



Abbott

Release Date: 8/22/19

REF	
GTIN	Product Name

2G28-91	<i>Abbott RealTime CT/NG II Amplification</i>
----------------	---

Components:

2G28L GHS 2G28V GHS 2G28L0099 2G28V0099	RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent
82535 825350099 337940099	AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent
2G28M GHS 2G28M0099	RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent
2G28Y GHS 2G28Y0001	RealTime CT/NG Internal Control / CT/NG Internal Control

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

1 Identification

Product identifier

Trade name: **RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent**

Article number:

2G28L GHS
2G28V GHS
2G28L0099
2G28V0099

Application of the substance / the preparation: For In Vitro Diagnostic Use

Details of the supplier of the safety data sheet

Supplier:

Abbott Australasia P/L (Diagnostics Division)
299 Lane Cove Road
Macquarie Park NSW 2113
Tel: +61 2 9857 1111
Abbott Australasia P/L (Molecular Division)
299 Lane Cove Road
Macquarie Park NSW 2113
Tel: +61 2 9857 1111

Informing department: see Supplier

Emergency telephone number

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675834.
- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.
- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.
1800 816 696 and (+61 2 9857 1111)

2 Hazard(s) Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Skin Corr. 3 H316 Causes mild skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

Label elements

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

Hazard pictograms:



Signal word: Warning

Hazard-determining components of labelling:

2-Methyl-4-isothiazolin-3-one

(Continued on page 2)

AUS

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 1)

Sodium azide

· **Hazard statements:**

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapours / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P302+P352 IF ON SKIN: Wash with plenty of water.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 This material and its container must be disposed of in a safe way.

· **Additional information:**

AUH032 Contact with acids liberates very toxic gas.

· **Routes of Exposure:** Skin

3 Composition and Information on Ingredients

· **Dangerous components according to EC criteria:**

CAS: 1185-53-1	Tromethamine hydrochloride Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	3.40%
CAS: 26628-22-8	Sodium azide Acute Tox. 1, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.083%
CAS: 2682-20-4	2-Methyl-4-isothiazolin-3-one Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317	0.015%

· **Additional information:**

For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

4 First Aid Measures

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:**

Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

· **After skin contact:**

Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

· **After eye contact:**

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.

· **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

· **Information for Medical Personnel:**

· **Most important symptoms and effects, both acute and delayed:**

Kidney effects

(Continued on page 3)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 2)

Allergic reactions

Possibly immune response

This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

5 Fire Fighting Measures

· Suitable extinguishing agents:

Dry chemical, carbon dioxide (CO₂), water spray or regular foam.

- Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

No further relevant information available.

· Protective equipment:

For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

· Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· Methods and material for containment and cleaning up

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

This product contains sodium azide, which is toxic and reactive. See Sections 10 and 13 for additional information that could affect handling and disposal of contaminated spill materials.

NOTE FOR LARGE-VOLUME SPILL: This product contains sodium azide, which reacts with acid to liberate hydrazoic acid, a very toxic gas. Select a disinfectant with the following properties if disinfection of materials used to absorb a large volume of spilled product is required:

- Do not use any chemical or product with a pH below 6 to disinfect waste that contains sodium azide. Hydrazoic acid, a toxic gas, will be released when the pH is lower than 6.
- Do not use any chemical or product that contains mercury or any other metal to disinfect waste that contains sodium azide. This will create metal azide compounds, which can be highly explosive under pressure or shock (percussion).
- Select a disinfectant that does not bubble, effervesce or otherwise generate aerosols.
- Do not use excess disinfectant.
- Failure to follow manufacturer's directions may lead to unexpected reactions with the waste.
- Do not use a disinfectant if you do not have the proper facility, equipment and other appropriate protective measures available to work with it safely.

(Continued on page 4)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 3)

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

Reference to other sections

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and Storage

Handling

- Precautions for safe handling:** Avoid contact with skin.
- Information about protection against explosions and fires:** No special measures required.

