CALCIUM PROPIONATE
Livestock

Executive Summary

Calcium propionate was petitioned for use as a livestock treatment for Milk fever and a mold inhibitor. Calcium propionate is a synthetic substance. Calcium propionate is a safe and effective treatment given for one or two days to prevent milk fever and/or to support treatment of milk fever. Calcium propionate is an extra calcium source for cattle. Calcium propionate is used as a mold inhibitor in key dietary aloe vera holistic therapy for treating various infections. Large levels of aloe vera liquid is added to dry feed pellets and cannot be made without calcium propionate to prevent mold growth on the product.

Calcium propionate 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." Calcium propionate 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.

Summary of TAP Reviewers' Analyses[1]

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

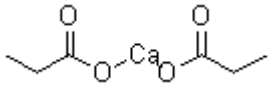
Identification

Chemical names: Calcium Propionate
CAS: 4075-81-4
Molecular formula: $Ca(C_2H_5COO)_2$
Molecular weight: 186.22
Other Names: Calciumpropionatemonohydrate; Propionic acid calcium salt hydrate; calcium dipropionate; Calcium propionate hydrate; Calcium Propionate; Calcium propionate [2]

[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.*

[2] Directly referenced from http://www.chemexper.com/

Structure:



Characterization

Composition:

Appearance: White powder with faint odor of propionic acid
Calcium propionate, after drying at 110°, contains not less than 99 percent. of $C_6H_{10}O_4Ca$. [3]

Properties:

Non-hazardous for air, sea and road freight.
Stability: Stable. Hygroscopic. Incompatible with strong oxidizing agents.
Toxicology: May act as a skin, eye or respiratory irritant. [4]
Melting Point: 300 °C
pH (10% aqueous solution): 6.2 - 9.0
Solubility in water: 1g / 3 ml of water [5]

Properties Chart: [6]

Appearance	White Crystalline Powder
Water Insoluble	0.3 % Max
Moisture Content	3 % Max
PH Value	7.0 To 9.0
Arsenic	NMT 3 PPMhttp://www.advantage2000.com/link_directory/dynamic-frameset.html?http://www.atulorganics.com/food.htm
Iron	50 PPM MAX
Lead	10 PPM MAX
Assay	Content of Calcium Propionate calculated on dried basis is minimum 98.0%

How Made:

"Propionic acid naturally occurs in animals and in dairy products in small amounts. It can be obtained from natural gas by the Fischer-Tropsch process, as a byproduct in the pyrolysis of wood, and by the action of microorganisms on a variety of materials in small yields. Very pure propionic acid can be obtained from propionitrile (Merck)." [7] "Substantial levels of propionate occur naturally in the diet and as part of the metabolism of odd chain fatty acids." [8]

Specific Uses:

[3] Directly referenced from http://www.inchem.org/documents/jecfa/jecmono/40abcj13.htm
[4] Directly referenced from http://physchem.ox.ac.uk/MSDS/CA/calcium_propionate.html
[5] Directly referenced from http://www.jefo.ca/fiches_anglais/calcium_propionate.html
[6] Directly referenced from http://www.advantage2000.com/link_directory/dynamic-frameset.html?http://www.atulorganics.com/food.htm
[7] Directly referenced from http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf
[8] Directly referenced from http://physchem.ox.ac.uk/MSDS/CA/calcium_propionate.html

"Propionic acid and its salts, sodium and calcium propionates are approved in the United States as GRAS (Generally Recognized As Safe) substances for food use. Their antimicrobial action is directed to molds and rope bacteria, with almost no effect on yeast, thus making them an ideal choice for products that use commercial yeast as an ingredient. Like other preservatives, propionates effectiveness is affected by the pH of the food, with 5.5 pH being the upper effective limit. They are used mainly as mold and rope inhibitors in bread; although they are also useful in cheese, non-alcoholic beverages, confections, fillings, frostings, fresh dough, pizza crust, puddings, gelatins, jams, jellies and some meat products." [9]

"Typical usage level of propionic acid and propionates is 0.1 to 0.4 %. Federal regulations limit the maximum level for flour, white bread and rolls at 0.32% based on the weight of the flour; for whole wheat products at 0.38% based on the weight of the flour; and for cheese products at 0.3 %. It is important to know that the addition of sodium and calcium propionate 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." [10]

"Calcium propionate is used as an inhibitor of mold and other microorganisms in food, animal feed, tobacco, pharmaceuticals in butyl rubber to improve process ability and Scorching resistance." [11]

Active ingredient (AI): Calcium propionate; AI Status: Cancelled - The active ingredient is no longer contained in any registered pesticide product.
[USEPA/OPP; Status of Pesticides in Registration, Reregistration and Special Review p.333 (Spring, 1998) EPA 738-R-98-002]**PEER REVIEWED**

Inhibitor of molds & other microorganisms in foods, tobacco, pharmaceuticals; in butyl rubber to improve processability and scorching resistance.
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 276]**PEER REVIEWED**

THERAP CAT: Antifungal agent
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 276]**PEER REVIEWED**

Feed grain preservative
[CHEMICAL PRODUCTS SYNOPSIS: Sodium Propionate-Calcium Propionate, 1983]**PEER REVIEWED**

Mold-inhibiting additive in bread, other foods, tobacco, pharmaceuticals, medicine (antifungal agent).
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 12th ed. New York, NY: Van Nostrand Rheinhold Co., 1993 207]**PEER REVIEWED**

Antimicrobial preservative useful in cosmetics.
[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V7 584]**PEER REVIEWED**

Calcium propionate ... encapsylated in hydrogenated vegetable oil /is/ used in chemically leavened products.

