

Safety Data Sheet

Section 1 : Identification

Product Name: ANTINUCLEAR ANTIBODY (ANA) TEST SYSTEM

Components: Substrate Slide
Conjugate ANA-HEp2 (FITC Conjugate)
Mounting Medium
ANA Positive (homogeneous pattern) Human Control Serum
ANA Negative Human Control Serum
IFA Diluent
Phosphate Buffered Saline (PBS)

Manufacturer Name: Bion Enterprises, Ltd.

Emergency Telephone Number: (847) 544-5044

Address: 455 State Street, Suite 100
Des Plaines, IL 60016

Telephone Number for Information: (847) 544-5044

Date Prepared: See bottom of page

Section 2: Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Product is not classified as hazardous according to 29CFR 1910 (OSHA Hazard Communication Standard)

2.2 GHS label elements, including precautionary statements

IFA Diluent

Symbol /Pictogram:



H-statements: H300, H310, H373, H400

Signal Word: Warning

P-statements: None

2.3 Other Hazards

FITC Conjugate / Control Serums: This mixture contains material of human or animal origin and is therefore considered considered potentially infectious.

For the full text of H-statements, and P-statements mentioned in this Section, see Section 16.

Section 3: Composition / Information on Ingredients

3.1 Substance

Not applicable.

3.2 Mixtures

FITC Conjugate: FITC Conjugate <0.001% in phosphate buffered saline; <0.001% Evans Blue; Sodium azide <0.09%, Thimerosal <0.1% as preservative and Bovine Serum Albumin (BSA) Fraction V

Hazardous component: Thimerosal

CAS-No. 54-64-8

Index-No. 080-004-00-7

Concentration <0.1%

Hazardous component: Evans blue dye

CAS-No. 314-13-6

Index-No. 611-030-00-4

Concentration <0.001%

Hazardous component: Sodium azide

CAS-No. 26628-22-8

Index-No. 011-004-00-7

Concentration <0.1%

Control Serums: Fetal Bovine Serum

Hazardous component: Thimerosal

CAS-No. 54-64-8

Index-No. 080-004-00-7

Concentration <0.1%

Mounting Medium: Phosphate buffered saline with 80% glycerol
This mixture does not contain any hazardous substances.

Phosphate Buffered Saline:

This mixture does not contain any hazardous substances.

IFA Diluent:

Hazardous component: Thimerosal

CAS-No. 54-64-8

Index-No. 080-004-00-7

Concentration <0.1%

FITC Conjugate / Control Serums / Mounting Medium / Phosphate Buffered Saline

Symbol/Pictogram: None

Signal Word: None

H-statements: H300, H310, H373, H400, H410

P-statements: None

For the full text of H-statements, and P-statements mentioned in this Section, see Section 16.

Section 4: First-Aid Measures

4.1 Description of first aid measures**After inhalation**

Fresh air. Consult a physician if feeling unwell.

After skin contact

Wash with plenty of water. Immediately remove any contaminated clothing. Treat affected areas with skin disinfectant. Consult physician.

After eye contact

In case of contact with eye flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After swallowing

Induce vomiting when the affected person is unconscious. Rinse your mouth immediately and drink plenty of water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Section 5: Fire-Fighting Measures

5.1 Extinguishing media**Suitable extinguishing media**

Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media

None known.

5.2 Special hazards arising from the substance or mixtureNot combustible. Danger of formation of toxic pyrolysis products. Fire can cause: Carbon monoxide (CO), Carbon dioxide (CO₂)**5.3 Advice for firefighters**

Special protective equipment for firefighters. In the event of fire, wear self-contained breathing apparatus. Fire residues and contaminated extinguishing water must be disposed of in accordance with local official regulations.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment, and emergency procedures

Advice for non-emergency personnel

Do not breathe vapours/aerosols. Avoid substance contact. Provide adequate ventilation. Evacuate the danger area. Follow emergency procedures. Consult an expert.

Advice for emergency responders

Protective equipment see Section 8.

6.2 Environmental precautions

Do not allow to enter into surface water, drains, or soil.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see Sections 7 and 10). Take up with liquid-absorbent material. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see Section 13.

Section 7: Handling and Storage

7.1 Precautions for safe handling

Advice on safe handling

When using do not eat, drink, or smoke. Thorough skin-cleaning after handling the product.

Hygiene measures

Handle in accordance with good industrial hygiene and safety procedures.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool, and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Do not store in unlabeled containers. Store at 2°C to 8°C.

Storage class: 12 (non-combustible liquids)

Section 8: Exposure Controls/Personal Protection

8.1 Control parameters

Phosphate Buffered Saline: No data available.

