

LactiproNXT and LactiproFLX FAQs - External

General

1. What is *Megasphaera elsdenii*?

Megasphaera elsdenii is an anaerobic bacterium that naturally occurs in the rumen. The strain NCIMB 41125 is patented by MS Biotec and was selected because it is a highly effective, versatile and robust strain of *Megasphaera elsdenii*. NCIMB 41125 grows well over a wide pH range and is a potent lactic acid utilizer that enables regulation of rumen pH and contributes to the development and maintenance of a healthy rumen and rumen environment.

2. Why is MS Biotec changing to a new formulation?

Many customers successfully manage the 14-day shelf-life of Lactipro *advance*[®], but it is a challenge. Our goal was to create a more customer-friendly formulation with longer shelf-life and to offer multiple application methods to meet customer needs. The LactiproFLX[®] capsule is a convenient form for use in dairies, hospitals/sick pens, sale barns and for small numbers of animals. LactiproNXT[®] is a lower volume drench, improving ease of administration. LactiproNXT requires only 20 mL be administered per head (40 mL per head for cows) rather than 50 mL (100 mL per head for cows) with Lactipro *advance*.

Lactipro *advance* will be discontinued once LactiproNXT and LactiproFLX are fully launched to the market.

3. Why do LactiproNXT and LactiproFLX have to be refrigerated?

If *Megasphaera elsdenii* is exposed to oxygen, the bacteria die. Our production process is unique, and MS Biotec and its affiliates are the only manufacturers in the world that can produce viable anaerobic bacteria on a large commercial scale.

MS Biotec's 2nd generation product known as Lactipro *advance* does not require refrigeration due to its short shelf life of 14 days from the date of manufacture. The short shelf life results in waste at both the MS Biotec production facility and at the customer location.

MS Biotec has spent 7 years developing production and quality control processes to transform Lactipro *advance* into LactiproNXT (drench formulation) and LactiproFLX (capsule formulation). This 3rd generation product is freeze-dried and offers 12-month shelf life from the time of manufacture. Refrigeration maintains the viability of freeze-dried *Mega e*TM.

4. How does freeze drying impact *Mega e*?

MS Biotec has developed a unique process to transform the bacterial culture into a stable, freeze-dried form. In this form, *Mega e* is alive, but in a dormant state. Bacterial growth resumes when the freeze-dried product is rehydrated before administration with the drench formulation and in the rumen with the capsule formulation. Freeze drying does not harm or slow the bacteria's ability to replicate.

5. Do LactiproNXT and LactiproFLX perform the same as Lactipro *advance*?

LactiproNXT and LactiproFLX have undergone extensive testing to ensure the bacteria's capacity to utilize lactate is unchanged from Lactipro *advance*.

Lactate utilization is characterized *in vitro* by inoculating a lactate growth medium with bacteria and monitoring bacterial growth. The growth characteristics of *Mega e* are understood and well-documented. Testing on LactiproNXT and LactiproFLX demonstrate bacterial growth is the same for all 3 products, providing assurance the freeze-dried bacteria will perform the same as the bacteria contained in Lactipro *advance*.

In vivo testing in feedlot steers demonstrated that lactic acid utilization capacity of the rumen was not different between freeze-dried, rehydrated *Mega e* and Lactipro *advance*.

6. How are LactiproNXT and LactiproFLX shipped?

At our facility, LactiproNXT and LactiproFLX are stored in the refrigerator at 40°F ± 4°. Both products are shipped to customers in specially designed, insulated shipping boxes to reach the customer within 3 days; neither product is shipped over the weekend. Shipping tests were conducted by MS Biotech on both LactiproNXT and LactiproFLX at a range of temperatures (including consistent 95°F exposure for 3 days). Following various temperature exposures, product was stored at 40°F and cell viability versus control was assessed over a 6-month period. Data demonstrate no negative impact on *Mega e* cell viability during 3-day shipment if product is placed in the refrigerator upon arrival and is consistently stored at 40°F. If product is in transit for more than 3 days, please contact customer service immediately.

LactiproNXT

7. What is the liquid in the LactiproNXT pouch?

The rehydrant is a mineral salt solution that provides optimal conditions for *Mega e* to become metabolically active once rehydrated.

8. How should LactiproNXT be handled when removing it from refrigeration?

Remove the appropriate amount of LactiproNXT from refrigeration and place it in a cooler or the insulated shipping box. Transport to processing location. Rehydrate pouches only as needed. If all pouches are not used, place unused pouches back in refrigeration. If a pouch is rehydrated, it must be used within 12 hours.

9. Why do I have to discard LactiproNXT 12 hours after rehydration?

Using LactiproNXT within 12 hours of rehydration ensures the *Mega e* bacteria administered are viable and ready to work in the rumen. Additionally, contaminants can enter rehydrated LactiproNXT through the drench gun tubing or the pouch connector at the customer location. A 12-hour discard ensures that contaminants, if present, do not reach a level of concern.

10. How do I discard unused LactiproNXT?

If LactiproNXT has not been activated, it can be discarded in with other trash.

If LactiproNXT has been activated, the ideal discard procedure is to drain the contents of the pouch into a 0.06% bleach solution (1:100 dilution of household bleach to liquid biological waste) for 30 minutes

and then discard the solution down the drain while running water. At minimum, LactiproNXT that has been activated for less than 12 hours can be discarded in a dumpster. If it has been activated for more than 12 hours, drain the contents down the drain while running water.

Please contact MS Biotec customer service if you have questions.

LactiproFLX

11. How should LactiproFLX be handled when removing it from refrigeration?

Each LactiproFLX capsule is individually sealed in foil. Open the LactiproFLX zipper pouch and remove the number of foil-sealed capsules needed. Place them in a cooler with an ice pack. Open the foil-sealed capsules only as needed at the time of administration. If any capsules are left after working cattle, place them back in cold storage and use these capsules first next time.

12. What should I do if LactiproFLX capsules get wet?

The capsules should be kept in their individual foil packaging until application to the animal. If opened capsules get wet, they must be discarded. Please contact MS Biotec customer service for assistance.