Storage:

- Requirements to be met by storerooms and containers:** Store only in the original container.
- Information about storage in one common storage facility:** Store in original packaging.
- Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls and personal protection

Components with limit values that require monitoring at the workplace:

CAS: 26628-22-8 Sodium azide (0.083 %)

REL (USA)	Peak limitation: 0.3** mg/m ³ , 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV (USA)	Peak limitation: 0.29** mg/m ³ , 0.11* ppm *as HN ₃ vapor **as NaN ₃
IOELV (European Union)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin
NES (Australia)	Peak limitation: 0.3 mg/m ³ , 0.11 ppm
WES (Australia)	Peak limitation: 0.3 mg/m ³ , 0.11 ppm

Personal protective equipment:

General protective and hygienic measures:

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Avoid contact with the skin.
Immediately remove all soiled and contaminated clothing.

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use

(Continued on page 5)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 4)

appropriate air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· **Protection of hands:**

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· **Eye protection:**

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**

Normal use: protect personal clothing from splatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and Chemical Properties

· **General Information**

· **Form:** Liquid
 · **Colour:** Colourless

· **Odour:** Odourless

· **pH-value at 20 °C:** 8.1
 · **Melting point/freezing point:** Not determined
 · **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable
 · **Inflammability (solid, gaseous):** Not applicable
 · **Auto igniting** Product is not self-igniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits**
 · **Lower:** Not determined
 · **Upper:** Not determined

· **Vapour pressure:** Not determined

· **Density at 20 °C** 1.001 g/cm³
 · **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**

· **Water:** Not miscible or difficult to mix

(Continued on page 6)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 5)

· Viscosity:

· **dynamic:** Not determined

· **Water:** 83.5 %

· **Solids content:** 0.0 %

10 Stability and Reactivity

· Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

· Possibility of hazardous reactions:

This product contains sodium azide. Sodium azide solutions are reported to:

- react with acids to release hydrazoic acid, a very toxic gas. Higher quantities of hydrazoic acid are released as the solution becomes more acidic (i.e., as the pH of the solution gets lower). Low quantities of hydrazoic acid can be released from sodium azide in water.

- react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds. Violent explosions have been reported during plumbing work on drain systems containing accumulations of azide on copper, lead, brass, or solder.

· Conditions to avoid:

No further relevant information available.

· Incompatible materials:

No further relevant information available.

· Hazardous decomposition products:

No dangerous decomposition products known.

11 Toxicological Information

· Acute toxicity

· LD/LC50 values that are relevant for classification:

· Ingredients (100% pure substance/s):		
CAS: 1185-53-1 Tromethamine hydrochloride		
Oral	LD50	<1,000 mg/kg (rabbit) 1,780-5,900 mg/kg (rat)
CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one		
Oral	LD50	60 mg/kg (mouse) By analogy to methylchloroisothiazolinone. 53 mg/kg (rat) By analogy to methylchloroisothiazolinone.

· Primary irritant effect:

· **Skin corrosion/irritation** No irritant effect.

· **Serious eye damage/irritation** No irritant effect.

· **Sensitisation:** Sensitization possible through skin contact.

· Additional toxicological information:

None

· Target organs/systems:

Kidneys

(Continued on page 7)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

Skin
Immune system

(Continued from page 6)

12 Ecological Information

· **Aquatic toxicity:**

CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one

LC50 96 h 0.19 mg/l (trout) (Flow through)

LC50 48 h (Static) 0.056 mg/l (other) (Crustacean - Acartia tonsa)

· **Additional ecological information**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. Refer to applicable local regulations for limit values of discharge into sewage system.

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable
- **vPvB:** Not applicable

13 Disposal considerations

· **Recommendation for disposal of unused product:**

Dispose in accordance with national, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per state or local regulations. The following may be particularly important when identifying appropriate disposal:
 - Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product. For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

· **Uncleaned packagings**

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

- **Recommended cleaning agent:** Water with cleansing agents, if necessary.

14 Transport information

· **UN-Number**

- **ADG, ADN, IMDG, IATA** None

· **UN proper shipping name**

- **ADG, ADN, IMDG, IATA** None

(Continued on page 8)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 7)

· Transport hazard class(es)

· ADG, ADN, IMDG, IATA

· Class None

· Packing group

· ADG, IMDG, IATA None

· Environmental hazards

· Marine pollutant: No

· Transport/Additional information

· ADG

· Remarks: Not restricted for transportation.

