

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

1.1. Product identifier

Trade name or designation of the mixture ALPHOSYL HC CREAM

Registration number -

Synonyms FORMULA NUMBER IB-0532 * ALPHOSYL HC CREAM (CONTAINING COAL TAR) * ALLANTOIN, COAL TAR EXTRACT AND HYDROCORTISONE ALCOHOL, FORMULATED PRODUCT

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Version number 07

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

Identified uses Medicinal 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

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
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

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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.

Supplemental label information None.

2.3. Other hazards

Assume that this product is capable of sustaining combustion.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
BEESWAX	5 - < 10	8012-89-3 232-383-7	-	-	
Classification:	DSD: - CLP: -				
CETYL ALCOHOL	5 - < 10	36653-82-4 253-149-0	-	-	
Classification:	DSD: Xi;R38 CLP: Skin Irrit. 2;H315				
OLEYL ALCOHOL	5 - < 10	143-28-2 205-597-3	-	-	
Classification:	DSD: Xi;R36/38 CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319				
COAL TAR	5	8007-45-2 232-361-7	-	648-081-00-7	M=10
Classification:	DSD: Carc. Cat. 1;R45, N;R50/53 CLP: Carc. 1A;H350, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
ALLANTOIN	2	97-59-6 202-592-8	-	-	
Classification:	DSD: - CLP: -				
ISOPROPYL PALMITATE	1 - < 3	142-91-6 205-571-1	-	-	
Classification:	DSD: Xi;R36/38 CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319				
Lecithin	1 - < 3	8002-43-5 232-307-2	-	-	
Classification:	DSD: - CLP: -				
PHENETHYL ALCOHOL	1 - < 3	60-12-8 200-456-2	-	-	
Classification:	DSD: Xn;R22, Xi;R36 CLP: Acute Tox. 4;H302, Eye Irrit. 2;H319				
SODIUM CITRATE, ANHYDROUS	1 - < 3	68-04-2 200-675-3	-	-	
Classification:	DSD: - CLP: -				
TRIETHANOLAMINE, PURE 99%	1 - < 3	102-71-6 203-049-8	-	-	
Classification:	DSD: Xi;R36 CLP: Eye Irrit. 2;H319				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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HYDROCORTISONE	0.54	50-23-7 200-020-1	-	-	
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Classification: **DSD:** Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21
CLP: Repr. 1B;H360D, STOT RE 2;H373

PARAFFIN OIL	< 0.3	8012-95-1 232-384-2	-	-	
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Classification: **DSD:** -
CLP: -

Other components below reportable levels 60 - < 70
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 Take off all contaminated clothing immediately. Wash contaminated clothing before reuse.
Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

Inhalation	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed Possible effects of overexposure in the workplace include: temporary decrease in white blood cell counts, suppression of adrenal glands, symptoms of hypersensitivity (such as skin rash, hives, itching), increased susceptibility to infection.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards Assume that this product is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2). Water.
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. Keep out of low areas. 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 SDS.

6.2. Environmental precautions Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

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 entry into waterways, sewer, basements or confined areas. 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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Do not get in eyes, on skin, or on clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Components	Type	Value	Note
ALLANTOIN (CAS 97-59-6)	OHC	1	>1000 - <=5000 mcg/m3
BEESWAX (CAS 8012-89-3)	OHC	1	
HYDROCORTISONE (CAS 50-23-7)	8 HR TWA	100 mcg/m3	
	OHC	3	Skin Reproductive hazard PROVISIONAL
		3	
ISOPROPYL PALMITATE (CAS 142-91-6)	OHC	2	
Lecithin (CAS 8002-43-5)	OHC	1	
PHENETHYL ALCOHOL (CAS 60-12-8)	OHC	2	
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)	8 HR TWA	5000 mcg/m3	
	OHC	1	

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 concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.
Individual protection measures, such as personal protective equipment	
General information	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin 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	Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Cream.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.

Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
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.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Ingestion	May be harmful if swallowed. May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	May be irritating to the skin.
HYDROCORTISONE	Steroid withdrawal rash. Increased sensitivity to bruising
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms	The possible consequences of overexposure include: suppression of adrenal glands, symptoms of hypersensitivity (such as skin rash, hives, itching), temporary decrease in white blood cell counts, increased susceptibility to infection.
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11.1. Information on toxicological effects

Acute toxicity	May be harmful if swallowed.
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Components	Species	Test results
ALLANTOIN (CAS 97-59-6)		
Acute		
<i>Oral</i>		
LD50	Rat	> 10000 mg/kg Literature data
BEESWAX (CAS 8012-89-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5 g/kg
CETYL ALCOHOL (CAS 36653-82-4)		
Acute		
<i>Oral</i>		
LD50	Rat	5 g/kg
COAL TAR (CAS 8007-45-2)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 7950 mg/kg Literature data
HYDROCORTISONE (CAS 50-23-7)		
Acute		
<i>Oral</i>		
	Mouse	5000 mg/kg Hydrocortisone
	Rat	5000 mg/kg Hydrocortisone

Components	Species	Test results
Subacute		
<i>Dermal</i>		
TDL0	Rat	2.3 mg/kg, 61 Day Hydrocortisone acetate
<i>Other</i>		
TDL0	Rat	175 mg/kg, 35 Day Hydrocortisone acetate, subcutaneous injection
Subchronic		
<i>Other</i>		
TDL0	Rat	175 mg/kg, 85 Day Hydrocortisone, subcutaneous injection
PARAFFIN OIL (CAS 8012-95-1)		
Acute		
<i>Oral</i>		
LD50	Mouse	22 g/kg
TRIETHANOLAMINE, PURE 99% (CAS 102-71-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 20000 mg/kg
<i>Oral</i>		
LD50	Rat	8000 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. May be irritating to the skin.	
Irritation Corrosion - Skin		
ALLANTOIN		Dermal irritancy study, Schwartz patch test in human volunteers; literature data Result: Non-irritant Species: Human
Serious eye damage/eye irritation	May be irritating to eyes.	
Eye		
ALLANTOIN		Acute ocular irritation; OECD 405, Literature data Result: Non-Irritating Species: Rabbit
HYDROCORTISONE		Read across, Corticosteroid Result: Not likely to be a severe irritant
Respiratory sensitisation	Health injuries are not known or expected under normal use.	
Skin sensitisation		
Sensitisation		
HYDROCORTISONE		Epidemiology, Occasionally from clinical use. Species: Human
ALLANTOIN		Patch test, Schwartz patch test in human volunteers; literature data Result: Not allergenic Species: Human SAR / QSAR, DEREK, Lhasa, UK Result: No structural alerts identified.
Germ cell mutagenicity	Health injuries are not known or expected under normal use.	
Mutagenicity		
HYDROCORTISONE		Ames, Hydrocortisone Result: negative Notes: Hydrocortisone Chromosomal Aberration Assay In Vitro, Hydrocortisone Result: positive Notes: Hydrocortisone GreenScreen mammalian cell mutation assay, Hydrocortisone Result: negative Notes: Hydrocortisone Micronucleus Test, Hydrocortisone Result: positive Notes: Hydrocortisone

