Sodium Propionate Crops

1 **Executive Summary** 2

3 Sodium propionate is a synthetic substance petitioned for use as a preservative for a seed coating. The reviewers were

- 4 unable to fully evaluate the petition since the specific polymer was not identified, the target pests and mode of action were
- 5 not specified, and the petition justification for use of the product in organic production was incomplete. 6
- 7 The reviewers unanimously found the substance to be synthetic and unanimously found no evidence to support adding
- 8 sodium propionate to the National List for the petitioned application or use. All noted that natural analogs exist, and may
- 9 be used without being added to the National List. One reviewer supported possibly adding the substance to the National
- 10 List as a preservative for certain specific biological soil amendments, pending a look at the alternatives to these other uses.
- 11 However, all reviewers explicitly considered the petitioned use to be incompatible with organic farming systems.
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Summary of TAP Reviewer's Analyses¹ 13

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Synthetic/ Nonsynthetic	Allow without restrictions?	Allow only with restrictions?
Synthetic (3)	Yes (0)	Yes (0)
Nonsynthetic (0)	No (3)	No (3)

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Identification 16

- Chemical Name: sodium propionate 17
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- 19 Other Names: Propionic acid, sodium salt.
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- 21 Trade Names: Mycoban, Niace.
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Characterization 27

- Composition: CH₃CH₂COONa 28
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30 **Properties:**

31 It is transparent crystals, granular, deliquescent in moist air, neutral to slightly alkaline in reaction to litmus. One gram

32 dissolves in ~1ml of water; in ~24 ml of alcohol. It is most active at an acid pH (Budavari, 1996). 33

34 How Made:

35 Sodium propionate is made from the reaction of sodium hydroxide with propionic acid. Propionic acid can be prepared by a 36 number of different methods. Propionic acid occurs naturally as the result of metabolic processes, and can be obtained through 37 fermentation of Propionibacterium (Wayman, 1962).

- 38
- 39 Synthetic propionic acid is manufactured either as a byproduct of acetic acid through the oxidation of n-butane (Hoechst
- 40 Celanese), or from ethylene and carbon monoxide (Union Carbide & Eastman) (Chemexpo, 2002). 280 millions pounds of
- propionic acid were sold in 2001, 17% of which went to make sodium or calcium propionate salts (Chemexpo, 2002). 41
- 42
- 43 Propionic acid can also be synthesized from the interaction of methanol and carbon monoxide in the presence of various
- 44 boric fluoride catalysts (Loder, 1938a; Loder, 1938b) and subsequent oxygenation (Loder, 1938c). Propionic acid can also
- 45 be produced by the oxidation of propionaldehyde (Hasche, 1942), and from the reaction of ethylene, carbon monoxide,
- 46 and steam (Larson, 1945). Other industrial processes currently reported as used to produce commercial quantities of
- 47 propionic acid include the liquid phase oxidation of heavy naphtha as a co-product with acetone, methyl ethyl ketone
- 48 (MEK), formic acid, and acetic acid, and from n-butane as a co-product with methanol, ethanol, acetone, MEK, formic
- 49 acid, acetic acid, *n*-butyric acid, and methyl formate (Ashford, 1994).

- 22 23 CAS Number: 137-40-6 24
- 25 Other Codes: INS 281, IFN 8-04-289

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.

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- 51 Propionic acid can also be produced by fermentation of starch or sugar by *Propionibacterium acidipropionici* (Carrondo et al.,
- 52 1988; Blanc & Goma, 1989). However, there has been a revival of interest in production from fermentation (Raeker et al.,
- 1992). Fermented propionic acid is used for fragrances and flavor agents (Samel et al., 1993).

55 Specific Uses:

56 Sodium propionate is used as a fungicide and for mold prevention. Most uses of sodium propionate are as a food additive,

57 in particular for use in baked goods, confections, and gelatin (Winter, 1989). It is also used in cosmetics. It is used as a

- 58 topical antifungal agent in livestock, and also as a preservative for hay and silage. These post-harvest and processing
- ⁵⁹ applications are not included in the petition and are not considered to any great detail in the TAP Review. Propionic acid
- is also used as an inert ingredient in various biorational pesticides and is used as a preservative in various fertilizer
 products.
- 61 pro 62

63 <u>Action</u>:

Propionic acid and its salts, including sodium propionate, is toxic to molds and certain bacteria based on the inability of the affected organisms to metabolize the three-carbon chain (Lindsay, 1996). It is most effective at an acid pH (Budavari, 1996).

