

Petitions should be submitted in duplicate to:  
National Organic Standards Board,  
c/o Robert Pooler, Agricultural Marketing Specialist,  
USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268,  
PO Box 96456,  
Washington, DC 20090-6456.  
Phone: (202) 720-3252.  
Fax: (202) 205-7808.  
E-mail: [nlpetition@usda.gov](mailto:nlpetition@usda.gov).

From:  
Kelly Shea  
Horizon Organic Dairy  
6311 Horizon Lane  
Longmont, CO 80503  
Phone: (303) 530-2711  
Fax: (303) 527-3392  
E-mail: [kellys@horizonorganic.com](mailto:kellys@horizonorganic.com)  
<http://www.horizonorganic.com>

**Petition for Amending the National List of the USDA's  
National Organic Program  
To include:**

**POLOXALENE**

**Category for inclusion on the National List:**

205.603.a

A synthetic, allowed for use in organic livestock production as a medical treatment

**\*\*Please note:** This petition is not endorsing any name brand product. However, research was obtained from or was found in conjunction with certain name brand products. Therefore, these sources have been noted.

According to the Online database system for FDA approve animal drugs (Drug Product Abstract) Poloxalene (tradename Therabloat) is an over-the-counter (OTC 039-729) treatment for cattle, any use class.

Poloxylene is the active ingredient in various bloat control and bloat treatments, such as TheraBloat (Pfizer 039-729 Chapter 1 Section 1.2 Trade Names and Sponsors: Arranged by NADA Number Health, Div Am Cyanamid 039-729 Therabloat ® Pfizer, Inc. OTC: 039-792).

Poloxalene is an over-the-counter (OTC) drug with no withdrawal time necessary before slaughter and no milk discard. (Center for Veterinary Medicine MEMO CVMM-27 FOOD AND DRUG ADMINISTRATION, CENTER FOR VETERINARY MEDICINE COMMUNICATIONS AND EDUCATION BRANCH, HFV-12, 301/594-1775)

**Other Names:**

Polyoxypropylene-polyoxyethylene glycol nonionic  
Block polymer  
Poloxanlene [9003-11-6]

**Synonyms:**

POP/POE condensate  
Poloxamer

**CAS Number:** 9003-11-6

**Chemical Composition:** C<sub>5</sub>H<sub>10</sub>O<sub>2</sub>

**ACX:** X1017331-2

**CFR Title 21:** 520.1840 Poloxalene and 558.464

**Specifications:**

No specifications are included in the CFR for this product.

**Conditions of use:**

Cattle: Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

**Indications:**

For treatment of legume (alfalfa, clover) bloat in cattle.

**Limitations:**

No limitations are included in the CFR for this species when using this product in this amount.

[Code of Federal Regulations]  
[Title 21, Volume 6, Parts 500 to 599]  
[Revised as of April 1, 2000]  
From the U.S. Government Printing Office via GPO Access  
[CITE: 21CFR520.1840]  
[Page 170-171]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS--Table of Contents  
Sec. 520.1840 **Poloxalene**.

(a) Chemical name. Polyoxypropylene-polyoxyethylene glycol nonionic block polymer.  
[[Page 171]]

- (b) Specifications. (1) Molecular weight range: 2,850 to 3,150.  
(2) Hydroxyl number: 35.7 to 39.4.  
(3) Cloud point (10 percent solution): 42 deg. C.-46 deg. C.  
(4) Structural formula:  
[GRAPHIC] [TIFF OMITTED] TR01JA93.415

(c) Sponsor. (1) See No. 000069 in Sec. 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d) (1) of this section.

(2) See No. 000069 in Sec. 510.600(c) of this chapter for sponsor of usage provided by paragraph (d) (3) of this section.

(3) See No. 036904 in Sec. 510.600(c) of this chapter for sponsor of usage provided by paragraph (d) (2) of this section.

(4) See No. 017800 in Sec. 510.600(c) of this chapter for sponsor of the usage provided by paragraph (d) (4) of this section.

