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

1.1 Product identifier	
Substance name	: CTC Control Cells 5496
1.2 Relevant identified uses of the	e substance or mixture and uses advised against
Use of the Sub- stance/Mixture	: Large Molecule Pharmaceutical intended for medical use, Assay reagent
1.3 Details of the supplier of the s	safety data sheet
Company	: Menarini Silicon Biosystems, Inc 3401 Masons Mill Rd #100 Huntingdon Valley, PA 19006 USA
Telephone	: 1 (800) 381-4929
Telefax	:
E-mail address Responsible/issuing person	: Us-info@siliconbiosystems.com
1.4 Emergency telephone number	

US: (303) 389-1805

International: +1 (303) 389-1805

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

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.

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible personse. Health Hazards, Risk Group 1



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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Remarks

: No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measure	sures
If inhaled	: If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	: Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water. If symptoms persist, call a physician. Wash contaminated clothing before re-use.
In case of eye contact	 Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.
If swallowed	: If swallowed, rinse mouth with water (only if the person is con- scious). Call a physician immediately.
4.2 Most important symptoms a	and effects, both acute and delayed

Symptoms	: No information available.

4.3 Indication of any 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 fire- : Combustible material fighting



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5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus. for firefighters

Further information : No information available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	 Special considerations for Biological Risk from anyparticular micro-organism is based on several factors including amount of infectious material present, infectious dose, mode of trans- mission, seriousness of illness, susceptibility of the host and availability of vaccines or drugs. In the event of an accidental release the emergency response team must respond based on a risk assessment and use per- sonal protective equipment as appropriate. Avoid direct contact with broken glass, plastic and other
	sharps. Avoid splashes and spray formation.
	Evacuate personnel to safe areas.
	Avoid direct contact and significant aerosol exposure.

6.2 Environmental precautions

Environmental precautions	: Should not be released into the environment.
-	Do not flush into surface water or sanitary sewer system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	 Small spills: Gently cover the spill with an absorbent towel or pad. Wet absorbent pad with 10% bleach solution. Allow 30 minutes contact time. Large spills: Allow the dust/aerosol to settle for 30 minutes or use appropriate respiratory protection. Dam up. Soak up with inert absorbent material. Add bleach (5.25% sodium hypochlorite) solution to a final liquid concentration of 10% (1 part bleach, mixed with 9 parts liquid) to absorbent materials. Allow 30 minute contact time. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations". Clean up with a 10% bleach (5.25% sodium hypochlorite) solution, 1 part bleach, mixed with 9 parts water is recommended for cleaning of surfaces and equipment. Clean spill location and adjacent surfaces thoroughly with ethanol or water with detergent.



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specific hazards.

6.4 Reference to other sections

For disposal information, see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	: Avoid splashes. Avoid formation of aerosol. Do not heat the product. Avoid inhalation, ingestion and contact with skin and eyes. Use personal protective equipment as required.
Advice on protection against fire and explosion	: No data available
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice. Remove gloves and wash hands when work with material is completed. Do not reuse gloves. Contaminated work clothing should not be allowed out of the workplace.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	: To maintain product quality, do not store in heat or direct sun- light. Store in original container. Keep container tightly closed in a dry and well-ventilated place. Keep away from heat. Keep frozen. Keep locked up.
Recommended storage tem- perature	: -20 °C
7.3 Specific end use(s)	
Specific use(s)	: Consult the technical guidelines for the use of this sub- stance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

The work area should be installed in accordance with the requirements of Biosafety level 1 (BSL1)

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment



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Eye p	protection	: No special precau	tions required.
	protection marks	: No special precau	tions required.
Skin	and body protection	: No special precau	tions required.
Resp	iratory protection	controlling expose There is remote p lized and inhaled If respiratory prot ties, the type as will depend upon hazards, physica sent.	ols should always be the primary method of sures. possibility that this product could be aeroso- in the workplace. tective equipment is needed for certain activi- well as the corresponding protection factor the risk assessment and air concentrations, and warning properties of substances pre- biratory protective equipment normally re-
Prote	ctive measures	the Environment	tive equipment must be selected based on al Health and Safety risk assessment. Con- ntal Health and Safety expert if necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: Vial
Colour	: clear, light yellow, to, amber
Odour	: No data available
рН	: 7,0
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No information available.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available



