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Material Safety Data Sheet

Version: 1.0
Accordance with EC No. 1907/2006
Revision Date: 20 Apr 2014
Print Date: 20 Apr 2014

Product #: 800003

Human Alpha-1 Antitrypsin, Recombinant

(rAAT)

95%+, Lyophilized Powder, Expressed in Rice

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Human Alpha-1 Antitrypsin, Recombinant, 95%+
SYNONYMS: rAAT, rSERPINA1, rA1AT, ralalpha1AT
PRODUCT #: 800003

SUPPLIER: Aspira Scientific
521 Cottonwood Drive
Milpitas, CA 95035
USA

TELEPHONE: 1-408-571-1100
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MANUFACTURER: Healthgen Biotechnology Co., Ltd.

EMERGENCY PHONE (Supplier): 1-408-571-1100
EMERGENCY PHONE (Manufacturer): +86 27 6878 9310

PREPARATION INFORMATION: Aspira Scientific
1-408-571-1100

CHEMICAL NAME: Alpha-1 Antitrypsin, recombinant human expressed in rice (*Oryza sativa*)
CHEMICAL FAMILY: Proteins and Derivatives
CHEMICAL FORMULA: N/A

PRODUCT USE: Research applications

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>EC NO.</u>	<u>EINECS</u>	<u>% (w/w)</u>
Alpha-1 antitrypsin, human	9041-92-3	232-924-7	N/A	≥ 95
Albumin, human (stabilizer)	70024-90-7	274-272-6	232-936-2	

No hazardous ingredients according to OSHA criteria.

SECTION 3: HAZARDS IDENTIFICATION

This substance is not classified as dangerous according to Directive 67/548/EEC.

EMERGENCY OVERVIEW:

OSHA Hazards
No known OSHA hazards.

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GHS Classification

Skin irritation (Category 3)

GHS Label Elements (including precautionary statements)

Pictogram	None
Signal word	Warning
Hazard statement(s)	H312: Causes mild skin irritation.
Precautionary statement(s)	None

HMIS Hazard Classification

Health:	1
Flammability:	0
Physical:	0

NFPA Hazard Rating

Health:	1
Fire:	0
Reactivity:	0

ROUTES OF ENTRY:

POTENTIAL HEALTH EFFECTS

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Skin:	May cause skin irritation.
Eyes:	May cause eye irritation.
Ingestion:	May be harmful if swallowed.

ACUTE HEALTH HAZARDS: May cause eye irritation.

CHRONIC HEALTH HAZARDS: The toxicological properties of this material have not been fully investigated. Expected low hazard for usual industrial handling.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Not characterized.

SECTION 4: FIRST AID MEASURES

EYES: Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids to flush. Seek medical aid if vision is affected or irritation persists.

SKIN: Flush skin with soap and rinse with plenty of water. Seek medical aid if irritation persists.

INGESTION: Do not give any oral treatment to unconscious person. Rinse mouth with water and consume 2-4 cups of water. Seek medical aid and treat symptomatically.

INHALATION: Remove from exposure to fresh air immediately. If not breathing, administer artificial respiration. If labored breathing, supply oxygen. Seek medical aid if cough develops or other symptoms appear following inhalation exposure.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: Treat symptomatically.

NOTES: Generally advised to consult a physician following exposure and supply this material safety data sheet.

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR (% BY VOLUME): UPPER: Not available. LOWER: Not available.

FLASH POINT: °F: Not available. °C: Not available. Method of Analysis: Not applicable.

AUTOIGNITION TEMPERATURE: °F: Not available. °C: Not available.

NFPA FLAMMABILITY HAZARD CLASSIFICATION: 0

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HMIS FLAMMABILITY HAZARD CLASSIFICATION:	0
CONDITIONS OF FLAMMABILITY:	Not flammable or combustible.
EXTINGUISHING MEDIA:	Use water spray, dry chemical, carbon dioxide or alcohol-resistant chemical foam.
SPECIAL FIRE-FIGHTING PROCEDURES:	Wear self-contained breathing apparatus for firefighting.
UNUSUAL FIRE AND EXPLOSION HAZARDS:	Not specified.
HAZARDOUS DECOMPOSITION PRODUCTS:	Hazardous decomposition products formed under fire conditions include oxides of phosphorus, hydrogen chloride gas and sodium oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES:	Observe proper personal protective equipment precautions. Vacuum or sweep up material and place into a suitable disposal closed container. Clean up spills immediately. Avoid generating dusty conditions. Provide ventilation.
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SECTION 7: HANDLING AND STORAGE

HANDLING AND STORAGE:	Provide appropriate exhaust ventilation at places where dust is formed for safe handling. Avoid contact with eyes, skin and clothing. For storage, keep container tightly closed in a dry and well-ventilated place. Opened containers must be carefully resealed and kept upright to prevent loss of product. Recommended storage temperature at - 20°C.
OTHER PRECAUTIONS:	Not specified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.
VENTILATION:	Ensure adequate ventilation.
PERSONAL PROTECTIVE EQUIPMENT RESPIRATORY PROTECTION:	Respiratory protection is not required. When protection is needed, follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Where protection from nuisance levels of dusts is desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
EYE PROTECTION:	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
SKIN PROTECTION:	Wear appropriate gloves to prevent skin exposure. Inspect gloves prior to use. Use proper glove removal techniques (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT:	Wear appropriate protective clothing to prevent skin exposure.