[9] Directly referenced from http://www.nysaes.cornell.edu/fst/fvc/Venture/venture3_chemical.html
[10] Directly referenced from http://www.nysaes.cornell.edu/fst/fvc/Venture/venture3_chemical.html
[11] Directly referenced from http://www.advantage2000.com/link_directory/dynamic-frameset.html?http://www.atulorganics.com/food.htm

[Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V16 645]**PEER REVIEWED**

MAJOR USES OF PROPIONATES ARE TO PREVENT MOLD AND ROPE IN BAKED GOODS AND MOLD IN CERTAIN TYPES OF CHEESE. /PROPIONATES/
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED**

Manufacturers:

Diversified Technology, 1625 State Avenue, Holly Hill, FL 32117, (904) 673-4136; Production site: Holly Hill, FL 32117
[SRI. 1998 Directory of Chemical Producers - United States of America. SRI International, Menlo Park, CA. 1998. 505]**PEER REVIEWED**

DuCoa L.P., 115 Executive Dr., P.O. Box 219, Highland, IL 62249, (618) 624-2070, (800) 780-9233; Production site: Verona, MO 65769
[SRI. 1998 Directory of Chemical Producers - United States of America. SRI International, Menlo Park, CA. 1998. 505]**PEER REVIEWED**

Hawkins Chemical, Inc., 3100 East Hennepin Ave., Minneapolis, MN 55413 (612) 331-6910, (800) 328-5460; Production site: St. Paul, MN 55106
[SRI. 1998 Directory of Chemical Producers - United States of America. SRI International, Menlo Park, CA. 1998. 505]**PEER REVIEWED**

Kemin Industries, Inc., 2100 Maury St., Box 70, Des Moines, IA 50301 (515) 266-2111; Production site: Des Moines, IA 50317
[SRI. 1998 Directory of Chemical Producers - United States of America. SRI International, Menlo Park, CA. 1998. 505]**PEER REVIEWED**

Niacet Corp., 400 47th St., Niagara Falls, NY 14303, (716) 285-1474, (800) 828-1207; Production site: Niagara Falls, NY 14304
[SRI. 1998 Directory of Chemical Producers - United States of America. SRI International, Menlo Park, CA. 1998. 505]**PEER REVIEWED** [12]

ABOUT 80% AS AN ANTIFUNGAL FOOD ADDITIVE IN BAKED GOODS, MOSTLY IN BREAD; ABOUT 20% AS AN ANTIFUNGAL AGENT IN OTHER APPLICATIONS, PRINCPLY AS AN ADDITIVE IN PROCESSED CHEESE (1973)
[SRI]**PEER REVIEWED**

Mold inhibitor-Baked goods, 80%; Feed grain preservative, 10%; and Misc, 10% (1983) /Sodium & calcium propionate/
[CHEMICAL PRODUCTS SYNOPSIS: Sodium Propionate-Calcium Propionate, 1983]**PEER REVIEWED**

Feed Addition Amounts [13]

[12] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA7QaWKw:1

[13] Directly referenced from http://www.adwia.com/products/001.htm

Propionic acid + calcium hydroxide (salt formation)
[Ashford, R.D. Ashford's Dictionary of Industrial Chemicals. London, England: Wavelength Publications Ltd., 1994. 170]**PEER REVIEWED**

General Manufacturing Information:

PROPIONATE COMPOUND IS A MIXTURE CONTAINING 10% EACH OF CALCIUM AND SODIUM PROPIONATES IN A JELLY FOR LOCAL APPLICATION. ... IS USED IN TREATMENT OF VULVOVAGINAL MONILIASIS.
[American Hospital Formulary Service. Volumes I and II. Washington, DC: American Society of Hospital Pharmacists, to 1984.,p. 84:04]**PEER REVIEWED**

BECAUSE PROPIONATE INHIBITS MOLD AND SPARES YEAST, IT HAS SUPERSEDED THE ACID PHOSPHATE AS AN ANTI-ROPE AGENT. /PROPIONATE/
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED**

... FOUND THAT BREAD WHICH CONTAINED 0.2% OF PROPIONATE (BASIS TOTAL DOUGH WEIGHT) SHOWED NO VISIBLE MOLD FOR OVER 8 DAYS IN BOTH WRAPPED AND UNWRAPPED CONDITION AT ROOM TEMP. /PROPIONATE/
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED**

... REPORTED THAT, FOR BREAD, 0.2% ... BY FLOUR WT EXTENDED MOLD-FREE LIFE TO SIX DAYS, AS COMPARED WITH FOUR DAYS FOR UNTREATED LOAVES. NO ODOR PROBLEMS WERE FOUND AT THIS LEVEL.
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED**

... REPORTED THAT ... A LEVEL OF 0.188% EFFECTIVELY INHIBITED ROPE IN BREAD HAVING A PH AS HIGH AS 5.8. AT PH 5.6 ... 0.15% WAS ... INHIBITORY.
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED**

