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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MIKAL JEFFERSON, individually, and on behalf of all others similarly situated,

Plaintiff,

v.

KRAFT HEINZ FOODS COMPANY, LLC,

Defendant.

Case No. 24-cv-2278

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiff Mikal Jefferson ("Plaintiff") on behalf of herself, all others similarly situated, and the general public, by and through her undersigned counsel, hereby brings this action against Kraft Heinz Foods Company, LLC ("Defendant" or "Kraft"), and upon information and belief and investigation of counsel, alleges as follows:

2. This is a California consumer class action for violations of the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* ("CLRA"), Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* ("UCL"), and for breach of express warranty.

3. Defendant manufactures, distributes, advertises, markets, and sells Capri-Sun beverage products. The packaging prominently displays on the front of the label the claim that these Products[1] are made with "**All Natural Ingredients.**"

4. This statement is false. Each of the Products are made with manufactured citric acid— an artificial ingredient used in food and beverage products.

5. Defendant's packaging, labeling, and advertising scheme is intended to give consumers the impression that they are buying a premium product that contains only natural ingredients.

6. Plaintiff, who purchased the Products in California, was deceived by Defendant's unlawful conduct and brings this action on her own behalf and on behalf of California consumers to remedy Defendant's unlawful acts.

JURISDICTION AND VENUE

7. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100

[1] "Products" means all Capri-Sun products labeled as containing "All Natural Ingredients" that include citric acid as an ingredient.

members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed $5,000,000 in the aggregate, exclusive of interest and costs.

8. This Court has personal jurisdiction over Defendant because Defendant conducts and transacts business in the State of California, contracts to supply goods within the State of California, and supplies goods within the State of California. Defendant, on its own and through its agents, is responsible for the distribution, marketing, labeling, and sale of the Products in California, specifically in this judicial district. The marketing of the Products, including the decision of what to include and not include on the labels, emanates from Defendant. Thus, Defendant has intentionally availed itself of the markets within California through its advertising, marketing, and sale of the Products to consumers in California, including Plaintiff. The Court also has specific jurisdiction over Defendant as it has purposefully directed activities towards the forum state, Plaintiff's claims arise out of those activities, and it is reasonable for Defendant to defend this lawsuit because it has sold deceptively advertised Products to Plaintiff and members of the Class in California. By distributing and selling the Products in California, Defendant has intentionally and expressly aimed conduct at California which caused harm to Plaintiff and the Class that Defendant knows is likely to be suffered by Californians.

9. Venue is proper pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this District. Plaintiff purchased the Products within this District.

PARTIES

10. Defendant Kraft Heinz Foods Company, LLC is a Pennsylvania corporation that maintains its principal place of business in Pittsburg, Pennsylvania. At all times during the class period, Defendant was the manufacturer, distributor, marketer, and seller of the Products.

11. Plaintiff Mikal Jefferson is a resident of San Bernadino County, California. Plaintiff purchased the Products during the class period in California. Plaintiff relied on Defendant's deceptive advertising and labeling claims as set forth below.

FACTUAL ALLEGATIONS

"ALL NATURAL INGREDIENTS" IS PROMINENTLY DISPLAYED ON THE LABELS OF THE PRODUCTS

12. The front labels for each of the Products prominently state that the Products are made with "All Natural Ingredients" thereby misleading reasonable consumers into believing that the Products are free from artificial ingredients. However, each of the Products contain an artificial ingredient called manufactured citric acid. Below is an example of a label for one of the Products:


ALL NATURAL INGREDIENTS
NO HIGH FRUCTOSE CORN SYRUP
NO ARTIFICIAL COLORS, FLAVORS OR PRESERVATIVES
Serving size 1 Pouch (177mL)
Amount per serving
Calories 50
% Daily Value*
Total Fat 0g 0%
Sodium 15mg 1%
Total Carbohydrate 12g 4%
Total Sugars 11g
Includes 8g Added Sugars 16%
Protein 0g
Not a significant source of saturated fat, trans fat, cholesterol, dietary fiber, vitamin D, calcium, iron and potassium.
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.
INGREDIENTS: FILTERED WATER; SUGAR; PEAR, GRAPE AND ORANGE JUICE CONCENTRATES; CITRIC ACID; MONK FRUIT CONCENTRATE; APPLE AND PINEAPPLE JUICE CONCENTRATES; NATURAL FLAVOR; MUSHROOM EXTRACT (TO PROTECT QUALITY).
KRAFT HEINZ FOODS COMPANY, CHICAGO, IL 60601
CAPRI-SUN® AND THE POUCH SHAPE™ ARE LICENSED TRADEMARKS OF THE CAPRI SUN GROUP.
DO NOT DRINK IF POUCH IS LEAKING, DAMAGED, OR SWOLLEN AS FERMENTATION CAN OCCUR.
Contact us at: 1-800-227-7478
PLEASE REFER TO CODE NUMBERS ON SIDE PANEL OR ON POUCH WHEN CONTACTING US.
Patents: www.kraftheinz.com/patents

THE MANUFACTURED CITRIC ACID IN THE PRODUCTS IS ARTIFICIAL

13. Defendant uses artificial manufactured citric acid in the Products.[2] Commercial food manufactures, including Defendant, use a synthetic form of citric acid that is derived from heavy chemical processing.[3] Commercially produced citric acid is manufactured using a type of black mold called *Aspergillus niger* which is modified to increase citric acid production.[4] Consumption of manufactured citric acid has been associated with adverse health events like joint pain with swelling and stiffness, muscular and stomach pain, as well as shortness of breath.[5] Defendant does not use natural citric acid extracted from fruit in the Products. This is because "[a]proximately 99% of the world's production of [citric acid] is carried out using the fungus *Aspergillus niger* since 1919."[6] As explained by a study published in the *Toxicology Reports Journal*:

> Citric acid naturally exists in fruits and vegetables. However, **it is *not* the naturally occurring citric acid, but the manufactured citric acid (MCA) that is used extensively as a food and beverage additive**. Approximately 99% of the world's production of MCA is carried out using the fungus *Aspergillus niger* since 1919. *Aspergilus niger* is a known allergen.[7]

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[2] Iliana E. Sweis, et al., *Potential role of the common food additive manufactured citric acid in eliciting significant inflammatory reactions contributing to serious disease states: A series of four case reports*, TOXICOL REP. 5:808-812 (2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/ and attached as **Exhibit A**.

[3] A. Hesham, Y. Mostafa & L. Al-Sharqi, *Optimization of Citric Acid Production by Immobilized Cells of Novel Yeast Isolates*, 48 MYCOBIOLOGY 122, 123 (2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7178817/

[4] *Id*; Pau Loke Show, et al., *Overview of citric acid production from Aspergillus niger*, FRONTIERS IN LIFE SCIENCE, 8:3, 271-283 (2015), available at https://www.tandfonline.com/doi/full/10.1080/21553769.2015.1033653

[5] Sweis, *et al.*, **Exhibit A**.

[6] *Id*.

[7] *Id*.

14. A technical evaluation report for citric acid, compiled by the United States Department of Agriculture Marketing Servies ("USDA AMS") further explains that it is not commercially feasible to use natural citric acid extracted from fruits:

> "Traditionally by extraction from citrus juice, [is] no longer commercially available. It is now extracted by fermentation of a carbohydrate substance (often molasses) by citric acid bacteria, *Aspergillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid."[8]

15. As one of the USDA AMS reviewers commented:

> "[Citric acid] is a natural[ly] occurring substance that commercially goes through numerous chemical processes to get to [its] final usable form. This processing would suggest that it be ***classified as synthetic***."[9]

16. When asked "Is this substance Natural of Synthetic?" USDA AMS reviewers state: "synthetic."[10]

17. Manufactured citric acid contains residues of synthetic chemicals. The *Toxicology Reports Journal* article explains that "the potential presence of impurities or fragments from the *Aspergillus niger* in [manufactured citric acid] is a significant difference that may trigger deleterious effects when ingested."[11] The article further explains:

> Given the thermotolerance of A. niger, there is great potential that byproducts of A. niger remain in the final [manufactured citric acid] product. Furthermore, given the pro-inflammatory nature of A. niger even when heat-killed, repetitive ingestion of [manufactured citric acid]

[8] **Exhibit B** at page 6.

[9] **Exhibit B** at page 5 (emphasis added)

[10] **Exhibit B** at pages 4-5.

[11] Sweis, *et al.*, **Exhibit A**.

> may trigger sensitivity or allergic reactions in susceptible individuals. Over the last two decades, there has been a significant rise in the incidence of food allergies.[12]

18. The Food and Drug Administration ("FDA") explains that the "Solvent extraction process for citric acid" is accomplished via "recovery of citric acid from conventional *Aspergillus niger* fermentation liquor may be safely used to produce food-grade citric acid in accordance with the following conditions: (a) The solvent used in the process consists of a mixture of n- octyl alcohol meeting the requirements of § 172.864 of this chapter, ***synthetic*** isoparaffinic petroleum hydrocarbons meeting the requirements of § 172.882 of this chapter, and tridodecyl amine. 12 C.F.R. § 173.280 (emphasis added). Chemical solvents such as n-octyl alcohol and synthetic isoparaffinic petroleum hydrocarbons are used to extract the citric acid that Defendant uses in the Products from *aspergillus niger* fermentation liquor. See 21 C.F.R § 173.280. The citric acid that Defendant uses in the Products is produced through chemical solvent extraction and contains residues of those chemical solvents.

19. The FDA has determined that manufactured citric acid is not natural; it is artificial. The FDA has sent warning letters to companies stating that certain products labeled as "natural" are misbranded because they contain citric acid as an ingredient. For example, on August 29, 2001, the FDA sent Hirzel Canning Company ("Hirzel") a warning letter regarding its canned tomato products.[13] With respect to Hirzel's Chopped Tomatoes Onions & Garlic and Chopped Mexican Tomatoes & Jalapenos, the FDA stated that these products could not bear the "All Natural" claim on the label because the products contained a synthetic ingredient, citric acid.[14]

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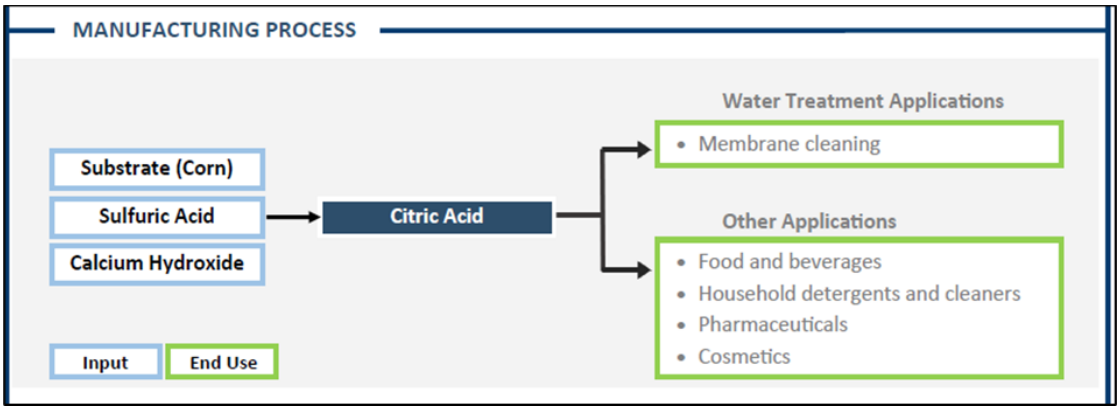
[12] *Id.*

[13] *See* **Exhibit C** attached hereto.

[14] *Id.*

20. Similarly, on August 16, 2001, the FDA sent Oak Tree Dairy Farm, Inc. ("Oak Tree") a warning letter regarding its "Oaktree Real Brewed Iced Tea," "Oaktree Fruit Punch," and "Oaktree All Natural Lemonade" products.[15] With respect to Oak Tree's "Oaktree Real Brewed Iced Tea," the FDA stated that this product could not bear the "100% Natural" and "All Natural" claims on the label because the product contained a synthetic ingredient, citric acid.[16]

21. The Environmental Protection Agency ("EPA") provides the following simple schematic of the manufacturing process for citric acid which includes the use of synthetic solvents like sulfuric acid:[17]



22. Dr. Ryan Monahan, a prominent functional medicine practitioner, notes that the "[p]resent day process of creating manufactured citric acid involves feeding sugars derived from GMO corn to black mold, which then ferments to form manufactured citric acid."[18] Dr. Monahan also notes that "*Aspergillus niger* is associated with systemic inflammatory issues, including respiratory,

[15] *See* **Exhibit D** attached hereto.

