# OFFICE OF THE TEXAS STATE CHEMIST

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## FEED INDUSTRY MEMORANDUM NO. 5-37

### **Definition of 3-Nitrooxypropanol**

#### **OBJECTIVE:**

To define 3-nitrooxypropanol use in lactating dairy cows per the enforcement discretion <u>letter</u> issued by the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) on May 24, 2024, and provide a mechanism for obtaining approval by the Office of the Texas State chemist (OTSC) to market 3-nitrooxypropanol in Texas.

#### **BACKGROUND:**

The Texas Commercial Feed Rules §61.22(5) (B) (iii) define the Office of the Texas State Chemist's authority to approve new ingredients. The OTSC policy applies only to 3-nitrooxypropanol when used for the reduction of methane emissions per pound of dry matter (DM) intake when incorporated at 27.2-36.3 mg 3-NOP per pound (60-80 mg per kilogram) of DM in the total mixed ration of lactating dairy cows and represents the OTSC interpretation of the FDA/CVM enforcement discretion <u>letter</u>. Data has demonstrated that 3-nitrooxypropanol will achieve its intended effect of reducing methane emissions per pound of DM intake and poses a low risk to humans or animals under the conditions of its intended use. The use of 3-nitrooxypropanol defined by the OTSC policy is well tolerated by lactating dairy cattle as outlined by the FDA/CVM enforcement discretion <u>letter</u> and supported by scientific literature.

#### POLICY:

- (a) 3-nitrooxypropanol is for further manufacture of feed for reduction of methane gas emissions per pound of dry matter intake in lactating dairy cows. It must be labeled with appropriate directions for use: Thoroughly mix 3-nitrooxypropanol into a total mixed ration at 540-720 g/ton of complete feed (100% dry matter basis) to provide 27.2-36.3 mg 3-nitrooxypropanol per pound (60-80 mg per kilogram) of dry matter intake. 3-nitrooxypropanol can be incorporated into a premix then included in the total mixed ration to ensure adequate uniformity. A commercial premix label must declare all ingredients, include guarantees to contain a minimum of 10% (w/w) 3-nitrooxypropanol and maximum of 60% (w/w) silicon dioxide (21 CFR 573.940), and have appropriate directions for use. Silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.
- (b) This policy applies to Texas and is viewed by the Office as consistent with the federal letter of enforcement discretion issued by FDA/CVM.

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