· IMDG

· Remarks: Not restricted for transportation.

· IATA

· Remarks: Not restricted for transportation.

15 Regulatory information

· Australian Inventory of Chemical Substances

CAS: 1185-53-1	Tromethamine hydrochloride
CAS: 7447-40-7	Potassium chloride
CAS: 139-33-3	EDTA, Disodium Salt
CAS: 26628-22-8	Sodium azide
CAS: 67-42-5	ethylenebis(oxyethylenenitrilo)tetra(acetic acid)
CAS: 2682-20-4	2-Methyl-4-isothiazolin-3-one
CAS: 7732-18-5	Water, distilled, or of similar purity

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

· Complete text for H (Hazard) codes displayed in Section 3:

Note: The respective H statements apply to the pure substances.

(Continued on page 9)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Oligonucleotide Reagent / CT/NG II Oligonucleotide Reagent

(Continued from page 8)

Contact supplier

Tel. Abbott Molecular Customer Service: 1-800-553-7042
Abbott Australasia P/L (Diagnostics Division)
Emergency Contact number: 1800 816 696 and +61 2 9857 1111

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
Acute Tox. 1: Acute toxicity – Category 1
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Skin Corr. 3: Skin corrosion/irritation – Category 3
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

* Data compared to the previous version altered.

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

1 Identification

Product identifier

Trade name: **AmpliQaq Gold Enzyme / AmpliQaq Gold Enzyme Filled / AmpliQaq Gold Enzyme Reagent**

Article number:

82535
825350099
337940099

Application of the substance / the preparation: For In Vitro Diagnostic Use

Details of the supplier of the safety data sheet

Supplier:

Abbott Australasia P/L (Diagnostics Division)
299 Lane Cove Road
Macquarie Park NSW 2113
Tel: +61 2 9857 1111
Abbott Australasia P/L (Molecular Division)
299 Lane Cove Road
Macquarie Park NSW 2113
Tel: +61 2 9857 1111

Informing department: see Supplier

Emergency telephone number

1800 816 696 and (+61 2 9857 1111)

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675834.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

2 Hazard(s) Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

The product is not classified, according to the Globally Harmonised System (GHS).

Label elements

GHS label elements None

Hazard pictograms: None

Signal word: None

Hazard statements: None

Routes of Exposure:

- Skin: No adverse effects expected when used as directed.

- Eye: No adverse effects expected when used as directed.

- Inhalation: No adverse effects expected when used as directed.

- Ingestion: No adverse effects expected when used as directed.

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

Trade name: AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent

(Continued from page 1)

3 Composition and Information on Ingredients

- **Dangerous components according to EC criteria:** None
- **Additional information:**
For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

4 First Aid Measures

- **After inhalation:**
Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Information for Medical Personnel:**
 - **Most important symptoms and effects, both acute and delayed:**
Cramps
Gastric or intestinal disorders
Nausea
Kidney effects

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
Dry chemical, carbon dioxide (CO₂), water spray or regular foam.
 - Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
 - For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.
- **Protective equipment:**
For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

AUS

(Continued on page 3)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories

Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

Trade name: AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent

(Continued from page 2)

6 Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

Methods and material for containment and cleaning up

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

Handling

Precautions for safe handling:

Avoid direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

Information about protection against explosions and fires: No special measures required.

Storage:

Requirements to be met by storerooms and containers: Store only in the original container.

Information about storage in one common storage facility: Store in original packaging.

Further information about storage conditions:

Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls and personal protection

Components with limit values that require monitoring at the workplace:

CAS: 56-81-5 Glycerol (50.00 %)

PEL (USA) Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV (USA) TLV withdrawn-insufficient data human occup. exp.