[16] *Id.*

[17] *See* **Exhibit E** attached hereto.

[18] Dr. Ryan Monahan, *Citric Acid: A Common Food Additive With An Uncommon Source* (2024) *available at* https://www.peacefulmountainmedicine.com/post/citric-acid-a-common-food-additive-with-an-uncommon-source

gastrointestinal, neurological and musculoskeletal. Due to the potential for fragments of *Aspergillus niger* to make their way into the finished product of manufactured citric acid, this toxic inflammatory substance is likely being ingested by consumers of products containing citric acid. Even with high-heat processing to kill it, research has shown *Aspergillus niger* can still elicit an inflammatory response."[19]

23. Clinical Nutritionist Serge Gregoire, notes that [f]ood manufacturers leave out that citric acid is derived from genetically modified black mold grown on GMO corn syrup" and that "[c]ompanies continuously capitalize on an ignorance-based market."[20] Gregoire states, "Citric acid production has become a refined and highly prized industrial process." Gregoire note that the Aspergillus niger used to produce citric acid is engineered to increase production of citric acid which has "resulted in countless generations of genetically modified mutant variants, now specialized for industrial-scale economics."[21]

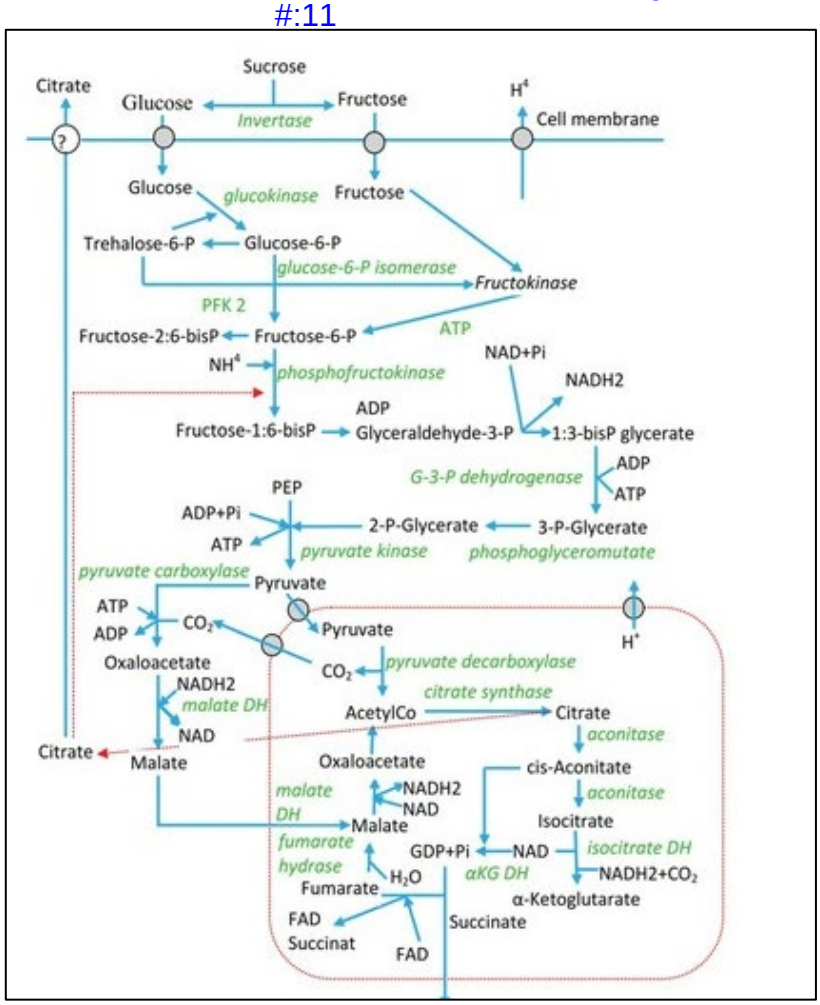
24. Below is a schematic representation of the metabolic reactions involved in citric acid production, the enzymes (italics), the known feedback loops (dashed lines) and their locations within the cellular structure of *Aspergillus niger*:[22]

[19] *Id.*

[20] Serge Gregoire, Avoid citric acid: a mold byproduct! (July 13, 2021) *available at* https://www.linkedin.com/pulse/avoid-citric-acid-mold-byproduct-serge-gregoire/

[21] *Id.*

[22] Show, P. L., Oladele, K. O., Siew, Q. Y., Aziz Zakry, F. A., Lan, J. C. W., & Ling, T. C. (2015). *Overview of citric acid production from Aspergillus niger*. FRONTIERS IN LIFE SCIENCE, 8(3), 271–283, *available at* https://doi.org/10.1080/21553769.2015.1033653



25. Dictionary definitions define "artificial" as something made by man. For example, "artificial" is defined as "made by human skill; produced by humans …"[23] Merriam-Webster's online dictionary states that "artificial" means "humanly contrived …"[24] Cambridge Dictionary states that "artificial" means "made by people, often as a copy of something natural."[25]

[23] *Artificial*, DICTIONARY.COM, *available at* https://www.dictionary.com/browse/artificial

[24] *Artificial*, MERRIAM-WEBSTER'S DICTIONARY, *available at* https://www.merriam-webster.com/dictionary/artificial

[25] *Artificial*, CAMBRIDGE DICTIONARY, *available at* https://dictionary.cambridge.org/us/dictionary/english/artificial

26. Below are images of the chemical process used to create manufactured citric acid for use in food and beverage products – a process that is visibly artificial:

REASONABLE CONSUMERS ARE DECEIVED BY DEFENDANT'S FALSE LABELING STATEMENT AND SUFFERED ECONOMIC INJURY

27. Consumers, like Plaintiff, relied on Defendant's "All Natural Ingredients" labeling statement. The "All Natural Ingredients" statement on the labels of the Products is material to reasonable consumers. "[F]oods bearing 'free-from' claims are increasingly relevant to Americans, as they perceive the products as closely tied to health … 84 percent of American consumers buy free-from foods because they are seeking out more natural or less processed foods. In fact, 43 percent of consumers agree that free-from foods are healthier than foods without a free-from claim, while another three in five believe the fewer ingredients a product has, the healthier it is (59 percent). Among the top claims free-from consumers deem most important are trans-fat-free (78 percent) and preservative-free (71 percent)."[26]

28. Plaintiff and the putative class members suffered economic injury as a result of Defendant's actions. Plaintiff and putative class members spent money that, absent Defendant's actions, they would not have spent. Plaintiff and putative class members are entitled to damages and restitution for the purchase price of the Products that were falsely labeled and advertised. Consumers, including Plaintiff, would not have purchased Defendant's Products, or would have paid less for the Products, if they had known the Products actually contain an artificial preservative ingredient.

PLAINTIFF'S PURCHASE OF THE PRODUCTS

29. Plaintiff Mikal Jefferson has purchased several flavors of the Products, including variety packs of the Products. Plaintiff's last purchase of the Products was in approximately October of 2024. Plaintiff has purchased the Products from retail stores located in San Bernardino County California, including

[26] *84% of Americans buy "free-from" foods because they believe them to be more natural or less processed*, Mintel (Sept. 3, 2015), *available at* https://www.mintel.com/press-centre/84-of-americans-buy-free-from-foods-because-they-believe-them-to-be-more-natural-or-less-processed/

Walmart stores. Plaintiff saw and relied on the "All Natural Ingredients" claim on the labels of the Products. Plaintiff would not have purchased the Products, or would have paid less for the Products, had she known that the products actually contain an artificial ingredient. As a result, Plaintiff suffered injury in fact when she spent money to purchase the Products she would not have purchased, or would have paid less for, absent Defendant's misconduct. Plaintiff desires to purchase the Products again if the labels of the products were accurate and if the products actually contained "All Natural Ingredients." However, as a result of Defendant's ongoing misrepresentations, Plaintiff is unable to rely on the Products' advertising and labeling when deciding in the future whether to purchase the Products.

NO ADEQUATE REMEDY AT LAW

30. Plaintiff and members of the class are entitled to equitable relief as no adequate remedy at law exists. The statutes of limitations for the causes of action pled herein vary. Class members who purchased the Products more than three years prior to the filing of the complaint will be barred from recovery if equitable relief were not permitted under the UCL.

31. The scope of actionable misconduct under the unfair prong of the UCL is broader than the other causes of action asserted herein. It includes Defendant's overall unfair marketing scheme to promote and brand the Products, across a multitude of media platforms, including the product labels, packaging, and online advertisements, over a long period of time, in order to gain an unfair advantage over competitor products. Plaintiff and class members may also be entitled to restitution under the UCL, while not entitled to damages under other causes of action asserted herein (e.g., the CLRA is limited to certain types of plaintiffs (an individual who seeks or acquires, by purchase or lease, any goods or services for personal, family, or household purposes) and other statutorily enumerated conduct).

32. A primary litigation objective in this litigation is to obtain injunctive relief. Injunctive relief is appropriate on behalf of Plaintiff and members of the

class because Defendant continues to misrepresent the Products as containing "All Natural Ingredients" when the Products actually contain an artificial ingredient. Injunctive relief is necessary to prevent Defendant from continuing to engage in the unfair, fraudulent, and/or unlawful conduct described herein and to prevent future harm—none of which can be achieved through available legal remedies (such as monetary damages to compensate past harm). Injunctive relief, in the form of affirmative disclosures or halting the sale of unlawful sold products is necessary to dispel the public misperception about the Products that has resulted from years of Defendant's unfair, fraudulent, and unlawful marketing efforts. Such disclosures would include, but are not limited to, publicly disseminated statements stating that the Products actually contain an artificial ingredient. An injunction requiring affirmative disclosures to dispel the public's misperception, and prevent the ongoing deception and repeat purchases, is also not available through a legal remedy (such as monetary damages). In addition, Plaintiff is currently unable to accurately quantify the damages caused by Defendant's future harm, because discovery and Plaintiff's investigation has not yet completed, rendering injunctive relief necessary. Further, because a public injunction is available under the UCL, and damages will not adequately benefit the general public in a manner equivalent to an injunction.

33. It is premature to determine whether an adequate remedy at law exists. This is an initial pleading and discovery has not yet commenced and/or is at its initial stages. No class has been certified yet. No expert discovery has commenced and/or completed. The completion of fact/non-expert and expert discovery, as well as the certification of this case as a class action, are necessary to finalize and determine the adequacy and availability of all remedies, including legal and equitable, for Plaintiff's individual claims and any certified class or subclass. Plaintiff therefore reserves her right to amend this complaint and/or assert additional facts that demonstrate this Court's jurisdiction to order equitable remedies where no adequate legal remedies are available for either Plaintiff and/or

any certified class or subclass. Such proof, to the extent necessary, will be presented prior to the trial of any equitable claims for relief and/or the entry of an order granting equitable relief.

CLASS ACTION ALLEGATIONS

34. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of the following Class:

> All persons who purchased the Products for personal use in California within the applicable statute of limitations until the date class notice is disseminated.

35. Excluded from the class are: (i) Defendant and its officers, directors, and employees; (ii) any person who files a valid and timely request for exclusion; (iii) judicial officers and their immediate family members and associated court staff assigned to the case; (iv) individuals who received a full refund of the Products from Defendant.

36. Plaintiff reserves the right to amend or otherwise alter the class definition presented to the Court at the appropriate time, or to propose or eliminate subclasses, in response to facts learned through discovery, legal arguments advanced by Defendant, or otherwise.

37. The Class is appropriate for certification because Plaintiff can prove the elements of the claims on a classwide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

38. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiff believes that there are thousands of consumers who are Class Members described above who have been damaged by Defendant's deceptive and misleading practices.

