and laboratory:

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

Test material

Lipex 205™, 100%

Results:

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

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:

S169 - AnoxKaldnes 09-290-3

8.02 Accumulation

Test name:

No data available for this test

Read across

No data

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

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 Loading Rate (NOELR) and Effect Loading Rate (EL) was determined after 72 hours of exposure to the WAFs. Pseudokircheniella subcapitata (green alga) was used for the test.
Toxicon AB, Härslöv, SE, 2010

Test material

Lipex 205™, 100%

Results:

The test article is non-toxic towards the green alga Pseudokirchneliella subcapitata in the test conditions used in this study.
72h EL50>100 mg/l
72h NOELR 100 mg/l

Read across

Read across	Same origin, similar processing. Unsaponifiable content in test material about 8%.

Reference ID:
S177 - Toxicon 025/10-3

Based on the available information, shea butters 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	CAS. No. 68956-68-3 is listed and valid to be used.
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	INCI name found
ENCS (Japan)	Combined list of existing and notified chemical substances as the Japanese Existing and New Chemical Substances Inventory.	No data
Japan	Japan Pharmacopoeia	No data
KECI (South Korea)	Korea Existing Chemicals Inventory	No Cas No. 68956-68-3)/ KE-no: KE-27312 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 Shea tree, ext. (91080-23-8) is listed and valid to be used.
NECI (Taiwan)	National Existing Chemical Inventory	Listed
Saudia Arabia	The Saudi Arabian Standards Organisation	No data
Malaysia	Chemicals Information Management System	No data
Mexico	Inventario Nacional de Sustancias Químicas	No data
Turkey		Yes. Local name: Yağlar, bitkisel; English name: Oils, vegetable

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

Not available

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 www.aakpersonalcare.com

11.2 Kosher

The product is produced according to Kosher.

Download latest version at www.aakpersonalcare.com

11.3 ISO 9001

The product is produced according to ISO 9001.

ISO certificate latest version available for downloading at www.aak.com/

11.4 EFFCI GMP

The product is produced according to EFFCI GMP.

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

11.6 Other

No other available

12. PATENTS

12.1 Patents

No data.

TRANSPORTS AND HANDLING - LIPEX® SheaTris™

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.

Drums: Melt the whole content until fluid or approx. 60C – 70C

Buckets: Melt the whole content until fluid or approx. 60C – 70C

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

13.3.2 Use of full package for partly use

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

Drums: Melt the whole content until at least 60C – 70C

Buckets: Melt the whole content until at least 60C – 70C

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

If LIPEX® SheaTris™ 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 (paste) 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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S018 Nolen, GA (1981), 'Biological evaluation of hydrogenated rapeseed oil', *Journal of the American Oil Chemists' Society*, 58 (1), 31-37.

S020 Weststrate, J.A. and G.W. Meijer (1998), 'Plant sterol-enriched margarines and reduction of plasma total- and LDL- cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects', *Eur.J.Clin.Nutr.*, 52 (5), 334-43.

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S027 Manorama, R, N Chinnasamy, and C Rukmini (1993), 'Multigeneration studies on red palm oil, and on hydrogenated vegetable oil containing mahua oil.', *Food Chem Toxicol*, 31 (5), 369-75.

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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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S033 Robinson, DS (1973), 'Plasma triglyceride metabolism.', *J Clin Pathol Suppl (Assoc Clin Pathol)*, 5 5-10.

15. DISCLAIMER

15.1 Disclaimer

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Ship-to -

Analytical Certificate

Delivery	**81400836 - 60**
Print date	2023-11-30
Your reference	
Our reference	Femke den Hartog
Material	8649-836 LIPEX® SheaTris™
Your material no.	
Date of shipment	2023-11-27

Batch 0002655267 / **Quantity** 18 KG / **Prod. date** 2023-08-12
Inspection lot 3236819

Characteristic	Result		Lower Limit	Target	Upper Limit
Acid value(IUPAC 2.201(m))					
Acid value	0.33	mg KOH/g			2.00
Colour Lovibond(Lovibond Tintometer)					
Colour 5 1/4" Red	2.8				4.0
Peroxide value(AOCS Cd 8b-90(m))					
Peroxide value	0.8	meq/kg			5.0
Unsaponifiable(AOCS Ca 6a-40(m))					
Unsaponifiable	42.1	%	40.0		55.0

This product is frozen directly after production, and taken out of frozen storage prior to delivery.

The shelf life is based upon date of shipment

Shelf life:
Plastic Pails-12 month from date of dispatch

Quality Control Manager
AAK Sweden AB

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

ZAO S25379 1

AAK Sweden AB
SE-374 82 Karlshamn
Sweden

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

Bank : Skandinaviska Enskilda Banken
Bic/Swift : ESSESESS
Giro : 5430-5438
Acc. no. : 51181061768
IBAN : SE20 5000 0000 0511 8106 1768

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

Flow Chart and composition for Lipex Shea TRIS