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Relati	ive density	: No data available	
Densi		: No data available	
Wa	ility(ies) ater solubility	: No data availabl	-
Sol	lubility in other solvents	: No data availabl	e
	ion coefficient: n- ol/water	: No data available	
Auto-	ignition temperature	: No data availab	le
Deco	mposition temperature	: No data availab	le
Explo	sive properties	: No data availabl	e
Oxidiz	zing properties	: No data availabl	e
9.2 Other	information		
Cond	uctivity	: No data availabl	e
		: No data availab	le

SECTION 10: Stability and reactivity

10.1	Reactivity	
	None reasonably foreseeable	
10.2	Chemical stability	
	Stable under recommended s	torage conditions.
10.3	Possibility of hazardous rea	actions
	Hazardous reactions	: No dangerous reaction known under conditions of normal use.
10.4	Conditions to avoid	
	Conditions to avoid	: To avoid thermal decomposition, do not overheat. Exposure to light.
10.5	Incompatible materials	
	Materials to avoid	: No data available
10.6	Hazardous decomposition p	products
	None known.	



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Effects on fertility

Effects on foetal develop-

Product:	
Acute oral toxicity	: Remarks: No data available
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available
Acute toxicity (other routes of administration)	: Remarks: No data available
Skin corrosion/irritation	
Product: Remarks: No data available	
Serious eye damage/eye irrit	ation
Product:	
Remarks: No data available	
Respiratory or skin sensitisa No data available	tion
Germ cell mutagenicity	
Product:	
Genotoxicity in vitro	: Remarks: No data available
Genotoxicity in vivo	: Remarks: No data available
Carcinogenicity	
<u>Product:</u> Remarks: No data available	
Reproductive toxicity	
Product:	

2

: Remarks: No data available

Remarks: No data available



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ment			
STO	T - single exposure		
Prod	uct:		
Rema	arks: No data available	•	
STO	T - repeated exposure	9	
No da	ata available		
Repe	eated dose toxicity		
No da	ata available		
Aspi	ration toxicity		
No da	ata available		

SECTION 12: Ecological information

12.1 Toxicity

Product:	
Toxicity to fish	: Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates	: Remarks: No data available
Toxicity to bacteria	: Remarks: No data available

12.2 Persistence and degradability

Product:

Biodegradability	: Remarks: No data available
Diodegradability	

12.3 Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Product:

Distribution among environ-	: Remarks: No data available
mental compartments	

12.5 Results of PBT and vPvB assessment

Product:

Assessment	: Remarks: No data available
	: This substance/mixture contains no components considered



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			rsistent, bioaccumulative and toxic (PBT), or and very bioaccumulative (vPvB) at levels of
2.6 Othe	er adverse effects		
Prod Addit matic	tional ecological infor-	: Remarks: Shoul	d not be released into the environment.
SECTIO	N 13: Disposal consi	iderations	
13.1 Was i Prodi	te treatment methods uct	tions. Decontaminate	with National, Federal, State and Local regula- e all waste before disposal (steam sterilization, ection and/or incineration).
SECTIO	N 14: Transport infor	rmation	
		rmation	
SECTION 14.1 UN n ADN	number		Y MODIFIED MICRO-ORGANISMS
14.1 UN n	number	: GENETICALLY	Y MODIFIED MICRO-ORGANISMS Y MODIFIED MICRO-ORGANISMS
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14.1 UN n ADN ADR RID	number G	: GENETICALLY : GENETICALLY : GENETICALLY	Y MODIFIED MICRO-ORGANISMS
14.1 UN n ADN ADR RID IMDC IATA	number G	: GENETICALLY : GENETICALLY : GENETICALLY : UN 3245	Y MODIFIED MICRO-ORGANISMS
14.1 UN n ADN ADR RID IMDC IATA	number G S oroper shipping name	: GENETICALLY : GENETICALLY : GENETICALLY : UN 3245	Y MODIFIED MICRO-ORGANISMS
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	ng group ification Code s	: Not assigned by : M8 : 9	regulation
Class Label	ng group ification Code s el restriction code	: Not assigned by : M8 : 9 : (E)	regulation
Class	ng group ification Code rd Identification Numb s	: Not assigned by : M8 er : 90 : 9	regulation
IMDG Packi Label EmS	ng group s	: Not assigned by : 9 : F-A, S-T	regulation
Packi aircra Packi	ng instruction (EQ) ng group	: 959 : E0 : Not assigned b : 3245	by regulation
Packi (pass	(Passenger) ng instruction enger aircraft) ng group s	 959 Not assigned to 3245 	by regulation
4.5 Envir	onmental hazards		
ADN Enviro	onmentally hazardous	: no	
ADR Enviro	onmentally hazardous	: no	
RID Enviro	onmentally hazardous	: no	
IMDG Marin	e pollutant	: no	
•	ial precautions for use	r	