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68 <u>Combinations</u>:

It was petitioned to be used as a seed treatment along with potassium sorbate and various unspecified polymers used to

- coat seed (Patil, 2001). It is used in baking as an antimycotic along with a variety of other ingredeints (Ponte and Payne,
- 1992). It is used with sodium benzoate, sodium nitrite, and hexamine as silage preservatives (Lingvall and Lättemäe, 1999).
- 72

73 <u>Status</u>

74 Historic Use:

- Propionic acid occurs naturally in various traditional cheeses, such as Swiss cheese. As such, it appears to be functional in inhibiting the growth of molds (Lindsay, 1996). The main historic uses in organic production appear to be as a preservative in biorational pesticides and various other biological fertilizers, such as fish and kelp meal.
- 78

79 OFPA, USDA Final Rule:

- 80 Not listed in the NOP Final Rule. Use as a seed treatment, biological soil amendment stabilizer, or hay and silage
- 81 treatment could be considered a seed treatment or production aid under 7 USC 6518(c)(1)(B)(i).

82

83 <u>Regulatory: EPA/NIEHS/Other Sources</u>

As inert ingredients in pesticides, EPA List 4. Listed as FDA GRAS.

86 Status Among U.S. Certifiers

- 87 Not listed in the standards of: California Certified Organic Farmers (CCOF), Maine Organic Farmers and Gardeners
- 88 Association (MOFGA), Northeast Organic Farming Association of New Jersey (NOFA-NJ), Northeast Organic Farming
- Association of New York (NOFA-NY), Northeast Organic Farming Association of Vermont (NOFA-VT), Oregon Tilth
- 90 Certified Organic (OTCO), and Organic Crop Improvement Association International (OCIA), Quality Assurance
- 91 International (QAI), Texas Department of Agriculture (TDA), and Washington State Department of Agriculture (WSDA).

92 93 <u>International</u>

- 94 CODEX not listed
- 95 EU 2092/91 Listed in Annex 2 D 1.5 Feed additives as "propionic acid only for silage."
- 96 IFOAM Not listed. However, a derogation to section 5.6.8 states that 'synthetic chemical fodder preservatives may be
- 97 allowed in special weather conditions.' While sodium propionate is not specifically mentioned as an example, propionic
- 98 acid is (IFOAM, 2000).
- 99 *Canada* not listed
- 100 Japan not listed
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102 Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

- The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.
 As an antimicrobial, sodium propionate has the potential to have detrimental interactions with beneficial soil
 organisms. However, *Propionobacter* and other organisms, including humans, produce propionic acid and its salts as
 part of normal metabolic processes.
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- The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

