Malic Acid
April 2003

Summary of TAP Reviewer's Analyses[1]

Malic acid was petitioned to include its use in organic processing operations. Synthetic DL- malic acid is being petition for use as a pH adjuster in processing operations. Malic acid is a food processing aid, which is used in bottled iced teas, dry mix beverages, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties, and sports drinks. Non- food uses of malic acid include pharmaceuticals, paints, metal cleaning, electroplating, soaps and as a chelating agent.

The NOP final rule does not list malic acid under sections 205.605 or 205.606 as an approved substance allowed in processing of "organic" products. The ruling does however list citric acid as an approved processing aid under section 205.605 if the citric acid used is produced by microbial fermentation of carbohydrate substances (non synthetic). NOSB standards dictate that malic acid must not be used for the sole purpose of a flavor, color, or texture enhancer or preservative. Malic acid is being petitioned for use as a pH adjuster. Malic acid is used also in beverage dry mixes, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties and other foods. Malic acid is used as a flavor enhancer and food acidulant.

All three reviewers have concluded that DL-malic acid is synthetic and should *not* be allowed on the national list because a non-synthetic viable alternative is available. L-malic acid can be produced by double fermentation, a process that may be more appropriate in the organic industry.

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

[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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Background

Malic acid is a dicarboxylic acid available as the racemic DL-malic acid and the two optically active isomers, D-malic acid and L-malic acid. L-Malic acid is the naturally occurring form. Malic acid occurs naturally in fruits including apples and cherries. Because of this, malic acid is commonly referred to as "apple acid." [2] Malic acid is produced in the metabolic cycles of humans, plants, and animals. In the kreb and glyoxylate cycles, malic acid provides cells with the carbon skeleton and energy necessary for amino acid formation. [3]

Identification [4]

Chemical names and other names:

DL-Malic Acid **[6915-15-7] (**Butanedioic acid, hydroxy-, (+-)-; DL-2-Hydroxybutanedioic acid; DL-Apple Acid; DL-hydroxybutanedioic acid; DL-Hydroxysuccinic acid; DL-malic acid**)**

L- Malic Acid **[97-67-6] (**Butanedioic acid, hydroxy-, (S)-; L-2-Hydroxybutanedioic acid; L-(-)-Apple Acid; L-Hydroxysuccinic acid; L-(-)-Malic acid; (S)-Malate)

D- Malic Acid **[636-61-3] (**D-Hydroxysuccinic acid; D(+)-Malic acid; (R)-Hydroxybutanedioic acid; (R)-Malate**)**

Characterization

Properties:
DL- Malic Acid
Molecular Weight 134.0884
Melting Point 101-103 deg

- a clean, mellow, smooth, persistent sourness,
- flavor enhancement and blending abilities,
- a high solubility rate,
- less hygroscopic than Citric or Tartaric acids,
- a lower melting point than other acids for easier incorporation into molten confections,
- and good chelating properties with metal ions.

It forms:

- economical acidulant blends with other acids,
- more soluble calcium salts than Citric acid, and
- effective buffering mixtures.

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[2] "Malic Acid." Healthwell. http://www.healthwell.com/healthnotes/Supp/Malic_Acid.cfm
[3] "Essential Metabolism." *Malic Acid.* Bartek Inc. http://www.bartek.on.ca/malic_acid.html
[4] "Malic Acid." Properties referenced from http://chemfinder.cambridgesoft.com/result.asp

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How Made:

DL- Malic acid is commercially produced by the catalytic hydration of maleic anhydride or by the hydration of fumaric acid. [5] DL- malic acid is made synthetically by catalytic oxidation of benzene to maleic acid, which is converted to malic acid by heating with steam under pressure. DL- malic acid is produced by the hydration of maleic anhydride (derived from butane), which is converted to maleic and then malic acid. *Bartek*, a manufacturer of malic acid, makes DL- malic acid by the catalytic conversion of butane gas, water, and oxygen to DL- malic acid. This process results in 99% DL-Malic acid and less than 1% fumaric acid. The general reaction for production of Malic Acid from Maleic Anhydride is:

1 molecule maleic anhydride + 2 molecules water = 1 molecule Malic Acid

A.E. Staley Inc. conducts the above reaction under controlled temperature and pressure.

A.E. Staley and *Bartek Ingredients Inc* produce DL-Malic acid. *A.E. Staley* certifies that the formulation of malic acid is in compliance with Good Manufacturing Practices in accordance with the applicable parts of Code of Federal Regulations No. 21. *A.E. Staley* certifies there is no potential for ethanol, benzene, choloform, 1,4-dioxane, methylene chloride or trichloethylene to be present in the finished malic acid products. *A.E. Staley* certifies that malic acid meets the requirements of USP/NF for Organic Volatile Impurities. [6] [7]

L-malic acid is produced by the fermentation of fumaric acid. Fumaric acid can be produced by the fermentation from glucose.

