

CELLSEARCH Tumor Phenotyping Reagent Her-2/Neu

Version	Revision Date:	SDS Number:	Date of last issue: 2016-12-06
1.35	2018-02-26	100000011147	Date of first issue: 2015-02-04

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

1.1 Product identifier

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

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

Use of the Sub- : Assay reagent
stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company : Menarini Silicon Biosystems, Inc.
3401 Masons Mill Rd #100
Huntingdon Valley, PA
19006 USA

Telephone : 1 (800) 381-4929

Telefax :

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

1.4 Emergency telephone number

US : (303)-389-1805
International: +1 (303)-389-1805

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Supplemental Hazard : Not a hazardous substance or mixture ac-
Statements : cording to Regulation (EC) No. 1272/2008.

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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Remarks : No hazardous ingredients

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 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.

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 cir-
cumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-
fighting : No information available.

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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.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.

6.3 Methods and material 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. Use personal protective equipment as required.

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.

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Recommended storage temperature : 2 - 8 °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

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m3	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m3	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			

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.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : brown
Odour : odourless

9.2 Other information

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

None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 2 000 mg/kg
Method: Calculation method

Skin corrosion/irritation

No data available

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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

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

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..

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : In accordance with National, Federal, State and Local regula-

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tions.

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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations : Restricted to professional users.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012-12-31

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



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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.

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