Product Documentation

LIPEX® 102 E75 (50%)™

8501

Version
Date 2024-01-15

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:	LIPEX® 102 E75 50%™
Art. No:	8501
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	**PEG-75 Shea Butter Glycerides**	**226993-83-5**	
US	PEG-75 Shea Butter Glycerides	226993-83-5	
China*	PEG-75 牛油树脂甘油酯类	226993-83-5	
Alternative INCI			

*) 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, shea butter, ethoxylated	226993-83-5	607-133-9
	Glycerides, C14-18 and C16-18- unsatd. mono- and di-, ethoxylated	70914-02-2	615-207-7
	Glycerides, C14-18 mono- and di-, ethoxylated	68153-76-4	614-329-8

Margrét Viborg
Global Regulatory Affairs Manager

2.1 Specifications

For specification see Product Data Sheet (PDS)

Download latest version at www.aakpersonalcare.com/

2.2 Typical values

For typical values see Product Data Sheet (PDS)

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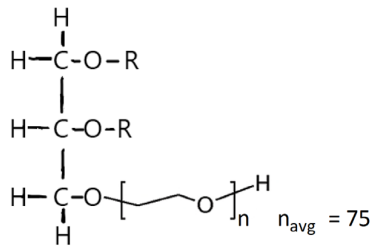
2.3 Certificate of Analysis

For example of COA, see Appendix.

2.4 Auxiliary chemical and physical data

Molecular weight ~3300 g/mol

Stucture



For other Chemical and Physical data, Download latest version at
www.aakpersonalcare.com/

3.1 Biological data

Botanical origin

INCI	Botanical origin	*)Geographical origin	Part used	Content %	Wild grown or cultivated
PEG-75 Shea Butter Glycerides	Vitellaria Paradoxa	West africa	Kernel	100	Wild grown

*)**Geographical origin may change**

3.2 Composition breakdown

INCI name (EU)	CAS	EINECS	Average Content %	Function
PEG-75 Shea Butter Glycerides	226993-83-5		50	Surfactant
Water	7732-18-5	231-791-2	50	

Palm content:

☐Containing palm

☐RSPO SG:

☐RSPO MB: CU-RSPO SCC-817671

☒Do not contain Palm

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

4.1 Production data

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		
Interesterification		
Esterification		
Winterization		
Solvent Fractionation		
Dry Fractionation		
Ethoxylation	x	
Molecular distillation		
Other processing	x	Mixing with water

5. BY-PRODUCTS AND OTHER IMPURITIES

5.1 AAK Contaminant standard

Not available, for more information please contact AAK.

5.2 Other Impurities specific substances

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

5.3 Impurities AAK Cosmetic Products

5.3.1 Allergens

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

5.3.2 Proteins

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

5.3.3 VOC – Volatile Organic Compounds

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

5.3.4 Sulphonates

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

5.3.5 Parabens

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

5.3.6 Phthalates

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

5.3.7 Silicones

Download “General statements AAK Cosmetic Ingredients” at aakpersonalcare.com

6.1 Stability data

OSI Value @ 120C Not applicable

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 102 E-75 50%

7.01 General read-across consideration and justification

Test name:

CIR Safety Report

Method and laboratory:

Review and safety assessment of PEG-derivatives of vegetable oils as used in cosmetics.

Test material:

130 varieties of PEG-derivatives of vegetable oils

Results:

The ingredient group comprising PEG-derivatives of vegetable oils is considered to be safe in present practices of use

Read across

Read across	Ethoxylated shea butter and ethoxylated mango oil are representatives of the generic group "PEGylated vegetable oils" referenced in this CIR report.

Reference ID:

S-267 Safety assessment of PEGylated oils as used in cosmetics. Burnett, CL et al, International Journal of Toxicology, Vol 33 (Suppl 4), 13S-39S, (2014)

Test name:

CIR Safety Report

Method and laboratory:

Safety assessment and review of ethoxylated glycerides, including PEG-75 shea butter.

Test material:

60 PEGylated vegetable glycerides

Results:

The PEGylated glycerides are concluded to be safe when used in current practices and formulated at non-irritating concentrations

Read across

Read across	PEG-75 shea butter and PEG-70 mango butter belong to this category

Reference ID:

S-298 Final report: Safety assessment of PEGylated alkyl glycerides as used in cosmetics. CIR Expert Panel, Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Test name:

Calculation of molecular weight in ethoxylated oils

Method and laboratory:

Theoretical considerations and calculations of molecular weight of PEG moieties in ethoxylated shea and mango butter

Test material:

Lipex 102 E-75 100%
Lipex 203 E-70 100%

Results:

The average ethoxylation degree per glyceride is estimated to be 25-30 for Lipex 102 E-75 and 20-25 for Lipex 203 E70 (molecular weights about 800-1100 Da).

Comments: In

In order to assess the toxicity of the PEG moieties in ethoxylated oils it is necessary to have an estimation of the molecular weights and especially the length of the EO chains

Read across

Original	Although the nominal designation of the size of the PEG in the ethoxylated shea and mango oils is 70-75, the stoichiometry of the reaction indicates that PEG-20 to PEG-25 are more relevant benchmarks for the safety assessment.

Reference ID:

S-269 Calculation of theoretical molecular weights in two ethoxylated oils. Alander, J, 2020.

Test name:

CIR Safety Report

Method and laboratory:

Safety assessment and review of PEG-stearates.

Test material:

PEG-2 to PEG-150 stearates

Results:

It is concluded that the listed PEG stearates are safe for use in cosmetics in the present practices.

Read across

Read across	Ethoxylated shea butter and mango butter contain a significant amount of PEG esters

Reference ID:

S-299 Final report on the safety assessment of PEG-2, -6, -8, -12, -20, -32, -40, -50, -100 and -150 stearates, Journal of the American College of Toxicology, 3(7), 17-34, (1983)

Test name:

CIR Safety Report

Method and laboratory:

Safety assessment of PEG diesters

Test material:

55 different PEG diesters

Results:

It is concluded that the listed PEG diesters are safe for use in cosmetics if formulated to be non-irritating

Read across

Read across	Ethoxylated shea butter and mango butter contain a significant amount of PEG di-esters

Reference ID:

S-300 Safety assessment of PEG diesters as used in cosmetics, CIR Expert Panel, (2015), Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Test name:

CIR Safety Report

Method and laboratory:

Review and safety assessment of PEG ethers of oleyl alcohol (Oleth-n) of different degrees of ethoxylation, n= (2-50)

Test material:

Polyethylene glycol ethers of oleyl alcohols (Oleth-n) with n=2-50

Results:

It was concluded that the PEG oleyl ethers reviewed are safe to use in cosmetics in the present use practices

Read across

Read across	Shea butter and mango butter contain oleyl moieties, making the Oleth category relevant as benchmark

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Safety assessment and review

Method and laboratory:

Review and safety assessment of PEGs and their derivatives used in cosmetics

Test material:

Large number of polyethylene glycols of different molecular weights and selected groups of their derivatives

Results:

All the reviewed PEGs and their derivatives are safe to use in cosmetics under the present conditions. Impurities such as 1,4-dioxane and ethylene oxide need to be monitored and removed.

