

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product Form: Mixture

Product Name: Positive Control

Product Code: P00347, P30C, P30C-CE

Intended Use of the Product

The Platelet PGD Test is a rapid, qualitative immunoassay that detects the presence of bacteria in platelets for transfusion.

Name, Address, and Telephone of the Responsible Party

Verax Biomedical Incorporated

148 Bartlett Street

Marlborough, MA 01752

1-866-948-3729

www.fenwalinc.com

EHS@fenwalinc.com

Emergency Telephone Number

Emergency number :1-760-476-9362

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

Label Elements

GHS-US Labeling

Not classified

Other Hazards Not available

Unknown Acute Toxicity (GHS-US): Not available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Water	(CAS No) 7732-18-5	80 - 90	Not classified
Human Platelet Lysate	-	7 - 13	Not classified
Albumins, blood serum (Human, Rabbit)	(CAS No) 9048-46-8	1 - 5	Not classified
C. minutissimum Lysate	-	0.1 - 1	Not classified
E. coli Lysate	-	0.1 - 1	Not classified
A. baumannii Lysate	-	0.1 - 1	Not classified
Lipoteichoic acid	(CAS No) 56411-57-5	0.1 - 1	Not classified
Sodium azide	(CAS No) 26628-22-8	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 STOT RE 2, H373

Full text of H-phrases: see section 16

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SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Keep at rest and in a position comfortable for breathing. If you feel unwell, seek medical advice.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Wash contaminated clothing before reuse. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persist.

Ingestion: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER/doctor/physician if you feel unwell.

Most Important Symptoms and Effects Both Acute and Delayed

General: Not available

Inhalation: Inhalation is not considered a potential route of exposure.

Skin Contact: Contact during a long period may cause light irritation.

Eye Contact: May cause minor eye irritation.

Ingestion: Abdominal pain.

Chronic Symptoms: Repeated or prolonged skin contact may cause dermatitis and defatting.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable

Explosion Hazard: Product is not explosive.

Reactivity: Stable at ambient temperature and under normal conditions of use.

Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing.

For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Stop release. Ventilate area.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

For Containment: Absorb and/or contain spill with inert material, then place in suitable container.

Methods for Cleaning Up: Clear up spills immediately and dispose of waste safely.

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Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. Do not eat, drink or smoke when using this product.

Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Keep away from heat and direct sunlight. Store in a dry, cool and well-ventilated place.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

Specific End Use(s)

The Platelet PGD Test is a rapid, qualitative immunoassay that detects the presence of bacteria in platelets for transfusion.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Sodium azide (26628-22-8)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	0.29 mg/m ³
USA ACGIH	ACGIH Ceiling (ppm)	0.11 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	0.3 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	0.1 ppm
Alberta	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Alberta	OEL Ceiling (ppm)	0.11 ppm
Alberta	OEL STEL (mg/m ³)	0.3 mg/m ³
British Columbia	OEL Ceiling (mg/m ³)	0.29 mg/m ³
British Columbia	OEL Ceiling (ppm)	0.11 ppm
Manitoba	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Manitoba	OEL Ceiling (ppm)	0.11 ppm
New Brunswick	OEL Ceiling (mg/m ³)	0.29 mg/m ³
New Brunswick	OEL Ceiling (ppm)	0.11 ppm
Newfoundland & Labrador	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Newfoundland & Labrador	OEL Ceiling (ppm)	0.11 ppm
Nova Scotia	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Nova Scotia	OEL Ceiling (ppm)	0.11 ppm
Nunavut	OEL Ceiling (mg/m ³)	0.27 mg/m ³
Nunavut	OEL Ceiling (ppm)	0.1 ppm
Northwest Territories	OEL Ceiling (mg/m ³)	0.27 mg/m ³
Northwest Territories	OEL Ceiling (ppm)	0.1 ppm
Ontario	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Ontario	OEL Ceiling (ppm)	0.11 ppm
Prince Edward Island	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Prince Edward Island	OEL Ceiling (ppm)	0.11 ppm
Québec	PLAFOND (mg/m ³)	0.3 mg/m ³
Québec	PLAFOND (ppm)	0.11 ppm
Saskatchewan	OEL Ceiling (mg/m ³)	0.29 mg/m ³
Saskatchewan	OEL Ceiling (ppm)	0.11 ppm

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Yukon	OEL Ceiling (mg/m ³)	0.3 mg/m ³
Yukon	OEL Ceiling (ppm)	0.1 ppm

Exposure Controls

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment: In case of splash hazard: safety glasses. Gloves. Protective clothing.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use NIOSH-approved air-purifying or supplied-air respirator where airborne concentrations of vapor or mist are expected to exceed exposure limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear to pale yellow liquid
Odor	: Odorless
Odor Threshold	: Not available
pH	: 7.6
Relative Evaporation Rate (butylacetate=1)	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20 °C	: Not available
Relative Density	: Not available
Density	: 0.966 g/cm ³ (at 20°C/68°F)
Specific Gravity	: Not available
Solubility	: Not available
Log Pow	: Not available
Log Kow	: Not available
Viscosity, Kinematic	: Not available
Viscosity, Dynamic	: Not available
Explosion Data – Sensitivity to Mechanical Impact	: Not available
Explosion Data – Sensitivity to Static Discharge	: Not available

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SECTION 10: STABILITY AND REACTIVITY

Reactivity: Stable at ambient temperature and under normal conditions of use.

