Potassium Sorbate

Livestock

Summary of TAP Reviewer's Analyses[1]

Potassium sorbate is petitioned for use in organic livestock production as mold inhibitor. Sorbic acid was first discovered in the Mountain Ash Tree (*Sorbus aucuparia or Sorbus americana*). Today most potassium sorbate is made synthetically. Potassium sorbate is a naturally occurring unsaturated fatty acid and is completely safe with regard to health and have the lowest allergenic potential of all food preservatives. Potassium sorbate was also petitioned for use in liquid livestock medications primarily aloe vera juice as a substitute for antibiotics and other various hormones. Studies have shown that a derivative of aloe (called Acemannan) has antitumor effects in animals and stimulates immune cells (principally macrophages) to produce cancer-fighting substances**.** Acemannan has now been approved for full use under the CarraVet® label by the USDA.

Potassium sorbate is not officially listed anywhere in the NOP final rule. As in section 205.600 of the NOP final rule, "any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria: (2) the substance's manufacture, used and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling." Potassium sorbate is not explicitly listed in section 205.603 as a synthetic substance, allowed for use in organic livestock production nor is it listed in section 205.604 as a prohibited substance.

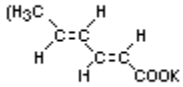
Synthetic/ Nonsynthetic	***Allow without restrictions?***	***Allow only with restrictions? (See Reviewers' comments for restrictions)***
Synthetic (3)	Yes (0) No (3)	Yes (2) No (1)

Identification

Chemical names: Potassium Sorbate
CAS No.: 24634-61-5 ;590-00-1
Molecular Weight: 150.22
Chemical Formula: $CH_3CH:CHCH:CHCOOK$
Other Names: 2,4-Hexadienoic Acid, Potassium Salt, K sorbate, 2,4-HEXADIENOIC ACID, (E,E)-, POTASSIUM SALT, POTASSIUM 2,4-HEXADIENOATE, POTASSIUM (E,E)-SORBATE, SORBISTAT, SORBISTAT-POTASSIUM

Structural formula

[1] *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 does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.*



SORBIC ACID 

DECARBOXYLATION OF SORBIC ACID

"Sorbic acid is often chemical altered when added to foods and this results in a loss of its antimicrobial properties. For example, certain moulds cause decarboxylation." [2] "Potassium sorbate contains not less than 98 percent and not more than the equivalent of 102 percent of $C_6H_7O_2K$." [3]

Characterization

Properties:

Appearance:
White crystals.
Odor:
Odorless.
Solubility:
Appreciable in water.
Specific Gravity:
1.363 @ 25C/20C
pH:
No information found.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
No information found.
Melting Point:
270C (518F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found. [4]

Stable. Incompatible with strong oxidizing agents.
Non-hazardous for air, sea and road freight. [5]

How Made:

"Potassium sorbate is a potassium salt version of sorbic acid, a polyunsaturated fat used to inhibit mold growth. It was first discovered by the French in the 1850's, having been derived from the mountain ash tree. It is widely used in the food industry and few substances have had the kind of extensive, rigorous, long-

[2] Pictures and information directly referenced from http://www.chemsoc.org/exemplarchem/entries/2001/caphane/additives.html#salts
[3] Directly referenced from http://www.inchem.org/documents/jecfa/jecmono/40abcj15.htm
[4] Directly referenced from http://www.jtbaker.com/msds/p6135.htm
[5] Directly referenced from http://physchem.ox.ac.uk/MSDS/PO/potassium_sorbate.html

term testing that sorbic acid and its salts have had. It has been found to be non-toxic even when taken in large quantities, and breaks down in the body into water and carbon dioxide in the Krebs Cycle" [6]
"Potassium Sorbate is the potassium salt of sorbic acid, a naturally occurring organic acid that has been used extensively as a fungistatic agent for foods. Sorbic acid was first discovered in the Mountain Ash Tree (*Sorbus aucuparia or Sorbus americana*). Today most potassium sorbate is made synthetically. It is a white crystalline powder, inexpensive (at typical usage levels), with basically no noticeable flavor at normal usage concentrations. Potassium sorbate is a naturally occurring unsaturated fatty acid and is completely safe with regard to health and have the lowest allergenic potential of all food preservatives." [7]
"Sorbic acid is blended with potassium hydroxide in equimolar portions and recrystallized with aqueous ethylene hydroxide to form potassium sorbate (Patil, 2001). Sorbic acid was first isolated by the hydrolysis of oils distilled from the mountain ash berry (Dorko et al., 1997) Commercial sources are now produced by the condensation of crotonaldehyde and ketene (Ashford, 1994). Yields are increased by reaction in the presence of a catalyst, such as boron trifluoride (Fernholz, Ruths, and Heimann-Trosien, 1962)."[8]
"SORBIC ACID IS REACTED WITH AN EQUIMOLAR PORTION OF POTASSIUM HYDROXIDE. THE RESULTING POTASSIUM SORBATE MAY BE CRYSTALLIZED FROM AQUEOUS ETHANOL." [9]

Specific Uses:

"When dissolved in water, potassium sorbate ionizes to form sorbic acid which is effective against yeasts, molds, and select bacteria, and is widely used at 250 ppm to 1000 ppm levels in cheeses, dips, yogurt, sour cream, bread, cakes, pies and fillings, baking mixes, doughs, icings, fudges, toppings, beverages, margarine, salads, fermented and acidified vegetables, olives, fruit products, dressings, smoked and salted fish, confections and mayonnaise. In many food products, sorbate and sodium benzoate are used together to provide greater protection against a wider variety of microorganisms (synergism)."[10] "Although the minimum inhibatory concentration for many fungi and bacteria is approx. 100 ppm, common usage levels range from 0.5 - 1.0%." [11] "Sorbic acid is widely used to inhibit yeast and mould growth in a variety of foods including cheese, baked products and wine. It may be added directly to the food, or incorporated into the packaging method, usually at a concentration of 0.3% by weight of the food and at such values, contributes no flavour." [12] "Furthermore, fur animal feed may be acidified intentionally when prolonged storage and improved hygienic quality of the wet feed are desired. This may be done by adding 0.3 - 0.6% of formic acid into the wet diet when mixing. Additionally, the feed may be acidified in order to alleviate urination problems with calculi."[13]

Action:

"Unfortunately, grain and feed provides an ideal environment for molds to proliferate. Raw materials or feeds in bulk storage are rich sources of energy, proteins and moisture and, thus, are highly conducive to mold growth."[14] "Potassium sorbate is the potassium salt of sorbic acid, and is much more soluble in water than the acid. Potassium sorbate will produce sorbic acid once it is dissolved in water and is the most widely used food preservative in the world. It is effective up to pH 6.5 but effectiveness increases as the pH decreases. Potassium sorbate has about 74% of the antimicrobial activity of the sorbic acid, thus requiring higher concentrations to obtain the same results that pure sorbic acid provides. Potassium sorbate is effective against yeasts, molds, and select bacteria, and is widely used at 0.025 to 0.10 % levels in cheeses, dips, yogurt, sour cream, bread, cakes, pies and fillings, baking mixes, doughs, icings, fudges, toppings,

[6] Directly referenced from http://www.soybean.com/ps.htm
[7] Directly referenced from http://www.ferlowbrothers.com/potassium_sorbate.htm
[8] Directly referenced from http://www.omri.org/Ksorbate_final.pdf (TAP report for crop use)
[9] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAZ_aGwR:1
[10] Directly referenced from http://www.ferlowbrothers.com/potassium_sorbate.htm
[11] Directly referenced from http://www.snowdriftfarm.com/askthechemist.html
[12] Directly referenced from http://www.chemsoc.org/exemplarchem/entries/2001/caphane/additives.html#salts
[13] Directly referenced from http://www.gov.ns.ca/nsaf/elibrary/archive/lives/furfacts/feedfish.htm
[14] Directly referenced from http://www.kemin.com/livestock-feed-ingredients/mold-antimicrobials.shtml

beverages, margarine, salads, fermented and acidified vegetables, olives, fruit products, dressings, smoked and salted fish, confections and mayonnaise." "Maximum level allowable by law is 0.1%. It is important to know that the addition of sodium benzoate and/or potassium sorbate to a food product will raise the pH by approximately 0.1 to 0.5 pH units depending on the amount, pH, and type of product. Additional adjustment of the pH might be needed to keep the pH at a safe level." [15]

