

GENERAL DESCRIPTION

ProKlenz NpH Sterile Detergent is a concentrated high performance formulated neutral detergent. ProKlenz NpH Sterile Detergent is designed to be diluted to 1% v/v using sterile Water for Injection (WFI) or other high quality grade water (e.g., United States Pharmacopeia [USP] Purified Water) for the cleaning and removal of residue build-up in aseptic processing areas. The product is 0.22 micron sterile-filtered, filled and double-bagged in an aseptic environment (ISO Class 5).

ProKlenz NpH Sterile Detergent is intended for the cleaning and removal of residues from hard non-porous surfaces in cleanrooms or other critical environments such as floors, walls, counters, tools, carts, cart wheels and other equipment.

FEATURES

BENEFITS

Formulated detergent	Cleans a broad-spectrum of soils with multiple cleaning mechanisms
Neutral pH	Excellent substrate compatibility; safe to use and dilute
Sterile formulation and packaging	Suitable for use in aseptic core (ISO Class 5) areas
Sterility tested per USP <71>	Minimized risk of bioburden introduction to facility
Manufactured under Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMP), ISO 9001 and ISO 13485 compliant quality system	Supports quality assurance and quality control

PHYSICAL PROPERTIES

Form.....	Colorless to light yellow, clear liquid
Specific Gravity (25°C [77°F])	1.04 typical
pH (Undiluted)	7.0 typical
Phosphate.....	None; 0% P
Rinsing	Excellent
Solubility	Complete

DIRECTIONS FOR USE

ProKlenz NpH Sterile Detergent is designed to be used on hard non-porous surfaces in pharmaceutical, biotechnology, cosmetic, nutraceutical, medical device, university and government research and laboratory animal research facilities that employ cleanrooms and other critical environments.

Open each bag and remove the bottle. Dilute to 1% v/v (1:99) by adding 2.6 oz. (77 mL) of product to 257 oz. (7.6 L) WFI or equivalent to make approximately 2 gal. (7.6 L), which is a typical volume per bucket. Wet surface thoroughly by spreading manually using a suitable mop head and remove residue using a pull and lift technique. Allow surface to air dry.

ProKlenz NpH Sterile Detergent is a complete product. Do not add other chemicals.

STORAGE AND DISPOSAL

Storage

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers. Store in an area where product is not exposed to extreme temperatures.

Disposal

Flush with plenty of water to a sanitary sewer. Dispose of empty containers and packaging in accordance with local, state and federal regulations.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

PRECAUTIONS

Information concerning human and environmental exposure may be reviewed on the Safety Data Sheet (SDS) for the product. For additional information regarding incidents involving human and environmental exposure, call 1-314-535-1395.

For further information, please contact:



STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.STERISLifeSciences.com