

What does it mean switching from Benzonase® endonuclease Emprove® Expert to Benzonase® endonuclease Safety Plus Emprove® Expert

Benzonase® endonuclease—the smart solution for DNA removal in biopharmaceutical production has proven its value for over 30 years. We balance efficiency and regulatory compliance by delivering reliability and high-quality due to manufacturing under GMP (ICH Q7). All Benzonase® endonuclease products share the same amino acid sequence (proven by LC-MS/MS mass spectrometry), robustness and activity. Additionally, to the stringent quality control and extensive documentation packages coming with Benzonase® endonuclease Emprove® Expert, the all new Safety Plus product elevates the high-quality level even further. Adding most recent manufacturing and analytical technologies it delivers elevated risk mitigation. Full non-animal-origin certification of the manufacturing process using a chemically defined fermentation medium and the addition of virus and mycoplasma testing are key features of Benzonase® endonuclease Safety Plus Emprove® Expert. Tailgate samples for the large pack size avoid opening of the pack during incoming goods control and add a further layer of product safety. Temperature strips have also been added to the packaging to monitor cold chain during shipping with its new features Benzonase® endonuclease Safety Plus Emprove® Expert is ideally suited for manufacturing of cell and gene therapy agents such as adeno associated and lenti viruses, oncolytic viruses and viral vector vaccines.

A thorough analysis by our technical and regulatory experts came to the conclusion that **Benzonase® endonuclease Emprove® Expert and Benzonase® endonuclease Safety Plus Emprove® Expert can be considered equivalent.**

- Both products are based on the same genetic sequence and have the same amino acid sequence (based on LC-MS/MS measurement)
- Both are manufactured at the same site using the identical quality management system
- Both are tested by the same validated analytical methods for product QC release
- The differences are based on the fermentation media (chemically-defined) for production, additional testing for the absence of mycoplasmata and adventitious viruses, and supplemental support (tailgate samples and temperature strips in packaging)

Based on this information and our understanding, there is no requirement for the user to re-qualify the product when moving from Benzonase® endonuclease Emprove® Expert to Benzonase® endonuclease Safety Plus Emprove® Expert.

Characteristics	Standard Benzonase® endonuclease EMPROVE®Expert	New Benzonase® endonuclease Safety Plus EMPROVE®Expert
Origin	<i>Serratia marcescens</i> , Production: <i>E. coli</i> K12 strain W3110; 30 kDa; pI 6.85; sequence homology (LC-MS/MS)	
Non-Animal-Origin (NAO), expressed in <i>E.coli</i> in chemically defined fermentation medium	No	Yes (animal origin-free)
Lot release <i>in-vitro</i> test for absence of adventitious viruses (3 cell lines)	No	Yes
Lot release testing for Mycoplasma	No	Yes
Tailgate Samples	No	Yes (with 5M unit size)
Shipment with temperature strips	No	Yes
Microbial testing	< 10 CFU/100,000 U	< 10 CFU/100,000 U
Endotoxins (LAL)	< 0.25 EU/1,000 U	< 0.25 EU/1,000 U
GMP manufacturing according to ICH Q7	Yes	Yes
FDA Drug master file (DMF) & Emprove® Dossiers	Yes	Yes
Long Term Product Availability	Both Benzonase® products will stay in portfolio	

Ordering Information

Description	Cat. No.
100,000 units	1.03773.1010
500,000 units	1.03773.0001
5,000,000 units (with 50,000 unit tailgate sample)	1.03773.0010
Residual Benzonase® endonuclease Detection	
Benzonase® ELISA Kit II	1.01681.0001

Disclaimer: The described regulatory assessment represents a general view of Merck. It remains the obligation of each customer to perform their own risk assessment for the respective product and to align it with the respective regulatory authorities.

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