Chart[16]

item	limit
potassium sorbate content	98.0%~102.0%
water	1% max
arsenic(as As)	3 ppm max
heavy Metals(as Pb):	10 ppm max
free alkali	passed
appearance:	white granular

Combinations:

"The main types of mold inhibitors are (1) individual or combinations of organic acids (for example, propionic, sorbic, benzoic, and acetic acids), (2) salts of organic acids (for example, calcium propionate and potassium sorbate), and (3) copper sulfate. Solid or liquid forms work equally well if the inhibitor is evenly dispersed through the feed. Generally, the acid form of a mold inhibitor is more active than its corresponding salt. Many factors influence the effectiveness of mold inhibitors, and proper attention to these factors can enhance the benefits they provide. Mold inhibitors cannot be effective unless they are completely and thoroughly distributed throughout the feed. Ideally, this means that the entire surface of each feed particle should come in contact with the inhibitor and that the inhibitor should also penetrate feed particles so that interior molds will be inhibited. The particle size of the carriers for mold-inhibiting chemicals should be small so that as many particles of feed as possible are contacted. In general, the smaller the inhibitor particles the greater the effectiveness. Some propionic acid inhibitors rely on the liberation of the chemical in the form of a gas or vapor from fairly large particle carriers. Presumably, the inhibitor then penetrates the air spaces between particles of feed to achieve even dispersion. Certain feed ingredients may also affect mold inhibitor performance. Protein or mineral supplements (for example, soybean meal, fish meal, poultry by-product meal, and limestone) tend to reduce the effectiveness of propionic acid. These materials can neutralize free acids and convert them to their corresponding salts, which are less active as inhibitors. Dietary fat tends to enhance the activity of organic acids, probably by increasing their penetration into feed particles. Certain unknown factors in corn also alter the effectiveness of organic acid inhibitors. When mold inhibitors are used at the concentrations typically recommended, they in essence produce a period of freedom from mold activity. If a longer mold-free period is desired, a higher concentration of inhibitor should be used. The concentration of the inhibitor begins to decrease almost immediately after it is applied as a result of chemical binding, mold activity, or both. When the concentration of the inhibitor is reduced until it is incapable of inhibiting mold growth, the mold begins to use the inhibitor as a food source and grows. In addition, feeds that are heavily contaminated with molds will require additional amounts of inhibitor to achieve the desired level of protection. The widespread use of pelleted feeds in the feed industry is beneficial to the use of mold inhibitors. The heat that the feed undergoes during pelleting enhances the effectiveness of organic acids. Generally, the higher the pelleting

[15] Directly referenced from http://www.nysaes.cornell.edu/fst/fvc/Venture/venture2_chemical.html
[16] Directly referenced from http://www.chinax.com/pages/wuzhou/potassium%20sorbate.htm

temperature, the more effective the inhibitor. Once mold activity commences in pellets, however, it proceeds at a faster rate than in nonpelleted feed because the pelleting process that makes feed more readily digestible by animals also makes it more easily digested by molds." **"**Toxins produced by molds are called *mycotoxins.* Mold growth and toxin production is favored by warm temperatures and high humidity typical of tropical and subtropical regions, including the southern United States. Some types of mycotoxin cause cancer in animals. Aflatoxin, a type of mycotoxin, is a potent liver toxin in all animals in which it has been tested. Of all the mycotoxins, aflatoxin is of greatest concern because it is highly toxic and potentially carcinogenic. Peanuts, corn, and cottonseed are the U.S. commodities which are most susceptible to contamination with aflatoxin. The Food and Drug Administration monitors foods for the presence of aflatoxin."[17] Swine are sensitive to mycotoxins, especially nursing or nursery-age swine. In general, mycotoxins cause reductions in feed intake, growth performance, and immune function when levels are relatively low. Producers must be aware that if one toxin is identified in a sample, the chances are high that other toxins are present. Some toxins may not have been identified as of yet, but research on known mycotoxins provides insight into the expected effects in swine and potential methods to reduce those effects. Table 3 contains a summary of the maximum permissible concentrations of mycotoxins in swine feeds. Aflatoxin B1 has been the most extensively studied. Twenty to 200 ppb will cause a decrease in feed intake and growth performance, which can be partially offset by increasing specific dietary nutrients such as lysine or methionine. In severe cases (1,000 to 5,000 ppb) of aflatoxicosis, one can expect acute effects including death. Aflatoxin M1 appears in milk of sows consuming aflatoxin-contaminated diets and may affect piglets nursing those sows. Feed concentrations of deoxynivalenol (DON) of 300 to 500 ppb are often associated with feed refusal, decreased weight gain, and increased incidence of infectious diseases. DON levels greater than 1000 ppb, will cause feed refusal or decrease in feed intake resulting in severe weight loss. It appears that pigs will often consume a sufficient amount of contaminated feed to induce vomiting. In fact, DON is also called vomitoxin because of its association with swine vomiting. T-2 toxin has detrimental effects on swine performance, but no effect levels have not been determined for commercial production environments. However, field observations indicated that T-2 and related compounds are associated with decreased productivity at feed concentrations of 200 ppb or less. Zearalenone will significantly affect the reproductive performance of swine. Prepuberal gilts are the most sensitive to zearalenone. The symptoms commonly observed when feeding diets contaminated with zearalenone include a reddening and increased size of the vulva, and increased size of mammary tissue. Zearalenone will cause embryonic mortality at certain stages of gestation. Fertility problems are often associated with zearalenone concentrations of 100 to 200 ppb in sow feeds.

Table 3. Maximum Mycotoxin Levels for Swine

	Maximum Dietary Concentration		
Swine Type	Deoxynivalenol ppb	Zearalenone ppb	Aflatoxin ppb
Pigs <75 lb	<300	200	20
Pigs 75 to 125 lb	<300	200	50
Pigs 125 lb to market	<300	200	100
Sow Herd	<300	100	50
Breeding Males	<300	100	50

[17] Directly referenced from http://spokane-county.wsu.edu/food/topic1.htm

These levels are based on extensive field observations.

Heat stress, marginal nutrient plane, crowding, disease exposure, the presence of more than one mycotoxin, and drug interactions, as well other factors, increase animals' susceptibility to mycotoxins. Thus these recommendations must be tempered with knowledge of the animals involved. Aflatoxin affects all poultry species. Although it generally takes relatively high levels to cause mortality, low levels can be detrimental if continually fed. Young poultry, especially ducks and turkeys, are very susceptible. As a general rule, growing poultry should not receive more than 20 ppb aflatoxin in the diet. However, feeding levels lower than 20 ppb may still reduce their resistance to disease, decrease their ability to withstand stress and bruising, and generally make them unthrifty. Laying hens generally can tolerate higher levels than young birds, but levels should still be less than 50 ppb. Aflatoxin contamination can reduce the birds' ability to withstand stress by inhibiting the immune system. This malfunction can reduce egg size and possibly lower egg production. In addition, one must pay special attention to the use of contaminated corn in layer rations because eggs are promptly used as human food and aflatoxin metabolites have been found in egg yolks. Mycotoxin levels found in most field situations tend to be low. Yet the combination of low levels of mycotoxins with the stresses associated with commercial production situations and/or exposure to disease organisms can produce effects in poultry which are subtle, indirect, and sometimes ill-defined. Since the effects of mycotoxins on poultry are dependant upon the age, physiological state, and nutritional status of the animals at the time of exposure, and since mold growth at various points within the feed production and distribution system can magnify mycotoxin problems, mycotoxicoses can be difficult to diagnose in field situations. Mycotoxins produced by the mold genus *Fusarium* include: T-2 toxin and it's chemical relatives (trichothecenes), deoxynivalenol (DON), fumonisin, and zearalenone. Other animals tend to be more sensitive to the effects of fumonisin, deoxynivalenol, and zearalenone when compared to poultry. Nevertheless, detection of these mycotoxins within poultry rations indicates that the ration or the ingredients within the ration have been subjected to mold activity. Since numerous other mycotoxins, as well as reduced nutritive value and palatability of feeds, are generated by mold activity, the presence of fumonisin, deoxynivalenol, or zearalenone in poultry feeds is cause for concern. T-2 toxin and trichothecenes can cause mouth and intestinal lesions as well as impair the birds' immune response, causing egg production declines, decreased feed consumption, weight loss, and altered feather patterns. While much is yet to be learned, T-2 toxin and related compounds are currently thought to be the most potent Fusarium mycotoxin for poultry.

DON alone has few effects in poultry. However, in field situations the DON level is sometimes associated with reduced feed consumption in layers and broiler breeders. This means that DON may be an indicator that T-2 or other unknown *Fusarium* mycotoxins are present. Although the effects of mycotoxins on horses are not well documented in scientific literature, in field situations apparent mycotoxin problems appear to be significant. Mycotoxins have been implicated in a variety of health problems including colic, neurological disorders, paralysis, hypersensitivity, and brain lesions. The cumulative effect of feeding low levels of mycotoxins may also contribute to a gradual deterioration of organ functions. This in turn affects growth rate, feed efficiency, fertility, respiration rate, the ability to perform work, and life span. Cases of mycotoxin-related horse deaths are consistently reported throughout the southeastern United States. Due to the lack of conclusive scientific research concerning the levels of various mycotoxins tolerated by the horse, emphasis should be placed on feeding mycotoxin-free grain and forage to all horses. Horses are herbivores with a simple stomach (nonruminant). The large intestine has an active microbial digestive ability to allow digestion of forages. However, in the horse the small intestine, which is the major site of absorption, occurs before the fermentative digestion. As a result, horses are more susceptible to mycotoxins than ruminants, since nutrient absorption occurs prior to fermentative digestion in the horse compared to ruminants in which absorption occurs after fermentative digestion. Productive or working horses have a high energy requirement and require a higher concentrate intake, and thus would be most susceptible to problems with mycotoxin-contaminated grains. Working horses would include growing horses less than two years of age, brood mares in late gestation and early lactation, and horses at moderate or intense work levels. Other horses, that are only lightly worked, would be more likely to be exposed to mycotoxin-contaminated hays or forages. Since moldy forages are generally less palatable than normal forage, horses fed moldy forages typically refuse feed before ingesting enough feed to cause severe intestinal tract

damage. Mild colic is typically noted in such cases. Unfortunately, most molds associated with grains fed to horses do not readily affect palatability. Consequently, horses are most often exposed to the mycotoxins found in grains. Grain mycotoxins are readily absorbed and should be considered to be potentially lethal for horses. If mycotoxin-contaminated feeds must be fed, follow these guidelines:

1. Levels in the total diet of mature, nonbreeding horses should not exceed the levels shown in Table 4.
2. Feed mycotoxin-free grains to growing horses (less than two years of age), breeding horses, and working horses.
3. Analyze the feed for mycotoxins often.

Table 4. Maximum Mycotoxin Levels for Mature, Nonbreeding Horses

MYCOTOXIN	LEVEL
Aflatoxin	50 ppb
T-2 Toxin	50 ppb
DON	400 ppb
Zearalenone	100 ppb
Fumonisin	2,000 ppb

Note: The above levels are based on field observations. Controlled scientific studies are needed to clarify specific mycotoxin tolerance and toxicity levels. Heat stress, marginal nutrient plane, crowding, disease exposure, the presence of more than one mycotoxin, and drug interactions, as well other factors, increase animals' susceptibility to mycotoxins. Thus these recommendations must be tempered with knowledge of the animals involved.

Aflatoxin-contaminated feed not only reduces animal performance and overall health, but it also creates risks of residues in milk. Aflatoxin is secreted into milk in the form of aflatoxin M1 with residues approximately equal to 1 to 2 percent (1.7 percent average) of the dietary level. This ratio is not influenced greatly by milk production level since higher producing cows consume more feed and have a slightly higher transmission rate. Due to risks of milk residues, dietary aflatoxin should be kept below 25 ppb. This level is conservative due to: (1) nonuniform distribution of aflatoxin in grain and feed, (2) uncertainties in sampling and analysis, and (3) the potential for having more than one source of aflatoxin in the diet. Replacement animals may tolerate 50 to 100 ppb aflatoxin. In dairy cattle DON is associated with reduced feed intake, lower milk production, elevated milk somatic cell counts, and reduced reproductive efficiency. Milk production loss appears to occur when diets contain more than 300 ppb DON. Although controlled research has shown no cause and effect relationship between DON levels and reduced milk production, field observations have shown that reductions in milk output of 25 pounds per cow were seen when DON was 500 ppb or more. This suggests that DON may serve as a marker for feed that was exposed to a situation conducive to mold growth and mycotoxin formation. The possible presence of other mycotoxins, or factors more toxic than DON, seems likely. Dietary levels of 300 to 500 ppb DON in dairy feeds indicate mycotoxin problems and warrant attention. Zearalenone causes estrogenic responses in dairy cattle, and large doses of this toxin are associated with abortions. Other responses of dairy animals to zearalenone may include reduced feed intake, decreased milk production, vaginitis, vaginal secretions, poor reproductive performance, and mammary gland enlargement in virgin heifers. Establishment of a tolerable level of

zearalenone for dairy cattle is difficult, and is at best only a guess based on a meager amount of data and field observations. As with DON, zearalenone may serve as a marker for toxic feed. It is suggested that zearalenone not exceed 250 ppb in the total diet. In dairy cattle T-2 toxin has been associated with feed refusal, production losses, gastroenteritis, intestinal hemorrhages, and death. T-2 has also been associated with reduced immune response in calves. Data with dairy cattle are not sufficient to establish a tolerable level of T-2 in the diet. Therefore, a practical recommendation may be to avoid T-2 in excess of 100 ppb in the total diet for growing or lactating dairy animals. Fumonisin is another commonly isolated mycotoxin. However, fumonisin has only recently been isolated and only enough data exist to know that levels in excess of 20,000 ppb are potentially toxic to ruminants. Aflatoxin and other mycotoxins can have considerable effects on beef cattle although the problems are usually less critical than for swine and poultry. Consumption of feeds highly contaminated with aflatoxin may reduce growth rate and increase the amount of feed required per pound of gain. Calves are generally more sensitive to feed contamination than adult cattle. In affected calves, some cases have revealed severe rectal straining and a prolapsed rectum. Lactating cows show a significant reduction in milk yield. Research has shown that high levels of aflatoxin can also cause liver damage in adult cattle. Feeding a high level of aflatoxin may also depress immune function, resulting in disease outbreaks. Based on the feeds available, those contaminated with aflatoxin should be fed at the lowest level possible and for the shortest period of time practical. The effects of aflatoxin fed to cattle depend on the level of aflatoxin in the ration, the length of the feeding period, and the age of the animal. If aflatoxin-contaminated feeds must be fed to beef cattle, follow these guidelines (on a dry matter basis):

1. Creep feeds and diets for gestating and lactating beef cows should contain less than 20 ppb of aflatoxin.
2. Unstressed, growing-finishing cattle in excess of 400 pounds may be fed diets containing up to 100 ppb of aflatoxin.
3. Diets for stressed feeder cattle should contain no more than 20 ppb of aflatoxin. Stressful conditions include weaning, shipping, extreme heat or cold, diseases, and parasites.
4. Animals destined for slaughter should receive aflatoxin-free diets for at least 3 weeks before slaughter.

Since cattle in the southeast are typically fed high forage diets, they are usually fed grain only as a supplement. Thus a relatively high level of aflatoxin can occur in the grain before it exceeds the tolerable dietary level. In general, cattle will eat about 2.5 percent of their body weight as dry matter. This can be used to calculate the contribution of grain to their total ration, and the tolerable level of aflatoxin in the grain. For example, growing calves weighing 600 pounds will consume about 15 pounds of total feed (600 lb multiplied by 2.5% equals 15 lb). If they are fed 3 pounds of grain plus forage-to-appetite, the grain will make up about 20 percent of their total diet (3 lb divided by 15 lb equals 20%). In this case the grain may contain up to 500 ppb of aflatoxin (100 ppb divided by 20% equals 500 ppb). Aflatoxin levels allowable in the grain, given different rates of inclusion in the beef ration, are illustrated (Table 5).

Table 5. Allowable Aflatoxin in Grain for Beef Cattle

Percentage of Grain in Diet	Aflatoxin Level in Total Diet		
	20 ppb	50 ppb	100 ppb
20%	100 ppb	250 ppb	500 ppb
40%	50 ppb	125 ppb	250 ppb
60%	33 ppb	83 ppb	167 ppb
80%	25 ppb	63 ppb	125 ppb

This table assumes that aflatoxin is contained only in grains.
This assumption is not always correct. Each dietary component should be tested for aflatoxin prior to use of any contaminated grains. Heat stress, marginal nutrient plane, crowding, disease exposure, the presence of more than one mycotoxin, and drug interactions, as well other factors, increase animals' susceptibility to mycotoxins.

Thus these recommendations must be tempered with knowledge of the animals involved.

Table 6. Maximum Mycotoxin Levels for Beef Cattle

MYCOTOXIN	LEVEL
DON	500 ppb
T-2	100 ppb
Zearalenone	250 ppb
Fumonisin	50,000 ppb

Heat stress, marginal nutrient plane, crowding, disease exposure, the presence of more than one mycotoxin, and drug interactions, as well other factors, increase animals' susceptibility to mycotoxins. Thus these recommendations must be tempered with knowledge of the animals involved." [18]

Prevention

Aflatoxicosis can only be prevented by feeding rations free of aflatoxin. Preventing aflatoxin contamination is outlined on the preceding page, but since preventing contamination is not always possible, here are a few **keys facts to remember when dealing with contaminated feeds in animal rations:**

• The recommended feeding level is 0 parts per billion (ppb).
• The level of aflatoxin an animal can tolerate will depend upon the age and sex of the animal, its health status, and overall management level of the farm.
• To avoid contamination of milk, lactating dairy cattle should not receive more than 20 ppb in the total ration.
• Calves should not receive milk from cows fed in excess of 20 ppb, because they can ingest aflatoxin from the milk.
• Beef cattle can tolerate slightly higher levels of aflatoxin, but yearlings and mature cows should not receive more than 400 ppb in the total ration. Weanlings should not receive more than 100 ppb in their total daily ration.
• Poultry and swine are more sensitive to aflatoxin contamination.

Under no circumstances should these livestock species be fed more than 20 ppb aflatoxin in their daily rations. [19]

Status

Historic Use by Organic Farmers:

"Mold inhibitors are commonly included in feeds these days. Contamination of feed ingredients has always been a problem in feeds. Many molds produce aflatoxins that are harmful to livestock and poultry.

[18] Directly referenced from http://www.ces.ncsu.edu/drought/dro-29.html#swine
[19] Directly referenced from http://agbiopubs.sdstate.edu/articles/FS907.pdf

Preventing ingredient contamination therefore is the highest priority. Applying an inhibitor as a prevention is next best. This is especially helpful for storage of feed or feed ingredients. Mold inhibitors are usually acid and require careful handling, specials pumps, piping, and proper application."[20] "Sorbic acid and other unsaturated aliphatic mono-carboxylic acids and their salts were discovered to be effective at inhibiting the growth of microorganisms between the late-1930s and mid-1940s (Gooding, 1945). Potassium sorbate use in food increased rapidly following this discovery (Dorko, 1997). However, there are few references that potassium sorbate has been used as a seed treatment or for any other crop uses in either organic or conventional agriculture. Only a few experimental references were found in the literature (Oshanina and Ovcharov, 1967; Davis and Pinckard, 1971), and there is no indication that potassium sorbate was ever used commercially. Potassium sorbate may also be used for conditionsing seeds, but this treatment is intended to be used on seeds for processing, not planting (White and Swick, 1986). The main historic used in organic production appears to be as an inert ingredient with biorational pesticides and as a preservative for various microbial inoculants and other biological soil amendments." [21]

Organic Certification

"The Texas Department of Agriculture [TDA] certifies producers, processors, distributors and retailers of organic food and fiber within the state.

TDA certifies a host of Texas grown crops and products made from grains (wheat, corn, and rice), beans (soybeans, mungbeans, pintos, and many other peas and beans), sesame, peanuts, fruits (blackberries, blueberries, strawberries, citrus, peaches, apples, melons), vegetables, herbs, **aloe vera**, mushrooms, sprouts and wildflower and grass seeds."[22]

CARRINGTON RECEIVES FULL U.S.D.A. APPROVAL FOR BIOLOGIC DRUG TO TREAT FIBROSARCOMA IN ANIMALS

August 15, 2000

"Aloe Falls formulations combine this pure aloe vera gel with herbs that complement the healing properties of aloe. The formulas are bottled in glass bottles by a special process that eliminates the need for commonly used preservatives such as sorbic acid, **potassium sorbate** and sodium benzoate. This special low-heat, or cold-process, maintains the activity of all the important aloe vera compounds. Aloe Falls formulas are rich in a full range of active polysaccharides, contain the active enzymes that aloe is known for, are a source of the lectins and other glycoproteins that are exciting researchers these days, as well as containing amino acids, vitamins, minerals and other essential nutrients. Much of the research with aloe vera has been done using gel from fresh aloe vera leaves. The benefits of fresh aloe leaves can be reduced due to the way they are processed and stabilized. One of the problems with current stabilization systems is that the preservatives used can interfere with the activity of the aloe.1 The common preservatives used - sorbic acid, **potassium sorbate** and sodium benzoate - are not derived from natural sources and have the potential to be cytotoxic (kills cells). Another concern is that improper processing may fail to remove all of the aloin and related compounds, which are very strong laxatives.2" [23] "Studies have shown that a derivative of aloe (called Acemannan) has antitumor effects in animals and stimulates immune cells (principally

[20] Directly referenced from http://www.asasea.com/technical/ft26-1995.html
[21] Directly referenced from http://www.omri.org/Ksorbate_final.pdf (TAP report for crop use)
[22] Directly referenced from http://www.agr.state.tx.us/license/regulatory/reg_organic.htm
[23] Directly referenced from http://yerba.com/aloeproc.htm

macrophages) to produce cancer-fighting substances. Aloe comes in liquid, tablets, and capsules." [24] "The USDA as a veterinary treatment for fibrosarcoma has approved injectable acemannan." [25] IRVING, Texas -- Carrington Laboratories, Inc. (NASDAQ: CARN) received a milestone validation of its complex carbohydrate technology platform with the issuance of a full license from the United States Department of Agriculture (USDA) for Acemannan Immunostimulant as a biologic drug for the treatment of fibrosarcoma in cats and dogs. Acemannan Immunostimulant has been clinically shown to extend survivability when used as an adjunct to surgery in the treatment of canine and feline fibrosarcoma. The product triggers an increase in natural killer cell and cytotoxic T-cell activity, improves tumor margination for easier surgical removal, and does not have the typical side effects associated with chemotherapy. Acemannan Immunostimulant has previously been available under a limited use license from the USDA, and was therefore subject to restrictions on sales and market penetration. Acemannan Immunostimulant will be nationally marketed and distributed under the CarraVet® label by Carrington¹s licensee, Veterinary Products Laboratories headquartered in Phoenix, Arizona."[26] "Acemannan is predominantly a b-(1,4)-linked galactomannan with acetylated mannose residues (Reynolds, 1985). The acute oral toxicity of acemannan in rats and mice is >5 g/kg (Fogleman *et al.*, 1992). For pharmaceutical aloe, corresponding figures were >5 g/kg in rats and >10 g/kg in mice (NLM, 1998). *Subacute/Subchronic Studies.* In preliminary oral repeat-dose studies, acemannan was given daily by gavage for 14 days to 5 groups of 5 male and 5 female rats at doses ranging from 1,000 to 5,000 mg/kg/day. Abnormal respiration, distended abdomens, and decreased defecation were observed in all dose groups. One female receiving 1,000, 1 male receiving 2,000, and 2 female rats receiving 5,000 mg/kg/day died. Deaths were considered due to the physical mixture which prevented stomach emptying. Dogs accepted up to 1,500 mg acemannan/kg/day po without apparent effect (Fogleman *et al*., 1992). Acemannan was administered po to groups of 40 male and 40 female Sprague-Dawley rats at 0, 200, 650, or 2,000 mg/kg/day for 6 months. Hematology and serum chemistry determinations and urinalyses conducted at 1, 3, and 6 months all showed values within the normal range. Necropsy examinations were conducted on all animals that died while on test, on 10 rats/sex/group at 90 days, and on all survivors at 6 months. Organ weights and gross and microscopic pathology from the treated rats were normal and similar to corresponding controls (Fogleman *et al*., 1992). Acemannan was also administered po to 4 groups of 4 male and 4 female beagle dogs from 7 months until 10 months of age. Doses were 0, 100, 400, or 1,500 mg/kg/day for 90 days. Serum chemistry, hematologic, and urinalysis data collected before initiation of exposure, at 45 days, and at termination were within normal limits. No significant gross or microscopic lesions associated with ingestion of acemannan were noted at necropsy (Fogelman *et al*., 1992)."[27]

OFPA, USDA Final Rule:

Potassium sorbate is not officially listed anywhere in the NOP final rule. As in section 205.600 of the NOP final rule, "any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria: (2) the substance's manufacture, used and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling." Potassium sorbate is not explicitly listed in section 205.603 as a synthetic substance, allowed for use in organic livestock production nor is it listed in section 205.604 as a prohibited substance. [28]

Regulatory: EPA/NIEHS/Other Sources

NFPA Ratings: Health: **0** Flammability: **0** Reactivity: **0**

FDA:

[24] Directly referenced from http://www.dcdoctor.com/pages/rightpages_wellnesscenter/dietandnutrition/nutritionguide/nutriguide_herbs.html#DIET-INFO-HERBS-aloe%20vera

[25] Directly referenced from http://members.shaw.ca/xuanf/n14e.htm

[26] Directly referenced from http://www.plant.uoguelph.ca/safefood/archives/animalnet/2000/8-2000/an-08-16-00-01.txt

[27] Directly referenced from http://ntp-server.niehs.nih.gov/htdocs/Chem_Background/ExecSumm/AloeVera.html#REG

[28] This information was referenced from http://www.ams.usda.gov/nop/regtext.htm

Code of Federal Regulations]
[Title 21, Volume 6]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE**: **21CFR582**.**3640**]

[Page 522]

TITLE 21--FOOD AND DRUGS

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

PART 582--SUBSTANCES GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart D--Chemical Preservatives

Sec. 582.**3640** Potassium sorbate.

(a) Product. Potassium sorbate.
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice. [29]

FDA

Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, U.S. Public Health Service, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities.

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 ENFORCE
06/10/1992

PRODUCT         Aloe Vera Juice in 1 quart and one gallon plastic
bottles.
                Recall #F-332-2.
CODE            Lot numbers:  0063, 0092, 0132, 0152, 0202, 0272, 0292,
0342,
                0342-1, 0362, 0362-1 (quarts); All lots (gallons).
MANUFACTURER    Superior Products, Company, Farmers Branch, Texas.
RECALLED BY     Manufacturer, by telephone February 27, 1992.  Firm-
initiated
                recall complete.
DISTRIBUTION    California.
QUANTITY        Firm estimates none remains on the market.
REASON          Product contains undeclared sulfites.[30]
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[29] Directly referenced from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=582.3640
[30] Directly referenced from http://www.fda.gov/bbs/topics/ENFORCE/ENF00149.html

FDA

Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities.

MARCH 27, 2002 02-12
RECALLS AND FIELD CORRECTIONS: FOODS -- CLASS I
RECALLS AND FIELD CORRECTIONS: DRUGS -- CLASS I

PRODUCT
Weider's Eyedrops (Aloeflex) NET WT. 1 fl. oz. (Aloe Vera juice). Recall
D-205-2.
CODE
Product is not coded, or if coded, coding is unknown. All codes were recalled.
RECALLING FIRM/MANUFACTURER
Recalling Firm: Aloe Flex Enterprises, Dickinson, TX, by letter dated December 11. 2001;
Manufacturer: Tennis Elbow Corporation, Dickinson, TX.
FDA initiated recall is complete.
REASON
Microbial contamination (Acinetobacter calcoaceticus-baumannii).
VOLUME OF PRODUCT IN COMMERCE
28.
DISTRIBUTION
TX. [31]

[Code of Federal Regulations]
[Title 21, Volume 6]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE**: **21CFR501.22**]

[Page 21-25]

TITLE 21--FOOD AND DRUGS

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

PART 501--ANIMAL FOOD LABELING--Table of Contents

Subpart B--Specific Animal Food Labeling Requirements

Sec. 501.**22** Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

(a)(1) The term artificial flavor or artificial flavoring means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant

[31] Directly referenced from http://www.fda.gov/bbs/topics/enforce/2002/ENF00736.html

material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in Secs. 172.515(b) and 582.60 of this chapter except where these are derived from natural sources.

(2) The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of

[[Page **22**]]

any volatile oil or other flavoring principle has been removed. Spices include the spices listed in subpart A of part 582 of this chapter, such as the following:

Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric.

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as spice and coloring unless declared by their common or usual name.

(3) The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in Sec. 172.510 of this chapter.

(4) The term artificial color or artificial coloring means any color additive as defined in Sec. 70.3(f) of this chapter.

(5) The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(b) A food which is subject to the requirements of section 403(k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403(k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions

of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403(k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403(k) of the act.

(f) A fruit or vegetable shall be exempt from compliance with the requirements of section 403(k) of the act with respect to a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(g) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients, the label either may declare each ingredient by its common or usual name or may state ``All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration.'' Any flavor ingredient not contained in

[[Page 23]]

one of these regulations, and any nonflavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, e.g., strawberry flavor, banana flavor, or natural strawberry flavor. In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, e.g., natural and artificial strawberry flavor. In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., artificial strawberry flavor.

(h) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way:

(1) Spice, natural flavor, and artificial flavor may be declared as spice, natural flavor, or artificial flavor, or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of Sec. 501.100(a)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, e.g., powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name salt.

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name monosodium glutamate.

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other

artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word natural and shall be immediately followed by the word flavored in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as artificially flavored.

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words with other natural flavor in letters not less than one-half the height of the letters

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used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) artificial or artificially flavored, in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(i) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if

the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(ii) If the finished product contains more than one flavor subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such food.

(iii) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor.

(4) A flavor supplier shall certify, in writing, that any flavor he supplies which is designated as containing no artificial flavor does not, to the best of his knowledge and belief, contain any artificial flavor, and that he has added no artificial flavor to it. The requirement for such certification may be satisfied by a guarantee under section 303(c)(2) of the act which contains such a specific statement. A flavor used shall be required to make such a written certification only where he adds to or combines another flavor with a flavor which has been certified by a flavor supplier as containing no artificial flavor, but otherwise such user may rely upon the supplier's certification and need make no separate certification. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of 3 years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized officer, or employee of the Food and Drug Administration or any other employee acting on behalf of the Secretary of Health and Human Services. Such certifications are regarded by the Food and Drug Administration as reports to the government and as guarantees or other undertakings within the meaning of section 301(h) of the act and subject the certifying party to the penalties for making any false report to the government under 18 U.S.C. 1001 and any false guarantee or undertaking under section 303(a) of the act. The defenses provided under section 303(c)(2) of the act shall be applicable to the certifications provided for in this section.

(ii) Wherever possible, the Food and Drug Administration shall verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable; provided that, whenever the Food and Drug Administration has reason to believe that the supplier or user may utilize this period to alter inventories or records, such additional time shall not be permitted. Where such additional time is provided, the Food and Drug Administration may require the certifying party

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to certify that relevant inventories have not been materially disturbed and relevant records have not been altered or concealed during such period.

(iv) The certifying party shall provide, to an officer or representative duly designated by the Secretary, such qualitative statement of the composition of the flavor or product covered by the certification as may be reasonably expected to enable the Secretary's representatives to determine which relevant raw and finished materials

and flavor ingredient records are reasonably necessary to verify the certifications. The examination conducted by the Secretary's representative shall be limited to inspection and review of inventories and ingredient records for those certifications which are to be verified.

(v) Review of flavor ingredient records shall be limited to the qualitative formula and shall not include the quantitative formula. The person verifying the certifications may make only such notes as are necessary to enable him to verify such certification. Only such notes or such flavor ingredient records as are necessary to verify such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: Provided, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to Sec. 501.100, bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., preservative, to retard spoilage, a mold inhibitor, to help protect flavor or to promote color retention.

[41 FR 38619, Sept. 10, 1976, as amended at 42 FR 14091, Mar. 15, 1977; 42 FR 15675, Mar. **22**, 1977]
Subparts C-E [Reserved]

[32]

”FDA regards K sorbate as GRAS (generally regarded as safe).”[33]

EPA:
(Pesticide Use)

ALPHABETIC ACTIVE CHEMICAL CODE REPORT

********** EDITION DATE: MARCH 31, 2002
****

ALPHABETIC ACTIVE CHEMICAL CODE LIST WITH 'C=COMMON, S=SYNONYM, T=TRADE'
THOSE COMPOUNDS WITH 'S' OR 'T' ARE NOT ACCEPTABLE INGREDIENTS ON A LABEL

075902 S 32 Potassium sorbate [34]

LOW RISK PESTICIDES

“EPA exempts certain low risk substances from federal pesticide regulation. Press Advisory: "Responding to President's call for Reducing Regulatory Burdens, EPA Exempts Certain Low Risk Substances from

[32] Law was directly referenced from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=501.22
[33] Directly referenced from http://www.snowdriftfarm.com/askthechemist.html
[34] Directly referenced from http://www.epa.gov/opppmsd1/DataSubmittersList/dslchem.htm

Federal Pesticide Regulation" (March 4, 1996; Exemption of Certain Pesticide Substances from Federal Insecticide, Fungicide, and Rodenticide Act Requirements - Final rule, 45 F.R. 8876 (March 6, 1996). The substances exempted by the final rule are: caster oil, (U.S.P. or equivalent), cedar oil, cinnamon and cinnamon oil, citric acid, citronella and citronella oil, cloves and clove oil, corn gluten meal, corn oil, cottonseed oil, dried blood, eugenol, garlic and garlic oil, geraniol, geranium oil, lauryl sulfate, lemongrass oil, linseed oil, malic acid, mint and mint oil, peppermint and peppermint oil, 2-Phenethyl propionate (2-phenylethyl propionate), **potassium sorbate**, putrescent whole egg solids, rosemary and rosemary oil, sesame and sesame oil, sodium chloride (common salt), sodium lauryl sulfate, soybean oil, thyme and thyme oil, white pepper, and zinc metal strips (consisting solely of zinc metal and impurities)." [35]

Status Among U.S. Certifiers

Oregon does not have specific limitations on materials used for crops and livestock. If the materials comply with USDA regulations, they are deemed acceptable for use in the state of Oregon. (Contact- Ron McKay) [36]

Pennsylvania is in accordance with guidelines proposed by OMRI.
(Contact- Martha Melton- state certifier) [37]

Minnesota does not have specific limitations on materials used for crops and livestock. If the materials comply with USDA regulations, they are deemed acceptable for use in the state of Minnesota. (Contact- Mary Hanks- state certifier) [38]

International

IFOAM: Basic standards 2002- not explicitly listed as approved food additive or processing aid[39]

NORTHERN IRELAND:

> **11.** Unless otherwise stated, any maximum or minimum specified in the Table for the content of any additive in any feeding stuff is so specified by reference to a complete feeding stuff with a moisture content of 12%.
>
> Part VIII
>
> Permitted Preservatives
>
> Chapter A

E202	Potassium sorbate	$C_6H_7O_2K$

EUROPEAN UNION: listed as a permitted food additive (E202)[40]
JAPAN: Japanese Agricultural Standards- not listed [41]
CANADA: Not explicitly listed as approved additive[42]

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

[35] Directly referenced from http://www.epa.gov/oppfead1/17b/may96.htm

[36] Information was referenced from a phone interview with Ron McKay, State Certifier, June 5, 2002.

[37] Information was referenced from a phone interview with Martha Melton, State Certifier, June 5, 2002

[38] Information was referenced from a phone interview with Mary Hanks, State Certifier, June 12, 2002

[39] This information was referenced from http://www.ifoam.org/standard/ibs_final02.html

[40] Information was referenced from http://www.foodstandards.gov.uk/multimedia/pdfs/elist_numbers.pdf

[41] Referenced from http://www.fas.usda.gov/gainfiles/200004/25647377.pdf

[42] Referenced from http://www.ocpro-certcanada.com/standard2001.pdf

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

"Potassium sorbate goes into solution as ionic potassium and sorbic acid. The degradation products are more hazardous than the product itself (Binas, 2001). Like potassium sorbate, sorbic acid has antifungal and antimicrobial activities. Sorbic acid is reported to have synergistic effects with sodium nitrite (Banerjee and Giri, 1986). Sorbate and nitrite form several species of direct acting mutagens and genotoxic agents, including ethylnitrolic acid and 1,4-dinitro-2-methylpyrrole (Hartman, 1983). Various microorganisms play a role in this transformation (Shu et al., 1991). This has been studied primarily in the context of sodium nitrite and potassium sorbate as food additives, and not under field conditions. However, sodium nitrate is used as a fertilizer on some organic farms in the United States. Nitrite can be formed reduced by denitrification and reduction of sodium nitrate under conditions of poor drainage and anaerobic conditions (see Brady, 1974.)"[43]

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

"Potassium sorbate is the potassium salt of sorbic acid. Both potassium sorbate and sorbic acid are novel, highly efficient, safe and nonpoisonous food preservatives recognized internationally as a best series. It is the substitute for the sodium benzoate as a traditional preservative. Potassium sorbate is the potassium salt of an unsaturated fatty acid, which participates in the normal fat metabolism in human body and will be oxidated into carbon dioxide and water finally. It will not be accumulated in human body."[44] "Potassium sorbate is a naturally occurring unsaturated fatty acid and is completely safe with regard to health and have the lowest allergenic potential of all food preservatives." [45]

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

"Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements." [46] Potassium sorbate is considered a low-risk pesticide. Therefore, the chances of environmental contamination if used in feed or medication are minimal. Potassium sorbate is non-toxic.

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

POTASSIUM SORBATE
CASRN: 590-00-1
For other data, click on the Table of Contents

Human Health Effects:

Human Toxicity Excerpts:

...CAN CAUSE EYE IRRITATION.
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 137]**PEER REVIEWED**

[43] Directly referenced from http://www.omri.org/Ksorbate_final.pdf (TAP report for crop use)
[44] Directly referenced from http://www.china-inc.com/jiangsu/daxin/pota~1.htm
[45] Directly referenced from http://www.ferlowbrothers.com/potassium_sorbate.htm
[46] Directly referenced from http://www.jtbaker.com/msds/p6135.htm

AGED, CONTACT DERMATITIS.
[FISHER AA; CUTANEOUS REACTIONS TO SORBIC ACID AND POTASSIUM SORBATE; CUTIS 25(4) 350 (1980)]**PEER REVIEWED**

Probable Routes of Human Exposure:

/IT/ MIGRATES TO FOOD FROM PACKAGING MATERIAL.
[Sax, N.I. Dangerous Properties of Industrial Materials. 4th ed. New York: Van Nostrand Reinhold, 1975. 1054]**PEER REVIEWED**

Clinical Effects:

SUMMARY OF EXPOSURE
0.2.1.1 ACUTE EXPOSURE
- Whether a substance is labeled a "corrosive" or "irritant" depends on several factors: the nature of the substance, concentration, viscosity, pH, molarity, oxidation-reduction potential, complexing affinity toward bivalent ions etc. It is difficult to determine if a substance is a corrosive or irritant at a particular concentration.
- Irritants are substances that cause inflammation and swelling, but not cellular death and tissue damage; a corrosive causes cellular damage and death.
- Inhalation exposure may result in headache, rhinorrhea, cough, shortness of breath, chest pain, bronchospasm and rarely upper airway swelling or pulmonary edema.
- Ingestion may cause irritation of the oral mucous membranes and esophagus.

HEENT
0.2.4.1 ACUTE EXPOSURE
- Irritants may cause swelling, redness and pain at any site, especially at mucous membranes. The mouth, nose, and eyes are susceptible to these effects.

RESPIRATORY
0.2.6.1 ACUTE EXPOSURE
- Cough, tachypnea, and wheezing are common after inhalation.

GASTROINTESTINAL
0.2.8.1 ACUTE EXPOSURE
- Nausea, vomiting and diarrhea are possible if ingested.

DERMATOLOGIC
0.2.14.1 ACUTE EXPOSURE
- Redness, swelling and pain may occur.

CARCINOGENICITY
0.2.21.2 HUMAN OVERVIEW
- Development of sinonasal neoplasms has been associated with exposure to wood dust and other irritants.

POTASSIUM SORBATE...GENERALLY RECOGNIZED AS SAFE (GRAS) FOR USE IN FOODS UNDER REGULATIONS OF US FDA. ... LIMITS ARE SET ON USE OF SORBATES IN

CERTAIN FOODS WHICH ARE UNDER STD OF IDENTITY. ...IN REGULAR CHEESE, MAX QUANTITY MAY NOT EXCEED 0.3% BY WT, CALCULATED AS SORBIC ACID. [47]

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.

"Sorbic acid is readily metabolized. Both man and rat appear to utilize identical metabolic mechanisms for oxidation of sorbate. The long-term studies suggest that the same no-effect level applies to the salts as to the free acid. Sorbic acid and K-sorbate corresponding to the specifications do not cause tumours when administered orally or subcutaneously. The earlier results of s.c. injection with an unidentified sample remain unexplained. Long-term studies on parasorbic acid which, it has been claimed, may be produced from sorbic acid, also produce no evidence of carcinogenic potential when given orally."[48] "There have been many studies investigating the migration of antimicrobials such as sodium benzoate, benzoic acid, propionic acid, and potassium sorbate from coatings into food. It appears that the most advantageous use of these films for antimicrobial properties would be the formation of a monolayer lipid and sorbic acid film, or a bilayer film composed of a hydrophilic base layer coated with a thin layer of lipid containing sorbic acid. The main issue involves the production of coatings with good surface tension that will stick to produce."[49]

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

"The three most common preservatives are sorbates, propionates, and benzoates. Choosing from these alternatives is highly dependant on the pH of your product. In general, the effective upper pH limit is about 6.5 for sorbates, 5.5 for propionates, and 4.5 for benzoates. When used at the pH levels of most mildly acidic food products (pH 5.5 - 6.0), sorbates are the more effective preservative against a wider spectrum of food spoilage microorganisms than benzoates or propionates. Sorbates' effectiveness increases with greater acidity. Above pH 4.0, sorbates are more effective than sodium benzoate and sodium or calcium propionate. At pH 2.5 to 3.0, sorbates are still somewhat more effective than sodium benzoate as a yeast and mold inhibitor, and more than twice as potent as propionates. Sorbates are at their optimum effectiveness when used below pH 6.0. However, they function up to pH 6.5 but are relatively ineffective at pH 7.0 and above." [50]

"**Preservatives**: static agents used to inhibit the growth of microorganisms, most often in foods. If eaten they should be nontoxic. Examples; calcium propionate, sodium benzoate, formaldehyde, nitrate, sulfur dioxide. Table 3 is a list of common preservative and their uses." [51]

Table 3. Common food preservatives and their uses

Preservative	Effective Concentration	Uses
Propionic acid and propionates	0.32%	Antifungal agent in breads, cake, Swiss cheeses
Sorbic acid and sorbates	0.2%	Antifungal agent in cheeses, jellies, syrups, cakes
Benzoic acid and benzoates	0.1%	Antifungal agent in margarine, cider, relishes, soft drinks
Sodium diacetate	0.32%	Antifungal agent in breads
Lactic acid	unknown	Antimicrobial agent in cheeses, buttermilk,

[47] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAICaicg:1
[48] Directly referenced from http://www.inchem.org/documents/jecfa/jecmono/v05je18.htm
[49] Directly referenced from http://www.cfsan.fda.gov/~comm/ift3exec.html#stp
[50] Directly referenced from http://www.gillco.com/pages/preserve.html
[51] Table and information directly referenced from http://www.bact.wisc.edu/Bact303/Controlofmicrobialgrowth

		yogurt and pickled foods
Sulfur dioxide, sulfites	200-300 ppm	Antimicrobial agent in dried fruits, grapes, molasses
Sodium nitrite	200 ppm	Antibacterial agent in cured meats, fish
Sodium chloride	unknown	Prevents microbial spoilage of meats, fish, etc.
Sugar	unknown	Prevents microbial spoilage of preserves, jams, syrups, jellies, etc.
Wood smoke	unknown	Prevents microbial spoilage of meats, fish, etc.

"Toxicurb is the most efficacious mould inhibitor that protects livestock from a wide range of mycotoxin poisoning. Prevents mould from germinating and proliferation with release of Monomoric Propionic acid in Toxicurb is the most effective mould killer. Specially treated Aluminum Silicate binds toxins if present in the feed." [52] "There are basically five different classes of food preservatives. This is using the strict term for food preservative as something that inhibits microbes from growing. They are:

- Benzoates
- Sorbates
- Propionates
- Nitrates
- Sulphites

Sorbates are compounds like potassium sorbate, calcium sorbate or sodium sorbate. Another name for these compounds is sorbic acid. These compounds prevent the growth of mold on/in cheeses, jelly, cake, syrup, dried fruits and wine. Sorbic acids are naturally found in plants and have been found to be safe for human consumption. They inhibit microbial growth in the same way that benzoates do. Propionates also inhibit microbial growth by inhibiting energy production. However, they do not require low pH's to inhibit the microbes. Compounds like sodium propionate and calcium propionate are placed in bread, biscuits, cakes, pastries and other flour products to prevent that ubiquitous mold from destroying them. As a result, bread does not have to be purchased every day to keep the mold monsters away. Calcium propionate is used more often than sodium propionate because it increases the amount of calcium people consume and also keeps down the amount of sodium people eat in the product. Propionates have been found to also be safe for human consumption. The next two members of the food preservation family are not as human-friendly as the preservatives mentioned above. Nitrates have, for a long time, been used in various meat products such as bacon, ham, sausage, beef jerky and hot dogs. Sodium nitrate is the most common compound used and it, along with the salt in the meat, keeps *Clostridium botulinum* from growing deep in the center of the meat product. *Clostridium botulinum* is a nasty bacterium that produces a protein toxin that causes paralysis and in some cases death. Preventing its growth is very important to food processors and consumers alike. Unfortunately, when nitrites are cooked they form compounds called nitrosamines. Nitrosamines have been shown to cause cancer. This is a very bad thing. With all the bad press nitrates get you would think that processors would get rid of them from their products. Good refrigeration would slow the growth of microbes enough to make the product safe. However, nitrates do a couple of things to the meat that food processors have found consumers like. Nitrates keep the meat a nice red color instead of the gray it would normally turn and it gives the meat a flavor that consumers are used to in the products. Another food preservative that gives some people problems are the sulphites (sulfites). These compounds include the sodium or potassium salts of sulfite, bisulfite, or metabisulfite. These compounds are used in dried fruit, lemon juice, molasses, wine and processed potatoes. They prevent the growth of bacteria. Unfortunately, they also destroy vitamin B-1 and are not to be used in foods rich in this vitamin (meats, for example). Sulfites can also be a problem for people with asthma. Other people can become allergic to this compound and have a very severe reaction to it. If you are one of those people you should not consume anything

[52] Directly referenced from http://www.toxinbinder.com/toxicurb.htm

preserved with sulphites." [53] "Detoxification of feed is still an elusive goal. However, certain feed additives have been successfully used to inhibit mold growth and to reduce the incidence of aflatoxicosis in animals. Organic acids such as propionic, sorbic and benzoic acids, as well as their salts such as calcium propionate and potassium sorbate, and copper sulfate can be used to inhibit mold growth in feed. Mineral clays such as zeolite and bentonite as well as hydrated sodium calcium aluminosilicate (HSCAS) can bind to aflatoxin, protecting animals from absorbing the toxin that may be in the feed. These products, according to FDA rules, cannot as yet be labeled as mycotoxin binders, and are sold as anticaking and free-flow feed additives."[54]

7. Its compatibility with a system of sustainable agriculture.

Sorbic acid and potassium salt (constituents of potassium sorbate) were listed as pesticides whose tolerances were revoked by the EPA in 1999. [55] Potassium sorbate is not acceptable as a use as a pesticide but little is mentioned as to the uses of potassium sorbate limitations as used in livestock. Potassium sorbate is used in aloe vera liquid medications for both humans and animals. Aloe Vera is a naturally occurring substance with will not interact with systems of other agriculture. It has been found to be non-toxic even when taken in large quantities, and breaks down in the body into water and carbon dioxide in the Krebs Cycle." [56] Potassium sorbate is not a detriment to agriculture but may be unacceptable when considering labeling a product with the organic label. "To be certified organic, means that farmers use:

- No synthetic pesticides or polluting synthetic fertilizers
- No fertilizer that contains human or industrial waste
- Crop rotation to protect soil from nutrient loss and erosion
- Manure composting and storage techniques that protect the soil and water from dangerous bacterial contamination
- **No chemical preservatives, colouring agents, waxes, or irradiation treatment to kill bacteria**
- Ethical animal treatment such as access to open pasture and exercise without cages or tethering
- No drugs given to livestock such as growth hormones or lactation promoters. Antibiotics are prohibited except in cases of extreme illness. Up to two treatments a year for dairy cows. No other livestock product can be sold as organic if treated
- No genetically modified organisms including seed and feed
- No animal byproducts fed to livestock" [57]

Potassium sorbate was petitioned as a feed additive to be used as a mold inhibitor. While potassium is non-toxic and environmentally safe, it may not be in compliance with organic farming due to the afore mentioned limitations.

Miscellaneous: [58]

EXTENT OF USE	REF.DOSAGE g/kg
Soy sauce, marmalade, man-made cream, agar soft sweets	0.1-1.0
Low-salt preserved vegetables insoy,	0.1-0.5

[53] Directly referenced from http://www.suite101.com/article.cfm/microbiology/84155
[54] Directly referenced from http://www.agnr.umd.edu/MCE/Publications/Publication.cfm?ID=137
[55] Referenced from http://www.epa.gov/oppfead1/fqpa/revoked.pdf
[56] Directly referenced from http://www.soybean.com/ps.htm
[57] Directly referenced from http://www.anarac.com/organic_farming.htm
[58] Table copied from http://www.wanglong.com/prod1.html

noodles, candide fruit, haw cake, fruit juice, tinned food	
Fruit juice, fruit drink, grape wine, fruit wine	0.1-0.6
Carbonated wine, soda water	0.05-0.2
Dried fish products, drinks of soy bean and milk, food of soy bean	0.1-1.0
Cake stuffing, lactobacillin drink	0.1-1.0
Tobacco	0.6-2
Cosmetics & toothpaste	0.6-2
Forage	**0.4-1.5**

TAP DISCUSSION

Reviewer #1 *[Ph.D., Professor of Food Science, Northeast]*

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

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

The issue of nitrate interaction in the soil is an interesting one. The major work I'm aware of was done in bacon and involved heating a product with KS - the major affect as I remember it was that the product gave a tingly taste sensation. On that basis the USDA decided not to permit KS to be used in cured meats to cut down nitrite/nitrate in cured meats. How this plays out in the soil is obviously not know - it might in fact be beneficial with respect to nitrate movement in the ground water - but a lot of research is needed to determine this. But give the limited use of such materials in feed, I suspect this really is not a major concern.

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

There seems to be no concern of merit in this area.

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

This is a major concern that I believe could have been better addressed in the report. It is clear from the work presented that the product is made "chemically," but no significant information about the process and the industrial pollution is presented. The disposal, misuse side is probably

not an issue.

4. The effects of the substance on human health.
This is a widely used chemical preservative and as such has a good safety record. Like an material, the material data safety sheet shows a worst case scenario. But there is nothing that suggests that this should be the area of concern.

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.
By using it in livestock, particularly cattle, one should in fact determine directly at what level KS, as an anti-bacterial will interfere with ruminant metabolism. Presumably if used in significant quantities (whatever that may be), then the product would presumably do its "antibacterial" thing in the rumen. However, given that the rumen pH is fairly high, the effectiveness of KS is generally quite low - but if the bacteria absorbed KS, the pH inside the bacteria would be the controlling factor. It seems as if either no information is available on this topic or it was not properly searched.

6. The alternatives to using the substance in terms of practices or other available materials.
Some of the substances listed on the chart presented with the formal presentation of the report are clearly less desirable than KS, however, materials like salt and sugar might well work in this application at fairly
high levels - but given the low dose that the current material is being proposed for use - it might actually work. It also ought to be asked if KS could be produced naturally in a way more consistent with organic production standards?

There is also the longer term, broader philosophical issue - does the program want to encourage the use of traditional "chemical preservatives"? This petition may simply be the first one in the door.

7. Its compatibility with a system of sustainable agriculture.

As shown in this section, "no chemical preservatives" seems to be part of the official language. On this basis I would question it - although I do think the question of the meaning of "chemical" preservative needs a more careful definition. The use of sugar to "preserve" jams and jellies is a form of chemical preservative - so I would argue under this ruling that jams and jellies cannot be organic. Sugar is certainly a chemical.

Additional Comments:
Organic laws in other countries are somewhat different from ours at this time. The listing of compatibility with sustainable agriculture is clearly taken from a foreign country giving the British spelling (which occurs on occasion throughout the document.) US law seems to be taking one of the strongest stands on some of the issues - so even citing state law is misleading. USDA at one

point proudly announced that its rules would be stronger than those of any of the states. (I remember that statement because I was trying to figure out why the US felt it had to go that way.)

Summary

Having read the report, plus more importantly the knowledge I have with respect to potassium sorbate (KS), which I used to do shelf-life extension work some years ago, I am generally comfortable with KS being considered a benign synthetic substance and, therefore, appropriate as a synthetic material for use with organic products for the limited use that is being proposed. Two concerns: The first is that the product is a classical "chemical preservative." As such it might be philosophically incompatible with organics. The second is the issues surrounding its manufacture, i.e., do all of the component chemicals and their manufacture meet the expectations for a compound that might be used with organic foods. This second question is one that I am unable to answer. However, if these questions are answered satisfactorily, I do believe that scientifically KS is an appropriate material to include on the list that it is being proposed for.

Reviewer 1 Conclusions

Given the description in the text of how it is made in practice, it is clearly synthetic material, even if it may be found in nature.

Reviewer 1 Recommendation Advised to the NOSB

Allow only with restrictions

The amount permitted should at most be the normal criteria of the minimal amount that is needed to be efficacious. However, this can be fairly high with KS (there are uses in some countries at the 3% level), this seems inappropriate for the use of a "chemical preservative in an organic material. I'm not sure how one deals with a classical "chemical preservative" philosophically in organic products. Clearly, the specific application seems to require a strong preservative to keep the "organic" product from spoiling. The question of storing the product for which the KS was petitioned frozen or using a natural preservative (e.g., a cranberry puree that would be high in benzoate) does not seem to have been considered.

Reviewer #2 *[Ph.D. Food Science, State Extension Specialist, Midwest]*

Comments on Database

The following information needs to be corrected or added to the database:
No additional information is required.

The Technical Advisory Panel's review of potassium sorbate, its chemistry and applications is adequate to understand how the compound would be useful in livestock production.

Observations/OFPA Criteria

Sorbate is a naturally occurring compound, even though it is now almost entirely produced using synthetic chemistry. The compound has a long history of use in human foods with no evidence of

any adverse effects. Certainly the biochemistry of this compound is better understood than the mixture it would be used to protect (specifically aloe vera juice.) It would seem to be an acceptable compound for use in organic livestock production.

Conversely, it is difficult to imagine labeling potassium sorbate as non-synthetic based on the methodology used to produce commercial quantities of the compound. Condensation reactions, use of inorganic catalysts and crystallization using ethylene hydroxide hardly meets the definition of "organic" most consumers would use. (On the other hand, a good organic chemist would find all of these reactions completely acceptable.)

Reviewer 2 Conclusion
Given the data presented in the Technical Advisory Panel review, it seems best to this reviewer to consider potassium sorbate a synthetic compound.

Reviewer 2 Recommendation Advised to the NOSB
It should be allowed with restrictions identical to those prescribed for its use in human foods (21CFR582.3640).

Reviewer 3: *[Ph.D. Chemistry, Professor, Department of Chemistry, Southwest US]*

Comments on Database
The following information needs to be corrected or added to the database:
No additional information is required.

Observations/OFPA Criteria
Potassium sorbate is the potassium salt of sorbic acid. While this can be found naturally, it is usually produced synthetically. It is used as a mold inhibitor.

Potassium sorbate and sorbic acid are very safe chemicals. There is essentially no toxic effect on humans or the environment. Disposal is simple and benign. There is nothing negative about this substance at all.

Reviewer 3 Conclusion
However, to be certified organic, no "chemical preservatives" and the use as a mold inhibitor counts within this category.

Reviewer 3 Recommendation Advised to the NOSB
Thus, until the above constraint is lifted or modified, use potassium sorbate as a mold inhibitor cannot be permitted. At such a time as the current policy is revised to allow certain 'chemical preservatives", I would recommend its use without restriction.

TAP Conclusion

All three TAP reviewers found potassium sorbate to be a synthetic material. Two reviewers support allowance of the substance in livestock with restrictions, while the other supports allowance without restriction only after the existing legislation concerning 'chemical preservatives' is modified. Concerns included the consistency of the method of manufacturing and use of potassium sorbate with organic practices.