(d) Conditions of use. (1) For treatment of legume (alfalfa, clover) bloat in cattle. Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

(2) For control of legume (alfalfa, clover) bloat in cattle. Administer, in molasses block containing 6.6 percent **poloxalene**, at the rate of 0.8 oz. of block (1.5 grams **poloxalene**) per 100 lbs. of body weight per day.

(3) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle. A 53-percent **poloxalene** top dressing on individual rations of ground feed. Dosage is 1 gram of **poloxalene** per 100 pounds of body weight daily. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat use of the drug if animals are exposed to bloat-producing conditions for more than 12 hours after the last treatment. Do not exceed the double dose in any 24-hour period.

(4) For control of legume (alfalfa, clover) and wheat pasture bloat

in cattle. Administer in molasses block containing 6.6 percent **poloxalene**, at the rate of 0.8 ounce of block (1.5 grams of **poloxalene**) per 100 pounds of body weight per day. Provide access to blocks at least

7 days before exposure to bloat-producing conditions.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39857, Aug. 29, 1975; 42 FR 41854, Aug. 19, 1977; 50 FR 5385, Feb. 8, 1985; 54 FR 33501, Aug. 15, 1989; 56 FR 50653, Oct. 8, 1991; 58 FR 26523, May 4, 1993; 60 FR 55659, Nov. 2, 1995]

**List of uses, rates, and applications also mode of action for handling uses:**

Bloat in cows is caused by the inability to remove gas from the rumen at the rate it is being produced. The general cause is feed-related, such as lush green alfalfa pastures or fine leafy alfalfa hay. This causes a frothy bloat, trapping the gas in small bubbles, which cannot be eructated. Obstructions along the esophagus caused by caseous lymphadenitis abscesses can reduce the ability to eructate the normal gas production. Some concentrate feeds such as barley may also cause bloat problems. As the rumen fills with gas, the left side of the animal enlarges and fills the triangle made by the back of the ribs, the processes along the loin, and the hip (the paralumbar fossa). Prevention of bloat depends on the cause. Certain management practices that are applicable to specific areas may reduce the potential of bloat. However, in emergency cases it is crucial to be able to treat bloat, depending on the type. Frothy bloats require some type of wetting agent such as poloxalene to break up the small bubbles.

**Active Ingredient(s):** Each fluid ounce (approx. 30 ml) contains Poloxalene 25 g

**Indications:** THERABLOAT® Drench Concentrate will relieve legume bloat in cattle within minutes when used as directed. For the best results administer at the earliest sign of bloat. If bloat has progressed in its severity to the degree that the animal is down, other means of treatment are also recommended (rumenotomy - rumen puncture). For oral use only - not for injection. May be used in lactating animals.

**Pharmacology:** Poloxalene lowers the surface tension of the frothy mass so the bubble film is weakened and can no longer contain the gas. The foam collapses back to the liquid level, unblocking the esophagus so that the animal can orally expel gases.

**Dosage and Administration:** THERABLOAT® is a highly concentrated form of poloxalene designed to be diluted with water and administered orally as a drench, or by stomach tube.

For animals up to 500 lb, use 1 fl oz of Drench Concentrate.

For animals over 500 lb, use 2 fl oz of Drench Concentrate.

Directions for preparing drench: Add the proper amount of concentrate to one (1) pint of water. Mix well and administer using a drenching bottle. If a stomach tube is to be used, add the concentrate to one (1) gallon of water.

**Caution(s):** Not for human use.

Keep this and all medication out of the reach of children.

For veterinary use only.

**Discussion:** Bloat (ruminal tympany) is the entrapment of gases, which eventually obstructs the esophagus, creating a closed cavity in the rumen. Bloat is usually caused by a change in diet. Legume forages such as alfalfa and clover and high-protein grain feeds can cause rapid production of fermentation gases (methane, CO<sub>2</sub>, and nitrogen). The

bubbles mix with the ruminal fluids to form a stable foam. The animal is unable to eructate and dies of asphyxia.

