Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 18.05.2015 Version number 1 Last alteration on 18.05.2015

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

· 1.1 Product identifier

· **Trade name:** **i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5**

· **Article number:**
06F12-01
06F12-13
06F12-14
06F12-15
06F12-16
06F12-17
06F13-01
06F14-01
06F15-01

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

No further relevant information available.

· **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 & Co.KG (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:

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.

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· **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.

(Continued on page 2)

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 1)

· 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008:** 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.

· 2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

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

55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0,0018%
	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	

· **Additional information:**
For the complete text of Risk (R) and/or 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. 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.

(Continued on page 3)

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 2)

· **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.

· **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.

· **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**
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

(Continued on page 4)

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(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.

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

· **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.
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.

· **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:**
The product does not contain any hazardous ingredients with occupational exposure limits.

· **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.

· **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)

(Continued on page 5)

Safety Data Sheet

according to 1907/2006/EC, Article 31

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 4)

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:**	Liquid
· **Colour:**	Clear
· **Odour:**	Odourless
· **Odour threshold:**	Not determined
· **pH-value:**	Not determined
· **Change in condition:**	
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Flash point:**	Not applicable
· **Inflammability (solid, gaseous):**	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

(Continued on page 6)

Safety Data Sheet

according to 1907/2006/EC, Article 31

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 5)

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

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

· **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**

· **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:**
Sensitization is possible with prolonged exposure, based on the reported properties of methylisothiazolones.

· **Additional toxicological information:** None

· **Target organs/systems:** Unknown

(Continued on page 7)

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 6)

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.

· **Additional ecological information**
· **General notes:** Not known to be hazardous to water.

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

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

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 national, state and local regulations.

· **European waste catalogue:**
Consult the responsible regulatory body for the assignment of disposal codes according to the European Waste Catalogue.
· **The following waste disposal key numbers are possible:**
18 01 07: chemicals other than those mentioned in 18 01 06

· **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.

(Continued on page 8)

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 18.05.2015 Version number 1 Last alteration on 18.05.2015

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 7)

SECTION 14: Transport information

· **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

· **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**
No further relevant information available.

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

SECTION 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

(Continued on page 9)

Safety Data Sheet

according to 1907/2006/EC, Article 31

Trade name: i-STAT Control Level 1, 2, and 3 / i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 / CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5

(Continued from page 8)

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

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

· **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. 3: Acute toxicity, Hazard Category 3
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1