

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 13/01/2023 Version: A

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

#### 1.1. Product identifier

Product form : Mixture

Product name : i-STAT PT<sup>plus</sup> Control Level 1 (CaCl<sub>2</sub> reconstitution solution); i-STAT PT<sup>plus</sup> Control Level 2

(CaCl<sub>2</sub> reconstitution solution)

Product code : 06P17-17; 06P17-18

Other means of identification : Each box contains 5 vials of lyophilized plasma and 5 vials of CaCl2 reconstitution solution.

CaCl<sub>2</sub> Vial Fill Volume 1.5mL

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

#### 1.2.1. Relevant identified uses

Use of the substance/mixture : For In Vitro Diagnostic Use

#### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Abbott Point of Care Inc. 400 College Road Princeton NJ 08540 1-800-827-7828

Abbott GmbH (Point of Care Division)
Max-Planck-Ring 2
65205 Wiesbaden, Germany
Tel.: (+49)-6122-58-0
oustechsvc@apoc.abbott.com

Abbott Point of Care
Technical Support
For US email <a href="mailto:techsvc@apoc.abbott.com">techsvc@apoc.abbott.com</a>
Phone 1-800-366-8020 option 1

email oustechsvc@apoc.abbott.com

# 1.4. Emergency telephone number

Emergency number

For outside of US

- : Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7days/week). Refer to Abbott contract number CCN 119.
  - -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 [CLP] and US Hazcom 2012

This product has been evaluated per the classification criteria in the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with the GHS.



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#### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP] and US Hazcom 2012

No labelling applicable

#### 2.3. Other hazards

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

# **SECTION 3: Composition/information on ingredients**

### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Mixture of chemical and/or biological substances for in vitro diagnostic use.

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Contains no hazardous ingredients at levels requiring disclosure by OSHA Hazard Communication Standard (29 CFR 1910.1200) or Regulation			

(EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

# **SECTION 4: First Aid measures**

#### 4.1. Description of first aid measures

First-aid measures general : Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing. First-aid measures after skin contact

: IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.

First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Get medical attention if you feel unwell.

# 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause minor respiratory irritation.

Symptoms/effects after skin contact : May cause minor skin irritation.

Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating. Symptoms/effects after ingestion : May cause minor gastrointestinal irritation.

# 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

2/10 13/01/2023 (Version: A) EU-US SDS - EN (English)



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# **SECTION 5: Firefighting measures**

# 5.1. Extinguishing media

: Dry powder. Foam. Carbon dioxide (CO2). Suitable extinguishing media

# 5.2. Special hazards arising from the substance or mixture

: Criteria for classification not met. Fire hazard Explosion hazard : Criteria for classification not met.

# 5.3. Advice for firefighters

: Do not enter fire area without proper protective equipment, including respiratory protection. Protection during firefighting

Complete protective clothing.

# **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

: Wear Protective equipment as described in Section 8. Protective equipment

**Emergency procedures** : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air

respirator, in case of emergency.

# 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

## 6.3. Methods and material for containment and cleaning up

For containment : Stop leak if safe to do so. Contain any spills with dikes or absorbents to prevent migration

and entry into sewers or streams.

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove

residual contamination. Wash with plenty of water and detergent. Keep in suitable, closed containers for disposal. This material and its container must be disposed of in a safe way,

and as per local legislation.

#### 6.4. Reference to other sections

No additional information available

## **SECTION 7: Handling and storage**

# 7.1. Precautions for safe handling

: Use only with adequate ventilation. Do not breathe vapours, mist. Keep container tightly Precautions for safe handling

closed in a cool place. Wash thoroughly after handling. Avoid contact with skin, eyes and clothing.

# 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in original container.

### 7.3. Specific end use(s)

No additional information available



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# **SECTION 8: Exposure controls/personal protection**

# 8.1. Control parameters

#### 8.1.1. National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

# 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

#### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Gloves. Protective goggles.

### Personal protective equipment symbol(s):





#### 8.2.2.1. Eye and face protection

#### Eye protection:

Use eye protection suitable to the environment. Avoid direct contact with eyes. EN 167(EU)

# 8.2.2.2. Skin protection

# Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure. [EN 14605:2005 and EN 13034:2005]

#### Hand protection:

Use gloves appropriate to the work environment. Gloves should be classified under Standard EN 374 or ASTM F1296.

# 8.2.2.3. Respiratory protection

# Respiratory protection:

Where vapour, mist, or dust exceed PELs or other applicable OELs, use European Standard EN 529:2005 approved dust/particulate respiratory protective equipment

#### 8.2.2.4. Thermal hazards

No additional information available

# 8.2.3. Environmental exposure controls

No additional information available



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# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state : Liquid Appearance : Solution Colour : Blue Odour : Mild to none Odour threshold : Not determined : Not applicable рΗ : Not determined Relative evaporation rate (butylacetate=1) : Not applicable Melting point Freezing point : Not determined Boiling point : Not determined Flash point : Not determined Auto-ignition temperature : Not applicable Decomposition temperature : Not applicable Flammability (solid, gas) : Not applicable Vapour pressure : Not determined Relative vapour density at 20°C : Not determined Relative density : Not determined Density : Not determined

Solubility : Soluble in aqueous solution.

