



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 1 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Product and Company Identification

PRODUCT NAME: ANA Screen Test Kit
SUPPLIER:
Name: Trinity Biotech USA
Address: 2823 Girts Rd.
Jamestown, NY 14701
USA
Phone number: 1 (716) 483-3851
Fax number: 1 (716) 488-1990
Emergency phone number: Contact national poisons unit.
Ireland 01- 837 9964
Belgium (+31) 30 2748888
France (+331).40.37.04.04
USA 1 (800) 603 8076

Kit components

Product Code	Description
2339000	ANA Screen Test Kit

Components

220NC	Negative Control
220HR	Conjugate
220SM	Stop Solution
220TM	Substrate
230AD	Sample Diluent
230AW	Wash Concentrate
200AN, 210AN	ANA Screening Test Pos. Control, Calibrator



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 2 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade Name: Negative Control

1. Identification of Substance

- Product Details
- Trade name: Negative Control
- Catalog or product number: 220NC
- Application of the substance / the preparation In-vitro laboratory reagent or component

SUPPLIER:

Name: Trinity Biotech USA
 Address: 2823 Girts Rd.
 Jamestown, NY 14701
 USA
 Phone number: 1 (716) 483-3851
 Fax number: 1 (716) 488-1990
 Emergency phone number: Contact national poisons unit.
 Ireland 01- 837 9964
 Belgium (+31) 30 2748888
 France (+331).40.37.04.04
 USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization

Description: Mixture of the substances listed below with non-hazardous additions

Listing of dangerous and non-hazardous components:		
EINECS: 268-338-3	Human Source Material	35-50%
CAS: 56-81-5 EINECS: 200-289-5 RTECS: MA 8050000	Glycerol	20-35%
CAS: 7732-18-5 EINECS: 231-791-2 RTECS: ZC 0110000		20-35%
	Goat Serum	1.0-2.5%

- Additional information
 Contains human sourced and / or potentially infectious components
 Contains added constituents of animal origin

3. Hazards identification

- Information pertaining to particular dangers for man and environment not applicable
Classification system
 The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data
NFPA ratings (scale 0-4)
 Health = 0
 Fire = 0
 Reactivity = 0

4. First Aid Measures

- **General Information** No special measures required
- **After inhalation** Supply fresh air; consult doctor in case of complaints
- **After skin contact** Immediately wash with water and soap and rinse thoroughly
- **After eye contact** Rinse opened eye for several minutes under running water
- **After swallowing** Induce vomiting and call for medical help



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 3 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Negative Control, cont.

5. Fire Fighting Measures

- **Suitable extinguishing agents** Use fire fighting measures that suit the environment
- **Protect equipment:** No special measures required

6. Accidental release measures

- **Person-related safety precautions:** Handle as potentially infectious
- **Measures for environment protection:** Prevent seepage into sewage system, workpits, and cellars.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
Disinfectant

Additional information: No dangerous substances are released

7. Handling and storage

- **Handling**
- **Information for safe handling :** No special precautions are necessary if used correctly
- **Information about protection against explosions and fires:** No special measures required
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:** None

8. Exposure controls and personal protection

Additional information about design of technical systems: No further data; see item 7

- **Components with limit cause that require monitoring at the workplace**

56-81-5	Glycerol
PEL (United States)	15* 5** mg / m ³ * Total dust ** Respirable fraction

- **Additional information:** The lists that were valid during the creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** Follow the usual biosafety practices for handling infectious materials
- **Breathing equipment:** Not required
- **Protection of hands:** Protective gloves
- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Goggles recommended during refilling

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 4 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Negative Control, cont.**9. Physical and Chemical Properties****General information:**

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Odorless

Change in condition:

- **Melting point / Melting range:** Undetermined
- **Boiling point / Boiling range:** Undetermined
- **Flash point:** > 100° C
- **Auto Igniting:** Product is not self-igniting
- **Danger of explosion:** Product does not present an explosion hazard
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **Solvent Content:**
- **Organic solvents:** 20-30%
- **Water:** 20-30%

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
- **Primary irritant effect on the eye:** No irritant effect
- **Sensitization:** No sensitizing effects known
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU 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**
- **Recommendation:** Can be disposed of with household garbage with prior chemical-physical or biological treatment following consultation with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations
- **Recommended cleansing agent:** Water (if necessary with cleansing agents)



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 5 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Negative Control, cont.

