Calcium Propionate TAP Supplement
January 27, 2003
CFNP

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. It is an extra calcium source for cattle and is used as a mold inhibitor and dietary aloe vera holistic therapy for treating various infections. Large levels of aloe vera liquid are 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, use and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling." Calcium propionate is successful in the treatment of milk fever and ketosis. It is also extensively used as a mold inhibitor. Generally, calcium propionate is deemed non-toxic and environmentally safe (unless burned) and the corresponding weak acid to this salt, propionic acid, is naturally occurring in animals and dairy products. [1]

Manufacturing Information:

"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)." [2] "Propionic acid is produced naturally during the fermentation of some cheeses such as Swiss cheese, in concentrations as high as 1%, thus inhibiting the growth of molds." [3]

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[1] "Registration eligibility document: propionic acid, and salts." EPA case 4078; Office of Pesticide Programs. September 1991. http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf
[2] Directly referenced from http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf
[3] "Chemical Food Preservatives: Propionates and Parabens." New York State Food Venture Center Newsletter, Cornell University. Summer 1998 Vol. 1 No.3.
http://www.nysaes.cornell.edu/fst/fvc/Venture/venture3_chemical.html

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Therapeutic Use in livestock:

Calcium propionate is marketed for use in the prevention and treatment of milk fever and ketosis in dairy cows but it is also frequently and increasingly used as a feed additive in conventional dairy farming as an anti-microbial/antifungal [4].

1. *Treatment of Milk Fever*

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. The results showed that treatment was beneficial in reducing subclinical hypocalcemia and reduced the incidence of milk fever in a herd having a problem with milk fever.{Goff, 1996 161 (1)}

In a Swedish study comparing the effectiveness of calcium propionate and calcium chloride, it was noted that there was a significant preventive effect of calcium propionate as compared with calcium chloride against milk fever. {Pehrson, 1998 101 (2)}

2. *Treatment of Ketosis*

The initiation of lactation at the time of parturition is a time of a great increase in demand for glucose in the cow. The dry matter intake of the typical diet of the parturient cow often cannot supply enough glucose to meet these increased demands. Therefore, glucose can come from amino acid breakdown in the liver, the mobilization of body fat, and from glucogenic precursors in a process called gluconeogenesis. The breakdown of muscle protein into simple amino acids for glucose synthesis results in a decrease in body muscle mass. As a by-product of this process, ketones are also produced. The breakdown of body fat and high non-essential fatty acid levels in the blood are associated with decreased feed intake at calving and an increased incidence of other pariparturient disease disorders. Calcium propionate acts as a valuable glucogenic precursor in the diet as it results in an increase in dietary net energy intake and provides glucose needed at extremely high demands at parturition. It is the major and most successful glucose precursor on the market today in many opinions.{Dan Giacomini, 2002 4 /id}

3. *Preservative (Mold Inhibitor)*

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 can be added to dry feed pellets and cannot be made without calcium propionate to prevent mold growth on the product.

[4] Both terms have been used interchangeably. Research in Cornell University has mentioned Calcium propionate as an antimicrobial while researches in Israel mentioned the additive as an antifungal.

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Use of Calcium Propionate:
In treatment of conventional as well as organic cows at high risk during the calving period, some veterinarians and farmers treat the livestock by drenching[5] in order to provide key electrolytes and nutrients to replace the space (volume) and weight lost when the calf, fluid, and membranes are lost at calving.

Drench ingredients may include:

1. Calcium propionate provides a rapid source of absorbable calcium. The propionate fraction is converted to blood glucose as an energy source. This product targets low blood calcium (hypocalcemia), milk fever, and ketosis.

2. Probiotics are microbes that can stimulate rumen fermentation and dry matter intake. New products are commercially available.

3. Alfalfa leaf meal is a rumen fermentable source of protein and carbohydrates. It is preferred by veterinarians that the cow consumes this forage resource (relative feed value over 150) to maintain or build a forage raft in the rumen.

4. Sodium bicarbonate would provide a source of sodium (electrolyte source) and buffer the rumen pH for optimal digestion and dry matter intake.

5. Protected choline could serve a methyl donor and export fat (lipid) out of the liver if fatty liver syndrome is a risk.

6. Rumen fluid can also be added to drench mixtures if a cow, heifer, or steer is on the farm. Field reports indicate cows off-feed respond quickly to rumen fluid drenches. {Hutjens, 2002 164 /(3)}

Historic Use in Organic Farming:

The use of this material by organic farmers is limited at this time and it is used as a short term therapy technique.

Section 2119 OFPA:

Question 1: How would calcium propionate interact detrimentally with other materials used in organic farming systems?

There are no known interactions with other materials used in the organic farming system and there are no known impacts on crops or soil organisms from the use of calcium propionate in livestock. 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

[5]The process of drenching includes pumping a predetermined amount of ingredients mixed in a fixed volume of water into the rumen of the cow.

by liver preparations to CO_2 and water (Huennekens et al., 1951). Therefore, use in feed would not result in concentrated levels in manure or urine.

The dominant interaction of this substance with other drugs relates to calcium chelation and subsequent reduced activity. In drugs like Tetracycline, an antibiotic-calcium complex is formed decreasing its systemic absorption.{Jeff Wilcke, 2002 162 /(4)} However, there are no specific known interactions with drugs allowed for organic production.

Question 3: The question asks about the probability of environmental contamination during manufacture, use, misuse, or disposal of calcium propionate.