Control Serum (Thimerosal only) / FITC Conjugate / IFA Diluent (Thimerosal only)

Exposure Limits

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium azide CAS No. 26628-22-8	Ceiling: 0.29 mg/m ³ Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S* (vacated) Ceiling: 0.1 ppm NH ₃ (vacated) Ceiling: 0.3 mg/m ³ NaN ₃	Ceiling: 0.1 ppm NH ₃ Ceiling: 0.3 mg/m ³ NaN ₃
Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Thimerosal CAS No. 54-64-8 (Sodium o-(ethylmercurithio) benzoate)	TWA: 0.1 mg/m ³	Not listed	IDLH: 10 mg/m ³ TWA: 0.05 mg/m ³ Ceiling: 0.1 mg/m ³

Mounting Medium

Exposure Limits

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin CAS No. 56-81-5	TLV: 10 mg/m ³	(vacated) TWA: 10 mg/m ³ (vacated) TWA: 5 mg/m ³ TWA: 15 mg/m ³ TWA: 5 mg/m ³	Not listed.

8.2 Exposure Controls

Appropriate engineering controls

Provide adequate ventilation.

Personal protective equipment

Eye/Face protection

Protective safety glasses (goggles) with side protection approved under appropriate government standards such as NIOSH (US).

Skin/Hand protection

Wear protective gloves while handling the product. Dispose of contaminated gloves after use in accordance with the applicable laws and good laboratory practices.

Body protection

Wear suitable personal protective clothing.

Respiratory protection

Not required if the product is used as intended.

Control of environmental exposure

Do not allow to enter drains, waterways, or soil.

Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance/Color	Coated Slide: Glass slide in foil pouch. Control Serum: Colorless fluid in polypropylene vial. FITC Conjugate: Light blue fluid in polyethylene bottle. Mounting Medium: Colorless fluid in polyethylene bottle. IFA Diluent: Clear purple fluid in polyethylene bottle. Phosphate Buffered Saline: Salt/Powder in foil pouch.
Odor	All components odorless
Odor Threshold	All components no data available
pH	Coated Slide: Not applicable Control Serum: Not applicable FITC Conjugate: Not applicable. IFA Diluent: Not applicable. Mounting Medium: 7.2 - 7.6 Phosphate Buffered Saline: 7.2 - 7.6
Melting point	All components no data available
Boiling Point	All components no data available
Flash point	All components no data available
Evaporation rate	All components no data available
Flammability (solid, gas)	All components no data available
Upper flammability or explosive limit	All components no data available
Lower flammability or explosive limit	All components no data available
Vapor pressure	All components no data available
Vapor density	All components no data available

Relative density	All components no data available
Water solubility	Coated Slide: Not soluble Control Serum: No data available. FITC Conjugate: No data available. Mounting Medium: No data available. IFA Diluent: No data available. Phosphate Buffered Saline: No data available.
Partition coefficient n-octanol/water	All components no data available
Autoignition temperature	All components no data available
Decomposition temperature	All components no data available
Viscosity	All components no data available
Explosive properties	Not classified as an explosive for all components
Oxidizing properties	None for all components
9.2 Other safety data	No additional information.

Section 10: Stability and Reactivity

- 10.1 Reactivity**
See section 10.3
- 10.2 Chemical Stability**
Recommended storage temperature: 2°C to 8°C.
- 10.3 Possibility of hazardous reactions**
Contact with acids releases toxic gases. Formation of nitrous gases is possible for the following: FITC conjugate. Avoid contact with metals. This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds and toxic gases. No information available on the following: Coated slide, Control serum, IFA diluent, Mounting medium and Phosphate buffered saline.
- 10.4 Conditions to avoid**
Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).
- 10.5 Incompatible metals**
Acids, heavy metals for the following: FITC conjugate. Avoid contact with metals. This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds and toxic gases. Avoid contact with strong oxidizing agents, metal, strong acids, and strong bases for the following: IFA Diluent. No information available on the following: Coated slide, Control serum, Mounting medium and Phosphate buffered saline.
- 10.6 Hazardous decomposition products**
Nitrous gases for the following: FITC conjugate. Irritating toxic fumes and gases, carbon monoxide, and sulfur oxides for the following: IFA Diluent. No information available on the following: Coated slide, Control serum, Mounting medium and Phosphate buffered saline.

Section 11: Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, and Phosphate Buffered saline.

Relevant ingredient for mounting medium:

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Glycerin Cas No. 56-81-5	12600 mg/kg (Rat)	>10 g/kg (Rabbit)	>2.75 mg/L/4h (Rat)(mist)

Relevant ingredients for IFA diluent:

Water (CAS NO.7732-18-5)

Oral LD50 Rat >90 mL/kg

Proprietary Component 2 (Trade Secret)

Inhalation LC50 Rat >42 g/m³; Oral LD50 Rat 3 g/kg; Dermal LD50 Rabbit >10 g/kg

Proprietary Component 3 (Trade Secret)

Oral LD50 Rat 17 g/kg

Proprietary Component 4 (Trade Secret)

Dermal LD50 Rabbit >4640 mg/kg; Oral LD50 Mouse 1700 mg/kg

Proprietary Component 5 (Trade Secret)

Oral LD 50 Rat 75 mg/kg

Skin corrosion/irritation

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Serious eye damage/irritation

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Skin Sensitization

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Germ cell mutagenicity

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Carcinogenicity

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

The mixture is not classified in carcinogenicity for the following: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

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

NTP: No ingredient of this product present at levels at or greater than or equal 0.1% is identified as known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels at or greater than or equal 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Teratogenicity

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Specific target organ toxicity – single exposure

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Specific target organ toxicity – repeated exposure

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Aspiration hazard

Not applicable for coated slide.

