According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

# BioOptimal™

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SECTI	ON 1: Identification o	f the substanc	ce/mixture and of the company/undertaking	3
1.1 Proe	duct identifier			
Tra	de name	: BioOptima	al™ (Containing 17 wt% Ethanol as preservative)	
1.2 Rele	evant identified uses of	the substance	or mixture and uses advised against	
	e of the Sub- nce/Mixture	: Biocides,	Preservatives for products during storage	
-	commended restrictions use	: Not applic	cable	
1.3 Deta	ails of the supplier of th	e safety data sł	heet	
Cor	mpany	Silver Buil	sei Bioprocess Europe S.A./N.V. ilding Boulevard Auguste Reyers 70 ussels Schaerbeek Belgium	
Tel	ephone	: +32-2-526	6-0500	
	nail address of person ponsible for the SDS	: bioproces	sseu-ml@aml.asahi-kasei.co.jp	

#### 1.4 Emergency telephone number

+44-1235-239670 (24hrs/7days; multi-language)

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Flammable liquids, Category 3

H226: Flammable liquid and vapour.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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Haza	rd pictograms	:		
Signa	al word	:	Warning	
Haza	rd statements	:	H226	Flammable liquid and vapour.
Preca	autionary statements	:	Prevention P210 P233 P280	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Wear protective gloves/ protective clothing/ eye protection/ face protection.
			<b>Response:</b> P303 + P36 P370 + P37	61 + P353 IF ON SKIN (or hair): Take off immedi- ately all contaminated clothing. Rinse skin with water.

#### 2.3 Other hazards

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.

Vapours may form explosive mixture with air.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ethanol	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 	>= 10 - < 20

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For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

4.1 Description of first aid measure	es
Protection of first-aiders :	No special precautions are necessary for first aid responders.
If inhaled :	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact :	Remove contaminated clothing and shoes.
In case of eye contact :	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed :	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

#### **4.2 Most important symptoms and effects, both acute and delayed** None known.

None known.

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

: Treat symptomatically and supportively.

### **SECTION 5: Firefighting measures**

# 5.1 Extinguishing media Suitable extinguishing media Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical Unsuitable extinguishing media High volume water jet 5.2 Special hazards arising from the substance or mixture Specific hazards during fire-fighting Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance

fighting		fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides

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Spec	e for firefighters ial protective equipment efighters	:		ed breathing apparatus for firefighting if nec- onal protective equipment.
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Remove all sources of ignition. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

		- · ·
Methods for cleaning up	:	<ul> <li>Non-sparking tools should be used.</li> <li>Soak up with inert absorbent material.</li> <li>Suppress (knock down) gases/vapours/mists with a water spray jet.</li> <li>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.</li> <li>Clean up remaining materials from spill with suitable absorbent.</li> <li>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.</li> <li>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</li> </ul>

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## **SECTION 7: Handling and storage**

7.1 Precautions for safe handling	
Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	<ul> <li>If sufficient ventilation is unavailable, use with local exhaust ventilation.</li> <li>Use explosion-proof electrical, ventilating and lighting equip- ment.</li> </ul>
Advice on safe handling	<ul> <li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</li> <li>Non-sparking tools should be used.</li> <li>Keep container tightly closed.</li> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</li> <li>Take precautionary measures against static discharges.</li> <li>Take care to prevent spills, waste and minimize release to the environment.</li> </ul>
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
7.2 Conditions for safe storage, i	ncluding any incompatibilities
7.2 Conditions for safe storage, i Requirements for storage areas and containers	<ul> <li>ncluding any incompatibilities</li> <li>Keep in properly labelled containers. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.</li> </ul>
Requirements for storage	: Keep in properly labelled containers. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and
Requirements for storage areas and containers	<ul> <li>Keep in properly labelled containers. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.</li> <li>Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Substances and mixtures Substances and mixtures Explosives Gases</li> </ul>

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#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m3	GB EH40

#### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Ethanol	Workers	Inhalation	Long-term systemic effects	380 mg/m3
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3

#### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry
		weight (d.w.)
	Marine sediment	2.9 mg/kg dry
		weight (d.w.)
	Soil	0.63 mg/kg dry
		weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food

#### 8.2 Exposure controls

#### **Engineering measures**

Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.

