

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

1.1. Product identifier

Trade name or designation of the mixture	Enzyme Conjugate 813, 813RUO
Registration number	-
Synonyms	None.
Product code	813, 813RUO
Issue date	01-December-2017
Version number	02
Revision date	31-July-2017
Supersedes date	24-July-2015

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

Identified uses	Assorted.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters BioMedica Diagnostics Inc.
 94 Wentworth Road, PO Box 1030
 Windsor, Nova Scotia CANADA B0N 2T0

Contact person Corporate Phone: 1-902-798-5105
 Corporate Fax: 1-902-798-1025
 Email: info@biomedicadiagnostics.com
 Website: www.biomedicadiagnostics.com

1.4. Emergency telephone number US, Canada, Puerto Rico & Virgin Islands 1-800-255-3924
 International +1-813-248-0585
 Australia 1-300-954-583
 Brazil 0-800-591-6042
 China 400-120-0751
 India 000-800-100-4086
 Mexico 01-800-099-0731

Contract number MIS9591327

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards		
Skin sensitisation	Category 1	H317 - May cause an allergic skin reaction.

Hazard summary May cause an allergic skin reaction.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: 2-Methyl-4-isothiazol-3-one

Hazard pictograms



Signal word Warning

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

Prevention

P261	Avoid breathing mist or vapour.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves.

Response

P302 + P352	IF ON SKIN: Wash with plenty of water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.

Storage

Store away from incompatible materials.

Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
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Supplemental label information Not applicable.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
2-Methyl-4-isothiazol-3-one	0.01 - 0.03	2682-20-4 220-239-6	-	613-167-00-5	
Classification:	Acute Tox. 3;H301, Acute Tox. 3;H311, Skin Corr. 1B;H314, Skin Sens. 1;H317, Acute Tox. 3;H331, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. If skin rash or an allergic skin reaction develops, get medical attention.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	If material is ingested, immediately contact a physician or poison control centre.

4.2. Most important symptoms and effects, both acute and delayed Headaches, nausea and vomiting. Dermatitis.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture None known.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.
For emergency responders	Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental precautions Do not allow to enter drains, sewers or watercourses.

6.3. Methods and material for containment and cleaning up Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid contact with skin and eyes. Persons susceptible for allergic reactions should not handle this product. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

7.2. Conditions for safe storage, including any incompatibilities Store in a closed container away from incompatible materials.

7.3. Specific end use(s) Assorted.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

Exposure guidelines Follow standard monitoring procedures.

8.2. Exposure controls

Appropriate engineering controls Provide adequate ventilation. Provide easy access to water supply and eye wash facilities.

Individual protection measures, such as personal protective equipment

General information Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Wear approved safety glasses or goggles.

Skin protection

- Hand protection Wear appropriate chemical resistant gloves.

- Other Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Clear, pale yellow liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Clear, pale yellow.
Odour	None.
Odour threshold	Not available.
pH	6.5 - 7.5
Melting point/freezing point	Not available.

Initial boiling point and boiling range	100 °C (212 °F)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Completely soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Stable at normal conditions.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Polymerization will not occur.
10.4. Conditions to avoid	Keep away from heat.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Carbon oxides. Nitrogen oxides.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation	Vapours may irritate throat and respiratory system and cause coughing.
Skin contact	May cause skin irritation. May cause eczema-like skin disorders (dermatitis).
Eye contact	May cause eye irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms Headaches, nausea and vomiting. Dermatitis.

11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	May cause eye irritation.
Respiratory sensitisation	No data available.
Skin sensitisation	May cause an allergic skin reaction.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available.
Aspiration hazard	No data available.

Mixture versus substance information	Not available.
Other information	No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	Not available.
Partition coefficient n-octanol/water (log Kow)	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	Not available.
Mobility in general	No data available.
12.5. Results of PBT and vPvB assessment	Not a PBT or vPvB substance or mixture.
12.6. Other adverse effects	Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Dispose waste and residues in accordance with applicable federal, state, and local regulations. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
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SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

2-Methyl-4-isothiazol-3-one (CAS 2682-20-4)

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

2-Methyl-4-isothiazol-3-one (CAS 2682-20-4)

Directive 94/33/EC on the protection of young people at work

2-Methyl-4-isothiazol-3-one (CAS 2682-20-4)

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006 as amended. Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Training information

Follow training instructions when handling this material.

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