14. Transport information

- **DOT regulations**
Hazard class
- **Land / transport ADR / RID (cross border)**
ADR / RID class
- **Maritime transport IMDG:**
IMDG class
- **Air transport ICAO-TI and IATA-DGR**
ICAO / IATA Class
- **Transport / Additional information:** *Not dangerous according to the above specifications*

15. Regulations

SARA (superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** *None of the ingredients are listed*
- **Section 313 (40CFR372.65):** *None of the ingredients are listed*
- **TSCA (Toxic Substances Control Act):**
56-81-5 *glycerol*
7732-18-5 *water*
7647-14-5 *sodium chloride*
7558-79-4 *disodium hydrogenorthophosphate*

Carcinogenicity categories:

- **IARC (International Agency for Research on Cancer):** *None of the ingredients are listed*
- **NTP (National Toxicology Program):** *None of the ingredients are listed*
- **OSHA-Ca (Occupational Safety & Health Administration):** *None of the ingredients are listed*

Markings according to EU guidelines:

- *Observe the general safety regulations when handling chemicals*
- *The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV)*
- **National Regulations:**
Class: NK
Share in %: 20-35%
- **Water hazard class:** *Generally not hazardous for water*

16. Other information:

- *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.*
- **Department issuing MSDS:** *Environmental Health and Safety*

Contact:

*Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 741-1000
Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 724-7000*



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 6 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Conjugate

1. Identification of Substance

Product details

- **Trade name:** Conjugate
- **Catalog or product number:** 220HR
- **Application of the substance / the preparation :** *In-vitro laboratory or reagent or component*

SUPPLIER:

Name: Trinity Biotech USA
Address: 2823 Girts Rd.
Jamestown, NY 14701
USA
Phone number: 1 (716) 483-3851
Fax number: 1 (716) 488-1990
Emergency phone number: Contact national poisons unit.
Ireland 01- 837 9964
Belgium (+31) 30 2748888
France (+331).40.37.04.04
USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization

CAS No. Description: *Stabilzyme Select HRP Conjugate Stabilizer
(Proprietary aqueous, protein-containing mixture preserved with 0.02%
Methylisothiazalone, 0.02% bromonitrodioxane, and 20 ppm Proclin 300)*


- **Additional information:** *Contains added constituents of animal origin*

3. Hazards identification

- **Information pertaining to particular dangers for man and environment:** *Not applicable*
- **Classification system**
The classification was made according to OSHA 29CFR 1910.1030, and is expanded upon from company and /or literature information.
- **NFPA ratings (scale 0-4)**
*Health = 1
Fire = 0
Reactivity = 0*

4. First Aid Measures

- **General Information** *No special measures required*
- **After inhalation** *Supply fresh air; consult doctor in case of complaints*
- **After skin contact** *Immediately wash with water and soap and rinse thoroughly*
- **After eye contact** *Rinse opened eye for several minutes under running water*
- **After swallowing** *Induce vomiting and call for medical help*

 TRINITY BIOTECH USA	MSDS	
	NAME OF PRODUCT: ANA Screen TEST KIT Product Code: 2339000 MSDS Number: 9000-MS Page 7 of 34	
MATERIAL SAFETY DATA SHEET	Effective date: Jan 2008	Revision B

Trade name: Conjugate, cont.

5. Fire Fighting Measures

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

6. Accidental release measures

- **Person-related safety precautions:** Not required
- **Measures for environment protection:** Prevent seepage into sewage system, workpits, and cellars.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
Disinfectant

Additional information: No dangerous substances are released

7. Handling and storage

- **Handling**
- **Information for safe handling :** No special precautions are necessary if used correctly
- **Information about protection against explosions and fires:** No special measures required
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:** None

8. Exposure controls and personal protection

Additional information about design of technical systems: No further data; see item 7

- **Components with limit values that require monitoring at the workplace:**

56-81-5	Glycerol
PEL (United States)	15* 5** mg / m ³ * Total dust ** Respirable fraction

- **Additional information:** The lists that were valid during the creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** Follow the usual precautionary measures for handling chemicals
- **Breathing equipment:** Not required
- **Protection of hands:** Protective gloves
- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Goggles recommended during refilling, safety glasses



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 8 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Conjugate, cont.

9. Physical and Chemical Properties

General information:

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Odorless

Change in condition:

- **Melting point / Melting range:** Undetermined
- **Boiling point / Boiling range:** 100° C
Not applicable
- **Flash point:**
- **Auto Igniting:** Product is not self-igniting
- **Danger of explosion:** Product does not present an explosion hazard
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **pH value at 20° C** 5.0-8.0

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
- **Primary irritant effect on the eye:** No irritant effect
- **Sensitization:** No sensitizing effects known
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU 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**
- **Recommendation:** Can be disposed of with household garbage with prior chemical-physical or biological treatment following consultation with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations
- **Recommended cleansing agent:** Water (if necessary with cleansing agents)



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 9 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Conjugate, cont.

14. Transport information

- **DOT regulations**
Hazard class
- **Land / transport ADR / RID (cross border)**
ADR / RID class
- **Maritime transport IMDG:**
IMDG class
- **Air transport ICAO-TI and IATA-DGR**
ICAO / IATA Class
- **Transport / Additional information:** *Not dangerous according to the above specifications*

15. Regulations

SARA (Superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** *Substance is not listed*
- **Section 313 (40CFR372.65):** *Substance is not listed*
- **TSCA (Toxic Substances Control Act):**
56-81-5 glycerol
7732-18-5 water

Carcinogenicity categories:

- **IARC (International Agency for Research on Cancer):** *Substance is not listed*
- **NTP (National Toxicology Program):** *Substance is not listed*
- **OSHA-Ca (Occupational Safety & Health Administration):** *Substance is not listed*

Markings according to EU guidelines:

- *Observe the general safety regulations when handling chemicals*
- *The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV)*
- **National Regulations:**
- **Water hazard class:** *Generally not hazardous for water*

