

Kit ingredients

Product: I-STAT ACT Level 2 Controls

Product code: 7G83-01

Substance number	Description	Count	Symbols
7G82/7G83Plasma	I-STAT Lyophilized Human Plasma	5	-
7G82/7G83CaCl2	I-STAT Calcium chloride solution	5	-

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 05.06.2007

Revision: 05.06.2007

1 Identification of substance:

- **Trade name:** *I-STAT Lyophilized Human Plasma*
- **Article number:** 7G82/7G83Plasma
- **Application of the substance / the preparation** *For In Vitro Diagnostic Use*
- **Supplier:**
Abbott Diagnostics
Abbott House
Norden Road
MAIDENHEAD
SL6 4XF Berkshire
England UK
Tel. (+44)1628773413
- **Emergency information:**
MSDS-Support@Abbott.com
Tel: ++44 (0) 1628 773355

2 Hazards identification

- **Hazard designation:** *Void*
- **Information pertaining to particular dangers for man and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system**
The classification is in line with current EC (European Community)-directives. It is expanded, however, by information from technical literature and by information furnished by supplier companies.
- **Additional information:**
This preparation 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.

3 Composition/information on ingredients

- **Chemical characterization:**
- **CAS No. Designation:**
Plasma (human)
- **Chemical characterization**
- **Dangerous components according to EC-criteria:** *Void*
- **Additional information** *For the wording of the listed risk phrases refer to section 16.*

4 First aid measures

- **General information:** *If signs of infection occur, seek medical attention.*
- **After inhalation** *Supply fresh air; consult doctor in case of symptoms.*
- **After skin contact:** *Rinse with water.*
- **After eye contact:** *Rinse opened eye for several minutes under running water.*
- **After swallowing:** *Seek medical treatment.*

5 Fire fighting measures

- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
- **Protective equipment:** *No special measures required.*

6 Accidental release measures:

- **Person-related safety precautions:** *See point 8.*
- **Measures for environmental protection:** *No special measures required.*
- **Measures for cleaning/collecting:** *Collect mechanically.*

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Trade name: I-STAT Lyophilized Human Plasma

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7 Handling and storage

- **Handling**
- **Information for safe handling:** No special precautions necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and containers:**
Refer to the package insert or product label for additional information on storage conditions.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.

8 Exposure controls and personal protection

- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the compilation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
It is recommended that human sourced materials should be handled according to good laboratory practices and safe handling procedures.
- **Breathing equipment:**
Not necessary, if room is well-ventilated.
Take precautions, if chemical concentrations exceed the exposure limits (if any) listed above.
- **Protection of hands:**
The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting.
Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.
- **Eye protection:** Not required

9 Physical and chemical properties:

- **General Information**

Form:	Solid
Colour:	Colourless
Odour:	Odourless
- **Change in condition**

Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
Flash point:	Not applicable
Self-inflammability:	Product is not selfigniting.
Danger of explosion:	Product is not explosive.
Density	Not determined
Solubility in / Miscibility with Water:	Soluble

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.

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Trade name: I-STAT Lyophilized Human Plasma

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- **on the eye:** No irritant effect.
- **Sensitization:** No sensitizing effect known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

13 Disposal considerations

- **Product:**
- **General notes:**
In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.
- **European waste catalogue:**
Please consult the responsible regulatory body for the assignment of disposal codes according to European Waste Catalogue.
- **Following waste disposal key number are possible:**
180107: chemicals other than those mentioned in 18 01 06
- **Uncleaned packagings:** There are no uniform EC-regulations for the disposal of packaging as waste.
- **Recommendation:** Non contaminated packagings can be used for recycling.

14 Transport information

- **Land transport ADR/RID (cross-border)**
- **ADR/RID-GGVS/E Class:** -
- **Remarks:** not restricted
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **Remarks:** not restricted
not restricted

* 15 Regulatory information

- **Designation according to EC guidelines:**
Observe the normal safety regulations when handling chemicals.
The product is not subject to identification regulations under EC Directives.