Mutagenicity		
HYDROCORTISONE		Rat UDS assay, Hydrocortisone Result: negative Notes: Hydrocortisone
ALLANTOIN		SAR / QSAR, DEREK, Lhasa, UK Result: No structural alerts identified.
Carcinogenicity		Health injuries are not known or expected under normal use. Contains a material (coal tar) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect. Contains a material (paraffin oil) classified as a carcinogen by external agencies. These effects are suspected to be due to impurities that are not expected to be present in purified material used in this product.
ALLANTOIN		2 year bioassay, 0.2% in diet; Literature data Result: negative Species: Rat
HYDROCORTISONE		Result: negative Species: Rat
ALLANTOIN		Notes: Hydrocortisone SAR / QSAR, DEREK, Lhasa, UK Result: No structural alerts identified.
IARC Monographs. Overall Evaluation of Carcinogenicity		
COAL TAR (CAS 8007-45-2)		1 Carcinogenic to humans.
TRIETHANOLAMINE, PURE 99% (CAS 102-71-6)		3 Not classifiable as to carcinogenicity to humans.
Reproductive toxicity		Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.
Reproductivity		
HYDROCORTISONE		Hydrocortisone Result: Developmental effects including cleft palate Species: Hamster Notes: Hydrocortisone Hydrocortisone acetate Result: Effects on fertility Species: Pig Hydrocortisone/ Hydrocortisone acetate Result: Developmental effects including cleft palate Species: Mouse Notes: Hydrocortisone Hydrocortisone/ Hydrocortisone acetate Result: Developmental effects including cleft palate Species: Rat Notes: Hydrocortisone Hydrocortisone/ Hydrocortisone acetate Result: Developmental effects including cleft palate, foetal lethality Species: Rabbit Notes: Hydrocortisone
Specific target organ toxicity - single exposure	Not assigned.	
Specific target organ toxicity - repeated exposure	.	
HYDROCORTISONE		Epidemiology Organ: Adrenals, Immune system, Bone, Eyes
Aspiration hazard	Not an aspiration hazard.	
Mixture versus substance information	No information available.	
Other information	Not available.	

Specific target organ toxicity - single exposure	Not assigned.	
Specific target organ toxicity - repeated exposure	.	
HYDROCORTISONE	Epidemiology Organ: Adrenals, Immune system, Bone, Eyes	
Aspiration hazard	Not an aspiration hazard.	
Mixture versus substance information	No information available.	
Other information	Not available.	
SECTION 12: Ecological information		
12.1. Toxicity	The product contains a substance which may cause long-term adverse effects in the environment. Contains a substance which causes risk of hazardous effects to the environment.	
Components	Species	Test results
ALLANTOIN (CAS 97-59-6)		
Acute		
IC50	Activated sludge	> 1000 mg/l, 3 hours Nominal
NOEC	Activated sludge	1000 mg/l, 3 hours

Components		Species	Test results
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 180 mg/l, 48 hours Measured
	NOEC	Daphnia	180 mg/l, 48 hours
Microtox	EC50	Microtox	7060 mg/l, 15 minutes
CETYL ALCOHOL (CAS 36653-82-4)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	676 mg/l, 96 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 1000 mg/l, 96 hours
		Fathead minnow (Adult Pimephales promelas)	> 500 mg/l, 5 days
COAL TAR (CAS 8007-45-2)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	0.048 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	0.64 mg/l, 96 hours Static test
		Rainbow trout (Juvenile Oncorhyncus mykiss)	0.43 mg/l, 96 hours Static test
HYDROCORTISONE (CAS 50-23-7)			
Aquatic			
Acute			
Crustacea	NOEC	Water flea (Daphnia magna)	0.1 mg/l, 6 days
PHENETHYL ALCOHOL (CAS 60-12-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Chronic			
Other	LC50	Pseudomonas putida	1320 mg/l, 17 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	490 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	287 mg/l, 48 hours
Fish	EC50	Golden ide/orfe (Adult Leuciscus idus)	220 - 460 mg/l, 96 hours Static test
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	161 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	2031 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	590 - 1018 mg/l, 96 hours Static test
Microtox	EC50	Microtox	18.8 mg/l, 15 minutes
TRIETHANOLAMINE, PURE 99% (CAS 102-71-6)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	565.2 - 658.3 mg/l, 48 Hours
Fish	LC50	Fathead minnow (Pimephales promelas)	10610 - 13010 mg/l, 96 Hours

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

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

COAL TAR 1.5 - 29200 Days Estimated

Half-life (Photolysis-atmospheric)

CETYL ALCOHOL 16.7 Hours Estimated

COAL TAR 2 - 240 Hours Estimated

PHENETHYL ALCOHOL 1.6 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ALLANTOIN 100 %, 10 days Modified Zahn-Wellens, DOC removal., Activated sludge

CETYL ALCOHOL 100 %, 2 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

0.4 %, < 1 day Other degradation test system, Activated sludge

SODIUM CITRATE, ANHYDROUS 30 - 60 %, 5 days BOD5

Percent degradation (Aerobic biodegradation-ready) 98 %, 2 days Modified Zahn-Wellens, Activated sludge

PHENETHYL ALCOHOL 87 %, 14 days MITI test, Activated sludge

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

ALLANTOIN -2.9 (Calculated).

