

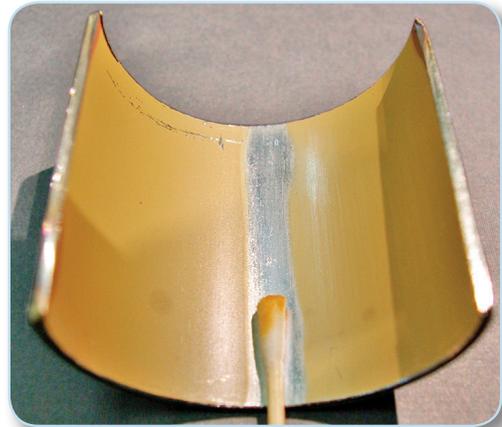
DEROUGING AND PASSIVATION

A Difficult Industry Challenge

Pharmaceutical manufacturing facilities house some of the world's most advanced stainless steel equipment. Stainless steel corrosion, or rouge, is an industry-wide problem that, left untreated, can cause:

- Problems with equipment cleaning and validation
- Equipment downtime
- Reduced equipment life
- Product contamination

Removing rouge and enhancing the corrosion resistance of stainless steel equipment are essential preventative maintenance requirements for any manufacturing facility.



Rouge

Rouge describes a variety of discolorations on stainless steel surfaces and is composed primarily of iron oxides. Sometimes rouge is generated elsewhere (e.g., a pump impeller) and then deposited on the stainless steel surface and can be relatively easy to remove. Under more extreme conditions (e.g., in steam systems), a black discoloration may be seen due to the formation of iron (II/III) oxide (magnetite). This type of rouge can be extremely difficult to remove.



Passivation

Although stainless steel is named *stainless*, it is really *stain resistant*. This property comes from its ability to spontaneously form a chromium-oxide-rich passive layer on the surface, which helps resist corrosion. Passivation is the process of using a chemical treatment to enhance this layer to improve its corrosion resistance.

Derouging and Passivation Considerations

Developing a successful procedure for derouging and passivation requires a careful balance of many factors including:

- The ability to successfully remove any visible rouge;
- Process constraints (e.g., temperatures, flow rates, etc.);
- Avoiding damage to surface finish caused by excessively aggressive chemistries;
- Operator safety when handling hazardous chemicals;
- Environmental concerns (e.g. phosphates, volatile compounds, etc.);
- Adherence to industry standards (e.g., ASTM A 967); and
- Concerns related to the use of chemicals that are not part of the validated process cleaning operations.

STERIS Can Help

Our formulated detergents, application experience, and technical support can help your company:

- Optimize your cleaning and stainless steel maintenance program;
- Maximize production uptime;
- Enhance and maintain the condition of your stainless steel process equipment; and
- Minimize the introduction of non-validated products and processes.

The STERIS Solution

Derouging

Removing rouge from process equipment can be very easy in some cases and extremely difficult in others. Therefore, there is no single "recipe" for performing a successful derouging operation. STERIS has developed a model operating procedure that consists of the following steps:

- A laboratory-based assessment to establish effective derouging parameters;
- A robust alkaline cleaning to remove organic residues;
- An acid treatment to remove iron oxides; and
- Process monitoring to assess the effectiveness of the treatment.



Passivation

Although passivation will occur spontaneously in the presence of oxygen, it can be enhanced with the use of chemical treatments. Analytical techniques like x-ray photoelectron spectroscopy (XPS) are commonly used to quantify the depth and quality of this passive layer by measuring the chromium-to-iron ratio (Cr/Fe).

Using our recommended derouging procedure, STERIS has shown that both CIP 200® and ProKlenz® TWO Acid detergents are effective for stainless steel passivation.

Products and Services

Formulated Detergents

STERIS detergents are designed for your most difficult cleaning challenges. They employ multiple cleaning mechanisms such as wetting, solubility, dispersion, emulsification, hydrolysis and oxidation which work together to penetrate, dissolve and rinse away process residues.

Alkaline Detergents

Alkaline Detergents are used to efficiently remove organic residues prior to derouging.

- CIP 100® Alkaline Detergent
- ProKlenz ONE Alkaline Detergent

Acid Detergents

Acid Detergents are used for derouging, passivation, and removing inorganic residues.

- CIP 200 Acid Detergent
 - Phosphoric acid, chelant and surfactant blend
- ProKlenz TWO Acid Detergent
 - Phosphate-free, organic acid formulation

Application Support

A highly qualified, industry-recognized team of chemists, microbiologists and engineers is available to offer product and process consultation for your derouging and passivation application. In addition to our years of hands-on experience with these applications, we have an extensive technical library of technical tips, laboratory reports, analytical methods and other documentation to support your application development and validation needs.



For more information about this application, please contact your local sales representative or visit our website at:

www.sterislifesciences.com/Market-Applications/Pharmaceutical-Manufacturing/Derouging-and-Passivation

STERIS has a comprehensive offering of detergents, disinfectants, skin care products and sterility assurance products that support your needs. We also have world class technical support to design the most effective cleaning program for your facility. Contact your local sales representative or refer to our website at www.sterislifesciences.com

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Document # M3523EN
Printed 01/2011

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