**Presentation:** 2 fl oz plastic bottle.

85-8620-06

**Compendium Code No.:** 03693537

**Association of Feed Control Officials (AAFCO):** R. J. Noel, Ph.D., AAFCO Secretary/Treasurer at Purdue University provided information on polyoxyethylene glycol showing it to have no restrictions in animal feed, except in calf milk replacers. It is governed by FDA Reg. 573.820

**Excerpt from the Food Additives Status List:** (intended to include all foods and drugs use named in regulations promulgated under Sections 401 (Food Standards), 409 (Food Additives) and 512 (Animal Drugs) of the Food, Drug and Cosmetic Act):

**Polyoxyethylene glycol (400) mono- & di- oleates** - EMUL, REG, In milk replacer formulations for calves - 573.820

**Polyoxyethylene (23) lauryl ether** - FEED, REG, Use: In feed blocks for cattle - 520.1846

**Polyoxyethylene (40) monostearate** - AF, REG, Defoaming agent comp - 173.340

**Polyoxyethylene-polyoxypropylene block polymers (avg molecular weight 1900)** - SANI, REG, GMP, Adequate drainage - 178.1010

**Polyoxyethylene-polyoxypropylene block polymers (avg molecular weight 2000)** - SANI, REG, GMP, Adequate drainage; May be used on glass containers for holding milk - 178.1010

**Polyoxyethylene-polyoxypropylene block polymers (avg molecular weight 2800)** - SANI, REG, < 80 ppm in soln - Adequate drainage - 178.1010

**Polyoxyethylene (20) sorbitan monooleate** - See Polysorbate 80 - 172.840

**Polyoxyethylene (20) sorbitan monostearate** - See Polysorbate 60 - 172.836

**Polyoxyethylene (20) sorbitan tristearate** - See Polysorbate 65 - 172.838

**Polyoxypropylene glycol (Minimum molecular weight 1000)** - BC, REG, GMP, In boiler water - 173.310

**Polypropylene glycol (Molecular weight 1200-3000)** - AF, REG, Defoaming agent comp used in beet sugar & yeast - 173.340

**Polysorbate 60 (Polyoxyethylene (20) sorbitan monostearate)** - EMUL, REG, < 0.40% alone or w/one or comb of sorbitan monostearate, Polysorbate 80, Polysorbate 65 - In whipped veg oil topping. Total amount any comb < 0.77% - 172.836; REG, < 0.46% alone or any w/sorbitan monostearate Polysorbate 65 - In cake mixes & cakes (dry wt basis). Total amt any comb < 0.66% - do; REG, < 0.5% of wt of finished pdts alone or in comb w/sorbitan monostearate - Part 163 (163.123, 163.130, 163.135, 163.140, 163.145, 163.150, 163.153, 163.155), Cocoa Pdts - do; REG, < 0.46% alone or any comb w/Sorbitan monostearate &/or Polysorbate 65 - In cake icing &/or cake filling containing shortening - do, Total amt any comb < 1.0% of finished wt; MISC, REG, < 0.2% - To impart greater opacity to sugar-type confectionery coatings - do; EMUL, REG, < 0.3% - In non- standardized dressings - do; REG, < 1.0% alone or comb Polysorbate 80 - In shortening & edible oils intended for use in foods where standards permit - do; REG, < 0.40% alone or/w sorbitan monostearate or/w polysorbate 65 - In veg oil/water emulsion