Read across

Read across	Polyethylene glycols are main components in ethoxylated vegetable oils with high degree of ethoxylation, either as esterified or as free PEG.

Reference ID:
S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

Test name:

CIR Safety Report

Method and laboratory:

Safety assessment and review of polyethylene glycols PEG-4 to PEG-180M

Test material:

Large number of PEGs with low to very high molecular weight

Results: It

It is concluded that PEGs are considered safe for cosmetic use in present practices

Read across

Read across	Ethoxylated shea butter and mango butter contain a significant amount of free PEG

Reference ID:
S-301 Final report: Safety assessment of triethylene glycol and polyethylene glycols (PEGs)-4 to PEG-180M and any PEGs >=4 as used in cosmetics, CIR Expert Panel, (2010), Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Test name:

Safety assessment and review

Method and laboratory:

Opinion and statement from EFSA on the safety of use of polyethylene glycols as a film coating agent in food supplements. The report also comprises a summary of existing toxicological studies.

Test material:

PEG-400, PEG-3000, PEG-3350, PEG-4000, PEG-6000, PEG-8000

Results:

The use of the listed PEGs are not seen as a safety concern when used as film forming agents in food supplement capsules.

Read across

Read across	Polyethylene glycols are main components in ethoxylated vegetable oils with high degree of ethoxylation, either as esterified or as free PEG.

Reference ID:
S-302 EFSA Question EFSA-Q-2005-277, EFSA Journal, 414, 1-22, (2006).

Test name:

Safety assessment and review

Method and laboratory:

Review and safety assessment of PEGs and their derivatives as used in cosmetics

Test material:

Various PEGs, PEG esters and PEGylated castor oil

Results:

The substances studied in this review are considered to be safe for use in cosmetics up to 100% concentration

Comments:

Summarized data for PEG-20 glyceryl isostearate, PEG-40 and PEG-60 hydrogenated castor oil and PEG/PPG-17/6 copolymer

Read across

Read across	This review is more recent and complements data in the CIR reviews.

Reference ID:

S-277 Safety evaluation of polyethylene glycol (PEG) compounds for cosmetic use, Jang H-J et al, Toxicological Research, 31(2), 105-136, (2015)

Due to scarcity of original data on the Lipex 102 E-75/Lipex 203 E-70, this safety assessment is largely based on summarizing the CIR safety assessments and other relevant literature. CIR reviews and other safety reviews exist for polyethylene glycols, ethoxylated fatty alcohols (ceteths, steareths, oleths, laureths), fatty acid mono- and diesters of polyethylene glycols as well as the PEGylated oils/glycerides.

The nomenclature of this substance category is not straight-forward. CIR has issued safety reviews for both "PEGylated oils" and "PEGylated glycerides" which are essentially the same. In this safety review both categories are considered to be exchangeable. However, the term "ethoxylated vegetable oils" are used in most places to describe this category.

Ethoxylated vegetable oils are complex reaction mixtures resulting from the addition of ethylene oxide to a glycerolyzed vegetable oil. In the process, a vegetable oil is first reacted with a suitable amount of glycerol to produce a mixture of mono-, di- and triglycerides. This mixture is then reacted with ethylene oxide in alkaline conditions. The product is characterized by the amount of ethylene oxide which is added. For example, the PEG-75 shea butter glycerides are reacted with 75 moles of EO per mole of triglyceride. In these conditions about 10 parts of the vegetable oil is used with 90 parts of ethylene oxide (w/w). The resulting mix is usually bleached using hydrogen peroxide, followed by purging with steam to remove residual ethylene oxide, hydrogen peroxide and 1,4-dioxane which is formed as a by-product from the ethylene oxide condensation. This process also removes traces of formaldehyde and acetaldehyde that may be present as impurities in the ethylene oxide.

The molecular composition of the reaction mixture is not well investigated. The typical molecular species present in ethoxylated shea butter are polyethylene glycol (n=25), mono- and di-ester of polyethylene glycol (n=25) with fatty acids from the starting material, mono- and di-glycerides that have reacted with ethylene oxide and glycerol that has reacted with ethylene oxide. In the case of shea butter the reaction mixture also contain the unsaponifiable matter from the starting material, part of which may have reacted with ethylene oxide.

From a safety assessment point of view, data on polyethylene glycols and polyethylene glycol alkyl ethers and esters with EO chain lengths above 20 or molecular weights of 800-1100 Da are used as a complement to the data presented on "PEGylated vegetable oils/PEGylated glycerides". These substances are well known after a long use in industrial and pharmaceutical applications as emulsifiers, surfactants, opacifiers, adjuvants and excipients.

7.02 Acute toxicity
7.02.1 Acute oral toxicity

Test name:

Summary of acute oral toxicity

Method and laboratory:

Summary in CIR report for PEGylated oils (Table 2 in report)

Test material:

PEGylated castor oil
Polyethylene glycols (n>=4)
Alkyl PEG ethers

Results: It

It is stated that PEGylated oils, PEGs and alkyl PEG ethers do not show any acute oral toxicity. Reported LD50 in rodents exceed 10-20 g/kg bw.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-267 Safety assessment of PEGylated oils as used in cosmetics. Burnett, CL et al, International Journal of Toxicology, Vol 33 (Suppl 4), 13S-39S, (2014)

Test name:

Summary of acute oral toxicity data

Method and laboratory:

Acute oral toxicity was summarized in CIR safety assessment of oleyl alcohol ethoxylates.

Test material:

PEG-6, PEG-75, Oleth-10

Results:

LD50 (rabbit) was 17.3 g/kg bw for PEG-6 and 76 g/kg bw for PEG-75. Oleth-10 was reported to have a LD50 of >5 g/kg bw in rats.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

In view of the data presented in the safety assessments and reviews, acute oral toxicity is not a concern for ethoxylated vegetable oils. The presented LD50 values for relevant read-across substance classes are very high and the ethoxylated oils are thus safe if accidentally ingested.

7.02.2 Acute inhalation toxicity

Test name:

Summary of acute inhalation toxicity data

Method and laboratory:

A summary of different acute inhalation toxicity studies is given.

Test material:

PEG-6 in saline
EO/PO copolymer aerosols
PEG/PEG derivatives in emulsions

Results:

No inhalation toxicity was observed in the cited studies for the listed substances, either due to lack of specific toxic effects or due to limited uptake of aerosol particles

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

Based on the safety assessments and reviews it can be concluded that ethoxylated vegetable oils are not acute toxic by the inhalation route. They are non-volatile and do not contribute to aerosol formation under normal use conditions. 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:

Summary of acute dermal toxicity data

Method and laboratory:

Summary in CIR report for PEGylated oils (Table 2 in report)

Test material:

PEGylated castor oil
Polyethylene glycols (n>=4)
Alkyl PEG ethers

Results: It

It is stated that PEGylated oils, PEGs and alkyl PEG ethers do not have any evidence of acute dermal toxicity. Reported LD50 in rodents exceed 2000 mg/kg bw.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-267 Safety assessment of PEGylated oils as used in cosmetics. Burnett, CL et al, International Journal of Toxicology, Vol 33 (Suppl 4), 13S-39S, (2014)

In view of the data presented in the safety assessments and reviews, acute dermal toxicity is not a concern for ethoxylated vegetable oils.