39. Commonality: There is a well-defined community of interest in the common questions of law and fact affecting all Class Members. The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

a. Whether Defendant is responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Products;

b. Whether Defendant's misconduct set forth in this Complaint demonstrates that Defendant engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of the Products;

c. Whether Defendant made misrepresentations concerning the Products that were likely to deceive the public;

d. Whether Plaintiff and the Class are entitled to injunctive relief;

e. Whether Plaintiff and the Class are entitled to money damages and/or restitution under the same causes of action as the other Class Members.

40. Typicality: Plaintiff is a member of the Class that Plaintiff seeks to represent. Plaintiff's claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased the Products. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

41. Adequacy: Plaintiff is an adequate Class representative because Plaintiff's interests do not conflict with the interests of the Class Members Plaintiff seeks to represent; the consumer fraud claims are common to all other members of the Class, and Plaintiff has a strong interest in vindicating the rights of the class; Plaintiff has retained counsel competent and experienced in complex class action litigation and Plaintiff intends to vigorously prosecute this action. Plaintiff has no interests which conflict with those of the Class. The Class Members' interests will be fairly and adequately protected by Plaintiff and proposed Class Counsel. Defendant has acted in a manner generally applicable to the Class, making relief appropriate with respect to Plaintiff and the Class Members. The prosecution of separate actions by individual Class Members would create a risk of inconsistent and varying adjudications.

42. The Class is properly brought and should be maintained as a class action because a class action is superior to traditional litigation of this controversy.

A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

a. The joinder of hundreds of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b. The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claim, thereby making it impracticable, unduly burdensome, and expensive to justify individual actions;

c. When Defendant's liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of Class claims;

e. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action;

f. This class action will assure uniformity of decisions among Class Members;

g. The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation; and

h. Class Members' interests in individually controlling the prosecution of separate actions is outweighed by their interest in efficient resolution by single class action;

43. Additionally or in the alternative, the Class also may be certified because Defendant has acted or refused to act on grounds generally applicable to the Class thereby making final declaratory and/or injunctive relief with respect to the members of the Class as a whole, appropriate.

44. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the Class, on grounds generally applicable to the Class, to enjoin and prevent Defendant from engaging in the acts described, and to require Defendant to provide full restitution to Plaintiff and the Class members.

45. Unless the Class is certified, Defendant will retain monies that were taken from Plaintiff and Class members as a result of Defendant's wrongful conduct. Unless a classwide injunction is issued, Defendant will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled.

FIRST CLAIM FOR RELIEF

Violation of California's Consumers Legal Remedies Act

Cal. Civ. Code § 1750 *et seq.*

46. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.

47. Plaintiff brings this claim under the CLRA individually and on behalf of the Class against Defendant.

48. At all times relevant hereto, Plaintiff and the members of the Class were "consumer[s]," as defined in California Civil Code section 1761(d).

49. At all relevant times, Defendant was a "person," as defined in California Civil Code section 1761(c).

50. At all relevant times, the Products manufactured, marketed, advertised, and sold by Defendant constituted "goods," as defined in California Civil Code section 1761(a).

51. The purchases of the Products by Plaintiff and the members of the Class were and are "transactions" within the meaning of California Civil Code section 1761(e).

52. Defendant disseminated, or caused to be disseminated, through its advertising, false and misleading representations, including the Products' labeling that the Products contain "All Natural Ingredients." Defendant failed to disclose

that the Products contain an artificial ingredient called citric acid. This is a material misrepresentation and omission as reasonable consumer would find the fact that the Products contain an artificial ingredient to be important to their decision in purchasing the Products. Defendant's representations violate the CLRA in the following ways:

a) Defendant represented that the Products have characteristics, ingredients, uses, and benefits which they do not have (Cal. Civ. Code § 1770(a)(5));

b) Defendant represented that the Products are of a particular standard, quality, or grade, which they are not (Cal. Civ. Code § 1770(a)(7));

c) Defendant advertised the Products with an intent not to sell the Products as advertised (Cal. Civ. Code § 1770(a)(9)); and

d) Defendant represented that the subject of a transaction has been supplied in accordance with a previous representation when it has not (Cal. Civ. Code § 1770(a)(16)).

53. Defendant violated the CLRA because the Products were prominently advertised as containing "All Natural Ingredients," but, in reality, the Products contain an artificial ingredient called citric acid. Defendant knew or should have known that consumers would want to know that the Products contain an artificial ingredient.

54. Defendant's actions as described herein were done with conscious disregard of Plaintiff's and the Class members' rights and were wanton and malicious.

55. Defendant's wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA, since Defendant is still representing that the Products have characteristics which they do not have.

56. Pursuant to California Civil Code section 1782(d), Plaintiff and the members of the Class seek an order enjoining Defendant from engaging in the methods, acts, and practices alleged herein.

57. Pursuant to California Civil Code section 1782, Plaintiff notified Defendant in writing by certified mail of the alleged violations of the CLRA and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of their intent to so act. If Defendant does not take corrective action within 30 days of receipt of Plaintiff's letter, then Plaintiff will amend her complaint to seek actual damages and punitive damages.

58. Pursuant to section 1780(d) of the CLRA, attached hereto is an affidavit showing that this action was commenced in a proper forum.

SECOND CLAIM FOR RELIEF

Violation of California's Unfair Competition Law

Cal. Bus. & Prof. Code § 17200 *et seq.*

59. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.

60. Plaintiff brings this claim under the UCL individually and on behalf of the Class against Defendant.

61. The UCL prohibits any "unlawful," "fraudulent," or "unfair" business act or practice and any false or misleading advertising.

62. Defendant committed unlawful business acts or practices by making the representations and omitted material facts (which constitutes advertising within the meaning of California Business & Professions Code section 17200), as set forth more fully herein, and by violating California's Consumers Legal Remedies Act, Cal. Civ. Code §§17500, *et seq.*, California's False Advertising Law, Cal. Bus. & Prof. § 17500, *et seq.*, 15 U.S.C. § 45, and by breaching express and implied warranties. Plaintiff, individually and on behalf of the other Class members, reserves the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

63. Defendant committed "unfair" business acts or practices by: (1) engaging in conduct where the utility of such conduct is outweighed by the harm to Plaintiff and the members of the a Class; (2) engaging in conduct that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Plaintiff and the members of the Class; and (3) engaging in conduct that undermines or violates the intent of the consumer protection laws alleged herein. There is no societal benefit from deceptive advertising. Plaintiff and the other Class members paid for a Product that is not as advertised by Defendant. Further, Defendant failed to disclose a material fact (that the Products contain an artificial preservative) of which they had exclusive knowledge. While Plaintiff and the other Class members were harmed, Defendant was unjustly enriched by its false misrepresentations and material omissions. As a result, Defendant's conduct is "unfair," as it offended an established public policy. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

64. Defendant committed "fraudulent" business acts or practices by making the representations of material fact regarding the Products set forth herein. Defendant's business practices as alleged are "fraudulent" under the UCL because they are likely to deceive customers into believing the Products actually contain no preservatives.

65. Plaintiff and the other members of the Class have in fact been deceived as a result of their reliance on Defendant's material representations and omissions. This reliance has caused harm to Plaintiff and the other members of the Class, each of whom purchased Defendant's Products. Plaintiff and the other Class members have suffered injury in fact and lost money as a result of purchasing the Products and Defendant's unlawful, unfair, and fraudulent practices.

66. Defendant's wrongful business practices and violations of the UCL are ongoing.

67. Plaintiff and the Class seek pre-judgment interest as a direct and proximate result of Defendant's unfair and fraudulent business conduct. The amount on which interest is to be calculated is a sum certain and capable of calculation, and Plaintiff and the Class seek interest in an amount according to proof.

68. Unless restrained and enjoined, Defendant will continue to engage in the above-described conduct. Accordingly, injunctive relief is appropriate. Pursuant to California Business & Professions Code section 17203, Plaintiff, individually and on behalf of the Class, seeks (1) restitution from Defendant of all money obtained from Plaintiff and the other Class members as a result of unfair competition; (2) an injunction prohibiting Defendant from continuing such practices in the State of California that do not comply with California law; and (3) all other relief this Court deems appropriate, consistent with California Business & Professions Code section 17203.

THIRD CLAIM FOR RELIEF

Breach of Express Warranty

69. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.

70. Plaintiff brings this claim for breach of express warranty individually and on behalf of the Class against Defendant.

71. As the manufacturer, marketer, distributor, and seller of the Products, Defendant issued an express warranty by representing to consumers at the point of purchase that the Products contain "All Natural Ingredients.

72. "Plaintiff and the Class reasonably relied on Defendant's misrepresentations, descriptions and specifications regarding the Products, including the representation that the Products contain "All Natural Ingredients."

73. Defendant's representations were part of the description of the goods and the bargain upon which the goods were offered for sale and purchased by Plaintiff and Members of the Class.

74. In fact, the Products do not conform to Defendant's representations because the Products contain an artificial ingredient called citric acid. By falsely representing the Products in this way, Defendant breached express warranties.

75. Plaintiff relied on Defendant's (the manufacturer) representations on the Products' labels and advertising materials which provide the basis for an express warranty under California law.

76. As a direct and proximate result of Defendant's breach, Plaintiff and Members of the Class were injured because they: (1) paid money for the Products that were not what Defendant represented; (2) were deprived of the benefit of the bargain because the Products they purchased were different than Defendant advertised; and (3) were deprived of the benefit of the bargain because the Products they purchased had less value than if Defendant's representations about the characteristics of the Products were truthful. Had Defendant not breached the express warranty by making the false representations alleged herein, Plaintiff and Class Members would not have purchased the Products or would not have paid as much as they did for them.

REQUEST FOR RELIEF

Plaintiff, individually, and on behalf of all others similarly situated, request for relief pursuant to each claim set forth in this complaint, as follows:

a. Declaring that this action is a proper class action, certifying the Class as requested herein, designating Plaintiff as the Class Representative and appointing the undersigned counsel as Class Counsel;

b. Ordering restitution and disgorgement of all profits and unjust enrichment that Defendant obtained from Plaintiff and the Class members as a result of Defendant's unlawful, unfair, and fraudulent business practices;

c. Ordering injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices as set forth herein, and ordering Defendant to engage in a corrective advertising campaign;

d. Ordering damages in amount which is different than that calculated for restitution for Plaintiff and the Class;

e. Ordering Defendant to pay attorneys' fees and litigation costs to Plaintiff and the other members of the Class;

f. Ordering Defendant to pay both pre- and post-judgment interest on any amounts awarded; and

g. Ordering such other and further relief as may be just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all claims in this Complaint so triable.

Dated: October 25, 2024

CROSNER LEGAL, P.C.

By: */s/ Michael T. Houchin*
MICHAEL T. HOUCHIN

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Attorneys for Plaintiff and the Proposed Class

Affidavit Pursuant to Civil Code Section 1780(d)

I, MICHAEL T. HOUCHIN, declare as follows:

1. I am an attorney duly licensed to practice before all of the courts of the State of California. I am one of the counsel of record for Plaintiff.

2. This declaration is made pursuant to § 1780(d) of the California Consumers Legal Remedies Act.

3. Defendant has done, and is doing, business in California, including in this judicial district. Such business includes the marketing, promotion, distribution, and sale of the Products within the State of California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed October 25, 2024 at San Diego, California.

CROSNER LEGAL, P.C.

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EXHIBIT A

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Potential role of the common food additive manufactured citric acid in eliciting significant inflammatory reactions contributing to serious disease states: A series of four case reports

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A B S T R A C T

Citric acid naturally exists in fruits and vegetables. However, it is not the naturally occurring citric acid, but the manufactured citric acid (MCA) that is used extensively as a food and beverage additive. Approximately 99% of the world's production of MCA is carried out using the fungus *Aspergillus niger* since 1919. *Aspergilus niger* is a known allergen. The FDA placed MCA under the category of GRAS without any research to substantiate this claim. In 2016, 2.3 million tons of MCA were produced, predominantly in China, and approximately 70% is used as a food or beverage additive. There have been no scientific studies performed to evaluate the safety of MCA when ingested in substantial amounts and with chronic exposure. We present four case reports of patients with a history of significant and repetitive inflammatory reactions including respiratory symptoms, joint pain, irritable bowel symptoms, muscular pain and enervation following ingestion of foods, beverages or vitamins containing MCA. We believe that ingestion of the MCA may lead to a harmful inflammatory cascade which manifests differently in different individuals based on their genetic predisposition and susceptibility, and that the use of MCA as an additive in consumable products warrants further studies to document its safety.

