

SAFETY DATA SHEET

CELLSEARCH Tumor Phenotyping Reagent Her-2/Neu



Version 1.11 Revision Date: 2016-11-08 SDS Number: 100000011147 Date of last issue: 2016-10-27
Date of first issue: 2015-07-14

1. PRODUCT AND COMPANY 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 : Janssen Diagnostics, LLC

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

Telephone : (877) 837-4339

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

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Hazardous components

| 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 conscious). 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.

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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

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

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 |
| | | 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,

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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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|------------|---|-----------|
| Appearance | : | liquid |
| Colour | : | brown |
| Odour | : | odourless |

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 |
|---------------------|---|--|

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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

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 : 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

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Persistence and degradability

No data available

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 regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling 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 -

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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

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