NES (Australia) Long-term value: 10 mg/m³

WES (Australia) Long-term value: 10 mg/m³

(Continued on page 4)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

Trade name: AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent

(Continued from page 3)

Personal protective equipment:

General protective and hygienic measures:

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

Protection of hands:

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Material of gloves and breakthrough time of the glove material:

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

Eye protection:

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

Body protection:

Normal use: protect personal clothing from splatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and Chemical Properties

General Information

· **Form:** Liquid
 · **Colour:** Colourless

· **Odour:** Odourless

· **pH-value at 20 °C:** 8
 · **Melting point/freezing point:** Not determined
 · **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous):** Not applicable

(Continued on page 5)



Abbott

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories

Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

Trade name: AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent

(Continued from page 4)

· Ignition temperature:	0 °C
· Auto igniting	Product is not self-igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Lower:	0.0 Vol %
· Upper:	0.0 Vol %
· Vapour pressure:	Not determined
· Density at 20 °C	1.15 g/cm ³
· Evaporation rate:	Not determined
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Viscosity:	
· dynamic:	Not determined
· Water:	44.0 %
· Solids content:	0.0 %

10 Stability and Reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Acute toxicity**
 - **LD/LC50 values that are relevant for classification:**
 - **Ingredients (100% pure substance/s):** Not applicable.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** No irritant effect.
 - **Serious eye damage/irritation** No irritant effect.
 - **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:** None
- **Target organs/systems:**
 - Kidneys
 - Gastrointestinal tract

AUS

(Continued on page 6)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories

Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

Trade name: AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent

(Continued from page 5)

12 Ecological Information

- **Aquatic toxicity:** No further relevant information available.
- **Additional ecological information**
 - **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. Refer to applicable local regulations for limit values of discharge into sewage system.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable
 - **vPvB:** Not applicable

13 Disposal considerations

- **Recommendation for disposal of unused product:**
Dispose in accordance with national, state and local regulations.
- **Uncleaned packagings**
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.
- **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.
- **Recommended cleaning agent:** Water with cleansing agents, if necessary.

14 Transport information

- **UN-Number**
 - ADG, ADN, IMDG, IATA None
- **UN proper shipping name**
 - ADG, ADN, IMDG, IATA None
- **Transport hazard class(es)**
 - ADG, ADN, IMDG, IATA
 - Class None
- **Packing group**
 - ADG, IMDG, IATA None
- **Environmental hazards**
 - **Marine pollutant:** No
- **Transport/Additional information**
 - **ADG**
 - **Remarks:** Not restricted for transportation.
 - **IMDG**
 - **Remarks:** Not restricted for transportation.

(Continued on page 7)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 23

Last alteration on 15.12.2015

Trade name: AmpliTaq Gold Enzyme / AmpliTaq Gold Enzyme Filled / AmpliTaq Gold Enzyme Reagent

(Continued from page 6)

- **IATA**
- **Remarks:** Not restricted for transportation.

15 Regulatory information

- **Australian Inventory of Chemical Substances**

All ingredients are listed.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

- **Complete text for H (Hazard) codes displayed in Section 3:**
Note: The respective H statements apply to the pure substances.

- **Contact supplier**

Tel. Abbott Molecular Customer Service: 1-800-553-7042
Abbott Australasia P/L (Diagnostics Division)
Emergency Contact number: 1800 816 696 and +61 2 9857 1111

- **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative

- *** Data compared to the previous version altered.**

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

1 Identification

Product identifier

Trade name: **RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent**

Article number:

2G28M GHS
2G28M0099

Application of the substance / the preparation: For In Vitro Diagnostic Use

Details of the supplier of the safety data sheet

Supplier:

Abbott Australasia P/L (Diagnostics Division)
299 Lane Cove Road
Macquarie Park NSW 2113
Tel: +61 2 9857 1111
Abbott Australasia P/L (Molecular Division)
299 Lane Cove Road
Macquarie Park NSW 2113
Tel: +61 2 9857 1111

Informing department: see Supplier

Emergency telephone number

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675834.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

1800 816 696 and (+61 2 9857 1111)

2 Hazard(s) Identification

Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Skin Corr. 3 H316 Causes mild skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Label elements

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

Hazard pictograms:



Signal word: Warning

Hazard-determining components of labelling:

2-Methyl-4-isothiazolin-3-one
Sodium azide

(Continued on page 2)

AUS

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 1)

· **Hazard statements:**

H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapours / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P302+P352 IF ON SKIN: Wash with plenty of water.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 This material and its container must be disposed of in a safe way.

· **Additional information:**

AUH032 Contact with acids liberates very toxic gas.