1. Introduction

Citric acid is a weak organic mono-constituent substance with the molecular formula $C_6H_8O_7$ and REACH designated IUPAC name 2-hydroxypropane1,2,3-tricarboxylic acid (Fig. 1). Citric acid is listed as an ingredient in a significant percentage of prepared foods, beverages, and medications. The average consumer is under the impression that the added citric acid listed in the ingredients of prepared foods, beverages and vitamins is derived from natural sources such as lemons and limes. However, the ingredient list is quite misleading since the added citric acid is not procured through natural sources. More accurate terminology would list this substance as *manufactured citric acid*.

Manufactured citric acid (MCA) is a ubiquitous substance and one of the most common food additives in the world. Approximately 99% of the world production of MCA is through microbial processes using predominantly a mutant strain of the black mold *Aspergillus niger* [1]. This method has been the industry standard for production of MCA since 1919, long before the FDA's involvement in evaluating food additives. When the FDA adopted the Food Additives Amendment in 1958, Congress excluded from the definition of Food Additive the common food ingredients in use before 1958, including MCA. Although the FDA has studied many food additives to ensure that they are within acceptable safety parameters, certain additives were granted GRAS (generally recognized as safe) status by the FDA due to lack of demonstrated harm over a history of prior use [2,3]. Thus, MCA was considered GRAS and did not undergo any FDA evaluation. MCA is one of the most common additives used today, with applications ranging from food to non-food industries. It is estimated that 70% is used in foods and beverages, 20% in the pharmaceutical and cosmetic industry, and 10% in cleaning detergents and softening agents [1]. In foods and beverages, it is used as a flavoring, a preservative, an acidulant, and to provide pH control. The growth of the processed foods industry, pharmaceuticals, and cosmetics is currently the driving force behind the rapid growth of the citric acid market globally.

Historically, citric acid was first isolated by William Scheele in England in 1784 from lemon juice imported from Italy [2]. Subsequently, Italy controlled the industrial production of citric acid from lemon juice and commanded a high price for the next 100 years, with peak production in 1915–1916 at 17,500 tons, after which it started to decline due to cost.[2] This led to attempts all over the world to find alternatives to its production with chemical and microbial techniques, including commercial production by sugar fermentation [2]. Citric acid was first manufactured using the fermentation process in 1919 in Belgium using Cytromices mold (now known as Penicillium), but this method was abandoned due to contamination and duration of fermentation [2]. In 1917, American food chemist James Currie had begun experimenting with a process of making citric acid from mold. Currie discovered that strains of Aspergillus niger provided high yields of citric

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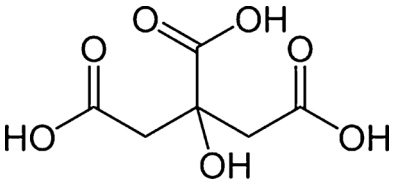

Fig. 1. REACH registration dossier 15,451 EC Number: 201-069-1 CAS Number: 77-92-9, 5949-29-1 IUPAC Name: 2-hydroxypropane-1,2,3-tricarboxylic acid Molecular Formula: $C_6H_8O_7$.
https://echa.europa.eu/registration-dossier/-/registered-dossier/15,451.

acid through a fermentation process using low cost molasses as the raw material [4]. This system was very cost effective and rapidly adopted. Pfizer started to produce citric acid from *Aspergillus niger* in 1919, and this method is still used today across the world, particularly in China.

The molecular formula of the natural citric acid obtained from lemons and limes and that of MCA is the same, $C_6H_8O_7$. However, the potential presence of impurities or fragments from the *Aspergillus niger* in MCA is a significant difference that may trigger deleterious effects when ingested. We have done several literature searches and have been unable to find any research evaluating the safety of long term or repetitive exposure to MCA, which has become ubiquitous in processed and pre-prepared foods, carbonated beverages, energy drinks, fruit drinks, nutritional supplements, pediatric and adult vitamins, confectioneries, processed dairy, common snacks, pharmaceuticals, cosmetics, detergents and cleansers. In certain common energy beverages, it is the second leading ingredient following water. We provide evidence with four case reports that ingestion of foods, beverages or supplements containing MCA may lead to increased inflammation, which in susceptible individuals affects the respiratory, gastrointestinal, neurological and musculoskeletal systems. Although MCA is an unnatural substance and is produced from *Aspergillus niger*, there has been a paucity of research to ascertain its safety with repetitive exposure over time. To our knowledge, this is the first scientific report revealing the potential inflammatory reactions related to ingestion of MCA.

2. Clinical findings

We have four case reports of individuals who demonstrate symptoms including: joint pain with swelling and stiffness, muscular pain, dyspnea, abdominal cramping and enervation that typically begin within 2–12 h of ingesting foods, beverages or vitamins containing MCA. Depending on the degree of symptoms, they resolve over a period of 8–72 h following ingestion. None of the four individuals in these case reports develop such symptoms when ingesting natural forms of citric acid such as in lemons and limes.

Table 1 lists 12 of the common foods and beverages that when consumed by these four individuals would consistently elicit the reported symptoms. It also lists the major ingredients found in these items, and the only ingredient found in all 12 items is MCA. The second most common ingredient is sugar, and none of the four subjects had any sensitivity to sugar. With the exception of the last item, all of the foods and beverages listed were consumed by all of the individuals described in the first three cases. Since manufacturers are not required to specify the exact amounts of listed ingredients, we cannot provide quantitative information regarding the amount of MCA ingested. However, in the United States product ingredients are listed in order of decreasing amounts. Although we cannot measure the exact amounts of MCA the subjects were exposed to, we know that the dose is higher in a diet soda drink where MCA is listed as the third leading ingredient after water and orange juice, and lower in ranch flavored potato chips where MCA is listed as the 18th of 25 ingredients. Subjects in the first three cases reacted to both the lower and higher doses of MCA. In the forth case, the exposure was only to an effervescent vitamin, which was a consistent dose. None of the subjects in any of the four cases initially knew that they were being exposed to MCA, nor that it might be problematic. It was later identified after their symptoms occurred and the foods and/or beverages consumed were examined. The exposures which resulted in the subjects' responses were typically limited to one food product or beverage per episode.

3. Case report 1

Case 1 is a 52 year-old Caucasian woman with a history of post-surgical hypothyroidism well-controlled with Synthroid and Cytomel, who is otherwise healthy. She reports developing severe diffuse joint and muscle pain in the upper and lower extremities with associated joint swelling, abdominal bloating with cramping and feeling enervated within 6–12 h of ingesting foods that contain MCA. Her symptoms began in her late 30's. Unaware of the etiology of her symptoms, she sought consultations with rheumatologists, immunologists and allergists, none of whom found an explanation. Over a five year period, she underwent extensive work-ups for auto-immune disease, rheumatoid arthritis, vitamin deficiencies, as well as adrenal and thyroid imbalance, all of which were negative. Due to the debilitating nature of her symptoms, she attempted to eliminate certain foods from her diet such as gluten, dairy, and yeast. However, her symptoms were minimally altered. After years of trial and error, she noted that her symptoms followed ingesting certain pre-prepared foods, the commonality being presence of citric acid in the listed ingredients.

By age 47, she began avoiding all foods with MCA and noted a remarkable absence of her symptoms. Subsequently, when she would feel the symptoms reported above after consuming pre-prepared foods or beverages, she would check the listed ingredients and always find that at least one of the foods consumed within the previous 12 h contained MCA. The extent of her joint pain, abdominal discomfort and enervation was directly correlated with the amount of MCA ingested at a given time. If she consumed a meal in which a food item contained MCA and consumed a drink in which MCA was one of the leading ingredients, her

Table 1
Identified Foods and Beverages.

Foods/Beverages	MCA	Sugar	Salt	Sodium Bicarbonate	Phenylalanine	Caffeine	Whey	Artificial Sweetener	Artificial Color
Diet Soda Drink	X				X	X		X	X
Energy Drink (Diet)	X			X	X	X		X	X
Energy Drink (Regular)	X	X		X		X			X
Energy Snack Bar	X	X		X					
Grape Leaves (preserved)	X								
Hummus (pre-prepared)	X		X						
Instant Oatmeal	X	X	X				X		X
Jelly Beans	X	X							X
Potato Chips (Ranch Flavor)	X	X	X				X		
Tonic Water	X	X							
Tortilla Chip	X		X						
Vitamin C (Effervescent)	X	X		X					

symptoms were worse and lasted longer than if she consumed a single food item in which MCA was listed as a more minor ingredient. Even pre-prepared organic foods that were free of all additives except MCA would elicit her symptoms.

4. Case report 2

Case 2 is a 68 year-old very healthy Caucasian male with allergic asthma previously treated with Prednisone, and adult onset Addison's Disease due to prolonged Prednisone exposure. He reports developing a triad of symptoms including dyspnea, significant enervation, and stiffness with edema of his prosthetic knee within 12 h of ingesting pre-prepared foods or beverages with citric acid listed in the ingredients. His symptoms resolve over a 36-48-hour period. At 68 years of age, he has a very active life style including a demanding career, significant travel and a healthy exercise routine. At 36 years of age, he developed ABPA (Allergic Bronchopulmonary Aspergillosis), which resolved leaving only a small area of fibrosis in his right upper pulmonary lobe. This is typically of no consequence, even with participation in heavy sports. He underwent a successful total left knee replacement at 67 years of age.

His symptoms related to ingesting foods or beverages containing MCA involve his relatively compromised systems including his lungs and his healing prosthetic knee, in addition to an overall sense of enervation. He describes that his enervation is not sleepiness, but enervation similar to that reported by persons with chronic fatigue syndrome. He eats an organic vegan diet and eliminates foods with preservatives in effort to improve his overall health. He notes that inadvertently ingesting pre-prepared foods with any amount of MCA results in recurrence of his symptoms, the severity of which is correlated with the amount of consumed foods or beverages containing MCA. During the week when he initially discovered the MCA correlation with his symptom, he had been consuming two very common energy beverages. He recalls experiencing greater swelling around his prosthetic knee and feeling quite depleted, not more energized. The more he consumed of the energy drinks, the worse he felt. Upon checking the labels, he found that the two energy beverages listed MCA as the second leading ingredient after water. Similar to the patient in Case 1, he notes that ingesting pre-prepared organic foods that are free of all additives except MCA also elicits his triad of symptoms.

5. Case report 3

Case 3 is a 75 year-old Caucasian woman with a history of atrial fibrillation, hypothyroidism, and Restless Leg Syndrome (RLS). She is on Digoxin and Xeralto for the atrial fibrillation, and is euthyroid on Synthroid. Her RLS is well-controlled on Mirapex. At 73 years of age, she reported a long-standing history of severe diffuse upper and lower extremity joint and muscle pain with associated swelling. Similar to the patient in Case 1, she underwent an extensive work-up for auto-immune disease, rheumatoid arthritis, vitamin deficiencies, and serum metal levels, all of which were negative. Due to the severity of her symptoms and lack of effective medical intervention, she began a long process of food elimination. This consisted of continuing a healthy vegetarian diet but eliminating all processed and pre-prepared foods. While preparing her foods from fresh organic ingredients, her symptoms improved to an almost negligible level.

Over time, as she began incorporating very few pre-prepared foods back into her diet, she began developing her symptoms of diffuse severe joint and muscle pain and swelling. The pre-prepared foods in her diet consisted of freshly prepared organic items with a minimal number of additives. Through a process of slowly eliminating various pre-prepared foods, she was able to identify the offending foods as those with citric acid listed in the ingredients. Her symptoms would begin within 6 h of exposure and resolve within 72 h of exposure. Also similar to Case 1, when she would feel the symptoms reported above after consuming pre-prepared foods or beverages, she would check the listed ingredients and always find that at least one of the foods consumed within the previous 6–12 h contained MCA. Similar to the patients in Case 1 and in Case 2, the severity of her symptoms after ingesting foods containing MCA directly correlated with the amount consumed.