Specific Uses:

Synthetic DL-Malic acid is used in tea production for pH adjustment. It is used to keep the pH of bottled teas to a level of 4.6 or below. Malic acid reduces the amount of flavors needed in certain foods and beverages by intensifying the previously existing flavors. In particular, this pertains to carbonated beverages. Malic acid extends the taste of foods by increasing the impact of certain flavors (improving aftertaste). This is normally the case with "still" or un-carbonated beverages, including teas, fruit juices, sports drinks, and calcium fortified beverages. The presence of malic acid in these types of beverages masks salty aftertastes and improves pH stability while enhancing fruit flavors. Malic acid is also typically added to drink mixes because of its rapid rate of dissolution. Malic acid is more sour than citric acid, therefore less acidulant is required, reducing unit

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[5] "The Acid List." *Acid Basics.* Kuntz. May 1993. Referenced from http://www.foodproductdesign.com/archive/1993/0593DE.html

[6] The 1995 U. S. Pharmacopoeia National Formulary, USP23NF18 references Method IV <467> for the determination of Organic Volatile Impurities. It states "Unnecessary testing may be avoided where a manufacturer has assurance, based on knowledge of the manufacturing process and controlled handling, shipping, and storage of an article, that there is no potential for specific toxic solvents to be present and that the material, if tested, will comply with established standards."

[7] All *A.E.Staley* written certified statements were on behalf of J. Michael Segraves, Product Manager*, A.E. Staley*, Decatur, IL

weight. (An acidulant is a food additive used to provide acidity and reduce pH.) In calcium supplements, malic acid controls the pH while adding a tart and fruity flavor. In calcium-fortified beverages, malic acid prevents turbidity resulting from precipitating calcium citrate. Malic acid enhances fruit flavors in hard and soft candies, gum, jams and preserves, and bakery products with fruit fillings. The *main* use of malic acid is pH adjustment. For bottled, shelved tea beverages the pH should be at 4.6 or below. Bottled teas are at a pH of around 7 without the addition of malic acid. Malic acid reduces the pH of those products that need to be bottled and shelved. Citric acid works as a modest acidulant with green teas, but malic acid is a better pH adjuster with black teas. Malic acid is more versatile for commercial tea production and storage.

Action:

Malic acid is used as a direct food additive to adjust pH. Malic acid is used to lower beverage pH while inhibiting bacteria growth. In tea production, malic acid is added after the brewing of the tea during the batching process to bottled tea products to achieve a pH of 4-5. A pH of 4.6 or below is desired for bottled tea products to stabilize food taste and microbial level of food products.

Combinations:

Typically, as you would expect, Citric acid will be used in citrus flavor product. Malic acid tends to be used in Berry, Cherry and apple flavored products. Fumaric acid will typically be found in grape, cranberry type flavors.

Blends of the acids are used to vary the perceived intensity of the acid taste. Citric acid tends to have a very tart taste that is quickly noticed, but will fade quickly. Malic acid tends to be a less intensely tart, but has a more lingering flavor profile. Blends of the two will create an intense lingering tartness giving a greater (perceived) sourness to your product.

"Acid blends contain roughly equal parts of tartaric, malic and citric acids. Acid blend is added to juice or wine to increase acidity. However, large quantities of citric acid are undesirable during fermentation. In addition, citric acid can give some wines an odd taste, so this material should be used with some caution. Acid blend is often used in non grape wines." [8]

Status

Historic Use by Organic Processors:

Bartek Ingredients Inc. began to produce malic acid for the organic industry in 1990.[9] Over 10 countries currently manufacture malic acid. Approximately twenty six percent of the total production is used for food and roughly fifty five percent is used in beverage products. About nineteen percent of manufactured malic acid is used in industry for

[8] "Wine Making Materials." Referenced from http://www.sdaws.org/material.htm
[9] Phone Interview. Daniel Sortwell, Bartek Ingredient, Inc., April 14, 2003.

industrial applications. These industrial applications may include use in coatings, polymers, and resins. [10]

OFPA, USDA Final Rule:

6510 HANDLING.

(a) **In General**. For a handling operation to be certified under this chapter, each person on such handling operation shall not, with respect to any agricultural product covered by this chapter

(1) Add any synthetic ingredient during the processing or any post harvest handling of the product;

DL-Malic is synthetically produced and is petitioned for use as a pH adjuster in the manufacturing of bottled tea products**.** [Malic acid is an acidulant in other foods, which could be organic.] NOSB standards dictate that malic acid must not be used for the sole purpose of a flavor, color, or texture enhancer or preservative.