/SUGGESTED LEVELS IN BAKED GOODS/: WHITE BREADS, BUNS, ROLLS, SPECIALTIES: 2.5-5 OUNCES/100 LB FLOUR; DARK BREADS, WHOLE OR CRACKED WHEAT, RYE: 3-6 OUNCES/100 LB FLOUR; PIE CRUST: 2-5 OUNCES/100 LB DOUGH; PIE FILLING 2-5 OUNCES/100 LB FILLING. /PROPIONATES, FROM TABLE/
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 140]**PEER REVIEWED**

... SHOWED 0.11% (BASIS OF FLOUR) ... TO BE ... EFFECTIVE ... IN CONTROL OF ROPE IN BREAD INOCULATED WITH VARIOUS LEVELS OF B MESENTERICUS, UP TO 9,700,000 BACTERIA PER LOAF.
[Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED**

Pesticide status: Cancelled
[United States Environmental Protection Agency/ Prevention, Pesticides and Toxic Substances; Status of Pesticides in Registration,

Reregistration, and Special Review. (1998) EPA 738-R-98-002 333]**PEER REVIEWED**

Calcium propionate /is used/ in bread. In Germany, 0.3-0.06 g/kg ... is added to the flour. Smaller amounts (0.15-0.30%) are used in the United States and England, depending on the expected shelf life. [Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA4 386]**PEER REVIEWED**

BOTH SODIUM AND CALCIUM PROPIONATE CAN BE USED IN BAKED GOODS. CALCIUM SALT IS PREFERRED IN BREAD ... SODIUM SALT ... FOR CAKES AND UNLEAVENED GOODS WHERE THE CALCIUM ION CAN INTERFERE WITH CHEMICAL LEAVENING. [Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Cleveland: The Chemical Rubber Co., 1972. 139]**PEER REVIEWED** [14]

Inclusion rate:
- **In feed:** 500gm/ton feed.
- **In the litter:** 4kg/ 100 cubic meters.

**Store in a cool dry place away from direct sunlight.

Action:

"Propionic acid is rapidly absorbed from the mammalian gastrointestinal tract (11). Propionic acid is a normal intermediary metabolite in the body. It is utilized by most organs and tissues, and can be metabolized to glucose, carbohydrates, amino acids, and lipids (9,11). It is produced in large quantities in ruminants. In nonruminants, propionic acid is one of the metabolic products from the breakdown of several amino acids. Propionic acid is formed in the oxidation of fatty acids and from the side chain of cholesterol." [15] "Propionic acid is not a component of the edible fats and oils, but arises in the intermediary metabolism of the body as the terminal three-carbon fragment in form of propionyl coenzyme A in the oxidation of odd-number carbon fatty acids. Oxidation of the side-chain of cholesterol by rat liver mitochondria yields propionate as the immediate product of cleavage (Mitropoulos & Myant, 1965). Propionates are metabolized and utilized in the same way as normal fatty acids and even after large doses no significant amounts of propionic are excreted in the urine (Bässler, 1957). In vitro propionic acid is completely oxidized by liver preparations to CO_2 and water (Huennekens et al., 1951).

The metabolic fate of propionates varies in microorganisms. Some have enzyme systems converting succinate to propionyl-coenzyme A and by various further steps to propionate, CO_2 or propionyl phosphate. Others convert propionic acid to B-alanine or directly to CO_2. The inhibiting effect for microbials is probably related to competition with acetate in the acetokinase systems, to blockage of pyruvate conversion to acetyl-coenzyme A and to interference with B-alanine in pantothenic acid syntheses (Bässler, 1959). In mammals observations have shown easy absorption from the gastrointestinal tract (Dawson et al., 1964) and absence of any excretion in the urine whatever the mode of administration. Decomposition by bacteria in the gut also occurs Hermann et al., 1938)." [16]

"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

[14] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA7QaWKw:1

[15] Directly referenced from http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf

[16] Directly referenced from http://www.inchem.org/documents/jecfa/jecmono/v05je16.htm

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." [17]

Combinations:

"Since propionic acid is utilized by most organs and tissues, and is metabolized to glucose, carbohydrates, amino acids and lipids when ingested by livestock and poultry, residues in meat, milk or poultry are considered to be negligible. Propionic acid or mixtures of methylene bispropionate and oxy (bismethylene) bispropionate are exempt from the requirements of a tolerance when used as a post-harvest fungicide on alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut hay, peavine hay, rye grass, sorghum grain, soybean hay, sudan grass, timothy, vetch, and wheat grain (40 CFR 180.1023). Propionic acid is also exempt from the requirement of a tolerance when applied (as an inert ingredient) to growing crops or to raw agricultural commodities after harvest as described in 40 CFR 180.1001(c). Propionic acid is Generally Recognized As Safe (GRAS) (21 CFR 184.1081), by FDA for use in food. Since no pesticide products currently contain calcium or sodium propionate as active ingredients, EPA intends to revoke tolerance exemptions established at 40 CFR 180.2(a) and 40 CFR 180.1015. The Agency also intends to establish for propionic acid exemptions from tolerances for meat, milk, poultry, and eggs as a result of application to livestock and poultry drinking water, poultry litter, and storage areas for silage and grain. The Agency has not yet determined whether it will require registrants to submit a petition for these exemptions or whether EPA will establish these exemptions on its own initiative. EPA will inform registrants of its decision in the near future." [18]

Status

Historic Use by Organic Farmers:

