

BIOPHARMA

HIGH PERFORMANCE EQUIPMENT CLEANING



HOW DO YOU CLEAN?

How *effective* is your current cleaning process?

Does your cleaning process limit your production and cause excessive downtime?

We deliver cleaning recommendations that are effective, compliant and deliver value. Effective cleaning is a combination of both physical and chemical processes. By understanding this combination and applying it to your specific residues and equipment, we deliver repeatable and reliable cleaning recommendations, which are optimized for your manufacturing. Furthermore, our recommendations deliver value by providing significant operational efficiency, safer operations and environmental advantages.

BUILDING BUSINESS EFFICIENCIES

WITH A PROPER CLEANING PROCESS
RESULTS IN:





INTRODUCING

CHEMATIC®

570

BLOOD FRACTIONATION COMPONENTS, CELL CULTURE, FERMENTATION, MEDIA & BUFFER SOLUTIONS

Biopharmas most effective non-chlorinated detergent for cleaning a wide variety of organic and proteinaceous process residues for clean-in-place (CIP) and clean-outof-place (COP).



The continued use of traditional chlorinated detergents *may* damage expensive production equipment.

Chematic 570 is an innovative alkaline detergent designed as an alternative to traditional highly alkaline chlorinated detergents for cleaning common residues found in the biopharmaceutical industry including proteinaceous residues, cell culture and fermentation residues, as well as media and buffer solutions.







PROTECTION

Chematic 570 not only provides the best clean, but also offers the best protection for process equipment over chlorinated alkaline cleaners.



FLEXIBILITY

Chematic 570 effectively cleans a wide variety of organic and proteinaceous process residues in CIP and COP.



VALIDATION

We facilitate cleaning validation with comprehensive support documentation, including specific analytical methods, toxicity and substrate compatibility reports.



SAVINGS

We work with our customers to provide a customized Custom Cleaning Evaluation (CCE) study. Our CCE provides clients with an optimized cleaning process for their residues and specific operations needs including water consumption, utility use and cleaning times. This is provided at no additional cost to our clients.



EXPERTS IN CLEANING CHALLENGING RESIDUES

Our detergents and cleaning recommendations tackle difficult proteinaceous residues, while reducing risk of rouging process equipment with our industry leading non-chlorinated alkaline cleaners.



CELL CULTURE & FERMENTATION



MEDIA & BUFFER SOLUTION



ALBUMIN



INJECTABLES/ VACCINES



BLOOD PRODUCTS





LET'S GET STARTED!

OUR PROCESS













Client provides data to Chematic Lab



Chematic Lab performs Cleaning Study



Field Trial



Analytical Tech Transfer Package



Achieve Validation





ANALYTICAL CLEANING VALIDATION RESULTS

WITH THE ANALYTICAL TECH TRANSFER PACKAGE

We go above and beyond in helping our clients achieve a validated state. As part of our customer offering, we provide our clients an analytical technical transfer package that includes everything your lab needs to validate Chematic formulated detergents are effectively removed from process equipment after a high performance clean.



Adhere to regulatory guidelines



The Dober lab performs testing to isolate the detergent components that are "last-to-leave" during cleaning



Chematic detergents have validated TOC and HPLC analytical methods, including ADE, PDE values



Train customer on how to execute analytical cleaning process, if needed



Test method transfer protocol performed simultaneously at Dober's lab and at customer's lab



Post test methods transfer, the customer will receive the test method, transfer data and results package as part of the Analytical Tech Transfer Package



Achieve validation





SCALING UP:

WORKING TOWARD A VALIDATED STATE

ACM Lab Study Recommendations





D@BER FORMULATED DETERGENTS

BIOPHARMA

CHEMATIC 570

Albumin
Cell Culture &
Fermentation
Media & Buffer
Solutions



CHEMATIC 573

Metal Oxides (Fe, Zn, Ti) Ethyl Cellulose Media & Buffer Solutions



CHEMATIC 7

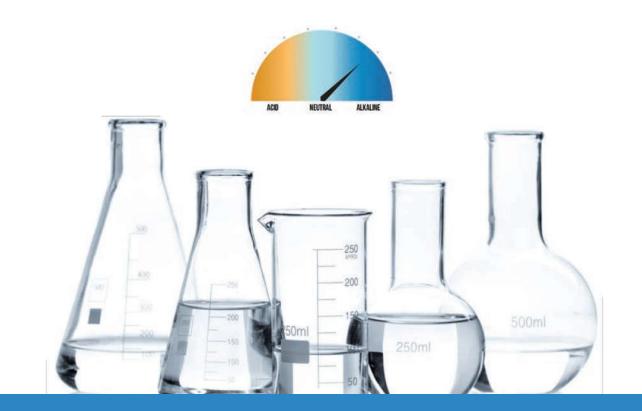
Hardness/Scale
Passivation
Cell Culture &



CHEMATIC 300

Veterinary Products
Hardness/Scale
Passivation
Cell Culture &
Fermentation









OUR COMMITMENT TO OUR CUSTOMERS

RIGOROUS STANDARDS

- ✓ Chematic production meets cGMP standards
- ✓ Complete lot traceability
- All raw materials are QC tested
- ✓ QC approval before release
- ✓ Product C of A's provided
- ✓ Change control policy

ADDITIONAL SERVICES & SUPPORT

- A cleaning process optimized for your equipment
- Analytical test methods provided under confidentiality
- Controlled formulation and detection method for all formulated Chematic detergents
- · Cycle development assistance
- · Committed to continuity of supply for the life of your product
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- Phone: 630.410.7300 | Toll Free: 800.323.4983
- www.dober.com

