



Material Safety Data Sheet

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SECTION 1 PRODUCT AND COMPANY INFORMATION

Trade Name: ProSep Ultra Plus Pre-packed Column

Catalogue Number(s): 175118521 1 ml column
175118522 2.5 ml column
175118523 5 ml column

Chemical Name: A polypropylene column with nylon end nuts containing a suspension of recombinant native (v) protein A covalently bound to porous glass in 0.1M acetate buffer and 1% benzyl alcohol.

Other trade names and synonyms: None

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SECTION 2 COMPOSITION / INFORMATION ON INGREDIENTS

Component	EINECS or ELINCS No.	CAS No.	Content (weight percent)	Symbol letters*	R Phrases**
v Protein A covalently bound to porous glass – v Protein A is derived from <i>E-coli</i> , using a process free of mammalian derived materials.	Not Assigned	Not Assigned	Approx 50%	Not Assigned	Not Assigned
Sodium acetate	204-823-8	127-09-3	0.2 %	Not Assigned	Not Assigned
Sodium chloride	231-598-3	7647-14-5	1.5 %	Not Assigned	Not Assigned
Benzyl alcohol	202-859-9	100-51-6	0.25 %	Xn	R20/22
Water	231-791-2	7732-18-5	Approx 48 %	Not Assigned	Not Assigned

* Symbol letters and categories of danger: **T+** = Very toxic, **T** = Toxic, **C** = Corrosive, **Xn** = Harmful, **Xi** = Irritant, **E** = Explosive, **F+** = Extremely flammable, **F** = Very flammable, **N** = Dangerous for the environment, **O** = Oxidising.

** The full text of each phrase is listed in Section 16.

Structural Components

Material	EINECS No.	CAS No.	Function
Polypropylene	Not listed	9003-07-4	Column
Nylon (polyamide)	Not listed	25038-54-4 and others	End nuts

SECTION 3 HAZARD IDENTIFICATION / EMERGENCY OVERVIEW

Appearance: White polymer housing containing white powder suspended in a clear liquid.

Classification: Minimal potential biohazard from *E-coli* v protein A. This product is unclassified according to Directive 1999/45/EC.

Adverse human health effects associated with the contained powder if released.

Contact with Eyes: Possible eye irritant. . Severe contact with the eyes may cause physical damage to the eyes

Ingestion: Possible gastro-intestinal tract irritant.

Inhalation (Short Term): Possible respiratory tract irritant.

Inhalation (Long Term): Low risk of silicosis (lungs) unless exposure is prolonged or repeated.

Skin Contact: Possible skin irritant. Prolonged or repeated contact with the skin may cause drying of the skin.

Target Organs: Lungs

Medical conditions aggravated by exposure: No Information has been found.

Adverse environmental effects: None expected.

Adverse physiochemical effects: None expected.

SECTION 4 FIRST AID MEASURES

- Contact with Eyes:** Flush eyes with plenty of water for at least 15 minutes; occasionally lifting upper and lower lids. Seek medical attention if irritation persists.
- Ingestion:** If victim is conscious and alert, give plenty of water. If unconscious, give nothing by mouth and seek medical attention for victim.
- Inhalation:** Remove exposed person to fresh air immediately. If breathing is difficult, administer oxygen. If victim is not breathing, administer artificial respiration. Get medical attention.
- Skin Contact:** Wash exposed skin with soap and water while removing contaminated clothing and shoes. Seek medical attention if irritation develops or persists. Launder contaminated clothing before wearing.

SECTION 5 FIRE FIGHTING MEASURES

- Flash Ignition Temperature:** Product is non-combustible. In a fire, the polymer components will melt and ignite and add to the intensity of the fire.
- Autoignition Temperature (ASTM D1929):** Polypropylene: approximately 350°C
- Suitable extinguishing media:** Water, carbon dioxide, dry chemical powder, or foam
- Unsuitable extinguishing media:** Not Applicable
- Special protective equipment for firefighters:** No special measures are required.
- Special exposure hazards:** Not Applicable

SECTION 6 ACCIDENTAL RELEASE

- Personal precautions:** Wear gloves, goggles and other protective clothing, including dust mask if the product is dry.
- Small spills:** Wipe up and collect in container for disposal. Wash area with dilute bleach solution, followed by detergent and water.
- Large spills:** Wipe up and collect in container for disposal. Wash area with dilute bleach solution, followed by detergent and water.
- Environmental precautions:** No environmental hazard is known.
- Clean up measures:** Allow aerosols to settle; wearing protective clothing, gently cover spill with absorbent paper towel and apply 1% sodium hypochlorite, starting at perimeter and working towards the centre; allow sufficient contact time (30 min) before clean up

