

SECTION 1: IDENTIFICATION

Product Identifier: cANCA Positive Control
 pANCA Positive Control
 cANCA Titratable Control
 pANCA Titratable Control
 ANCA Negative Control

Recommended Use and Restrictions on Use: For In Vitro diagnostic use only

Responsible Party:

Name: Immuno Concepts N.A. Ltd.

Address: 9825 Goethe Road Suite 350, Sacramento, CA, 95827, USA

www.immunoconcepts.com

Technical Support: 1-800-251-5115; technicalsupport@immunoconcepts.com

SECTION 2: HAZARD(S) IDENTIFICATION**Chemical Classification(s)**

Not classified in accordance to EC No. 1272/2008

Signal Word

None

Hazard Statement(s)

None

Symbol(s)

None

Precautionary Statement(s)

None

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous and non-hazardous ingredients are listed only if present at a concentration of 1% or greater (0.1% for carcinogens).

| Component | CAS # | Percent Range |
|--------------|-----------|---------------|
| Water | 7732-18-5 | 78 – 97%* |
| Base sera | NA | ≤ 20%* |
| Bovine serum | 9048-46-8 | < 2 – 2%* |

*Specific percentages of composition are being withheld as a trade secret.

This product contains materials of animal origin.

SECTION 4: FIRST – AID MEASURES**First Aid: Eyes**

Immediately flush eyes with plenty of water for at least 15 minutes. If irritation persists, get medical attention.

First Aid: Skin

Wash immediately with soap and water. If irritation persists, get medical attention.

First Aid: Ingestion

If the material is swallowed, get immediate medical attention or advice. Do not induce vomiting.

First Aid: Inhalation

Move person to non-contaminated air. If the affected person is not breathing, apply artificial respiration.

SECTION 5: FIRE – FIGHTING MEASURES**General Fire Hazards**

None; See section 9 for Flammability Properties.

Hazardous Combustion Products

Trace amounts of toxic vapors and fumes.

Extinguishing Media

Use carbon dioxide, dry chemical, water spray, or alcohol-resistant foam.

Unsuitable Extinguishing Media

None

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear. Use water spray to keep fire-exposed containers cool.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Recovery and Neutralization

None

Materials and Methods for Clean-Up

Soak-up with inert absorbent material. Keep in suitable closed container and hold for waste disposal. Ventilate area and wash spill site after material pick up is complete.

Emergency Measures

Isolate area. Keep unnecessary personnel away.

Personal Precautions and Protective Equipment

Wear appropriate attire to minimize skin contact.

Environmental Precautions

Do not allow product to enter drains.

Prevention of Secondary Hazards

None

SECTION 7: HANDLING AND STORAGE

Handling Procedures

Wash skin thoroughly after handling.

Storage Procedures

Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatibilities

Avoid contact with strong oxidizing agents, metals, strong acids, and strong bases.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Exposure Limits

This product does not contain any substances with occupational exposure limit values.

Engineering Measures

Ensure that eyewash and safety showers are close to the workstation location. Ensure adequate ventilation.

Personal Protective Equipment: Respiratory

Use NIOSH/MSHA approved respirators if exposure limits are exceeded or if irritation or other symptoms are experienced.

Personal Protective Equipment: Hands

Use impervious gloves.

Personal Protective Equipment: Eyes

Wear NIOSH approved safety glasses or face shield.

Personal Protective Equipment: Skin and Body

Wear lab coat to minimize skin contact.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|--------------------------------|-----------------------------------|---|----|
| Appearance: | Colorless, unless specified below | Flammability (solid, gas): | ND |
| cANCA Pos. control: | Yellow | Upper Flammability Limit (UFL): | ND |
| H+ & pANCA Pos. control: | Green | Lower Flammability Limit (LFL): | ND |
| Physical State: | Liquid | Vapor Pressure: | ND |
| Odor: | None | Vapor Density: | ND |
| Odor Threshold: | ND | Relative Density: | ND |
| pH: | 7.4 ± 0.2 | Solubility(ies): | ND |
| Melting/Freezing Point: | ND | Partition Coefficient (n-octanol/water): | ND |
| Boiling Point: | ND | Auto Ignition Temperature: | ND |
| Flash Point: | ND | Decomposition Temperature: | ND |
| Evaporation Rate: | ND | Viscosity: | ND |

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability

This is stable material.

Hazardous Reaction Potential

Will not occur.

Conditions to Avoid

None

Incompatible Products

Avoid contact with strong oxidizing agents, metals, strong acids, and strong bases.

