

Version Revision Date: SDS Number: Date of last issue: -

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1. PRODUCT AND COMPANY IDENTIFICATION

Substance name : CTC Control Cells

5496

Manufacturer or supplier's details

Company : Janssen Diagnostics, LLC

Address : 700 US Highway Route 202

South Raritan, NJ 08869

US

Telephone : (877) 837-4339

Emergency telephone : CHEMTREC IN: 000-800-100-7141

number CHEMTREC International: +1 703-527-3887

E-mail address : SDSJanssen@its.jnj.com

Responsible/issuing person

Recommended use of the chemical and restrictions on use

Recommended use : Large Molecule Pharmaceutical intended for medical use

Assay reagent

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid



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Hazardous components

Chemical name	CAS-No.	Concentration (%
		w/w)
Sodium chloride (NaCl)	7647-14-5	>= 10 - < 20

4. 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.

Most important symptoms and effects, both acute and

delayed

No information available.

Notes to physician Treat symptomatically.

5. FIREFIGHTING MEASURES

Suitable extinguishing media Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Specific hazards during fire-

fighting

Combustible material

Specific extinguishing meth-

ods

No information available.

for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emergency procedures

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 per-



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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.

Environmental precautions : Should not be released into the environment.

Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and 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 sec-

tion "Disposal considerations".

Clean up with a 10% bleach (5.25% sodium hypochlorite) solution, 1 part bleach, mixed with 9 parts water is recom-

mended 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

specific hazards.

7. HANDLING AND STORAGE

Advice on protection against

fire and explosion

No data available

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.

Conditions for safe storage : 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



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : The work area should be installed in accordance with the re-

quirements 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

Respiratory protection : Engineering controls should always be the primary method of

controlling exposures.

There is remote possibility that this product could be aeroso-

lized 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 pre-

sent.

No personal respiratory protective equipment normally re-

quired.

Hand protection

Remarks : No special precautions required.

Eye protection : No special precautions required.

Skin and body protection : No special precautions 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Vial

Colour : clear, light yellow, to, amber

Odour : No data available

pH : 7,0



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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

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

Conductivity : No data available

: No data available

10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat.

Exposure to light.



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Incompatible materials : No data available

Hazardous decomposition

products

None known.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Remarks: No data available

Acute toxicity estimate: > 5 000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of :

administration)

Remarks: No data available

Components:

Sodium chloride (NaCl):

Acute oral toxicity : LD50 Oral (Rat): 3 000 mg/kg

Assessment: The component/mixture is low toxic after single

ingestion.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Product:

Remarks: No data available

Components:

Sodium chloride (NaCl): Remarks: No data available

Serious eye damage/eye irritation

Product:

Remarks: No data available

Components:

Sodium chloride (NaCl):



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Remarks: No data available

Respiratory or skin sensitisation

Components:

Sodium chloride (NaCl): Remarks: No data available

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Components:

Sodium chloride (NaCl):

Germ cell mutagenicity -

Assessment

No information available.

Carcinogenicity

Product:

Remarks: No data available

Components:

Sodium chloride (NaCI):

Carcinogenicity - Assess-

ment

: No information available.

Reproductive toxicity

Product:

Effects on fertility

Remarks: No data available

Effects on foetal develop-

ment

Remarks: No data available

Components:

Sodium chloride (NaCl):

Reproductive toxicity - As-

sessment

: No information available.

Teratogenicity - Assessment : No information available.



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STOT - single exposure

Product:

Remarks: No data available

Components:

Sodium chloride (NaCl): Remarks: No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

Components:

Sodium chloride (NaCl):

Toxicity to fish : LC50 (Fish): 6 750 mg/l

Exposure time: 96 h

EC50 (Daphnia (water flea)): 2 024 mg/l

Exposure time: 48 h

Persistence and degradability

Product:

Biodegradability : Remarks: No data available

Components:

Sodium chloride (NaCl):

Biodegradability : Remarks: No data available



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Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

Components:

Sodium chloride (NaCI):

Bioaccumulation : Remarks: No data available

Mobility in soil

Product:

Distribution among environ-

mental compartments

Remarks: No data available

Components:

Sodium chloride (NaCI):

Mobility : Remarks: No data available

Other adverse effects

Product:

Results of PBT and vPvB

assessment

Remarks: No data available

Additional ecological infor-

mation

Should not be released into the environment.

