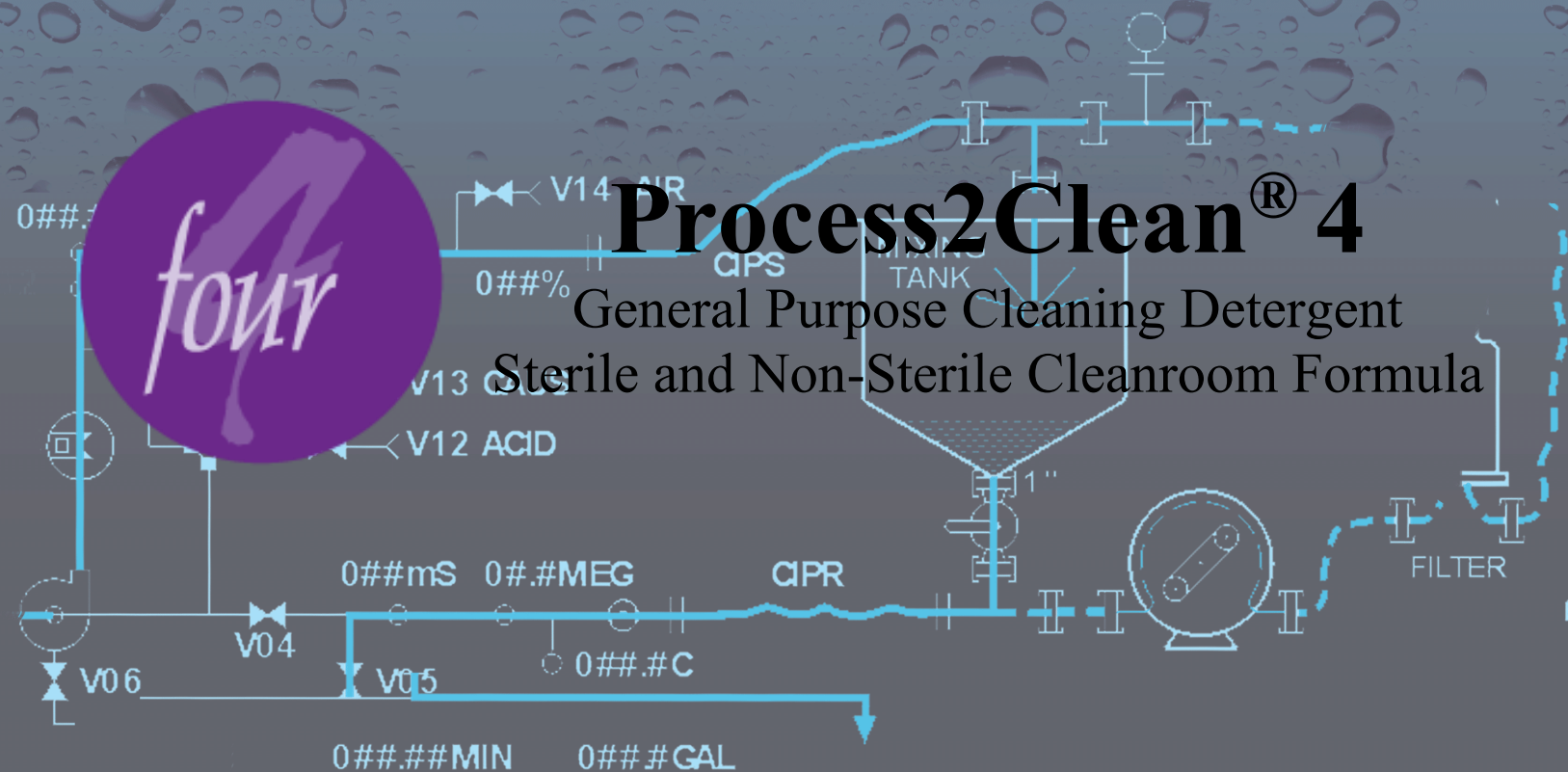


VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



Product Description

Process2Clean 4 is a high performance, concentrated, liquid neutral pH cleaning agent that is extremely effective in removing a wide array of residues. This stabilized formula, with elevated foam characteristics, can be used as a stand-alone cleaner or as an additive to alkaline cleaners to enhance their cleaning capabilities. Its unique formulation of chelating agents, glycolic acid, Water for Injection, unique proprietary surfactants, and other critically essential cleaning agents is capable of cleaning a multitude of product and non-product contact surfaces. **Process2Clean 4** is phosphate free and has excellent detergency with the ability to rinse free from systems.

Process2Clean 4 is available either sterile or non-sterile in 1 gallon, 5 gallon, 30 gallon, 55 gallon, or 275 gallon containers. Sterile **Process2Clean 4** is manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100) then subsequently double bagged. All sterile product is lot sterility tested according to current USP compendium and is completely lot traceable from start to finish. Non-Sterile versions are delivered with a lot specific Certificate of Analysis, whereas, sterile versions are delivered with a lot specific Certificate of Analysis and Certificate of Sterility.

Product Use

Process2Clean 4 has been specifically designed for the pharmaceutical, biotechnology, cosmetic, medical device, food & beverage, and research & development industries. Optimal use includes: all low agitation applications, spray systems, soak systems, or manual applications.