6. Case report 4

Case 4 is a 43 year-old Indian woman without any past medical history, except for undergoing *in-vitro* fertilization at 39 years of age resulting in a successful full-term pregnancy. She does not take any medications and has no allergies. She is a very health-conscious vegetarian, consuming only a raw diet and prepares all of her food from fresh ingredients at home. From 41 through 42 years of age, she began ingesting an effervescent form of Vitamin C (ascorbic acid) tablets on a regular (not daily) basis. She developed severe enervation and mental fatigue during that two year period. Her medical work-up for these symptoms was negative. Her symptoms limited her ability to perform her daily professional tasks as a physician. Unlike the other three cases, her symptoms would develop within two hours after drinking the effervescent Vitamin C, and resolve within 8–12 h. Since she did not consume any other medications or supplements, she was able to determine that her symptoms were limited to the days when she consumed the effervescent Vitamin C, and decided to discontinue the supplement. Her symptoms of enervation and mental fatigue resolved shortly after the discontinuation. Weeks later, she elected to try a different brand of Vitamin C pills. The only difference between the two formulations was the absence of MCA in the pill form as compared to the effervescent form. She did not experience any symptoms of mental fatigue or enervation with the new form of Vitamin C pills that did not contain MCA. She could not provide any information regarding MCA in foods since she consumed a raw diet and did not consume pre-prepared foods that would potentially contain additives.

7. Discussion

Aspergillus was first described and named in 1729 by the Italian priest and biologist, Pier Antonio Micheli. He studied the fungus under the microscope and noted that it had the shape of an aspergillum (holy water sprinkler) and named the genus accordingly.[5] *Aspergillus niger* is an asexual saprophytic fungus thatis very thermotolerant and can thrive in freezing conditions and very hot weather [5]. It produces its spores on an asexual structure called the conidium. The *Aspergillus* genus includes several hundred fungal species [6], of which 16 are known to be harmful to humans, causing allergies, infections and diseases. The three most common species known to affect humans are the *A. fumigatus, A. flavus*, and *A. niger* [7]. Because aspergillosis is not a reportable infection in the United States, the exact number of cases is difficult to determine. Milder, allergic forms of aspergillosis are thought to be more common than the invasive form of the infection [7]. Furthermore, the incubation period for aspergillosis is unclear and seemingly varies depending on the load of Aspergillus and the individual's immune response [7].

Aspergillus niger is one of the most abundant species of *Aspergillus* in nature as it can grow on a large variety of substances, even in environments with very little nutrients available [7], Although *Aspergillus niger* is not as deadly as other *Aspergillus* species, it can cause sickness and allergic reactions. *Aspergillus niger* is considered very harmful to those with a weak immune system or those who have a sensitive allergy to fungi. Most people can handle the inhalation of a moderate amount of *Aspergillus niger* spores. Those who suffer from leukemia, AIDS, immunosuppression (transplant patients), severe fungal allergies and other immune deficiencies could become very sick from the intake of the spores [7]. Allergic reactions can be severe in individuals who are very allergic to fungi.

When inhaled, *A. niger* can cause hypersensitivity reactions such as

asthma and allergic alveolitis. It has been a significant cause of asthma in certain parts of the world such as Iran [8]. It has also been the cause of otomycosis [9], cutaneous infections [10], pneumonia [11], and invasive pulmonary aspergillosis [12]. The ability of *A. niger* to elicit an inflammatory response is not limited to the live spores. *A. niger* that is killed at 68 °C for 4 h to ensure destruction of the spores has been shown to elicit an immune response with measurable quantities of the pro-inflammatory cytokine IL-6 [13]. Therefore, remnant fragments of *A. niger* that is killed could still elicit inflammatory responses.

Aspergillus niger contains several toxins, some harmless and others harmful to certain people. The main toxins it contains are ochratoxin A (OTA) and malformin C. OTA is a known carcinogenic mycotoxin with nephrotoxic and immunotoxic potential in animals [14]. Individuals are at risk of exposure to OTA if they ingest food contaminated with it such as wine, beer, coffee, dried vine fruit, pork, poultry, dairy, spices, and cacao [14]. Toxicity from OTA is considered serious enough that it is among the 20 mycotoxins monitored in food [15,16]. Animals exposed to OTA develop DNA adducts, which are covalent modifications of the DNA. This is believed to interfere with the DNA repair system and cell cycle control and may serve as the initiating point of carcinogenesis [14].

Despite its contribution to pathogenesis, *A. niger* is widely used in the food industry for the production of citric acid and gluconic acid, and many enzymes such as a-amylase, amyloglucosidase, cellulases, lactase, invertase, pectinases, and acid proteases [5]. Over the past several decades, there have been significant genetic modifications of *A. niger* to increase MCA production and decrease production of unwanted by-products resulting in genetically modified mutant variants of this mold. The two main types of modification include gamma radiation-induced mutagenesis of *A. niger* to increase its fermentation activity and genetic modification in the laboratory to enhance the pathway to increase production of MCA and decrease in other non-MCA producing pathways [17]. Nearly all MCA begins with highly processed glucose from corn syrup derived from corn, and less so from beet sugar, cane molasses, and fruit waste [18].

Although Brazil and India produce MCA, China is the largest single participant in MCA production. China accounted for 59% of the world's production and 74% of the world's exports of MCA in 2015 [19]. By 2015, Asia was the largest consumer of MCA, accounting for 28% of world consumption, followed closely by North America accounting at 23% and Western Europe accounting at 22% of world consumption, while China accounted for 12% of the world consumption. Due to new biotechnological production units mostly located in China, the global supply of MCA in the last two decades rose to 2.3 million tons in 2016 becoming the single largest chemical obtained via biomass fermentation and the most widely used organic acid [20]. It is expected that China will not only remain the largest producer of MCA during 2015–2020, but that Chinese manufacturers will expand to establish manufacturing plants in other countries to secure more of the MCA global market [19]. The global citric acid market production has been growing at a rate of 3.5% during 2009–2016, and is expected to be at 2.7 million tons by 2022 [21]. According to Credence Research, the global MCA market is projected to reach USD 3.66 Billion by 2022 [22].

Given the thermotolerance of *A. niger*, there is great potential that byproducts of *A. niger* remain in the final MCA product. Furthermore, given the pro-inflammatory nature of *A. niger* even when heat-killed [13], repetitive ingestion of MCA may trigger sensitivity or allergic reactions in susceptible individuals. Over the last two decades, there has been a significant rise in the incidence of food allergies. Among children aged 0–17 years, the prevalence of food allergies increased from 3.4% in 1997–1999 to 5.1% in 2009–2011 [23,24]. The significant rise in the global use of MCA in foods and the rise in the incidence of food allergies pose concern over a possible potential relationship. Given the increase in the use of MCA and the increase in the incidence of allergies, it is conceivable that MCA production contaminants are eliciting a low grade inflammatory response which results in chronic low grade allergies. Recent studies have revealed that the incidences of allergic and autoimmune diseases have been increasing in parallel, making them a serious health-care burden [25]. Food allergies and sensitivities have been documented to occur with greater frequency in conditions such as asthma, Autism Spectrum Disorder (ASD), Juvenile Idiopathic Arthritis (JIA) and Fibromyalgia (FM) [26,27]. Numerous research studies have identified elevation in certain pro-inflammatory cytokines such as IL-1B, IL-6, IL-8, and TNF-a as a significant and common thread of the inflammatory process in asthma [28–31], ASD [32–35], JIA [36–38], and FM [39–41].

8. Conclusion

We recognize the limitations of the level of evidence from our four case reports. We cannot conclusively affirm that MCA is the causative factor in the subjects' inflammatory symptoms. However, our findings demonstrate a significant likelihood that MCA may be the culprit and are suggestive of valid concerns which warrant proper double blind studies to determine presence or absence of harm.

We hypothesize that since MCA is a product of *Aspergillus niger*, there are contaminants from the production process that remain in the final product. We hypothesize that there are proteins or other by-products of the *A. niger* or substances from the manufacturing process which remain in MCA after its production process and these lead to an inflammatory process, and possibly unlike natural citric acid, MCA is highly inflammatory itself. We further hypothesize that when we consume foods with MCA, we are consuming the proteins or by-products of the *A. niger* or the highly concentrated unnatural form of citric acid, and with repeat exposure over time we are either developing elevation in pro-inflammatory cytokines such as IL-6 or building antibodies against the *A. niger* proteins that lead to inflammatory symptoms, or the MCA itself may contain yet unidentified substances or by- products from the production process that are inflammatory to our body.

Given the ubiquitous presence of MCA and repetitive exposure to it through ingesting common foods and beverages, we may be re-introducing small amounts of *A. niger* proteins or byproducts into our bodies, and repeatedly eliciting an insidious low grade immune response. With the repetitive exposure and insult, the immune system maintains a low grade inflammatory response. Over time, the chronic inflammatory state can impact various systems in the body depending on the individual's weaker or compromised organ system. Ingestion of the MCA leads to an inflammatory cascade which manifests differently in different individuals based on their genetic predisposition, susceptibility and underling medical history, as well as the degree of stress exerted by environmental factors. We further hypothesize that these inflammatory reactions may play a causative role in allergic asthma, FM, JIA, and possibly CFS, and lead to increased inflammation in the musculoskeletal system leading to idiopathic joint and muscle inflammation/pain and inflammation in the gastro-intestinal system leading to conditions such as irritable bowel syndrome.

Unlike naturally occurring citric acid, manufactured citric acid is ubiquitous in the average diet of both adults and children. With the expected continued increase in its production to meet the demand of an expanding global market, it is imperative to ascertain its safety. Due to its GRAS status, manufactured citric acid has escaped proper scrutiny for nearly a century. Since it is not a natural substance but created using *Aspergillus niger*, a black mold proven to cause allergic reactions and disease in humans, it is difficult to understand how it has been protected under GRAS classification and has not been empirically studied. It only seems prudent that a thorough investigation of the manufactured form of citric acid be undertaken. With an unexplained increase in inflammatory diseases, it is difficult to justify its ubiquitous use without proper investigation. Additional research is mandatory to evaluate the potential of MCA to cause inflammatory symptoms in the body, or to contain *Aspergillus* proteins or by-products from the manufacturing process which may be inflammatory with repetitive exposure.

We conclude that there is enough anecdotal data to support the need for thorough evaluation of the safety and risks associated with the ubiquitous use of the currently manufactured citric acid in our foods, beverages and other ingested substances, and to ensure that the final product is highly purified, non-inflammatory and void of pro-inflammatory contaminants.

Conflict of interest

No competing interests nor conflict of interest

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EXHIBIT B

NON 5
SYN 5
allowed

NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: Citric Acid

CATEGORY: Synthetic Allowed **Complete?:** 3/16

✓ **NOSB Database Form**

✓ **References**

✓ **MSDS (or equivalent)**

✓ **FASP (FDA)**

✓ **Date file mailed out:** 1/8/95

✓ **TAP Reviews from:** Steve Taylor
Steven Harper
Bob Durst

Supplemental Information:

Microbial form only ...
because of substrate might be
a product

MISSING INFORMATION: _____

NOSB/NATIONAL LIST COMMENT FORM/BALLOT

Use this page to write down comments and questions regarding the data presented in the file of this National List material. Also record your planned opinion/vote to save time at the meeting on the National List.

Name of Material Citric Acid

Type of Use: ____ **Crops;** ____ **Livestock;** ✓ **Processing**

TAP Review by:

1. Steve Taylor
2. Steven Harper
3. Bob Durst

Comments/Questions:

My Opinion/Vote is:

Signature _____ **Date** _____

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steve Taylor

Is this substance Natural or Synthetic? Explain (if appropriate)

Natural

Please comment on the accuracy of the information in the file:

This material should be added to the National List as:

____ **Synthetic Allowed** ____ **Prohibited Natural**

or, ____ **This material does not belong on the National List because:**

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

Made by fermentation. Fermentation is natural but process does ~~story~~ involve use of other substances: substrates: corn syrup, sucrose ammonium bicarbonate

Any additional comments or references?

Need to find out more about process and processing aids to make determination.

Signature Steve Taylor **Date** 3-5-95

2.