"Propionate is used by the liver to make glucose. Glucose is used by the cow to make lactose, the sugar in milk. For this reason, total milk production is very closely related to the total glucose supply at the udder. Propionate's second function involves the cow's fat metabolism. When the cow's energy demands for milk production exceed the amount of energy she is eating, she begins to break down some of her body fat stores. Fats are first broken down into smaller pieces, called non-esterified fatty acids (NEFA's), and carried to the liver. At the liver, they are broken down to form acetate and through this process, energy is generated. Acetate must then be broken down to carbon dioxide and water to yield more energy, however, this process requires some propionate. If there is not enough propionate available (which is often the case when cows are making a lot of milk sugar), the excess acetate builds up in the liver, then acetate molecules combine to make acetone, acetoacetate, and beta-hydroxybutyrate. These products are released from the liver into the cow's bloodstream, causing the ketosis symptoms." [19]

"Trials were conducted to test the efficacy of a calcium propionate paste as an aid to prevent milk fever and to improve the health of dairy cows. Each calcium propionate treatment tube supplied 37 g of calcium. In trials involving Holstein herds and a Jersey herd, two (trials 1 and 2) or three (trial 3) calcium propionate tubes were given at calving and again 12 h after calving. For the Jersey herd, calcium propionate treatment (two tubes) reduced the incidence of milk fever from 50% to 29% in treated cows. Plasma obtained 24 h after calving from treated cows had higher calcium, lower NEFA, and lower B-hydroxybutyrate concentrations than did the plasma from control cows. No other benefits of calcium propionate treatment were significant for health or for productivity of the cows. Calcium propionate treatment had no significant effects on blood calcium, NEFA, or B-hydroxybutyrate in the Holstein herds studied. However, calcium

[17] Directly referenced from http://www.ces.ncsu.edu/drought/dro-29.html#mold
[18] Directly referenced from http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf
[19] Directly referenced from http://www.farme.com/assets/articles/KETONEweb.htm

propionate did reduce the number of cows with sub-clinical hypocalcemia (<=7.5 mg/dl of plasma calcium) at 24 h after calving in both trials involving Holstein cows. Calcium propionate treatment was beneficial in reducing subclinical hypocalcemia in all trials and reduced the incidence of milk fever in a herd having a problem with milk fever." [20] "Oral administration of calcium chloride and calcium propionate [has] been shown to raise blood calcium in cows. This is why some dairymen purchase calcium chloride in a caulking gun system and treat cows at calving time. We also know that giving l.0 to 1.5 pounds of calcium propionate in 3 to 5 gallons of water by esophageal pump provides important energy and raises plasma calcium concentrations for several hours following calving. The propionate also provides a food energy source for cows. Drs. S. Stokes and J. Goff published their work in Professional Animal Scientist, Volume 17:115-122, June, 2001. They also wrote a summary of their work in Hoards Dairyman, September 10, 2001, page 575. Drs. Stokes and Goff conducted a field trial on a large dairy in Texas. They examined the effects of force feeding 1.5 pounds of calcium propionate or 300 milliliters of propylene glycol administered in 2.5 gallons of water. The dairy force fed 169 cows at calving and again 24 hours later. The control group was force fed water with nothing added to it. The results showed that daily milk production was 96, 99, and 92 pounds per cow per day for those groups force fed calcium propionate, propylene glycol, or water alone, respectively. Milk production for cows fed propylene glycol was significantly higher that those fed calcium propionate. Cows force fed propylene glycol and calcium propionate produced significantly more milk verses those force fed only water. Cows fed propylene glycol or calcium propionate also had significantly less metritis then the control group. The researchers conclusion was that the cost of treatment was justified by the higher milk production." [21]

U. S. Production:

(1972) 9.71X10+9 GRAMS
(1975) PROBABLY GREATER THAN 9.08X10+5 GRAMS
(1984) 8.51X10+9 g
[USITC. SYN ORG CHEM-U.S. PROD/SALES 1984 p.255]

(1993) 16,382 kg
[United States International Trade Commission. Synthetic Organic Chemicals - United States Production and Sales, 1993. USITC Publication 2810, Nov. 1994. Washington, D.C.,p. 3-71]

U. S. Imports:

(1972) NEGLIGIBLE
(1975) NEGLIGIBLE
(1984) 7.56X10+7 g /propionates/
[BUREAU OF THE CENSUS. U.S. IMPORTS FOR CONSUMPTION AND GENERAL IMPORTS 1984 p.1-357]

U. S. Exports:

(1972) NEGLIGIBLE
(1975) NEGLIGIBLE

Project Goals:	To evaluate calcium propionate and propylene glycol delivered as a drench at calving on blood measurements, health events, and milk production in a commercial dairy.
Relevance:	At the onset of lactation, the cow must cope with a tremendous increase in calcium demand and energy demand by the mammary gland. Cows failing to meet these demands can develop milk fever