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

In view of the presented data on acute toxicity by the oral, dermal and inhalation routes, and the long history of safe use in industrial and pharmaceutical applications, ethoxylated vegetable oils are not considered to pose an issue for human health under normal and foreseeable use conditions.

7.03 Irritation & corrosivity

7.03.1 Skin irritation and corrosivity

Test name:

Summary of skin irritation data

Method and laboratory:

Skin irritation studies reported in CIR safety report for PEGylated oils:
1. Skin irritation study using male guinea pigs. Multiple applications on healthy and damaged skin were observed up to 72 h after application.
2. Single application of microemulsion to mouse ear, observed for 6 days.

Test material:

Study 1. Microemulsion with 20% PEG-35 castor oil
Study 2. Microemulsion with 20% PEG-40 hydrogenated castor oil

Results:

1. Slight irritation was observed at the 1st hour reading on animals with damaged skin. No irritation was seen on healthy skin, neither immediately nor long-term. The material was classified as non-irritating to the skin.
2. No erythema or other signs of irritation was observed.
It was concluded that PEG-35 and PEG-40 hydrogenated castor oil are not irritating to the skin.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-267 Safety assessment of PEGylated oils as used in cosmetics. Burnett, CL et al, International Journal of Toxicology, Vol 33 (Suppl 4), 13S-39S, (2014)

Test name:

Summary of skin irritation data

Method and laboratory:

Skin irritation data were reported in CIR safety assessment of oleyl alcohol ethoxylates.

Test material:

Polyethylene glycols and Oleth-10/Oleth-20

Results:

The PEGs are not irritating to skin in animal tests in short and/or long-term tests. Oleth-10

was observed to be minimally to mildly irritant. Oleth-20 was more irritating at 10% dilution than at 50% and determined to be minimally irritant to irritant to the skin.

Comments:

Pure PEGs are not irritating while the more surface active oleths can show some skin irritancy depending on the conditions.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Summary of skin irritation data

Method and laboratory:

Skin irritation studies have been compiled from many sources by CIR.

Test material:

PEG-20 almond glycerides
PEG-60 almond glycerides
PEG-12 palm kernel glycerides
PEG-45 palm kernel glycerides
PEG-10 olive glycerides
PEG-75 shea butter glycerides
PEG-6 caprylic/capric glycerides
PEG-7 glyceryl cocoate

Results: In

In general the PEG derivatives of alkyl glycerides are non-irritating and non-sensitizing. Some animal studies indicate that PEG-20/PEG-60 almond glycerides and PEG-12/PEG-45 palm kernel glycerides can be mild irritants or irritants but human clinical tests show absence of irritation.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-298 Final report: Safety assessment of PEGylated alkyl glycerides as used in cosmetics. CIR Expert Panel, Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Based on the safety assessments and reviews, it can be concluded that ethoxylated vegetable oils based on long-chain fatty acids are not irritating or corrosive to the skin. Ethoxylates based on medium chain fatty acids may show skin irritation effects when undiluted.

7.03.2 Eye & mucous membrane irritation and corrosivity

Test name:

Summary of eye irritation data

Method and laboratory:

Eye irritation study reported in CIR safety report for PEGylated oils:
Albino rabbits were used in a Draize test applying different potential glaucoma drug formulations with up to 13.5% PEG-35 hydrogenated castor oil.

Test material:

Formulations with up to 13.5% PEG-35 hydrogenated castor oil.

Results:

Formulations with up to 13.5% PEG-35 hydrogenated castor oil were well tolerated and determined to be non-irritating to the eye.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-267 Safety assessment of PEGylated oils as used in cosmetics. Burnett, CL et al, International Journal of Toxicology, Vol 33 (Suppl 4), 13S-39S, (2014)

Test name:

Summary of eye irritation data

Method and laboratory:

Eye irritation data were summarized in CIR safety assessment of oleyl alcohol ethoxylates. Tests were performed on rabbits using the Draize test.

Test material:

Polyethylene glycols and Oleth-10/Oleth-20

Results:

PEGs (-6, -8, -32 and -75) are non-irritating to mildly irritating in animal tests.
Oleth-20 tested at 5-70% dilution in water was moderately irritating to the eye at 50-70% but non-irritating at 5% dilution.
Oleth-10 tested undiluted was observed to be moderately irritating to the eye.

Comments:

Pure PEGs are not irritating while the more surface active oleths can show some eye irritancy depending on the conditions.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Summary of eye irritation data

Method and laboratory:

Eye and mucous membrane irritation studies have been compiled from many sources by CIR.

Test material:

PEG-7 glyceryl cocoate (10%, 11% in water)
PEG-10 sunflower glyceride
PEG-8 caprylic/capric glycerides (3% in water)
PEG-6 caprylic/capric glycerides (undiluted, 4% in water, 5% in water)
PEG-75 shea butter glycerides (1%)

Results:

Indiluted PEG derivatives of medium chain fatty acids can be strong eye irritants. Aqueous dilutions up to 10% are usually not eye or mucous membrane irritants.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-298 Final report: Safety assessment of PEGylated alkyl glycerides as used in cosmetics. CIR Expert Panel, Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Based on the safety assessments and reviews, it can be concluded that ethoxylated vegetable oils based on long chain fatty acids are not irritating or corrosive to the eye or mucous membranes at use concentrations. Short chain ethoxylates can be irritating to the eye when undiluted.

7.03.3 Summary and discussion on irritation and corrosivity

Based on the safety assessments and review it is concluded that ethoxylated vegetable oils with long-chain fatty acids (C16-C18), such as ethoxylated shea butter and ethoxylated mango oil, pose a minimal risk to cause skin or eye irritation in use concentrations. It is also concluded that the ethoxylated vegetable oils are not corrosive to skin, eyes or mucous membranes. Short and medium chain (C8-C12) ethoxylated oils and glycerides can show some eye irritation in undiluted form.

7.04 Skin sensitization

Test name:

Summary of skin sensitization data

Method and laboratory:

A summary of skin sensitization studies is given, including photo-induced allergenicity.

Test material:

PEGs
PEG stearates
Laureths
Steareths
PEG-7 glyceryl cocoate
PEG-35 castor oil

Polysorbates

Results:

PEGs with molecular weights ranging from 200-8000 did not show irritating or sensitizing effects in HRIPT testing.
Other studies indicate the absence of sensitizing effects for PEG stearates.
Case reports and subsequent investigations indicate that damaged and elderly skin are more prone to sensitization from PEG derivatives. In some cases the increased incidence of reactions is attributed to oxidized impurities in the test materials.