16. Other information:

- *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.*
- **Department issuing MSDS:** *Environmental Health and Safety*

Contact:

*Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 741-1000*

*Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 724-7000*



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 10 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Stop Solution

1. Identification of Substance

Product details

- **Trade name: Stop Solution**
- **Catalog or product number: 220SM**
- **Application of the substance / the preparation : In-vitro laboratory or reagent or component**

SUPPLIER:

Name: Trinity Biotech USA
Address: 2823 Girts Rd.
Jamestown, NY 14701
USA
Phone number: 1 (716) 483-3851
Fax number: 1 (716) 488-1990
Emergency phone number: Contact national poisons unit.
Ireland 01- 837 9964
Belgium (+31) 30 2748888
France (+331).40.37.04.04
USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization

- **CAS No. Description:** 7732-18-5 water
- **Identification number(s):**
EINECS Number: 231-791-2

Chemical Characterization

Listing of dangerous and non-hazardous components:

Sulfuric Acid

CAS	7664-93-9	C: R35	1.0 – 2.5%
EINECS	231-639-5		
RTECS	WS 5600000		

3. Hazards identification

- **Information pertaining to particular dangers for man and environment:** Not applicable
- **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0

4. First Aid Measures

- **General Information:** Immediately remove any clothing soiled by the product
- **After inhalation:** Seek immediate medical advice
- **After skin contact;** Immediately rinse with water
- **After eye contact:** Rinse opened eye for several minutes under running water, then consult a doctor
- **After swallowing** Rinse mouth with water. Seek medical attention



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 11 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Stop Solution, cont.

5. Fire Fighting Measures

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

6. Accidental release measures

- **Person-related safety precautions:** Wear protective equipment (See section 8) Keep unprotected persons away
- **Measures for environment protection:** Do not allow to enter sewers, surface, or ground water
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
Use neutralizing agent
Dispose contaminated material as waste according to item 13

7. Handling and storage

- **Handling**
- **Information for safe handling :** No special precautions are necessary if used correctly
- **Information about protection against explosions and fires:** No special measures required
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:** Keep receptacle tightly sealed

8. Exposure controls and personal protection

Additional information about design of technical systems: No further data; see item 7

- **Components with limit values that require monitoring at the workplace:**

7647-01-0 Hydrochloric acid

PEL (United States)	Short term value: C 7 mg/m ³ , C 5 ppm
REL (United States)	Short term value: C 7 mg/m ³ , C 5 ppm
TLV (United States)	Short term value: C 7 mg/m ³ , C 5 ppm NIC-C 2; C 2, 98: NIC-A4

- **Additional information:** The lists that were valid during the creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** Follow the usual precautionary measures for handling chemicals. Avoid contact with the eyes and skin. Immediately remove all soiled and contaminated clothing
- **Breathing equipment:** Not required
- **Protection of hands:** Protective gloves
- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Tightly sealed goggles

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 12 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Stop Solution, cont.**9. Physical and Chemical Properties****General information:**

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Odorless

Change in condition:

- **Melting point / Melting range:** 0°C
- **Boiling point / Boiling range:** 100° C
Not applicable
- **Flash point:**
- **Danger of explosion:** Product does not present an explosion hazard
- **Vapor pressure at 20°C** 23 hPa
- **Density at 20°C:** 1 g/cm³
- **Solubility in / Miscibility with Water:** Fully miscible
- **pH value at 20° C** < 2..5
- **Organic solvents:** 0.0%
- **Water:** 50-100%

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
- **Primary irritant effect on the eye:** No irritant effect
- **Sensitization:** No sensitizing effects known

12. Ecological information

- **General notes:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system

13. Disposal considerations

- **Product**
- **Recommendation:** Hand over to hazardous waste disposers
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 13 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Stop Solution, cont.

14. Transport information

- **DOT regulations**
Hazard class
- **Land / transport ADR / RID (cross border)**
ADR / RID class
- **Maritime transport IMDG:**
IMDG class
- **Air transport ICAO-TI and IATA-DGR**
ICAO / IATA Class
- **Transport / Additional information:** *Not dangerous according to the above specifications*

15. Regulations

SARA (Superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** 7647-01-0 Hydrochloric Acid
7664-93-9 Sulphuric Acid
- **Section 313 (40CFR372.65):** 7647-01-0 Hydrochloric Acid
7664-93-9 Sulphuric Acid
- **TSCA (Toxic Substances Control Act):** *Substance is listed*

Carcinogeny categories:

- **IARC (International Agency for Research on Cancer):** 7647-01-0 Hydrochloric Acid 3
7664-93-9 Sulphuric Acid 1
- **NTP (National Toxicology Program):** *Substance is not listed*
- **OSHA-Ca (Occupational Safety & Health Administration):** *Substance is not listed*

Markings according to EU guidelines:

- *The product has been classified and marked in accordance with EU directives / Ordinance on Hazardous Materials*
- **National Regulations:**
- **Water hazard class:** *Water hazard class 1 (Self-assessment): Slightly hazardous for water*

16. Other information:

- *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.*
- **Department issuing MSDS:** *Environmental Health and Safety*