[20] Directly referenced from http://www.vmtrc.ucdavis.edu/s_jarabst.html
[21] Directly referenced from http://www.lava-net.jp/PMNews/2001/01-10/01-10-01.html

	or ketosis, are less productive and more susceptible to other metabolic diseases and infectious diseases.
Materials & Methods:	Cows and heifers were divided and assigned to one of three groups. At calving, animals received the scheduled drench; this was followed by a second drench 24 hours post calve. Drench treatments included either a control (2.5 gallons water), calcium propionate (1.5 lbs + 2.5 gals water) or propylene glycol (300 mls + 2.5 gallons water). Blood samples were drawn prior to each drench (calving and 24 hours later) and again on day 4 and day 10 of milk. Measurements included calcium, magnesium, glucose, and non-esterified fatty acids (NEFA). Health events in the fresh period were followed on each animal and monthly milk weights are being recorded.
Results:	One hundred sixty nine animals (110 cows and 59 heifers) completed this trial. In general, this herd had a low incidence of metabolic disorders and most animals calved within normal blood parameters of calcium, magnesium, and glucose concentrations. The occurrence of metabolic disorders in trial cows was low: 1.8% retained placentas; 1.8% ketosis, 0.6% hypocalcemia, 2.4% displaced abomasums, and 4.1% metritis. No cows receiving calcium propionate were diagnosed with metritis, while the control group had a greater incidence of metritis than cows receiving the propylene glycol drench. Average DIM at which metritis was diagnosed was 8, thus the additional calcium or energy at calving may have improved smooth muscle contraction and assisted in better uterine involution. There was no effect of drench on calcium status of the animals post-calve. There were expected differences in blood constituent concentrations between parity (cows typically have lower blood calcium than heifers at calving). All plasma calcium concentrations were higher than those reported in previous research, which may reflect the attention given to maintaining an effective dietary cation-anion difference in this herd. Drenching with additional energy, as either propylene glycol or calcium propionate, had no effect on blood glucose. Plasma NEFA tended to respond to oral drench, with the animals receiving propylene glycol having lower NEFA levels than those receiving either the control or calcium propionate treatment (Figure 1). Milk production, both heifers and cows averaged across all periods, was significantly greater in animals receiving propylene glycol as compared to controls. Although not statistically significant, milk yield in cattle receiving the calcium propionate treatment averaged 4.6 pounds more milk than control animals. It appeared that heifers received no benefit from additional calcium (Figure 2); however, cows in their 2nd lactation or greater receiving calcium propionate averaged 3.9 pounds more milk than their counterparts receiving the control (Figure 3).
Conclusions:	Low blood calcium concentration results in the loss of muscle tone in the gut, uterus, and teat sphincter. This loss of muscle tone, combined with the immunosuppression at calving, predisposes these animals to displaced abomasum, retained placentas, uterine prolapse, and mastitis. Additionally, the reduced feed intake often noted with hypocalcemic conditions further aggravates the negative energy balance commonly observed in early lactation. Supplying both additional calcium and energy during the metabolic and feed intake challenge at calving may be of benefit to the cow. Considering the economic implications of milk fever and the low per-head cost of calcium propionate, oral drenching would be a break-even practice at only a 0.5 % incidence of milk fever in the herd. [22]

[22] Directly referenced from http://stephenville.tamu.edu/~sstokes/drenching.html

"Kemin Industries, Inc., of Des Moines, Iowa, has been granted an exclusive license to an ARS- patented gel that may cut milk fever in dairy cows by 50 percent. Milk fever is a metabolic disorder that usually occurs within 24 hours after cows give birth. Each year, about 500,000 U.S. dairy cows develop severe milk fever, a disease that costs producers $150 million a year.

According to ARS researchers, the gel may be given orally to cows when they give birth and for the first two days of lactation. Other oral formulations now used for treating milk fever contain calcium chloride, which is irritating to the cow's mucous membranes and to the skin of the person administering the treatment.

The ARS-formulated gel delivers calcium propionate, a less irritating form of calcium. Another advantage of calcium propionate is that cows can use it to make glucose for energy. All lactating dairy cows are energy-deficient for two reasons: They are using a large amount of glucose to make milk, and immediately after calving they can't eat enough feed to meet their energy needs.

In ARS field trials with an Iowa Jersey dairy herd, the gel reduced the incidence of milk fever from 50 percent in untreated cows to 29 percent in treated cows." [23]

OFPA, USDA Final Rule:

Calcium propionate 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." Calcium propionate 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.

Regulatory: EPA/NIEHS/Other Sources

EPA: "As the federal pesticide law FIFRA direct, EPA is conducting a comprehensive review of older pesticides to consider their health and environmental effects and make decisions about their future use. Under this pesticide reregistration program, EPA examines health and safety data for pesticide active ingredients initially registered before November 1, 1984, and determines whether they are eligible for reregistration. In addition, all pesticides must meet the new safety standard of the Food Quality Protection Act of 1996. Pesticides for which EPA had not issued Registration Standards prior to the effective date of FIFRA 88 were divided into three lists based upon their potential for human exposure and other factors, with List B containing pesticides of greater concern and List D pesticides of less concern. Calcium propionate is found on List D. Case No: 4078; Case Status: RED Approved 09/91 - OPP has made a decision that some/all uses of the pesticide are eligible for reregistration, as reflected in a Reregistration Eligibility Decision (RED) Document. Active ingredient (AI): Calcium propionate; AI Status: Cancelled - The active ingredient is no longer contained in any registered pesticide product. Thus, we characterize it as cancelled." [24]

FDA: [Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1221]

[Page 488-489]

TITLE 21--FOOD AND DRUGS

[23] Directly referenced from http://www.ars.usda.gov/is/pr/1998/980416.htm
[24] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA7QaWKw:1

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

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1221 Calcium propionate.