Sodium Propionate

Crops

110 The molar toxicity of sodium propionate is about twice that of sodium chloride or table salt (Gosselin et al., 1984). Propionic acid reported an oral LD₅₀ of 2 g/kg (US EPA, 1991). The 'safe' level of sodium propionate in the diet of a 111 112 model insect, Agria affinis was determined to be 400 ppm (Singh and House, 1970). It is a skin and eye irritant and 113 decomposes into an irritant. Because it is corrosive and readily absorbed, sodium propionate is more toxic through 114 the skin than when ingested. The dermal LD_{50} on rabbits is 0.5 g/kg. 115 116 Sodium propionate is not considered a carcinogen (Niacet, 2001). Tests for the teratogenicity and reproductive 117 toxicity for calcium propionate and sodium propionate are negative (US EPA, 1991). There is some evidence that 118 propionic acid is a mutagen (FASEB, 1979). One study reported that rats exposed to sodium propionate showed insignificant levels of cell injury (Sugihara, Shimomichi, and Furuno, 1997). 119 120 121 Sodium propionate readily breaks down into sodium and propionic acid. Under anaerobic conditions, propionic acid 122 serves as a carbon source to various microorganisms that metabolize it into acetic acid, methane, carbon dioxide, and 123 water (US EPA, 1991). 124 125 3. The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance. 126 The production of propionic acid has the greatest probability of environmental contamination, and that probability 127 depends on whether it is produced by fermentation or from petroleum or other fossil fuels. The fermentation process 128 involves the use of sulfuric acid and various solvents to strip the propionic acid from the bacteria. The amount of 129 toxic by-products resulting from this process is still relatively small compared with the potential for contamination 130 resulting from the extraction and refining of petroleum. An assessment of the environmental impact of petroleum 131 production is beyond the scope of this TAP Review. 132 133 Propionic acid and its salts are considered only slightly toxic to birds, fish, aquatic invertebrates, and mammals (US 134 EPA, 1991). 135 The effects of the substance on human health. 136 4. 137 Propionic acid is considered Generally Recognized As Safe for food (21 CFR 184.1784). Propionic acid is used as a textbook example of how a substance can test positively as a carcinogenic on laboratory animals but not be considered a human 138 139 carcinogen (Klaasen, 2001). The greatest risk of exposure and adverse human health effects is considered occupational, given 140 the eye and skin hazards. Dietary exposure from pesticidal use is considered very low (US EPA, 1991). 141 The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on 142 143 soil organisms (including the salt index and solubility of the soil), crops and livestock. 144 Sodium propionate has a highly variable effect on various microorganisms. It is effective at inhibiting certain molds and 145 fungi, but is selective. Sodium propionate actually stimulates the growth of the nitrogen-fixing actinomycete, Frankia, under 146 laboratory conditions (Ringø et al., 1995). 147 148 Propionic acid should inhibit the growth of soil bacteria and fungi. It would also inhibit the growth of yeast that 149 contaminated stored seed coated with a protein/carbohydrate polymer. Sodium propionate is being petitioned to be 150 used as a shelf-life extender for a seed coating. The microbial growth inhibition comes at a cost, however. Exposure 151 of microbes to weak acids and bases can turn on resistance genes and "train" the organisms to resist other 152 environmental stresses (Russell, 1991; Piper et al., 2001). Mild acid treatment of Vibro parahaemolyticus (HCl at pH 5) 153 has been shown to increase the bacteria's resistance to lower pH and give cross protection against heat stress (Wong, 1998). Lever & Johnson (1993) reported similar findings on Salmonella typhimurium. Taormina and Beuchat (2001) also 154 155 show that exposing Listeria monocytogenes to mild alkali or chlorine induces resistance to strong disinfectants agents and 156 heat. 157 158 Short chain fatty acid preservatives like propionic acid have been specifically shown to induct resistance to 159 environmental stresses in Salmonella typhimurium and yeasts in the genus Saccharomyces (Piper et al., 2001; Stratford & Anslow, 1996; and Kwon & Ricke, 1998). Kwon & Ricke (1998) show that exposure of Salmonella typhimurium to 160 propionic acid can induce acid resistance in as little as 30 minutes. Weak acid resistance is becoming a problem in the 161 162 food industry where acids such as sorbic and propionic are widely used to preserve food against yeast and fungi spoilage (Piper et al., 2001). Propionic acid is currently being phased into the meat packing industry as an antibacterial 163 spray for beef carcasses (Hardin et al., 1995). Weak organic acid antimicrobials are important to the food industry, and 164 165 manufacturers should use them wisely. Indiscriminate use can lead to widespread acid tolerance in microbial 166 populations(Levy, 2001). 167 168 Salt index: Sodium propionate is 23.93% sodium (Budavari, 1996). 169

Sodium Propionate

Crops

- 170 Sodium propionate is GRAS for use in animal feed with no limitations or restrictions other than following good 171 manufacturing and feeding practice (21 CFR 582.3784). Propionates are often regarded as beneficial to animal health because they control Aspergillus flavus, the organism responsible for the production of aflatoxins (Raeker et al., 1992). Sodium 172 173 propionate used with other preservatives significantly improves the hygienic quality and storage stability of silage made from 174 unchopped and wilted grass (Lingvall and Lättemäe, 1999). However, sodium propionate showed higher incidents of 175 abnormalities in developing chick embryos exposed to 10 mg/egg via air cell (FASEB, 1979). 176 177 The alternatives to using the substance in terms of practices or other available materials. 6. 178 The petitioned use, and only crop application supported in the literature, is as a seed treatment. This is tied to the practice of 179 coating the seed, as the coating materials are susceptible to mold and pathogen development. One obvious alternative is to 180 not coat the seed. Admixtures are documented to decrease the storage life of seeds, particularly those that absorb moisture 181 and serve as a substrate for plant pathogens (Agarwal and Sinclair, 1996). By not coating the seed with such substances, one 182 could effectively increase the storage life. If coating the seed is desirable, then timing the treatment to within two weeks of 183 planting should be sufficient to avoid infection, based on the information provided in the petition (Patil, 2001). This would 184 preclude saving coated seed for more than a season. 185 186 Proper seed storage begins at planting. Some varieties are more prone to seed-borne diseases than others (Agrawal and 187 Sinclair, 1996). By sowing disease-free seed, one is more likely to reap disease-free seed. Techniques are available to exclude, 188 quarantine, and reduce inoculum (Maude, 1996). Selecting a field that has not grown a host crop for a suitable period reduces 189 the chance of soil-borne infection (Agrawal and Sinclair, 1996). Preventing infection in the field is an important step to 190 maintaining disease-free seed. 191 192 Harvest is a critical stage for preventing seed-borne diseases. Timing must be right. Delayed harvest favors seed infection 193 (Agrawal and Sinclair, 1996). Yet seed should not be harvested too soon either. Seeds should be harvested when the 194 moisture levels are low enough to prevent the growth of mold. Care should be taken in harvesting to not damage the seeds 195 in a way that permits opportunistic infection by mold or bacteria. Test methods are available to help predict and ensure storability (Neergaard, 1977). Once harvested, seeds need to be maintained in cool, dry conditions (Copeland and 196 197 McDonald, 1995). Insect damage can also create opportunities for infection (Neergaard, 1977; Agrawal and Sinclair, 1996). 198 Construction and maintenance of appropriate storage containers and facilities can also regulate conditions so that they favor long-term seed storage (Neergaard, 1977). 199 200 201 A number of biological control agents are commercially available to protect seeds from microbial pathogens, including 202 Bacillus subtilis, Trichoderma spp., and Gliocladium spp. (Campbell, 1989; OMRI, 2001). Biological control methods are 203 compatible and are particularly well suited for use with coating technology (Campbell, 1989). Copper sulfate [7 CFR 204 205.601(i)(2)] and elemental sulfur [7 CFR 205.601(i)(8)] both appear on the National List and are both effective as seed 205 treatments (Maude, 1996). Various natural edible plant extracts show efficacy as antimicrobial agents, including Chinese 206 chive, cinnamon, and Corni fructus (Mau, Chen, and Hsieh, 2001).
- 208 7. Its compatibility with a system of sustainable agriculture.

Synthetic biocides are not considered compatible with a system of sustainable agriculture, with few exceptions. However,
compared with other synthetic fungicides that have long been used to treat seed planted by organic producers, propionic acid
is considerably less toxic to both humans and soil organisms. Because propionic acid can be derived from bacteria, it would
be possible to obtain that substance from a natural, renewable source by either fermentation or inoculation. Therefore, the
nonsynthetic analog is clearly sustainable, but the synthetic form is not.

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218 **TAP Reviewer Discussion**

219 <u>**Reviewer 1**</u> [research chemist who serves on an organic certification committee, East Coast]

Sodium propionate is the salt of propionic acid. Propionic acid is an aliphatic monocarboxylic fatty acid. Propionic acid is
a corrosive liquid with a strong odor (Chichester & Tanner, 1972). It has antifungal properties, but the odor makes it
undesirable as a food additive and the calcium or sodium salts are used instead. Sodium propionate has a pleasant cheeselike flavor and can be used in food products (Chichester & Tanner, 1972). It is used as a preservative in baked goods and
cheese products. With propionic acid, the salts are also used to preserve animal feed and corn (Samel et al., 1993).
Propionic acid producing the bacteria *Propionibacterium acidipropionici* are sold as liquid cultures to inoculate silage.