Not applicable for product as supplied.



SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

Other regulations	: Restricted to professional users. For use by laboratories for research.
	Biosafety Regulations and Guidelines: World Health Organization, Laboratory biosafety manual 3rd ed., ISBN 92 4 154650 6 (LC/NLM classification: QY 25) WHO/CDS/CSR/LYO/2004.11.

15.2 Chemical safety assessment

SECTION 16: Other information

Date and Number Formats

This document uses the following notation for printing dates and numbers:				
Date:	Dec 31th, 2012	as	2012-12-31	
Numbers:	123456,78	as	123 456,78	

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.

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

1.1 Product identifier

Trade name	:	Histopaque Matrix for Control Cells
Substance name	:	Histopaque Matrix for Control Cells

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

Use of the Sub-	: Assay reagent
stance/Mixture	

1.3 Details of the supplier of the safety data sheet

Company	:	Menarini Silicon Biosystems, Inc. 3401 Masons Mill Rd #100 Huntingdon Valley, PA 19006 USA		
Telephone	:	1 (800) 381-4929		
Telefax	:			
E-mail address Responsible/issuing person	:	Us-info@siliconbiosystems.com		
Emergency telephone number				

1.4 Emergency telephone number US : (303)-389-1805 International: +1 (303)-389-1805

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Supplemental Hazard	:	Not a hazardous substance or mixture ac-
Statements		cording to Regulation (EC) No. 1272/2008.

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.



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: Liquid

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
sodium azide	26628-22-8 247-852-1	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

	If inhaled	:	If breathed in, move person into fresh air. Consult a physician.
	In case of skin contact	:	Take off contaminated clothing and shoes immediately. Wash off with plenty of water. If symptoms persist, call a physician.
	In case of eye contact	:	Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.
	If swallowed	:	If swallowed, rinse mouth with water (only if the person is con- scious). Call a physician immediately.
4.2 N	Most important symptoms and	e	ffects, both acute and delayed
	Symptoms	:	No information available.

4.3 Indication of any 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 cir-



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		cumstances and	the surrounding environment.	
5.2 Special	hazards arising from	n the substance or mi	ixture	
Specific hazards during fire- fighting		: No information a	vailable.	
5.3 Advice	for firefighters			
Special protective equipment for firefighters		t : In the event of fire, wear self-contained breathing apparatus		
Further information : No information available.		vailable.		

SECTION 6: Accidental release measures

6.1 Personal precautions, protect	tive equipment and emergency procedures
Personal precautions	: In the event of an accidental release the emergency response team must respond based on a risk assessment and use per- sonal protective equipment as appropriate.
6.2 Environmental precautions	
Environmental precautions	: Should not be released into the environment.
6.3 Methods and material for cont	tainment and cleaning up
Methods for cleaning up	 Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers. Small spills: Gently cover the spill with an absorbent towel or pad. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the sec- tion "Disposal considerations".

6.4 Reference to other sections

For disposal information, see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	 To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Use personal protective equipment as required.
Advice on protection against fire and explosion	: No data available
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.