(a) Calcium propionate ($C_6H_{10}CaO_4$, CAS Reg. No. 4075-81-4) is the calcium salt of propionic acid. It occurs as white crystals or a crystalline solid, possessing not more than a faint odor of propionic acid. It is prepared by neutralizing propionic acid with calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 60, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in Sec. 170.3(o)(2) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in Sec. 170.3(n)(1) of this chapter; cheeses as defined in Sec. 170.3(n)(5) of this chapter; confections and frostings as defined in Sec. 170.3(n)(9) of this chapter; gelatins, puddings, and

[[Page 489]]

fillings as defined in Sec. 170.3(n)(22) of this chapter; and jams and jellies as defined in Sec. 170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived. [25]

Code of Federal Regulations]
[Title 21, Volume 1]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR582.3221]

[Page 522]

TITLE 21--FOOD AND DRUGS

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

[25] Directly referenced from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=184.1221

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

Subpart D--Chemical Preservatives

Sec. 582.3221 Calcium propionate.

(a) Product. Calcium propionate.
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice. [26]

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) [27]

Pennsylvania is in accordance with guidelines proposed by OMRI.
(Contact- Martha Melton- state certifier) [28]

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) [29]

International

JAPAN: not officially listed in Japanese final rule[30]
EUROPEAN UNION: listed as a currently permitted food additive (E282 Calcium propionate)[31]
IFOAM: not officially listed as approved in IFOAM standards [32]

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.*

"[Calcium propionate is] incompatible with strong oxidizing agents." [33] "Calcium propionate is not toxic at 1% of the diet, no limits exist on its use although, as with all short chain fatty acids, its flavor/odor is readily detectable." [34] There are no transportation regulations. "On the basis of low toxicity and low potential for exposure, hazard to non target organisms is expected to be minimal." [35]

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.*

"The [Environment Protection] Agency has reviewed the available ecotoxicity data base on file for propionic acid. A review of the studies in the data base indicate that propionic acid is no more than slightly

[26] Directly referenced from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=582.3221
[27] Information was referenced from a phone interview with Ron McKay, State Certifier, June 5, 2002.
[28] Information was referenced from a phone interview with Martha Melton, State Certifier, June 5, 2002
[29] Information was referenced from a phone interview with Mary Hanks, State Certifier, June 12, 2002
[30] Information referenced from http://www.fas.usda.gov/gainfiles/200004/25647377.pdf
[31] Information referenced from http://www.foodstandards.gov.uk/multimedia/pdfs/elist_numbers.pdf
[32] Referenced from http://www.ifoam.org/standard/ibs_final02.html
[33] Directly referenced from http://physchem.ox.ac.uk/MSDS/CA/calcium_propionate.html
[34] Directly referenced from http://www.uaf.edu/coop-ext/efnep/preservatives.html#propionate
[35] Directly referenced from http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf

toxic to birds, fish, aquatic invertebrates, and mammals. As indicated above, review of registered uses of propionic acid indicates that all uses are either indoor treatments or limited outdoor uses for animal watering. On the basis of low toxicity and low potential for exposure, hazard to nontarget organisms is expected to be minimal. Based on the above discussion, all ecological effects data requirements are waived for propionic acid." "The Agency does not anticipate significant risks associated with the specified use of propionic acid. No hazard or exposure issues have been identified that need to be addressed further. Therefore, no environmental fate or ecological effects data are required to support the reregistration of propionic acid." [36]

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

"SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices." "SODIUM AND CALCIUM PROPIONATES ... PRESENT LITTLE HAZARD IN STORAGE." [37]

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

Human Health Effects:

Emergency Medical Treatment:

Emergency Medical Treatment:

EMT Copyright Disclaimer:

Portions of the POISINDEX(R) database are provided here for general reference. THE COMPLETE POISINDEX(R) DATABASE, AVAILABLE FROM MICROMEDEX, SHOULD BE CONSULTED FOR ASSISTANCE IN THE DIAGNOSIS OR TREATMENT OF SPECIFIC CASES. Copyright 1974-1998 Micromedex, Inc. Denver, Colorado. All Rights Reserved. Any duplication, replication or redistribution of all or part of the POISINDEX(R) database is a violation of Micromedex' copyrights and is strictly prohibited.

The following Overview, *** NON-TOXIC INGESTION ***, is relevant for this HSDB record chemical.

Life Support:

- This overview assumes that basic life support measures have been instituted.

Clinical Effects:

SUMMARY OF EXPOSURE

0.2.1.1 ACUTE EXPOSURE

- A non-toxic ingestion occurs when the victim consumes a nonedible product which usually does not produce symptoms. The importance of knowing that a product is nontoxic is that overtreatment is avoided and, more importantly, the victim and parents are not placed in the jeopardy of a panicky automobile ride to the physician or nearest hospital (Comstock, 1978).
- Materials referenced to this management have been

[36] Directly referenced from http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf
[37] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA7QaWKw:1

considered very unlikely to produce any toxicity except in enormous doses. For example, ballpoint pen cartridges, even if sucked completely dry by a child, do not contain enough toxic materials to cause illness (Mofenson et al, 1984).