Regulatory: EPA/NIEHS/Other Sources
FDA
The Food and Drug Administration has affirmed malic acid generally recognized as safe (GRAS), except for infant foods, if used in accordance with the levels and uses presented below for various products. [11]

Sec. 184.1069 Malic acid.
The ingredients are used as a flavor enhancer
Flavoring agent and adjuvant
pH control agent
3.4 percent for non-alcoholic beverages
3.0 percent for chewing gum
0.8 percent for gelatins, pudding, and fillings
6.9 percent for hard candy
2.6 percent for jams and jellies
3.5 percent for processed fruits and fruit juices
0.7 percent for all other food categories

EPA [051101 21]
Malic acid is listed on the EPA active chemical code report with no restrictions.

Malic acid is an EPA acceptable ingredient for label use. [12]

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[10] "Economic Aspects." *Concise Encyclopedia of Chemical Technology*. John Wiley & Sons, Inc. 4th Edition. New York, 1999. pp 1101.
[11]" Code of Federal Regulations, Title 21." U.S. Food and Drug Administration. Directly Referenced from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=184.1069
[12] "Active Chemical Code Report." *United States Environmental Protection Agency, Office of Pesticide Programs.* Referenced from http://www.epa.gov/opppmsd1/DataSubmittersList/dslchem.htm

Status Among U.S. Certifiers

OMRI- The April 21, 2002, OMRI Generic Materials List cites malic acid as "Prohibited under 205.105(c) and at 205.301(f)(4)."

Pennsylvania Certified Organic- approved use of malic acid by Honest Tea through 12/31/02 and during the petition process until 9/31/03.

Texas Department of Agriculture- TDA Materials list was not in compliance with new NOP final list of approved substances and is currently being amended to national standards. NOP standards are currently being used in the state of Texas. The NOP final rule does not list malic acid under sections 205.605 or 205.606 as an approved substance allowed in processing of "organic" products.

International

Europe
Synthetic malic acid is approved for use as an allowable material used in organic food processing in Annex VI, section A- No restrictions. EU 2092/91-Standards for Organic Food Production.

Canada
No restrictions on malic acid in Appendix D of the Permitted Substances List for Processing- National Standard of Canada Organic Agriculture- CAN/CGSB-32-310

Australia
The Organic Federation of Australia Inc. issued a Guide to the Use of the National Standard for Organic Produce. In Annex II, includes malic acid as a substance approved for post harvest/ storage treatments. Under this category, malic acid is permitted as a food additive. [13]

Japan
DL-Malic acid is not restricted for use as a food additive in Article 5, Food Additives Table 1 of the Japanese Agricultural Standard of Organic Agricultural Product Processed Foods.

Note- Japanese document was the only document to mention a specific form of malic acid. Other lists simply had malic acid generically listed except for Europe that specified malic acid as a synthetic additive.

[13] "Substances Permitted as Post Harvest/Storage Treatments." Organic Federation of Australia Inc. http://www.ofa.org.au/magus/ofa.nsf/subMenu/NT00000E76?OpenDocument#SEC10

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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.*** Malic acid is being considered as a processing material.

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.*** See processor criterion 3, below. Malic acid (both the L- and the DL-forms) is completely biodegradable.

3. ***The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*** This is considered under processor criterion 2 below.
4. ***The effects of the substance on human health.*** This is considered in the context of nutrition in processor criterion 3 below, as well as in consideration of the GRAS status of malic acid and residues in processor criterion 5 below.
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.*** In so far as malic acid is not released into the agroecosystem, there is no direct effect.
6. ***The alternatives to using the substance in terms of practices or other available materials.*** See discussion of alternatives under processor criterion 1, below.
7. ***Its compatibility with a system of sustainable agriculture.*** This is considered more specifically in the context of organic handling in processor criterion 6 below.

Processing materials - Criteria From the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if:

1. **It cannot be produced from a natural source and has no organic ingredients as substitutes.**

DL-malic acid is a synthetic material. L-malic acid is produced by the fermentation of fumaric acid. Fumaric acid, in turn, can be produced by fermentation from glucose. Although several U.S patents have issued in the past 30 years for the production of natural L-malic acid by fermentation, a natural source of L-malic acid is not commercially available at present.

Organic vinegar and lemon juice also are acidulants. Lactic acid and citric acid are non-synthetic acidulants already on the National List [§205.605(a)(1)]. Each of these has a different solubility and taste profile than malic acid.

2. **Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6510 of the OFPA.**

DL-Malic acid is commercially produced by the catalytic hydration of maleic anhydride or by the hydration of fumaric acid. [14] DL-Malic acid is made synthetically by catalytic oxidation of benzene to maleic acid, which is converted to malic acid by heating with steam under pressure. DL- malic acid is produced by the hydration of maleic anhydride (derived from butane), which is converted to maleic and then malic acid. DL-Malic acid also is made by the catalytic conversion of butane gas, water, and oxygen directly to DL- malic acid.