Chemical Stability: Stable at standard temperature and pressure.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

Hazardous Decomposition Products: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute Toxicity : Not classified

LD50 and LC50 Data Not available

Skin Corrosion/Irritation: Not classified (pH: 7.6).

Serious Eye Damage/Irritation: Not classified (pH: 7.6).

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Inhalation is not considered a potential route of exposure.

Symptoms/Injuries After Skin Contact: Contact during a long period may cause light irritation.

Symptoms/Injuries After Eye Contact : May cause minor eye irritation.

Symptoms/Injuries After Ingestion: Abdominal pain.

Chronic Symptoms: Repeated or prolonged skin contact may cause dermatitis and defatting.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Sodium azide (26628-22-8)	
ATE (oral)	5.000 mg/kg body weight

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Sodium azide (26628-22-8)	
LC50 Fish 1	0.8 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss)
LC 50 Fish 2	0.7 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)

Persistence and Degradability

Positive Control	
Persistence and Degradability	Not established.

Bioaccumulative Potential

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Bioaccumulative Potential	Not established.

Mobility in Soil Not available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

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SECTION 14: TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

Transport by sea Not regulated for transport

Air transport Not regulated for transport

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium azide (26628-22-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on SARA Section 302 (Specific toxic chemical listings)

Listed on SARA Section 313 (Specific toxic chemical listings)

SARA Section 302 Threshold Planning Quantity (TPQ)

500 (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solution form)

SARA Section 313 - Emission Reporting

1.0 %

Albumins, blood serum (9048-46-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations

Sodium azide (26628-22-8)

U.S. - Colorado - Hazardous Wastes - Discarded Chemical Products, Off-Specification Species, Container and Spill Residues

U.S. - Connecticut - Hazardous Air Pollutants - HLVs (30 min)

U.S. - Connecticut - Hazardous Air Pollutants - HLVs (8 hr)

U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities

U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations

U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Emission Levels (ELs)

U.S. - Louisiana - Reportable Quantity List for Pollutants

U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1

U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2

U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity

U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1

U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2

U.S. - Massachusetts - Right To Know List

U.S. - Massachusetts - Toxics Use Reduction Act

U.S. - Michigan - Occupational Exposure Limits - Ceilings

U.S. - Michigan - Occupational Exposure Limits - Skin Designations

U.S. - Michigan - Polluting Materials List

U.S. - Minnesota - Chemicals of High Concern

U.S. - Minnesota - Hazardous Substance List

U.S. - Minnesota - Permissible Exposure Limits - Ceilings

U.S. - Minnesota - Permissible Exposure Limits - Skin Designations

U.S. - Nebraska - "P" Listed Hazardous Wastes

U.S. - New Hampshire - Regulated Toxic Air Pollutants - Ambient Air Levels (AALs) - 24-Hour

U.S. - New Hampshire - Regulated Toxic Air Pollutants - Ambient Air Levels (AALs) - Annual

U.S. - New Jersey - Discharge Prevention - List of Hazardous Substances

U.S. - New Jersey - Environmental Hazardous Substances List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - New Jersey - Special Health Hazards Substances List

U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances

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U.S. - North Dakota - Air Pollutants - Guideline Concentrations - 1-Hour
U.S. - North Dakota - Hazardous Wastes - Discarded Chemical Products, Off-Specification Species, Container and Spill Residues
U.S. - Ohio - Extremely Hazardous Substances - Threshold Quantities
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Tennessee - Occupational Exposure Limits - Ceilings
U.S. - Tennessee - Occupational Exposure Limits - Skin Designations
U.S. - Texas - Effects Screening Levels - Long Term
U.S. - Texas - Effects Screening Levels - Short Term
U.S. - Vermont - Hazardous Waste - Acutely Hazardous Wastes
U.S. - Vermont - Permissible Exposure Limits - Ceilings
U.S. - Vermont - Permissible Exposure Limits - Skin Designations
U.S. - Washington - Dangerous Waste - Discarded Chemical Products List
U.S. - Washington - Permissible Exposure Limits - Ceilings
U.S. - Washington - Permissible Exposure Limits - Skin Designations
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights 25 Feet to Less Than 40 Feet
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights 40 Feet to Less Than 75 Feet
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights 75 Feet or Greater
U.S. - Wisconsin - Hazardous Air Contaminants - All Sources - Emissions From Stack Heights Less Than 25 Feet

Canadian Regulations

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Uncontrolled product according to WHMIS classification criteria.

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List) inventory.

WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
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Sodium azide (26628-22-8)

Listed on the Canadian DSL (Domestic Substances List) inventory.

Listed on the Canadian Ingredient Disclosure List

WHMIS Classification	Class D Division 1 Subdivision A - Very toxic material causing immediate and serious toxic effects
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Albumins, blood serum (9048-46-8)

Listed on the Canadian DSL (Domestic Substances List) inventory.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION

Indication of Changes : 9/7/2016

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Party Responsible for the Preparation of This Document

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Fenwal Inc.

Phone Number: 847-550-2300

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

North America GHS US 2012 & WHMIS