

SAFETY DATA SHEET



Version 1.0 Revision Date: 15.11.2016 SDS Number: 100000011994 Date of last issue: -
Date of first issue: 15.11.2016

SECTION 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 number : **CHEMTREC AU: +(61)-290372994**
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

SECTION 2. HAZARDS IDENTIFICATION

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

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- 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.
-

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protec-
tive equipment and emer-
gency 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 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.
- Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.
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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 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 specific hazards.

SECTION 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.

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.

Conditions for safe storage : 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

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SECTION 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 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

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.

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.

SECTION 9. 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

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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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: None reasonably foreseeable.
Chemical stability	: Stable under recommended storage conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
Conditions to avoid	: To avoid thermal decomposition, do not overheat. Exposure to light.
Incompatible materials	: No data available
Hazardous decomposition products	: None known.

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SECTION 11. TOXICOLOGICAL INFORMATION

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

Chronic toxicity

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 development : Remarks: No data available

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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

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

Further information

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 89.97 %

Persistence and degradability

Product:

Biodegradability :
Remarks: No data available

Bioaccumulative potential

Product:

Bioaccumulation :
Remarks: No data available

Mobility in soil

Product:

Distribution among environmental compartments :
Remarks: No data available

Other adverse effects

Product:

Results of PBT and vPvB assessment :
Remarks: No data available

Additional ecological :
Should not be released into the environment.

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information

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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

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 aircraft) : 959
Packing instruction (EQ) : E0
Packing instruction (passenger aircraft) : 959

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.

National Regulations

ADG

UN number : UN 3245
Proper shipping name : GENETICALLY MODIFIED MICROORGANISMS
Class : 9
Packing group : Not assigned by regulation
Labels : 9

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SECTION 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.

SECTION 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 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

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

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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.

AU / EN

SAFETY DATA SHEET

Histopaque Matrix for Control Cells



Version 1.12 Revision Date: 27.10.2016 SDS Number: 100000010980 Date of last issue: 12.08.2016
Date of first issue: 18.09.2015

SECTION 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 number : CHEMTREC AU: +(61)-290372994
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

SECTION 2. HAZARDS IDENTIFICATION

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
sodium azide	26628-22-8	< 10

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

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Histopaque Matrix for Control Cells



Version 1.12 Revision Date: 27.10.2016 SDS Number: 100000010980 Date of last issue: 12.08.2016
Date of first issue: 18.09.2015

- 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.
-

SECTION 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.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protec-
tive 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
pad.
Large spills + Small spills: Keep in suitable, closed containers
for disposal. Treat recovered material as described in the sec-
tion "Disposal considerations".
-

SECTION 7. HANDLING AND STORAGE

- Advice on protection against : No data available
-

SAFETY DATA SHEET
Histopaque Matrix for Control Cells



Version 1.12 Revision Date: 27.10.2016 SDS Number: 100000010980 Date of last issue: 12.08.2016
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fire and explosion

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.

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

Conditions for safe storage : 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

SECTION 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	Peak limit	0.11 ppm 0.3 mg/m ³	AU OEL
Further information: The exposure standards are established as gravimetric (mg/m ³) values and converted into volumetric values				
		C (Vapour)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.29 mg/m ³ (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 present.
 No personal respiratory protective equipment normally required.

Hand protection

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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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : clear

Solubility(ies)
Water solubility : soluble

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous reactions : 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

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

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Histopaque Matrix for Control Cells



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Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Chronic toxicity

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

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 : EC50 (Daphnia pulex (Water flea)): 4.2 mg/l
aquatic invertebrates 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

Bioaccumulative potential

No data available

Mobility in soil

No data available

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Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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

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.

National Regulations

ADG

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Restricted to professional users.

R-phrases(s) : R22 Harmful if swallowed.

S-phrases(s) : S60 This material and its container must be disposed of as hazardous waste.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

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Histopaque Matrix for Control Cells



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