· **Routes of Exposure:** Skin

3 Composition and Information on Ingredients

· **Dangerous components according to EC criteria:**

CAS: 1185-53-1	Tromethamine hydrochloride Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	2.994%
CAS: 26628-22-8	Sodium azide Acute Tox. 1, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.084%
CAS: 2682-20-4	2-Methyl-4-isothiazolin-3-one Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317	0.015%

· **Additional information:**

For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

4 First Aid Measures

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:**

Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

· **After skin contact:**

Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

· **After eye contact:**

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.

· **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

· **Information for Medical Personnel:**

· **Most important symptoms and effects, both acute and delayed:**

Kidney effects
Allergic reactions

(Continued on page 3)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 2)

Possibly immune response

This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

Respiratory irritation

5 Fire Fighting Measures

· Suitable extinguishing agents:

Dry chemical, carbon dioxide (CO₂), water spray or regular foam.

- Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

No further relevant information available.

· Protective equipment:

For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

· Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· Methods and material for containment and cleaning up

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

This product contains sodium azide, which is toxic and reactive. See Sections 10 and 13 for additional information that could affect handling and disposal of contaminated spill materials.

NOTE FOR LARGE-VOLUME SPILL: This product contains sodium azide, which reacts with acid to liberate hydrazoic acid, a very toxic gas. Select a disinfectant with the following properties if disinfection of materials used to absorb a large volume of spilled product is required:

- Do not use any chemical or product with a pH below 6 to disinfect waste that contains sodium azide. Hydrazoic acid, a toxic gas, will be released when the pH is lower than 6.
- Do not use any chemical or product that contains mercury or any other metal to disinfect waste that contains sodium azide. This will create metal azide compounds, which can be highly explosive under pressure or shock (percussion).
- Select a disinfectant that does not bubble, effervesce or otherwise generate aerosols.
- Do not use excess disinfectant.
- Failure to follow manufacturer's directions may lead to unexpected reactions with the waste.
- Do not use a disinfectant if you do not have the proper facility, equipment and other appropriate protective measures available to work with it safely.

(Continued on page 4)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 3)

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

Reference to other sections

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and Storage

Handling

- Precautions for safe handling:** Avoid contact with skin.
- Information about protection against explosions and fires:** No special measures required.

Storage:

- Requirements to be met by storerooms and containers:** Store only in the original container.
- Information about storage in one common storage facility:** Store in original packaging.
- Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls and personal protection

Components with limit values that require monitoring at the workplace:

CAS: 26628-22-8 Sodium azide (0.084 %)

REL (USA)	Peak limitation: 0.3** mg/m ³ , 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV (USA)	Peak limitation: 0.29** mg/m ³ , 0.11* ppm *as HN ₃ vapor **as NaN ₃
IOELV (European Union)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin
NES (Australia)	Peak limitation: 0.3 mg/m ³ , 0.11 ppm
WES (Australia)	Peak limitation: 0.3 mg/m ³ , 0.11 ppm

Personal protective equipment:

General protective and hygienic measures:

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Avoid contact with the skin.
Immediately remove all soiled and contaminated clothing.

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use

(Continued on page 5)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 4)

appropriate air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· **Protection of hands:**

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· **Eye protection:**

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**

Normal use: protect personal clothing from splatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and Chemical Properties

· **General Information**

· **Form:** Liquid
 · **Colour:** Colourless

· **Odour:** Odourless

· **pH-value at 20 °C:** 8
 · **Melting point/freezing point:** Not determined
 · **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable
 · **Inflammability (solid, gaseous):** Not applicable
 · **Auto igniting** Product is not self-igniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits**
 · **Lower:** Not determined
 · **Upper:** Not determined

· **Vapour pressure:** Not determined

· **Density at 20 °C** 1.002 g/cm³
 · **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**
 · **Water:** Fully miscible

(Continued on page 6)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 5)

· Viscosity:

· dynamic: Not determined

· Water: 92.4 %

· Solids content: 0.0 %

10 Stability and Reactivity

· Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

· Possibility of hazardous reactions:

This product contains sodium azide. Sodium azide solutions are reported to:

- react with acids to release hydrazoic acid, a very toxic gas. Higher quantities of hydrazoic acid are released as the solution becomes more acidic (i.e., as the pH of the solution gets lower). Low quantities of hydrazoic acid can be released from sodium azide in water.
- react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds. Violent explosions have been reported during plumbing work on drain systems containing accumulations of azide on copper, lead, brass, or solder.