SECTION 7 HANDLING AND STORAGE

- Pressure Considerations:** The normal working pressure of 10 bar (145 psig) and maximum pressure of 20 bar (290 psig) should be carefully observed.
- Handling:** Wear safety glasses or goggles, and gloves. Take precautions to avoid spillage. Wash hands thoroughly after use.
- Storage:** Do not freeze.

SECTION 8 EXPOSURE CONTROL AND PERSONAL PROTECTION

	Normal Handling Conditions	Emergency Response Conditions
Respiratory protection:	Respiratory protection is not required under normal conditions of use. If respiratory protection is deemed necessary, follow OSHA respirator regulations in 29 CFR 1910.134 (or local equivalent) Use a NIOSH-approved dust/mist mask (or local equivalent).	Respiratory protection is not required under normal conditions of use. If respiratory protection is deemed necessary, follow OSHA respirator regulations in 29 CFR 1910.134 (or local equivalent) Use a NIOSH-approved dust/mist mask (or local equivalent).
Ventilation:	Under ordinary conditions of use, local exhaust should not be required. If processing technique is such that glass dust is generated use local exhaust to control exposure below applicable exposure limits.	Under ordinary conditions of use, local exhaust should not be required. If processing technique is such that glass dust is generated use local exhaust to control exposure below applicable exposure limits.
Eye protection:	Wear safety glasses or goggles.	Wear safety glasses or goggles.
Skin protection:	Appropriate protective clothing and gloves to prevent skin contact under conditions of use.	Appropriate protective clothing and gloves to prevent skin contact under conditions of use.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

- Appearance:** White polymer housing containing white powder suspended in clear aqueous solution. Stable and non-combustible. Properties below are associated with the contained media.
- Odor:** None
- Odor Threshold:** Benzyl alcohol 5.5 ppm
- pH:** 5.2
- Melting Point:** Protein bonded to the glass particles will decompose upon heating beyond dryness.
- Boiling Point:**
- Flash Ignition Point:** Product is not combustible
- Explosive Properties:** Not considered to present an explosion hazard.
- Oxidizing Properties:** Not considered to present an oxidizing hazard.
- Vapor pressure, 20 °C:** <13 mmHg

Physical and Chemical Properties (continued)

Specific Gravity (Water = 1.0):	Not available
Solubility:	Polymeric materials, Glass particles - insoluble
Vapor Density, 20 °C:	Not available
Viscosity, centipoise:	Not available
Partition coefficient (n-octanol/water):	Not available

SECTION 10 STABILITY AND REACTIVITY

Chemical Stability:	Stable
Incompatible With:	Strong oxidizers, organic solvents.
Hazardous Decomposition Products:	Oxides and other compounds of carbon, and nitrogen.
Conditions to Avoid:	Pressurization exceeding 20 bar (290 psig)
Hazardous Polymerization:	Will not occur.

SECTION 11 TOXICOLOGICAL INFORMATION

These toxicological properties are related to the contained media, if released.

Inhalation:	May cause irritation of respiratory tract. Low risk of silicosis (lungs) unless exposure is prolonged or repeated
Ingestion:	. May cause irritation of gastro-intestinal tract.
Skin Contact:	May cause skin irritation. Prolonged or repeated contact with the skin may cause drying of the skin.
Eye Contact:	May cause eye irritation. with the eyes may cause physical damage to the eyes
Carcinogenicity:	Not listed as carcinogenic by IARC, NIOSH, NTP, or OSHA.
Chronic Toxicity:	Risk of silicosis upon prolonged or repeated inhalation of fine glass powders.
Toxicology Data:	<i>Nature of biohazard:</i> This product contains <i>E.coli</i> v protein A immobilised on porous glass. Although free v protein A may be biohazardous, its bioavailability is dramatically reduced in immobilised form and so presents very little risk in this product. <i>Cytotoxicity:</i> An independent study of cytotoxicity potential of <i>E.coli</i> derived v protein A found no evidence of cytotoxicity.

