

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version 1.12 Revision Date: 2016/11/08 SDS Number: 100000011147 Date of last issue: 2016/10/27
Date of first issue: 2015/09/22

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 name of supplier : Janssen Diagnostics, LLC

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

Telephone : (877) 837-4339

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

Emergency telephone number : **CHEMTREC JP: +(81)-345209637**
CHEMTREC International: +1 703-527-3887

Recommended use of the chemical and restrictions on use

Recommended use : Assay reagent

2. HAZARDS IDENTIFICATION

GHS Classification

Not a dangerous substance or mixture according to the Globally Harmonised System (GHS).

GHS label elements

Not a dangerous substance or mixture according to the Globally Harmonised System (GHS).

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS/ISHL number
sodium azide	26628-22-8	>= 0.1 - < 1	1-482

For explanation of abbreviations see section 16.

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version 1.12 Revision Date: 2016/11/08 SDS Number: 100000011147 Date of last issue: 2016/10/27
Date of first issue: 2015/09/22

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 con-
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 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.
-

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
-

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version 1.12 Revision Date: 2016/11/08 SDS Number: 100000011147 Date of last issue: 2016/10/27
Date of first issue: 2015/09/22

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

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 : 2 - 8 °C

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version 1.12 Revision Date: 2016/11/08 SDS Number: 100000011147 Date of last issue: 2016/10/27
Date of first issue: 2015/09/22

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

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.

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: > 2,000 mg/kg

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version 1.12 Revision Date: 2016/11/08 SDS Number: 100000011147 Date of last issue: 2016/10/27
Date of first issue: 2015/09/22

Method: Calculation method

Acute dermal 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

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

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version 1.12 Revision Date: 2016/11/08 SDS Number: 100000011147 Date of last issue: 2016/10/27
Date of first issue: 2015/09/22

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

Hazardous to the ozone layer

Not applicable

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.

National Regulations

Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

SAFETY DATA SHEET
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version	Revision Date:	SDS Number:	Date of last issue: 2016/10/27
1.12	2016/11/08	100000011147	Date of first issue: 2015/09/22

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

SAFETY DATA SHEET

CELLSEARCH Tumor Phenotyping Reagent Her-2/Neu



Version	Revision Date:	SDS Number:	Date of last issue: 2016/10/27
1.12	2016/11/08	100000011147	Date of first issue: 2015/09/22

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Waste Disposal and Public Cleansing Law

Industrial waste

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 : yyyy/mm/dd
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 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
CELLSEARCH Tumor Phenotyping Reagent
Her-2/Neu



Version	Revision Date:	SDS Number:	Date of last issue: 2016/10/27
1.12	2016/11/08	10000011147	Date of first issue: 2015/09/22

JP / EN