

BIOTEK WASH & CLEAN
Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier: **BIOTEK WASH & CLEAN**
 Substance type: CLP Mixture

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

Use of the Substance/Mixture : CLEANER

Recommended restrictions on use : Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet:

COMPANY IDENTIFICATION
 Ecolab Ltd.
 PO Box 11; Winnington Avenue
 Northwich, Cheshire., CW8 4DX, United Kingdom
 TEL: + 44 (0)1606 74488

LOCAL COMPANY IDENTIFICATION
 Ecolab Ltd.
 PO Box 11; Winnington Avenue
 Northwich, Cheshire., CW8 4DX, United Kingdom
 TEL: + 44 (0)1606 74488

For Product Safety information please contact: msdseame@nalco.com

1.4 Emergency telephone number:

Emergency telephone number : Trans-European
 +441618841235
 +32-(0)3-575-5555 Trans-European Address European
 Economic Area HQ

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Section: 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture


Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Category 1	H314
Serious eye damage, Category 1	H318
Chronic aquatic toxicity, Category 3	H412

The classification of this product is based only on its extreme pH value (in accordance with current European legislation).

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.
 H412 Harmful to aquatic life with long lasting effects.

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Precautionary Statements	Prevention:	
	P273	Avoid release to the environment.
	P280	Wear protective gloves/ eye protection/ face protection.
	Response:	
	P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:
Amines, C12-14 alkyldimethyl, N-oxides

2.3 Other hazards

None known.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS**3.2 Mixtures****Hazardous components**

Chemical Name	CAS-No. EC-No. REACH No.	Classification (REGULATION (EC) No 1272/2008)	Concentration: [%]
Amines, C12-14 alkyldimethyl, N-oxides	308062-28-4 01-2119490061-47-0000	Acute toxicity Category 4; H302 Skin irritation Category 2; H315 Serious eye damage Category 1; H318 Acute aquatic toxicity Category 1; H400 Chronic aquatic toxicity Category 2; H411	2.5 - < 3
2,2'-(octadec-9-enylimino)bisethanol	25307-17-9 246-807-3 01-2119510876-35	Acute toxicity Category 4; H302 Skin corrosion Category 1B; H314 Serious eye damage Category 1; H318 Acute aquatic toxicity Category 1; H400 Chronic aquatic toxicity Category 1; H410	1 - < 2.5
Didecyl-Dimethyl-Ammonium chloride	7173-51-5 230-525-2 01-2119945987-15	Acute toxicity Category 4; H302 Skin corrosion Category 1B; H314 Chronic aquatic toxicity Category 2; H411 Acute aquatic toxicity Category 1; H400	0.5 - < 1
Substances with a workplace exposure limit :			
Potassium Hydroxide	1310-58-3 215-181-3 01-2119487136-33	Acute toxicity Category 4; H302 Skin corrosion Category 1A; H314 Corrosive to metals Category 1; H290	0.25 - < 0.5
Isopropanol	67-63-0 200-661-7 01-2119457558-25	Flammable liquids Category 2; H225 Eye irritation Category 2; H319 Specific target organ toxicity - single exposure Category 3; H336	0.1 - < 0.25

For the full text of the H-Statements mentioned in this Section, see Section 16.

Section: 4. FIRST AID MEASURES

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4.1 Description of first aid measures

- If inhaled : Remove to fresh air.
Treat symptomatically.
Get medical attention if symptoms occur.
- In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes.
Use a mild soap if available.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
Get medical attention immediately.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
Get medical attention immediately.
- If swallowed : Rinse mouth with water.
Do NOT induce vomiting.
Never give anything by mouth to an unconscious person.
If conscious, give 2 glasses of water.
Get medical attention immediately.
- Protection of first-aiders : In event of emergency assess the danger before taking action.
Do not put yourself at risk of injury. If in doubt, contact emergency responders. Use personal protective equipment as required.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Indication of immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

Section: 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Not flammable or combustible.
- Hazardous combustion products : Depending on combustion properties, decomposition products may include following materials:
Carbon oxides
nitrogen oxides (NO_x)

5.3 Advice for firefighters

- Special protective equipment for firefighters : Use personal protective equipment.