used as milk or cream substitute in beverage coffee - do; REG, < 4.5% by wt of nonalcoholic mix - As foaming agent in nonalcoholic beverages used in mixing - do; REG/FS, 0.5% by wt of flour alone or w/other emul - As a dough conditioner in yeast-leavened bakery pdts, 136.3 - do; EMUL, REG, GMP, Alone or w/sorbitan monostearate in formulations of white mineral oil &/or petroleum wax for ctgs on raw fruits & vgs - do; REG, 0.5% dry wt. basis - As dispersing agent in art sw gelatin desserts & mixes - do; REG, Total amt comb < 1.0%; < 0.05% in finished pdt - As emulsifier in chocolate flavored syrups - do; REG, As surfactant & wetting agent for natural & artificial colors in food; < 4.5% by wt of mix - In powdered soft drink mixes; < 0.5% by wt of mix - In sugar base gelatin dessert mixes; < 3.6% by wt. of mix - In art sw gelatin dessert mixes; < 0.5% by wt. of mix - In sugar based pudding mixes; < 0.5% by wt. of mix - In art sw pudding mixes - do; REG, < 0.1% followed by either < 8% acetic anhydride or < 7.5% vinyl acetate - In modifying food starch < 2.5% acetyl groups - 172.892; AF, REG, GMP, Defoaming agent comp - 173.340; REG, diluent for color additive mixtures for drug use exempt from certification - 73.1001; FEED, REG, GMP alone or comb/ Sorbitan monostearate - In mineral premixes or diet suppl for animal feeds - 573.840

**Petition justification statement:**

It is very crucial to have poloxalene available, as a life saving measure, in the event a cow is experiencing severe bloat. When an animal is suffering from frothy bloat, it is imperative to do all we can, swiftly and immediately, to relieve the pain and save the animal's life.

The reason we appreciate this treatment is because it is a lot quicker acting then old home remedies like mineral oil and laundry detergents. These products we not beneficial to the cow's health and we not always reliable. They also took quite a bit of time to act, and the animal was meanwhile greatly suffering.

The manual way of letting off the severe bloat is to use the trocar (to puncture a hole in their side ) to relieve the gas. In this method, you stab them the cow all the way into the stomach where the gas is located, and let is leak out their side. You then hope it heals without peritonitis (infection from the wound). As you can imagine, this is extremely painful and traumatic for the cow.

We very, very seldom need to use a poloxalene-based product. So far, in the year 2000, out of all our herds, we may have treated 5 cows with this medicine. Bloat under the proper management is a very minimal problem. Most bloat occurs on very green, rich pasture.

[Code of Federal Regulations]  
[Title 26, Volume 6, Parts 500 to 599]  
[Revised as of April 1, 1998]  
From the U.S. Government Printing Office via GPO Access  
[CITE: 21CFR558.464]

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS--Table of Contents

Subpart B--Specific New Animal Drugs for Use in Animal Feeds

Sec. 558.464 Poloxalene.

(a) Approvals. (1) Dry Type A medicated articles: 53 percent to 000069 in Sec. 510.600(c) of this chapter.

(2) Liquid Type A medicated articles: 99.5 percent to 000069 in Sec. 510.600(c) of this chapter.

(b) Conditions of use. (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A article and liquid Type A article must be thoroughly blended and evenly distributed in feed prior to use. This may be accomplished by adding the Type A article to a small quantity of feed, mixing thoroughly, then adding this mixture to the remaining feed and again mixing thoroughly. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.

[40 FR 39857, Aug. 29, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995]

[Code of Federal Regulations]  
 [Title 21, Volume 6, Parts 500 to 599]  
 [Revised as of April 1, 2000]  
 From the U.S. Government Printing Office via GPO Access  
 [CITE: 21CFR520.1840]

[Page 170-171]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS--Table of Contents

Sec. 520.1840 Poloxalene.

(a) Chemical name. Polyoxypropylene-polyoxyethylene glycol nonion block polymer.

[[Page 171]]

- (b) Specifications. (1) Molecular weight range: 2,850 to 3,150.  
 (2) Hydroxyl number: 35.7 to 39.4.  
 (3) Cloud point (10 percent solution): 42 deg. C.-46 deg. C.  
 (4) Structural formula:  
 [GRAPHIC] [TIFF OMITTED] TR01JA93.415

(c) Sponsor. (1) See No. 000069 in Sec. 510.600(c) of this chapter for the sponsor of the usage provided by paragraph (d)(1) of this section.

