Poloxalene

Livestock

Identification

Chemical Name(s):
Poloxyporopylene-poloxyethylene glycol nonionic block polymer
Polyethylene-polypropylene glycol (USP)

CAS Number:
9003-11-6

Other Codes:
ACX no. X1017331-2

Other Names:
Poloxanlene, POP/POE condensate, Poloxamer

Trade names:
Therabloat, Bloat Guard Drench Concentrate,
Bloat Guard Top Dressing,
Purina Saf-T-Block BG, Sweetlix Bloat Guard

Summary of Advised Recommendation*

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic (3)	*Allowed (2)*	*As a drench for emergency treatment of ruminal tympany(bloat) in cattle (2)*
	Prohibited (1)	*None (1)*

Characterization

Composition:
$C_5H_{10}O_2$

Properties:
Molecular weight range: 2,850 to 3,150.
Hydroxyl number: 35.7 to 39.4.
Cloud point (10% solution): 42 deg. C. to 46 deg. C.

How Made:
Poloxalene is considered a co-polymer of propylene oxide (PO) and ethylene oxide (EO). Propylene oxide, polypropylene oxide, and its copolymers with ethylene oxide have the largest volume and importance in the polyurethane and surfactant industry (Kirk-Othmer 1996b). The annual production of PO in the US was close to 2 billion kg as of 1996. There are two principal processes used: the traditional chlorohydrin process and indirect oxidation by the hydroperoxide process that uses a molybdenum catalyst. Both processes start with propylene (propene) derived from cracking of petroleum. The chlorhydrin process involves reaction of propylene ($CH_3CH=CH_2$) and chlorine in the presence of water to produce two isomers of propylene chlorhydrin. This is followed by dehydrochlorination using caustic soda or lime to produce propylene oxide and salt. The hydroperoxide process involves oxidation of propylene to PO by an organic hydroperoxide, producing an alcohol as a co-product. One of the possible alcohols (tert-butanol, TBE) produced as a by-product from this process is used as feedstock for MTBE, a gasoline additive. (Kirk-Othmer 1996b)

Ethylene oxide (epoxyethane) is formed by oxidation of ethylene (also derived from cracking of petroleum) with oxygen, using a silver catalyst at 250 deg. C. at 20 atm. The primary uses for ethylene oxide is in the manufacture of derivatives such as surfactants, ethanolamines, ethylene glycol and polyethylene glycols used in cosmetics, food additives,

** This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA (7 USC 6517(m)). The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and is not intended to incorporate commercial availability, socio-economic impact or any other factor that the NOSB and the USDA may want to consider in making their decisions.*

pharmaceuticals, ointments, textile processing, and as water soluble lubricants, among many other uses (Kirk-Othmer 1996a, Clugston 1998). PO and EO are highly reactive and both are considered hazardous. Ethylene oxide is used as a fumigant and sterilizing agent, as an anti-microbial pesticide to fumigate spices, and has been studied as rocket fuel and component of munitions (Kirk-Othmer 1996a). However, the EOPO copolymers are considered low hazard, low vapor pressure liquids. Contact with skin, eyes, or inhalation causes irritation. There are no known acute or chronic affects associated with polyols (Kirk-Othmer 96b). The stability of some resulting polyalkene polymers (such as polypropylene) is of concern in the case of indiscriminate use due to the unreactivity and non-biodegradability (Clugston, 98).

Specific Uses:
Petitioned for treatment of legume (alfalfa, clover) bloat (ruminal tympany) in cattle. It is also used as a surfactant and dispersant in pesticide formulations (Baur, et al. 1997, Meister 2000). Poloxamer has listed functions as emulsifiers, surfactants, or stabilizers (USP 2000).

Action:
Bloat is caused by the entrapment of fementation gases in the rumen. The bubbles mix with the ruminal fluids to form a stable foam. Poloxalene is a non-ionic surfactant that 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.

Combinations:
Poloxalene may be administered as a drench (orally through a tube), preventively fed in a molasses block containing 6.6% poloxalene, and as a top dressing for feed using a 53% poloxalene top dressing on individual rations of ground feed (21CFR 520.1840).

