SAFC

Pharma & Biopharma Raw Material Solutions



The Deviron® Detergent Portfolio

Our Emprove® detergents for a sustainable Triton™ X-100 replacement in biologics manufacturing

Biologics manufacturing processes include critical steps such as viral inactivation or cell lysis that are typically performed with detergents.

Triton™ X-100 detergent (4-tert-octylphenol polyethoxylate) is the primary component templated in biomanufacturing processes, but as of January 2021, its unauthorized use has been prohibited in the European Union by the European Commission, due to its listing to REACH¹ (Registration, Evaluation, Authorization and Restriction of Chemicals).

In response to the global implications of restrictions on Triton™ X-100, we have developed the Deviron® C16 Emprove® Evolve detergent and the Deviron® 13-S9 Emprove® Expert detergent.

A comparison table is available to aid product evaluation and selection.

| | Deviron® C16 Emprove® Evolve Detergent | Deviron® 13-S9 Emprove® Expert Detergent | Triton™ X-100 Emprove® Expert Detergent |
|--|---|---|---|
| Product code | 108693 | 108694 | 108643 |
| Surfactant type | Zwitterionic (pI 8.9) | Non-ionic | Non-ionic |
| Chemical name | N,N-Dimethyltetradecylamin- N-oxide | Alcohols, C11-15-secondary, ethoxylated | 4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated |
| CAS number | 3332-27-2 | 68131-40-8 | 9036-19-5 |
| Critical micelle concentration (CMC) | 0.002-0.003% wt (24 °C) | 0.005% wt (24 °C) | 0.013% wt (24 °C) |
| Biodegradability (Readily biodegradable: >60% within 28 days) OECD 301 | Readily biodegradable: 88% degradation (OECD 301B) | Readily biodegradable: 74% degradation (OECD 301B) | Substance of Very High Concern as defined by REACH ¹ |
| Virus inactivation efficiency LRV ≥ 4 (@ ≥0.5% wt,15-25 °C) | Better or comparable to benchmark | Better or comparable to benchmark | Benchmark |
| Cell lysis efficiency for viral vector processing | Better or comparable to benchmark | Better or comparable to benchmark | Benchmark |
| Endotoxin removal for plasmid manufacturing (with Natrix® Q chromatography membrane) detergent as Wash Buffer Supplement | 99.997% removal | 99.969% removal | 99.997% removal |
| Emprove [®] & M-Clarity [™] | Emprove® Evolve, MQ400, (ISO9001 or equivalent) | Emprove® Expert, MQ500, (IPEC-PQG GMP) | Emprove® Expert, MQ500, (IPEC-PQG GMP) |
| Composition | 30% aqueous solution | Pure substance (100%) | Pure substance (100%) |
| Available formats | 1 L, 2.5 L, 25 L | 1 L, 2.5 L, 25 L | 1 L, 2.5 L, 25 L, 190 L |
| Customized Certificate of Analysis options | Available | Available | Available |
| Toxicology Report | Available | Available | NA |

Reference: 1 https://echa.europa.eu/

Choosing Fit-For-Purpose Raw Materials

As a supplier of thousands of raw materials for biologics manufacturing, we know the importance of quality and consistency. Our M-Clarity™ and Emprove® programs are designed to provide customers with the transparency and information needed to select fit-for-purpose raw materials and access to detailed documentation to meet regulatory requirements.

To learn more about our M-Clarity $^{\text{TM}}$ attributes, click here or download our brochure

For our Emprove® Program click here or download our brochure



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