Contact:

*Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 741-1000*

*Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 724-7000*



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 14 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Substrate

1. Identification of Substance

Product details

- **Trade name:** Substrate
- **Catalog or product number:** 220TM
- **Application of the substance / the preparation :** *In-vitro laboratory or reagent or component*

SUPPLIER:

Name: Trinity Biotech USA
Address: 2823 Girts Rd.
Jamestown, NY 14701
USA
Phone number: 1 (716) 483-3851
Fax number: 1 (716) 488-1990
Emergency phone number: Contact national poisons unit.
Ireland 01- 837 9964
Belgium (+31) 30 2748888
France (+331).40.37.04.04
USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization

- **Description:** *Mixture of the substances listed below with non-hazardous additions*
Listing of dangerous and non-hazardous components:

Water

CAS	7732-18-5		50-100%
EINECS	231-791-2		
RTECS	ZC 0110000		

Methanol

CAS	67-56-1	T.F: R11-23/24/25-39/23/24/25	10-20%
EINECS	200-659-6		
RTECS	PC 1400000		

Acetone

CAS	67-64-1	Xi, F, R11-36-66-67	5-10%
EINECS	200-662-2		
RTECS	AL 3150000		

Dimethyl Sulfoxide

CAS	67-68-5		2.5 -5%
EINECS	200-664-3		
RTECS	PV 6210000		

3,3',5,5' tetramethylbenzidine

CAS	54827-17-7	T: R23/24/25	0.01-0.1%
EINECS	259-364-6		



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 15 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Substrate, cont.

3. Hazards identification

- **Information pertaining to particular dangers for man and environment:** Not applicable
- **NFPA ratings (scale 0-4)**
Health = 0
Fire = 2
Reactivity = 0

4. First Aid Measure

- **General Information:** Immediately remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest, provide artificial respiration
- **After inhalation:** Supply fresh air or oxygen; call for doctor
- **After skin contact:** Immediately rinse with water and soap and rinse thoroughly
- **After eye contact:** Rinse opened eye for several minutes under running water, then consult a doctor
- **After swallowing:** Rinse mouth with water. Seek medical attention.

5. Fire Fighting Measures

- **Suitable extinguishing agents:** CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protect equipment:** Wear self-contained respiratory protective device

6. Accidental release measures

- **Person-related safety precautions:** Wear protective equipment (See section 8) Keep unprotected persons away
- **Measures for environment protection:** Prevent seepage into sewage system, workpits, and cellars. Do not allow to enter sewers, surface, or ground water
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
Ensure adequate ventilation
Dispose contaminated material as waste according to item 13

7. Handling and storage

- **Handling**
- **Information for safe handling :** Ensure good ventilation/exhaustion at the workplace
No special precautions are necessary if used correctly
- **Information about protection against explosions and fires:** Protect from heat
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:** Keep receptacle tightly sealed. Store in cool, dry conditions in well sealed receptacles



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 16 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Substrate, cont.

8. Exposure controls and personal protection

Additional information about design of technical systems: No further data; see item 7

- **Components with limit values that require monitoring at the workplace:**

67-56-1 Methanol

PEL (United States)	260 mg/m ³ , 200 ppm
REL (United States)	Short term value: 325 mg/m ³ , 250 ppm Long term value: 260 mg/m ³ , 200 ppm Skin
TLV (United States)	Short term value: 328 mg/m ³ , 250 ppm Long term value: 262 mg/m ³ , 200 ppm Skin, BEI

67-64-1 Acetone

PEL (United States)	2400 mg/m ³ , 1000 ppm
REL (United States)	590 mg/m ³ , 250 ppm
TLV (United States)	Short term value: 1792 mg/m ³ , 750 ppm Long term value: 1188 mg/m ³ , 500 ppm BEI

7722-84-1 Hydrogen Peroxide Solution

PEL (United States)	1.4 mg/m ³ , 1 ppm
REL (United States)	1.4 mg/m ³ , 1 ppm
TLV (United States)	1.4 mg/m ³ , 1 ppm

- **Additional information:** The lists that were valid during the creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** Keep away from foodstuffs, beverages, and feed. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin
- **Breathing equipment:** In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure, use respiratory device that is independent of circulating air

Protection of hands: Protective gloves

- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Tightly sealed goggles



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 17 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Substrate, cont.

9. Physical and Chemical Properties

General information:

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Like alcohol
- **Melting point / Melting range:** Undetermined
- **Boiling point / Boiling range:** Undetermined
- **Flash point:** >70°C
- **Auto igniting:** Product is not self-igniting,
- **Danger of explosion:** Product is not explosive, however, formation of explosive air / vapor mixtures are possible.
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **Organic solvents:** 10-25%
- **Water:** 75-100%

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**
LD/LC50 values for hazardous component per OSHA criteria:

67-56-1 Methanol

Oral	LD50	5628 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rat)

67-64-1 Acetone

Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rat)

67-68-5 Dimethyl Sulfoxide

Oral	LD50	14500 mg/kg (rat)
------	------	-------------------

- **Primary irritant effect on the skin:** Irritant to skin and mucous membranes
- **Primary irritant effect on the eye:** Irritant effect
- **Sensitization:** No sensitizing effects known
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 18 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Substrate, cont.