The EPA has conducted a review of the scientific database and other relevant information supporting the re-registration of propionic acid and has determined that the database is sufficient to allow the EPA to conduct reasonable risk assessments. The data available to the EPA support the conclusion that the currently registered uses of propionic acid will not result in unreasonable adverse effects to the environment or human health. The EPA review of data base studies indicates that propionic acid is "no more than slightly toxic to birds, fish, aquatic invertebrates, and mammals." Under anaerobic conditions, propionic acid is metabolized to carbon dioxide and water, proving to be a carbon source to many organisms. [6]

If released into soil, propionic acid is expected to have very high mobility based upon an estimated Koc[7] 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.

Question 4: Potential Human Health problems resulting from exposure

<u>Human Exposure Hazards:</u>

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 [calcium propionate] and other consumer products containing propionic acid. (SRC)" [8]

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,

[6] "Registration eligibility document: propionic acid, and salts." EPA case 4078; Office of Pesticide Programs. September 1991. http://www.epa.gov/oppsrrd1/REDs/old_reds/4078red.pdf

[7] Soil adsorption coefficient (Koc)- Most important factor influencing a chemical's mobility. The higher the Koc value, the more strongly the chemical is bound to soil, and thus the less likely it is to move from the point of application.(Ambrust)

[8] Directly referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAxBaW3C:1

residues in meat, milk or poultry are considered to be negligible. Propionic acid products are approved for use in both human food and animal feed. Based on this information, the probability of adverse human health effects due to consumption is extremely low.

The National Research Council was unable to prove or disprove a direct relationship between potential hazards to human health and the use of anti-microbials, such as calcium propionate. The report stated that, "A direct relationship between anti-microbial use in animals and human health cannot be adequately established."[9] The data from the US, UK, and Germany, complied in the National Academy Press research paper, do not include whether self-imposed restrictions have increased or reduced adverse human health effects. There is no clear relationship between human health effects and therapeutic uses of anti-microbials in animals. Therefore, calcium propionate is unlikely to produce any toxicity unless administered and/or consumed in enormous doses.

Sources from the state of Minnesota say that calcium propionate should not be recommended as a mold inhibitor because it is believed that the use of such products will harm both public and animal health, by increasing antibiotic resistance. This is only speculation. This would seemingly only occur if very large amounts of calcium propionate were administered continuously to the same species. Oral, inhalation, eye, and dermal exposure routes to calcium propionate show very low risk of detrimental or life long human health problems.

Question 5: What would be the impact on soil organisms or crops from using calcium propionate in livestock?

There are no known interactions with other materials used in the organic farming system and no suspected impacts on crops or soil organisms from the use of calcium propionate in livestock.{Dan Giacomini, 2002 4 /(5)}

Question 6: Information is needed on alternatives available in an organic system.

<u>Possible Alternatives for use other than for Milk Fever treatments:</u>

1. *Providing livestock with clean living environments with fresh water and food supplies.*
2. *Biosecurity*

This entails the isolation of infectious animals from those who are not ill. This can cut down on disease exposure of livestock.

3. *Probiotics*

"Providing animals with probiotics, mixtures of beneficial bacteria added to animal feed, can also help them resist infections and, hence, can reduce the use of antimicrobials and the development of resistance."{2001 2 /(6)}

4. *Propionic acid in some form is used in some areas as a mold inhibitor/feedstuff preservative in making hay for livestock.*

[9] Proposed ideal studies for studying the effect of anti-microbials in animal feed on human health are available at http://books.nap.edu/books/0309030447/html/35.html{1980 1 /id}

In areas where they have regular rains all summer, preservatives that allow haymakers to bale the hay at a slightly higher moisture content are beneficial. This is typically in the areas east of the Rocky Mountains.{Dan Giacomini, 2002 4 /(7)}

Effectiveness of Specific Alternatives:

One potential alternative that could be considered for approval for organic livestock production is potassium sorbate. "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" [10] 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." [11]

A study of fungistatic activity of antifungal compounds, calcium propionate and Agrosil in pelleted feeds showed that the addition of 0.3% calcium propionate to the cattle ration before pelleting prevented mold proliferation during one month of storage while the number of fungal colonies counted in pellets treated with a possible alternative, .15% Agrosil, markedly increased over that period. When both materials were applied at .2% concentration, the feeds treated with either of the agents were visibly moldy after 17 days of storage. {Paster, 1985 6 /(8)}

Another study compared the efficiency of propionic acid and calcium propionate as a fungistat. This showed that in summer conditions, propionic acid appears to be more effective in slowing fungal population density than in feeds treated with calcium propionate.{Paster, 1979 163 /(9)}

Question 7: The question asks about the use of calcium propionate in a system of sustainable agriculture.

Concentrated propionic acid is normally sprayed directly onto hay as it goes into a baler. Inevitably, the mist from such a procedure gets on perimeter residing plants and into the soil/ground. Unless very large quantities were to be saturated into the soil supply and existing plants, a system of sustainable agriculture should be easily maintained. Farmers in Southwest Virginia carry out this procedure regularly and have had no incidents of crop failures due to propionic mist exposure. This is a very common procedure by most farmers and is of very little risk to agriculture. Should propionic acid or its salt, calcium

[10] Directly referenced from http://www.soybean.com/ps.htm
[11] Directly referenced from http://www.ferlowbrothers.com/potassium_sorbate.htm

propionate be exposed to crops and soil by indirect routes, no detrimental interference with sustainable agriculture should occur. [12]

[12] Phone Interview: Chris Teutsch, Virginia Tech Southern Piedmont AREC (Agricultural Research and Extension Center). January 21, 2003.