

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 30.05.2017

Version number 1

Last alteration on 30.05.2017

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

1.1 Product identifier

· Trade name: **iSTAT ACT Control Level 1 (Calcium Chloride Vial) / iSTAT ACT Control Level 2 (Calcium Chloride Vial) / iSTAT PT Control Level 1 (Calcium Chloride Vial) / iSTAT PT Control Level 2 (Calcium Chloride Vial)**

· Article number:

06P17-13 CALC
06P17-14 CALC
06P17-15 CALC
06P17-16 CALC

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.

(+49)-6122-58-0

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

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(Continued from page 1)

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.

· 2.2 Label elements

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

· Hazard pictograms: None

· Signal word: None

· Hazard statements: None

· Precautionary statements:

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

· 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 Mixtures

· Dangerous components according to EC criteria: None

· 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.

(Continued on page 3)

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Trade name: iSTAT ACT Control Level 1 (Calcium Chloride Vial) / iSTAT ACT Control Level 2 (Calcium Chloride Vial) / iSTAT PT Control Level 1 (Calcium Chloride Vial) / iSTAT PT Control Level 2 (Calcium Chloride Vial)

(Continued from page 2)

- **After skin contact:**
Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **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 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

(Continued on page 4)

ENG

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Trade name: iSTAT ACT Control Level 1 (Calcium Chloride Vial) / iSTAT ACT Control Level 2 (Calcium Chloride Vial) / iSTAT PT Control Level 1 (Calcium Chloride Vial) / iSTAT PT Control Level 2 (Calcium Chloride Vial)

(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) listed above.

(Continued on page 5)

Safety Data Sheet

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(Continued from page 4)

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection. Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· **Protection of hands:**

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

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

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

· **Eye protection:**

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

· **Body protection:**

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

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/freezing point:** Not determined
· **Initial boiling point and boiling range:** Not determined

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

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

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

· **Density** Not determined
· **Relative density:** Not determined

(Continued on page 6)

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(Continued from page 5)

· 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** Based on available data, the classification criteria are not met.
 - **LD/LC50 values that are relevant for classification:**
 - **Ingredients (100% pure substance/s):** Not applicable.
 - **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 (carcinogenicity, 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.

ENG

(Continued on page 7)

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(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.

SECTION 14: Transport information

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

(Continued on page 8)

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(Continued from page 7)

· **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**

· 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

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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(Continued on page 9)

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(Continued from page 8)

· **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**

Abbott GmbH & Co.KG (Point of Care Division)

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

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· **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

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