



VELTEK ASSOCIATES, INC.

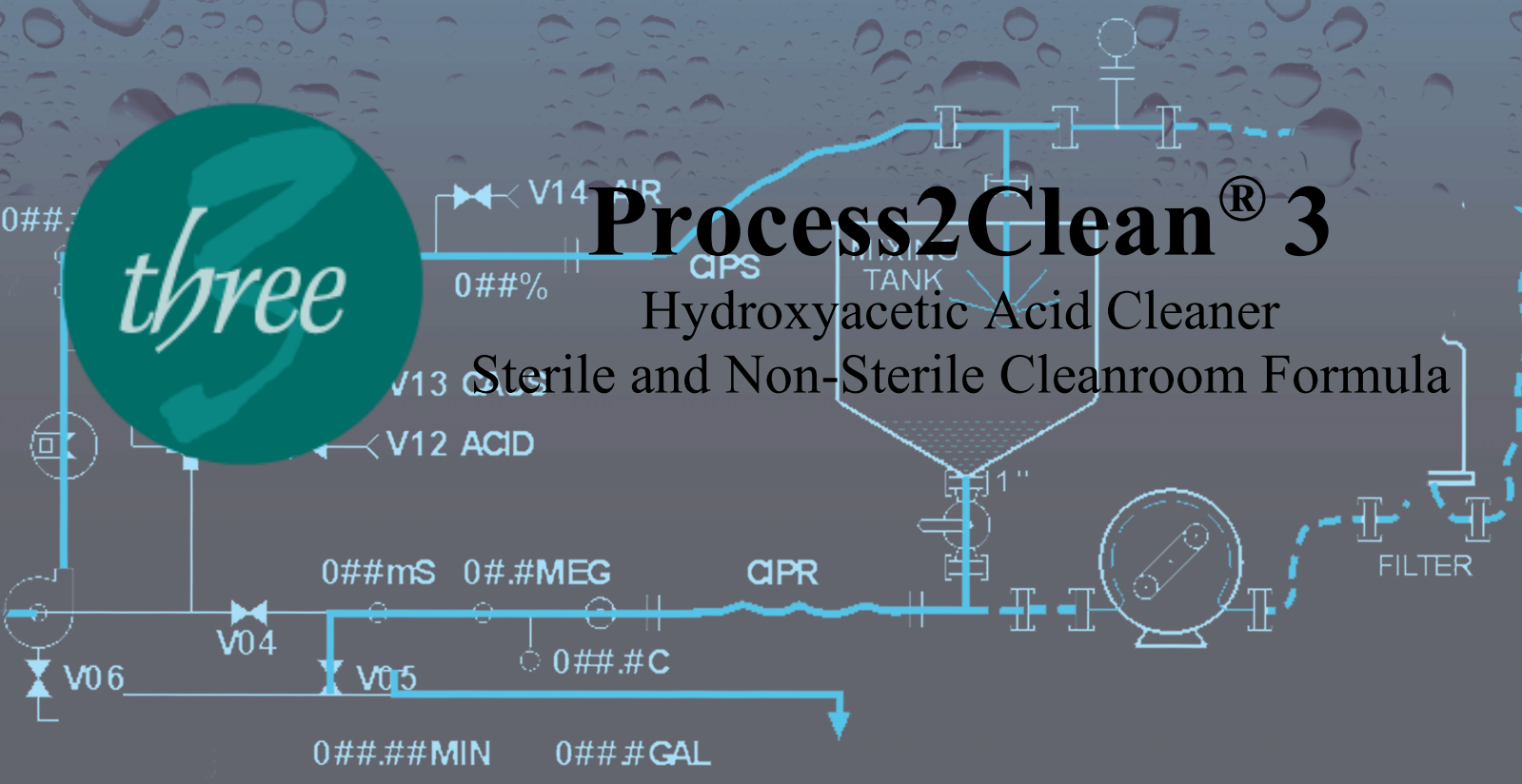
TECHNICAL DATA FILES



Process2Clean[®] 3

Hydroxyacetic Acid Cleaner

Sterile and Non-Sterile Cleanroom Formula



Product Description

Process2Clean 3 is a high performance, concentrated, liquid hydroxyacetic acid cleaner/descaler detergent, and is extremely capable of removing a wide array of residues. This stabilized cleaning agent is helpful in the removal of free metals with routine use reducing corrosion, pitting, and rusting. Its unique formulation of hydroxyacetic acid, chelating agents, 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 3** is phosphate free, is minimal to no foaming at all temperatures, has excellent detergency, and is very free rinsing.

Process2Clean 3 is available either sterile or non-sterile in 1 gallon, 5 gallon, 30 gallon, 55 gallon, or 275 gallon containers. Sterile **Process2Clean 3** 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 3 has been specifically designed for the pharmaceutical, biotechnology, cosmetic, medical device, food & beverage, and research & development industries. Optimal use applications include: automated washer equipment, spray systems, soak, and manual cleaning. Under recommended use dilution applications and conditions, **Process2Clean 3** is compatible with stainless steel, soft metals, glass, and a variety of plastics.

Process2Clean 3 is extremely effective in removing a wide assortment of inorganic soils including but not limited to scale deposits, fine chemicals, polymers, particulate carbons, and coatings. **Process2Clean 3** is especially effective on antacid formulations.

Typical use dilution for **Process2Clean 3** 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 at all temperatures is ideal for optimal automatic 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
- Routine use reduces corrosion, pitting, and rusting
- Use aids in the elimination of free metals