12. Ecological information

- **General notes:** Water hazard class 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course, or sewage system
Danger to drinking water if even small quantities leak into the ground

13. Disposal considerations

- **Product**
- **Recommendation:** Dispose of waste in accordance to applicable national, regional, or local regulations
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations

14. Transport information

- **DOT regulations**
Hazard class
- **Land / transport ADR / RID (cross border)**
ADR / RID class
- **Maritime transport IMDG:**
IMDG class
- **Air transport ICAO-TI and IATA-DGR**
ICAO / IATA Class
- **Transport / Additional information:** Not dangerous according to the above specifications

15. Regulations

SARA (Superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** None of the ingredients are listed
- **Section 313 (40CFR372.65):** 67-56-1 Methanol
- **TSCA (Toxic Substances Control Act):** All ingredients are listed

Carcinogenicity categories:

- **IARC (International Agency for Research on Cancer):**
7722-84-1 Hydrogen peroxide solution 3
- **NTP (National Toxicology Program):** None of the ingredients are listed
- **OSHA-Ca (Occupational Safety & Health Administration):** None of the ingredients are listed

Markings according to EU guidelines:

- Observe the general safety regulations when handling chemicals
- The product has been classified and marked in accordance with EU directives and the Ordinance on Hazardous Materials (GefStoffV)
- **National Regulations:**
Class III Share in % - 2.5-5%
- **Water hazard class:** Water hazard class 2 (Self-assessment): Hazardous for water



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 19 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Substrate, cont.

16. Other information:

- *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.*
- **Department issuing MSDS:** Environmental Health and Safety

Contact:

*Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 741-1000*

*Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 724-7000*



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 20 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Sample Diluent

1. Identification of Substance

Product details

- Trade name: Sample Diluent
- Catalog or product number: 230AD
- Application of the substance / the preparation : In-vitro laboratory or reagent or component

SUPPLIER:

Name: Trinity Biotech USA
 Address: 2823 Girts Rd.
 Jamestown, NY 14701
 USA
 Phone number: 1 (716) 483-3851
 Fax number: 1 (716) 488-1990
 Emergency phone number: Contact national poisons unit.
 Ireland 01- 837 9964
 Belgium (+31) 30 2748888
 France (+331).40.37.04.04
 USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization:

CAS no. Description: 7732-18-5 water

Identification Number: EINECS Number: 231-791-2

- Description: Mixture of the substances listed below with non-hazardous additions

Listing of dangerous and non-hazardous components:

Water

CAS	7732-18-5	50-100%
EINECS	231-791-2	
RTECS	ZC 0110000	

Goat Serum

	2.5-5%
--	--------

Sodium Chloride

CAS	7647-14-5	Xi; R 36/38	1.0-2.5%
EINECS	231-598-3		

- Additional information: Contains added constituents of animal origin



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 21 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Sample Diluent , cont.

3. Hazards identification

- **Information pertaining to particular dangers for man and environment:**
The product does not have to be labeled due to the calculation procedure of the "General Classification" guideline for preparations of the EU in the latest valid version
- **Classification system**
The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data
- **NFPA ratings (scale 0-4)**
*Health = 0
Fire = 0
Reactivity = 0*

4. First Aid Measure

General Information: *No special measures required*

- **After inhalation:** *Supply fresh air or oxygen; consult doctor in case of complaints*
- **After skin contact:** *Immediately rinse with water and soap and rinse thoroughly*
- **After eye contact:** *Rinse opened eye for several minutes under running water*
- **After swallowing** *induce vomiting and call for medical help*

5. Fire Fighting Measures

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

6. Accidental release measures

- **Person-related safety precautions:** *Not required*
- **Measures for environment protection:** *Prevent seepage into sewage system, workpits, and cellars*
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
- **Additional information:** *No dangerous substances are released*

7. Handling and storage

- **Handling**
- **Information for safe handling :** *No special precautions are necessary if used correctly*
- **Information about protection against explosions and fires:** *No special measures required*
- **Storage**
- **Requirements to be met by storerooms and receptacles:** *No special measures required*
- **Information about storage in one common storage facility:** *Not required*
- **Further information about storage conditions:** *None*



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 22 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Sample Diluent, cont.

8. Exposure controls and personal protection

Additional information about design of technical systems: No further data; see item 7

- Components with limit values that require monitoring at the workplace:

26628-22-8 Sodium Azide

REL (United States)	Short term value: C 0.3**mg/m ³ , C 0.1* ppm * as HN3 vapor; **as NaN3
TLV (United States)	Short term value: C 0.3** mg/m ³ , C 0.1* ppm * as HN3 vapor; **as NaN3

- **Additional information:** The lists that were valid during the creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** The usual precautionary measures for handling chemicals should be followed
- **Breathing equipment:** Not required
- **Protection of hands:** Protective gloves-The glove material has to be impermeable and resistant to the product/the substance/the preparation
- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Goggles recommended during refilling, Safety glassed

9. Physical and Chemical Properties

General information:

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Odorless

Change in condition:

- **Melting point / Melting range:** Undetermined
- **Boiling point / Boiling range:** 100°
- **Flash point:** Not applicable
- **Auto igniting:** Product is not self-igniting
- **Danger of explosion:** Product does not present an explosion hazard
- **Vapor pressure at 20°C:** 23 hPa
- **Density at 20°C:** 1,002 g/cm³
- **Solubility in / Miscibility with Water:** Fully miscible
- **pH value at 20°C:** 5.0-8.0
- **Organic solvents:** 0-0%
- **Water:** 50-100%

10. Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications
- **Dangerous reactions:** This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
- **Dangerous products of decomposition:** No dangerous decomposition products known



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 23 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Sample Diluent, cont.