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steven Harper

Is this substance Natural or Synthetic? Explain (if appropriate)

Synthetic

Please comment on the accuracy of the information in the file:

Good

This material should be added to the National List as:

__x__ **Synthetic Allowed** ____ **Prohibited Natural**

or, ____ **This material does not belong on the National List because:**

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

No.

Any additional comments or references?

Signature Steven Harper **Date** 3/10/95

3.

USDA/TAP Reviewer Comment Form

Material: Citric acid

Reviewer: Bob Durst

Is this substance Natural or Synthetic? Explain (if appropriate)

It is a natural occurring substance that commercially goes through numerous chemical processes to get to it's final usable form. This processing would suggest that it be classified as synthetic.

Please comment on the accuracy of the information in the file:

The file is accurate.

This material should be added to the National List as:

__X__ Synthetic Allowed,

_____ Prohibited Natural, or

_____ This material does not belong on the National List because:

Are there any restriction or limitations that should be placed on this material by use or application on the National List?

Must be listed on the ingredient label if it used used.

Unless it is actually derived from a natural source the labeling must not indicate that it is a natural compound.

Any additional comments or references?

As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.

Since citrus juices are a high natural source of citric acid, it might be advisable to find a manufacturer that is willing to isolate citric acid from organically grown fruit in an organically acceptable manner, and get a natural citric acid.

Signature Robert W. Durst Date 3/4/95

NOSB Materials Database

4.

Identification

Common Name	**Citric Acid**	**Chemical Name**	B-hydroxy-tricarboxylic acid C6H8O7
Other Names	Citric Acid, Anhydrous USP/FCC		
Code #: CAS	77-92-9	**Code #: Other**	21 CFR 182-1033
N. L. Category	Synthetic Allowed	**MSDS**	◉ yes ○ no

Chemistry

Family	Aliphatic Acid
Composition	$C_6H_8O_7$
Properties	Colorless, translucent crystals, (or) white granular to fine crystalline powder, odorless, strong acid taste.
How Made	Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substrate (often molasses) by citric acid bacteria, *Aspergillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid.

Use/Action

Type of Use	Processing
Specific Use(s)	Production of fruit products, juices, oils, fats etc. for pH control, flavor enhancer, flavoring agent or adjuvant, leavening agent, sequestrant, antioxidant, solvent, antimicrogial agent, surface-active agent.
Action	Optimizes stability of frozen foods by enhancing the action of antioxidants and inactivating enzymes. Brings out flavor in carbonated beverages. Acts as a synergist for antioxidants employed in inhibiting rancidity in foods containg fats and oils.
Combinations	pure substance

Status

OFPA	
N. L. Restriction	Currently considered synthetic by NOSB.
EPA, FDA, etc	FDA -GRAS
Directions	
Safety Guidelines	Eye irritant, dust may cause mild respiratory irritation.
State Differences	
Historical status	Always been allowed in organic processing and considered natural.
International status	Allowed by IFOAM, EU and Codex.

NOSB Materials Database

5.

OFPA Criteria

2119(m)1: chemical interactions Not Applicable

2119(m)2: toxicity & persistence Not Applicable

2119(m)3: manufacture & disposal consequences

Microbial fermentation --Clarification --Precipitation --Dissolution --Crystallization --Drying --Sifting --packaging. The NOSB judged that citric acid produced by natural fermentation of carbohydrate substrates and purified by the lime-sulfuric method is synthetic because the citric acid comes into contact with lime and sulfuric acid and because of the chemical change from citric acid to calcium citrate and then back to citric acid during purification.

Biomass residuals are usually recycled as animal feeds and for agriculture.

2119(m)4: effect on human health

Material has been affirmed as GRAS by FDA for use in foods. The amount of citrate added to foods by food processors is about 500 mg per person per day. This amount occurs naturally in 2 ounces of orange juice and does not constitute a significant addition to the total body load.

Long term oral over exposure may cause damage to tooth enamel. Considered an irritatant to eyes and respiratory system during manufacture and handling. Recommended use of eye and respiratory protection during handling. Oral LD50 (rat) 11,700 mg/kg; dermal (acute) tested on skin of rabbit 500mg/24 hr moderate; eye 750 mg/24hr severe. FDA tests show no effect on reproduction, teratogenicity or oncogenicity in rats.

2119(m)5: agroecosystem biology Not Applicable

2119(m)6: alternatives to substance

Lactic acid (has some taste problems and not used in infant foods).
Vinegar (strange taste in some foods).
Citrus juices.

2119(m)7: Is it compatible?

Compatible

References

1. FDA. 1977. Evaluation of the health aspects of citric acid, sodium citrate, potassium citrate, calcium citrate, ammonium citrate, triethyl citrate, isopropyl citrate, and stearyl citrate as food ingredients. SCOGS-84. Life Science Research Office, 9650 Rockville Pike, Bethesda, Maryland 20014.

2. Ag Partners of Davis, *Materials Report for Citric Acid*, 1995. Organic Trade Association, Greenfield, MA

6.

MSDS for CITRIC ACID, MONOHYDRATE Page 1

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1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CITRIC ACID, MONOHYDRATE
FORMULA: HOC(COOH)(CH2COOH)2 H2O FORMULA WT: 210.14
CAS NO.: 5949-29-1
COMMON SYNONYMS: 2-HYDROXY-1,2,3,PROPANE-TRICARBOXYLIC ACID, MONOHYDRATE
PRODUCT CODES: 0118,0120,0119,0110
EFFECTIVE: 12/01/86 REVISION #02

PRECAUTIONARY LABELLING
BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 0 NONE
FLAMMABILITY - 1 SLIGHT
REACTIVITY - 0 NONE
CONTACT - 1 SLIGHT
HAZARD RATINGS ARE 0 TO 4 (0 = NO HAZARD; 4 = EXTREME HAZARD).
LABORATORY PROTECTIVE EQUIPMENT: SAFETY GLASSES; LAB COAT

PRECAUTIONARY LABEL STATEMENTS
CAUTION
MAY CAUSE IRRITATION
DURING USE AVOID CONTACT WITH EYES, SKIN, CLOTHING. WASH THOROUGHLY AFTER HANDLING. WHEN NOT IN USE KEEP IN TIGHTLY CLOSED CONTAINER.
SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

---

2 - HAZARDOUS COMPONENTS

COMPONENT	%	CAS NO.
CITRIC ACID, MONOHYDRATE		05949-29-1

---

3 - PHYSICAL DATA

BOILING POINT: N/A VAPOR PRESSURE(MM HG): N/A
MELTING POINT: N/A VAPOR DENSITY(AIR=1): N/A
SPECIFIC GRAVITY: 1.54 EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): APPRECIABLE (MORE THAN 10 %) % VOLATILES BY VOLUME: 0
APPEARANCE & ODOR: WHITE, ODORLESS POWDER.

---

4 - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP N/A
FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
FIRE EXTINGUISHING MEDIA
USE WATER SPRAY, CARBON DIOXIDE, DRY CHEMICAL OR ORDINARY FOAM.

SPECIAL FIRE-FIGHTING PROCEDURES
FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.

TOXIC GASES PRODUCED: CARBON MONOXIDE, CARBON DIOXIDE

---

5 - HEALTH HAZARD DATA

TOXICITY TEST RESULTS AND SAFETY AND HEALTH EFFECTS ARE LISTED FOR THE ANHYDROUS PRODUCT.
TOXICITY: LD50 (ORAL-RAT)(G/KG) - 11.7
LD50 (IPR-RAT)(MG/KG) - 883
LD50 (SCU-RAT)(MG/KG) - 5500
LD50 (ORAL-MOUSE)(MG/KG) - 5040
CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO
EFFECTS OF OVEREXPOSURE
DUST MAY IRRITATE NOSE AND THROAT.
DUST MAY CAUSE HEADACHE, COUGHING, DIZZINESS OR DIFFICULT BREATHING.
DUST MAY IRRITATE OR BURN MUCOUS MEMBRANES.
CONTACT WITH SKIN OR EYES MAY CAUSE IRRITATION.

TARGET ORGANS: EYES, SKIN
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED
ROUTES OF ENTRY: INHALATION, EYE CONTACT, SKIN CONTACT

EMERGENCY AND FIRST AID PROCEDURES
INGESTION: IF SWALLOWED AND THE PERSON IS CONSCIOUS, IMMEDIATELY GIVE LARGE AMOUNTS OF WATER. GET MEDICAL ATTENTION.
INHALATION: IF A PERSON BREATHES IN LARGE AMOUNTS, MOVE THE EXPOSED PERSON TO FRESH AIR. GET MEDICAL ATTENTION.
EYE CONTACT: IMMEDIATELY FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. GET MEDICAL ATTENTION.
SKIN CONTACT: IMMEDIATELY WASH WITH PLENTY OF SOAP AND WATER FOR AT LEAST 15 MINUTES.

---

6 - REACTIVITY DATA

STABILITY: STABLE HAZARDOUS POLYMERIZATION: WILL NOT OCCUR
INCOMPATIBLES: STRONG BASES
DECOMPOSITION PRODUCTS: CARBON MONOXIDE, CARBON DIOXIDE

---

7 - SPILL AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE
WEAR SUITABLE PROTECTIVE CLOTHING. CAREFULLY SWEEP UP AND REMOVE.
DISPOSAL PROCEDURE
DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL ENVIRONMENTAL REGULATIONS.

---

8 - PROTECTIVE EQUIPMENT

VENTILATION: USE ADEQUATE GENERAL OR LOCAL EXHAUST VENTILATION TO KEEP FUME OR DUST LEVELS AS LOW AS POSSIBLE.
RESPIRATORY PROTECTION: NONE REQUIRED WHERE ADEQUATE VENTILATION CONDITIONS EXIST. IF AIRBORNE CONCENTRATION IS HIGH, USE AN APPROPRIATE RESPIRATOR OR DUST MASK.
EYE/SKIN PROTECTION: SAFETY GLASSES WITH SIDESHIELDS, NITRILE GLOVES RECOMMENDED.

8.

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9 - STORAGE AND HANDLING PRECAUTIONS

SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)
SPECIAL PRECAUTIONS
KEEP CONTAINER TIGHTLY CLOSED. SUITABLE FOR ANY GENERAL CHEMICAL STORAGE AREA.

---

10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION

DOMESTIC (D.O.T.)
PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

INTERNATIONAL (I.M.O.)
PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

9.

05 MAY 94 PAGE 1

DOCNUM=1937

U.S. FOOD AND DRUG ADMINISTRATION
FOOD ADDITIVE SAFETY PROFILE

CITRIC ACID

CAS#:	000077929	HUMAN CONSUMPTION:	90.5367	MG/KG BW/DAY/PERSON
FASP#:	1937	MARKET DISAPPEARANCE:	106833333.333LBS/YR	
TYPE:	ASP	MARKET SURVEY:	87	
NAS#:	2306	JECFA:	NL-C	
FEMA#:	2306	JECFA ADI:		MG/KG BW/DAY/PERSON
GRAS#:	3	JECFA ESTABLISHED:	1979	
POTENTIAL BEVERAGE USE		LAST UPDATE:	931115	
FW:	192.12	DENSITY:	LOGP:	

STRUCTURE CATEGORIES: A6

COMPONENTS:

SYNONYMS:
CITRIC ACID, ANHYDROUS
2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID
HYDROXYTRICARBOXYLIC ACID, BETA-
1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-
ACIDE CITRIQUE

CHEMICAL FUNCTION: F

TECHNICAL EFFECT:
PH CONTROL AGENT
FLAVOR ENHANCER
FLAVORING AGENT OR ADJUVANT
LEAVENING AGENT
SEQUESTRANT
ANTIOXIDANT
SOLVENT OR VEHICLE
SURFACE-ACTIVE AGENT
ANTIMICROBIAL AGENT
ENZYME

CFR REG NUMBERS:

173.165	172.755	182.6033
182.1033	PART 133	PART 146
161.190	PART 169	PART 150
155.130	145.145	131.111
131.112	131.136	131.144
131.138	131.146	146.187
150.161	150.141	166.40
169.115	169.140	169.150
173.160	173.280	145.131
166.110	184.1033	

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY 1-12 FROM SCOGS-84

BOX 4A: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE RAT OR MOUSE STUDIES

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
DATA FROM SCOGS-84

10.