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WORK HYGIENIC PRACTICES: Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of work. Use personal protective equipment. Avoid dust formation and breathing dust.

EXPOSURE GUIDELINES: No OSHA PEL exposure limits are listed for this chemical.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: White.

ODOR: Not characterized.

PHYSICAL FORM: Lyophilized powder.

pH: 5.0 - 7.0 (in 10 mg/mL water)

BOILING POINT: °F: Not available. °C: Not available.

MELTING POINT: °F: Not available. °C: Not available.

FREEZING POINT: °F: Not available. °C: Not available.

VAPOR PRESSURE (mmHg): Not available. at °F: Not applicable. °C: Not applicable.

VAPOR DENSITY (AIR = 1): Not available. at °F: Not applicable. °C: Not applicable.

SPECIFIC GRAVITY (H₂O = 1): Not available. at °F: Not applicable. °C: Not applicable.

EVAPORATION RATE: Not available. at °F: Not applicable. °C: Not applicable.

BASIS (=1): Not available.

SOLUBILITY IN WATER: 100%, clear (in 10 mg/mL water)

PERCENT SOLIDS BY WEIGHT: 100%

PERCENT VOLATILE (w/v): None. at °F: Not applicable. °C: Not applicable.

VOLATILE ORGANIC COMPOUNDS: With water (lbs/gal): None. Without water (lbs/gal): None.

MOLECULAR WEIGHT: Approx. 43.1k Da

VISCOSITY: Not available. at °F: Not applicable. °C: Not applicable.

SECTION 10: STABILITY AND REACTIVITY

STABILITY: Stable under recommended storage conditions and normal temperatures and pressures.

CONDITIONS TO AVOID: Incompatible materials, dust generation, excess heat or temperatures below -20°C.

INCOMPATIBLE MATERIALS: Strong oxidizing agents. Strong acids and strong bases.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Nature of decomposition products not known. Hazardous decomposition products formed under fire conditions include oxides of phosphorus, hydrogen chloride gas and sodium oxides. No data available on other hazardous decomposition products.

HAZARDOUS POLYMERIZATION: Will not occur.

POLYMERIZATION CONDITIONS TO AVOID: Not applicable.

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SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

ACUTE TOXICITY:	Oral LD50	No data available.
	Inhalation LC50	No data available.
	Dermal LD50	No data available.
	Other information on acute toxicity	No data available.
DERMAL TOXICITY:	Skin corrosion/irritation	No data available.
	Serious eye damage/eye irritation	No data available.
	Respiratory or skin sensitization	No data available.
TOXICITY:	Genotoxicity/ Mutagenicity	No data available.
	NO(A)EL	No data available.
	Reproductive toxicity	No data available.
	Germ cell mutagenicity	No data available.
	Neurotoxicity	No data available.
	Specific target organ toxicity - single exposure (Globally Harmonized System)	No data available.
	Specific target organ toxicity - repeated exposure (Globally Harmonized System)	No data available.
CARCINOGENICITY:	Carcinogenicity	No data available.
	Teratogenicity	No data available.

Not listed-no component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP, OSHA, CA Prop 65.

EPIDEMIOLOGY: No data available.

POTENTIAL HEALTH EFFECTS:

Inhalation Exposure	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion Exposure	May be harmful if swallowed.
Skin Exposure	May cause skin irritation.
Eye Exposure	May cause eye irritation.

SIGNS AND SYMPTOMS OF EXPOSURE: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SYNERGISTIC EFFECTS: No data available.

RTECS: Not available.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

Ecotoxicity	No data available. No information available.
Environmental	No information reported.
Persistence and degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
PBT and vPvB assessment	No data available.
Other adverse effects	No data available.

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SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult a licensed professional waste disposal service expert about waste material disposal requirements. Dispose of as unused product and non-recyclable solutions as appropriate for chemical classification in observation of all federal, state, local and environmental regulations and laws. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

RCRA HAZARD CLASS:

RCRA P-Series	None listed.
RCRA U-Series	None listed.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION (DOT) Not a DOT-controlled material.

PROPER SHIPPING NAME:	Not applicable.
HAZARD CLASS:	Non-hazardous.
ID NUMBER:	Not applicable.
PACKING GROUP:	Not applicable.
LABEL STATEMENT:	Not applicable.

INTERNATIONAL LAND TRANSPORTATION (ADR/RID) This substance is considered to be non-hazardous for transport.

PROPER SHIPPING NAME:	Not applicable.
HAZARD CLASS:	Non-hazardous.
ID NUMBER:	Not applicable.
PACKING GROUP:	Not applicable.
LABEL STATEMENT:	Not applicable.

