SAFETY DATA SHEET



Atellica™ IM HER-2/neu Quality Control (H2n QC)

SDS #:

10995594

Section 1. Identification

Product identifier : Mtellica™ IM HER-2/neu Quality Control (H2n QC)

Product code : 10995594

Product type : Liquid.

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

Not applicable.

Manufactured/supplied : Siemens Healthcare Diagnostics Inc.

511 Benedict Avenue

Tarrytown, NY 10591-5097 USA

1-877-229-3711

(800) 424-9300 (CHEMTREC) (24/365)

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication

Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for

employees and other users of this product.

Classification of the substance or mixture

: Not classified.

Additional information : Not available.

Sodium azide may react with lead or copper plumbing to form highly explosive metal

azides.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise : None known.

classified

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
sodium azide	0.095	26628-22-8

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower

eyelids. Check for and remove any contact lenses. Get medical attention if irritation

occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get

medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes.

Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position

comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed

to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact: No specific data.Inhalation: No specific data.Skin contact: No specific data.Ingestion: No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities

have been ingested or inhaled.

Specific treatments: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

: In case of fire, use water spray (fog), foam or dry chemical.

Unsuitable extinguishing

media

: None known.

Specific hazards arising

from the chemical

: No specific data.

Hazardous thermal decomposition products

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable

: In a fire or if heated, a pressure increase will occur and the container may burst.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill

: Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

Advice on general occupational hygiene

: Put on appropriate personal protective equipment (see Section 8).

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
sodium azide	ACGIH TLV (United States, 3/2015). Notes: as hydrazoic acid vapor C: 0.11 ppm, (as Hydrazoic acid vapor) Form: as Hydrazoic acid vapor ACGIH TLV (United States, 3/2015). C: 0.29 mg/m³, (as Sodium azide) Form: as Sodium azide NIOSH REL (United States, 10/2013). Absorbed through skin. Notes: NAN3 CEIL: 0.3 mg/m³, (NAN3) NIOSH REL (United States, 10/2013).
	Absorbed through skin. Notes: as HN3

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Section 8. Exposure controls/personal protection

CEIL: 0.1 ppm, (as HN3)

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin. Notes: as HN3

CEIL: 0.1 ppm, (as HN3)

OSHA PEL 1989 (United States, 3/1989). Absorbed through skin. Notes: as NaN3

CEIL: 0.3 mg/m3, (as NaN3)

Appropriate engineering controls

: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Physical state Liquid. Color Colorless. Odorless Odor

pН 7

Flash point Not available.

Flammability (solid, gas) : Not relevant/applicable due to nature of the product.

Relative density

Solubility in water : Not relevant/applicable due to nature of the product.

Partition coefficient: n-

octanol/water

: Not available.

Auto-ignition temperature

: Not available. **Viscosity** : Not available.

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Section 10. Stability and reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous

reactions

products

: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Hazardous decomposition

: Under normal conditions of storage and use, hazardous decomposition products should

not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sodium azide	LD50 Dermal LD50 Dermal LD50 Oral	Rat	20 mg/kg 50 mg/kg 27 mg/kg	-

Irritation/Corrosion

Not available.

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely

routes of exposure

: Not available.

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

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Section 11. Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.
 Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
sodium azide	Acute EC50 0.348 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours
	Acute EC50 4.2 to 6.2 mg/l Fresh water Acute LC50 9000 μg/l Fresh water	Daphnia - Daphnia pulex - Larvae Crustaceans - Gammarus	48 hours 48 hours
		lacustris	40 Hours
	Acute LC50 0.68 mg/l Fresh water Chronic NOEC 5600 µg/l Marine water	Fish - Lepomis macrochirus Algae - Macrocystis pyrifera	96 hours 96 hours

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

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Section 12. Ecological information

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

Section 14. Transport information

DOT Classification

UN number Not regulated.

UN proper shipping name

Transport hazard class(es)

Packing group

Environmental hazards

No.

Additional information

TDG Classification

UN number Not regulated.

UN proper shipping name

Transport hazard class(es)

Packing group

Environmental hazards

No.

Additional

information

ADR/RID

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Mellica™ IM HER-2/neu Quality Control (H2n QC) Section 14. Transport information Not regulated. **UN** number **UN** proper shipping name **Transport** hazard class(es)

Packing group Environmental No. hazards **Additional**

information

IMDG

Not regulated. **UN number**

UN proper shipping name

Transport hazard class(es)

Packing group Environmental

No.

Additional information

hazards

IATA

UN number Not regulated.

UN proper shipping name

Transport hazard class(es)

Packing group

Environmental hazards

No.

Additional information

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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Section 14. Transport information

Transport in bulk according to Annex II of MARPOL and

: Not available.

the IBC Code

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)** : Not listed

Clean Air Act Section 602

: Not listed

Class I Substances

Clean Air Act Section 602 Class II Substances

: Not listed

DEA List I Chemicals

(Precursor Chemicals)

: Not listed

DEA List II Chemicals

: Not listed

(Essential Chemicals)

SARA 302/304

Composition/information on ingredients

			SARA 302 TPQ		SARA 304 RQ	
Name	%	EHS	(lbs)	(gallons)	(lbs)	(gallons)
sódium azide	0.095	Yes.	500	-	1000	-

SARA 304 RQ : 1052631.6 lbs / 477894.7 kg [126246.4 gal / 477894.7 L]

SARA 311/312

Classification : Not applicable. **Composition/information on ingredients**

Name	%	hazard	Sudden release of pressure		(acute) health	Delayed (chronic) health hazard
sodium azide	0.095	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : None of the components are listed. **New York** : None of the components are listed. **New Jersey** : None of the components are listed. Pennsylvania None of the components are listed.

International regulations

Chemical Weapons : Not listed

Convention List Schedule I

Chemicals

Chemical Weapons Convention List Schedule

II Chemicals

: Not listed

Chemical Weapons

Convention List Schedule

III Chemicals

: Not listed

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Section 16. Other information

History

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: ATE = Acute Toxicity Estimate **Key to abbreviations**

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as

modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

▼ Indicates information that has changed from previously issued version.

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