SAFETY DATA SHEET



SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation

STIEPROX LIQUID

of the mixture

Registration number -

Synonyms STIEPROX SHAMPOO * SEBIPROX LIQUID * SEBIPROX SHAMPOO * FORMULATION CODE:

290A; 297A; 488A * STIEFEL PRODUCT * CICLOPIROX OLAMINE, FORMULATED PRODUCT

Issue date 21-September-2015

Version number 03

Revision date 06-May-2016

Supersedes date 21-September-2015

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Medicinal Product.

Cosmetic Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

Uses advised against

No other uses are advised.

1.3. Details of the supplier of the safety data sheet

Stiefel Laboratories, Inc. (a GSK company)

GlaxoSmithKline UK 980 Great West Road

Brentford, Middlesex TW8 9GS UK

UK General Information (normal business hours): +44-20-8047-5000

GlaxoSmithKline US 5 Moore Drive

Research Triangle Park, NC 27709 USA

US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com Website: www.gsk.com

1.4. Emergency telephone

number

TRANSPORT EMERGENCIES:

 UK In-country toll call:
 +(44)-870-8200418

 International toll call:
 +1 703 527 3887

available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.3. Other hazardsThis product will support combustion at elevated temperatures.

See section 11 for additional information on health hazards.

Material name: STIEPROX LIQUID

SDS UK

1/40

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name		%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
SODIUM LAURETH SUL	FATE	10 - < 20	9004-82-4	-	-	
Classification:	Acute Tox	к. 4;Н302, Еуе	Irrit. 2;H319, Aqua	tic Chronic 3;H412		
COCAMIDOPROPYL BE (HUNTSMAN)	TAINE	5 - < 10	61789-40-0 263-058-8	-	-	
Classification:	Aquatic A	cute 1;H400, A	Aquatic Chronic 1;H	1410		
COCAMIDE DIETHANOI	_AMINE	3 - < 5	61791-31-9 263-163-9	-	-	
Classification:	Aquatic A	cute 1;H400, A	Aquatic Chronic 1;H	1410		
Hexylene glycol		3 - < 5	107-41-5 203-489-0	-	603-053-00-3	
Classification:	Skin Irrit.	2;H315, Eye Ir	rit. 2;H319			
OLEYL ALCOHOL		1 - < 3	143-28-2 205-597-3	-	-	
Classification:	Skin Irrit.	2;H315, Eye Ir	rit. 2;H319			
CICLOPIROX OLAMINE		1 - 1.5	41621-49-2 255-464-9	-	-	
Classification:	Skin Irrit.	2;H315, Eye Ir	rit. 2;H319, STOT	SE 3;H335, Aquatic Acute 1;H4	400	
FRAGRANCE TIMOTEL	AF 17050	< 1	Unassigned	-	-	
Classification:	Skin Sens	s. 1;H317, Aqu	atic Chronic 2;H41	1		
	JAIII JEIIS	5. 1,11317, Aqu	2-	1		

Other components below reportable levels 60 - < 65

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance. PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label

where possible). Ensure that medical personnel are aware of the material(s) involved, and take

precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large

amount does occur, call a poison control centre immediately. Do not induce vomiting without

advice from poison control center.

4.2. Most important symptoms and effects, both acute and

None known. Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed

delayed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards

This product will support combustion at elevated temperatures.

5.1. Extinguishing media

Suitable extinguishing

media

Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing

media

None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting

procedures

Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the

6.2. Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

6.3. Methods and material for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other

sections

For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No special control measures required for the normal handling of this product. Avoid prolonged

exposure.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame.

Medicinal Product. 7.3. Specific end use(s)

Cosmetic Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Components	Туре	Value	Note
CICLOPIROX OLAMINE (CAS 41621-49-2)	OHC	2	PROVISIONAL
COCOAMIDOPROPYL BETAINE (CAS 61789-40-0)	OHC	1	PROVISIONAL
UK. EH40 Workplace Exposure L	imits (WELs)		
Components	Туре	Value	
Hexylene glycol (CAS	STEL	123 mg/m3	

Material name: STIEPROX LIQUID

107-41-5)

Components Type Value

25 ppm
TWA 123 mg/m3
25 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring

procedures

Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect Not available.

Predicted no effect concentrations (PNECs)

Exposure guidelines
8.2 Exposure controls

8.2. Exposure controls

Appropriate engineering controls

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in

discussion with the supplier of the personal protective equipment. Follow all local regulations if

personal protective equipment (PPE) is used in the workplace.

Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g.

EN 166).

Skin protection

Eye/face protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select

suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min

permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or

contamination. (EN 14605 for splashes, EN ISO 13982 for dust).

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing

concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic,

inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material

and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance

from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations

Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Liquid.

Form Viscous liquid.

Colour Yellow/orange.

Odour Not available.

Odour threshold Not available.

PH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point > 96 °C (> 204.8 °F) Closed cup (Estimation based on components).

Evaporation rate Not available.
Flammability (solid, gas) Not applicable.
Upper/lower flammability or explosive limits

Flammability limit - lower Not available

(%)

133375 Version #: 03 Revision date: 06-May-2016 Issue date: 21-September-2015

Flammability limit - upper

(%)

Not available.

Not available. Vapour pressure Vapour density Not available. Not available. Relative density

Solubility(ies)

Not available. Solubility (water) Solubility (other) Not available. **Partition coefficient** Not available.

(n-octanol/water)

Not available. Auto-ignition temperature **Decomposition temperature** Not available. Not available. **Viscosity** Not available. **Explosive properties** Not available. Oxidising properties

9.2. Other information No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Material is stable under normal conditions. 10.2. Chemical stability

10.3. Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid Keep away from heat, sparks and open flame. Contact with incompatible materials.

Strong oxidising agents. 10.5. Incompatible materials

None known. Irritating and/or toxic fumes and gases may be emitted upon the product's 10.6. Hazardous

decomposition. decomposition products

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Health injuries are not known or expected under normal use. Skin contact

Eye contact Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Health injuries are not known or expected under normal use. May be harmful if swallowed. Ingestion

However, ingestion is not likely to be a primary route of occupational exposure.

None known. Direct contact with eyes may cause temporary irritation. **Symptoms**

11.1. Information on toxicological effects

Expected to be a low hazard for usual industrial or commercial handling by trained personnel. **Acute toxicity**

Components Test results **Species**

CICLOPIROX OLAMINE (CAS 41621-49-2)

Acute

Oral

LD50 Rat 2350 mg/kg

Chronic

Oral

LOEL Rat 2800 mg/kg/day 28 Day Study

COCAMIDOPROPYL BETAINE (HUNTSMAN) (CAS 61789-40-0)

Acute

Oral

LD50 Mouse > 2000 mg/kg

Hexylene glycol (CAS 107-41-5)

Acute

Oral

LD50 Rat > 2000 mg/kg

Material name: STIEPROX LIQUID

Test results Components **Species**

SODIUM LAURETH SULFATE (CAS 9004-82-4)

Acute Oral

LD50 Rat 1288 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Health injuries are not known or expected under normal use. Direct contact with eyes may cause Serious eye damage/eye

temporary irritation. irritation

Respiratory sensitisation No studies have been conducted.

None known. This product is not expected to cause skin sensitisation. Skin sensitisation

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result Carcinogenicity

of occupational exposure.

Contains no ingredient listed as toxic to reproduction Reproductive toxicity

Specific target organ toxicity -

single exposure

Not assigned.

Specific target organ toxicity -

repeated exposure

Not assigned.

Not established. **Aspiration hazard**

Mixture versus substance

information

No information available.

Other information Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

Contains a substance which causes risk of hazardous effects to the environment. 12.1. Toxicity

Components **Species** Test results

CO

EC50

COCAMIDOPROPYL BETA	INE (HUNTSMAN	I) (CAS 61789-40-0)	
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.55 mg/l, 96 hours
	NOEC	Green algae (Scenedesmus subspicatus)	0.09 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	6.5 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	1.6 mg/l, 48 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	2 mg/l, 96 hours semi-static test conditions
	NOEC	Zebra fish (Adult Brachydanio rerio)	1.7 mg/l, 96 hours semi-static test conditions
Microtox	MIC	Pseudomonas	> 3000 mg/l, 16 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	3.6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
Hexylene glycol (CAS 107-4	11-5)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	3200 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	12800 mg/l, 96 hours Flow-through test
		Fathead minnow (Adult Pimephales promelas)	8690 mg/l, 96 hours Flow-through test

Material name: STIEPROX LIQUID

Microtox

Rainbow trout (Adult Salmo gairdneri)

