

**1. Identification of the substance/preparation and of the company/undertaking**

- **Trade name of the product:** cGMP 1 000 tests  
**Product code:** 62GM2PEB
- Reagents of the *in-vitro* test:** Donor conjugate  
Acceptor conjugate  
Standard  
Control  
Diluent  
Conjugate buffer
- **Manufacturer/supplier identification:** Cisbio Bioassays  
Parc Marcel Boiteux  
B.P. 84175  
30204 Bagnols sur Cèze  
  
Switchboard  
  
Phone: +33 (0) 4 66 79 67 05  
Fax: +33 (0) 4 66 79 19 20  
E-Mail: bioassays@cisbio.com
- **Emergency telephone number:** Customer service  
  
Phone: +33 (0) 4 66 79 67 05  
Fax: +33 (0) 4 66 79 19 20  
E-Mail: bioassays@cisbio.com  
Internet <http://www.htrf.com>

**2. Composition/information on ingredients**

• **Chemical characterization :**

Reagents	Ingredients	Format	Percent (w/w)
Donor conjugate	Bovine serum albumin free protease	lyophilized	0.1 - 1
Acceptor conjugate	Bovine serum albumin free protease	lyophilized	0.1 - 1
Calibrator	Bovine serum albumin free protease	lyophilized	0.1 - 1
Control	Bovine serum albumin free protease	lyophilized	0.1 - 1
Buffer	KF (potassium fluoride) Triton X100	liquid	< 25 < 25
Diluent	Bovine serum albumin free protease NaN3 Micr-O-protect (MIT-BND)	liquid	0.1 - 1 < 0.1 0.01 - 0.1

• **Hazardous ingredients:**

CAS No.	Name	Symbol	Risk phrases
7789-23-3	Potassium fluoride	T	R 23/24/25
26628-22-8	Sodium azide	T+	R 22-32 50/53
9002-93-1	Triton X 100	Xn	R 22-41
26172-54-3	2-Methyl-4-isothiazolin-3-one Hydrochloride (MIT)	C	R 34-42/43
30007-47-7	5-Bromo-5-nitro-1,3-dioxane (BND)	Xn	R 22-38

**3. Hazards identification (reagents)**

- **Hazards identification (buffer reagent) :** Xn Harmful
- **Identification of special hazards to man and the environment:** Harmful by contact with skin and if swallowed.
- **Albumin :** Potentially harmful and infectious.

#### 4. First-aid measures

- **Contamination: Projection into eyes  
Skin contact** Remove contaminated clothing. Flush eyes or skin with plenty of water immediately at least 15 minutes.
- **Inhalation:** Supply for fresh air; if not breathing, give artificial respiration; at breathing problems supply oxygen .
- **Ingestion:** Secure that the person is conscious, flush mouth with water. Immediately call a physician.  
Clean contaminated clothing.

#### 5. Fire-fighting measures

- **General statements:** Avoid contact with eyes, skin and clothing.
- **General advice:** Suit extinguishing measures to surroundings.  
Pay attention to the usual fire and explosion hazards.
- **Suitable extinguishing media:** Water spray jet, carbon dioxide, extinguishing powder or suitable extinguishing foam.
- **Protecting equipment for fire-fighting:** Put on breath protecting equipment, wear protecting clothing to prevent from contact with skin and eyes.

#### 6. Accidental release measures

- **Personal precautions:** Avoid reagent contact.
- **Environmental precautions:** Prevent from getting into sewage, water, ground.
- **Methods of cleaning up:** Remove pollutes with absorbing paper.  
Clean the polluted place with sodium hypochlorite solution (5%).  
All the material used for cleaning up must be disposed of as infectious laboratory waste.

#### 7. Handling and storage

- **Handling**  
**Advices for safe handling:** No special measures necessary at proper use.  
**Precautions:** Do not pipet by mouth.  
Do not eat, drink or smoke in areas, where kit-reagents are handled.  
Wear suitable one-way rubber gloves at work.  
Avoid any splash and formation of aerosols.  
Further advices see point 8.
- **Storage**  
**Conditions for safe storage / specific design for storage rooms and containers:** Keep reagents in tightly closed original containers.  
Store in a cool dry place (2-8°C).

#### 8. Exposure controls / personal protection

- **Personal protective equipment**  
**Respirator protection:** Required if dust and aerosols are generated  
**Hand protection:** Protective gloves  
**Eye protection:** Safety glasses  
**Body protection:** Protective clothing  
**General protective and sanitary measures:** Safety shower, eyewash.  
Change contaminated clothing immediately.  
Wash hands after work.  
Preventive skin protection is recommended.

#### 9. Physical and chemical properties

- **Appearance**  
**Physical state of buffer:** liquid      **Odour:** odourless

- **Safety parameters**

pH: 7  
Melting point / melting range: Not applicable.  
Flash point: Not applicable.  
Relative density: Data not available.

10. **Stability and reactivity**

- **Conditions to avoid:** Strong heating.
- **Hazardous reactions:** None.
- **Hazardous decomposition products:** In case of fire liberation of dangerous decomposition products (hydrogen fluoride) possible.

11. **Toxicological information**

- **Toxicity:** No information available
- **General advice:** Soluble inorganic fluoride contact with eyes, skin and mucous membranes leads to irritant and corrosive effects. Systematic effect: Decrease of calcium-level in blood, excitement, cramps, disturbances of blood circulation and central nervous system.
- **Supplementary toxicological advice:** Other hazardous properties cannot be excluded .Due to the method calculation of the EC General Classification in the latest valid version the product presents the following hazards: **Harmful**

12. **Ecological information**

- **General advices:** Prevent from getting into sewage, water, ground.
- **Mobility and (bio)accumulation potential:** No information available.
- **Ecotoxicity:** Ecotoxic effects of the product are not to be expected. Quantitative data on the ecological effect of this product are not available.
- **Other informations:** No ecological problems are to be expected when the product is handled and used with due care and attention.


13. **Disposal consideration:**

- **Product:** The product must be disposed of as a laboratory chemical according to local regulations. Please contact responsible authority. Used reagents plates and reagent kits dispose of as potential infectious laboratory waste.
- **Contaminated packaging:** Dispose of according to local regulations. Recommendation: Remove residues. Empty containers should be returned to local recyclers.
- **Pollutes:** Remove pollutes with absorbing paper. Clean the polluted place with sodium hypochlorite solution (5%). All the material used for cleaning up must be disposed of as infectious laboratory waste.

14. **Transport information:**

No dangerous article according to applicable transport regulations.

15. **Regulations:**

	<b>MATERIAL SAFETY DATA SHEET</b> in accordance with CE regulation n°1907/2006. Annexe 2  <b>cGMP 1 000 tests</b>	Date : 01-02-2010  Version : 1  Page 4 of 4
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● **Reminder of risk (buffer reagent)**

Potassium fluoride < 25 % (w/w), CAS No: 7789-23-3  
Indication of danger : Xn : Harmful  
R- Phrases : R21/22 :Harmful by contact with skin and if swallowed.  
S- Phrases : 26-45 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**16. Other information**

● **Recommended use:**

For research use only

● **Attention:**

This safety data sheet has been drafted in conformity with CE regulation n°1907/2006 Annexe 2. It completes the Instruction for Use but does not replace it. This information is based on our present knowledge relative to the product at the date it was issued. All information provided in this document is given in good faith based on the present knowledge status. The user's attention is drawn to possible risks related to using the product for any purposes or in any way not allowed in this document. This safety information in no way dispenses users from thoroughly knowing and applying all regulatory texts related to their activity.

Any user is solely responsible for the precautions undertaken when using the product.