

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

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 substance or mixture and uses advised against

Use of the Sub- : Large Molecule Pharmaceutical intended for medical use,
stance/Mixture Assay reagent

1.3 Details of the supplier of the safety data sheet

Company : Janssen Diagnostics, LLC
700 US Highway Route 202
08869 South Raritan, NJ
US

Telephone : +18778374339

Telefax :

E-mail address : SDSJanssen@its.jnj.com
Responsible/issuing person

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237
CHEMTREC International: +1 703-527-3887

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

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

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 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 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 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 cir-
cumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire- : Combustible material
fighting

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

5.3 Advice for firefighters

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

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 any particular micro-organism is based on several factors including amount of infectious material present, infectious dose, mode of transmission, 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 personal 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.
Special consideration may need to be evaluated based on

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

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 sunlight. 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 temperature : -20 °C

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/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

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

Eye protection : No special precautions required.

Hand protection
Remarks : No special precautions required.

Skin and body protection : No special precautions required.

Respiratory protection : Engineering controls should always be the primary method of controlling exposures.
There is remote possibility that this product could be aerosolized and inhaled in the workplace.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
No personal respiratory protective equipment normally required.

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental 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

pH : 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

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Solubility in other solvents : No data available

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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Explosive properties : No data available

Oxidizing properties : No data available

9.2 Other information

Conductivity : No data available

: 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.
Exposure to light.

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

None known.

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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 irritation

Product:

Remarks: No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Product:

Remarks: No data available

Reproductive toxicity

Product:

Effects on fertility : Remarks: No data available

Effects on foetal develop- : Remarks: No data available

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

ment

STOT - single exposure

Product:

Remarks: No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data 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

12.3 Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Product:

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : Remarks: No data available

: This substance/mixture contains no components considered

Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

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:

Additional ecological information : Remarks: Should not be released into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : In accordance with National, Federal, State and Local regulations.
Decontaminate all waste before disposal (steam sterilization, chemical disinfection and/or incineration).

SECTION 14: Transport information

14.1 UN number

ADN : GENETICALLY MODIFIED MICRO-ORGANISMS
ADR : GENETICALLY MODIFIED MICRO-ORGANISMS
RID : GENETICALLY MODIFIED MICRO-ORGANISMS
IMDG : UN 3245
IATA : UN 3245

14.2 UN proper shipping name

ADN :
ADR :
RID :
IMDG : GENETICALLY MODIFIED MICRO-ORGANISMS
IATA : Genetically modified micro-organisms

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 3245

14.4 Packing group

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

ADN

Packing group : Not assigned by regulation
Classification Code : M8
Labels : 9

ADR

Packing group : Not assigned by regulation
Classification Code : M8
Labels : 9
Tunnel restriction code : (E)

RID

Packing group : Not assigned by regulation
Classification Code : M8
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : Not assigned by regulation
Labels : 9
EmS Code : F-A, S-T

IATA (Cargo)

Packing instruction (cargo aircraft) : 959
Packing instruction (EQ) : E0
Packing group : Not assigned by regulation
Labels : 3245

IATA (Passenger)

Packing instruction (passenger aircraft) : 959
Packing group : Not assigned by regulation
Labels : 3245

14.5 Environmental hazards

ADN

Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Version	Revision Date:	SDS Number:	Date of last issue: 2016-07-09
1.8	2016-08-12	100000011994	Date of first issue: 2015-12-15

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.

BE / EN

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

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 : Janssen Diagnostics, LLC
700 US Highway Route 202
08869 South Raritan, NJ
US

Telephone : +18778374339

Telefax :

E-mail address : SDSJanssen@its.jnj.com
Responsible/issuing person

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237
CHEMTREC International: +1 703-527-3887

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.

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

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	$\geq 0,1 - < 0,25$

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 Most important symptoms 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 cir-

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

cumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

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

Further information : No information available.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective 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 personal protective equipment as appropriate.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.

6.3 Methods and material for containment 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 section "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.

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

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 sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition. Keep locked up. Keep refrigerated.

Recommended storage temperature : 2 - 8 °C

7.3 Specific end use(s)

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m ³	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m ³	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			

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 of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
No personal respiratory protective equipment normally required.

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Con-

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

sult a Environmental 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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 2 000 mg/kg
Method: Calculation method

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

Components:

sodium azide:

Acute oral toxicity : LD50 (Rat): 27 mg/kg

Skin corrosion/irritation

No data available

Respiratory or skin sensitisation

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

No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

sodium azide:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,7 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 4,2 mg/l
Exposure time: 96 h

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

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

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 regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling 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

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.

Histopaque Matrix for Control Cells

Version	Revision Date:	SDS Number:	Date of last issue: 2016-06-30
1.36	2016-08-12	100000010980	Date of first issue: 2015-02-04

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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