#### Personal protective equipment

Eye/face protection	:	Wear the following personal protective equipment: Safety glasses Equipment should conform to BS EN 166
Hand protection Material	:	Natural Rubber

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Remarks		: Choose gloves to protect hands against chemicals dependi on the concentration and quantity of the hazardous sub- stance and specific to place of work. For special application we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufactu er. Wash hands before breaks and at the end of workday. Breakthrough time is not determined for the product. Chang gloves often!		
Skin and body protection		sistance data and tial. Wear the followin If assessment de atmospheres or fl tective clothing. Skin contact mus	e protective clothing based on chemical re- d an assessment of the local exposure poten- g personal protective equipment: monstrates that there is a risk of explosive lash fires, use flame retardant antistatic pro- t be avoided by using impervious protective aprons, boots, etc).	
Respiratory protection		sure assessment ommended guide	exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection. d conform to BS EN 14387	
Filter type		: Organic vapour t	ype (A)	

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	40 °C
Evaporation rate	:	No data available

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	Flammability (solid, gas)		:	Not applicable	
Upper explosion limit / Upper flammability limit		:	No data available		
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	
	Relative	e vapour density	:	No data available	
	Relative	e density	:	No data available	
	Density	1	:	No data available	
	Solubili Wat	ty(ies) ter solubility	:	No data available	
	Partitio octanol	n coefficient: n- /water	:	Not applicable	
	Auto-ig	nition temperature	:	does not ignite	
	Decom	position temperature	:	The substance o	r mixture is not classified self-reactive.
	Viscos Visc	ity cosity, kinematic	:	No data available	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
9.2	Other in	nformation			
	Flamm	ability (liquids)	:	No data available	
	Particle	esize	:	Not applicable	

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions

Flammable liquid and vapour. Vapours may form explosive mixture with air.

:

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		Can	react with s	strong oxidizing agents.		
10.4 Con	ditions to avoid					
Conc	litions to avoid	: Hea	t, flames an	d sparks.		
10.5 Inco	mpatible materials					
Mate	rials to avoid	: Oxio	lizing agents	8		
10.6 Haza	ardous decompositior	products				
No h	azardous decompositio	n products	are known.			
SECTIO	N 11: Toxicological	informatio	n			
11 1 Info	mation on toxicologi	al affacta				
	rmation on toxicologie nation on likely routes		ation			
expo	•		contact			
		Inges				
		Eye	contact			
Acut	e toxicity					
	classified based on avai	lable inform	ation.			
<u>Com</u>	ponents:					
Etha	nol:					
Acut	e oral toxicity		(Rat): 10,4 od: OECD 1	70 mg/kg Fest Guideline 401		
Acut	e inhalation toxicity	: LC50	(Rat, male)	): 116.9 mg/l		
		•	sure time: 4			
		lest	atmosphere	: vapour		
Acut	e dermal toxicity	: LD50	(Rabbit): >	15,800 mg/kg		
Skin	corrosion/irritation					
Not c	classified based on avai	lable inform	ation.			
<u>Com</u>	ponents:					
Etha	nol:					
Spec		: Rabb				
Meth Resu			: OECD Test Guideline 404 : No skin irritation			
Rest	int int	. INU S	nii iiiitatiofi			
Sori	ous ovo damado/ovo i	rritation				

#### Serious eye damage/eye irritation

Not classified based on available information.

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#### Components:

#### Ethanol:

Species	:	Rabbit	
Method	:	OECD Test Guideline 405	
Result	:	Irritation to eyes, reversing v	within 21 days

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

#### Ethanol:

Test Type	:	Mouse ear swelling test (MEST)
Exposure routes	:	Skin contact
Species	:	Mouse
Result	:	negative

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

#### Ethanol:

Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo :	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: Ingestion Result: negative

#### Carcinogenicity

Not classified based on available information.

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#### **Reproductive toxicity**

Not classified based on available information.