Status

Historic Use
Poloxalene is used by conventional producers as an effective antidote and preventive measure for pasture bloat.

OFPA, USDA Final Rule
OFPA 6509(d) requires that producers not use any subtherapeutic doses of antibiotics, not use synthetic internal parasiticides on a routine basis, or administer medication, other than vaccinations, in the absence of illness. OFPA 6509(c)(3) requires that producers shall not use growth promoters and hormones, including antibiotics and synthetic trace elements used to stimulate growth or production. OFPA 6517 (c)(1)(B)(I) provides that a synthetic substance can be added to the National List in the categories that include livestock parasiticides and medicines.

Poloxamer is listed by the US Pharmocopeia as a pharmaceutic aid, including surfactant, ointment base, tablet binder and emulifying agent. Poloxalene is listed as a surfactant (USP 2000).

The NOP final rules at 7 CFR 205.238(b) allows the use of synthetic medication in the case of illness, provided the medication is listed in 205.603.

Regulatory
Regulated by FDA as a New Animal drug, 21CFR 520.1840 and as a New Animal Drug for use in Feeds at 21 CFR558.464.

EPA/NIEHS/Other Appropriate Sources
EPA – Polyoxyethylene-polyoxypropylene copolymer is on EPA List 4B, "inert ingredients for which EPA has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment" (EPA, 97).

NIEHS – no listing in the National Toxicology Database.

Status Among U.S. Certifiers
An informal survey of 30 US agencies resulted in twelve responses from certifiers. Nine reported no experience with this material. Two agencies specifically prohibit its use, and one reported they considered natural alternatives to be adequate.

International

CODEX- Livestock standards at Step 8 (final adoption scheduled for July 2001) allows chemical allopathic veterinary drugs or antibiotics, when acceptable alternative preventive methods do not exist, provided that they are used under veterinarian's care with a minimum withholding of 48 hours or double the withdrawal time.

EU 2092/91 – Similar to Codex, with an additional proviso that animals treated more than 2 times or maximum of 3 times per year with chemical veterinary drugs can no longer be marketed as organic (Annex I, Section B 4).

IFOAM – similar to Codex and EU, natural products and preventive methods preferred, but use of veterinary medicines is permitted under control of certification agency.

Canada – Similar to CODEX with the withdrawal period "at least double the permitted federal withdrawal period allowed for veterinary drugs" (CGSB, 1999).

Section 2119 OFPA 7 U.S.C. 6518(m)(1-7) Criteria

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*
   When used as a drench at the labeled rate of 1 fluid ounce for animals up to 500 lbs., and 2 fluid ounces at over 500 lbs., this material is unlikely to have a negative impact on organic farming system.

2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*
   FDA does not list any withdrawal times or residue tolerances for poloxalene. (21CFR)

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
   The production of organic polymers from petroleum sources is a large volume chemical manufacturing process that has significant environmental impact.

4. *The effects of the substance on human health.*
   Poloxalene is listed by USP for use as pharmeuceutic aid. It is reported to have no known toxicity (Winters, 99) and is not listed in the National Toxicology Program Database.

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*
   Not known, but probably of minor impact.

6. *The alternatives to using the substance in terms of practices or other available materials.*
   Description of the disorder:
   Bloat (ruminal tympany) is considered a feeding problem, and occurs in both beef and dairy cattle when the normal process of eructation or belching is interrupted and the gases produced in the rumen by fermentation cannot be expelled. Sheep can also be affected, though are much less susceptible than cattle. The rumen rapidly swells, the cow experiences severe pain and may, in extreme cases, die within a few minutes of showing clinical signs. The causal factor of pasture bloat is a foaming or frothiness of the ruminal contents into a stable persistent foam. It usually occurs when animals are pastured on lush legume pastures, and also may occur on wheat pasture (Ensminger 91, Webster 93). Another type of bloat is called feedlot or grain bloat, thought to be associated with the feeding of finely ground grain, or when high concentrate low roughage rations have been fed for 60 days or longer (Radostitis 94, Ensminger 91). Pasture bloat has a seasonal occurrence when the pasture is lushest. Spring and autumn are the most dangerous seasons when the plants contain a high content of soluble proteins.

   The extent of incidence is not reliably known (Radostitis, 91). A survey of 312 farms in New Zealand over a period of 2 months revealed that 87% of all farms experienced bloat ranging from mild to severe (Radostitis, 94). Enmsminger contends that bloat is widespread, more severe in some areas than others, and causes average annual losses in beef and dairy cattle of more than $100 million (Ensminger 91). Grazing systems that rely on rotational grazing may be prone to bloat in the springtime, if the cows are moved frequently to gain access to large quantities of fresh herbage. A New Zealand reference suggests cows that are given their daily pasture allowance in one break should be drenched for bloat control once per 24 hours before they move onto their fresh break each day, or that paddocks be opened up to a larger pasture so cows are not rotated as much in the spring (Holmes, 87).

   Prevention of pasture bloat:
   1) Avoid straight legume pastures and immature legumes.
   2) Feed a coarse grass hay prior to turning onto lush pasture.

3) feed dry forage along with pasture
4) Avoid a rapid full from an empty start.
5) Keep animals continuously on pasture after they are once turned out.
6) Keep salt and water conveniently accessible at all times and wait until dew is off alfalfa before grazing.
7) Plant bloat resistant cultivars of legumes, such as birdsfoot trefoil, sainfoin, and cicer milkvetch (*Astralagus cicer*), and mix legumes with grasses in the pasture (Ensminger 91, Majak 95).
8) Some animals have a genetic disposition for bloat, and this trait can be evaluated in a breeding program (Majak 1990, Radostitis 94).

Treatment:
Animals should be immediately moved off the bloating pasture. Mild cases may be treated by keeping the animal on its feed and moving, drenching either with 1 pint of corn oil or soybean oil or 1-2 oz. poloxalene. Severe cases should be treated by a veterinarian or owners when no time is available. In severe cases, when there is gross distension, mouth breathing with protrusion of the tongue and staggering a rumenotony (puncturing of the rumen with a trocar) may be necessary to save the animal. Once the animal falls down it will die in a few minutes. Irrigation and cleansing of the wound usually results in uneventful recovery (Radostitis, 1994).

Alternative drenches include sodium bicarbonate and non-toxic oils, including mineral oil and vegetable oils. Continued administration of mineral oil causes restriction of carotene absorption and rescues the carotene and tocopherol content of the butter produced. Linseed oil, soy oil, and whale oil have undesirable effect on the quality and flavor of the milk. Peanut oil and tallow are the most satisfactory. New Zealand systems have had success with administering anti-foaming agent or oils in drinking water with an automatic dose syringe in the milking parlor (Radostitis, 1994). Oils are sometimes sprayed on pastures as preventive agents, and then the pastures are strip grazed.

In addition to poloxalene, other synthetic treatments include alcohol ethoxylate detergents (not approved on the National List), and controlled release antibiotics (prohibited by the Final Rule). Both poloxalene and alcohol ethoxylate detergents are faster acting than the oils, which are more suited for prevention than treatment (Radostitis, 94).

Poloxalene is also available in molasses blocks, or as a feed topdressing, but there is sometimes a question of effectiveness if the animal does not voluntarily ingest it.

7. Its compatibility with a system of sustainable agriculture.
Clearly, there are many preventive measures that can be taken to avoid pasture bloat. Organic farmers seeking to establish a pasture based system for ruminants may occasionally experience unforeseen incidence of pasture bloat that requires an emergency remedy. Use of this synthetic material could be justified to alleviate animal suffering on a very occasional basis.

TAP Reviewer Discussion*

Reviewer 1

[Veterinarian with ovine (sheep) experience]

Poloxalene is a synthetic product and is used in the treatment of acute bloat in ruminants, which is a life-threatening condition.

I think the product fares well under the 7 OFPA criteria with the exception of the possible environmental impacts. As it is a derivative of petroleum, of course it would be nice to not have to use it. However, I think its use in organic agriculture should be limited enough that the environmental issue alone is not justification for disallowing its use.

While I have used sodium bicarbonate and non-toxic oils, and have had farmers use them, they are best used in mild cases of bloat as they take longer to have an effect. The use of polaxalene is extremely effective in severe cases of bloat and could fall under the category of good animal welfare.

Bloat can be controlled largely by using the management strategies outlined in the OFPA criteria *[see number 6 alternatives]*. It is critical that all organic livestock producers use these preventative measures.
Many farmers can go for years and never have a case of bloat and then have two or three cases in a row. Weather is a factor, as is the animal's intake preference at the time when the legumes may cause the highest incidence of bloat. In other words, there are some things that can't be controlled and those times are when farmers need to have a medication such as poloxalene at their disposal. I particularly liked the proviso in the EU 2092/91 stating that besides a doubling of the withdrawal time, any animal treated a maximum of three times a year be withdrawn from the organic herd. In this case, as there is no withdrawal time, a minimum of 48 hours could be used for a withdrawal period.

Advised Recommendation
I agree with the recommendation that poloxalene, only in the drench form, be allowed for use as a medical treatment for emergency use only in the case of severe acute bloat. For milder cases of bloat, the alternative drenches of oils and sodium bicarb should be sufficient. The prophylactic use of poloxalene in molasses blocks or as a top drench should be prohibited.

Reviewer 2

[Doctor of Veterinary Medicine with a degree in public health, former state health department official, a researcher in pharmaceuticals and biological products, with experience in organic certification]

The file was fairly complete on this substance with all sources in agreement (including additional references assimilated by this reviewer) that poloxalene is a synthetic material. I will restrict my review to a brief comment on the first six OFPA criteria with reference to poloxalene and a somewhat lengthier discussion regarding the seventh criteria. My review also assumes that the use being considered is only as a drench for emergency use in cases of pasture bloat in cattle. Bloat occurs in sheep but seems to be predominantly a concern for bovine health (Merck Veterinary Manual, 1998), and poloxalene is considered less effective in sheep in any case (Radostits, 1994). Poloxalene also does not seem to be considered a treatment of choice for feedlot bloat in cattle nor for grain bloat in dairy (Merck Veterinary Manual, 1998).

Compatibility with OFPA Criteria

1) The potential of the substance for detrimental chemical interaction with other materials used in organic farming systems.

> I agree with the OMRI review that when used as a drench, the negative impact on other materials used in organic farming systems is likely to be minimal. Poloxalkols have been known to increase the absorption of fat-soluble substances in humans (Blacow, 1975) If emergency overdosing or prophylactic overuse occurs in cattle, given the lengthy duration of effect by poloxalene, disruption of feed ration balancing may theoretically be a concern.

** OMRI's information is enclosed in square brackets in Italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are edited for any identifying comments, redundant statements, and typographical errors. Text removed is identified by ellipses [. . .] Statements expressed by reviewers are their own, and do not reflect the opinions of any other individual or organizations.*

2) The toxicity and mode of action of the substance and its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

Again when used as a drench, there appears to be little concern for the environment due to the small amounts employed and the paucity of data indicating that poloxalene itself is a significant environmental contaminant. As far as toxicity to the animal is concerned, a review of the Center for Veterinary Medicine (CVM) website for reports of animal poisonings from veterinary use products covering the period 1987-1998 indicated that there were only 3 incidents with poloxalene with 60 animals exposed and only 3 deaths.

Its use as an ingredient of medicated free-choice supplemental feed would bring it under the general warning of the Center for Veterinary Medicine against free-choice systems as representing a great potential for drug overdosing resulting in animal safety hazards or human food safety residue concerns. (*Benz 1998*)

3) The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.

While the use of poloxalene itself as proposed here may not pose a significant risk to the environment, it is derived from polypropylene oxide and ethylene oxide. These chemicals have significant and deleterious impacts and belong to the family of synthetic polymers produced from petroleum sources that basically comprise a field of study in environmental and human toxicology unto themselves.

4) The effects of the substance on human health.

No reports of human poisonings from the veterinary use of poloxalene were present in the CVM database nor much mention of human toxicity at all (except as noted above for increasing absorption of fat-soluble substances) in any of the sources that I reviewed.

5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.

I have nothing to add to the *[presented]* findings on this, except to agree that there is probably minor impact.

6) The alternatives to using the substance in terms of practices or other available materials.

Bloat is a serious problem and the annual mortality of dairy cattle grazing on pasture may be as high as 1%. Bloat may occur on the first day after being turned out but is more likely on the second or third day. Death may occur as soon as 1 hour after grazing begins, but more commonly does not result until 3-4 hours after symptoms begin. (Merck Veterinary Manual, 1998)

The alternatives to poloxalene are to use other anti-foaming agents such as vegetable oils (e.g., peanut, corn, and soybean oil), or mineral oils (paraffins), sodium bicarbonate, diocytl sodium sulfosuccinate, household detergent, ethoxylate detergents, and ionophores (Merck Veterinary Manual, 1998). The vegetable oils would appear to pass muster under OFPA criteria, as perhaps would mineral oil and sodium bicarbonate for regulated use. Tying a 1-inch diameter stick or piece of wood in the affected animal's mouth like a bit on a horse bridle to increase salivation, walking the animal around, passing a stomach tube, trocarization (via a small skin incision) and placement of a large-bore cannula (1 in. in diameter) into the rumen, rumenotomy (via a 4-8 in. incision into the rumen itself) are other approaches to treatment. They are often employed in combination with administration of anti-foaming agents. Pasture management and culling chronic bloaters are methods of prevention.

All the sources I reviewed indicated that vegetable oils and mineral oil are effective treatments. In fact the Merck Manual discusses poloxalene only in the control and prevention section not under treatment. However, Radostits et al. state that surfactants are preferred to oils because they are faster, require smaller doses, and have a longer period of effectiveness.

7) Its compatibility with a system of sustainable agriculture.

This material is not compatible with a system of organic, sustainable agriculture. It is synthetic and is derived from chemicals that are significant environmental contaminants, and thus the use of poloxalene in organic farming would be contributing (in principle, if not in quantity) to their continued manufacture and dispersal in the environment. There are acceptable methods for the prevention of this disorder and while allowing the emergency use of this chemical for unforeseen incidence of pasture bloat may seem reasonable, it is "enabling" lax pasture management and animal husbandry practices contrary to the principles of organic, sustainable agriculture.

Moreover, other antifoaming agents do exist, which are compatible with organic criteria. While poloxalene may be the most convenient and perhaps the most effective, the other antifoaming agents discussed are also effective. Poloxalene is not indispensable to the treatment or management of bloat. In fact, there is a narrow window of time, place, and patient when it is the treatment of choice. It is not considered as effective a treatment for pasture bloat in sheep as in cattle, nor in cattle is it considered effective for feedlot bloat or grain bloat in dairy herds. Its utility, even in bovine pasture bloat, is limited to situations when symptoms are noted after it is too late to employ simpler corrective measures such as walking the animal around or fitting a bit into its mouth, but before the bloat has progressed to the point where a rumenotomy is required to save the life of the animal. As the petitioner for this product noted, they treated only 5 cows "out of all our herds" so far that year (apparently late in the year 2000). Because of this narrow range of situations when it would be the treatment of choice, I don't believe that its use can be justified to alleviate animal suffering. If the animal is visibly suffering, trocarization or rumenotomy is called for and the resultant expulsion of gas would provide relief and permit appropriate follow-up treatment not requiring poloxalene.

Advised Recommendation

Given that the initial "bright line" for compatibility with organic principles is non-synthetic versus synthetic origin, this threshold should not be passed unless there are compelling reasons to do so. In the case of poloxalene, the fact that it may be used only on a very occasional basis and that it is more convenient than other approaches does not justify crossing that "bright line."

Reviewer 3

[Doctor of Veterinary Medicine with experience in animal nutrition, holistic animal health and organic agriculture]

In the *Summary of Advised Recommendations* I think the wording should be changed from legume bloat to bloat or ruminal tympany. This wording should be used throughout any regulation. My reason for this is to keep an overly zealous inspector from disallowing its use for cases of bloat not related to legumes. [.….]

I believe the above use would conform to the OFPA rule that allows the use of synthetic materials to treat acute disease conditions and to alleviate animal suffering on an occasional basis.

In the past, I have used mineral oil as well as poloxalene to treat bloat. My experience was that the poloxalene gave the best results. Almost any oils given as a drench will work some of the time but all have there own problems with organic use. Mineral oil is, I believe, a prohibited substance. With any of the natural oils there is now the possibility of GMO contamination.

Given the need in emergency veterinary medicine, lack of toxicity, low usage rate and low dosage rate I would suggest approval of the use of poloxalene in an organic environment provided that it was only used to treat acute bloat. The Farm Management Plan should include measures to minimize the incidence of bloat and poloxalene should not be used as a "crutch" to cover up poor management.

Compatibility with OFPA criteria

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*

I agree with the [TAP statement that low rates used are unlikely to have a negative impact…]

2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*

"FDA does not list any withdrawal times or residue tolerances for poloxalene. (21CFR)"
TAP Review also stated : "EPA – Polyoxyethylene-polyoxypropylene copolymer is on EPA List 4B, "inert ingredients for which EPA has sufficient information to conclude that their current use patterns in pesticide products will not adversely affect public health and the environment" (EPA, 97)."

I agree with the above statement*[s]* and do not believe the emergency use of this product in ruminal tympany would result in any environment contamination.

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*

[cites TAP information…] It would seem that the miniscule amount of this total that is used on livestock would not contribute to any significant environmental impact.

TAP Review also stated: "The stability of some resulting polyalkene polymers (such as polypropylene) is of concern in the case of indiscriminate use due to the unreactivity and non-biodegradability (Clugston, 98)."
I do not believe the use of this substance in ruminal tympany constitutes 'indiscriminate use'**.**

4. *The effects of the substance on human health.*

In light of the [information presented in the TAP review], I believe use of this product in cattle to treat acute ruminal tympany would have no effect on human health.

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*

I agree that any impact would be minor to almost non-existent. Also note …FDA does not list any withdrawal times or residue tolerances for poloxalene. (21CFR)

[Since EPA classes it as a list 4B inert ingredient for pesticides I …] do not believe the emergency use of this product in ruminal tympany would result in any environment contamination.

6. *The alternatives to using the substance in terms of practices or other available materials.*

Of course there are many alternatives to almost anything. However, in my opinion, the mere presence of other oils etc should not preclude the use of another product that has been used safely by dairymen for decades. Also note from TAP Review that "Both poloxalene and alcohol ethoxylate detergents are faster acting than the oils, which are more suited for prevention than treatment (Radostitis, 94)." When treating ruminal tympany response time to any treatment is of the utmost importance.

I think this product should be allowed for emergency use even though it is a synthetic.
[…….] I believe this material should be used only as treatment for acute ruminal tympany and should not be in feed or blocks.

7. *Its compatibility with a system of sustainable agriculture.*

[….] I agree that poloxalene (even thought synthetic) should be allowed for emergency use to treat acute ruminal tympany and that such use is compatible with a system of sustainable agriculture

Advised Recommendation:
Even though Poloxalene is a synthetic, I believe the product should be allowed for occasional use ONLY to treat acute cases of ruminal tympany. I think a withholding period of 24 to 48 hours would be indicated.

Conclusion

Poloxalene is clearly synthetic and prohibited unless added to the National List for medical use. The TAP reviewers are divided and do not have a consensus recommendation. Two of the reviewers favor its allowance for emergency use only based on a need to prevent suffering and promote animal welfare. The third reviewer finds the rare emergency use not to be a compelling reason for considering as a permitted synthetic and does not see it as indispensable given that other treatments are available for cases of mild bloat, and other emergency treatments are called for in life threatening circumstances. This is supported by the lack of historic allowance, or demonstrated need by existing certification agencies. The two reviewers who favor limited allowance also suggested either an extended withdrawal time, or a limited allowance for a permitted number of emergency treatments per year for organic animals. No data to support an

extended withdrawal time has been presented, but the NOSB may want to consider an overall policy for frequency of emergency treatment or develop criteria for emergency use medication in general.

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