Partition coefficient n-octanol/water (Log Pow) : Not determined Viscosity, kinematic : Not determined Viscosity, dynamic : Not determined

Explosive properties : Criteria for classification not met
Oxidising properties : Criteria for classification not met

Explosive limits : Not applicable

#### 9.2. Other information

### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

# **SECTION 10: Stability and reactivity**

# 10.1. Reactivity

No additional information available.

## 10.2. Chemical stability

No additional information available.

# 10.3. Possibility of hazardous reactions

No additional information available.

## 10.4. Conditions to avoid

No additional information available.

# 10.5. Incompatible materials

No additional information available.



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#### 10.6. Hazardous decomposition products

No additional information available.

# **SECTION 11: Toxicological information**

# 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

: Not classified Acute toxicity (oral) Acute toxicity (dermal) : Not classified : Not classified Acute toxicity (inhalation) : Not classified Skin corrosion/irritation Serious eye damage/irritation : Not classified Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified Carcinogenicity Not classified Reproductive toxicity Not classified STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified

#### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

#### 11.2.2. Other information

Other information : No additional information available

# **SECTION 12: Ecological information**

## 12.1. Toxicity

Ecology – general : No information available.

Hazardous to the aquatic environment, short-term

(acute)

Not classified

Hazardous to the aquatic environment, long-term

: Not classified

(chronic)

# 12.2. Persistence and degradability

i-STAT PT <sup>plus</sup> Control Level 1 (C	CaCl <sub>2</sub> reconstitution solution); i-STAT PTF	olus Control Level 2 (CaCl <sub>2</sub> reconstitution solution)
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Persistence and degradability No information available.

# 12.3. Bioaccumulative potential

# i-STAT PTPlus Control Level 1 (CaCl2 reconstitution solution); i-STAT PTPlus Control Level 2 (CaCl2 reconstitution solution)

Bioaccumulative potential No information available.



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#### 12.4. Mobility in soil

# i-STAT PTPlus Control Level 1 (CaCl₂ reconstitution solution); i-STAT PTPlus Control Level 2 (CaCl₂ reconstitution solution)

No information available.

Ecology – soil

# 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

#### 12.7. Other adverse effects

No additional information available

# **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Waste treatment methods

- : Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without a permit.
- Product/Packaging disposal recommendations
- Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

# SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

# 14.1. UN number or ID number

UN-No. (ADR) : Not applicable UN-No. (IMDG) : Not applicable UN-No. (IATA) : Not applicable UN-No. (ADN) : Not applicable UN-No. (RID) : Not applicable

# 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

# 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable



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IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

#### 14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

# 14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

#### 14.6. Special precautions for user

#### Overland transport

Not applicable

### Transport by sea (IMDG)

Not applicable

#### Air transport (IATA)

Not applicable

# Inland waterway transport

Not applicable

#### Rail transport

Not applicable

# 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

# **SECTION 15: Regulatory information**

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

# 15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

This device is compliant with the requirements of EU regulation 2017/746 on In-vitro Diagnostic Devices (IVDR)



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#### 15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed SZW-lijst van mutagene stoffen : None of the components are listed SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed SZW-lijst van reprotoxische stoffen – : None of the components are listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

#### **US Federal regulations**

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb. 2019, as amended Feb. 2021, or are otherwise exempt or regulated by other agencies such as FDA or FIFRA

#### **US State regulations**

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

#### 15.2. Chemical safety assessment

No additional information available

# **SECTION 16: Other information**

Abbreviations and acronyms		
ACGIH	American Conference of Governement Industrial Hygienists	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
ED	Endocrine disrupting properties	
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LD50	Median lethal dose	
OEL	Occupational Exposure Limit	
OSHA	Occupational Safety and Health Administration	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	



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Abbreviations and acronyms		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STOT	Specific target organ toxicity	
TRGS	Technical Rules for Hazardous Substances	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Data sources : Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Classification for the USA in accordance with 29 CFR 1910.1200 (2012).

Classification for the EU in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and

packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and

1999/45/EC, and amending Regulation (EC) No 1907/2006.

Classification for Turkey in accordance with the Classification, Labelling and Packaging of Substances and Mixtures (SEA) Regulation published in the Official Journal numbered

28848 on December 11, 2013. ECHA (European Chemicals Agency).

Training advice : Normal use of this product shall imply use in accordance with the instructions for use and

corresponding product packaging.

# Indication of changes:

Revision A: Created new SDS to align with Regulation (EC) No. 1272/2008 [CLP] and US Hazcom 2012.

Other information : Author: Pace.

SDS Prepared by: Pace Analytical Services, Inc. Product Regulatory Services Group 1800 Elm Street Minneapolis, MN 55414 United States 612-656-1175

paceSDS@pacelabs.com

Classification according to Regulation (EC) No. 1272/2008	Classification procedure	
Not hazardous	Calculation method	

Safety Data Sheet (SDS), EU-US

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