Microtox

9450 mg/l, 96 hours Flow-through test

3070 mg/l, 5 minutes

Components Species Test results

SODIUM LAURETH SULFATE (CAS 9004-82-4)

Aquatic

Acute

Crustacea EC50 Water flea (Ceriodaphnia dubia) 3.12 mg/l, 48 hours

12.2. Persistence and

degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

COCAMIDOPROPYL BETAINE (HUNTSMAN) 97 %, 28 days Modified Zahn-Wellens, DOC removal.,

Activated sludge

99 %, 28 days Modified Zahn-Wellens, DOC removal.,

Activated sludge

Percent degradation (Aerobic biodegradation-ready)

COCAMIDOPROPYL BETAINE (HUNTSMAN) 100 %, 20 Days Modified Sturm test., Activated sludge

84 %, 30 days Closed Bottle test, Activated sludge

100 % River die away, River water

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

CICLOPIROX OLAMINE 2.6 (Calculated). SODIUM LAURETH SULFATE 1.99 (calculated)

12.4. Mobility in soilNot available.Mobility in generalNot available.12.5. Results of PBTNot available.

SODIUM LAURETH SULFATE

and vPvB assessment

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some

product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied. Empty containers should be taken to an approved waste handling site for recycling or

disposal.

EU waste codeThe Waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not

discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable

regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number UN3082

14.2. UN proper shipping Environmentally hazardous substance, liquid, n.o.s. (SODIUM LAURETH SULFATE,

name COCOAMIDOPROPYL BETAINE)

14.3. Transport hazard class(es)

Class 9
Subsidiary risk Label(s) 9
Hazard No. (ADR) 90
Tunnel code E
14.4. Packing group III
14.5. Environmental hazards No.

14.6. Special precautions Not available.

for user

IATA

14.1. UN number UN3082

^{*} Estimates for product may be based on additional component data not shown.

14.2. UN proper shipping Environmentally hazardous substance, liquid, n.o.s. (SODIUM LAURETH SULFATE,

COCOAMIDOPROPYL BETAINE)

14.3. Transport hazard 9

class(es)

name

Subsidiary class(es) 14.4. Packing group III
14.5. Environmental hazards Yes
Labels required 9
ERG Code 9L

14.6. Special precautions

for user

Other information

Allowed with restrictions.

Not available.

Cargo aircraft only Additional Information:

Passenger & cargo Allowed with restrictions.

IMDG

14.1. UN number UN3082

14.2. UN proper shipping ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (SODIUM LAURETH

name SULFATE, COCOAMIDOPROPYL BETAINE), MARINE POLLUTANT

14.3. Transport hazard class(es)

Class 9
Subsidiary risk Label(s) 9
14.4. Packing group III
14.5. Environmental hazards
Marine pollutant Yes

EmS F-A, S-F 14.6. Special precautions Not available.

for user

14.7. Transport in bulk Not established.

according to Annex II of

MARPOL73/78 and the IBC Code

ADR; IATA; IMDG



Marine pollutant



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at

work, as amended

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended

Hexvlene alvcol (CAS 107-41-5)

Directive 94/33/EC on the protection of young people at work, as amended

Not listed.

Other regulations The product is classified and labelled in accordance with EC directives or respective national laws.

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations Follow national regulation for work with chemical agents.

15.2. Chemical safety

assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

Not available List of abbreviations

GSK Hazard Determination References

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation

methods and test data, if available.

Full text of any H-statements not written out in full under

Sections 2 to 15

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation.

H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Material name: STIEPROX LIQUID 133375 Version #: 03 Revision date: 06-May-2016 Issue date: 21-September-2015

Product and Company Identification: Synonyms **Revision information**

SECTION 2: Hazards identification: Hazard summary SECTION 2: Hazards identification: Hazard statements

SECTION 2: Hazards identification: Prevention SECTION 2: Hazards identification: Response

SECTION 2: Hazards identification: Supplemental label information

Composition / Information on Ingredients: Ingredients

SECTION 7: Handling and storage: 7.1. Precautions for safe handling

SECTION 12: Ecological information: Mobility in general

Regulatory Information: United States

Training information Disclaimer

Follow training instructions when handling this material.

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and

the suitability of the material or product for any particular purpose.

Material name: STIEPROX LIQUID

SDS UK 133375 Version #: 03 Revision date: 06-May-2016 Issue date: 21-September-2015