Propionates have antimicrobial activity against mold. They have little activity against yeast or bacteria, except for the

- 228 bacteria that cause rope (Chichester & Tanner, 1972).
- 229

Sodium Propionate

230 Propionic acid is a weak acid (HA). The dissociation of the acid to H⁺ and A⁻ is governed by the pH of the solution, with low pH favoring the undissociated acid (Cherrington et al., 1991). Fatty acid preservatives generally inhibit microbe 231 232 growth, causing cell stasis or lag phases in growth, rather than killing microbe cells (Stratford & Anslow, 1996). The main 233 antimicrobial effect of fatty acids like propionic is attributed to the undissociated acid penetrating the microbial cell wall 234 and then disassociating in the higher pH cytoplasm. The H+ released is believed to inhibit glycolysis and growth (Stratford 235 & Anslow, 1996; Piper et al., 2001). The antimicrobial activity is therefore very dependent on the pH of the material being 236 preserved. The propionates work best at low pHs (\leq 5). They can be used at lower effectiveness at pHs up to 6.0 237 (Chichester & Tanner, 1972). 238 239 1) Interactions 240 Sodium propionate and propionic acid are stable compounds. They are incompatible with strong bases, and with both 241 strong oxidizing and reducing agents (MSDS). The compounds are antimicrobial to many soil fungi, but would be 242 metabolized by other fungi and bacteria. Microorganisms can metabolize propionates to acetic acid via malonic 243 semialdehyde, or to succinate via several pathways (Wegener et al., 1968). Exposure to weak acids like propionic can 244 induce resistance in bacteria and yeast to other environmental stresses (see section 5). 245 246 2) Toxicity 247 As stated above, the compound inhibits growth of fungi and some bacteria. However, as other carboxylic acids it is 248 metabolized by microbes. Fish and rat toxicity is low (Samel et al., 1993). Neither propionic acid nor the sodium salt 249 shows any apparent genotoxicity or teratogenicity (Samel et al., 1993; Chichester & Tanner, 1972). 250 251 3) Environmental Contamination 252 There are no unusual problems with manufacturing propionic acid. Dust from powdered propionates can be eye and skin 253 irritants, but can be controlled by normal industrial powder handling procedures. 254 255 4) Human Health 256 Propionic acid is easily metabolized by mammals in the same way as other fatty acids. It occurs naturally in Swiss cheese at 257 concentrations up to 1 wt. % and is a normal metabolite of rumen flora (Chichester & Tanner, 1972). 258 259 Propionic acid is corrosive and can irritate eyes and mucus membranes (MSDS). Weak solutions, however, have been used 260 as a treatment for eye infections without significant irritation (Samel et al., 1993). 261 262 5) Effects in agroecosystem 263 [See paragraphs two and three in #5 above.] 264 265 6) Alternatives 266 The weak acid preservatives in the petition would be used for protection of a polymer seed coating. There are two 267 questions regarding the need to place the preservative on the National List of Allowed Synthetics: (1) Are there 268 alternatives to the seed coating, and (2) Are there alternatives to the synthetic weak acid preservative? 269 270 Neither the seed coating nor its purpose is described in the petition. It is difficult to evaluate the alternatives to the 271 petitioned preservatives without some knowledge of the material that they are meant to preserve. If the seed coat is the 272 OMRI Listed material produced by the petitioning company, and assuming that the material uses a similar technology to a 273 related non-Organic product by the same company, we will attempt to address question 1. 274 275 The purpose of the seed coating is to slow hydration of sown seed. Inhibiting hydration allows cold susceptible seeds to 276 be sown earlier in the planting season than normally possible (Ni, 2001). A normal planting time or proper choice of plant 277 variety for local conditions would eliminate the need to coat. 278 279 The polymer to be protected by the sodium propionate appears to be very susceptible to attack by mold. Carbohydrate 280 polymers based on alginic acid, ethyl cellulose, or maltodextrins exist that can be formulated to be less susceptible to mold. 281 282 Naturally derived fatty acids such as lauric, palmatic, or linoleic acid also have antimicrobial activity and could be 283 substituted for sorbic or propionic acid (Kabara et al., 1972). Natural extracts of cinnamon, Chinese chive, or Welsh 284 onions also have been shown to be useful antimicrobials (Mau et al., 2001; Fan and Chen, 1999). Welsh Onion extract is 285 more active against yeast than either sorbates or propionates at neutral pH (Fan and Chen, 1999). Essential plant oils such 286 as oregano or lemongrass show activity against both bacteria and fungi (Hammer et al., 1999). They can penetrate fungal 287 cell walls, opening holes from which cell contents leak out (Piper et al., 2001). [P]ropionic acid [is] widely used in the food 288 industry due to its mild taste and lack of odor. Taste or odor are not an issue with seed coatings, and the use of 289 preservatives better suited for food products seems unnecessary, especially in light of resistance issues.