L-malic acid is produced by the fermentation of fumaric acid, but this production method does not appear to be commercial at this time. Fumaric acid can be produced by the fermentation from glucose or by chemical synthesis. L-Malic acid produced by fermentation of fumaric acid which is itself produced by fermentation from glucose would appear compatible with organic handling as described in the OFPA.

3. **If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.**

The Food and Drug Administration has affirmed malic acid as generally recognized as safe (GRAS), except for use in infant foods, when used in accordance with the levels and uses for various products. [21 CFR 184.1069] [15] The restriction on baby food relates to the slow rate of metabolism of the unnatural D-malic acid, which is half of DL-malic acid. Slowly metabolized D-malic acid can cause acidosis in infants. The upper limit of DL-malic acid is established based on the amount of D-lactic acid which may not be metabolized by mammals. Unmetabolized D-malic acid is excreted in the urine.

Acidulants reduce pH to levels where bacterial growth is inhibited, thus preventing spoilage and its associated ill effects on human health.

4. **Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.**

5. **Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.**

Sec. 184.1069 Malic acid (which allows both L-malic acid and DL-malic acid) The ingredients are used as a flavor enhancer, flavoring agent and adjuvant, and pH control agent. The ingredients are used in foods, except baby foods, at the following maximum levels:

3.4 percent for non-alcoholic beverages;
3.0 percent for chewing gum;
0.8 percent for gelatins, pudding, and fillings;
6.9 percent for hard candy;

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[14] "The Acid List." *Acid Basics.* Kuntz. May 1993. Referenced from http://www.foodproductdesign.com/archive/1993/0593DE.html

[15]" Code of Federal Regulations, Title 21." U.S. Food and Drug Administration. Directly Referenced from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=184.1069

2.6 percent for jams and jellies;
3.5 percent for processed fruits and fruit juices;
3.0% for soft candies; and
0.7 percent for all other food categories

The Food Chemicals Codex specifications for food grade malic acid are:

Assay Not less than 99.0% and not more than 100.5% of $C_4H_6O_5$.
Fumaric Acid Not more than 1.0%.
Lead Not more than 2 mg/kg.
Maleic Acid Not more than 0.05%.
Optical (Specific) Rotation : Between –0.10° and +0.10°.
Residue on Ignition Not more than 0.1%.
Water-Insoluble Matter Not more than 0.1%. [16]

6. **Its use is compatible with the principles of organic handling.**

A main principle of organic handling is to avoid compromising the organic integrity of the organic agricultural product you are starting with. That means not adding anything artificial or synthetic. It seems much more compatible with the principle of organic food handling to use a food acid produced by fermentation or a food acid judged nonsynthetic or a naturally sour food source such as vinegar or lemon juice, rather than one made by the catalytic conversion of butane.

7. **There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.**

Other acidulants yield different taste profiles. No data were provided documenting the different taste profiles in bottled tea at the indicated pH. However, the literature indicates that the taste profiles are different.

DL-malic acid reaches the environment through volatilization from plants. The photooxidation of hydrocarbons with hydroxylation will lead to the formation of malic acid in ambient air. In the atmosphere, malic acid will degrade because it has a half life of 2 days. Wet and dry decomposition can remove malic acid particulates from air. When decomposing, malic acid may give off toxic fumes including carbon monoxide and carbon dioxide [humans give off carbon monoxide and carbon dioxide too]. DL-malic acid will biodegrade if released to soil or water. High concentrations of DL-malic acid are not likely to be found in the environment because DL-malic acid will quickly degrade and decompose without harm to surrounding plants or various other inhabitants. [17] [D-Malic acid degrades much more slowly than L-malic acid.]

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[16] "Revised Monograph - Malic Acid." *Institute of Medicine Food and Nutrition Board Committee on Food Chemicals Codex.* Referenced from http://www.iom.edu/iom/iomhome.nsf/WFiles/Malic%20Acid/$file/Malic%20Acid.pdf

[17] "Environmental Fate and Exposure." *National Library of Medicine, Toxnet.* Referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA6jaOJj:1

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

DL-malic acid has a vapor pressure of 1.28 e-4 mm Hg at STP (Standard Temperature and Pressure, 25 deg C). Due to this fact, malic acid could simultaneously exist in the vapor and particulate stage in ambient air. Decomposition, both wet and dry, could remove particulate malic acid from air. Biological screening tests have indicated that once released to the soil, DL-malic acid will biodegrade quite rapidly without harming soil organisms. DL-malic acid will also biodegrade quickly once released to water supplies. Those processes including hydrolysis, aquatic volatilization, bioconcentration and absorption to sediment of malic acid are not important when considering environmental fate. [18]

The effects of the substance on human health.