Comments:

PEGs and PEG derivatives are safe for use on healthy intact skin. Some care should be exercised when applying these substances on damaged or elderly skin. The oxidation status of the PEG derivatives should be monitored to avoid reactions to low molecular weight aldehydes and acids.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

7.04.1 Summary and discussion of sensitization

Based on the safety assessments and reviews, it can be concluded that ethoxylated vegetable oils are not sensitizing or allergenic. However, it is important in this context to ensure that the ingredient is not heavily oxidized as oxidation may cause formation of low molecular weight aldehydes and other sensitizing molecules. Damaged and elderly skin is also more sensitive to the effect of the oxidized impurities. It is also important to make sure the ingredient is free of formaldehyde and acetaldehyde that may occur as contaminants in the ethylene oxide used for the manufacturing of the ethoxylated vegetable oils.

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

Test name:

Summary of sub-chronic oral toxicity data

Method and laboratory:

The repeated dose toxicity of PEG-8 Caprylic/Capric Glycerides is cited in the CIR safety assessment of PEGylated glycerides. A blend of 40% PEG-8 caprylic/capric glycerides, 40% apricot kernel oil PEG-6 esters and 20% ethoxydiglycol was administered to 10F+10M Wistar rats for 4 weeks. Dosage was 5, 10 or 20 ml/kg bw/day of test substance, given by gavage. Hematological, urinalysis and histopathological parameters were studied.

Test material:

PEG-8 caprylic/capric glycerides
PEG-6 apricot kernel oil
Ethoxydiglycol

Results:

Adverse effects on histopathological parameters and clinical conditions were seen at 10 and 20 ml/kg bw/day but at 5 ml/kg bw/day the test substance was well tolerated. Based on the results a NOAEL of 5 ml/kg bw/day was assigned.

Read across

Read across	PEG-8 is a typical representative of ethoxylated vegetable oils with medium chain fatty acids

Reference ID:

S-298 Final report: Safety assessment of PEGylated alkyl glycerides as used in cosmetics. CIR Expert Panel, Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Test name:

Repeated dose oral toxicity

Method and laboratory:

Species: Sprague-Dawley rats (20 male, 20 female)
Duration: 28 days
Dosage: 250, 500 and 1000 mg/kg bw/day diluted in corn oil
Administration: Gavage

Test substances were synthesized by standard procedures.

Test animals were observed daily for pharmacotoxic effects and body weights were monitored weekly. Hematological and histopathological measurements were taken at the end of the test period.

Test material:

1,2-dioleoyl-glycerol-3-dodecaethylene glycol (PEG-12 dioleate)
1,2-distearoyl-glycerol-3-dodecaethylene glycol (PEG-12 distearate)

Results:

No visual signs of toxicity were observed during the test period. Body weights were normal

and food intake and utilization was not affected by the test substances. Hematological parameters were normal. No effects on kidney or liver function was observed. The NOAEL is set at the highest tested level (1000 mg/kg bw/day) for these two substances.

Read across

Read across	The two tested substances are good model substances for ethoxylated vegetable oils

Reference ID:

S-307 Acute and sub-chronic (28-day) oral toxicity study in rats fed with novel surfactants. Bidhe & Ghosh, AAPS PharmSci, 6(2), 1-10, (2004)

Test name:

Summary of sub-chronic oral toxicity data

Method and laboratory:

Sub-chronic oral toxicity was summarized in the CIR safety assessment of oleyl alcohol ethoxylates. Feeding studies with rats (4% in diet, 90 days) and dogs (2% in diet, 1 year) are reported.

Test material:

PEG-6, PEG-20M (rats)
PEG-8, PEG-32 and PEG-75 (dogs)

Results:

No adverse effects or treatment related mortalities were observed in these studies.

Read across

Read across	See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Summary of sub-chronic oral toxicity data

Method and laboratory:

Sub-chronic oral toxicity was summarized in the CIR safety assessment of oleyl alcohol ethoxylates. Feeding studies with rats (0.01-5.0 % in diet, 90 days) and beagle dogs (0.04-5.0 % oleth-20, 90 days).

Test material:

Oleth-20

Results:

High (2.5-5% oleth-20 in diet) led to lower body weights in both male and female rats due to decreased food intake. No hematologic or other toxicological parameters were affected. Lowered weight gain was also observed in the high dose (5% in diet) study in the dogs. No hematologic or other toxicological parameters were affected.

Read across

Read across	See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Summary of sub-chronic oral toxicity data

Method and laboratory:

A comprehensive summary of repeated dose oral toxicity is given (table 6 in reference).

Test material:

PEG-4 to PEG-10M
PEG stearates
PEG laurates
Laureths
Steareths

Results:

Toxic effects of lower molecular weight PEGs at high dosage included damage on liver and kidneys. At doses below 1000 mg/kg bw/day (recommended max dosage for repeated dose studies) the toxicity was very low.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

Test name:

Summary of sub-chronic oral toxicity data

Method and laboratory:

A comprehensive summary of repeated dose oral toxicity is given. Several relevant studies on polyethylene glycols of different molecular weights are cited. A 90-day, GLP-compliant, study on Fisher 344 rats, using PEG-400 given at doses of 1.1, 2.8 and 5.6 g/kg bw/day, is discussed in detail. The purpose of this study is to examine specifically renal toxicity effects of the PEG-400.

Test material:

Polyethylene glycols with different molecular weights

Results:

The 90-day, GLP-compliant, study shows effects on urinary and hematological parameters which disappear in the recovery period. Statistically significant increases in organ weights are attributed to the relative decrease in body weight observed in the study. The NOAEL is set at the lowest tested dosage, 1.1 g/kg bw/day due to the effects on urinary parameters.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-302 EFSA Question EFSA-Q-2005-277, EFSA Journal, 414, 1-22, (2006).

7.05.2 Inhalation studies

Test name:

Summary of sub-chronic inhalation toxicity data

Method and laboratory:

A comprehensive summary of repeated dose inhalation toxicity is given (table 6 in reference).

Test material:

PEG-4 to PEG-75

Results:

The limited available data (3 cited studies) indicate no specific hazard for this endpoint.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

7.05.3 Dermal administration

Test name:

Summary of sub-chronic dermal toxicity data

Method and laboratory:

Sub-chronic dermal toxicity was summarized in the CIR safety assessment of oleyl alcohol ethoxylates. Tests were done on rabbits (daily application, 5 days per week, 18 weeks, 2 ml/kg bw/day, PEG-6) in one study. In another study, 0.8 ml of 40% dilution of PEG-20M was administered for 30 days on rabbits.

Test material:

PEG-6, undiluted
PEG-20M, 40% in water

Results:

No evidence of dermal toxicity was found for the PEG-6 or the PEG-20M.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Summary of sub-chronic dermal toxicity data

Method and laboratory:

A comprehensive summary of repeated dose dermal toxicity is given (table 6 in reference).

