



VELTEK ASSOCIATES, INC.

# TECHNICAL DATA FILES



## Process2Clean® 1

Alkaline Detergent

Sterile and Non-Sterile Cleanroom Formula

*\*Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.\**

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## **Product Description**

**Process2Clean 1** is a high performance, concentrated, liquid alkaline detergent, and is VAI's most effective broad spectrum cleaning agent for removing a wide array of residues. This premium detergent is optimal for use in any automation cleaning (CIP) application. Its unique formulation includes Water for Injection (WFI), potassium hydroxide, chelating agent, surfactant system, and other critically essential cleaning agents provides a stabilized formula that is capable of cleaning a multitude of product and non-product contact surfaces. **Process2Clean 1** is phosphate free, has minimal to no foaming, and has excellent detergency and rinsing capabilities.

**Process2Clean 1** is available either sterile or non-sterile in 1 gallon, 5 gallon, 30 gallon, 55 gallon, or 275 gallon containers. Sterile **Process2Clean 1** is manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 7 cleanroom (Grade B) 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 1** has been specifically designed for the pharmaceutical, biotechnology, cosmetic, medical device, food & beverage, and research & development industries. Optimal use applications include: automated washers, spray systems, soak, or manual washing. Under recommended use dilution applications and conditions, **Process2Clean 1** is suitable for use with stainless steel, glass, enamel, plastics, and most elastomers.

**Process2Clean 1** is extremely effective in removing a wide assortment of soils including but not limited to, proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers, waxes, fats, and most all types of organics.

Typical use dilution for **Process2Clean 1** 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 chelating agents allows for hard water tolerance
- Premium surfactants equal great wetting abilities for optimal penetration
- High concentration translates into low cost per use
- Minimal to no foaming is ideal for optimal automated cleaning
- 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
- Unique formulation that removes a wide array of soils
- Compatible at use dilution on most all substrates
- Multiple container sizes available for optimal application

## 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 1 – Alkaline Detergent	
Test	Specifications
Specific Gravity:	1.20 – 1.40
pH (1% solution):	11.8 – 13.8
Color:	Colorless
Alkalinity as CaCO <sub>3</sub> :	20.0 – 28.0%
IR Scan:	Match Reference
Conductivity (1% Solution):	10.0 – 15.0 mS
Lead:	<10 ppm
Iron:	<10 ppm
Technical Data	Specifications
Ingredients:	Potassium Hydroxide, Tetrasodium EDTA, WFI, Chelating Agent, Surfactant System
KOH Range:	10 – 20%
Tetrasodium EDTA Range:	5 – 15%
Surfactant Mixture:	<1%
Appearance:	Clear
Characteristic:	Alkaline
Odor:	Slight Odor
P Content:	0.00%
Detergency:	Excellent
Solubility:	Miscible with water
Foaming:	Minimal to none
Rinsing:	Excellent
Biodegradable:	Yes
Storage Recommendation:	Ambient
Flash Point:	Not flammable
Expiration Period:	3 years

### **Veltek Associates, Inc.**

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## Ordering Information

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



PC-1-1G-01



PC-1-55G-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 1** 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

Upon request, the following additional documentation is available:

- Sample lot certificates and documentation
- Safety Data Sheet SDS# VEL-013
- 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](mailto:processcleaning@sterile.com), or visit our website at [www.sterile.com](http://www.sterile.com) for more information.

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