Human Health Effects

Dl-malic acid is a skin and eye irritant. Occupational human exposure normally occurs through dermal contact and inhalation.

Clinical Effects:

SUMMARY OF EXPOSURE

ACUTE EXPOSURE

INGESTION - may produce mild to moderate oral and esophageal burns with more severe burns occurring in the stomach. Perforations occur rarely. Pyloric strictures may develop after moderate to severe burns, generally delayed 3 weeks after ingestion.

Initial signs and symptoms may not reliably predict the extent GI burns.

DERMAL - Severe burns may occur. Complications may include cellulitis, sepsis, contractures, osteomyelitis, and systemic toxicity.

INHALATION - may result in dyspnea, pleuritic chest pain, pulmonary edema, hypoxemia, bronchospasm, pneumonitis, tracheobronchitis and persistent pulmonary function abnormalities. Pulmonary dysfunction similar to asthma has been reported.

EYE - Irritation may develop. Splash contact may cause corneal erosions.

HEENT ACUTE EXPOSURE

Eye exposure may result in pain, swelling, corneal erosions and blindness.

CARDIOVASCULAR ACUTE EXPOSURE

Cardiovascular collapse may develop soon after severe poisonings.

RESPIRATORY ACUTE EXPOSURE

Inhalation may produce dyspnea, pleuritic chest pain, upper airway edema, pulmonary edema, hypoxemia, bronchospasm, pneumonitis, and persistent pulmonary function abnormalities. Airway hyperreactivity has also been reported.

The onset of respiratory symptoms may be delayed for several hours.

NEUROLOGIC ACUTE EXPOSURE

Abnormal neuropsychologic function has been reported following hydrochloric acid exposure from a leaking tanker truck.

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[18] "Environmental Fate." *National Library of Medicine, Toxnet.* Referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA6jaOJj:1

GASTROINTESTINAL ACUTE EXPOSURE
Ingestion of acids may result in burns, gastrointestinal bleeding, gastritis, perforations, dilation, edema, necrosis, vomiting, stenosis, fistula, and duodenal/jejunal injury.

HEPATIC ACUTE EXPOSURE
Systemic toxicity may result in acute hepatic injury. Hepatic injury has been reported following chronic exposure to chromic acid.

GENITOURINARY ACUTE EXPOSURE
Renal failure is a rare complication of severe poisonings. Hemoglobinuria may develop secondary to hemolysis. Nephritis may develop after hydrochloric acid ingestion.

ACID-BASE ACUTE EXPOSURE
Metabolic acidosis may develop following significant acid ingestion.

FLUID-ELECTROLYTE ACUTE EXPOSURE
Massive fluid and electrolyte shifts may occur with extensive dermal or gastrointestinal burns. Hyperkalemia may occur with hemolysis. Hyperphosphatemia, hypocalcemia and hyperchloremia have been reported.

HEMATOLOGIC ACUTE EXPOSURE
Hemolysis may occur following significant acid ingestion. Disseminated intravascular coagulation has been reported.

DERMATOLOGIC ACUTE EXPOSURE
Chemical burns to the skin are often associated with concurrent thermal burns and trauma. Complications seen with thermal burns including cellulitis, sepsis, contractures, osteomyelitis, may occur as well as systemic toxicity from absorbed acid. Deep or extensive burns may require grafting.
Alopecia was reported following application of an acidic formulation of a hair-relaxing product.

CHRONIC EXPOSURE
Prolonged or repeated exposure to chromic acid mist can result in dermatitis. Ulcerations may also occur. [19]

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.

DL-malic acid's atmospheric half-life is two days. Carboxylic acids are generally resistant to aqueous hydrolysis therefore malic acid does not generally hydrolyze in the environment. The half-life of DL-malic acid in water is about 940 days due to DL-malic acid's rate constant of 8.5e8 l-mol/sec. Malic acid's solubility of 592,000 mg/L (at 26 deg C) indicate that the bioconcentration of malic acid in aquatic organisms is not an environmental concern. DL-malic acid has a pH of 3.4 indicating that it will exist mainly in the iodized form when exposed to environmental media. DL-malic acid is essentially non-volatile from water due to the Henry's law constant of 8.4X10-13 atm-cu m/mole. Studies in Japan and Los Angeles show average environmental concentrations of malic