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	7.2 Conditions for safe storage, including any incompatibilities				
Requirements for storage areas and containers		light. Store in c in a dry, cool a	duct quality, do not store in heat or direct sun- original container. Keep containers tightly closed nd well-ventilated place. Keep away from heat rignition. Keep locked up. Keep refrigerated.		
Recommended storage tem- perature		: 2 - 8 °C			
7.3 Specifi	c end use(s)				
Specifi	ic use(s)	: Consult the teo	chnical guidelines for the use of this sub-		

stance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

		r		
Components	CAS-No.	Value type (Form	Control parameters	Basis
		of exposure)		
sodium azide	26628-22-8	TWA	0,1 mg/m3	2000/39/EC
Further information	Identifies the	possibility of significa	ant uptake through the skin, I	ndicative
		STEL	0,3 mg/m3	2000/39/EC
Further information	Identifies the	possibility of signification	ant uptake through the skin, I	ndicative
		OELV - 8 hrs	0,1 mg/m3	IE OEL
		(TWA)	(Sodium azide)	
Further information	Substances which have the capacity to penetrate intact skin when they come			nen they come
	in contact with	n it, and be absorbed	I into the body, Indicative Oc	cupational Ex-
	posure Limit Value			
		OELV - 15 min	0,3 mg/m3	IE OEL
		(STEL)	(Sodium azide)	
Further information			ity to penetrate intact skin wl	
	in contact with	n it, and be absorbed	I into the body, Indicative Oc	cupational Ex-
	posure Limit \	/alue		

8.2 Exposure controls

Engineering measures

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Eye protection	: No special precautions required.	
Hand protection Remarks	: Disposable gloves	
Skin and body protection	: No special precautions required.	
Respiratory protection	: Engineering controls should always be the primary method c controlling exposures.	of



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		ties, the type as w will depend upon hazards, physica sent.	tective equipment is needed for certain activi- well as the corresponding protection factor the risk assessment and air concentrations, and warning properties of substances pre- biratory protective equipment normally re-
Protec	tive measures	the Environmenta	ective equipment must be selected based on al Health and Safety risk assessment. Con- ntal Health and Safety expert if necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: clear
Solubility(ies) Water solubility	: soluble

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity None reasonably foreseeable. 10.2 Chemical stability Stable under recommended storage 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 To avoid thermal decomposition, do not overheat. 10.5 Incompatible materials Materials to avoid Strong acids and strong bases Strong oxidizing agents Reducing agents

10.6 Hazardous decomposition products

None known.



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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Product:	
Acute oral toxicity	: Acute toxicity estimate: > 2 000 mg/kg Method: Calculation method
Components:	
sodium azide:	
Acute oral toxicity	: LD50 (Rat): 27 mg/kg
Skin corrosion/irritation	
No data available	
Respiratory or skin sensiti	sation
No data available	
Germ cell mutagenicity	
No data available	
Carcinogenicity	
No data available	
Reproductive toxicity	
No data available	
STOT - single exposure	
No data available	
STOT - repeated exposure	
No data available	
Repeated dose toxicity	
No data available	
Aspiration toxicity	

SECTION 12: Ecological information

12.1 Toxicity		
<u>Componen</u> sodium azie		
Toxicity to fi	sh	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,7 mg/l Exposure time: 96 h
Toxicity to d aquatic inve	aphnia and other rtebrates	: EC50 (Daphnia pulex (Water flea)): 4,2 mg/l Exposure time: 96 h



Histopaque Matrix for Control Cells Version Revision Date: SDS Number: Date of last issue: 2017-08-02 1.47 2018-01-09 100000010980 Date of first issue: 2015-02-26 Toxicity to algae : IC50 : 272 mg/l Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 38,5 mg/l 12.2 Persistence and degradability No data available .

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

13.1 Waste treatment methods

Product	: In accordance with National, Federal, State and Local regula- tions.
Contaminated packaging	: Empty containers should be taken to an approved waste han- dling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good



Version	Revision Date:	SDS Number:	Date of last issue: 2017-08-02
1.47	2018-01-09	10000010980	Date of first issue: 2015-02-26

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user Not applicable

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

Other regulations : Restricted to professional users.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Full text of H-Statements

H300	: Fatal if swallowed.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012-12-31
Numbers:	123456,78	as	123 456,78

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