INLAND WATER WAYS TRANSPORTATION (ADN) This substance is considered to be non-hazardous for transport.

PROPER SHIPPING NAME:	Not applicable.
HAZARD CLASS:	Non-hazardous.
ID NUMBER:	Not applicable.
PACKING GROUP:	Not applicable.
LABEL STATEMENT:	Not applicable.

WATER TRANSPORTATION (IMDG) This substance is considered to be non-hazardous for transport.

PROPER SHIPPING NAME:	Not applicable.
MARINE POLLUTANT:	No.
HAZARD CLASS:	Non-hazardous.
ID NUMBER:	Not applicable.
PACKING GROUP:	Not applicable.
LABEL STATEMENT:	Not applicable.

AIR TRANSPORTATION (IATA-DGR and ICAO-TI) This substance is considered to be non-hazardous for transport.

PROPER SHIPPING NAME:	Not applicable.
HAZARD CLASS:	Non-hazardous.
ID NUMBER:	Not applicable.
PACKING GROUP:	Not applicable.
LABEL STATEMENT:	Not applicable.

This material is not considered dangerous according to the above specifications.

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SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

- Occupational Safety and Health Administration (OSHA):** No known OSHA hazards.
- Toxic Substance Control Act (TSCA):** Alpha-1 antitrypsin is not on TSCA Inventory.
Albumins, human A class (CAS 70024-90-7) is on TSCA Inventory.
- Comprehensive Response Compensation and Liability Act (CERCLA):** Not available.
- Superfund Amendments and Reauthorization Act (SARA Title III):**
- | | |
|----------------------------------|---|
| 302 Reportable Components | No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. |
| 311/312 Hazards | No SARA Hazards. |
| 313 Reportable Components | This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. |

STATE REGULATIONS:

- Massachusetts Right-To-Know Components:** None.
- Pennsylvania Right-To-Know Components:** Albumins, human A class (CAS 70024-90-7).
- New Jersey Right-To-Know Components:** Albumins, human A class (CAS 70024-90-7).
- California Prop. 65 Components:** This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

INTERNATIONAL REGULATIONS:

- European/International Regulations** This product is classified and labeled in accordance with Directive 1999/45/EC. The health hazard classification has been determined based upon the composition and hazard data of each ingredient. Physical and health hazard information on the mixtures has not been determined. Any physical and health hazard information noted is based on an evaluation of data of the pure ingredient and the concentration of each ingredient.
- | | |
|--|----------------------|
| Hazard Classification Code: | None. |
| Indication of Danger: | None. |
| Risk Code: | R36/37/38 |
| Safety Code: | S7, 8, 26, 5, 63, 64 |
| WGK Germany: | 1 |
| Registry of Toxic Effects of Chemical Substances (RTECS): | Not available. |
| Harmonized System Code: | Not available. |
| Hazardous Substance Data Bank CASRN: | Not available. |
| Listed European Food Additive: | Not available. |
| Foreign Inventory List: | Not available. |
- This product does not need to be labeled in accordance with EC directives or respective national laws.
- Canadian DSL/NDSL** Not listed on Canada's DSL List.
- Canada Ingredient Disclosure List** Not listed on Canada's Ingredient Disclosure List.

SECTION 16: OTHER INFORMATION

- OTHER INFORMATION:** *For laboratory research use only. This product has not been approved for diagnostic or therapeutic use.* Manufactured by Healthgen Biotechnology Co., Ltd. The product is produced in an ISO 9001:2008 certified manufacturing facility according to quality management system provisions and complies with local manufacturing GLP and GMP practices. This product is licensed under U.S. Patent No. 7,723,571 and corresponding Patent No. 1865064 in the European Union, Patent No. 4.680.237 in Japan and Patent Nos. ZL 2006 1 0019285.9 and ZL 20005 1 0019084.4 in China with patent pending in Canada.

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PREPARATION INFORMATION: Aspira Scientific

DISCLAIMER:

Aspira Scientific supplies Material Safety Data Sheets (MSDS) for purchased products based on OSHA regulations for Hazard Communication, 29 CFR 1910.1200, and 1907/2006/EC directives. The above information is believed to be accurate but is not to be considered as a warranty, guarantee or specification of the product quality. It is related to the materials specifically indicated and does not apply if these are used in combination with other materials or during processes not indicated in the text of this material safety data sheet. The information in this document is based on the best information currently available and is applicable to the product with regard to appropriate safety precautions and is only intended for use as a guide. Aspira Scientific shall not be held liable for any claims, losses or damages resulting from handling or from contact with the above product and we make no warranty of merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.

Federal and California Hazard Communication regulations stipulate that any food, food additive, color additive, drug, cosmetic or medical or veterinary device or product, including materials intended for use as ingredients in such products, as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 USC 301) or the Virus Serum Toxic Act of 1913 (21 USC 151) and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture do not require labeling and regulations.