

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

### 1.1. Product identifier

**Trade name or designation of the mixture** NIX DERMAL CREAM

**Registration number** -

**Synonyms** NIX DERMAL CREAM 5% (CANADA) \* NIX DERMAL CREME POUR LA PEAU 5% \* NIX CREAM \* LOTRIX CREAM \* LOXAZOL HYDROFIELE CREME \* LYCLEAR CREAM \* LYCLEAR DERMAL CREAM \* ZALVOR CREAM \* PERMETHRIN, FORMULATED PRODUCT

**Issue date** 22-August-2014

**Version number** 05

**Revision date** 22-August-2014

### 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

#### 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** Expected to be non-combustible.  
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
PERMETHRIN	5	52645-53-1 258-067-9	-	613-058-00-2	M=1000
<b>Classification:</b>	<b>DSD:</b>	Xn;R20/22, R43, N;R50/53			
	<b>CLP:</b>	Acute Tox. 4;H302, Skin Sens. 1;H317, Acute Tox. 4;H332, Aquatic Acute 1;H400, Aquatic Chronic 1;H410			
GLYCERYL MONOSTEARATE	4.0 - 5.0	31566-31-1 250-705-4	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
GLYCERIN	2	56-81-5 200-289-5	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
POLYOXYETHYLENE (20) SORBITAN MONOOLEATE	<1.0	9005-65-6 500-019-9	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
FORMALDEHYDE 35% SOLUTION	<0.3	50-00-0 200-001-8	-	605-001-00-5	
<b>Classification:</b>	<b>DSD:</b>	Carc. Cat. 3;R40, T;R23/24/25, C;R34, R43			
	<b>CLP:</b>	Acute Tox. 3;H301, Acute Tox. 3;H311, Skin Corr. 1B;H314, Skin Sens. 1;H317, Acute Tox. 3;H331, STOT SE 3;H335, Carc. 2;H351			
PARAFFIN OIL	0.1 - 0.2	8012-95-1 232-384-2	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
2,6-DI-TERT-BUTYL-P-CRESOL	<0.1	128-37-0 204-881-4	-	-	
<b>Classification:</b>	<b>DSD:</b>	Xn;R22, N;R50/53			
	<b>CLP:</b>	Acute Tox. 4;H302, Aquatic Acute 1;H400, Aquatic Chronic 1;H410			
SODIUM HYDROXIDE	<0.1	1310-73-2 215-185-5	-	011-002-00-6	
<b>Classification:</b>	<b>DSD:</b>	C;R35			
	<b>CLP:</b>	Skin Corr. 1A;H314			

Other components below reportable levels 70.0 - 80.0

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

<b>Inhalation</b>	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.
<b>Skin contact</b>	Take off immediately all contaminated clothing. Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Eye contact</b>	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. Call a physician or poison control centre immediately.
<b>Ingestion</b>	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

The possible consequences of overexposure include: symptoms similar to alcohol intoxication, symptoms of hypersensitivity (such as skin rash, hives, itching).

#### 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** Expected to be non-combustible.

#### 5.1. Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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** 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

PERMETHRIN (CAS  
52645-53-1)

8 HR TWA

200 mcg/m3

POLYOXYETHYLENE (20)  
SORBITAN MONOOLEATE  
(CAS 9005-65-6)

OHC

2

OHC

1

##### UK. EH40 Workplace Exposure Limits (WELs)

##### Components

##### Type

##### Value

##### Form

2,6-DI-TERT-BUTYL-P-CR  
ESOL (CAS 128-37-0)

TWA

10 mg/m3

FORMALDEHYDE 35%  
SOLUTION (CAS 50-00-0)

STEL

2.5 mg/m3

TWA

2 ppm

2.5 mg/m3

2 ppm

GLYCERIN (CAS 56-81-5)  
SODIUM HYDROXIDE  
(CAS 1310-73-2)

TWA

10 mg/m3

Mist.

STEL

2 mg/m3

#### 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. 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.

##### Skin protection

##### - Hand protection

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

##### - Other

Not normally needed.

##### Respiratory protection

No personal respiratory protective equipment normally required.

##### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

#### Hygiene measures

For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. An occupational/industrial hygiene monitoring method has been developed for this material.

