

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519

CellSave Preservative 100 Tubes



Version 1.12 Revision Date: 2016/10/27 SDS Number: 100000011151 Date of last issue: 2016/09/20
Date of first issue: 2015/09/22

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : CellSave Preservative 100 Tubes
Substance name : CellSave Preservative 100 Tubes
Chemical nature : Liquid

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 CN: 4001-204937
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

Emergency Overview

Appearance : liquid
Colour : clear
Odour :

May cause an allergic skin reaction.

GHS Classification

Skin sensitisation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

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P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P321 Specific treatment (see supplemental first aid instructions on this label).

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

May cause an allergic skin reaction.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
IMIDUREA	39236-46-9	>= 30 - < 50
DINAEDTA	Not Assigned	>= 3 - < 5

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-

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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 circumstances and the surrounding environment.

Specific hazards during fire-fighting : No information available.

Specific extinguishing methods : 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 emergency procedures : 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.

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 section "Disposal considerations".

7. HANDLING AND STORAGE

Handling

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.

Avoidance of contact : None known.

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Storage

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 : 4 - 30 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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.

Eye/face protection : No special precautions required.

Skin and body protection : No special precautions required.

Hand protection

Remarks : Disposable gloves

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

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Appearance : liquid

Colour : clear

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 : None known.

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:

IMIDUREA:

Acute oral toxicity : LD50 (Rat): 11,300 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.5 mg/l
Exposure time: 1 h

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

DINAEDTA:

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Components:

IMIDUREA:

Result: No skin irritation

DINAEDTA:

Species: Rabbit

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Result: No skin irritation

Serious eye damage/eye irritation

Components:

IMIDUREA:

Result: No eye irritation

DINAEDTA:

Species: Rabbit

Result: No eye irritation

Respiratory or skin sensitisation

Components:

IMIDUREA:

Method: Maximisation Test

Result: May cause sensitisation by skin contact.

Method: Local Lymph Node Assay (LLNA) in mice

Result: May cause sensitisation by skin contact.

Germ cell mutagenicity

Components:

IMIDUREA:

Genotoxicity in vitro : Test Type: Ames test
Metabolic activation: with and without metabolic activation
Result: negative
GLP: yes

: Test Type: Chromosome aberration test in vitro
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Germ cell mutagenicity - Assessment : No information available.

DINAEDTA:

Genotoxicity in vitro : Test Type: Ames test
Species: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative

Carcinogenicity

Components:

IMIDUREA:

Carcinogenicity - : No information available.

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Assessment

Reproductive toxicity

Components:

IMIDUREA:

Teratogenicity - Assessment : No information available.

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

IMIDUREA:

Species: Rat

NOAEL: 200 mg/kg

LOAEL: 500 mg/kg

Application Route: Oral

Species: Rabbit

NOAEL: 200 mg/kg

Application Route: Dermal

Aspiration toxicity

No data available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

IMIDUREA:

Toxicity to fish : Remarks: No data available

DINAEDTA:

Toxicity to fish : (Poecilia reticulata (guppy)): 320 mg/l
Exposure time: 96 h
Test Type: LC50

Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l

Persistence and degradability

Components:

IMIDUREA:

Biodegradability : Remarks: No data available

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DINAEDTA:

Biodegradability : Remarks: No data available

Biochemical Oxygen Demand (BOD) : 10 mg/g
Incubation time: 8 d

Bioaccumulative potential

Components:

IMIDUREA:

Bioaccumulation : Remarks: No data available

DINAEDTA:

Bioaccumulation : Remarks: No data available

Mobility in soil

Components:

IMIDUREA:

Distribution among environmental compartments : Remarks: No data available

DINAEDTA:

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

IMIDUREA:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

DINAEDTA:

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

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.

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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

GB 6944/12268

Not regulated as a dangerous good

15. REGULATORY INFORMATION

National regulatory information

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 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 Tox-

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icology 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

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