




# MATERIAL SAFETY DATA SHEET


## Revision History

Revision	Date	Description of changes
00	2017.06.01	Established the MSDS for STANDARD E TB-Feron ELISA
01	2017.11.22	1. Changed the product name from STANDARD E TB-Feron ELISA to STANDARD™ E TB-Feron ELISA 2. Changed the CI (Company Identity)

Written by	Reviewed by	Approved by
		
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RA	RA/MSL	Vice President

# 1. MATERIAL SAFETY DATA SHEET

## 1) STANDARD™ E TB-Feron ELISA(STANDARD E TB-Feron ELISA)

1. Product and company identification				
<b>Product Name</b>	STANDARD™ E TB-Feron ELISA(STANDARD E TB-Feron ELISA)			
<b>Reference Code.</b>	ETBF01G			
<b>Manufacturer Information</b>				
Name	SD BIOSENSOR, Inc.			
Address	Head office: C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, KOREA			
Telephone	+82 31 300 0400			
Fax	+82 31 300 0499			
2. Composition/Information on ingredients				
Component	Description	Safety Information		
Antibody coated plate	96 wells coated with monoclonal anti-IFN- $\gamma$	Not hazardous		
STANDARDS	Recombinant human IFN- $\gamma$ , Proclin 300	Not hazardous		
ELISA Diluents	Phosphate buffered saline and Proclin 300	Not hazardous		
Wash Buffer	PBS-PolySorbate 20 and Proclin 300	See below		
Amplification conjugate	Monoclonal anti-IFN- $\gamma$ conjugatedBiotin and proclin 300	Not hazardous		
Enzyme conjugate	HRP conjugated Streptavidin and proclin 300	Not hazardous		
TMB Substrate	Tetramethyl-benzidine(TMB) and Hydrogen peroxidase	Not hazardous		
Stop solution	1N Sulfuric acid	Not hazardous		
Adhesive plate sealer	-	-		
Instruction for use	-	-		
3. Hazards identification				
Component	Composition	CAS No.	EC-No.	Concentration
PBS-PolySorbate 20	Sodium chloride USP, Sodium phosphate dibasic	-	-	-
<b>GHS - Classification</b>				
<b><u>PBS-PolySorbate20</u></b>				
<b>Pictogram</b>				
				
<b>Signal Word</b>	Warning			
<b>Hazard statement(s)</b>	H315 - Causes skin irritation H319 - Causes serious eye irritation H335 - May cause respiratory irritation			
<b>Precautionary Statements</b>	P280 - Wear protective gloves/protective clothing/eye protection/face protection P302+ P352 - IF ON SKIN: Wash with plenty of soap and water P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy			

to do. Continue rinsing

#### 4. First aid measures

**General advice:** Consult a physician. Move out of dangerous area.

**If inhaled:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact:** Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

**In case of eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital.

**If swallowed:** DO NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

#### 5. Fire-Fighting measures

**Condition of flammability:** Not flammable or combustible.

##### Suitable extinguishing media

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

##### Special protective equipment for firefighters

Wear self contained breathing apparatus for firefighting if necessary.

#### 6. Accidental release measures

##### Personal precautions

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas.

##### Environmental precautions

Do not let product enter drains. Discharge into the environment must be avoided.

##### Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

#### 7. Handling and storage

##### Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Avoid inhalation of vapor or mist.

##### Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 2~8 °C

##### Incompatible products

Strong bases. metals. cyanides.

##### Incompatible materials

Heat sources.

#### 8. Exposure controls & personal protection

**Appropriate engineering controls**

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

**Personal protective equipment:** Avoid all unnecessary exposure.

**Hand protection:** Wear protective gloves.

**Eye protection:** Chemical goggles or face shield.

**Skin and body protection:** Wear suitable protective clothing.

**Respiratory protection:** Wear appropriate mask.

**Other information:** Do not eat, drink or smoke during use.

**9. Physical and chemical properties**

<b>Appearance</b>	Variable, generally aqueous liquids. Exceptions are the solid plate and plate sealer.
<b>Safety data</b>	
Odour	no data available
Odour Threshold	no data available
pH	no data available
Melting point/freezing point	no data available
Initial boiling point and boiling range	no data available
Flashing point	no data available
Evaporation rate	no data available
Flammability (solid, gas)	no data available
Upper/lower flammability	no data available
Vapor pressure	no data available
Solubility	no data available
Vapor density	no data available
Relative density	no data available
Partition coefficient: n-octanol/water	no data available
Auto-ignition temperature	no data available
Decomposition temperature	no data available
Viscosity	no data available
Formula mass	no data available

**10. Stability and reactivity****PBS-PolySorbate20****Reactivity**

no data available

**Chemical stability**

Stable under recommended storage conditions.