SECTION 12 ECOLOGICAL INFORMATION

Ecotoxicity: No data is available on the Ecotoxicity of ProSep Ultra Plus

Environmental Fate: No data is available on the Environmental Fate of ProSep Ultra Plus

The polymeric components of this product are expected to have very low biodegradability and to persist in contact with soils and natural waters.

SECTION 13 DISPOSAL INFORMATION

European Union: When disposal is required, this product should be considered according to the European Waste catalogue (European commission decision of 03/05/01 modifying directives 94/3/CE and 75/442/CE) as part of the following category:

Pharmaceutical MSFU with residual dangerous substances 07 05 13* solid wastes containing dangerous substances

Pharmaceutical MSFU without residual dangerous substances 07 05 14 solid wastes other than those mentioned in 07 05 13

United States: The components of this product are not listed as RCRA D, F, P, or U Series hazardous wastes. Wastes containing these products should be disposed of in a manner consistent with federal, state and local regulations.

SECTION 14 TRANSPORTATION INFORMATION

This product is not currently regulated by USDOT, ICAO/IATA, ADR or IMO as hazardous materials or dangerous goods.

Note: No special transport requirements are applicable, other than storage between 2-8°C should delays occur.

SECTION 15 REGULATORY INFORMATION

Australia Hazchem Code: None allocated

Poisons Schedule Number: Not applicable

California No Significant Risk Level: None of the chemicals in this product are known to Millipore Corporation to be listed.

Canada WHMIS: Unclassified

Section 15 – Regulatory Information (continued)

European Union

Symbols: None
 Category of danger: None
 Risk phrases: None
 Safety phrases: Not applicable
 OECD/High Production Volume (HPV) chemicals: Not applicable
 WEEE: Not applicable
 RoHS: Not applicable

Japan

Poisonous and Deleterious Substances Control Law: None of the constituents of these products are listed by the Poisonous Deleterious Substances Control Law.

United States

Toxic Substances Control Act (TSCA): One or more of the components of ProSep Ultra Plus are not listed on the Toxic Substances Control Act (TSCA) Chemical Inventory. In the United States, its use is restricted to research and development or FDA regulated activities. See regulations in 40 CFR 710 for details.

Occupational Exposure

Limits	Component	OSHA PEL	NIOSH REL	ACGIH TLV
	v protein A covalently bound to porous glass	None established	None established	None established
	Glass dust, high silica, amorphous	1 mg/m ³ TWA	6 mg/m ³ TWA	0.1 mg/m ³ TWA (fused silica)
	Sodium Chloride	None established	None established	None established
	Sodium Acetate	None established	None established	None established
	Benzyl Alcohol	None established	None established	None established

SECTION 16 ADDITIONAL INFORMATION

Risk phrases referred to under Section 2: R20/22 Harmful by inhalation and if swallowed.

This product consists of surface modified porous glass particles in the range 37-74 micron and presents no respiratory hazard. However, if the glass is treated roughly, mechanical shearing may cause the particle size to fall into the hazardous range below 10 micron. To prevent this, avoid handling these products dry and never use magnetic or paddle stirrers.

Abbreviations Used	
ACGIH	American Conference of Government Industrial Hygienists
ADR	European agreement on the international carriage of dangerous goods on road
CAS	Chemical Abstract Service
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	United States Environmental Protection Agency
IARC	International Agency for Research in Cancer.
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	Regulations regarding the transportation of dangerous goods on ocean-going vessels issued by the International Maritime Organization.
LC ₅₀	Lethal Concentration 50% is the concentration of a chemical which kills 50% of a sample population
LD ₅₀	Lethal Dose 50% is the dose of a chemical which kills 50% of a sample population.
LDLo	Lowest observed lethal dose
MSFU	Manufacture, Formulation, Supply and Use (Section 13)
NIOSH	National Institute of Occupational Safety and Health (US)
NTP	National Toxicology Program (US)
OSHA	United States Occupational Safety and Health Administration
RID	International regulations concerning the international carriage of dangerous goods by rail.
RTECS	Registry of Toxic Effects of Chemical Substances (US)
WHMIS	Workplace Hazardous Materials Information System (Canada)

The pressure limitations noted in Sections 7 and 10 of 10 bar working and 20 bar maximum applied pressure must be observed.

This safety data sheet has been prepared to comply with the requirements of European Union Directive 2001/58/EC and ANSI Z400.1-1998.

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