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Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. In the event of fire and/or explosion do not breathe fumes.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel : Ensure adequate ventilation.
Keep people away from and upwind of spill/leak.
Avoid inhalation, ingestion and contact with skin and eyes.
When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Ensure clean-up is conducted by trained personnel only.
Refer to protective measures listed in sections 7 and 8.

Advice for emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.

6.2 Environmental precautions

Environmental precautions : Do not allow contact with soil, surface or ground water.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up : Stop leak if safe to do so.
Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Flush away traces with water.
For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

6.4 Reference to other sections

See Section 1 for emergency contact information.
For personal protection see section 8.
See Section 13 for additional waste treatment information.

Section: 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling : Do not ingest. Do not breathe spray, vapour. Do not get in eyes, on skin, or on clothing. Wash hands thoroughly after handling. Use only with adequate ventilation.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Do not store near acids. Keep out of reach of children. Keep container tightly closed. Store in suitable labelled containers.

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Suitable material : Keep in properly labelled containers.

7.3 Specific end uses

Specific use(s) : CLEANER

Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Potassium Hydroxide	1310-58-3	OELV - 15 min (STEL)	2 mg/m ³	IR_OEL
Isopropanol	67-63-0	OELV - 8 hrs (TWA)	200 ppm	IR_OEL
Further information	Sk	Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body		
		OELV - 15 min (STEL)	400 ppm	IR_OEL
Further information	Sk	Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body		

DNEL

Potassium Hydroxide	:	End Use: Workers Exposure routes: Inhalation Value: 1 mg/m ³
		End Use: Consumers Exposure routes: Inhalation Value: 1 mg/m ³
Isopropanol	:	End Use: Workers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 888 mg/cm ²
		End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 500 mg/m ³
		End Use: Consumers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 319 mg/cm ²
		End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 89 mg/m ³
		End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 26 ppm

PNEC

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Isopropanol	:	Fresh water Value: 140.9 mg/l
		Marine water Value: 140.9 mg/l
		Intermittent use/release Value: 140.9 mg/l
		Fresh water Value: 552 mg/kg
		Marine sediment Value: 552 mg/kg
		Soil Value: 28 mg/kg
		Sewage treatment plant Value: 2251 mg/l
		Oral Value: 160 mg/kg

8.2 Exposure controls

Appropriate engineering controls

Effective exhaust ventilation system.

Maintain air concentrations below occupational exposure standards.

Individual protection measures

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

Eye/face protection (EN 166) : Safety goggles
Face-shield

Hand protection (EN 374) : Recommended preventive skin protection
Gloves
Nitrile rubber
butyl-rubber
Breakthrough time: 1 – 4 hours
Minimum thickness for butyl-rubber 0.7 mm for nitrile rubber 0.4 mm or equivalent (please refer to the gloves manufacturer/distributor for advise).
Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

Skin and body protection (EN 14605) : Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing including appropriate safety shoes

Respiratory protection (EN 143, 14387) : When respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization,

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consider the use of certified respiratory protection equipment meeting EU requirements (89/656/EEC, (EU) 2016/425), or equivalent, with filter type:A-P

Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : blue

Odour : characteristic

Flash point : > 100 °C

pH : 13, 100 %
(20 °C)

Odour Threshold : no data available

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

Evaporation rate : no data available

Flammability (solid, gas) : no data available

Upper explosion limit : no data available

Lower explosion limit : no data available

Vapour pressure : no data available

Relative vapour density : no data available

Relative density : 1.01 - 1.03

Solubility(ies)

Water solubility : soluble in cold water, soluble in hot water

Solubility in other solvents : no data available

Partition coefficient: n-octanol/water : no data available

Auto-ignition temperature : no data available

Thermal decomposition : no data available

Viscosity, dynamic : no data available

Viscosity, kinematic : no data available

Explosive properties : no data available

Oxidizing properties : no data available

9.2 Other information

no data available

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Section: 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Strong acids

10.6 Hazardous decomposition products

Hazardous decomposition products : Depending on combustion properties, decomposition products may include following materials:
Carbon oxides
nitrogen oxides (NOx)

Section: 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation, Eye contact, Skin contact

Toxicity

Product

Acute oral toxicity : Acute toxicity estimate : > 2,000 mg/kg
Acute inhalation toxicity : There is no data available for this product.
Acute dermal toxicity : There is no data available for this product.
Skin corrosion/irritation : There is no data available for this product.
Serious eye damage/eye irritation : There is no data available for this product.
Respiratory or skin sensitization : There is no data available for this product.
Carcinogenicity : There is no data available for this product.
Reproductive effects : There is no data available for this product.
Germ cell mutagenicity : There is no data available for this product.

