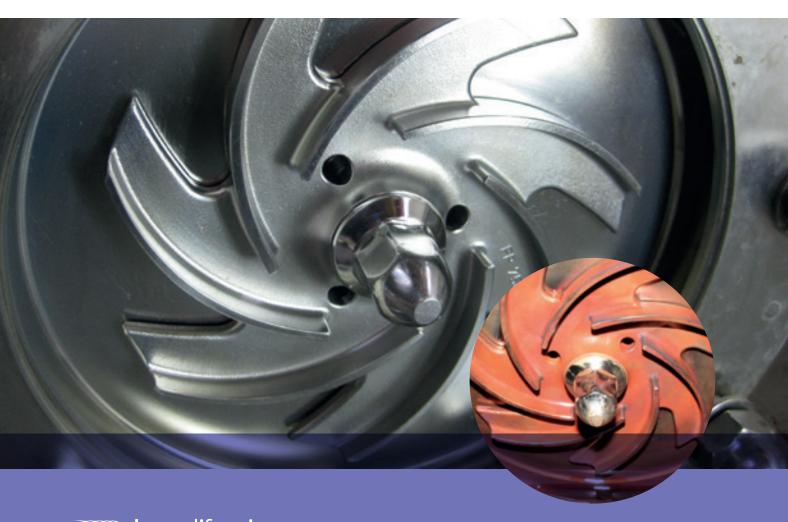


deconex® Derouging systems pH-neutral solutions against rouge

Quick, highly effective and efficient



borer life sciences



Rouge: undesirable disturbance of the passive layer

On stainless steel surfaces, there is a dynamic chemical equilibrium between metal oxides. At room temperature and in air, the chromium oxide layer predominates and forms the typical passive layer that protects surfaces against corrosion.

What is rouge?

Temperatures above 50 °C in "closed" systems such as containers and pipelines, the exclusion of atmospheric oxygen as well as a harsh environment such as purified water (PW), water for injection (WFI) or chemicals, disturb the equilibrium of the passive layer. As a result, iron oxides form larger and larger accumulations and condense into a rouge layer, regardless of the surface treatment.

Rouge is not acceptable

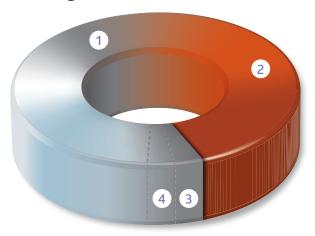
The most common type of rouge consists of reddish particles that contain a lot of iron oxides. The condition of surfaces is a central topic of guidelines such as ASME BPE Part SF "Process Contact Surface Finishes". A change in the surface is critical because it can lead to a change in cleaning properties

- · Visible rouge does not meet the "visually clean" criterion
- · Rouge does not correspond to the validated condition
- The migration of rouge particles into the product is possible
- · As corrosion, rouge reduces the service life of equipment

An efficient strategy against rouge reduces these risks and ensures the quality of pharmaceutical product manufacturing.

So don't wait until you discover rouge and production is affected. Take an active, risk-based approach with our processes and procedures and maintain surfaces in a defined condition

Development and spreading of rouge



1 Rouge originates

If the natural passive layer on stainless steel surfaces is disrupted, rouge can develop. This is especially the case if the surfaces are exposed to hot, low-ion and oxygen-poor water for a long time.

2 Rouge spreads

At the beginning of the process, iron oxides colour the surfaces reddish-brown. Since rouge is very easy to wipe off in the early stages, there is a risk of particles migration.

3 pH-neutral derouging

The pH-neutral deconex® DEROUGE System quickly and reliably removes rouge from your equipment. You will achieve excellent results and optimal safety at work and in the process.

4 Passivation after derouging

Chemically assisted passivation after derouging helps the passive layer to rebuild faster.

The periodic removal of rouge and a subsequent passivation ensure the "defined condition" of product contact surfaces as demanded by cGMP.











Efficient and gentle on material: with system against rouge

With the deconex® derouging systems, rouge class I and II can be removed quickly and reliably from stainless steel surfaces. The pH-neutral process achieves maximum performance even at the lowest application concentration and thus meets the increased requirements for equipment and environmental protection.

The deconex® DEROUGE Systems are suitable for controlled derouging processes in the pharmaceutical industry, biotechnological production and in the cosmetics industry, as well as in the supply of pure water.

The system is especially suitable for derouging operations in $% \left\{ 1\right\} =\left\{ 1$

- o production facilities
- o tanks and distribution systems for water (PW or WFI)
- o purified steam systems
- o process containers, e.g. in vaccine production
- o autoclaves
- o lyophilisers

Thanks to proven material compatibility, the use of deconex® DEROUGE Systems extends the service life of valuable equipment and components and leads to savings in production.

Literatur Tipp

Pharmaceutical Engineering, the official magazine of ISPE T. Blitz, et al. (2015): Tests on rouging and experiences dealing with rouging in pharmaceutical production, publication in 3 parts

Request a free copy (reprint) from lifesciences@borer.ch



Broad product portfolio, comprehensive documentation: highly effective and safe

Derouge it yourself!