· Conditions to avoid: No further relevant information available.

· Incompatible materials: No further relevant information available.

· Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological Information

· Acute toxicity

· LD/LC50 values that are relevant for classification:

· Ingredients (100% pure substance/s):		
CAS: 1185-53-1 Tromethamine hydrochloride		
Oral	LD50	<1,000 mg/kg (rabbit) 1,780-5,900 mg/kg (rat)
CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one		
Oral	LD50	60 mg/kg (mouse) By analogy to methylchloroisothiazolinone. 53 mg/kg (rat) By analogy to methylchloroisothiazolinone.

· Primary irritant effect:

- Skin corrosion/irritation No irritant effect.
- Serious eye damage/irritation No irritant effect.

· Sensitisation: Sensitization possible through skin contact.

· Additional toxicological information: None

· Target organs/systems:

Respiratory tract

(Continued on page 7)



Abbott

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 6)

Kidneys
Skin
Immune system

12 Ecological Information

· **Aquatic toxicity:**

CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one

LC50 96 h 0.19 mg/l (trout) (Flow through)

LC50 48 h (Static) 0.056 mg/l (other) (Crustacean - Acartia tonsa)

· **Additional ecological information**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. Refer to applicable local regulations for limit values of discharge into sewage system.

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable
- **vPvB:** Not applicable

13 Disposal considerations

· **Recommendation for disposal of unused product:**

Dispose in accordance with national, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per state or local regulations. The following may be particularly important when identifying appropriate disposal:
- Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product. For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

· **Uncleaned packagings**

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

- **Recommended cleaning agent:** Water with cleansing agents, if necessary.

14 Transport information

· **UN-Number**

- **ADG, ADN, IMDG, IATA** None

· **UN proper shipping name**

- **ADG, ADN, IMDG, IATA** None

(Continued on page 8)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 7)

· Transport hazard class(es)

- ADG, ADN, IMDG, IATA
- Class None

· Packing group

- ADG, IMDG, IATA None

· Environmental hazards

- Marine pollutant: No

· Transport/Additional information

- ADG
 - Remarks: Not restricted for transportation.
- IMDG
 - Remarks: Not restricted for transportation.
- IATA
 - Remarks: Not restricted for transportation.

15 Regulatory information

· Australian Inventory of Chemical Substances

All ingredients are listed.

· Directive 2012/18/EU

- Named dangerous substances - ANNEX I None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

· Complete text for H (Hazard) codes displayed in Section 3:

Note: The respective H statements apply to the pure substances.

· Contact supplier

Tel. Abbott Molecular Customer Service: 1-800-553-7042
 Abbott Australasia P/L (Diagnostics Division)
 Emergency Contact number: 1800 816 696 and +61 2 9857 1111

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods

(Continued on page 9)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Activation Reagent / CT/NG Activation Reagent / Activation Reagent

(Continued from page 8)

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (Division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: persistent, bioaccumulative and toxic

vPvB: very persistent and very bioaccumulative

Acute Tox. 1: Acute toxicity – Category 1

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Corr. 3: Skin corrosion/irritation – Category 3

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· * **Data compared to the previous version altered.**

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

1 Identification

Product identifier

· Trade name: **RealTime CT/NG Internal Control / CT/NG Internal Control**

· Article number:

2G28Y GHS

2G28Y0001

· Application of the substance / the preparation: For In Vitro Diagnostic Use

Details of the supplier of the safety data sheet

· Supplier:

Abbott Australasia P/L (Diagnostics Division)

299 Lane Cove Road

Macquarie Park NSW 2113

Tel: +61 2 9857 1111

Abbott Australasia P/L (Molecular Division)

299 Lane Cove Road

Macquarie Park NSW 2113

Tel: +61 2 9857 1111

· Informing department: see Supplier

· Emergency telephone number

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675834.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

1800 816 696 and (+61 2 9857 1111)

2 Hazard(s) Identification

Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008:

Skin Corr. 3 H316 Causes mild skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Label elements

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms:



· Signal word: Warning

· Hazard-determining components of labelling:

2-Methyl-4-isothiazolin-3-one

Sodium azide

· Hazard statements:

H316 Causes mild skin irritation.