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- Teratogenicity : There is no data available for this product.
- STOT - single exposure : There is no data available for this product.
- STOT - repeated exposure : There is no data available for this product.
- Aspiration toxicity : There is no data available for this product.

Components

- Acute oral toxicity : Amines, C12-14 alkyldimethyl, N-oxides
LD50 rat: 1,064 mg/kg
- 2,2'-(octadec-9-enylimino)bisethanol
LD50 rat: 1,260 mg/kg
- Didecyl-Dimethyl-Ammonium chloride
LD50 rat: 329 mg/kg
- Potassium Hydroxide
LD50 rat: 333 mg/kg
- Isopropanol
LD50 rat: 5,840 mg/kg

Components

- Acute inhalation toxicity : Isopropanol
LC50 rat: > 30 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Components

- Acute dermal toxicity : Didecyl-Dimethyl-Ammonium chloride
LD50 rabbit: 2,930 mg/kg
- Isopropanol
LD50 rabbit: 12,870 mg/kg

Potential Health Effects

- Eyes : Causes serious eye damage.
- Skin : Causes severe skin burns.
- Ingestion : Causes digestive tract burns.
- Inhalation : May cause nose, throat, and lung irritation.
- Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

- Eye contact : Redness, Pain, Corrosion
- Skin contact : Redness, Pain, Corrosion
- Ingestion : Corrosion, Abdominal pain

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Inhalation : Respiratory irritation, Cough

Further information : no data available

Section: 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Product

Environmental Effects : Harmful to aquatic life with long lasting effects.

Toxicity to fish : no data available

Toxicity to daphnia and other aquatic invertebrates : no data available

Toxicity to algae : no data available

Components

Toxicity to fish : Amines, C12-14 alkyldimethyl, N-oxides
LC50: 2.67 mg/l

2,2'-(octadec-9-enylimino)bisethanol
96 h LC50 Danio rerio (zebra fish): 0.1 mg/l

Didecyl-Dimethyl-Ammonium chloride
96 h LC50 Fish: 1 mg/l

Isopropanol
96 h LC50 Pimephales promelas (fathead minnow):
9,640 mg/l

Components

Toxicity to daphnia and other aquatic invertebrates : Amines, C12-14 alkyldimethyl, N-oxides
EC50 Daphnia magna (Water flea): 3.1 mg/l

2,2'-(octadec-9-enylimino)bisethanol
48 h EC50 Daphnia magna (Water flea): 0.043 mg/l

Isopropanol
LC50 Daphnia magna (Water flea): > 10,000 mg/l

Components

Toxicity to algae : Amines, C12-14 alkyldimethyl, N-oxides
LC50: 0.143 mg/l
NOEC: 0.067 mg/l

2,2'-(octadec-9-enylimino)bisethanol
72 h EC50 Pseudokirchneriella subcapitata
(microalgae): 0.0538 mg/l

Components

Toxicity to bacteria : Isopropanol
1,050 mg/l

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Components

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : 2,2'-(octadec-9-enylimino)bisethanol
21 d EC50: 0.0463 mg/l

12.2 Persistence and degradability

Product

no data available

Components

Biodegradability : Amines, C12-14 alkyl dimethyl, N-oxides
Result: Readily biodegradable.

2,2'-(octadec-9-enylimino)bisethanol
Result: Readily biodegradable.

Didecyl-Dimethyl-Ammonium chloride
Result: Eliminated from aquatic environment

Potassium Hydroxide
Result: Not applicable - inorganic

Isopropanol
Result: Readily biodegradable.

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

Product

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

no data available

Section: 13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1 Waste treatment methods

Product : The product should not be allowed to enter drains, water courses or the soil.

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Where possible recycling is preferred to disposal or incineration.
 If recycling is not practicable, dispose of in compliance with local regulations.
 Dispose of wastes in an approved waste disposal facility.