DOCNUM=1937

BOX 4C: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
DATA FROM SCOGS-84

BOX 7: ACUTE TOXICITY INFORMATION

STUDY: 2 SOURCE: J TAKEDA RES LAB 30:25-31
SPECIES: RAT YEAR: 1971
LD50: 12000 MG/KG BW
COMMENTS:

STUDY: 1 SOURCE: J TAKEDA RES LAB 30:25-31
SPECIES: MOUSE YEAR: 1971
LD50: 5000 MG/KG BW
COMMENTS:

BOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

STUDY: 3 COMPLETENESS: SOURCE: REV PORT FARM 20:41-46
TYPE: SHORT TERM YEAR: 1970
SPECIES: RAT LEL: 200 MG/KG BW/DAY
DURATION: 9 DAYS HNEL:
EFFECTS: BODY WEIGHT DECREASE
SITES:
COMMENTS: INITIAL DECREASE IN WEIGHT DID NOT PERSIST
NOT USED FOR PRIORITY RANKING

STUDY: 4 COMPLETENESS: SOURCE: J TAKEDA RES LAB 30:25-31
TYPE: SHORT TERM YEAR: 1971
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
DURATION: 42 DAYS HNEL: 2260 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS SPLEEN
COMMENTS: SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES

STUDY: 5 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED 34:86-89
TYPE: SUBCHRONIC RODENT YEAR: 1945
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: 90 DAYS HNEL: 600 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: BODY WEIGHT, BLOOD, HISTOPATH AND REPRODUCTION OBSERVED

STUDY: 6 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED 34:86-89
TYPE: SUBCHRONIC MAMMAL (NON-RODENT) YEAR: 1945
SPECIES: DOG LEL: > MG/KG BW/DAY
DURATION: 112 DAYS HNEL: 1380 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: NO BEHAVIORAL, BIOCHEMICAL OR HISTOPATHOLOGICAL ABNORMALITIES

STUDY: 10 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: RAT LEL: > MG/KG BW/DAY

11.

DURATION: 10 DAYS HNEL: 295 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 9 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: MOUSE LEL: > MG/KG BW/DAY
DURATION: 10 DAYS HNEL: 241 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 11 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: HAMSTER LEL: > MG/KG BW/DAY
DURATION: 5 DAYS HNEL: 272 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-10 OF GESTATION

STUDY: 12 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: RABBIT LEL: > MG/KG BW/DAY
DURATION: 13 DAYS HNEL: 425 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-18 OF GESTATION

STUDY: 8 COMPLETENESS: SOURCE: J AGRIC FOOD CHEM 5:759-760
TYPE: RAT ONCOGENICITY YEAR: 1957
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: 728 DAYS HNEL: 2000 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: MALES ONLY

STUDY: 7 COMPLETENESS: SOURCE: VOEDING 17:137-148
TYPE: REPRODUCTION (3-GENERATION) YEAR: 1956
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: HNEL: 800 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS:

BOX 3: GENETIC TOXICITY STUDIES

STUDY: 15 COMPLETENESS: SOURCE:
TYPE: YEAR:
SPECIES: LEL: MG/KG BW/DAY
DURATION: HNEL:
EFFECTS:
CELLS:
COMMENTS:

EXHIBIT C

Inspections, Compliance, Enforcement, and Criminal Investigations

Hirzel Canning Company 29-Aug-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

August 29, 2001
WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Karl A. Hirzel, President
Hirzel Canning Company
411 Lemoyne Road
Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of you firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of the Federal Food Drug , and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

Dei Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)

The above product is misbranded within the meaning of Section 403 (a)(l) of the Act in that its labeling 1s false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is ?fresh," when in fact it has been thermally processed. The Food and drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such as "packed from lies tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

Dei Fratelli Fresh & Read CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei ratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labelin is false or misleading. The statements "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact the have been thermally processed. In addition, according to the ingredient statements, the products contain at east two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli ® ***. CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)((l)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based on the information m the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other thing, the product contains no more than 360 mg of sodium.

Furthermore, the Dei Fratelli ® *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(l)(A) of the Act because the labels bear nutrient content claims that are not authorize by regulation for the Act or are not consistent with an authorizing regulation. The claims include "** *a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source' is considered to be an unauthorized synonym for "high." FDA has define the nutrient content claim "high" in 21 CFR 101.54(b). ?High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "*** great source of *** Lycopene" is not authorized. In addition, the Dei Fratelli ® *** CONCENTRATE/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result m enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as part of the common or usual name of an ingredient. Ingredients must be declared b their common or usual & name, as stated in section 403(I)(2) of the Act and 21 CFR 101.4(a (l). Optional information, such as the term "fresh? is not permitted.

Also, the Dei Fratelli ® *** CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chlorid and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the ream le to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA?s policy regarding the use "natural", means that nothing artificial or synthetic as been included m, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen(15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 t the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,
Henry Fielden
District Director
Cincinnati District

Page Last Updated: 08/14/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

EXHIBIT D

Inspections, Compliance, Enforcement, and Criminal Investigations

Oak Tree Farm Dairy, Inc. 16-Aug-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administratio
New York District
158-15 Liberty Avenu
Jamaica, NY 1143

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
August 16, 2001
Ref: NYK-2001-113

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

Dear Mr. Classey:

On May 17 and June 5 and 7,2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations, Part 101 - ,Food Labeling(21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product i also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.226).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is you responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your "OAKTREE ALL NATURAL LEMONADE" and "OAKTREE FRUIT PUNCH". Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punc label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1.

However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6 1993, copy enclosed). FDA?s policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms" 100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the "OAKTREE ALL NATURAL LEMONADE" label must be followed by a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

You should notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

/s/

Robert L. Hart

Acting District Director

Page Last Updated: 08/14/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

EXHIBIT E

Citric Acid

$C_6H_8O_7$

D Direct Use Chemical

(liquid or solid)

Inputs to Manufacturing Process:
Substrate (corn, other source of glucose)

% of Total Domestic Consumption Attributed to Water Sector:
Less than 5%

Product Family:
Corn Substrate

CAS No.: 77-92-9

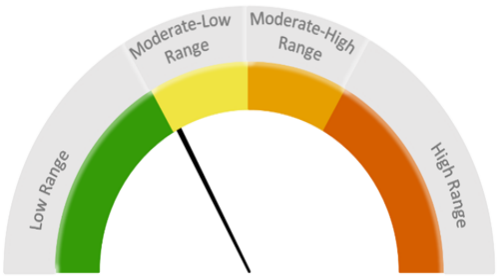
Derivative Water Treatment Chemicals:
None

Understanding Chemical Supply Chains
Map of Suppliers & Manufacturers

Shelf Life:
24+ Months

RISK OF SUPPLY DISRUPTION (Assessed in 2022)

RISK RATING: Moderate-Low



RISK DRIVERS

Production of citric acid depends on fermentation of a substrate, most commonly corn. Recovery and refinement of crude product may utilize one of three methods, one common method requiring calcium hydroxide and sulfuric acid. Domestic manufacturing has decreased over the past 20 years, and demand is increasingly met through imports.

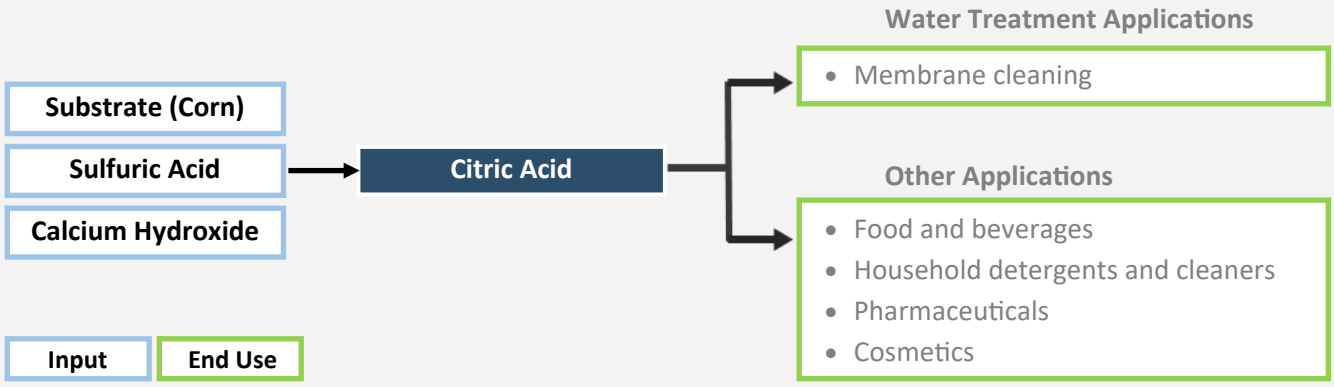
RISK PARAMETERS

Criticality: High. Essential and widely used for membrane cleaning.

Likelihood: Moderate-Low. Significant price increases, but no history of supply disruptions between 2000 and 2022.

Vulnerability: Moderate-Low. Domestic manufacturing is limited and meeting domestic demand depends on imports.

MANUFACTURING PROCESS



DOMESTIC PRODUCTION AND CONSUMPTION, AND INTERNATIONAL TRADE

Domestic Manufacturing Locations (2015):
11, distributed throughout the U.S.

International Trade (2019)

Primary Trading Partner (Imports): Thailand

Primary Trading Partner (Exports): Canada

Domestic Consumption (2015):
96 M kg

- Domestic Production (32 M kg)
- Imports for Consumption (75 M kg)
- Export of Domestic Production (12 M kg)

EPA

Product Description

Manufactured citric acid ($C_6H_8O_7$), an organic acid, is one of the most common additives in food and beverage products across the world. Citric acid is produced almost exclusively through microbial processes, utilizing a substrate and strain of mold or yeast.

Use in Water Treatment

Citric acid is used directly in water treatment for membrane cleaning.

Use as a Precursor to Other Water Treatment Chemicals

Citric acid is not used to manufacture other water treatment chemicals.

Other Applications

Citric acid has a wide range of applications, most commonly in food and beverage production as a flavoring, preservative, and acidulant. It is also commonly used in formulating cleaning agents, pharmaceutical, and personal care products (NCBI, 2022; USITC, 2022a).

Primary Industrial Consumers

In 2012, the primary use of citric acid is production of a foods and beverages (65%), household detergents and cleaners (23%), pharmaceuticals (5%), cosmetics (2%), and industrial and other uses (5%) (USITC, 2015).

Manufacturing, Transport, & Storage

Manufacturing Process

The primary method for the commercial manufacture of citric acid is the two-step process of fermentation followed by recovery and refinement.

Commercial fermentation requires a substrate and a mold or yeast. Corn is the most common substrate used in the United States. Through the metabolic reactions, the substrate is turned to glucose and fermented into crude citric acid.

Subsequent recovery and refinement of the citric acid is performed by one of three common methods: the lime/sulfuric acid method, the solvent extraction method, or the ion exchange method. It is unclear which method is most common to domestic production. All three methods proceed with a preciptation step, followed by recovery of a citric acid slurry which is then evaporated, crystalized, and dried (USITC, 2017).

Product Transport

Citric acid, available as a solution or in granular form, is widely transported in container and bulk by truck, rail, barge, and ship.

Storage and Shelf Life

Citric acid should be stored in a tightly closed container and kept in cool, dry conditions. When stored properly, citric acid (anhydrous and monohydrate) can have a shelf life of in excess of 24 months (Cargill, 2010; Puritan Products, 2017).

Domestic Production & Consumption

Domestic Production

Production data was collected from the 2016 EPA Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) for the year 2015[1], while trade data was collected from the U.S. International Trade Commission (USITC) Dataweb, as characterized in Table 1. Both production and trade data are specific to citric acid.

Table 1. Citric Acid Production and Trade Data Sources

Production and Trade Data			
Category	**Data Source**	**Identifier**	**Description**
Domestic Production	2016 TSCA Chemical Data Reporting	CAS No.: 77-92-9	Citric Acid
Imports and Exports	U.S. International Trade Commission	HS Code: 2918.14	Citric Acid

Total U.S. domestic manufacturing of citric acid reported under the CDR was approximately 32 million kilograms (M kg) in 2015; however, several leading manufacturers claimed confidential business information and did not report production volumes to EPA (EPA, 2016). The number of domestic manufacturing locations shown in Figure 1 represents operating facilities as of 2015. Supply of NSF/ANSI Standard 60 certified citric acid for use in drinking water treatment is widely available (NSF International, 2021). For a more current listing of manufacturing locations and supplier locations, visit the U.S. Environmental Protection Agency's (EPA's) Chemical Locator Tool (EPA, 2022a).

