New pH neutral/non-hazardous derouging procedure provides first-class results in fraction of the time associated with conventional derouging.

DEROUGE STAINLESS STEEL WITHOUT THE USE OF HARSH CHEMICALS

In sanitary and high purity applications, it is common practice for systems and components to be fabricated from stainless steel. Indeed, 316L stainless steel is the workhorse in these applications and in most cases, performs admirably. Stainless steels achieve corrosion resistance from the passive layer formed on the surface; however, it is not completely inert and the passive layer of the stainless steel surface breaks down or "ages" over time. As this happens, due to aggressive environments, or even corrosion damage, the surface will develop a rust-colored layer known as rouge. A rouged surface is not only unattractive, but in terms of safe process management, is unacceptable owing to the elevated surface roughness and possible release of foreign particles into the process stream. The only remedy to restore the systems integrity is to intensively clean the material surface using chemicals removing the rouge layer with its high iron oxide content and to subsequently create a new passive layer of chromium oxide. In the past it has been acceptable to remove rouging by using powerful, acid cleaning solutions. Today, a new concept has been developed using a pH neutral, non-hazardous cleaning solution achieving first-class results. This new process has been designed to be so safe, and risk free that it can even be performed by the owner achieving the same end results.

“It's stainless, it shouldn’t rust!!” That is a very common misconception among many users. In all actuality, stainless steel is an iron based alloy with the most common 316L stainless steel containing approximately 64% iron. Stainless steel achieves corrosion resistance due to an ultra-thin, protective layer rich with chromium-oxide on the surface. In everyday use, this thin protective layer is constantly exposed to a variety of influences, particularly in pharmaceutical applications containing high chlorides. Chloride ions are very harmful to stainless steel. Chlorides will react with the chromium-oxide in the passive layer to form chromium-chloride which is very soluble. The remaining layer is rich with iron and iron nickel which will turn rust-colored and eventually corrode. Previously, the most common remediation process was to use powerful, acid, cleaning agents (for example, phosphoric/sulfuric acid mixtures with an acid content typically > 30%) with aggressive additives. With this and similar processes, It is necessary to dispose of the remaining solution and rinse waters as hazardous waste.

Ateco Services AG, through its U.S. distribution partner, UltraClean Electropolish Inc., now offers an environmental friendly chemical procedure void of aggressive chemicals, yet very effective on even heavily rouged equipment.

The new agent allows both flooding and spraying processes and circulation through the pipes. Autoclaves can be cleaned quickly and safely. 1a) autoclave before cleaning, 1b) autoclave three months after derouging, still perfect surface through the newly created passive layer.

Gently but thorough cleaning

You do not always need to bring out the heavy artillery to achieve top-class results and chemistry, in particular, is a prime example of this. Modern production procedures are increasingly forgoing the use of caustic, acidic or similarly hazardous substances. Catalysts in the form of chelating agents speed up reactions and often even allow an improved outcome through a targeted reaction. This approach has now been transferred to derouging. The new procedure is based on two steps using different chemical formulations. The reagents are supplied in
concentrated form and are diluted with purified water on site. The concentration of the ready-to-use solution can be adjusted by varying the amount of concentrate added according to the degree of rouge present. This controls cost and helps protect the environment. Our derousing and passivation solutions can be applied through immersion, flooding, and spraying procedures. This means that beside the known applications for cleaning pipe systems, even autoclaves (image 1a,b), batch, production and storage tanks (image 2a,b) or even freeze-drying systems (image 3a,b) can be effortlessly cleaned.

Frank Zimmermann, Deputy Pharma Production Plant Manager, said "We use a variety of different stainless steel systems in our production such as WFI-Loop (Water for Injection), clean steam distribution systems, autoclaves and washing machines. We have signed a service contract with Ateco which helps us to optimally maintain our systems and to comply with the relevant health regulations regarding stainless steel surfaces. The new pH neutral procedure which has been used here brings us first-class results".

Unopened concentrate can be stored over a long period of time allowing small derousing treatments to be carried out at short notice as required in-house without outside contractors.

**Procedure**

The kits of derousing concentrate can be stored unopened for up to two years. There are two kit sizes available with the appropriate Diruneutra concentrate to mix up to 250 L or 1,000 L of derousing solution. The concentration can be increased up to four times the amount. Depending on the capacity of the equipment and the severity of rouge present, the concentration is well mixed in the system to be treated using 75 to 85 °C hot, De-ionized water. Should the equipment to be deroused using the spray method, for example via a CIP system, then it is must be rendered inert with nitrogen to a residual oxygen content of less than 0.5 % prior to adding the derousing kit. Once the system is inert, the solution can be moved through the system using spray nozzles, circulation pumps or agitators. Only the system parts wetted by the solution will be cleaned. The derousing process takes between 30 and 240 minutes, depending upon temperature and severity of rouge present. Reactivity of the solution can be monitored by periodically testing. Once the exposure time is complete or the derousing solution is no longer active, a prescribed amount of Diruclean NS is added and mixed with the pH neutral solution. This step stops the reaction of the Diruneutra derousing product and after approximately 45 minutes of circulation, the pH neutral residual solution can be emptied into the in-house waste water system. The equipment surfaces and piping systems should then be flushed through for at least five minutes with either hot or cold running water. The subsequent bare metal stainless steel surface still requires a controlled renewal of the passive layer rich in chromium oxide.

In order to do this, the system is filled with cold, demineralized water (< 30 °C) and Hydrogen Peroxide concentrate is added in the prescribed amount. All the surfaces to be passivated must now be continually wetted with the solution for at least 45 minutes.

The Hydrogen Peroxide oxidation solution is then also emptied into the waste water system and the system is flushed through.
with running water for five minutes and a final conductivity test is performed. The procedure is finished once a difference between input and output conductivity of the rinse water is less than 1.0 µS/cm.

Freeze drying systems are usually somewhat larger. The spray process is particularly suitable in order to balance costs against benefits. Here is an example of an adjustment plate before (3a) and after (3b) derouging.

The new pH neutral Diruneutra derouging procedure offers the user several advantages:

- No aggressive chemicals with disposal regulations are used.
  - Disposal costs are eliminated
  - No neutralization is required
  - Any by-product is considered non-hazardous waste

- The proper volume of concentrates can be obtained in advance for targeted use as required.
  - This means that projects can be scheduled when production is paused without disturbing processing schedules.
  - It is possible for owners to perform the work using in house personnel on projects that require immediate attention
  - The required times to perform derouging procedures are considerably shortened, jobs that have taken over 24 hours can now be performed in one shift.

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