- Contaminated packaging : Dispose of as unused product.
 Empty containers should be taken to an approved waste handling site for recycling or disposal.
 Do not re-use empty containers.
- Guidance for Waste Code selection : Organic wastes containing dangerous substances. If this product is used in any further processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

Section: 14. TRANSPORT INFORMATION

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport (ADR/ADN/RID)

- 14.1 UN number: Not applicable.
 14.2 UN proper shipping name: PRODUCT IS NOT REGULATED DURING TRANSPORTATION
 14.3 Transport hazard class(es): Not applicable.
 14.4 Packing group: Not applicable.
 14.5 Environmental hazards: No
 14.6 Special precautions for user: Not applicable.

Air transport (IATA)

- 14.1 UN number: Not applicable.
 14.2 UN proper shipping name: PRODUCT IS NOT REGULATED DURING TRANSPORTATION
 14.3 Transport hazard class(es): Not applicable.
 14.4 Packing group: Not applicable.
 14.5 Environmental hazards: No
 14.6 Special precautions for user: Not applicable.

Sea transport (IMDG/IMO)

- 14.1 UN number: Not applicable.
 14.2 UN proper shipping name: PRODUCT IS NOT REGULATED DURING TRANSPORTATION
 14.3 Transport hazard class(es): Not applicable.
 14.4 Packing group: Not applicable.
 14.5 Environmental hazards: No
 14.6 Special precautions for user: Not applicable.
 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

BIOTEK WASH & CLEAN**Section: 15. REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:****INTERNATIONAL CHEMICAL CONTROL LAWS****15.2 Chemical Safety Assessment:**

No Chemical Safety Assessment has been carried out on the product.

Section: 16. OTHER INFORMATION**Procedure used to derive the classification according to REGULATION (EC) No 1272/2008**

Classification	Justification
Skin corrosion 1, H314	Based on product data or assessment
Serious eye damage 1, H318	Based on product data or assessment
Chronic aquatic toxicity 3, H412	Calculation method

Full text of H-Statements

H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
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.

Full text of other abbreviations

ADN – European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS – Australian Inventory of Chemical Substances; ASTM – American Society for the Testing of Materials; bw – Body weight; CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR – Carcinogen, Mutagen or Reproductive Toxicant; DIN – Standard of the German Institute for Standardisation; DSL – Domestic Substances List (Canada); ECHA – European Chemicals Agency; EC-Number – European Community number; EC_x – Concentration associated with x% response; EL_x – Loading rate associated with x% response; EmS – Emergency Schedule; ENCS – Existing and New Chemical Substances (Japan); ErC_x – Concentration associated with x% growth rate response; GHS – Globally Harmonized System; GLP – Good Laboratory Practice; IARC – International Agency for Research on Cancer; IATA – International Air Transport Association; IBC – International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC₅₀ – Half maximal inhibitory concentration; ICAO – International Civil Aviation Organization; IECSC – Inventory of Existing Chemical Substances in China; IMDG – International Maritime Dangerous Goods; IMO – International Maritime Organization; ISHL – Industrial Safety and Health Law (Japan); ISO – International Organisation for Standardization; KECI – Korea Existing Chemicals Inventory; LC₅₀ – Lethal Concentration to 50 % of a test population; LD₅₀ – Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL – International Convention for the Prevention of Pollution from Ships; n.o.s. – Not Otherwise Specified; NO(A)EC – No Observed (Adverse) Effect Concentration; NO(A)EL – No Observed (Adverse) Effect Level; NOELR – No Observable Effect Loading Rate; NZIoC – New Zealand Inventory of Chemicals; OECD – Organization for Economic Co-operation and Development; OPPTS – Office of Chemical Safety and Pollution Prevention; PBT – Persistent, Bioaccumulative and Toxic substance; PICCS – Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR – (Quantitative) Structure Activity Relationship; REACH – Regulation (EC)

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No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID – Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT – Self-Accelerating Decomposition Temperature; SDS – Safety Data Sheet; TCSI – Taiwan Chemical Substance Inventory; TRGS – Technical Rule for Hazardous Substances; TSCA – Toxic Substances Control Act (United States); UN – United Nations; vPvB – Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Safety Data Sheet : IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Geneva: World Health Organization, International Agency for Research on Cancer.

The possible key literature references and data sources which may have been used in conjunction with the consideration of expert judgment to compile this Safety Data Sheet: European regulations/directives (including (EC) No. 1907/2006, (EC) No. 1272/2008), supplier data, inter-net, ESIS, IUCLID, ERICards, Non European official regulatory data and other data sources.

Prepared By : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.