(Continued on page 2)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

H317 May cause an allergic skin reaction.

(Continued from page 1)

Precautionary statements:

- P261 Avoid breathing mist / vapours / spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P501 This material and its container must be disposed of in a safe way.

Additional information:

AUH032 Contact with acids liberates very toxic gas.

Routes of Exposure: Skin

3 Composition and Information on Ingredients

Dangerous components according to EC criteria:

CAS: 1185-53-1	Tromethamine hydrochloride Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	1.006%
CAS: 26628-22-8	Sodium azide Acute Tox. 1, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.047%
CAS: 2682-20-4	2-Methyl-4-isothiazolin-3-one Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317	0.015%

Additional information:

For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

4 First Aid Measures

General information: Immediately remove any clothing soiled by the product.

After inhalation:

Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

After skin contact:

Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.

After swallowing: Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

Information for Medical Personnel:

Most important symptoms and effects, both acute and delayed:

- Kidney effects
- Allergic reactions
- Possibly immune response

(Continued on page 3)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

This product may cause skin sensitization reactions in some people. See Section 11 for additional information. (Continued from page 2)

5 Fire Fighting Measures

· Suitable extinguishing agents:

Dry chemical, carbon dioxide (CO₂), water spray or regular foam.

- Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

No further relevant information available.

· Protective equipment:

For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

· Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· Methods and material for containment and cleaning up

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbents around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

This product contains sodium azide, which is toxic and reactive. See Sections 10 and 13 for additional information that could affect handling and disposal of contaminated spill materials.

NOTE FOR LARGE-VOLUME SPILL: This product contains sodium azide, which reacts with acid to liberate hydrazoic acid, a very toxic gas. Select a disinfectant with the following properties if disinfection of materials used to absorb a large volume of spilled product is required:

- Do not use any chemical or product with a pH below 6 to disinfect waste that contains sodium azide. Hydrazoic acid, a toxic gas, will be released when the pH is lower than 6.
- Do not use any chemical or product that contains mercury or any other metal to disinfect waste that contains sodium azide. This will create metal azide compounds, which can be highly explosive under pressure or shock (percussion).
- Select a disinfectant that does not bubble, effervesce or otherwise generate aerosols.
- Do not use excess disinfectant.
- Failure to follow manufacturer's directions may lead to unexpected reactions with the waste.
- Do not use a disinfectant if you do not have the proper facility, equipment and other appropriate protective measures available to work with it safely.

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

(Continued on page 4)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

(Continued from page 3)

Reference to other sections

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and Storage

Handling

- Precautions for safe handling:** Avoid contact with skin.
- Information about protection against explosions and fires:** No special measures required.

Storage:

- Requirements to be met by storerooms and containers:** Store only in the original container.
- Information about storage in one common storage facility:** Store in original packaging.
- Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls and personal protection

Components with limit values that require monitoring at the workplace:

CAS: 26628-22-8 Sodium azide (0.047 %)

REL (USA)	Peak limitation: 0.3** mg/m ³ , 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV (USA)	Peak limitation: 0.29** mg/m ³ , 0.11* ppm *as HN ₃ vapor **as NaN ₃
IOELV (European Union)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin
NES (Australia)	Peak limitation: 0.3 mg/m ³ , 0.11 ppm
WES (Australia)	Peak limitation: 0.3 mg/m ³ , 0.11 ppm

Personal protective equipment:

General protective and hygienic measures:

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Avoid contact with the skin.

Immediately remove all soiled and contaminated clothing.