[19] "Malic Acid." *Human Health Effects.* National Library of Medicine, HSDB. Referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAAiTaWPe:1

acid as 23 ng/cu m and 14.3 ng/cu m. This is indicative of malic acid concentrations of both urban and suburban environments. L-malic acid naturally occurs in plants and fruits, including apples. Its presence is unlikely to cause adverse effects on soil organisms, crops or livestock. [20] Studies in Australia have found that some acid tolerant plants actually secrete malic acid, which is used in protecting their tips from toxic aluminum. "Soil acidification is a more serious problem than salinity, in terms of area affected and cost to the economy." Farming actually increases acidity levels in the soil because alkalinity levels are decreased. Soil acidification is actually a worse problem than soil salinity. Aluminum and manganese are the two main toxic elements that actually ruin crop production by infecting the soil. L-Malic acid is a normal constituent of plant cells that actually binds to toxic aluminum in the soil making it non-toxic. L-Malic acid is actually beneficial to maintaining a system of sustainable agriculture by riding soils of the effects of harmful toxins. [21]

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

Citric acid was shown to have the same effect on making toxic aluminum present in soil non-toxic and is a suitable alternative to using malic acid as a flavor enhancer and or pH adjuster. Citric acid is produced by sucrose fermentation technique using Aspergillus niger. Citric acid is recovered by precipitation, evaporation or crystallization. It is available in two forms: monohydrate or anhydrous (approximately 8.6% moisture. Citric acid is also available in solution form. The product obtained by fermentation is identical to naturally occurring acid. Fumaric Acid is derived from malic acid; a catalytic process adds a water molecule. In solid form it is a white crystalline, free-flowing powder. Fumaric acid is listed as GRAS. Fumaric is moderately hygroscopic, yet compared to the other organic acids it has poor solubility in water. (At 40°C, only 1.5 grams can dissolve in 100 grams of water.) The acid flavor in solution is much stronger and last longer than citric acid. Because of its low solubility at low temperatures, fumaric should be used in products with high temperatures, including hot beverages, gelatin or pudding mixes. Fumaric acids advantage is its intense flavor. Lactic Acid is chemically synthesized or produced by sucrose or lactose fermentation. Lactic acid is available in liquid form, in concentrations of 50 to 90%, unlike other acidulants. Lactic acid also exists in powder form. Tartaric acid is also an organic acid alternative to malic acid. Tartaric Acid can be manufactured synthetically or recovered from natural sources. Natural or L+ tartaric acid, used in the food industry, is insoluble tartrates called argols, found in wine. It is a white, crystalline powder with a strong fruit acid flavor, approximately 10% stronger than citric acid. It is highly soluble in water but slightly hydroscopic. The major use of tartaric acid is as a raw material for the production of DATEM emulsifiers (diacetyl tartaric acid esters of monoglycerides). Tartanic acid can be used for similar functions of citric acid.[22]

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[20] "Environmental Fate and Exposure." *National Library of Medicine, Toxnet.* Referenced from http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~AAA6jaOJj:1

[21] "Acid Soils, A Ticking Time Bomb?" *Commonwealth Scientific and Industrial Research Organization Fact Sheet.* Referenced from http://www.pi.csiro.au/Brochures/FactSheets/soilandland/acid.htm

[22] "The Acid List." *Food Product Design, Acid Basics.* Design Elements. Kuntz, 1993. Referenced from

Its compatibility with a system of sustainable agriculture.

DL-malic acid production generates small levels of solid, liquid and airborne waste. Airborne malic acid is primarily in particulate form. Solid waste is mainly nontoxic malic acid salts. Those malic acid solutions of concentrations of about 1% are readily biodegradable. [23]

Reveiwer 1 *[Ph.D Biochemistry, Adjunct Professor, Research and Consulting, Eastern US]*

1. Comments on Database

The Identification and Characterization sections are reasonably complete and fairly accurate.

The Status section does not address the question: has malic acid (DL- or L-) been used by organic processors in the past?
The OMRI citation ["Status Among U.S. Certifiers] is incorrect. The April 21, 2002, OMRI Generic Materials List cites malic acid as "Prohibited under 205.105(c) and at 205.301(f)(4)."

2. OFPA Criterion Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*

I agree with the criterion evaluation. However, I am not convinced that no commercial source of L-malic acid is available, given the several U.S. patents granted in the past for making L-malic acid and the desire of beverage manufacturers to have "all-natural" claims. L-malic acid can be commercially produced by fermentation from fumaric acid produced by fermentation of glucose. This makes some L-malic acid similar to citric acid and lactic acid, which have already been placed on the National List. Fermentation is a process accepted in the OFPA.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*

I agree with the criterion evaluation.

The chemical synthesis of DL-malic acid involves relatively simple "organic chemistry" with minimal risk of environmental contamination during its manufacture. The usage level is relatively low and the material is biodegradable. Nonetheless, the

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http://www.foodproductdesign.com/archive/1993/0593DE.html
[23] "Malic Acid." *Concise Encyclopedia of Chemical Technology*. John Wiley & Sons, Inc. 4th Edition. New York, 1999. pp 1100-1101.

manufacture of DL-malic acid via chemical synthesis is incompatible with organic handling [205.105(c); 205.301(f)(4)].