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If the seed coating uses the Fantesk technology developed by USDA scientists, essential oil preservatives would fit into the polymer very well. In the Fantesk technology, a starch and oil are turned into a gel through steam processing. The oil droplets remain suspended in the starch, and will not un-mix during further processing. Essential oil preservatives could be incorporated into the main vegetable oil (probably soy), and would present a large contact surface to invading

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297 Propionic acid extracted from *Propionibacterium acidipropionici* should be considered a natural product (like fermentation

298 based citric acid). Sodium propionate derived from this propionic acid would still be synthetic. Propionic acid, however, is

- 299 completely miscible with water and most organic solvents (Samel et al., 1993). It should be possible to incorporate the
- 300 natural acid into the polymer seed coating.
- 301 302 <u>7) Compatibility</u>

microbes.

Sodium propionate is an antimicrobial of low toxicity. It inhibits microbial growth rather than kill organisms. It is not
listed for organic food processing or as an organic feed additive. Weak acid preservatives have a long history in food
storage, starting with acetic acid (vinegar). Widespread use is now creating a problem with acid resistant bacteria and fungi.
Better management of these antimicrobials in the food industry is needed. Non-food uses of sodium propionate should be
limited. Besides natural fermentation derived natural sodium propionate, alternatives unsuitable for use in food products
(strong taste and odor) can be substituted for sodium propionate in non-food applications.

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310 The use of sodium propionate to extend the shelf life of a polymer seed coating is not compatible in a system of

- 311 sustainable agriculture, which extends from the soil to the table. Proper planting would eliminate the need for a seed coat
- that limits moisture uptake. It has not been demonstrated in the literature packet accompanying this TAP Review that the
- 313 particular polymer chosen for this product is the best chemical for seed coatings.
- 314315 <u>Reviewer 1 Conclusion</u>

316 Synthetic sodium propionate is a weak acid antimicrobial. It is most active at low pH. It has been shown to "train"

bacteria and fungi to become more resistant to environmental stresses. Since it is an important antimicrobial in the food

- industry, use for a non-food seed coat is not advisable. Natural antimicrobials would be more suitable for crop use.
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Synthetic sodium propionate should not be added to the National List of Synthetic Materials for use in organic cropproduction.

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323 **<u>Reviewer 2</u>** [M.S. Plant Breeding with experience in the seed trade and as an organic farmer, West Coast]

Sodium propionate should be considered as a preservative in fish and kelp meals. Since it is on EPA List 4 and is therefore allowed in approved biorational pesticide formulations as an inert ingredient, it should be granted the same status in soil amendments. Based on the TAP Review presented (with perhaps some further discussion of alternatives for those specific purposes), I would vote to add it to the National List for those uses.

328329 <u>Alternatives</u>

330 It is very difficult to assess alternatives because the petition lacked the basic information of what seed species it is used for 331 and against what "molds". There is also no indication of what the coating polymer is that is used in conjunction with

- 332 it....The petitioner has stated that the material is needed to prevent mold formation and to extend the shelf life of his
- 333 product, but not why his product is necessary for organic production. The TAP Review also gives no indication of why

the coating is necessary. Therefore, the alternatives all are very general, but have to be looked at as what is historically supported in organic farming practice.

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Biological control agents, copper sulfate, elemental sulfur, and some plant extracts are all mentioned as alternative seed
treatments, but the viability of these cannot be assessed without knowing if they target the same "molds" and without
knowing if there has been any commercial product development in the latter three materials.

