SAFETY DATA SHEET

PathTROL™ Allergy Controls

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product name:	**PathTROL™ Allergy Control Sera (Levels 1 & 2)**
1.1 Code:	**PW80101** (Level1) and **PW80201** (Level 2)
1.2 Recommended use:	Internal Quality Control of Allergy Assays
1.3 Manufacturer:	Pathway Diagnostics Ltd Eclipse House, Curtis Road Dorking, RH4 1EJ, UK Tel: + 44 (0)1306 888777 Fax: + 44 (0)1306 883883 Email: info@pathwaydiagnostics.com
1.4 Emergency Phone:	+ 44 (0)1306 888777

2. COMPOSITION / INGREDIENTS INFORMATION

3.1 Substance	The product is a mixture.
3.2 Mixture	The product consists of human serum and preparations of human fluids and tissues. It contains 0.02 % sodium azide**.**

Hazardous substances in the mixture:

Name of substance:	Sodium azide
EC-No.:	247-852-1
CAS-No.:	26628-22-8
Index-No.:	011-004-00-7
Concentration:	0.02 %
H-Statements:	H300: Fatal if swallowed H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects

3. HAZARDS IDENTIFICATION

3.1 Classification:	The products are classified as non-hazardous according to EC 1272/2008 and 1999/45/EC.
3.2 Label elements:	The products are not a hazardous mixture according to EC 1272/2008, therefore specific labelling is not required.
3.3 Other hazards:	The usual hygiene and safety measures when handling potentially infectious material should be followed.

4. FIRST AID MEASURES

4.1 Skin Contact:	If a component of this product contacts the wash immediately with soap and plenty of water and treat the contaminated skin with a skin disinfectant against bacteria, viruses and fungi according to the recommendations of the manufacturer of the disinfectant. Seek medical advice.
4.2 Eye Contact:	If a component of this kit enters the eyes and causes discomfort, wash eyes gently under potable running water for at least 10 minutes, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.
4.3 Inhalation:	Fresh air. If cessation of breathing occurs apply artificial respiration, Immediately seek medical assistance.
4.4 Ingestion:	If a component of this kit is ingested, wash mouth out with water and seek medical attention.

4.5 Other: In case of injury and contamination with human serum material it is strongly recommended to obtain medical attention.

4.6 Most important symptoms and effects, both acute and delayed:

None known.

4.7 Indication of any immediate medical attention and special treatment needed:

No information available.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media: No limitation. For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam.

5.2 Flammable properties: None known

5.3 Advice for fire fighters: Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions: In case of spillage: Sweep up spilled liquid carefully. Disinfect contaminated area.
Absorbent material: No restriction
For limitation of damage: Special measures are not necessary

6.2 Environmental precautions:

Do not empty into drains, waters and soil.

6.3 Methods and materials for containment and cleaning up:

Sweep up spilled liquid carefully. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Disinfect contaminated area.

6.4 Reference to other sections:

Indications about waste treatment see section.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Use only with personal protective equipment (see section 8). Do not smoke, eat and drink. Wash and disinfect hands regularly.

Measures to avoid fire or explosions:

No special measures necessary.

Measures to avoid dust and aerosols:

Transfer liquid cautiously and with a low flow rate.

Measures to protect the environment:

Use product in self-contained areas. Avoid spillage into the environment.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Store containers tightly closed and upright.

Storage temperature: 2 - 8 °C

Requirements for storage areas and containments:

Electrical equipment in the storage areas should be state of the art.

7.3 Specific end use(s)

Specific uses: Laboratory chemical

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1 Control parameters

Sodium azide: Maximum workplace concentration according to EU Directive 2000/39/EC: 0,1 mg/m3 (TWA), 0,3 mg/m3 (STEL). Consult local authorities for acceptable exposure limits. When used properly a contamination of the air is very unlikely.

8.2 Exposure controls: Avoid contact with skin, eyes and clothing. Wash hands directly after use.

Individual protection measures – personal protective equipment:

Eye/face protection:	Safety glasses acc. EN 166 (EU), NIOSH (US)
Hand protection:	Latex or Nitrile gloves acc. EN 374
Additional skin protection:	Laboratory coat and trousers
Respiratory protection:	Usually not necessary.
Heat/cold protection:	Usually not necessary.

Environmental exposure controls

Avoid spillage into drains, waters and soil.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Form:	liquid
Colour:	yellow-orange
Odour:	odourless
Odour threshold:	not applicable
pH:	ca. 7.2
Melting point:	ca. 0 °C
Boiling point:	ca. 100 °C
Flash point:	no information available
Evaporation rate:	no information available
Flammability:	no information available
Explosion limits:	no information available
Vapour pressure:	no information available
Relative vapour density:	no information available
Density:	ca. 1.0 g/ml
Solubility:	soluble in water
Partition coefficient:	no information available
Auto-ignition temperature:	no information available
Decomposition temperature:	no information available
Viscosity:	no information available
Explosive properties:	no information available
Oxidizing properties:	no information available

9.2 Other data: None

10. STABILITY AND REACTIVITY

10.1 Reactivity:	No hazardous reactions known when handled properly.
10.2 Chemical stability:	Stable when stored at 2 - 8 °C.
10.3 Possibility of hazardous reactions:	No hazardous reactions known when handled properly.
10.4 Conditions to avoid:	Light, heat (Do not initiate any hazardous reaction, but render the product useless.)
10.5 Incompatible materials:	Strong oxidizing substances (Do not initiate any hazardous reaction, but render the product useless). Metal or metal salts can induce the formation of explosive azides.

10.6 Hazardous decomposition products:

No hazardous decomposition products known.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: For the product (mixture) no information available.
For the component sodium azide in pure form:
LD50 oral: 27 mg/kg (rat), LD50 dermal: 20 mg/kg (rabbit)

Skin irritation: no information available

Eye irritation: no information available

Sensitisation: no information available

Germ cell mutagenicity: no information available

Carcinogenicity: no information available

Reproductive toxicity: no information available

Specific target organ toxicity – single exposure:
no information available

Specific target organ toxicity – repeated exposure:
no information available

Aspiration hazard: no information available

11.2 Further information: The product contains human material. HBV-DNA, HCV-RNA and HIV antibodies are not detectable, but as no test method can offer complete assurance, the absence of HBV, HCV, HIV-1, HIV-2 or other infectious agents cannot be guaranteed. Therefore, every human material should be regarded as potentially infectious. For this reason, the control serum should be handled with the same precautions as patients' samples.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: For the product (mixture) no information available.
For the component sodium azide in pure form: EC50 – Daphnia p. (Water flea) – 4.2 mg/l/48h

12.2 Persistence and degradability:
No information available.

12.3 Bio-accumulative potential:
No information available.

12.4 Mobility in soil: No information available.

12.5 Results of PBT and vPvB assessment:
None of the substances used are listed as PBT or vPvB relevant.

12.6 Other adverse effects: When used properly no ecologically adverse effects are expected

13. DISPOSAL CONSIDERATIONS

13.1 Measures for waste treatment

Product: Waste product has to be disposed of by the procedures for potentially infectious material, according to local and national legislation (disinfection and combustion).

Packaging: Dispose of in a manner in accordance with local and national regulations.

14. TRANSPORT INFORMATION

14.1 UN-Number: UN3373. Not dangerous goods according to ADR/RID, IMGD, IATA.

14.2 Proper UN shipping name: Biological Substance, Category B. Not dangerous goods according to ADR/RID, IMGD, IATA.

14.3 Transport hazard classification: 6.2. Not dangerous goods according to ADR/RID, IMGD, IATA.

14.4 Packing group: Not dangerous goods according to ADR/RID, IMGD, IATA.

14.5 Environmental hazard: Not dangerous goods according to ADR/RID, IMGD, IATA.

14.6 Special precautions for user: Not dangerous goods according to ADR/RID, IMGD, IATA

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC-Code:
Not applicable.

15. REGULATORY INFORMATION

15.1: Classification of product according to EC Directive 1999/45/EC: Non-hazardous mixture therefore, labelling of the product is not necessary. The material complies with all applicable rules and orders under the Toxic substances control act (TSCA) 19 CFR 12.121.

15.2: National legislation: For further product information, we recommend consideration of any appropriate corresponding National Legislation.

15.3: Chemical safety assessment is not necessary for this product.

16. OTHER INFORMATION

16.2: All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Pathway Diagnostics Ltd. shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

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