Abbott

Release Date: 6/28/21

REF GTIN	Product Name
06P17-25 **00054749004966** **06P17-26** **00054749004973** **06P17-24** **00054749004959**	***i STAT TBI Control Level 1&2 and i STAT TBI Calibration Verification Level 1-3***

Components:

TBI CON. LEV. 1 **TBI CON. LEV. 2** **TBI CAL.VER. LEV.1** **TBI CAL.VER. LEV.2** **TBI CAL.VER. LEV.3**	**i-STAT TBI Control Level 1 & 2 / i-STAT TBI Calibration Verification Level 1-3**

Safety Data Sheet

according to 1907/2006/EC, Article 31

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

· 1.1 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

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

· **Product category** PC0 Other

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

· 1.3 Details of the supplier of the safety data sheet

· **Supplier:**
Abbott GmbH (Point of Care Division)
Max-Planck-Ring 2
65205 Wiesbaden, Germany
Tel.: (+49)-6122-58-1389

MSDS-Support@Abbott.com

· 1.4 Emergency telephone number

(+49)-6122-58-0 (English only)
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.

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SECTION 2: Hazards identification

· 2.1 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:**
This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with either CLP or GHS.

· 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008:** None

· **Hazard pictograms:** None

· **Signal word:** None

· **Hazard statements:** None

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· **Additional information:**
EUH032 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)
- parenteral contact (e.g. by injection, puncture)

· 2.3 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.

· **Results of PBT and vPvB assessment:**
· **PBT:** Not applicable
· **vPvB:** Not applicable

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SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· **Dangerous components according to EC criteria:**		
CAS: 67-56-1 EINECS: 200-659-6	Methanol Flam. Liq. 2, H225; Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT SE 1, H370	<1.00%

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

SECTION 4: First aid measures

· 4.1 Description of 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)

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- 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)

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

· **4.3 Indication of any immediate medical attention and special treatment needed:**
No additional relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **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.

· **5.2 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.

· **5.3 Advice for firefighters**

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

SECTION 6: Accidental release measures

· **6.1 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.

· **6.2 Environmental precautions**
Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· **6.3 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

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.

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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.

· **6.4 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.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling:** Handle as a potentially infectious material.

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

· **7.2 Conditions for safe storage, including any incompatibilities**

· **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.

· **7.3 Specific end use(s):** No additional relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
CAS: 67-56-1 Methanol (1.00 %)	
IOELV (European Union)	Long-term value: 260 mg/m³, 200 ppm Skin
WEL (Great Britain)	Short-term value: 333 mg/m³, 250 ppm Long-term value: 266 mg/m³, 200 ppm Sk

· **8.2 Exposure controls**

· **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.

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· **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 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.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· **General Information**

· **Appearance:**	
· **Form:**	Solution
· **Colour:**	Amber
· **Odour:**	Odourless
· **Odour threshold:**	Not determined
· **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

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· **Vapour pressure:**	Not determined
· **Density**	Not determined
· **Relative density:**	Not determined
· **Evaporation rate:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Not miscible or difficult to mix
· **dynamic:**	Not determined
· **Water:**	40.0 %
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.2 Chemical stability:**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.

· **10.3 Possibility of hazardous reactions:** No dangerous reactions known.

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

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

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

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **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

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Dermal	TDLo (Carcinogen)	30 mg/kg/d (human) 30 mg/kg/3days intermittent intravenous - infant LDLo 150 mg/kg/2days intramuscular - infant LDLo
	Mutagenicity	(human) unscheduled DNA synthesis - human liver 1 mmol/L DNA inhibition - human bone marrow 1500 umol/L DNA inhibition - human lymphocyte 1 mmol/L cytogenetic analysis - human leukocyte 100 mg/L cytogenetic analysis - human lymphocyte 500 mg/L
	Target Organ Effects	(human) 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.

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

· **Sensitisation:** Based on available data, the classification criteria are not met.

· **Additional toxicological information:** None
· **Target organs/systems:** Unknown
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and degradability:** No further relevant information available.
· **12.3 Bioaccumulative potential:** No further relevant information available.
· **12.4 Mobility in soil:** 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.

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· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable
· **vPvB:** Not applicable

· **12.6 Other adverse effects:** No further relevant information available.

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SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

· **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

· **The following waste disposal key numbers are possible:**
18 01 06: chemicals consisting of or containing dangerous substances
· **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.

SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, ADN, IMDG, IATA** None

· **14.2 UN proper shipping name**
· **ADR, ADN, IMDG, IATA** None

· **14.3 Transport hazard class(es)**
· **ADR, ADN, IMDG, IATA**
· **Class** None

· **14.4 Packing group**
· **ADR, IMDG, IATA** None

· **14.5 Environmental hazards**
· **Marine pollutant:** No

· **14.6 Special precautions for user** Not applicable

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· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

· **Transport/Additional information**

· **ADR**

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

· **IMDG**

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

· **IATA**

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

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**

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

· 15.2 Chemical safety assessment A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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· **Complete text for H (Hazard) codes displayed in Section 3:**
Note: The respective H statements apply to the pure substances.
H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H331 Toxic if inhaled.
H370 Causes damage to organs.

· **Contact supplier**
Abbott GmbH (Point of Care Division)
Tel.: (+49)-6122-58-1389

· **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

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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
Flam. Liq. 2: Flammable liquids Category 2
Acute Tox. 3: Acute toxicity Category 3
STOT SE 1: Specific target organ toxicity (single exposure) Category 1

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