(2) See No. 000069 in Sec. 510.600(c) of this chapter for sponsor usage provided by paragraph (d)(3) of this section.

(3) See No. 036904 in Sec. 510.600(c) of this chapter for sponsor usage provided by paragraph (d)(2) of this section.

(4) See No. 017800 in Sec. 510.600(c) of this chapter for sponsor the usage provided by paragraph (d)(4) of this section.

(d) Conditions of use. (1) For treatment of legume (alfalfa, clover) bloat in cattle. Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

(2) For control of legume (alfalfa, clover) bloat in cattle. Administer, in molasses block containing 6.6 percent poloxalene, at a rate of 0.8 oz. of block (1.5 grams poloxalene) per 100 lbs. of body weight per day.

(3) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle. A 53-percent poloxalene top dressing on individual rations of ground feed. Dosage is 1 gram of poloxalene per 100 pounds body weight daily. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat use of the drug if animals are exposed to bloat-producing conditions for more than 12 hours after th



last treatment. Do not exceed the double dose in any 24-hour period.

(4) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle. Administer in molasses block containing 6.6 percent poloxalene, at the rate of 0.8 ounce of block (1.5 grams of poloxalene per 100 pounds of body weight per day. Provide access to blocks at least 7 days before exposure to bloat-producing conditions.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39857, Aug. 29, 1975; 42 FR 41854, Aug. 19, 1977; 50 FR 5385, Feb. 8, 1985; 54 FR 33501, Aug. 15, 1989; 56 FR 50653, Oct. 8, 1991; 58 FR 26523, May 4, 1993; 60 FR 55659, Nov. 2, 1995]



Toll-Free: 1-877-487-2436

[Close Window](#)

# THERABLOAT® DRENCH CONCENTRATE

*Pfizer Animal Health*

Bloat Preparation

brand of poloxalene

NADA No.: 039-729

**Active Ingredient(s):** Each fluid ounce (approx. 30 mL) contains:

Poloxalene	25 g
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**Indications:** THERABLOAT® Drench Concentrate will relieve legume bloat in cattle within minutes when used as directed. For the best results administer at the earliest sign of bloat. If bloat has progressed in its severity to the degree that the animal is down, other means of treatment are also recommended (rumenotomy - rumen puncture). For oral use only - not for injection. May be used in lactating animals.

**Pharmacology:** Poloxalene lowers the surface tension of the frothy mass so the bubble film is weakened and can no longer contain the gas. The foam collapses back to the liquid level, unblocking the esophagus so that the animal can orally expel gases.

**Dosage and Administration:** THERABLOAT® is a highly concentrated form of poloxalene designed to be diluted with water and administered orally as a drench, or by stomach tube.

For animals up to 500 lb, use 1 fl oz of Drench Concentrate.

For animals over 500 lb, use 2 fl oz of Drench Concentrate.

Directions for preparing drench: Add the proper amount of concentrate to one (1) pint of water. Mix well and administer using a drenching bottle. If a stomach tube is to be used, add the concentrate to one (1) gallon of water.

**Caution(s):** Not for human use.

Keep this and all medication out of the reach of children.

For veterinary use only.

**Discussion:** Bloat (ruminal tympany) is the entrapment of gases which eventually obstructs the esophagus, creating a closed cavity in the rumen. Bloat is usually caused by a change in diet. Legume forages such as alfalfa and clover and high-protein grain feeds can cause rapid production of fermentation gases (methane, CO<sub>2</sub>, and nitrogen). The bubbles mix with the ruminal fluids to form a stable foam. The animal is unable to eructate and dies of asphyxia.