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341 ... There is ... no indication of what coating polymer is used other than a brand name product. The question about what 342 the storage life of uncoated and preservative free seeds was not answered ... /*One*/ can only assume that the coating

- polymer is natural ... If a product is on the market without these preservatives, then it is unclear why the preservatives are
- necessary. It is also troubling that the petitioner only conducted experiments with both materials together instead of a
- 344 necessary. It is also froubling that the perturber only conducted experiments with both materials together instead of a345 controlled experiment with each material individually as well as the two combined. No additional information was
- provided as to why the seeds would be coated with a polymer at all. Does it help germination in cold soil? Help prevent
- 347 damping off? Keep moisture in the seed?
- 348
- 349 Without a basic understanding of why seeds benefit from this treatment, it can only be concluded by this reviewer that the 350 alternatives presented, particularly not treating the seeds in the first place, are superior choices. The materials mentioned as

coating agents in the alternative section are also very intriguing but without any information presented on whether they have been actually used rather than just experimented with, it would come back to the untreated seed being best.

353 354 <u>Compatibility</u>

Neither the petition nor the TAP review is compelling as to why the material should be considered compatible with organic production.... That being said, this reviewer sees that there may be situations where this material may play a role in organic agriculture....

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As mentioned *[in]* the TAP review . . . "The main historic use 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." These uses may encompass a seed treatment if there were more complete information in a petition, but use as a seed treatment should not be looked at by itself, without the other uses as preservatives in inoculants and biological amendments also considered. In these historic uses, the small amount used . . . the benefits in each situation of use, as well as the fate in the soil may result in a determination that this material is indeed compatible with sustainable agriculture for several uses. This reviewer would welcome the opportunity for a full review of uses of this material.

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367 ... If a new section of the TAP Review is prepared covering the alternatives to these materials for all uses in crop
 368 production such as preservatives in fish, kelp, microbial products and soil amendments, ... these materials [might] have a
 369 compatible place in organic agriculture for several uses that may include seed treatments. As it stands, however, the
 370 petition is so incomplete as to make [it impossible to determine that this use is compatible with a system of sustainable agriculture].

371372 <u>Reviewer 2 Conclusion</u>

This material as presented should not be allowed for this particular use in organic systems. This is primarily because not enough reason to allow it was provided in the petition. Based on the TAP Review presented (with perhaps some further discussion of alternatives for those specific purposes), I would probably vote to add the material to the National List for use as a preservative in biological and microbial soil amendments.

378 <u>Reviewer 3</u> [Ph.D. food science and nutrition, minor in biochemistry. Organic processing consultant, organic inspector, 379 nutrition researcher. Western US]

... [P]ropionates are functionally fungistatic agents. At proper concentrations of 0.02-0.05%, they inhibit the growth of
 mold, yeast, and some aerobic bacteria in foods (Aurand, Wood, and Wells, 1989). [*They*] also can be applied and are used
 on wrappers for food products such as cheese and can be added to the dough or batter of baked products to sharply

inhibit mold growth . . . [and are] widely used in the food industry (Meyer, 1978).

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Solution propionate appears to be used at concentrations of 50 to 150 milligrams per 100 pounds of seeds. . . In other words, the concentration of anti-microbial is sufficient to inhibit microbial growth or vegetation of bacterial spores. In the soil . . . the concentration of anti-microbial [hypothetically] becomes further diluted especially in the presence of irrigation water thereby diluting the anti-microbial concentration rendering it much less effective in anti-microbial activity. . .

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In the soil, \ldots propionates at their diluted levels become assimilated by soil microorganisms as a carbon source, with eventual metabolism by microorganisms to CO₂ under anaerobic soil conditions. One could also explain these hypotheses on the following: "The solution to the pollution is the dilution."

393394 *Interactions*

Both propionic and sorbic acid either in their salt form or in disassociated form are weak acids. At the usage level for sodium propionate of 50 to 150 milligrams per 100 pounds of seeds, I think the risk of creating detrimental interactions

sodium propionate of 50 to 150 milligrams per 100 pounds of seeds, I think the risk of creating detrimental interactions with beneficial soil microorganisms is very, very low. This is predicated on the ionization potential and low amounts used according to Part 4 Item B of the petition by Seedbiotics.