Our deconex® derouging systems are designed for use by internal qualified technicians. Our detailed instructions for use and documentation support them in the planning and safe implementation of efficient derouging operations. This means

you are independent of external service providers and can carry out the derouging processes whenever these are required and the facilities are available.

deconex® derouging systems are available as practical sets for easy use:

	Set 50 L	Set 250 L	Set 1000 L
deconex® DEROUGE System 2.0	Item 21392	Item 21393	Item 21396
deconex® DEROUGE 2.0 liquid	1 x 1 L	1 x 5 L	1 x 20 L
deconex® DEROUGE P 2.0 powder	4 x 1 kg	2 x 10 kg	8 x 10 kg
deconex® DEROUGE System		Item 21358	Item 21359
deconex® DEROUGE liquid		1 x 5 L	1 x 20 L
deconex® DEROUGE P powder		1 x 1.5 kg	4 x 1.5 kg
deconex® DEROUGE Z liquid		1 x 1 kg	1 x 6 kg

ACDS Activity Check Safe and easy verification of the derouging solution's activity Item 528200.00-FL50 50 ml ready-to-use solution Set with practical pipettes and instructions for use. The colour change indicates when the solution is no longer active.

Following the derouging process, we recommend passivation with deconex® CIP protect or deconex® CIP boost:

Process parameters	deconex® CIP protect	deconex® CIP boost*
Concentration (V/V)	2.0 % to 3.0 %	3.0 % to 4.0 %
Temperature	60 °C to 80 °C	Up to 50 °C
Contact time	60 min.	45 min.
Circulation	Yes, if possible	Yes, if possible

*This product is only available in continental Europe





The right derouging system for each process

Depending on the type of equipment, your requirements and the available technical possibilities, our derouging systems offer the ideal solution.

		dimension in	
Beschreibung	deconex® DEROUGE System	deconex® DEROUGE System 2.0 derouging	
	The classic Maximum derouging performance with lowest application concentration	In a class of its own · No inertisation required · Works quickly and effectively · Phosphate-free	
Inert atmosphere	Required, e.g. with N ₂	Not required, works in ambient atmosphere	
Komponenten	3 components, liquid and powder	2 components, liquid and powder	
Applications	Spray processes and flooding	Primary spray processesEnsure controlled ventilation at all times	
Target temperature	75°C to 80°C	 Typically 60 °C to 80 °C Easy-to-remove rouge can be eliminated from as low as 25 °C 	
Treatment time	0.5 to 4 hrs	0.5 to 2 hrs, at low temperatures from 3 hrs	
First rinsing	Addition of deconex® DEROUGE Z at the end of derouging	Only with water; mandatory before opening of the equipment	
Rinsing and passivation	Recommended	Recommended	
In-process control	Initially and every 30 min. with ACDS Activity Check for derouging systems	Initially and if required with ACDS Activity Check for derouging systems	

Passivation: a perfect surface for maximum product quality

After each derouging process, chemically supported surface passivation with deconex® CIP protect or deconex® CIP boost is highly recommended.

Often, the equipment has to be put back into operation immediately after maintenance. This does not leave enough time for a spontaneous formation of the passive layer by the oxygen present in the air.

The advantages of deconex® derouge system at a glance

pH-neutral processes increase safety at work and maintain the value and condition of the equipment thanks to treatment that is particularly gentle on materials.

Fast processes reduce operating costs thanks to short downtimes.

Superb effectiveness and excellent results even where conventional methods reach their limits.

Easy to use thanks to practical sets for preparing a defined amount of working solution.





Borer Chemie AG

The specialists in cleaning and disinfection

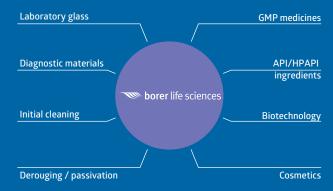
Competence and innovation - worldwide

We have been researching, developing and manufacturing products in Switzerland for demanding applications in the field of cleaning and disinfection since 1965. Our deconex® and decosept® branded products are used in the industrial sector, in hospital hygiene, in laboratories, in the pharmaceutical sector and in hand and surface disinfection. We distribute our products worldwide through a network of subsidiaries and distribution partners.



Demonstrably clean: focus on residue-free cleaning

Analytically clean surfaces are not only required for laboratory glassware cleaning, but also for validated cleaning, for example in pharmaceutical production according to GMP. The combination of a specific cleaning method and the right cleaning agent results in effective and residue-free cleaning. Optimised processes reduce downtimes and increase productivity. They also ensure that the value of production facilities is maintained.



deconex® CLEAN study: a unique service

We share our expertise in the development of cleaning processes with our customers in the form of a deconex® CLEAN study. With our products and comprehensive documentation, the cleaning validation process is successful. Users also benefit from the programmes at our Borer Cleaning Academy. Through education and individual training, they are able to improve their expertise in demanding cleaning.

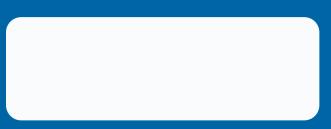




advanced cleaning solutions

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