#### 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.

<b>Form</b>	Cream.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## SECTION 11: Toxicological information

<b>General information</b>	Occupational exposure to the substance or mixture may cause adverse effects.
<b>Information on likely routes of exposure</b>	
<b>Ingestion</b>	May be harmful if swallowed. Do not ingest. Health injuries are not known or expected under normal use.
<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	May be irritating to the skin. Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. May be irritating to eyes. Avoid contact with eyes.
<b>Symptoms</b>	The possible consequences of overexposure include: symptoms similar to alcohol intoxication, symptoms of hypersensitivity (such as skin rash, hives, itching).
<b>11.1. Information on toxicological effects</b>	
<b>Acute toxicity</b>	May be harmful if swallowed. Health injuries are not known or expected under normal use.

Components	Species	Test results
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	890 mg/kg
GLYCERIN (CAS 56-81-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
PARAFFIN OIL (CAS 8012-95-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	22 g/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	1350 mg/kg
<i>Oral</i>		
LD50	Rat	104 - 340 mg/kg

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

<b>Skin corrosion/irritation</b>	May be irritating to the skin. Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	May be irritating to eyes. Health injuries are not known or expected under normal use.
<b>Respiratory sensitisation</b>	Health injuries are not known or expected under normal use.
<b>Skin sensitisation</b>	Health injuries are not known or expected under normal use.
<b>Germ cell mutagenicity</b>	Health injuries are not known or expected under normal use.
<b>Carcinogenicity</b>	Health injuries are not known or expected under normal use. Contains a material (formaldehyde 35% solution) classified as a carcinogen by external agencies.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)	3 Not classifiable as to carcinogenicity to humans.
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)	1 Carcinogenic to humans.
PERMETHRIN (CAS 52645-53-1)	3 Not classifiable as to carcinogenicity to humans.

<b>Reproductive toxicity</b>	Health injuries are not known or expected under normal use.
<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Mixture versus substance information</b>	No information available.
<b>Other information</b>	Not available.

## SECTION 12: Ecological information

**12.1. Toxicity** The product contains a substance which may cause long-term adverse effects in the environment.

Components	Species	Test results
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 1.44 mg/l, 48 hours Static test
Fish	EC50	Orange-red killfish (Adult Oryzias latipes) 5.3 mg/l, 48 hours Static test

Components		Species	Test results
PERMETHRIN (CAS 52645-53-1)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 1.9 mcg/l, 72 hours Measured
	NOEC	Algae	1.9 mcg/l
Crustacea	EC50	Water flea (Daphnia magna)	1.25 mcg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	0.79 mcg/l, 96 hours Flow-through test
		Fathead minnow (Adult Pimephales promelas)	3 mcg/l, 96 hours Static renewal test
		Rainbow trout (Adult Oncorhyncus mykiss)	0.62 mcg/l, 96 hours Flow-through test
Microtox	EC50	Microtox	0.56 mg/l, 5 minutes
Chronic			
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	1.4 mcg/l, 32 days Flow-through test
	Growth test NOEC	Fish	0.66 mcg/l, 32 days
POLYOXYETHYLENE (20) SORBITAN MONOOLEATE (CAS 9005-65-6)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	471 mg/l, 96 hours
SODIUM HYDROXIDE (CAS 1310-73-2)			
Aquatic			
Acute			
Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	45.4 mg/l, 96 hours Static test
* Estimates for product may be based on additional component data not shown.			
12.2. Persistence and degradability		No data is available on the degradability of this product.	
Photolysis			
Half-life (Photolysis-aqueous)			
PERMETHRIN			33 Days Estimated
Half-life (Photolysis-atmospheric)			
PERMETHRIN			9.8 Hours Estimated
Half-life (Photolysis-soil)			
PERMETHRIN			30 Days Estimated
Hydrolysis			
Half-life (Hydrolysis-basic)			
PERMETHRIN			50 Days
Biodegradability			
Percent degradation (Aerobic biodegradation-inherent)			
PERMETHRIN			50 - 85 %, 28 days, Lake water
Percent degradation (Aerobic biodegradation-ready)			
2,6-DI-TERT-BUTYL-P-CRESOL			4.5 %, 28 days Modified MITI test, Activated sludge
			< 10 %, 20 Days Closed Bottle test, Residential sludge
POLYOXYETHYLENE (20) SORBITAN MONOOLEATE			52 %
Percent degradation (Aerobic biodegradation-soil)			
PERMETHRIN			> 50 %, 28 days
12.3. Bioaccumulative potential			
Partition coefficient			
n-octanol/water (log Kow)			
FORMALDEHYDE 35% SOLUTION			0.35
GLYCERIN			-1.76
PERMETHRIN			6.5