Process2Clean 4 is not suitable for automated recirculation cleaning applications. Under recommended use dilution applications and conditions, **Process2Clean 4** is suitable for use on most all process and environmental substrates. In addition, it is an excellent cleaner for use on equipment exteriors, walls, floors, and ceilings.

Process2Clean 4 is extremely effective in removing a wide assortment of soils including but not limited to ointments, creams, oils, waxes, polymers, and petrolatum based products.

Typical use dilution for **Process2Clean 4** is 0.5% - 5.0%. Precise temperature, concentration, and cleaning time will depend on the degree and type of soil present. All surfaces should be rinsed thoroughly to remove all product and soil residues following cleaning.

Features and Benefits

- Formulation with elevated wetting agents allows for use in all water hardness conditions
- Premium surfactants equal great wetting abilities for optimal penetration
- High concentration translates into low cost per use
- Elevated foaming characteristics that rinses free
- Is ecologically safe because it contains no phosphates
- Available lot specific documentation packages ensure product consistency and integrity
- Detergency capabilities eliminates the need to use a hazardous organic solvent
- Is a mild formulation that cleans most surfaces safely and effectively
- Compatible at use dilution on most all substrates
- Multiple container sizes available for optimal application

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Quality and Manufacturing

- Sterile versions are aseptically filled into gamma irradiated sterile components
- Sterile versions are sterility tested according to current USP compendium
- Completely traceable from start to finish
- Delivered with lot specific documentation
- Formulated with Water for Injection, premium proprietary surfactants, and chelating agents

Process2Clean 4 – General Purpose Cleaning Detergent	
Certificate of Analysis	Specifications
Specific Gravity:	1.000 – 1.200
Clarity:	Clear
APHA Color:	<150
pH (1% solution):	8.0 – 10.0
Appearance:	Yellow
Conductivity (1% solution):	0.8 – 2.1 mS
Heavy Metals:	<10 ppm
IR Scan:	Match Reference
Iron:	<10 ppm
Technical Data	Specifications
Ingredients:	Tetrasodium EDTA, DGMM ether, Hydroxyacetic Acid (Glycolic acid), Chelants, Surfactants, WFI
Glycolic Acid Content:	1 – 5%
Tetrasodium EDTA Content:	5 – 15%
DGMM ether Content:	5 – 10%
Surfactant Mixture:	<1%
Characteristic:	Neutral pH
Odor:	Slight Odor
P Content:	0.00%
Detergency:	Excellent
Solubility:	Miscible with water
Foaming:	Moderate to high
Rinsing:	Excellent
Biodegradable:	Yes
Storage Recommendation:	Ambient
Flash Point:	Not flammable
Expiration Period:	3 years

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Ordering Information

Process2Clean 4 – General Purpose Cleaning Detergent		
Part Number	Description	Qty/cs.
PC-4-1G-01	Process2Clean 4, 1 Gallon, Non-Sterile	4
PC-4-1G-02	Process2Clean 4, 1 Gallon, Sterile	4
PC-4-5G-01	Process2Clean 4, 5 Gallon Drum, Non-Sterile	1
PC-4-5G-02	Process2Clean 4, 5 Gallon Drum, Sterile	1
PC-4-30G-01	Process2Clean 4, 30 Gallon Drum, Non-Sterile	1
PC-4-30G-02	Process2Clean 4, 30 Gallon Drum, Sterile	1
PC-4-55G-01	Process2Clean 4, 55 Gallon Drum, Non-Sterile	1
PC-4-55G-02	Process2Clean 4, 55 Gallon Drum, Sterile	1
PC-4-275G-01	Process2Clean 4, 275 Gallon Drum, Non-Sterile	1



PC-4-1G-01



PC-4-30G-01

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Critical Ongoing Residue Evaluation (CORE)

The CORE program is a service offered within the VAI Laboratories division of VAI. The focus of the division is to provide our clients with a specialized laboratory service that can assist them in performing product contact cleaning evaluation studies as an external service. This department tests user product residues on Stainless Steel coupons in our unique CORE Analysis Chamber to determine the level of cleaning achieved by our Process2Clean detergents. Testing is designed around our client's product residues and detergent choice to provide you, the client, a sound scientific rationale in your Process2Clean detergent selection. CORE ultimately helps the end user implement the necessary internal and external regulatory expectations and choose the correct Process2Clean detergent by performing and providing analytical methods of detection, process cleaning compatibility, TOC curves, conductivity curves, toxicological reports, and controlled documents to assist in validation.

An extensive validation support package for **Process2Clean 4** that includes last-to-rinse studies and analytical methods of detection (specific and non-specific) are available to complement VAI's CORE laboratory testing. VAI's comprehensive pharmaceutical program enables us to customize an optimal cleaning program to meet your specific needs.

Additional Documentation Available Upon Request

- Sample lot certificates and documentation
- Safety Data Sheet SDS# VEL-016
- Product Validation Report
- In-use Validation Report
- Chemical Compatibility Recommendations Report
- CORE reports



Process2Clean detergents have been specifically formulated for critical process cleaning applications and to effectively remove a multitude of pharmaceutical and biotechnology, lab animal, cosmetic, medical device, and food & beverage product manufacturing residues. All products are formulated with WFI and follow the highest quality manufacturing standards in VAI's GMP manufacturing facility. Call 610-644-8335, email processcleaning@sterile.com, or visit our website at www.sterile.com for more information.

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