

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

### 1.1 Product identifier

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

· Article number:

06P17-13 PLASMA  
06P17-14 PLASMA  
06P17-15 PLASMA  
06P17-16 PLASMA

### 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

(+49)-6122-58-0

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

· 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)

# Safety Data Sheet

according to 1907/2006/EC, Article 31

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**Trade name: iSTAT ACT Control Level 1 (Plasma Vial) / iSTAT ACT Control Level 2 (Plasma Vial) / iSTAT PT Control Level 1 (Plasma Vial) / iSTAT PT Control Level 2 (Plasma Vial)**

(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

· **Precautionary statements:**

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

· **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

## 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. 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.

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

(Continued on page 3)

# Safety Data Sheet

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(Continued from page 2)

· **Information for Medical Personnel:**

This product contains human sourced and/or potentially infectious components. See package insert / instructions for use for details. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection.

· **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 (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.

· **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**

Handle as a potentially infectious material.

Avoid causing dust.

If material is released or spilled, minimize exposure by using appropriate personal protective equipment as listed in Section 8. Keep unprotected persons away.

· **6.2 Environmental precautions** No special measures required.

· **6.3 Methods and material for containment and cleaning up**

Damp down dust with water spray.

Sweep up material and place into a suitable disposal container.

Vacuum (HEPA filter or equivalent recommended) or wet sweep products that are powders to avoid dust dispersal.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

(Continued on page 4)

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**Trade name: iSTAT ACT Control Level 1 (Plasma Vial) / iSTAT ACT Control Level 2 (Plasma Vial) / iSTAT PT Control Level 1 (Plasma Vial) / iSTAT PT Control Level 2 (Plasma Vial)**

(Continued from page 3)

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.

## 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:

Combustible - finely divided dust may be explosive.

### 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.

(Continued on page 5)

# Safety Data Sheet

according to 1907/2006/EC, Article 31

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Last alteration on 30.05.2017

**Trade name: iSTAT ACT Control Level 1 (Plasma Vial) / iSTAT ACT Control Level 2 (Plasma Vial) / iSTAT PT Control Level 1 (Plasma Vial) / iSTAT PT Control Level 2 (Plasma Vial)**

(Continued from page 4)

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. 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:** Solid  
 · **Colour:** Yellow-brown

· **Odour:** Mild  
 · **Odour threshold:** Not determined

· **pH-value:** Not applicable

**Change in condition:**

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

· **Flash point:** Not applicable

(Continued on page 6)



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(Continued from page 5)

· <b>Inflammability (solid, gaseous):</b>	Not determined
· <b>Auto igniting</b>	Product is not self-igniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits</b>	
· <b>Lower:</b>	Not determined
· <b>Upper:</b>	Not determined
· <b>Vapour pressure:</b>	Not applicable
· <b>Density</b>	Not determined
· <b>Relative density:</b>	Not determined
· <b>Evaporation rate:</b>	Not applicable
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not applicable
· <b>9.2 Other information</b>	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

(Continued on page 7)

# Safety Data Sheet

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(Continued from page 6)

- **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.

## 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:** Generally not hazardous for 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 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:**

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.

(Continued on page 8)



# Safety Data Sheet

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(Continued from page 7)

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

#### · 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.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any (Continued on page 9)

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according to 1907/2006/EC, Article 31

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Last alteration on 30.05.2017

## **Trade name: iSTAT ACT Control Level 1 (Plasma Vial) / iSTAT ACT Control Level 2 (Plasma Vial) / iSTAT PT Control Level 1 (Plasma Vial) / iSTAT PT Control Level 2 (Plasma Vial)**

(Continued from page 8)

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**

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.**