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

(Continued on page 5)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

(Continued from page 4)

Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· **Protection of hands:**

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· **Eye protection:**

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**

Normal use: protect personal clothing from splatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and Chemical Properties

· **General Information**

· **Form:** Liquid
 · **Colour:** Colourless

· **Odour:** Odourless

· **pH-value at 20 °C:** 8.1
 · **Melting point/freezing point:** Not determined
 · **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable
 · **Inflammability (solid, gaseous):** Not applicable
 · **Auto igniting** Product is not self-igniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits**
 · **Lower:** Not determined
 · **Upper:** Not determined

· **Vapour pressure:** Not determined

· **Density at 20 °C** 0.994 g/cm³
 · **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**
 · **Water:** Fully miscible

· **Viscosity:**
 · **dynamic:** Not determined

· **Water:** 98.9 %

(Continued on page 6)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

(Continued from page 5)

· **Solids content:** 0.0 %

10 Stability and Reactivity

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions:**

This product contains sodium azide. Sodium azide solutions are reported to:

- react with acids to release hydrazoic acid, a very toxic gas. Higher quantities of hydrazoic acid are released as the solution becomes more acidic (i.e., as the pH of the solution gets lower). Low quantities of hydrazoic acid can be released from sodium azide in water.
- react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds. Violent explosions have been reported during plumbing work on drain systems containing accumulations of azide on copper, lead, brass, or solder.

· **Conditions to avoid:** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

· **Acute toxicity**

· **LD/LC50 values that are relevant for classification:**

· Ingredients (100% pure substance/s):		
CAS: 1185-53-1 Tromethamine hydrochloride		
Oral	LD50	<1,000 mg/kg (rabbit) 1,780-5,900 mg/kg (rat)
CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one		
Oral	LD50	60 mg/kg (mouse) By analogy to methylchloroisothiazolinone. 53 mg/kg (rat) By analogy to methylchloroisothiazolinone.

· **Primary irritant effect:**

- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritant effect.

· **Sensitisation:** Sensitization possible through skin contact.

· **Additional toxicological information:** None

· **Target organs/systems:**

Kidneys
Skin
Immune system

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

(Continued from page 6)

12 Ecological Information

· **Aquatic toxicity:**

CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one

LC50 96 h 0.19 mg/l (trout) (Flow through)

LC50 48 h (Static) 0.056 mg/l (other) (Crustacean - Acartia tonsa)

· **Additional ecological information**

· **General notes:** Generally not hazardous for water.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable

· **vPvB:** Not applicable

13 Disposal considerations

· **Recommendation for disposal of unused product:**

Dispose in accordance with national, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per state or local regulations. The following may be particularly important when identifying appropriate disposal:

- Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product.

For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

· **Uncleaned packagings**

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommended cleaning agent:** Water with cleansing agents, if necessary.

14 Transport information

· **UN-Number**

· **ADG, ADN, IMDG, IATA** None

· **UN proper shipping name**

· **ADG, ADN, IMDG, IATA** None

· **Transport hazard class(es)**

· **ADG, ADN, IMDG, IATA**

· **Class** None

· **Packing group**

· **ADG, IMDG, IATA** None

(Continued on page 8)

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

(Continued from page 7)

· Environmental hazards

· **Marine pollutant:** No

· Transport/Additional information

· ADG

· **Remarks:** Not restricted for transportation.

· IMDG

· **Remarks:** Not restricted for transportation.

· IATA

· **Remarks:** Not restricted for transportation.

15 Regulatory information

· Australian Inventory of Chemical Substances

All ingredients are listed.

· Directive 2012/18/EU

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

· Complete text for H (Hazard) codes displayed in Section 3:

Note: The respective H statements apply to the pure substances.

· Contact supplier

Tel. Abbott Molecular Customer Service: 1-800-553-7042

Abbott Australasia P/L (Diagnostics Division)

Emergency Contact number: 1800 816 696 and +61 2 9857 1111

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (Division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: persistent, bioaccumulative and toxic

vPvB: very persistent and very bioaccumulative

Acute Tox. 1: Acute toxicity – Category 1

Acute Tox. 3: Acute toxicity – Category 3

(Continued on page 9)



Abbott

Safety Data Sheet

according to WHS Regulations

© Abbott Laboratories Release date 22.08.2019

Version number 7

Last alteration on 15.12.2015

Trade name: RealTime CT/NG Internal Control / CT/NG Internal Control

(Continued from page 8)

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Corr. 3: Skin corrosion/irritation – Category 3

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· *** Data compared to the previous version altered.**