Fermentation of glucose to fumaric acid and then on to L-malic acid is a process compatible with organic handling as described in the Act. It also allows the eventuality of organically produced L-malic acid.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*

I agree with the criteria evaluation. The proviso that malic acid not be used in infant foods relates to the difficulty of metabolizing the unnatural D-malic acid that makes up 50% of DL-malic acid. Other food acids are completely metabolized in our bodies.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

No criterion evaluation is provided in this section. However, earlier provided information indicates that DL-malic acid is used for "intensifying the previously existing flavors" and "enhancing fruit flavors" in bottled tea and other beverages.

DL-Malic acid is used to reduce the pH of bottled tea from neutrality to a pH less than 4.6. At pH values less than 4.6, the pathogenic Clostridium botulinum bacteria cannot grow and produce botulin, the toxin that produces botulism. The reduction in pH allows the production of a shelf-stable product by the process of pasteurization rather than by the much more drastic process of sterilization.

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*

I agree with the criterion evaluation. However, the criterion evaluation needs to be amended to include the heavy metal tolerance listed in the Food Chemicals Codex monograph for malic acid.

6. *Its use is compatible with the principles of organic handling.*

I agree with the criterion evaluation. Adding synthetic DL-malic acid to organically produced food is inconsistent with §205.105(c) and §205.301(f)(4). Adding L-malic acid produced by fermentation of fumaric acid produced by fermentation of carbohydrate substrate would be consistent with the principles of organic handling (just like the use of citric acid, lactic acid, vinegar, and lemon juice would be).

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*

I agree with the criterion evaluation. There are insufficient data to support the petitioner's position that no other food acidulants and no blends of acidulants yield an acceptable product. No comparisons have been reported here.

3. Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

The OFPA permits the use of a synthetic substance in food processing when the "substance is necessary to the production and handling of the agricultural product because of unavailability of wholly natural substitute products." [7 USC 6517(c)(1)(A)(ii)]

In my opinion, DL-malic acid **[6915-15-7]** is a synthetic substance and L-malic acid [97-67-6] ***can be*** a non-synthetic ("wholly natural substitute") material. Based on searching the U.S. patent database and the internet for L-malic acid, I cannot conclude that there is "unavailability of wholly natural substitute products" for DL-malic acid. Moreover, it has not been established that acidulants already on the National List cannot substitute for DL-malic acid. No comparative data have been provided.

Accordingly, in my opinion, DL-malic acid should not be allowed for use in organic processing and handling. L-malic acid should be allowed if documented to be produced by "double fermentation" (glucose fermented to fumaric acid; fumaric acid fermented to L-malic acid).

4. Recommendation Advised to the NOSB:

*a. The substance DL-malic acid is s*ynthetic.
The substance L-malic acid can be non-synthetic.

b. The substance DL-malic acid should not be added to the National List of Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic".
The substance L-malic acid produced by "double fermentation" should be added to the National List of Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic" as a "nonsynthetic allowed."

c. Annotation Suggested, including justification:
The annotation currently in force for citric acid should be applied to L-malic acid: "produced by microbial fermentation of carbohydrate substrates", since other forms of malic acid are synthetic.

Reviewer 2 *[MS, Biochemistry, Forensic Drug Testing, Adjunct Instructor, Eastern US]*

1. Comments on Database

The Identification and Characterization sections are reasonably well summarized and accurate.

2. OFPA Criterion Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*

Malic Acid
April 2003

I agree with the criterion evaluation in part. However the statement that a natural source of L-malic acid is not commercially available seems questionable. An Internet search of L-malic acid revealed both domestic and foreign suppliers of L-malic acid in multi kg quantities. The method of production of the L-malic acid was not readily available but the conclusion that a natural source L-malic acid is not available commercially may be inaccurate or at least premature.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6510 of the OFPA.*

I agree with the criterion evaluation in part. The environmental risks associated with the synthesis of DL-malic acid are minimal and the material biodegrades quickly. Section 6510 of the OFPA prohibits the addition of any synthetic ingredient during the processing of the product and the use of DL-malic acid would be incompatible with organic handling unlike the use of L-malic acid that has been obtained from sugar fermentation by microorganisms.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*

I agree with the criterion evaluation. Food acids are readily metabolized. Several carboxylic acids are part of the metabolic processes in cells.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

No criterion evaluation was provided in this section. In the specific uses and action section of the application information was provided to indicate that DL-malic acid would be used primarily for pH adjustment of bottled teas but its benefit as a flavor enhancer and microbial level stabilizer was also extensively discussed.

5. Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.