**Possibility of hazardous reactions**

no data available

**Conditions to avoid**

no data available

**Hazardous decomposition products**

No dangerous decomposition products known

**11. Toxicological information****PBS-PolySorbate 20****Acute toxicity****Oral LD50**

no data available

**Inhalation LC50**

no data available

**Dermal LD50**

no data available

**Other information on acute toxicity**

no data available

**Skin corrosion/irritation**

no data available

**Serious eye damage/eye irritation**

no data available

**Respiratory or skin sensitization**

no data available

**Germ cell mutagenicity**

no data available

**Carcinogenicity**

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Reproductive toxicity**

no data available

**Teratogenicity**

no data available

**Specific target organ toxicity - single exposure (Globally Harmonized System)**

no data available

**Specific target organ toxicity - repeated exposure (Globally Harmonized System)**

no data available

**Aspiration hazard**

no data available

**Synergistic effects**

no data available

**12. Ecological information****Toxicity**

no data available

**Persistence and degradability**

no data available

**Bioaccumulative potential**

no data available  
**Mobility in soil**  
no data available  
**PBT and vPvB assessment**  
no data available  
**Other adverse effects**  
no data available

### 13. Disposal considerations

#### Product

Offer surplus and non-recyclable solutions to a licensed disposal company

#### Contaminated packaging

Dispose of as unused product.

### 14. Transport information

#### **PBS-PolySorbate 20**

#### **LAND TRANSPORT(DOT)**

Proper Shipping Name                      Not dangerous goods.

Hazard Class-Primary:

UN/ID No.:

Packing Group

Subsidiary Risk

#### **AIR TRANSPORT(ICA0/IATA)**

Proper Shipping Name                      Not dangerous goods.

Hazard Class-Primary:

UN/ID No.:

Packing Group

#### **MARINE TRANSPORT**

#### **(IMDG/IMO)**

Not dangerous goods.

Proper Shipping Name

Hazard Class-Primary:

Packing Group

EmS

### 15. Regulatory information

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

no data available

#### **Chemical Safety Assessment**

For this product a chemical safety assessment was not carried out

### 16. Other information

#### **Others**

This Material Safety Data Sheet(MSDS) is prepared on basis of the information obtained from

Korea Occupational Safety & Health Agency(KOSHA), however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. It shall be used only as a guide and it does not represent any guarantee of the properties of the product. We assume no responsibility for any damage resulting from handling or from contact with the above product.

## 2) TB-Feron tubes

1) Product and company identification			
<b>Product Name</b>	TB-Feron tubes		
<b>Catalogue No.</b>	07TBFA10 07TBFA20 07TBFA30		
<b>Manufacturer Information</b>			
Name	SD BIOSENSOR, INC.		
Address	Head office: C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, KOREA		
Telephone	+82 31 300 0400		
Fax	+82 31 300 0499		
2) Hazards identification			
<b>NEPA Ratings</b>	Health=0, Flammability=0, Reactivity=0		
<b>Principle routes of exposure</b>	Ingestion, inhalation, skin/eye contact		
<b>Inhalation</b>	May cause irritation of respiratory tract		
<b>Ingestion</b>	Harmful if swallowing, ingestion of strips or other solid pieces may cause choking		
<b>Skin contact</b>	May cause irritation in contact with skin		
<b>Eye contact</b>	Contact with eyes may cause irritation		
<b>Medical conditions aggravated by exposure</b>	None Known		
<b>Additional information</b>	None		
3) Composition/Information on ingredients			
#	Part	Material	Amount
1	TB-Feron Mitogen Tube	Mitogen	Q.S.
		Heparin	Q.S.
2	TB-Feron Nil Tube	Heparin	Q.S.
3	TB-Feron TB Antigen Tube	Recombinant Human IFN- $\gamma$	Q.S.
		Heparin	Q.S.
Pursuant to United States OSHA Regulations 29 CFR Part 1910.1200, This Product Is Not Considered To Contain Hazardous Materials.			
<b>EU classification</b> <sub>(1999/45/EC)</sub>	Not applicable		
<b>EU risk and safety phrases</b>	None		
4) Emergency first aid measures			
<b>Inhalation</b>	Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen		
<b>Skin contact</b>	Rinse with plenty of water. If skin irritation persists, call a physician.		
<b>Ingestion</b>	Consult a physician. Do not induce vomiting without medical advice		
<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water. Do not rub eyes		
<b>Notes to physician</b>	None determined		
5) Fire-Fighting measures			
<b>Initial boiling point</b>	100 °C		
<b>Flash Point(Method used)</b>	None		
<b>Flammable limits</b>	Not applicable		
<b>Extinguishing media</b>	Use whatever is required for the surrounding area		



