



i-STAT PT^{plus} Control Level 1 (Plasma) i-STAT PT^{plus} Control Level 2 (Plasma)

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 ^{plus} Control Level 1 (Plasma); i-STAT PT ^{plus} Control Level 2 (Plasma)
Product code	: 06P17-17; 06P17-18
Other means of identification	: Each box contains 5 vials of lyophilized plasma and 5 vials of CaCl ₂ reconstitution solution. Plasma volume per vial is 1mL

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)-6122-58-1389
oustechsvc@apoc.abbott.com

Abbott Point of Care
Technical Support
For US email techsvc@apoc.abbott.com
Phone 1-800-366-8020 option 1
For outside of US
email oustechsvc@apoc.abbott.com

1.4. Emergency telephone number

Emergency number : 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.

Adverse physicochemical, human health and environmental effects

No additional information available



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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 %

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.

The human-sourced material used in this product has been tested and found to be:

- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for HCV (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)

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 advice/attention.
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.



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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.
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 product 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 : Sweep up spilled material without making dust. Clean surface thoroughly to remove residual contamination. Wash with plenty of water and detergent. Apply a suitable disinfectant. 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

Precautions for safe handling : Handle as a potentially infectious material. Use only with adequate ventilation. Do not breathe dust. Keep container tightly 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.



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7.3. Specific end use(s)

No additional information available

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



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8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Lyophilized pellet
Colour	: Straw colored
Odour	: Mild to none
Odour threshold	: Not determined
pH	: Not applicable
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: Not applicable
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.



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10.5. Incompatible materials

No additional information available.

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

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
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 %
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11.2.2. Other information

Other information	: No additional information available
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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 (chronic)	: Not classified

12.2. Persistence and degradability

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Persistence and degradability	No information available.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	No information available.
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12.4. Mobility in soil

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Ecology – soil	No information available.
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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 %
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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

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



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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 – Vruchtbaarheid : None of the components are listed
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 Government 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.

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

Safety Data Sheet (SDS), EU-US

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