**Presentation:** 2 fl oz plastic bottle.

85-8620-06

Disclaimer: Every effort has been made to ensure the accuracy of the information published. However, it remains the responsibility of the readers to familiarize themselves with the product information contained on the product label or package insert. Compendium Code No.: 03693537

[Close Window](#)

**FDA Approved Animal Drug Products**  
**Online Database System**  
**Drug Product Abstract**

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Please note that the US Code of Federal Regulations (21 CFR version April 1, 2000) is the official source of regulatory information concerning approved animal drug products.

**039-729 (OTC)**

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<b>Tradename</b>	Therabloat ®
<b>(s)</b>	
<b>Sponsor</b>	Pfizer, Inc.
<b>Ingredient(s)</b>	Poloxalene
<b>Species</b>	Cattle, any use class
<b>Route(s)</b>	Per Os
<b>DoseForm(s)</b>	Liquid

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### **CFR Indications**

520.1840 Poloxalene.

#### **Specifications:**

No specifications are included in the CFR for this product.

#### **Conditions of use:**

Cattle

#### **Amount:**

Administer as a drench at the rate of 25 grams for animals up to 500 pounds and 50 grams for animals over 500 pounds of body weight.

#### **Indications:**

For treatment of legume (alfalfa, clover) bloat in cattle.

Limitations:

No limitations are included in the CFR for this species when using this product in this amount.



To see the complete 21 CFR Part 520.1840

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**CFR Tolerance  
For Poloxalene:**

No tolerances



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 [Return to \*your\* results page.](#)

 [Return to the Search Menu](#)

## Pooler , Bob

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**From:** Kelly Shea [KellyS@HORIZONORGANIC.com@]  
**Sent:** Thursday, December 07, 2000 7:40 AM  
**To:** Pooler , Bob  
**Subject:** RE: Research articles on poploxadene

Thank you, thank you, thank you; I'll send the information gathered as soon as possible.

-----Original Message-----

**From:** Pooler , Bob [mailto:Bob.Pooler@usda.gov]  
**Sent:** Thursday, December 07, 2000 7:16 AM  
**To:** 'Kelly Shea'  
**Subject:** RE: Research articles on poploxadene

I searched the FDA website which provided the "nada" information, attached. I have included information about the FDA Division of Animal Research and the contact information of the DAR Director. I suggest contacting DAR and request the information you need. DAR may believe the research information is too numerous to place on the website.

-----Original Message-----

**From:** Kelly Shea [mailto:KellyS@HORIZONORGANIC.com]  
**Sent:** Wednesday, December 06, 2000 1:35 PM  
**To:** Pooler , Bob  
**Cc:** 'ebr(a)omri.org'  
**Subject:** RE: Research articles on poploxadene

Thanks for the suggestion. Do you know the best way to locate these articles? I did 4 or 5 days worth of Internet searches and didn't find any additional information other than what I submitted. Any guidance would be thoroughly appreciated.

Kelly Shea  
Farm Relations Manager-West  
HORIZON ORGANIC DAIRY  
(719) 372-9233  
<http://www.horizonorganic.com>

-----Original Message-----

**From:** Pooler , Bob [mailto:Bob.Pooler@usda.gov]  
**Sent:** Wednesday, December 06, 2000 9:24 AM  
**To:** 'kellys@horizonorganic.com'  
**Cc:** 'ebr@omri.org'  
**Subject:** Research articles on poploxadene

Kelly Shea,

We have received the petition on poloxalene. During the approval process for a drug, the FDA usually examines extensive research reports on the drug. Your petition on Poloxalene has only a small amount of research information. Submitting copies of the FDA research reports or similar reports to support the petition would be beneficial to the petition process.

Thank you

Bob Pooler

**Pooler , Bob**

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**To:** kellys@horizonorganic.com  
**Cc:** ebr@omri.org  
**Subject:** Research articles on poploxalene

Kelly Shea,

We have received the petition on poloxalene. During the approval process for a drug, the FDA usually examines extensive research reports on the drug. Your petition on Poloxalene has only a small amount of research information. Submitting copies of the FDA research reports or similar reports to support the petition would be beneficial to the petition process.

Thank you

Bob Pooler