* 16 Other information:

- These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
- **Contact supplier:**
Abbott Diagnostics, Quality & Regulatory Manager
Abbott Diagnostics, Customer Service Manager
 - *** Data compared to the previous version altered.**

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Safety Data Sheet

according to 1907/2006/EC, Article 31

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1 Identification of substance:

- **Trade name:** *I-STAT Calcium chloride solution*
- **Article number:** 7G82/7G83CaCl2
- **Application of the substance / the preparation** *For In Vitro Diagnostic Use*
- **Supplier:**
Abbott Diagnostics
Abbott House
Norden Road
MAIDENHEAD
SL6 4XF Berkshire
England UK
Tel. (+44)1628773413
- **Emergency information:**
MSDS-Support@Abbott.com
Tel: ++44 (0) 1628 773355

2 Hazards identification

- **Hazard designation:** *Void*
- **Information pertaining to particular dangers for man and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system**
The classification is in line with current EC (European Community)-directives. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

3 Composition/information on ingredients

- **Chemical characterization**

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

CAS: 10043-52-4	calcium chloride	 Xi; R 36	1.1%
EINECS: 233-140-8			

- **Additional information** *For the wording of the listed risk phrases refer to section 16.*

4 First aid measures

- **General information:** *No special measures required.*
- **After inhalation** *Supply fresh air; consult doctor in case of symptoms.*
- **After skin contact:** *Rinse with water.*
- **After eye contact:** *Rinse opened eye for several minutes under running water.*
- **After swallowing:** *In case of persistent symptoms consult doctor.*

5 Fire fighting measures

- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
- **Protective equipment:** *No special measures required.*

6 Accidental release measures:

- **Person-related safety precautions:** *See point 8.*
- **Measures for environmental protection:** *Dilute with much water.*
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

7 Handling and storage

- **Handling**
- **Information for safe handling:** *No special precautions necessary if used correctly.*
- **Information about protection against explosions and fires:** *No special measures required.*

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Trade name: I-STAT Calcium chloride solution

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- **Storage:**
- **Requirements to be met by storerooms and containers:**
Refer to the package insert or product label for additional information on storage conditions.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.

8 Exposure controls and personal protection

- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the compilation were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures should be adhered to general rules for handling chemicals.
- **Breathing equipment:**
Not necessary, if room is well-ventilated.
Take precautions, if chemical concentrations exceed the exposure limits (if any) listed above.
- **Protection of hands:**
The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting.
Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.
- **Eye protection:** Safety glasses recommended during refilling.

9 Physical and chemical properties:

- **General Information**

Form:	Fluid
Colour:	Colourless
Odour:	Odourless
- **Change in condition**
 - Melting point/Melting range:** Not determined
 - Boiling point/Boiling range:** Not determined
- **Flash point:** Not applicable
- **Self-inflammability:** Product is not selfigniting.
- **Danger of explosion:** Product is not explosive.
- **Vapour pressure at 20°C:** 23 hPa
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions:** No dangerous reactions known.
- **Dangerous products of decomposition:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritant effect.
- **Sensitization:** No sensitizing effect known.

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Trade name: I-STAT Calcium chloride solution

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· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

- **General notes:** Generally not hazardous for water.

13 Disposal considerations

- **Product:**

- **General notes:**

In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.

- **European waste catalogue:**

Please consult the responsible regulatory body for the assignment of disposal codes according to European Waste Catalogue.

- **Following waste disposal key number are possible:**

180107: chemicals other than those mentioned in 18 01 06

- **Uncleaned packagings:** There are no uniform EC-regulations for the disposal of packaging as waste.

- **Recommendation:** Non contaminated packagings can be used for recycling.

14 Transport information

- **Land transport ADR/RID (cross-border)**

- **ADR/RID-GGVS/E Class:** -

- **Remarks:** not restricted

- **IMDG Class:** -

- **Marine pollutant:** No

- **Air transport ICAO-TI and IATA-DGR:**

- **ICAO/IATA Class:** -

- **Remarks:** not restricted

not restricted

15 Regulatory information

- **Designation according to EC guidelines:**

Observe the normal safety regulations when handling chemicals.

The product is not subject to identification regulations under EC Directives.

16 Other information:

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant R-phrases**

36 Irritating to eyes.

- **Contact supplier:**

Abbott Diagnostics, Quality & Regulatory Manager

Abbott Diagnostics, Customer Service Manager

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

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