399400 <u>Toxicity</u>

401 Sodium propionate partially disassociates in an aqueous environment into propionic acid. EPA studies have shown

402 (September, 1991) that rats fed sodium propionate at the large dose of 4000 mg. Kg/day showed no adverse effects, no

- 403 evidence of teratogenicity, and were found to have no mutagenic effects in further studies. Its metabolism as a normal
- 404 intermediary metabolite in the body as propionic acid can be metabolized to glucose, amino acids, and lipids. This

405 evidence suggests very little risk of toxicological and/or deleterious environmental effects or consequences.

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407 <u>Environmental Contamination</u>

408 The justification is based on non-GMO manufacturing inputs with an approved material caustic soda-sodium hydroxide,

409 which is on the National List *[for processing]*. I highly suggest that additional information be obtained that answers my

410 questions on specific manufacturing operations. This additional information will either confirm my analysis of the

411 chemistry of the manufacturing operation and therefore support my suggestion or contribute to its justification as a 412 prohibited synthetic. 413 414 In order to assess the environmental impact of the production process proposed by the Niacet Corporation, sodium 415 hydroxide is used. Sodium hydroxide is approved [for processing] by the USDA per 205.605 in 7CFR 205. The flow diagram 416 provided in the petition shows a source of propionic acid entering a reaction with caustic soda (sodium hydroxide). A more detailed explanation is required as to the role of extraction, purification, and source of propionic acid. For example, 417 418 if propionic acid is produced by fermentation with non-GMO organisms and caustic soda is used to lyse the bacterial cells 419 to release the propionic acid as the sodium salt, then the process may have significant merit in its compatibility with 420 organic systems. 421 422 ... [T]he process [presented poses] minimal affects from an environmental aspect. My recommendation would be to request 423 further information on the production process chemistry and operations. Furthermore, propionic acid acts as a carbon 424 source by many microbes and is metabolized to CO2 and water under anaerobic environmental conditions. Therefore, the 425 risk of propionic acid during its use as an environmental contaminate or through its misuse should be negligible according 426 to . . . EPA (1991). 427 428 Human Health 429 There has not been consistent scientific evidence from the literature that shows that at the recommended usage levels there is any 430 evidence of adverse affects on human heath. Propionic acid is a short chain fatty acid and is metabolized in the human body as 431 any free fatty acid. 432 433 Interactions with Agroecosystems 434 Recent studies (Lingvall and Lättemäe, 1999) suggest that sodium propionate when added as one of several other inhibitors was 435 successful in inhibiting the growth of undesired fungi in silage. 436 437 <u>Compatibility</u> 438 Additional information needs to be obtained as to how the sodium propionate is manufactured. If it can be demonstrated 439 that the source of propionic acid is microorganisms from non-GMO sources and substrates with the use of caustic soda (NaOH) to create the sodium salt of propionic acid, then its compatibility with sustainable agriculture may be argued. 440 441 However, in either case it must be considered a synthetic biocide because of the use of sodium hydroxide, which indeed 442 does cause a chemical modification of the propionic acid to sodium propionate or the sodium salt of propionic acid. 443 444 **Reviewer 3** Conclusion 445 In summary, sodium propionate is clearly synthetic [when produced as described in the petition]. However if it were 446 [naturally] produced from fermentation with non-GMO microorganisms and substrates, I would suggest [that it be allowed 447 ø/nly when manufactured from non-GMO microorganisms and substrates. . . [P]ropionic acid is found as a naturally 448 occurring weak acid in many foods which means the only difference from a chemical point of view is the creation of the 449 sodium salt of propionic acid. /To be allowed in organic crop production, propionic acid/ must be produced as a function of 450 fermentation of non-GMO microorganisms and substrates. 451 [End of TAP Reviewer Comments] 452 453 **Conclusion** 454

Sodium propionate is synthetic. Given the questions remaining about the justifications for use, the broad-spectrum effects
that it has on soil organisms, and the availability of alternative methods and materials, the reviewers unanimously agreed
that the substance should not be added to the National List for the petitioned use or application.

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* = included in packet

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