- o While almost anything, including water and table salt, may cause illness if taken in excessive amounts or by other than the normal route, normal exposures from these products would not be expected to produce toxicity (Horev & Cohen, 1994).
- o Some agents are harmful in manners different from that expected. A broken thermometer is dangerous not from the inert metallic mercury, but from the broken glass (Mofenson et al, 1984). Most patients calling are more worried about mercury, which they think of as poison, than the glass.
- o General guidelines for determining if an exposure can be categorized as non-toxic (reviewed in Weisman, 1998; Mofenson et al, 1984):

1. Absolute identification of the product, its ingredients, and its concentration.
2. Absolute assurance that only the identified product was involved in the exposure.
3. The exposure must be unintentional.
4. "Signal words" identified by the Consumer Product Safety Commission (i.e. Caution, Warning, Danger) must not be found on the label.
5. A reliable approximation of the quantity of the substance involved in the exposure.
6. The route of exposure can be assessed accurately from the patient's available history.
7. Following the exposure, the patient is symptom-free.
8. A follow-up consultation with the patient must be possible. In the case of a pediatric exposure, the parent must appear to be reliable.

Laboratory:

- o In most cases it will not be necessary to perform laboratory tests. However, if a patient is developing symptoms from what should be a non-toxic product, appropriate evaluation and treatment should be performed.

Treatment Overview:

ORAL EXPOSURE

- o Even though a substance may be considered non-toxic for the amount ingested or packaged, it should not be considered as non-toxic in any amounts. Even ingestions of various foodstuffs can cause adverse symptoms if large amounts are eaten (green apples, garlic, onion).
- o The most important fact to remember is to treat the patient not the poison, especially when the diagnosis is unknown.
- o Knowing that the product is listed as non-toxic helps avoid overtreating the patient or being over zealous in getting a patient to professional medical care.
- o If there is a question of simultaneous ingestion of a product which may be more dangerous, the management on

the more toxic agent should be consulted.

INHALATION EXPOSURE

- Although inhalation of common dust may not be considered toxic, it is certainly a hazard if there is inhalation of too many particles. Individuals should be removed from exposure to too high a concentration of even relatively non-toxic substances.

EYE EXPOSURE

- Foreign materials in the eye may not cause a toxic reaction, but injury from a foreign body may occur. In such cases, the patient should be observed for eye irritation and should seek medical assistance if the irritation becomes significant.

DERMAL EXPOSURE

- Foreign materials spilled on the skin may not represent a toxic or irritation hazard in small quantities, but may produce adverse effects if applied in large quantities or if used over a significant period of time. Whenever possible, foreign materials should be removed from the skin with simple washing. Should skin irritation or erythema occur, a patient may wish to seek medical assistance.

Range of Toxicity:

- These agents are considered not to be a toxic hazard in the quantities available through normal exposure or package size. [38]

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.*

"Propionic acid's production and use as a feed and corn preservative, and chemical intermediate may result in its release to the environment through various waste streams. It's use to control fungi and bacteria in drinking water for livestock and poultry is expected to result in its direct release to the environment. It is also released to the environment with the manufacture and use of coal-derived and shale oil liquid fuels and during the disposal of coal liquefication and gasification and wood preserving chemical waste byproducts. Textile mills, sewage treatment facilities, municipal and industrial landfills, hazardous waste sites, and gasoline and diesel fueled engines can release propionic acid to the environment. If released to air, a vapor pressure of 3.53 mm Hg at 25 deg C indicates propionic acid will exist solely as a vapor in the ambient atmosphere. Vapor-phase propionic acid will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 11 days. Photolysis of propionic acid is not expected to be important fate processes. Propionic acid is miscible in water and monitoring data has shown that physical removal from air by wet deposition is an important removal mechanism. If released to soil, propionic acid is expected to have very high mobility based upon an estimated Koc of 1.2. Volatilization from moist soil surfaces is not expected to be an important fate process based upon a Henry's Law constant of 4.45X10-7 atm-cu m/mole. Propionic acid may volatilize from dry soil surfaces based upon its vapor pressure. Biodegradation is likely to be the most important removal mechanism of propionic acid from soil. If released into water, propionic acid is not expected to adsorb to suspended solids and sediment in water based upon the estimated Koc. Biodegradation is likely to be the most important removal mechanism of propionic acid from water. A pKa of 4.87 indicates propionic

[38] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA7QaWKw:1

acid will exist in the ionized form at pH values of 5 to 9 and therefore volatilization from water surfaces is not expected to be an important fate process. Hydrolysis is not expected to occur due to the lack of hydrolyzable functional groups. Occupational exposure to propionic acid may occur through inhalation and dermal contact with this compound at workplaces where propionic acid is produced or used. The general population may be exposed to propionic acid via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with this compound and other consumer products containing propionic acid. (SRC)" [39]

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

Other mold inhibitors include sodium propionate and potassium sorbate. "At concentrations up to 0.004 mol/l the acid is fungistatic (Peck & Rosenfeld, 1938). Sodium and calcium propionate inhibit moulds and fungi at specific concentrations varying from 0.0125% to 1.25% at pH 5.5 and sodium propionate at 1.6% to 6% inhibits various bacteria (Keeney & Boyles, 1943). In tests with a number of microorganisms it has been shown that the bacteriostatic and fungistatic activity of sodium propionate was greater in acid than in neutral or slightly alkaline solution, which suggests that the antimicrobial action is due to the undissociated acid (Heseltine, 1952b and Preservatives Report 1959)." [40] "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-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" [41] 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." [42]

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

"When heated to decomposition it emits acrid smoke and irritating fumes." [43] "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, coloring 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" [44]

[39] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAxBaW3C:1
[40] Directly referenced from http://www.inchem.org/documents/jecfa/jecmono/v05je16.htm
[41] Directly referenced from http://www.soybean.com/ps.htm
[42] Directly referenced from http://www.ferlowbrothers.com/potassium_sorbate.htm
[43] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA7QaWKw:1

[44] Directly referenced from http://www.anarac.com/organic_farming.htm

Calcium propionate was petitioned as a feed additive to be used as a mold inhibitor. While calcium propionate is non-toxic and environmentally safe (unless burned), it may not be in compliance with organic farming due to the afore mentioned limitations.

