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

1.1 Product identifier

Trade name CellSave Preservative 100 Tubes

Substance name : CellSave Preservative 100 Tubes

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

Use of the Substance/Mixture : Assay reagent

1.3 Details of the supplier of the safety data sheet

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

Telephone : +18778374339
:

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

1.4 Emergency telephone number +32 14 60 24 44

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)


Skin sensitisation , Category 1 H317: May cause an allergic skin reaction.

Classification (67/548/EEC, 1999/45/EC)

Sensitising R43: May cause sensitisation by skin contact.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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:
 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.

Hazardous components which must be listed on the label:
 39236-46-9 IMIDUREA

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.
 IMIDUREA : No information available.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
IMIDUREA	39236-46-9 254-372-6	Xi; R43	Skin Sens.1; H317	>= 25 - < 50

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 immediately with plenty of water.

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- 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 conscious).
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 circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : 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.
Evacuate personnel to safe areas.

6.2 Environmental precautions

- Environmental precautions : Should not be released into the environment.

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6.3 Methods and materials 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. For personal protection see section 8.
- Advice on protection against fire and explosion : No data available
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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.
- Storage temperature : 4 - 30 °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

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Contains no substances with occupational exposure limit values.

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.
Consult a Environmental Health and Safety expert if necessary.

Environmental exposure controls

General advice : Should not be released into the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : clear

9.2 Other information

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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 : None known.

10.6 Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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

Skin corrosion/irritation

Components:

IMIDUREA :

Result: No skin irritation

Serious eye damage/eye irritation

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Components:

IMIDUREA :

Result: No eye irritation

Respiratory or skin sensitisation

Components:

IMIDUREA :

Result: May cause sensitisation by skin contact.

Method: Maximisation Test (GPMT)

Result: May cause sensitisation by skin contact.

Method: Local Lymph Node Assay (LLNA) in mice

Germ cell mutagenicity

Components:

IMIDUREA :

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

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

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

Germ cell mutagenicity-
Assessment : No information available.

Carcinogenicity

Components:

IMIDUREA :

Carcinogenicity -
Assessment : No information available.

Reproductive toxicity

Toxicity to reproduction/fertility

No data available

Reprod.Tox./Development/Teratogenicity

Components:

IMIDUREA :

Teratogenicity - Assessment : No information available.

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STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

IMIDUREA :

Rat: NOAEL: 200 mg/kg

LOAEL: 500 mg/kg

Application Route: Oral

Rabbit: NOAEL: 200 mg/kg

Application Route: Dermal

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

IMIDUREA :

Toxicity to fish : No data available

12.2 Persistence and degradability

Components:

IMIDUREA :

Biodegradability : No data available

12.3 Bioaccumulative potential

Components:

IMIDUREA :

Bioaccumulation : No data available

12.4 Mobility in soil

Components:

IMIDUREA :

Distribution among : No data available

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environmental compartments

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.

Components:

IMIDUREA :

Assessment : No information available.

12.6 Other adverse effects

Components:

IMIDUREA :

Additional ecological information : 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

ADN

Not dangerous goods

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.2 Proper shipping name

ADN

Not dangerous goods

ADR

Not dangerous goods

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RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.3 Transport hazard class

ADN

Not dangerous goods

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.4 Packing group

ADN

Not dangerous goods

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.5 Environmental hazards

ADN

Not dangerous goods

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.6 Special precautions for user

For personal protection see section 8.

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

No data available

SECTION 15: Regulatory information

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

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Major Accident Hazard Legislation
96/82/EC : Update:
Not applicable

Notification status

REACH : Not in compliance with the inventory
CH INV : The formulation contains substances listed on the Swiss
Inventory
TSCA : On TSCA Inventory
DSL : All components of this product are on the Canadian DSL.
AICS : On the inventory, or in compliance with the inventory
NZIoC : On the inventory, or in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : On the inventory, or in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : On the inventory, or in compliance with the inventory

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 R-Phrases

R43 May cause sensitisation by skin contact.

Full text of H-Statements

H317 May cause an allergic skin reaction.

Full text of other abbreviations

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.

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006



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