

**CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu**

Version 1.38 Revision Date: 2016/11/22 SDS Number: 100000011147 Date of last issue: 2016/11/10
Date of first issue: 2015/02/04

SECTION 1. IDENTIFICATION

Product name : CELLSEARCH Tumor Phenotyping Reagent Her-2/Neu
Substance name : CELLSEARCH Tumor Phenotyping Reagent Her-2/Neu

Manufacturer or supplier's details

Company name of supplier : Janssen Diagnostics, LLC

Address : 700 US Highway Route 202
South Raritan, NJ 08869
US

Telephone : (877) 837-4339
E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-527-3887

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

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
sodium azide	26628-22-8	>= 0.1 - < 1

SECTION 4. FIRST AID MEASURES

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

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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.

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.
- Further information : 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".

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SECTION 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 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	C	0.1 ppm (HN3)	NIOSH REL
		C (Vapour)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.1 ppm (Ammonia)	OSHA P0
		C	0.29 mg/m ³ (Sodium azide)	ACGIH
		C	0.3 mg/m ³ (Sodium azide)	NIOSH REL
		C	0.3 mg/m ³ (Sodium azide)	OSHA P0
		C	0.1 ppm 0.3 mg/m ³	CAL PEL

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 activ-

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ities, 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 : 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : brown

Odour : odourless

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 : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

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Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**sodium azide**

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**IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

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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

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
manufactured with a Class I or Class II ODS as defined by the
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +
B).

SECTION 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.

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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**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

SODIUM PHOSPHATE	7558-79-4	0.12 %
DIBASIC		

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

SODIUM PHOSPHATE	7558-79-4	0.12 %
DIBASIC		

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

sodium azide	26628-22-8	0.1 - 1 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
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SODIUM PHOSPHATE DIBASIC	7558-79-4	0.1 - 1 %
sodium azide	26628-22-8	0.1 - 1 %

New Jersey Right To Know

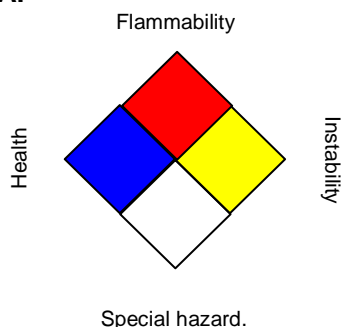
water	7732-18-5	90 - 100 %
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California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations

: Restricted to professional users.

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2016/11/22

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

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