Test material:

PEG-4 to PEG-20M
PEG stearates
Laureths
Steareths

Results:

No systemic dermal toxicity was observed in the cited studies. There are observations of local skin irritation, especially on damaged skin.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

7.05.4 Other routes of administration

Test name:

Repeated systemic toxicity

Method and laboratory:

Species: dogs
Administration: intravenous
Dosage: 4.23, 6.34 and 8.45 g/kg bw/day in saline
Duration: 30 days

Test material:

PEG-400

Results:

Dogs receiving 6.34 and 8.45 g/kg bw of showed dry mouth and nasal mucosa. Dogs given 8.45 g/kg bw shoved renal swelling 24 hours after last dosing. No significant histological changes were observed 21 days after last dosing.
Toxicity of PEG-400 is concluded to be low and any effects observed at high dose are reversible.

Reference ID:

S-296 Systemic toxicity and toxicokinetics of a high dose of polyethylene glycol 400 in dogs following intravenous injection. Li et al, Drug and Chemical Toxicology, 34, 208-212, (2011)

7.05.5 Human studies

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

7.05.6 Summary and discussion

Ethoxylated vegetable oils such as PEG-75 shea glycerides and PEG-70 mango glycerides have not been investigated for their sub-chronic and chronic toxicity. The following conclusion is based on studies performed on polyethylene glycols which constitute a large part of the composition of the ethoxylated vegetable oils. Data on PEG-8 caprylate/caprate is also considered.

Polyethylene glycols of 4-75 oxyethylene groups as well as PEG-n esters, PEG-n hydrogenated castor oil and ethoxylated sorbitan esters (polysorbates) 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, ethoxylated vegetable oils are not

considered to pose an issue for sub-chronic and chronic toxicity under normal and foreseeable handling and use conditions. A conservative maximum exposure limit from the studies presented can be set to 1000 mg/kg bw/day for NOAEL estimation.

7.06 Reproduction toxicity

7.06.1 Non-human studies

Test name:

Summary of reproductive and developmental toxicity

Method and laboratory:

Reproductive and developmental toxicity assessment of PEGs and derivatives were summarized and discussed in the CIR safety assessment of oleyl alcohol ethoxylates.

Test material:

Ethylene glycol and its ethers

Results:

While it is known that ethylene glycol, mono-methyl glycol and other short chain ethylene oxide adducts can be reproduction toxic, it was concluded that long chain derivatives pose no hazard in this context. The presence of the short chain adducts in commercial ethoxylates is limited.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-270 Final report on the safety assessment of oleth-2….-50, CIR Expert Panel, International Journal of Toxicology, 18 (Suppl 2), 17-24, (1999)

Test name:

Summary of reproductive toxicity data

Method and laboratory:

A summary of the reproductive and developmental toxicity studies for PEGs and PEG derivatives is given.

Test material:

PEG-6,-32, -75 (no dosage given)
PEG-4 (up to 2000 mg/kg bw/day)
PEG-8 (no dosage given)

Results:

No notable adverse effects on reproduction and development were generally observed.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

7.06.2 Human studies

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

7.06.3 Developmental toxicity/teratogenicity

7.06.3.1 Non-human studies

Test name:

Summary of developmental toxicity data

Method and laboratory:

A summary and review of the reproductive and developmental toxicity studies for PEGs and PEG derivatives is given.

Test material:

PEG-4 (dosage up to 10000 mg/kg bw/day)
PEG-6, 8 (>2 ml/kg)
PEG-6, -32, -75 (no dosage given)
PEG-8 & -40 stearates (no dosage given)
PEG-35 castor oil
(no dosage given)
PEG-20 sorbitan laurate (500, 5000 mg/kg bw/day)

Results:

In general no developmental or teratogenic effects were observed in the cited studies, except at very high dosages (23000 mg/kg bw/day of PEG-8) and in some poorly documented studies.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGSs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

7.06.3.2 Human studies

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

7.06.4 Summary and discussion of reproductive toxicity

Ethoxylated vegetable oils such as PEG-75 shea glycerides and PEG-70 mango glycerides have not been investigated for their effects on reproduction and developmental toxicity. The following conclusion is based on studies performed on polyethylene glycols which constitute a large part of the composition of the ethoxylated vegetable oils.
Polyethylene glycols of 4-75 oxyethylene groups as well as PEG-n esters, PEG-n hydrogenated castor oil and ethoxylated sorbitan esters (polysorbates) 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, ethoxylated vegetable oils are not considered to pose an issue for reproductive toxicity under normal and foreseeable handling and use conditions. A conservative maximum exposure limit from the studies presented can be set to 1000 mg/kg bw/day for NOAEL estimation.

7.07 Mutagenicity/genotoxicity
7.07.1 In vitro data

Test name:

Summary of mutagenicity and genotoxicity data

Method and laboratory:

Data reported in CIR safety report for PEGylated oils.
1) Ames' test with 5 Salmonella typhimurium strains.
2) Chromosome aberration study in Chinese hamster V79 cells
3) Mouse micronucleus test

Test material:

PEG-60 hydrogenated castor oil

Results:

The PEG-60 hydrogenated castor oil was not found to be genotoxic, neither in the reverse mutation test, in the chromosome aberration test or the mouse micronucleus test.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-267 Safety assessment of PEGylated oils as used in cosmetics. Burnett, CL et al, International Journal of Toxicology, Vol 33 (Suppl 4), 13S-39S, (2014)

Test name:

Summary of mutagenicity and genotoxicity data

Method and laboratory:

The mutagenic potential of PEGylated glycerides is summarized by CIR.

Test material:

PEG-6 caprylic/capric glycerides
PEG-7 glyceryl cocoate
PEG-10 olive glycerides

Results:

No mutagenic effects of the listed substances were observed in Ames' tests with or without metabolic activation.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-298 Final report: Safety assessment of PEGylated alkyl glycerides as used in cosmetics. CIR Expert Panel, Available at the Cosmetic Ingredient Review website https://www.cir-safety.org/

Test name:

Summary of mutagenicity and genotoxicity data

Method and laboratory:

The EFSA opinion report on polyethylene glycols reviews and summarizes mutagenicity assessments for several types of polyethylene glycols. The report cites data from Ames' tests, sister chromatid exchange (SCE), unscheduled DNA synthesis (UDS) as well as Chinese hamster epithelial cell (CHEL) and mouse lymphoma assays.

Test material:

PEG-200
PEG-400
PEG-3000
PEG-6000

Results:

Ames' tests with/without metabolic activation show no signs of mutagenic effects. Inconclusive data were observed with the other assays, specifically a lack of clear dose-response effects. The EFSA panel concludes that the weak positive effects of seen in some studies are not toxicologically relevant.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-302 EFSA Question EFSA-Q-2005-277, EFSA Journal, 414, 1-22, (2006).

7.07.2 In vivo data

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

7.07.3 Human studies

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

7.07.4 Summary and discussion of mutagenicity

Ethoxylated vegetable oils such as PEG-75 shea glycerides and PEG-70 mango glycerides have not been investigated for their mutagenic/genotoxic effects. The following conclusion is based on studies performed on polyethylene glycols which constitute a large part of the composition of the ethoxylated vegetable oils.

Polyethylene glycols of 4-75 oxyethylene groups as well as PEG-n esters, PEG-n hydrogenated castor oil and ethoxylated sorbitan esters (polysorbates) 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, ethoxylated vegetable oils are not considered to pose an issue for mutagenicity or genotoxicity under normal and foreseeable handling and use conditions.