TAP Reviewers' Discussion

Reviewer 1 *[Ph.D. Chair- Food Science, State Extension Specialist & Professor of Food Science, Midwest]*

Observations/OFPA Criteria

Calcium propionate is a naturally occurring compound and is a normal part of lipid metabolism in many organisms. The compound has a long history of use in human foods with no evidence of any adverse effects while providing numerous benefits in terms of food quality and flavor. Certainly the biochemistry of this compound is better understood than the dietary therapy it would be used to prevent mold growth in.

Review 1 Conclusions

There seems to be no reason to restrict its use in organic agriculture.

Reviewer 1 Recommendations Advised to the NOSB

Given the data presented in the Technical Advisory Panel review, it seems best to this reviewer to consider calcium propionate a Synthetic compound. It probably should be Added to the National List with restrictions identical to those prescribed for its use in human foods (21CFR184.1221).

Reviewer 2 *[Ph.D. Chemistry, Professor, Department of Chemistry, Southwest US]*

Observations/OFPA Criteria

Calcium propionate is a synthetic substance. It is the calcium salt of propionic acid, which is made primarily through processing of fossil fuels. The acid is also made in nature through metabolic processes.

Use of calcium propionate is suggested as both a treatment and prevention for milk fever as well as a mold inhibitor. These applications will be considered separately.

As far as a treatment for milk fever, while one could argue that propionic acid is non-synthetic, given that is produced via metabolism of fatty acids, the bulk of the calcium propionate used is undoubtedly made in a plant. Therefore, one must consider the case for an exemption. Calcium propionate would not be harmful to human health nor the environment. In addition, it is consistent with organic farming and handling. Its disposal would not create any problems. There is no doubt that its use is effective, not only in providing calcium, but also a pathway for metabolic glucose synthesis.

The use as mold treatment, however, is less compelling. To be certified organic, no "chemical preservatives" and the use as a mold inhibitor counts within this category.

Reviewer 2 Conclusions

In summary, calcium propionate should be allowed as a milk fever treatment but not as a mold inhibitor.

Reviewer 2 Recommendations Advised to the NOSB

The substance is Synthetic.

For Livestock, the substance should be Added to the National List with restrictions.

Reviewer 3 *[PhD, Food Science; J.D. Research, consulting and teaching activities related to food processing and food packaging. Associate Professor, Department of Food Science, Central U.S.]*

Observations/OFPA Criteria

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

I agree with the criteria evaluation.

(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.

I agree with the criteria evaluation. Calcium propionate is quite safe at very high levels in food systems. Historically upper usage limits were established at the threshold of odor and flavor.

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

The criteria evaluation is correct. Large concentrations of this substance could persist for extended periods dry landfills especially in cool areas.

(4) The effects of the substance on human health.

I agree with the criteria evaluation.

(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 with the criteria evaluation. Calcium propionate is safer than a great many agrochemicals.

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

Glucose solutions containing calcium and magnesium are commonly given to cows with milk fever, but dietary supplement or pre-freshening treatment to prevent the disease would be desirable. The use of aloe vera preserved using calcium propionate could help to prevent milk fever. The calcium propionate should improve the efficacy of the aloe vera treatment. Other mold inhibitors and physical processes are available to limit mold growth on feeds, but would not serve as a calcium supplement for dairy animals. These alternative processes would increase processing costs for feeds containing holistic supplements. Lowering the water activity of the feed could reduce or eliminate usage of preservatives. Calcium propionate is one of the least toxic and most soluble calcium sources available, and would comprise a good means of treating milk fever.

(7) Its compatibility with a system of sustainable agriculture.

Calcium propionate is a synthetic salt produced from the reaction of calcium hydroxide with propionic acid. Propionic acid can be naturally produced.

Calcium propionate has good mycostatic properties and some bacteriostatic properties. The question then is what alternatives (if any) are more consistent with sustainable agriculture systems.

Reviewer 3 Conclusion

Calcium propionate is synthetic. It is safe, and an effective treatment and/or preventative for milk fever without the addition of aloe vera. It is more soluble and less toxic than most inexpensive calcium sources. It may be more acceptable in organic dairy farming operations than bone meal or micro-ground coral. Propionic acid is a normal component in many dairy products.

Reviewer 3 Recommendations Advised to the NOSB

Calcium propionate is Synthetic, but propionic acid occurs naturally in biological systems.

Calcium propionate is an easily applied, non-persistent preventative and treatment for milk fever. There would be no carryover into milk or meat.

Calcium propionate would aid in preventing mold growth in feeds. The risk of mycotoxins in the feeds would thus be reduced.

Due to the high level of safety of calcium propionate, and the low potential for environmental harm calcium propionate should be Added to the National List.

TAP Conclusion

Of the three reviewers, one reviewer supports the use of calcium propionate without restriction, while the other two support restricted use. All agree that it should be considered as a synthetic material. One reviewer specifies that calcium propionate should be allowed as a milk fever treatment, but not as a mold inhibitor since the reviewer considers it a chemical preservative.