#### Components:

#### Ethanol:

Effects on fertility

: Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### Repeated dose toxicity

#### Components:

#### Ethanol:

Species	:	Rat
NOAEL	:	1,730 mg/kg
LOAEL	:	3,200 mg/kg
Application Route	:	Ingestion
Exposure time	: 9	90 Days

#### Aspiration toxicity

Not classified based on available information.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### Components:

Ethonol	
Ethano	

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h
		EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h

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	Toxicity	to microorganisms	:	EC50 (Protozoa): Exposure time: 4	
	Toxicity icity)	to fish (Chronic tox-	:	Exposure time: 10	
		v to daphnia and other invertebrates (Chron- ity)	:	Exposure time: 9	d magna (Water flea)
12.2	Persist	ence and degradabi	lity		
	<u>Compo</u>	onents:			

#### Ethanol:

Biodegradability	: Result: Readily biodegradable.
	Biodegradation: 84 %
	Exposure time: 20 d

#### 12.3 Bioaccumulative potential

#### Components:

#### Ethanol:

Partition coefficient: n- : log Pow: -0.35 octanol/water

#### 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

#### Product:

Endocrine disrupting poten-	:	This substance/mixture does not contain components consid-
tial		ered to have endocrine disrupting properties for environment
		according to UK REACH Article 57(f).

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#### **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product	<ul> <li>Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.</li> </ul>
Contaminated packaging	: Empty containers should be taken to an approved waste han- dling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or ex- pose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

#### **SECTION 14: Transport information**

14.1 UN number

#### ADN Not regulated as a dangerous good : Not regulated as a dangerous good ADR : RID Not regulated as a dangerous good : IMDG Not regulated as a dangerous good : ΙΑΤΑ Not regulated as a dangerous good : 14.2 UN proper shipping name ADN Not regulated as a dangerous good : ADR Not regulated as a dangerous good : RID Not regulated as a dangerous good : IMDG : Not regulated as a dangerous good ΙΑΤΑ Not regulated as a dangerous good : 14.3 Transport hazard class(es) ADN Not regulated as a dangerous good : ADR Not regulated as a dangerous good : RID Not regulated as a dangerous good : IMDG Not regulated as a dangerous good : ΙΑΤΑ Not regulated as a dangerous good : 14.4 Packing group

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ADN		: Not regulated as a dangerous good		
Remar	ks	: Transport in accordance to special provision 144		
<b>ADR</b> Remar	ks	<ul><li>Not regulated as a dangerous good</li><li>Transport in accordance to special provision 144</li></ul>		
RID		: Not regulated as a dangerous good		
Remarks		: Transport in accordance to special provision 144		
IMDG		: Not regulated as a dangerous good		
IATA (Cargo)		: Not regulated as a dangerous good		
IATA (Passenger)		: Not regulated as a dangerous good		
14.5 Enviro	onmental hazards			
Not reg	gulated as a dangerou	s good		
14.6 Speci	al precautions for us	er		

## Not applicable

Remarks

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

: Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) on substances that deplete the ozone	:	Not applicable

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layer					
UK REACH List of substances subject to authorisation : Not applicable (Annex XIV)					
GB Export and import of hazardous chemicals - Prior : Not applicable Informed Consent (PIC) Regulation					
Active	substance	: 45.6 g/kg Ethanol			
Control of Major Accident Hazards Regulations 2015 (COMAH) Quantity 1 Quantity 2					
P5c		FLAMMABLE L		50,000 t	

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information :	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.				
Full text of H-StatementsH225:H319:	Highly flammable liquid and vapour. Causes serious eye irritation.				
Full text of other abbreviations					
Eye Irrit. : Flam. Liq. : GB EH40 : GB EH40 / TWA :	Eye irritation Flammable liquids UK. EH40 WEL - Workplace Exposure Limits Long-term exposure limit (8-hour TWA reference period)				

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AllC - Australian Inventory of Industrial Chemicals; 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; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - 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;

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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) 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; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods: vPvB - Very Persistent and Very Bioaccumulative

#### Further information

Sources of key data used to :	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

H226

#### Classification of the mixture:

Classification procedure:

Flam. Liq. 3

Based on product data or assessment

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN