

Release Date: 12/15/15

REF		
GTIN	Product Name	
2N40-070	Abbott RealTime HBV VL Calibrator Kit	
Components:		
2G34A0001 GHS	HBV PCR Calibrator A	
2G34B0001 GHS	HBV PCR Calibrator B	



according to 1907/2006/EC, Article 31

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

Product identifier

· Trade name: HBV PCR Calibrator A

· Article number: 2G34A0001 GHS

· 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 Hazards identification

Classification of the substance or mixture

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

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

· Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements:

P261 Avoid breathing mist / vapours / spray.

P280 Wear protective gloves/protective clothing/eye protection.

P272 Contaminated work clothing should not be allowed out of the workplace.

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P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents / container in accordance with local regulations.

· Additional information:

Refer to section 15 for labelling per Directives 67/548/EEC or 1999/45/EC. AUH032 Contact with acids liberates very toxic gas.

- Hazard designation
 - · Routes of Exposure: Skin
- · Other hazards This product may cause skin sensitization (allergic reactions) in some people.

3 Composition/information on ingredients

Dangerous components according to EC criteria:

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

0.0149%

Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Skin Sens. 1, H317

· Additional information:

For the complete text of Risk (R) and/or 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 eve 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

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

5 Firefighting 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

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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.

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.

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.

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· 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.

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

- · Information about storage in one common storage facility: Store in original packaging.
- · Further information about storage conditions: Protect from heat and direct sunlight.

8 Exposure controls/personal protection

Components with limit values that require monitoring at the workplace:

26628-22-8 Sodium azide (0.085 %)

REL (USA) Peak limitation: 0.3** mg/m³, 0.1* ppm

*as HN3; **as NaN3; Skin

TLV (USA) Peak limitation: 0.29** mg/m³, 0.11* ppm

*as HN3 vapor **as NaN3

IOELV (European Union) Short-term value: 0.3 mg/m³

Long-term value: 0,1 mg/m³

Skin

NES (Australia) Peak limitation: 0.3 mg/m³, 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. 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:

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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 spatters 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

3 Filysical and chemical properties		
General Information		
· Form:	Liquid	
· Colour:	Colourless	
· Odour:	Odourless	
pH-value at 20 °C:	8.1	
· Melting point/Melting range:	Not determined	
 Boiling point/Boiling range: 	Not determined	
· Flash point:	Not applicable	
Inflammability (solid, gaseou	s): Not applicable	
· Auto igniting	Product is not self-igniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits		
· Lower:	Not determined	
· Upper:	Not determined	
Density at 20 °C	0.994 g/cm ³	
· Evaporation rate:	Not determined	
Solubility in / Miscibility with		
· Water:	Fully miscible	
· Viscosity:		
· dynamic:	Not determined	
· Water:	98.6 %	

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.

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- 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):		
1185	1185-53-1 Tromethamine hydrochloride		
Oral	LD50	<1000 mg/kg (rabbit)	
		1780 - 5900 mg/kg (rat)	
2682	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.
- · Additional toxicological information: None
- Target organs/systems:

Kidneys

Skin

Immune system

12 Ecological information

· Aquatic toxicity:

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

- AUS



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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
- 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.

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Labelling according to Directives 67/548/EEC or 1999/45/EC

· Code letter and hazard designation of product:



Xi Irritant

· Hazard-determining components of labelling:

2-Methyl-4-isothiazolin-3-one

- · Risk phrases:
- 43 May cause sensitisation by skin contact.
- · Safety phrases:
- 24 Avoid contact with skin.
- 35 This material and its container must be disposed of in a safe way.
- 37 Wear suitable gloves.
- 46 If swallowed, seek medical advice immediately and show this container or label.

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) and/or R (Risk) codes displayed in Section 3: Note: The respective H and/or R 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:

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 Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

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Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· * Data compared to the previous version altered.

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

Product identifier

· Trade name: HBV PCR Calibrator B

· Article number: 2G34B0001 GHS

· 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 Hazards identification

Classification of the substance or mixture

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

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

· Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements:

P261 Avoid breathing mist / vapours / spray.

P280 Wear protective gloves/protective clothing/eye protection.

P272 Contaminated work clothing should not be allowed out of the workplace.

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Trade name: HBV PCR Calibrator B

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P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents / container in accordance with local regulations.

· Additional information:

Refer to section 15 for labelling per Directives 67/548/EEC or 1999/45/EC. AUH032 Contact with acids liberates very toxic gas.

- Hazard designation
 - · Routes of Exposure: Skin
- · Other hazards This product may cause skin sensitization (allergic reactions) in some people.

3 Composition/information on ingredients

Dangerous components according to EC criteria:

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

0.0149%

Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Skin Sens. 1, H317

· Additional information:

For the complete text of Risk (R) and/or 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 eve 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

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

5 Firefighting 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

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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.

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.

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.

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· 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.

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

- · Information about storage in one common storage facility: Store in original packaging.
- · Further information about storage conditions: Protect from heat and direct sunlight.

8 Exposure controls/personal protection

Components with limit values that require monitoring at the workplace:

26628-22-8 Sodium azide (0.085 %)

REL (USA) Peak limitation: 0.3** mg/m³, 0.1* ppm

*as HN3; **as NaN3; Skin

TLV (USA) Peak limitation: 0.29** mg/m³, 0.11* ppm

*as HN3 vapor **as NaN3

IOELV (European Union) Short-term value: 0.3 mg/m³

Long-term value: 0,1 mg/m³

Skin

NES (Australia) Peak limitation: 0.3 mg/m³, 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. 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:

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according to 1907/2006/EC, Article 31

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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 spatters 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

9 Physical and Chemical pi	operties
· General Information	
· Form:	Liquid
· Colour:	Colourless
· Odour:	Odourless
· pH-value at 20 °C:	8.1
· Melting point/Melting range:	Not determined
 Boiling point/Boiling range: 	Not determined
· Flash point:	Not applicable
Inflammability (solid, gaseou	S): Not applicable
· Auto igniting	Product is not self-igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits	
· Lower:	Not determined
· Upper:	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:	98.6 %

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.

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- 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):		
1185	-53-1 ⁻	Tromethamine hydrochloride	
Oral	LD50	<1000 mg/kg (rabbit)	
		1780 - 5900 mg/kg (rat)	
2682	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.
- · Additional toxicological information: None
- Target organs/systems:

Kidneys

Skin

Immune system

12 Ecological information

· Aquatic toxicity:

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

– AU



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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
- **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.

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Labelling according to Directives 67/548/EEC or 1999/45/EC

· Code letter and hazard designation of product:



Xi Irritant

· Hazard-determining components of labelling:

2-Methyl-4-isothiazolin-3-one

- · Risk phrases:
- 43 May cause sensitisation by skin contact.
- · Safety phrases:
- 24 Avoid contact with skin.
- 35 This material and its container must be disposed of in a safe way.
- 37 Wear suitable gloves.
- 46 If swallowed, seek medical advice immediately and show this container or label.

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.

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· Complete text for H (Hazard) and/or R (Risk) codes displayed in Section 3:

Note: The respective H and/or R 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:

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 Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

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Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· * Data compared to the previous version altered.

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