



**Abbott**

**Release Date:** 6/28/21

<b>REF</b>	Product Name
<b>GTIN</b>	

<b>06P17-25</b> <b>00054749004966</b> <b>06P17-26</b> <b>00054749004973</b> <b>06P17-24</b> <b>00054749004959</b>	<i><b>i STAT TBI Control Level 1&amp;2 and i STAT TBI Calibration Verification Level 1-3</b></i>
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Components:

<b>TBI CON. LEV. 1</b>  <b>TBI CON. LEV. 2</b> <b>TBI CAL.VER. LEV.1</b> <b>TBI CAL.VER. LEV.2</b> <b>TBI CAL.VER. LEV.3</b>	<b>i-STAT TBI Control Level 1 &amp; 2 / i-STAT TBI Calibration Verification Level 1-3</b>
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## 1 Identification

### Product identifier

Trade name: **i-STAT TBI Control Level 1 & 2 / i-STAT TBI Calibration Verification Level 1-3**

Article number:

TBI CON. LEV. 1

TBI CON. LEV. 2

TBI CAL.VER. LEV.1

TBI CAL.VER. LEV.2

TBI CAL.VER. LEV.3

Product category PC0 Other

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 (Point of Care Division)

299 Lane Cove Road

Macquarie Park NSW 2113

Tel: +61 2 9857 1111

Informing department: see Supplier

Emergency telephone number

Tel.: (+49)-6122-58-1389

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 675922.

- 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

The classification is in alignment with current European regulations. It incorporates information from technical literature and information provided by supplier companies.

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

Additional information:

AUH032 Contact with acids liberates very toxic gas.

Routes of Exposure:

For bloodborne pathogens and potentially infectious materials:

- non-intact skin

- mucous membranes (which includes, but is not limited to, the lining of the nose, mouth and throat)

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- parenteral contact (e.g. by injection, puncture)

### Other hazards

This product contains human-sourced components. No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious.

## 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. Seek medical attention and appropriate follow-up.

### After skin contact:

Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.

### After eye contact:

Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.

• **After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

### Information for Medical Personnel:

This product contains human-sourced and/or potentially infectious material. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced material should be considered potentially infectious.

The human-sourced material used in this product has been tested and found to be:

- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for anti-HCV (antibodies to hepatitis C virus)
- Nonreactive for HIV-1 Ag or HIV-1 RNA (human immunodeficiency virus type 1 antigen or human immunodeficiency virus type 1 ribonucleic acid)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)
- Nonreactive for syphilis bacteria (*Treponema pallidum pallidum*)

• **Most important symptoms and effects, both acute and delayed:** None expected

## 5 Fire Fighting Measures

### Suitable extinguishing agents:

Dry chemical, carbon dioxide (CO<sub>2</sub>), water spray or regular foam.

- Caution: CO<sub>2</sub> 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.

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### 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

Handle as a potentially infectious material.

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

Apply a suitable disinfectant. Select a disinfectant that is effective against bloodborne infectious agents, as well as other microbial agents that you might expect to be prevalent in your population. A disinfectant that is effective against Mycobacterium tuberculosis is generally effective against all known viruses and non-sporeforming bacteria, and is suitable for most clinical laboratory situations.

NOTE: Commercial disinfectants must be used according to manufacturer directions. Disinfectants are typically hazardous chemicals that react with many chemicals, materials and living tissues. Obtain and review the manufacturer's safety information before using the disinfectant.

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:** Handle as a potentially infectious material.

• **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.

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- **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: 67-56-1 Methanol (1.00 %)

PEL (USA)	Long-term value: 260 mg/m <sup>3</sup> , 200 ppm
REL (USA)	Short-term value: 325 mg/m <sup>3</sup> , 250 ppm Long-term value: 260 mg/m <sup>3</sup> , 200 ppm Skin
TLV (USA)	Short-term value: 328 mg/m <sup>3</sup> , 250 ppm Long-term value: 262 mg/m <sup>3</sup> , 200 ppm Skin; BEI
IOELV (European Union)	Long-term value: 260 mg/m <sup>3</sup> , 200 ppm Skin
WES (Australia)	Short-term value: 328 mg/m <sup>3</sup> , 250 ppm Long-term value: 262 mg/m <sup>3</sup> , 200 ppm Sk

#### CAS: 56-75-7 Chloramphenicol (0.10 %)

WEEL (USA)	Long-term value: 0.5 mg/m <sup>3</sup>
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### · Ingredients with biological limit values:

#### CAS: 67-56-1 Methanol (1.00 %)

BEI (USA)	15 mg/L Medium: urine Time: end of shift Parameter: Methanol (background, nonspecific)
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### · 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.