Based on the above information, these substances do 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:

Summary of carcinogenicity data

Method and laboratory:

A summary of carcinogenicity studies for PEGs and PEG derivatives is given.

Test material:

PEG-4
PEG-32
PEG MW= 100 kDa
PEG-20 sorbitan oleate

Results:

No evidence of carcinogenicity in validated dietary studies was found. Several studies have been invalidated due to insufficient study designs and durations. The lack of mutagenicity for PEGs and PEG derivatives further strengthen the conclusion.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

Test name:

Summary of carcinogenicity data

Method and laboratory:

The EFSA opinion report on polyethylene glycols reviews and summarizes several animal studies on the carcinogenic potential of this substance group.
The cited studies are published between 1944-1968 and comprise the administration of up to 4 g/kg bw/day

Test material:

PEG-200
PEG-400
PEG-1540
PEG-4000

Results:

No carcinogenic effects were observed in any of the cited studies.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-302 EFSA Question EFSA-Q-2005-277, EFSA Journal, 414, 1-22, (2006).

7.08.2 Human studies

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

7.08.3 Summary and discussion of carcinogenicity

No studies indicating a risk for carcinogenicity for ethoxylated vegetable oils have been found by any exposure route. The absence of functional groups suggesting carcinogenic activity and the lack of mutagenic effects support this conclusion. It is necessary to ensure that the levels of 1,4-dioxane, formaldehyde and ethylene oxide in the product are below the maximum permitted levels.

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:

Summary of ADME data

Method and laboratory:

The toxicokinetics and metabolism of various PEG derivatives were reviewed and summarized.

Test material:

PEGs
Laureths
Polysorbates

Results:

Low molecular weight PEGS (PEG-4, -6, -8) are easily absorbed in the gastrointestinal tract and excreted via the urine (50% in 24 h for PEG-8). Less than 10% of PEG-75 is absorbed in oral intake and higher MW PEGs are not absorbed at all.
PEGs are not absorbed through intact skin but can penetrate through damaged skin. PEG-2 and PEG-9 stearate can reduce the skin barrier function but PEG-40 stearate does not. Short chain laureths (laureth-1, laureth-2) can be absorbed through skin while the more polar laureth-10 has only a limited absorption.
PEGs are excreted unchanged via urine and faeces although a small part can be oxidized to acids and carbon dioxide. Esters of polyethylene glycols are first hydrolyzed to the corresponding PEG and fatty acids.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

7.09.2 Dermal administration

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

7.09.3 Inhalation route

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

7.10 Photoinduced toxicity

7.10.1 Phototoxicity: photoirritation / photosensitisation

Test name:

Summary of phototoxicity and photoirritation

Method and laboratory:

A summary of phototoxicity and photoirritation studies is given.

Test material:

PEG-7 glyceryl cocoate
PEGs in general

Results:

Absence of phototoxicity is postulated due to lack of chromophores in the PEG and PEG derivatives.
PEG-7 glyceryl cocoate was found to have no phototoxic effects in mice.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-268 Safety assessment of polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Fruijtier-Pölloth, C, Toxicology, 214, 1-38, (2005)

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)

Test name:

Summary of human studies involving polyethylene glycols

Method and laboratory:

Polyethylene glycols with high molecular weight (PEG-3350 & PEG-4000) are frequently used as oral laxatives and the toxicology in humans is well investigated. The EFSA report summarizes the clinical studies. In one study, daily administration for 30 days of 5.9 or 11.8 grams of PEG-3350 or 10 & 20 grams of PEG-4000 were given to 266 male & female patients in a double-blind, placebo controlled study. Several other studies are cited.

Test material:

PEG-3350
PEG-4000

Results:

All test compounds were well tolerated and only mild side-effects were observed.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-302 EFSA Question EFSA-Q-2005-277, EFSA Journal, 414, 1-22, (2006).

7.11 Special investigations

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

7.12 Summary and NOAEL statement

Based on the data presented in Chapter 7.1 to 7.11, the NOAEL is set to 1000 mg/kg bw/day for systemic exposure for ethoxylated vegetable oils as well as other substances of the same read-across category.

8 Ecological data
8.01 Degradability

Test name:

Biodegradability OECD 301D

Method and laboratory:

OECD 301D Closed Bottle Test

Safepharm Laboratories Ltd, Derby, UK
1994

Test material:

Lipex 102 E-75™, 100%

Results:

The test article is "not readily biodegradable" according to the criteria specified in OECD guidelines for degradability testing. The final degradation reaches 32% after 28 days.

Read across

Original

Reference ID:

S-171 Assessment of the ready biodegradability of Lipex 102 E-75, SafePharm Laboratories, 753/1, (1994)

Test name:

Biodegradation

Method and laboratory:

Scientific biodegradation study using OECD 301 E test for ready biodegradability.

Test material: 6

6 ethoxylated fatty alcohols with 10-18 carbons and 4-11 units of ethylene oxide

Results:

All the tested fatty alcohol ethoxylates are readily biodegradable. The individual rates depend on fatty alcohol chain length and degree of ethoxylation. Physicochemical parameters such as CMC and initial surfactant concentration influence the biodegradation.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-271 Primary biodegradation of commercial fatty-alcohol ethoxylate surfactants: Characteristic parameters, Jurado, E. et al, Journal of Surfactants and Detergents, 10, 145-153, (2007)

Test name:

Biodegradation PEGs

Method and laboratory:

Scientific study investigating the effect of molecular structure on the biodegradability of polyethylene glycols and polyethylene glycol ethers with aliphatic and/or aromatic moieties. Biodegradation was measured by a non-standard method evaluating carbon dioxide production, using an acclimatized sewage sludge microflora. The duration of the tests was 26 days.

Test material:

PEGs (MW 300-4000 Da)
Ethoxylated fatty alcohols
Ethoxylated nonylphenols

Results:

Polyethylene glycols with molecular weights below 600 Da were readily biodegradable. PEGs with molecular weights above 1000 Da were not readily biodegradable.

Comments:

Lipex 102 E-75 has PEG moieties with 20-25 oxyethylene units, corresponding to a molecular weight of 880-1100 Da, indicating poor biodegradability.

Reference ID:

S-294 Biodegradability of nonionic surfactants: Screening test for predicting rate amd ultimate biodegradation, Sturm, R.N., JAOCS, 50, 159-167, (1973)

Literature data and original data on shea butter ethoxylate show that biodegradability of longer chain polyethylene glycols is low, while short chain polyethylene glycols and ethoxylated fatty alcohols are readily biodegradable. The maximum molecular weight for biodegradability is estimated to be around 600 Da, corresponding to about 13 oxyethylene units. The ethoxylated vegetable oils are hydrolyzed in the sewage conditions and the released fatty acids are degraded, however, the residual polyethylene glycol units are too long for fast biodegradation.

8.02 Accumulation

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

8.03 Aquatic toxicity

Test name:

Aquatic toxicity PEG

Method and laboratory:

Doctoral thesis on development of fish toxicity screening models. Chapter 4 covers the testing of polyethylene glycols of various molecular weights (2000-12000 Da) as model compounds. Zebrafish embryo mortalities are reported.