No data available: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

11.2 Additional Information

Not applicable for coated slide.

Quantitative data on the toxicity of this product are not available for the following: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

Section 12: Ecological Information

12.1 Toxicity

No Information available for coated slide.

Quantitative data on the toxicity of this mixture are not available for the following: Control serum, FITC conjugate, Mounting medium and Phosphate buffered saline.

Aquatic toxicity

IFA Diluent Proprietary Component 2 (Trade Secret)

Test & Species

96 Hr LC50 Lepomis macrochirus
96 Hr LC50 Lepomis macrochirus
96 Hr LC50 Pimephales promelas
96 Hr LC50 Pimephales promelas
96 Hr LC50 Pimephales promelas
96 Hr LC50 Pimephales promelas
48 Hr EC50 Daphnia magna
48 Hr EC50 Daphnia magna

Conditions

5560-6080 mg/L (flow -through)
12946 mg/L (static)
6020-7070 mg/L (static)
7050-m/L (semi-static)
6420-6700 mg/L (static)
4747-7824 mg/L (flow-through)
1000 mg/L
340.7-469.2 mg/L (static)

12.2 Persistence and degradability

All components no data available.

12.3 Bioaccumulative potential

No data available for coated slide.

No bioaccumulation expected for the following: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

12.4 Mobility in soil

All components no data available.

12.5 Results of PBT and vPvB assessment

This substance/mixture does not contain components in concentrations of 0.1% or higher classified as either persistent, Bioaccumulative and toxic (PBT) or very persistent and very Bioaccumulative (vPvB).

12.6 Endocrine disrupting properties

All components no data available.

12.7 Other adverse effects

No data available for coated slide.

Do not allow to enter drains, waterways, or soil for the following: Control serum, FITC conjugate, IFA diluent, Mounting medium and Phosphate buffered saline.

12.8 Additional ecological information

All components entry into the environment should be avoided.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Waste should be disposed of in accordance with federal, state, and local environmental control regulations. When disposing of FITC Conjugate, flush drains with copious amounts of water. Disposal of packaging according to the instructions of public authorities.

Section 14: Transportation Information

DOT (US)

Not dangerous goods.

IMDG

Not dangerous goods.

IATA

Not dangerous goods.

Further Information

Not classified as dangerous in the meaning of transport regulations.

Section 15: Regulatory Information

15.2 Chemical safety assessment

For all components, a chemical safety assessment was not carried out.

US Regulations**Sara 302 Components and Sara 313 Components (IFA Diluent only)**

This product contains one or more of the following chemicals that require to be identified under SARA Section 302 (40 CFR Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Proprietary Component 3 (Trade secret)

CERCLA: 5000lb final RQ; 2270kg final RQ

Sara 302 Components

These products (Control serum, FITC conjugate, Mounting medium and Phosphate buffered saline) do not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels.

Sara 313 Components

These products (Control serum, FITC conjugate, Mounting medium and Phosphate buffered saline) do not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

CWA (Clean Water Act)

These product does not contain any substances regulated as pollutants in accordance with the Clean Water Act (40 CFR 116.4)

U.S. State Right -to-know regulations

For Control serum, FITC conjugate, Mounting medium and Phosphate buffered saline.

California Proposition 65

These products do not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Massachusetts Right to Know Components

No components are subject to the Massachusetts Right to Know Act.

Chemical Name	New Jersey	Pennsylvania
Sodium azide 26628-22-8	X	X

U.S. State Right -to-know regulations

For IFA Diluent only.

Component	CAS No.	CA	MA	MN	NJ	PA	RI
Proprietary Component 3	Trade Secret	X	X	X	X	X	X

Component Analysis - Inventory

Component	CAS No.	TSCA
Water	7732-18-5	Yes
Proprietary Component 1	Trade Secret	Yes
Proprietary Component 2	Trade Secret	Yes
Proprietary Component 3	Trade Secret	Yes
Proprietary Component 4	Trade Secret	Yes
Proprietary Component 5	Trade Secret	Yes
Proprietary Component 6	Trade Secret	Yes

Section 16: Other Information

Safety data for product including all components. This product is intended for professional laboratory use. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Full text to the H-Statements mentioned in heading 2:

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

List of abbreviations:

ACGIH	American Conference of Governmental Industrial Hygienists
Ceiling	Maximum Limit Value
CWA	Clean Water Act
DOT	Department of Transportation
IATA	International Air Transport Association
IDLH	Immediately Dangerous to Life or Health
IMDG	International Maritime Code for Dangerous Goods
LD	Lethal Dose
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety & Health Administration
PBT	Persistent (P), Bioaccumulative (B), Toxic (T)
PEL	Permissible Exposure Limits
TLV	Threshold Limit Value
TWA	Time-weight Average
vPvB	Very persistent (vP), very Bioaccumulative (vB)

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.