11. Toxicological information

- **Acute toxicity**
- **Primary irritant effect on the skin:** No irritant effect
- **Primary irritant effect on the eye:** No irritant effect
- **Sensitization:** No sensitizing effects known
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU 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.
- **Target organs:** Not applicable

12. Ecological information

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

13. Disposal considerations

- **Product**
- **Recommendation:** Dispose of waste in accordance to applicable national, regional, or local regulations. Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations
- **Recommended cleansing agent:** Water, if necessary with cleaning agents

14. Transport information

- **Transport / Additional information:** Not dangerous according to the above specifications

15. Regulations

SARA (Superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** None of the ingredients are listed
- **Section 313 (40CFR372.65):** None of the ingredients are listed
- **TSCA (Toxic Substances Control Act):**
7732-18-5 Water
7647-14-5 Sodium Chloride
26628-22-8 Sodium Azide
7558-79-4 Disodium Hydrogenorthophosphate
9000-70-8 Gelatins
7558-80-7 Sodium Dihydrogen phosphate

Carcinogenicity categories:

- **IARC (International Agency for Research on Cancer):** None of the ingredients are listed
- **NTP (National Toxicology Program):** None of the ingredients are listed
- **OSHA-Ca (Occupational Safety & Health Administration):** None of the ingredients are listed

Markings according to EU guidelines:

- The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV)
Observe the general safety regulations when handling chemicals
- **National Regulations:**
- **Water hazard class:** Generally not hazardous for water



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 24 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Sample Diluent, cont.

16. Other information:

- *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.*
- **Department issuing MSDS:** *Environmental Health and Safety*

Contact:

*Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 741-1000*

*Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 724-7000*



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 25 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Wash Buffer

1. Identification of Substance

Product details

- Trade name: **Wash Buffer**
- Catalog or product number: 230AW
- Application of the substance / the preparation : In-vitro laboratory or reagent or component

SUPPLIER:

Name: Trinity Biotech USA
 Address: 2823 Girts Rd.
 Jamestown, NY 14701
 USA
 Phone number: 1 (716) 483-3851
 Fax number: 1 (716) 488-1990
 Emergency phone number: Contact national poisons unit.
 Ireland 01- 837 9964
 Belgium (+31) 30 2748888
 France (+331).40.37.04.04
 USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization

- CAS no. Description: 7332-18-5 Water
- Identification number: EINECS 231-791-2
- Description: Mixture of the substances listed below with non-hazardous additions

Listing of dangerous and non-hazardous components:

Water

CAS	7732-18-5	50-100%
EINECS	231-791-2	
RTECS	ZC 0110000	

Sodium Chloride

CAS	7647-14-5	Xi, R 36/38	10-20%
EINECS	231-598-3		

Disodium hydrogenorthophosphate

CAS	7558-79-4	Xn: R 20/21	1.0-2.5%
EINECS	231-448-7		
RTECS	WC 4500000		

Tween 20

CAS	9005-64-5	0.1-2.5%
RTECS	WG 2931000	



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 26 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Wash Buffer, cont.

3. Hazards identification

- **Information pertaining to particular dangers for man and environment:** The product does not have to be labeled due to the calculation procedure of the "General Classification" guideline for preparations of the EU in the latest version
- **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0

4. First Aid Measure

- **General Information:** No special measures required
- **After inhalation:** Supply fresh air; consult doctor in case of complaints
- **After skin contact;** Immediately rinse with water and soap and rinse thoroughly
- **After eye contact:** Rinse opened eye for several minutes under running water
- **After swallowing** Induce vomiting and call for medical help

5. Fire Fighting Measures

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

6. Accidental release measures

- **Person-related safety precautions:** Not required
- **Measures for environment protection:** Prevent seepage into sewage system, workpits, and cellars
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
- **Additional information:** No dangerous substances are released

7. Handling and storage

- **Handling**
- **Information for safe handling:** No special precautions are necessary if used correctly
- **Information about protection against explosions and fires:** No special measures required
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special measures required
Information about storage in one common storage facility: Not required
- **Further information about storage conditions:** None



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 27 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Wash Buffer, cont.

8. Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7
- **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 creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required
- **Protection of hands:** Protective gloves, the glove material has to be impermeable and resistant to the product/the substance/the preparation.
- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Eye goggles recommended during refilling, safety glasses

9. Physical and Chemical Properties

General information:

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Odorless
- **Melting point / Melting range:** Undetermined
- **Boiling point / Boiling range:** Undetermined
- **Flash point:** Not applicable
- **Auto igniting:** Product is not self-igniting
- **Danger of explosion:** Product does not present an explosion hazard
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **pH value at 20°C:** 5.0-8.0
- **Organic solvents:** 0-0%
- **Water:** 50-100%

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



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 28 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: Wash Buffer, cont.

11. Toxicological information

- **Acute toxicity**
- **Primary irritant effect on the skin:** No irritant effect
- **Primary irritant effect on the eye:** No irritant effect
- **Sensitization:** No sensitizing effects known
- **Additional toxicological information:**
*The product is not subject to classification according to the calculation method of the General EU 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.*
- **Target organs:** Not applicable

12. Ecological information


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

13. Disposal considerations

- **Product**
- **Recommendation:** Dispose of waste in accordance to applicable national, regional, or local regulations
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations
- **Recommended cleansing agent:** Water, if necessary with cleansing agents

14. Transport information

- **DOT regulations**
Hazard class
- **Land / transport ADR / RID (cross border)**
ADR / RID class
- **Maritime transport IMDG:**
IMDG class
- **Air transport ICAO-TI and IATA-DGR**
ICAO / IATA Class
- **Transport / Additional information:** Not dangerous according to the above specifications

 <p>TRINITY BIOTECH USA</p>	<p style="text-align: right;">MSDS</p> <p>NAME OF PRODUCT: ANA Screen TEST KIT Product Code: 2339000</p> <p>MSDS Number: 9000-MS</p> <p>Page 29 of 34</p>
<p>MATERIAL SAFETY DATA SHEET</p>	<p>Effective date: Jan 2008 Revision B</p>

Trade name: Wash Buffer, cont.

15. Regulations

SARA (Superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** None of the ingredients are listed
- **Section 313 (40CFR372.65):** None of the ingredients are listed
- **TSCA (Toxic Substances Control Act):** All ingredients are listed

Carcinogenity categories:

- **IARC (International Agency for Research on Cancer):** None of the ingredients are listed
- **NTP (National Toxicology Program):** None of the ingredients are listed
- **OSHA-Ca (Occupational Safety & Health Administration):** None of the ingredients are listed

Markings according to EU guidelines:

- Observe the general safety regulations when handling chemicals
- The product is not subject to identification regulations under EU directives and the Ordinance on Hazardous Materials (GefStoffV)
- **National Regulations:**
- **Water hazard class:** Generally not hazardous for water

16. Other information:

- 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.
- **Department issuing MSDS:** Environmental Health and Safety

Contact:

Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive, Hercules, California, 94547 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive, Hercules, California, 94547 1(510) 724-7000



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 30 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: ANA Screen Test Positive Control, Calibrator

1. Identification of Substance

Product details:

Trade name: ANA Screen Test Positive Control, Calibrator

Catalog or product number: 200AN, 210AN

SUPPLIER:

Name: Trinity Biotech USA

Address: 2823 Girts Rd.
Jamestown, NY 14701
USA

Phone number: 1 (716) 483-3851

Fax number: 1 (716) 488-1990

Emergency phone number: Contact national poisons unit.

Ireland 01- 837 9964

Belgium (+31) 30 2748888

France (+331).40.37.04.04

USA 1 (800) 603 8076

2. Composition Information on Components

Chemical Characterization

- Description:** Mixture of the substances listed below with non-hazardous additions

Listing of dangerous and non-hazardous components:

Water

CAS	7732-18-5	35-50%
EINECS	231-791-2	
RTECS	ZC 0110000	

Glycerol

CAS	56-81-5	50-100%
EINECS	200-289-5	
RTECS	MA 8050000	

Human Source Material

EINECS	268-338-3	2.5-5%
--------	-----------	--------

Goat Serum	2.5-5%
-------------------	--------

- Additional information:**

Contains human sourced and/or potentially infectious components

Contains added constituents of animal origin



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 31 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: ANA Screen Test Positive Control, Calibrator, cont.

3. Hazards identification

- **Information pertaining to particular dangers for man and environment:** *The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data*
- **NFPA ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0

4. First Aid Measure

- **General Information:** *No special measures required*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints*
- **After skin contact;** *Immediately rinse with water and soap and rinse thoroughly*
- **After eye contact:** *Rinse opened eye for several minutes under running water*
- **After swallowing** *Induce vomiting and call for medical help*

5. Fire Fighting Measures


- **Suitable extinguishing agents:** *Use fire fighting measures that suit the environment.*
- **Protect equipment:** *No special measures required*

6. Accidental release measures

- **Person-related safety precautions:** *Handle as potentially infectious*
- **Measures for environment protection:** *Prevent seepage into sewage system, workpits, and cellars*
- **Measures for cleaning/collecting:**
Disinfectant
Absorb with liquid-binding material (sand diatomite, acid binders, universal binders, sawdust)
- **Additional information:** *No dangerous substances are released*

7. Handling and storage

- **Handling**
- **Information for safe handling:** *No special precautions are necessary if used correctly*
- **Information about protection against explosions and fires:** *No special measures required*
- **Storage**
- **Requirements to be met by storerooms and receptacles:** *No special measures required*
- **Information about storage in one common storage facility:** *Not required*
- **Further information about storage conditions:** *None*

 TRINITY BIOTECH USA	MSDS	
	NAME OF PRODUCT: ANA Screen TEST KIT Product Code: 2339000 MSDS Number: 9000-MS Page 32 of 34	
MATERIAL SAFETY DATA SHEET	Effective date: Jan 2008	Revision B

Trade name: ANA Screen Test Positive Control, Calibrator, cont.

8. Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7
- **Components with limit values that require monitoring at the workplace:**

56-81-5 Glycerol

PEL (United States)	15*, 5** mg/m ³ *Total dust ** Respirable fractions
---------------------	---

26628-22-8 Sodium Azide

REL (United States)	Short term value: C 0.3** mg/m ³ , C 0.1* ppm *as HN3 vapor; **as NaN3
TLV (United States)	Short term value: C 0.3** mg/m ³ , C 0.1* ppm *as HN3 vapor; **as NaN3

- **Additional information:** The lists that were valid during the creation were used as basis
- **Personal protection equipment**
- **General protective and hygienic measures:** The usual biosafety measures for handling infectious materials.
- **Breathing equipment:** Not required
- **Protection of hands:** Protective gloves, the glove material has to be impermeable and resistant to the product/the substance/the preparation.
- **Material of gloves:** Synthetic
- **Penetration time of glove material:** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed
- **Eye protection:** Eye goggles recommended during refilling, safety glasses

9. Physical and Chemical Properties

General information:

- **Form:** Liquid
- **Color:** Whitish
- **Odor:** Odorless
- **Melting point / Melting range:** Undetermined
- **Boiling point / Boiling range:** Undetermined
- **Flash point:** Not applicable
- **Auto igniting:** Product is not self-igniting
- **Danger of explosion:** Product does not present an explosion hazard
- **Density:** Not determined
- **Solubility in / Miscibility with Water:** Fully miscible
- **Water:** 35-50%

10. Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications
- **Dangerous reactions:** This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
- **Dangerous products of decomposition:** No dangerous decomposition products known



TRINITY BIOTECH USA

MSDS

NAME OF PRODUCT:

ANA Screen TEST KIT
Product Code: 2339000

MSDS Number: 9000-MS

Page 33 of 34

MATERIAL SAFETY DATA SHEET

Effective date: Jan 2008

Revision B

Trade name: ANA Screen Test Positive Control, Calibrator, cont.

11. Toxicological information

- **Acute toxicity**
- **Primary irritant effect on the skin:** No irritant effect
- **Primary irritant effect on the eye:** No irritant effect
- **Sensitization:** No sensitizing effects known
- **Additional toxicological information:**
*The product is not subject to classification according to the calculation method of the General EU 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**
- **Recommendation:** Can be disposed of with household garbage with proper chemical-physical or biological treatment following consultation with the waste disposal facility and the pertinent authorities and adhering to the necessary technical regulations
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations

14. Transport information

- **DOT regulations**
Hazard class
- **Land / transport ADR / RID (cross border)**
ADR / RID class
- **Maritime transport IMDG:**
IMDG class
- **Air transport ICAO-TI and IATA-DGR**
ICAO / IATA Class
- **Transport / Additional information:** Not dangerous according to the above specifications

 <p>TRINITY BIOTECH USA</p>	<p style="text-align: right;">MSDS</p> <p>NAME OF PRODUCT: ANA Screen TEST KIT Product Code: 2339000</p> <p>MSDS Number: 9000-MS</p> <p>Page 34 of 34</p>
<p>MATERIAL SAFETY DATA SHEET</p>	<p>Effective date: Jan 2008 Revision B</p>

Trade name: ANA Screen Test Positive Control, Calibrator, cont.

15. Regulations

SARA (Superfund Amendments and Reauthorization Act of 1986-USA)

- **Section 302 / 304 (40CFR355.30 / 40CFR355.40):** None of the ingredients are listed
- **Section 313 (40CFR372.65):** None of the ingredients are listed
- **TSCA (Toxic Substances Control Act):**
 - 56-81-5 Glycerol
 - 7732-18-5 Water
 - 7647-14-5 Sodium Chloride
 - 26628-22-8 Sodium Azide
 - 7558-79-4 Disodium Hydrogenorthophosphate

Carcinogeny categories:

- **IARC (International Agency for Research on Cancer):** None of the ingredients are listed
- **NTP (National Toxicology Program):** None of the ingredients are listed
- **OSHA-Ca (Occupational Safety & Health Administration):** None of the ingredients are listed

Markings according to EU guidelines:

- Observe the general safety regulations when handling chemicals
- The product is not subject to identification regulations under EU directives and the Ordinance on Hazardous Materials (GefStoffV)
- **National Regulations:**
 - Class NK
 - Share in % 35-50%
- **Water hazard class:** Generally not hazardous for water

16. Other information:

- 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.
- **Department issuing MSDS:** Environmental Health and Safety

Contact:

Life Science Group, Environmental Health and Safety, 2000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Noble Drive,
Hercules, California, 94547 1(510) 724-7000