

GENERAL DESCRIPTION

One Solution st Water For Injection is manufactured to meet United States Pharmacopeia (USP) specifications for Water for Injection (WFI). The product is 0.22 micron sterile-filtered, filled and double-bagged in a classified (ISO Class 8) environment, and terminally sterilized by gamma irradiation to a 10⁻⁶ Sterility Assurance Level (SAL).

One Solution st WFI is intended for use as a diluent for sterilants, disinfectants, sanitizers or cleaners, for the cleaning or disinfection of hard non-porous surfaces in cleanrooms or other critical environments such as floors, walls, counters, tools, carts and other equipment. It can also be used to dilute cleaners and disinfectants intended for use on product contact surfaces, and for rinsing of hard non-porous surfaces (both product contact and non-product contact cleanroom environmental surfaces). It should not be used for intravenous injection or as a diluent in a drug dosage form.

FEATURES

BENEFITS

Sterile diluent 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 Good Manufacturing Practices (cGMP), ISO 9001 and ISO 13485 compliant quality system

Supports quality assurance and quality control (FDA) current

PHYSICAL PROPERTIES

Form	Colorless
Odor	None
Clarity	Clear
Specific Gravity (25°C [77°F]).....	1.0 typical
Total Organic Carbon (TOC) at filling	<500 ppb
Endotoxin at filling	≤0.25 EU/mL
Conductivity @ 25°C [77°F]) at filling	≤1.3 μS/cm

DIRECTIONS FOR USE

One Solution st WFI is intended for use as a diluent for sterilants, disinfectants, sanitizers or cleaners, for the cleaning of 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. The product may also be used as a rinsing agent in these applications.

Open each bag and remove the bottle. Empty contents into an appropriate cleaning vessel or bucket. Add the appropriate amount of sterilant, disinfectant, sanitizer or cleaner according to the directions for use of the corresponding product.

If frozen, thaw and remix before use.

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

Dispose of empty containers and packaging in accordance with local, state and federal regulations.

SERVICE

Sales

Service is one of the most critical ways to verify the 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:



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