HYDROCORTISONE 1.61 (Measured).

PHENETHYL ALCOHOL 1.36

TRIETHANOLAMINE, PURE 99% -1

Bioconcentration factor (BCF)

CETYL ALCOHOL > 9999 Measured

COAL TAR 5 - 5500 Estimated

PHENETHYL ALCOHOL 6 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CETYL ALCOHOL 3.58 - 4.67 Estimated

COAL TAR 1.17 - 4.2 Calculated

PHENETHYL ALCOHOL 1.46 Estimated

Mobility in general

Volatility

Henry's law

ALLANTOIN < 0 atm m³/mol Estimated

CETYL ALCOHOL 0.000073 atm m³/mol Estimated

COAL TAR 0 - 0.011 atm m³/mol Measured

PHENETHYL ALCOHOL 0 atm m³/mol Measured, 25 C

12.5. Results of PBT and vPvB assessment Not available.

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).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
EU waste code	The 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 allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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 name	Environmentally hazardous substances, liquid, n.o.s. (ALPHOSYL HC CREAM (CONTAINING COAL TAR))
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Hazard No. (ADR)	Not available.
Tunnel code	Not available.
14.4. Packing group	III
14.5. Environmental hazards	Yes
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	UN3082
14.2. UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (ALPHOSYL HC CREAM (CONTAINING COAL TAR))
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	9
14.5. Environmental hazards	No.
ERG Code	9L
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed.
Additional Information:	
Passenger & cargo	Allowed.

IMDG

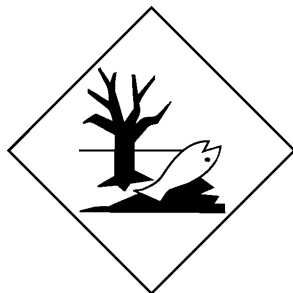
14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ALPHOSYL HC CREAM (CONTAINING COAL TAR))
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
14.6. Special precautions for user	Not available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

ADR; IATA; IMDG





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

Not listed.

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

Not listed.

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

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 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

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) 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

COAL TAR (CAS 8007-45-2)

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

COAL TAR (CAS 8007-45-2)

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

COAL TAR (CAS 8007-45-2)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

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

COAL TAR (CAS 8007-45-2)

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

COAL TAR (CAS 8007-45-2)

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. Pregnant women should not work with the product, if there is the least risk of exposure.

National regulations

Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. 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

List of abbreviations	Not available.
References	GSK Hazard Determination
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 statements or R-phrases and H-statements under Sections 2 to 15	<p>R22 Harmful if swallowed.</p> <p>R36 Irritating to eyes.</p> <p>R36/38 Irritating to eyes and skin.</p> <p>R38 Irritating to skin.</p> <p>R45 May cause cancer.</p> <p>R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.</p> <p>R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>R61 May cause harm to the unborn child.</p> <p>R62 Possible risk of impaired fertility.</p> <p>H302 Harmful if swallowed.</p> <p>H315 Causes skin irritation.</p> <p>H319 Causes serious eye irritation.</p> <p>H350 May cause cancer.</p> <p>H360D May damage the unborn child.</p> <p>H373 May cause damage to organs through prolonged or repeated exposure.</p> <p>H400 Very toxic to aquatic life.</p> <p>H410 Very toxic to aquatic life with long lasting effects.</p>
Revision information	<p>Product and Company Identification: Product and Company Identification</p> <p>Composition / Information on Ingredients: Ingredients</p> <p>Physical & Chemical Properties:</p> <p>Transport Information: Material Transportation Information</p> <p>Regulatory Information: United States</p> <p>GHS: Classification</p>
Training information	Follow training instructions when handling this material.
Disclaimer	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.