Components:

Sodium chloride (NaCI):

Environmental fate and

pathways

: No data available

Results of PBT and vPvB

assessment

No information available.

Additional ecological infor-

mation

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regula-

tions.

Decontaminate all waste before disposal (steam sterilization,

chemical disinfection and/or incineration).



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14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : GENETICALLY MODIFIED MICRO-ORGANISMS

Proper shipping name

Class : 9

Packing group : Not assigned by regulation

Labels : 9

IATA-DGR

UN/ID No. : UN 3245

Proper shipping name : Genetically modified micro-organisms

Class : 9

Packing group : Not assigned by regulation

Labels : 3245 Packing instruction (cargo : 959

aircraft)

Packing instruction (EQ) : E0
Packing instruction : 959

(passenger aircraft)

IMDG-Code

UN number : UN 3245

Proper shipping name : GENETICALLY MODIFIED MICRO-ORGANISMS

Class : 9

Packing group : Not assigned by regulation

Labels : 9 EmS Code : F-A, S-T Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

Restricted to professional users.

For use by laboratories for research.

16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% re-



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sponse; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC -No Observed (Adverse) Effect Concentration: NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS -Workplace Hazardous Materials Information System

Date format : dd.mm.yyyy

Numbers : 123 456,78

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IN / EN

Histopaque Matrix for Control Cells



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2016-08-12

 1.12
 2016-10-27
 100000010980
 Date of first issue: 2015-07-14

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Histopaque Matrix for Control Cells

Substance name : Histopaque Matrix for Control Cells

Manufacturer or supplier's details

Company : Janssen Diagnostics, LLC

Address : 700 US Highway Route 202

South Raritan, NJ 08869

US

Telephone : (877) 837-4339

Emergency telephone : CHEMTREC IN: 000-800-100-7141

number CHEMTREC International: +1 703-527-3887

E-mail address : SDSJanssen@its.jnj.com

Responsible/issuing person

Recommended use of the chemical and restrictions on use

Recommended use : Assay reagent

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

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Chemical name	CAS-No.	Concentration (%
		w/w)
sodium azide	26628-22-8	>= 0,1 - < 1

4. 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.

Most important symptoms and effects, both acute and

delayed

No information available.

Notes to physician : Treat symptomatically.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Specific hazards during fire-

fighting

No information available.

Specific extinguishing meth-

ods

No information available.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

: 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.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and 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

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pad.

Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the sec-

tion "Disposal considerations".

7. HANDLING AND STORAGE

Advice on protection against

fire and explosion

No data available

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.

Conditions for safe storage

To maintain product quality, do not store in heat or direct sun-

light.

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 tem: :

perature

2 - 8 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sodium azide	26628-22-8	C (Vapour)	0,11 ppm (Hydrazoic acid)	ACGIH
		С	0,29 mg/m3 (Sodium azide)	ACGIH

Engineering measures

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

Personal protective equipment

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 pre-

sent.

No personal respiratory protective equipment normally re-

quired.

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Hand protection

Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : No special precautions 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.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : clear

Solubility(ies)

Water solubility : soluble

10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous reac-

tions

No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat.

Incompatible materials : Strong acids and strong bases

Strong oxidizing agents

Reducing agents

Hazardous decomposition

products

None known.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 5 000 mg/kg

Method: Calculation method

Components:

sodium azide:

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

Skin corrosion/irritation

No data available

Serious eye damage/eye 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

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

Persistence and degradability

No data available

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Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

Restricted to professional users.

16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response

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