<b>Special firefighting procedures</b>	It is always best to wear a self-contained breathing apparatus.
<b>Unusual fire and explosion hazard</b>	None determined
<b>6) Spill or Leak procedures</b>	
<b>Steps to be taken in case material is released or spilled</b>	Pick up and place in a disposal container
<b>7) Handling and storage</b>	
Store the test kits at temperatures and conditions as indicated on the product label. See product test kit package or insert for instructions on handling product	
<b>8) Personal protection</b>	
<b>Ventilation</b>	Use general room ventilation, there is no special respiratory protection required
<b>Protective gloves and other protective equipment</b>	Not required
<b>Eye protective</b>	Not needed or required to use this product
<b>9) Physical data</b>	
<b>Test device</b>	
<b>Appearance and odor</b>	Plastic cassette with applied chemicals and desiccant bead
<b>pH</b>	Not applicable
<b>Solubility in water</b>	Not soluble
<b>Physical Characteristics</b>	Not significant
<b>Assay diluent</b>	
<b>Appearance and odor</b>	Colorless or light yellow, free of particulate matter
<b>Solubility in water</b>	Soluble
<b>Physical Characteristics</b>	Not significant
<b>10) Reactivity data</b>	
<b>Stability</b>	This product is stable as sold if used as directed. There are no specific conditions to avoid.
<b>11) Toxicological information</b>	
<b>Chronic effect of over exposure</b>	None currently known. None of the components are listed as a carcinogen or suspected carcinogen
<b>Inhalation, Skin Contact and Eye Contact</b>	Not considered health risks
<b>Ingestion</b>	If ingestion should occur the patient may feel uncomfortable. Treat as indicated
<b>Acute toxicity values</b>	Not applicable
<b>12) Ecological information</b>	
Ecological effects of the product strips have not been determined	
<b>13) Disposal considerations</b>	
<b>Primary Container Type</b>	Aluminum foil pouch in a fiberboard box. Membrane with applied chemicals in a plastic cassette.
<b>Waste Disposal Method</b>	Each disposal facility must determine proper disposal methods to comply with Local, State and Federal Environmental Regulations. Incineration of the product could produce trace amounts of toxic gasses. Check your local regulations before incineration
<b>14) Transport information (JATA regulation)</b>	
<b>Proper shipping name</b>	Not regulated
<b>UN number</b>	Not applicable
<b>Hazard class</b>	Not applicable
<b>Subsidiary risks</b>	Not applicable
<b>Packing group</b>	Not applicable

<b>Label(s)</b>	Not applicable
<b>Packing instruction</b> <small>(Passenger aircraft)</small>	Not applicable
<b>Packing instruction</b> <small>(cargo aircraft)</small>	Not applicable
<b>Unit volume</b>	See products labels
<b>Primary container type</b>	Aluminum pouch in a fiberboard box
<b>Sales unit</b>	1 package
<b>15) Regulatory information</b>	
<b>SARA 311/312</b>	Hazard categories for SARA section 311/312
<b>Reporting</b>	Not hazardous
<b>Canadian WHMIS classification</b>	Not a controlled products
<b>EU classification</b> <small>(1999/45/EC)</small>	Not applicable
<b>EU risk and safety phrases</b>	None
<b>16) Other information</b>	
None	