Observe universal precautions and other appropriate biosafety practices for handling potentially infectious material.

#### · 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.

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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:** Solution
- **Colour:** Amber

- **Odour:** Odourless

- **pH-value at 20 °C:** 7.3
- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** Not determined

- **Flash point:** Not applicable
- **Auto igniting** Product is not self-igniting.

- **Explosive properties:** Product does not present an explosion hazard.
- **Lower:** Not determined
- **Upper:** Not determined
- **Vapour pressure:** Not determined

- **Density** Not determined
- **Evaporation rate:** Not determined

- **Solubility in / Miscibility with**
- **Water:** Not miscible or difficult to mix
- **dynamic:** Not determined

- **Water:** 40.0 %

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### 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):**

**CAS: 56-75-7 Chloramphenicol**

Oral	LD50	500 mg/kg (guinea pig) 1,500 mg/kg (mouse) 2,500 mg/kg (rat) Reproductive effects: 23 gm/kg oral-rat TDLo 1-21 day(s) pregnant female continuous 2500 mg/kg oral-rat TDLo 9 day(s) pregnant female continuous 2500 mg/kg oral-rat TDLo 11 day(s) pregnant female continuous 2 gm/kg oral-rat TDLo 8 day(s) pregnant female continuous
	TDLo (Carcinogen)	400 mg/kg/d (human) 400 mg/kg oral - woman LDLo 440 mg/kg oral - infant LDLo
Dermal	TDLo (Carcinogen)	30 mg/kg/d (human) 30 mg/kg/3days intermittent intravenous - infant LDLo 150 mg/kg/2days intramuscular - infant LDLo

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	<p>Mutagenicity</p> <p>Target Organ Effects</p>	<p>(human)</p> <p>unscheduled DNA synthesis - human liver 1 mmol/L</p> <p>DNA inhibition - human bone marrow 1500 umol/L</p> <p>DNA inhibition - human lymphocyte 1 mmol/L</p> <p>cytogenetic analysis - human leukocyte 100 mg/L</p> <p>cytogenetic analysis - human lymphocyte 500 mg/L</p> <p>(human)</p> <p>immune system (blood), immune system (sensitizer). Chronic exposure: Repeated or prolonged contact may cause local irritation with burning or itching, angioneurotic edema, urticaria, vesicular and maculopapular dermatitis and anaphylaxis in sensitive individuals. Blood dyscrasias and bone marrow hypoplasia including aplastic anemia and death have been reported following local application. Hematopoietic reactions may occur at some time after exposure is discontinued. Repeated exposure may cause sensitization to occur. Prolonged use of eyedrops containing chloramphenicol has been reported to cause hypoplasia of the bone marrow and death due to aplastic anemia. Optic neuritis with atrophy and blindness has been reported due to prolonged systemic administration of high doses. Irreversible aplasia may occur following repeated or prolonged therapy or long after therapy has been discontinued. Blood dyscrasias may include hemolysis of red blood cells, erythroid hypoplasia, agranulocytosis.</p>
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- **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:** Unknown

## 12 Ecological Information

- **Aquatic toxicity:** No further relevant information available.
- **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 federal, state and local regulations and institutional requirements. The following may be particularly important when identifying appropriate disposal:

  - Potentially infectious. See Section 4, Information for Medical Personnel, for more information.
  - See Section 6, Measures for cleaning/collecting for information when institutional or regulatory requirements include any sort of treatment of potentially infectious waste.

### • European waste catalogue:

HP12 Release of an acute toxic gas

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- **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 Industrial Chemicals

CAS: 7732-18-5	Water, distilled, or of similar purity
CAS: 50-70-4	Sorbitol
CAS: 67-56-1	Methanol
CAS: 143-33-9	sodium cyanide
CAS: 3810-74-0	Streptomycin sulphate
CAS: 128-37-0	Butylated hydroxytoluene

- **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

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

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

- **Contact supplier**

Abbott Australasia P/L (Point of Care Division)

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

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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.**

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