- Compatible at use dilution on most all substrate materials
- Multiple container sizes available for optimal application

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

T: 610-644-8335 F: 610-644-8336 www.sterile.com Rev: 09Aug2019

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 3 – Hydroxyacetic Acid Cleaner	
Certificate of Analysis	Specifications
Specific Gravity:	1.020 – 1.220
Clarity:	Clear
APHA Color:	<= 150
pH (1% solution):	1.67 – 3.67
Appearance:	Clear – Pale Yellow
Heavy Metals:	<10 ppm
Iron:	<10 ppm
Acidity:	17.0 – 27.0%
Technical Data	Specifications
Ingredients:	HEDTA, Hydroxyacetic Acid (Glycolic Acid), Alcohols, Surfactants, Chelants, WFI
Hydroxyacetic Acid Content:	25 – 35%
HEDTA Content:	<1%
Surfactant Mixture:	<1%
Characteristic:	Acidic
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.

15 Lee Boulevard, Malvern, PA 19355-1234

T: 610-644-8335 F: 610-644-8336 www.sterile.com Rev: 09Aug2019

Ordering Information

Process2Clean 3 – Hydroxyacetic Acid Cleaner		
Part Number	Description	Qty/cs.
PC-3-1G-01	Process2Clean 3, 1 Gallon, Non-Sterile	4
PC-3-1G-02	Process2Clean 3, 1 Gallon, Sterile	4
PC-3-5G-01	Process2Clean 3, 5 Gallon Drum, Non-Sterile	1
PC-3-5G-02	Process2Clean 3, 5 Gallon Drum, Sterile	1
PC-3-30G-01	Process2Clean 3, 30 Gallon Drum, Non-Sterile	1
PC-3-30G-02	Process2Clean 3, 30 Gallon Drum, Sterile	1
PC-3-55G-01	Process2Clean 3, 55 Gallon Drum, Non-Sterile	1
PC-3-55G-02	Process2Clean 3, 55 Gallon Drum, Sterile	1
PC-3-275G-01	Process2Clean 3, 275 Gallon Drum, Non-Sterile	1



PC-3-1G-01



PC-3-55G-01

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

T: 610-644-8335 F: 610-644-8336 www.sterile.com Rev: 09Aug2019

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 3** 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-015
- 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.

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

T: 610-644-8335 F: 610-644-8336 www.sterile.com Rev: 09Aug2019