Test material:

PEGs with molecular weights 2000, 3000, 4000, 6000, 8000 and 12000

Results:

PEGs with molecular weights <= 4000 Da were not toxic and no LC50 could be determined. PEG 6000 had an LC50 of 90.8 g/l, PEG 8000 36.3 g/l and PEG 12000 38.8 g/l. The effect on the zebra fish eggs and embryos was associated with dehydration of the egg at high concentrations of the PEG.

Read across

Read across See the comments on the generic read across justification

Reference ID:

S-295 Limits of the fish embryo toxicity test with Danio rerio as an alternative to the acute fish toxicity test. Chapter 4, p 41-54. Henn, K. Dissertation, University of Heidelberg, (2011)

Only limited data for aquatic toxicity of ethoxylated vegetable oils or relevant read-across substance classes have been found. The existing data on polyethylene glycols with molecular weights between 2000-4000 Da indicate that fish toxicity is very low but more information will be needed for full evaluation of aquatic toxicity.

9.1 EU

9.1.1 Statement on EU Cosmetic Regulation EC 1223/2009
Latest statement, download “Statement on EU Cosmetic Regulation” at aakpersonalcare.com

9.1.2 EU Cosmetic Regulation EC 1223/2009, Annex II and III
Latest statement, download “Statement on EU Cosmetic Regulation” at aakpersonalcare.com

9.1.3 EU REACH 1907/2006
Latest statement, download “REACH Statement” at aakpersonalcare.com

9.1.4 EU SVHC (Substance of Very High Concern)
Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

9.2 Other country specific regulations:

9.2.1 US (California) Proposition 65
Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

9.2.2 China – NMPA
Latest statement, download “NMPA Statement” at aakpersonalcare.com

9.2.3 UK REACH
Latest statement, download “UK REACH Statements” at aakpersonalcare.com

9.2.4 Turkey - KKDIK
Latest statement, download “Turkey-KKDIK and SEA Statement” at aakpersonalcare.com

9.2.5 Australia - TGA
Latest statement, download “AAK PC Products and TGA status” at aakpersonalcare.com

9.3 Other non-Country specific regulatory issues

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

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

9.3.3 Nagoya Protocol / Biodiversity and Access Benefit Sharing regulation
Latest statement, download “General Statement AAK Ingredients” at aakpersonalcare.com

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

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

9.4 Inventory lists

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

In the Table below, column 3:

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

EC (EU)	EC-inventory	Listed
TSCA (U.S.)	Toxic Substances Control Act	Listed
DSL (Canada)	Domestic Substances List	CAS 68153-76-4 listed. At NDSL and ICL 70914-02-2 is listed and valid to be used.
AICS (Australia)	The Australian Inventory of Chemical Substances	CAS 68153-76-4 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.	No data
Japan	Japan Pharmacopoeia	No data
KECI (South Korea)	Korea Existing Chemicals Inventory	Listed and KE-17837, CAS 70914-02-2 KE-17837
PICCS (Philippines)	Philippine Inventory of Chemicals and Chemical Substances	Cas 70914-02-2 and 68153-76-4 is listed and valid to be used.
NZIoC (New Zealand)	New Zealand Inventory of Chemicals	Cas 70914-02-2 and 68153-76-4 is listed and valid to be used.
NECI (Taiwan)	National Existing Chemical Inventory	Cas 70914-02-2 and 68153-76-4 is listed and valid to be used.
Saudia Arabia	The Saudi Arabian Standards Organisation	No data
Malaysia	Chemicals Information Management System	No data
Mexico	Inventario Nacional de Sustancias Químicas	No data
Turkey		No data

10.1 Official standards

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

10.2 Private standards

10.2.1 Ecocert, Cosmos or Natrue

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

10.2.2 Vegan and Vegetariam claim

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

10.2.3 Other

10.3 Other Statements

10.3.1 BSE/TSE statements:

Not available, please contact AAK for more information.

10.3.2 GMO statement

Not available, please contact AAK for more information.

10.3.3 Other:

No data

11. CERTIFICATES

11.1 Halal
Not available

11.2 Kosher
Not available

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
No data

11.5 Food Safety/ FSSC 22000
N/A

11.6 Other
No other available

12. PATENTS

12.1 Patents

No data.

TRANSPORTS AND HANDLING – Lipex 102 E-75 50%

13.1 Transports

No data available

13.2 storage unopen package

Storage to fulfill shelf life:

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

See Product data sheet for more information.

Retest of batch:

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

13.3 Handling of product for use

13.3.1 Use of full package

Recommended melting temperature.

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

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

Note: This product contains 50% water When heating if possible, keep lid on packaging to minimize water evaporation

13.3.2 Use of full package for partly use

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

Drums: Melt the whole content until at least 60C

Buckets: Melt the whole content until at least 60C

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

At lower temperatures a precipitate may form on prolonged storage. If the material has been stored at low temperatures and has started to crystallize it is important to melt the whole content before use. Recommended melting temperature for product in drums, is at least 60 C. Melt the whole content and homogenize. Keep melting time as short as possible to avoid oxidation of the product.

Note: This product contains 50% water When heating if possible, keep lid on packaging to minimize water evaporation

Note:

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

14. REFERENCES

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15. DISCLAIMER

15.1 Disclaimer

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Ship-to -

Analytical Certificate

Delivery	**81115252 - 50**
Print date	2022-01-11
Your reference	
Our reference	Femke den Hartog
Material	8501-834 LIPEX 102 E-75 50%
Your material no.	
Date of shipment	2022-01-11

Batch 1-21162 / **Quantity** 60 KG / **Prod. date** 2021-04-30
Inspection lot 2779498

Characteristic	Result		Lower Limit	Target	Upper Limit
Acid value(IUPAC 2.201(m))					
Acid value	0.85	mg KOH/g			2.00
Colour Gardner(AOCS Td 1a-64)					
Colour Gardner	2				3
Saponification Value(IUPAC 2.202)					
Saponification Value	10.5	mg KOH/g			18.0
Water content(Vatten LB)					
Water content	49.6	%	48.0		52.0
Total aerobic count(M&H; NMKL 83-3)					
Total aerobic count	< 1.0	log cfu/g			2.0
Cloudpoint(TC276/WG2N30 930809C)					
Cloudpoint	70.0	℃	66.0		71.0