Hazardous Decomposition Products

Irritating toxic fumes and gases.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Component Analysis – LD50/LC50

No LD50/LC50's are available for this product's components.

Potential Health Effects: Skin Corrosion Property/Stimulativeness

This product is not reported to have any skin irritation effects.

Potential Health Effects: Eye Critical Damage/Stimulativeness

This product is not reported to have any eye irritation effects.

Potential Health Effects: Ingestion

May be harmful if swallowed.

Potential Health Effects: Inhalation

This product is not reported to have any inhalation hazard effects.

Respiratory Organs Sensitization/Skin Sensitization

This product is not reported to have any sensitization effects.

Generative Cell Mutagenicity

This product is not reported to have any mutagenic effects.

Carcinogenicity

A: General Product Information

This product is not reported to have any carcinogenic effects.

B: Component Carcinogenicity

This product does not contain components reported to have any carcinogenic effects.

Reproductive Toxicity

This product is not reported to have any reproductive toxicity effects.

Specified Target Organ General Toxicity: Single Exposure

This product is not reported to have any specific target organ toxicity single exposure effects.

Specified Target Organ General Toxicity: Repeated Exposure

This product is not reported to have any specific target organ toxicity repeated exposure effects.

Aspiration Respiratory Organs Hazard

Not an aspiration hazard.

California Proposition 65 Component Hazard

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

A: General Product Information

This product is not reported to have any ecotoxicity effects.

B: Component Analysis – Ecotoxicity – Aquatic Toxicity

No information available for the components of the product.

Persistence/Degradability

No information available for the product.

Bioaccumulation

No information available for the product.

Mobility in Soil

No information available for the product.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Instructions

See section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

Disposal of Contaminated Containers or Packaging

Observe all local, regional, and national regulations. Offer surplus and non-recyclable solutions to a licensed disposal company.

SECTION 14: TRANSPORT INFORMATION

| | | | |
|--------------------------------|------|--------------------------------------|------|
| UN Information | | Environmental Hazards | |
| Number: | None | Marine Pollutant: | None |
| Shipping Name: | None | Transport in Bulk: | None |
| Transport Hazard Class: | None | Special Precautions for User: | NA |
| Packing Group: | None | IMDG Information | |
| | | Shipping Name: | None |

SECTION 15: REGULATORY INFORMATION

EU Marking & Labeling:

Symbol(s):

None

Risk Phrases:

None

Substance Analysis – Inventory

| Component/CAS# | Listed | | |
|---------------------------|--------|---------|------|
| | OSHA | CAN DSL | TSCA |
| Water 7732-18-5 | No | Yes | Yes |
| Base sera NA | NA | NA | NA |
| Bovine serum 9048-46-8 | NA | Yes | NA |

SECTION 16: OTHER INFORMATION

Certificate of Origin

Products of Bovine, Ovine and/or Caprine Origin used in the manufacture of Immuno Concepts' products are derived from animals born and raised in the United States of America or Canada and do not contain any hazardous materials.

I hereby certify that at the origin of the shipments and within a radius of 25km, there has been no animal epidemic during the time of manufacturing or dispatch, under the OIE list A, nor has there been any reported disease in the last 24 months from which the products and product components are obtained and reported.

Authorized Signature

Date

Key/Legend

ACGIH = American Conference of Governmental Industrial Hygienists; ADG = Australian Code for the Transport of Dangerous Goods by Road and Rail; ADR/RID = European Agreement of Dangerous Goods by Road/Rail; AS = Standards Australia; DFG = Deutsche Forschungsgemeinschaft; DOT = Department of Transportation; DSL = Domestic Substances List; EEC = European Economic Community; EINECS = European Inventory of Existing Commercial Chemical Substances; ELINCS = European List of Notified Chemical Substances; EU = European Union; HMIS = Hazardous Materials Identification System; IARC = International Agency for Research on Cancer; IMO = International Maritime Organization; IATA = International Air Transport Association; MAK = Maximum Concentration Value in the Workplace; NDSL = Non-Domestic Substances List; NFPA = National Fire Protection Association; NOHSC = National Occupational Health & Safety Commission; NTP = National Toxicology Program; STEL = Short-term Exposure Limit; TDG = Transportation of Dangerous Goods; TLV = Threshold Limit Value; TSCA = Toxic Substances Control Act; TWA = Time Weighted Average; NA = Not applicable; ND = Not determined

Literature References

Available on request.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Immuno Concepts, N.A. Ltd, shall not be held liable for any damage resulting from handling or contact with the above product.

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