<b>Bioconcentration factor (BCF)</b>		
2,6-DI-TERT-BUTYL-P-CRESOL		230 - 2500 Measured, Cyprinus carpio, carp
PERMETHRIN		2800 Measured, Pimephales promelas, fathead minnow
<b>12.4. Mobility in soil</b>		
<b>Adsorption</b>		
<b>Soil/sediment sorption - log Koc</b>		
PERMETHRIN		4.02 - 4.93 Measured
<b>Mobility in general</b>		
<b>Volatility</b>		
<b>Henry's law</b>		
2,6-DI-TERT-BUTYL-P-CRESOL		0.000004, 25 Estimated
PERMETHRIN		0 atm m <sup>3</sup> /mol, 25 C Estimated
<b>12.5. Results of PBT and vPvB assessment</b>	Not available.	
<b>12.6. Other adverse effects</b>	Not available.	

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	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 of contents/container in accordance with local/regional/national/international regulations.
<b>Special precautions</b>	Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

<b>General</b>	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.
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### ADR

<b>14.1. UN number</b>	UN3082
<b>14.2. UN proper shipping name</b>	Environmentally hazardous substance, liquid, n.o.s. (NIX DERMAL CREAM (CONTAINING PERMETHRIN))
<b>14.3. Transport hazard class(es)</b>	
Class	9
Subsidiary risk	-
Label(s)	9
Hazard No. (ADR)	90
<b>Tunnel code</b>	Not available.
<b>14.4. Packing group</b>	III
<b>14.5. Environmental hazards</b>	No.
<b>14.6. Special precautions for user</b>	Not available.

### IATA

<b>14.1. UN number</b>	UN3082
<b>14.2. UN proper shipping name</b>	Environmentally hazardous substance, liquid, n.o.s. (NIX DERMAL CREAM (CONTAINING PERMETHRIN))
<b>14.3. Transport hazard class(es)</b>	9
<b>Subsidiary class(es)</b>	-
<b>14.4. Packing group</b>	III
<b>Labels required</b>	9
<b>14.5. Environmental hazards</b>	No.
<b>ERG Code</b>	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. (NIX DERMAL CREAM (CONTAINING PERMETHRIN))

**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

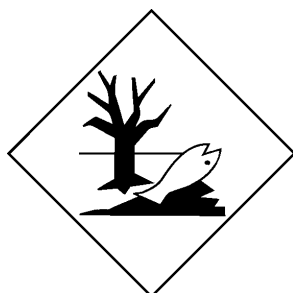
**14.6. Special precautions for user** Not available.

**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**



**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**

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**

PERMETHRIN (CAS 52645-53-1)

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  
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work  
Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding  
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)

#### 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  
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)  
PERMETHRIN (CAS 52645-53-1)  
SODIUM HYDROXIDE (CAS 1310-73-2)

Directive 94/33/EC on the protection of young people at work  
FORMALDEHYDE 35% SOLUTION (CAS 50-00-0)  
PERMETHRIN (CAS 52645-53-1)  
SODIUM HYDROXIDE (CAS 1310-73-2)

<b>Other regulations</b>	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.
<b>National regulations</b>	Follow national regulation for work with chemical agents.
<b>15.2. Chemical safety assessment</b>	No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

<b>List of abbreviations</b>	Not available.
<b>References</b>	GSK Hazard Determination
<b>Information on evaluation method leading to the classification of mixture</b>	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
<b>Full text of any statements or R-phrases and H-statements under Sections 2 to 15</b>	R20/22 Harmful by inhalation and if swallowed. R22 Harmful if swallowed. R23/24/25 Toxic by inhalation, in contact with skin and if swallowed. R34 Causes burns. R35 Causes severe burns. R40 Limited evidence of a carcinogenic effect. R43 May cause sensitization by skin contact. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H301 Toxic if swallowed. H302 Harmful if swallowed. H311 Toxic in contact with skin. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H331 Toxic if inhaled. H332 Harmful if inhaled.

H335 May cause respiratory irritation.  
H351 Suspected of causing cancer.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

**Revision information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Physical & Chemical Properties:  
Ecological Information: Reports  
Transport Information: Material Transportation Information  
Regulatory Information: Risk Phrases - Class.  
GHS: Classification

**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.