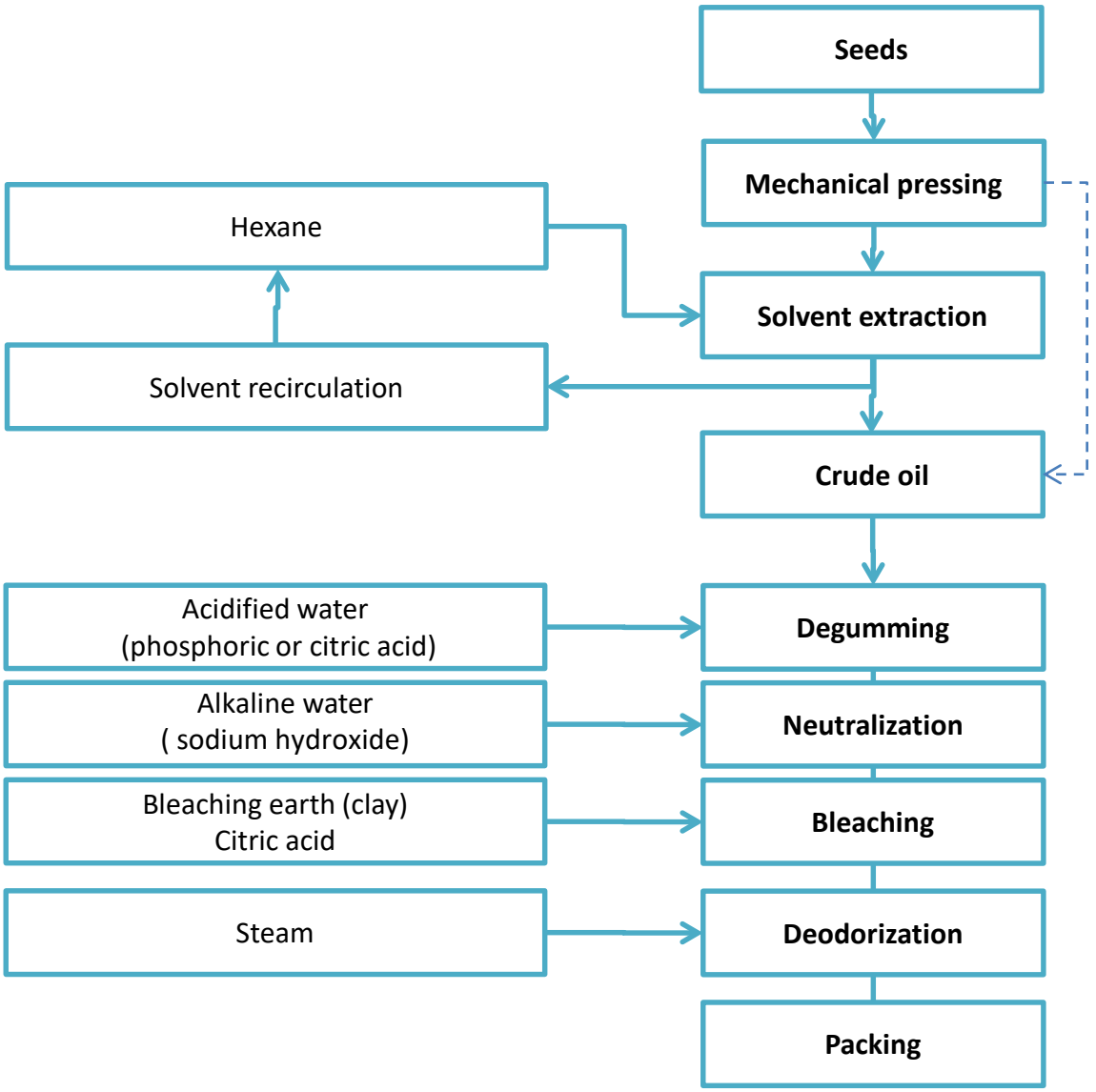
Recommended Shelf Life:
18 months from production

Quality Control Manager
AAK Sweden AB

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

ZAO S12125 1

Lipex 102 E75 Ethoxylated product



Explanations what each step contribute with

Separates crude oil from seed

Separates crude oil from seed

Removes phospholipids, metals and proteins

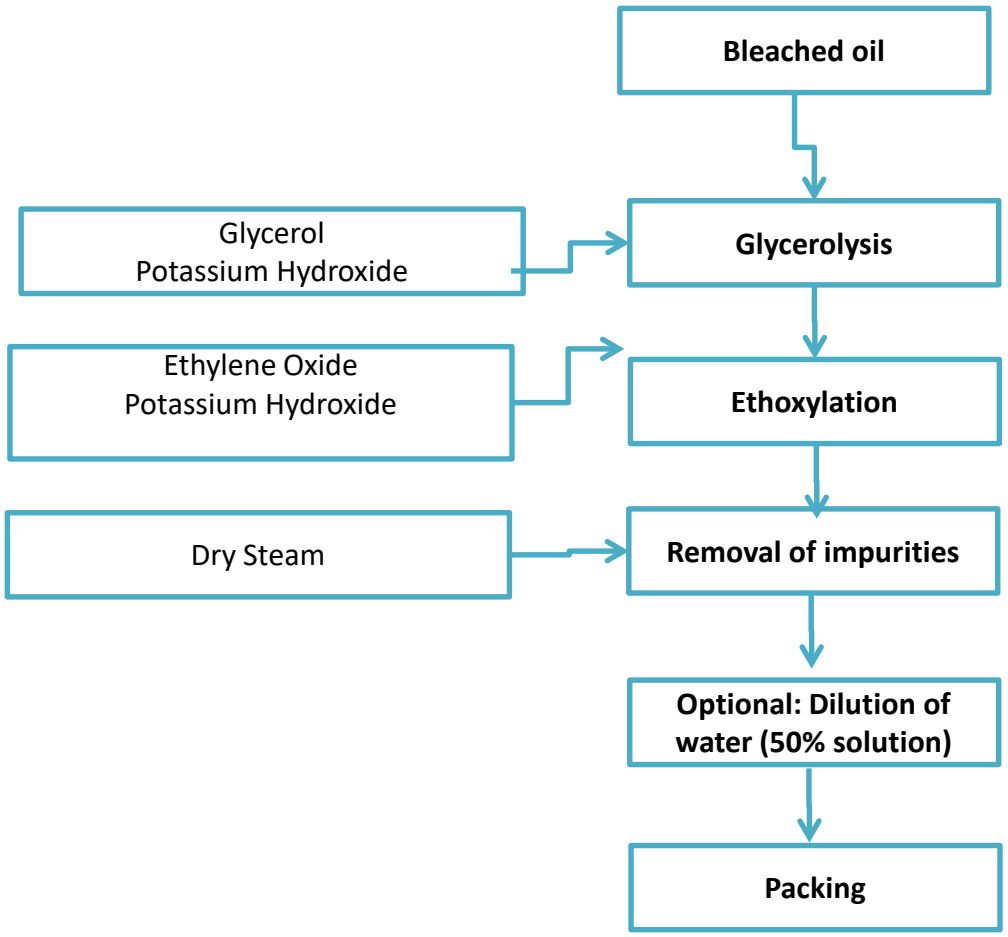
Removes free fatty acids, metals and proteins

Removes pigments, metals and proteins

Removes flavours, free fatty acids and oxidation products

See Disclaimer

Lipex 102 E75 Ethoxylated product



Explanations what each step contribute with

Produces a mixture of mono-, di- and triglycerides

Neutralises catalyst and stops reaction

Removes traces of ethylene oxide, dioxane, formaldehyde and acetaldehyde

Makes ingredient easier to handle

See Disclaimer