I agree with the criterion evaluation

6. Its use is compatible with the principles of organic handling.

I agree with the criterion evaluation. The use of DL-malic acid produced synthetically is inconsistent with the provisions of OFPA Section 6510 Handling. This objection could be overcome by the use of L-malic produced by fermentation of carbohydrates or the use of approved sour food sources as the petitioner suggests.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*

I agree with the criterion evaluation. Different acidulants may produce different taste profiles but no data was presented to support this. Other food acidulants or blends of acidulants may be available to produce the results the petitioner is seeking but no comparisons have been presented in this application.

3. Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

DL-malic acid [6915-15-7] is in my opinion a synthetic compound and L-malic acid [97-67-6] produced by enzymatic fermentation of carbohydrates by microorganisms is non-synthetic. There appear to be numerous sources for L-malic acid and other acidulants on the National List may be an adequate replacement for DL-malic acid. The petitioner has not provided any comparative data to justify the inclusion of DL-malic acid as " necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; "(OFPA, Section 6517 National List).

Therefore, in my opinion, DL-malic acid should not be permitted for use in organic processing and handling.

4. Recommendation Advised to the NOSB:

The substance DL-malic acid is synthetic.

The substance DL-malic acid should not be added to the National List.

Reviewer 3 *[USDA Accredited Certifier, Mid-West, US]*

1. Comments on Database

Malic acid was petitioned to include its use in organic processing as a pH adjuster. Malic acid occurs naturally in fruits including apples and cherries. It is commercially produced by the catalytic hydration of maleic anhydride or by the hydration of fumaric acid. DL-malic acid is made synthetically by catalytic oxidation of benzene to maleic acid, which is converted to malic acid by heating with steam under pressure.

Historical use in organics in the US includes allowance by:

- OMRI- Organic Materials Review Institute (January 2001 Processing and Handling Materials OMRI Generic Materials list).
- Pennsylvania Certified Organic- approved use of malic acid by Honest Tea through 12/31/02 and during the petition process until 9/31/03.

Commentor's note: No certifier should be allowing synthetic Malic Acid at this time as it is not in compliance with CFR 205 or with OFPA.

2. OFPA Criterion Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*

DL-malic acid is a synthetic material. L-malic acid is produced by the fermentation of fumaric acid. Fumaric acid, in turn, can be produced by fermentation from glucose.

Organic vinegar and lemon juice also are acidulants. Lactic acid and citric acid are non-synthetic acidulants already on the National List [§205.605(a)(1)].
Fumaric acid can be produced by the fermentation from glucose or by chemical synthesis. L-Malic acid produced by fermentation of fumaric acid which is itself produced by fermentation from glucose would appear compatible with organic handling as described in the OFPA.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6510 of the OFPA.

DL-Malic acid is commercially produced by the catalytic hydration of maleic anhydride or by the hydration of fumaric acid. DL-Malic acid is made synthetically by catalytic oxidation of benzene to maleic acid, which is converted to malic acid by heating with steam under pressure. DL- malic acid is produced by the hydration of maleic anhydride (derived from butane), which is converted to maleic and then malic acid. DL-Malic acid also is made by the catalytic conversion of butane gas, water, and oxygen directly to DL- malic acid.

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.

Yes, there possible negative effects of Malic Acid on human health.

3. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

Malic Acid
April 2003

The *main* use of synthetic malic acid is pH adjustment. Citric acid works as a modest acidulant with green teas, but malic acid is a better pH adjuster with black teas. Malic acid is more versatile for commercial tea production and storage. Malic acid is used as a direct food additive to adjust pH. Malic acid is used to lower beverage pH while inhibiting bacteria growth.

4. Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.

Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.

Its purpose is to adjust ph, and although the petition is not for improving taste, this seems to be the main reason it is preferred over other acids.

5. Its use is compatible with the principles of organic handling.

A main principle of organic handling is to avoid compromising the organic integrity of the organic agricultural product you are starting with. That means not adding anything artificial or synthetic. It seems much more compatible with the principle of organic food handling to use a food acid produced by fermentation or a food acid judged nonsynthetic or a naturally sour food source such as vinegar or lemon juice, rather than one made by the catalytic conversion of butane.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
There are alternatives to malic acid for this application.

3. Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

Under 2218 (c) of OFPA:

(c) GUIDELINES FOR PROHIBITIONS OR EXEMPTIONS. (1) EXEMPTION FOR PROHIBITED SUBSTANCES. The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if:
(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

Malic acid is not necessary to the handling of this product, and there are natural substitutes.

And:(iii) is used in handling and is non-synthetic but is not organically

produced;

Malic Acid is synthetic.

Malic acid does not meet the criteria set forth in OFPA for placement of a synthetic on the National List.

4. Recommendation Advised to the NOSB:

The substance DL-malic acid is synthetic.

The substance DL-malic acid should not be added to the National List.