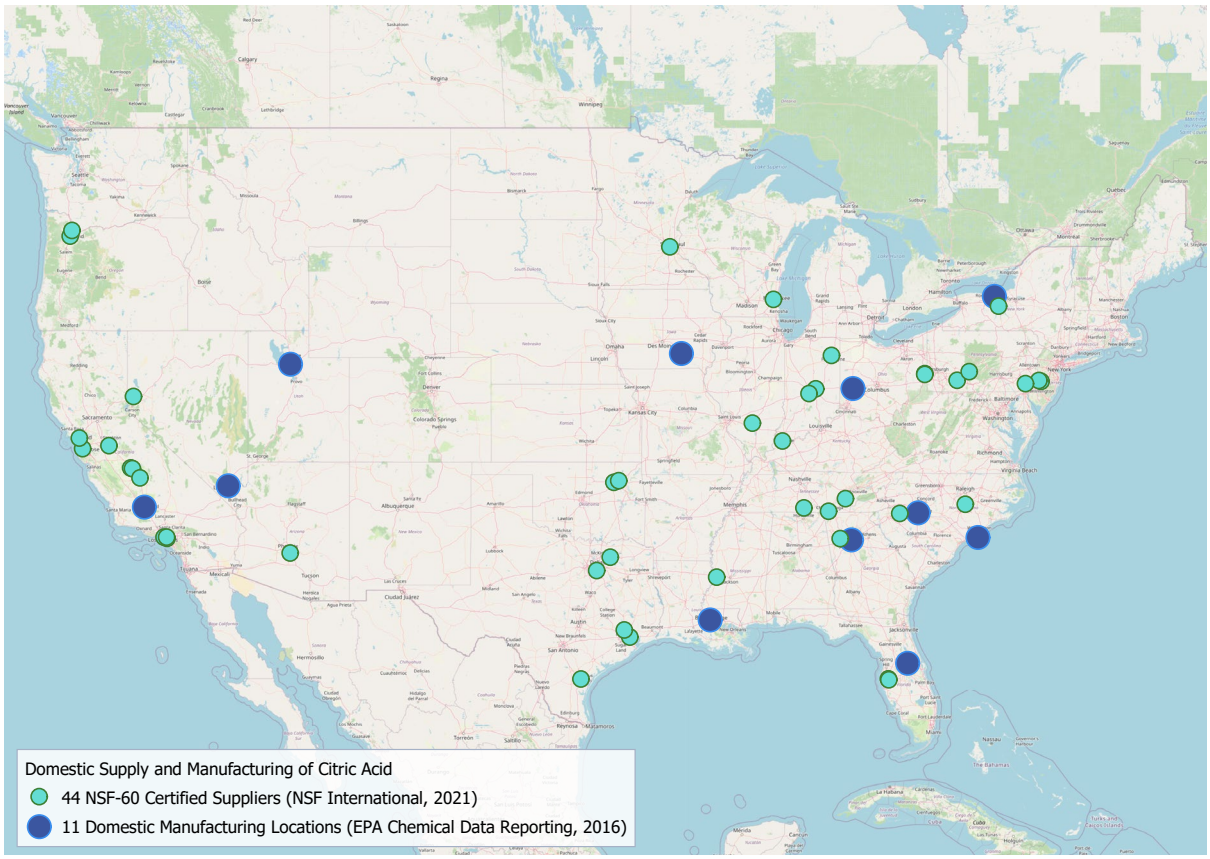


Figure 1. Domestic Supply and Manufacturing of Citric Acid

[1] Although 2019 CDR data is available, reporting is less complete when compared to 2015 data due to an increase in the number of companies claiming confidential business information (CBI). In both instances, CBI may account for a significant volume of citric acid produced that is not reflected in CDR reporting.

Domestic Consumption

U.S. consumption of citric acid in 2015 is estimated at 96 M kg. This includes production of 32 M kg, import of 75 M kg, minus export of 12 M kg (EPA, 2016; USITC, 2022a), as shown in Figure 2.

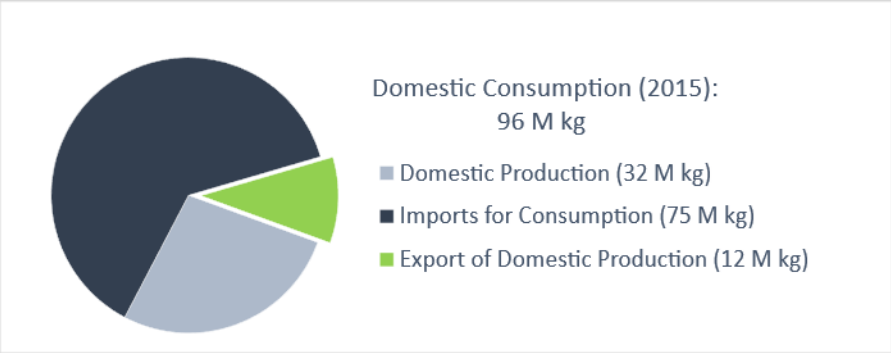


Figure 2. Domestic Production and Consumption of Citric Acid in 2019

Trade & Tariffs

Worldwide Trade

Worldwide import and export data for citric acid are reported through the World Bank's World Integrated Trade Solutions (WITS) software, as a category specific to citric acid. In 2021, the U.S. ranked tenth worldwide in total exports and second in total imports. In 2021, China ranked first worldwide in total exports while Germany ranked first in total imports (WITS, 2022), as shown in Table 2.

Table 2. WITS Worldwide Export and Import of Citric Acid in 2021

2021 Worldwide Trade Citric Acid (HS Code 2918.14)			
Top 5 Worldwide Exporters		Top 5 Worldwide Importers	
China	1,067 M kg	Germany	147 M kg
Belgium	114 M kg	**United States**	**113 M kg**
Thailand	106 M kg	India	102 M kg
Germany	34 M kg	Mexico	77 M kg
Netherlands	33 M kg	Poland	59 M kg

Domestic Imports and Exports

Domestic import and export data are reported by USITC in categories specific to citric acid. Figure 3 summarizes imports for consumption[2] and domestic exports[3] of citric acid between 2015 and 2020. During this period, the overall quantity of exports and imports remained relatively steady, with imports for consumption consistently exceeding domestic exports. Over this five-year period, Canada was the primary recipients of domestic exports while Thailand was the primary source of imports for consumption (USITC, 2022a).

[2] Imports for consumption are a subset of general imports, representing the total amount cleared through customs and entering consumption channels, not anticipated to be reshipped to foreign points, but may include some reexports.

[3] Domestic exports are a subset of total exports, representing export of domestic merchandise which are produced or manufactured in the U.S. and commodities of foreign origin which have been changed in the U.S.

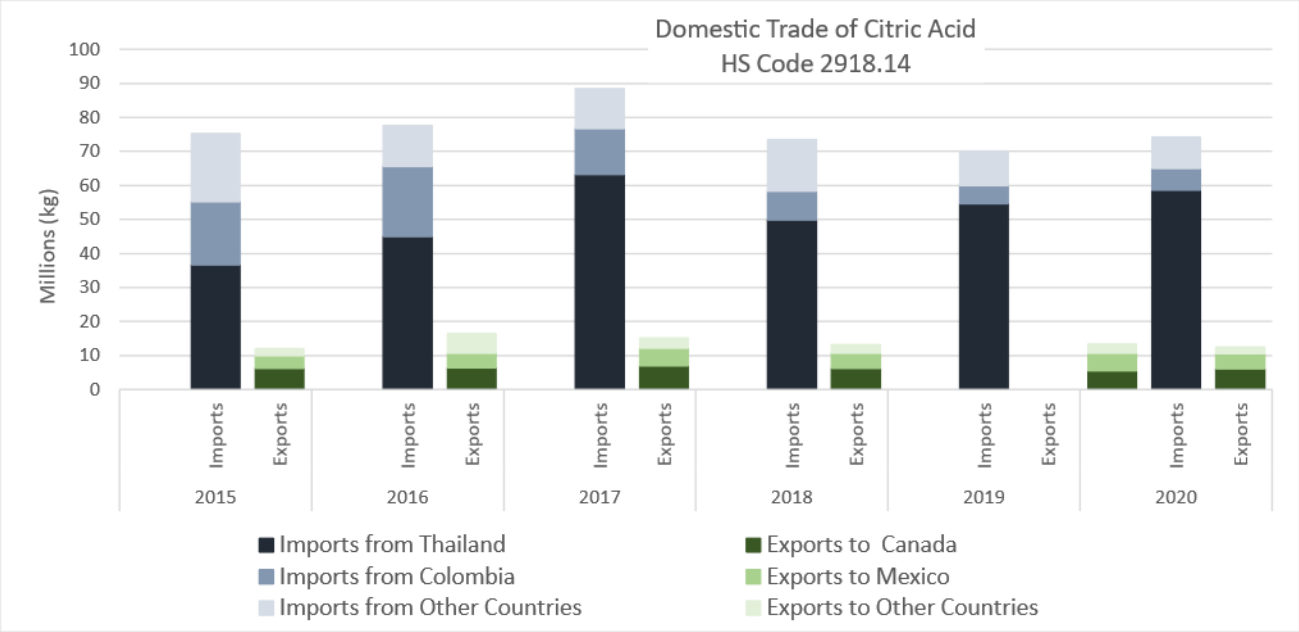


Figure 3. USITC Domestic Import and Export of Citric Acid between 2015 and 2020

Tariffs

There is a 6% general duty, and a 25% additional duty on imports from China (USITC, 2022b), as summarized in Table 3.

Table 3. Domestic Tariff Schedule for Citric Acid in 2021

HS Code	General Duty	Additional Duty – China (Section 301 Tariff List)	Special Duty
2918.14	6%	25%	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG)[4]

Market History & Risk Evaluation

History of Shortages

Domestic manufacturing has decreased over the past 20 years, and domestic demand is increasingly met through imports. In 2021, supply of citric acid became tight, due to reliance on imports to meet domestic demand and logistical and feedstock challenges of imported citric acid. Due to reliance on imports, periodic increases in price for citric acid have occurred, however there are no notable citric acid domestic supply chain disruptions impacting the water sector between 2000 and 2022.

Risk Evaluation

The complete risk assessment methodology is described in *Understanding Water Treatment Chemical Supply Chains and the Risk of Disruptions* (EPA, 2022b). The risk rating is calculated as the product of the following three risk parameters:

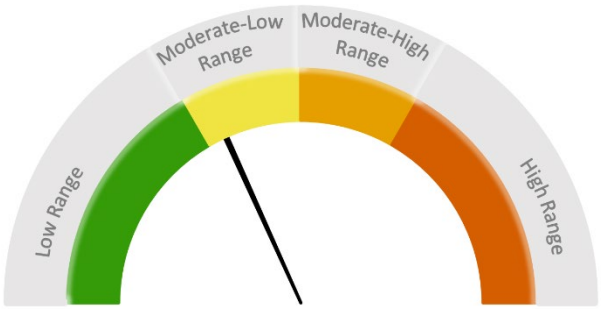
[4] Symbols used to designate the various preference programs and trade agreements. A full list of special trade agreements and associated acronyms can be found at https://help.cbp.gov/s/article/Article-310?language=en_US and the General Notes Section of the Harmonized Tariff Schedule https://hts.usitc.gov/current

Risk = Criticality x Likelihood x Vulnerability	
Criticality	Measure of the importance of a chemical to the water sector
Likelihood	Measure of the probability that the chemical will experience a supply disruption in the future, which is estimated based on past occurrence of supply disruptions
Vulnerability	Measure of the market dynamics that make a chemical market more or less resilient to supply disruptions

The individual parameter rating is based on evaluation of one or more attributes of the chemical or its supply chain. The ratings and drivers for these three risk parameters are shown below in Table 4.

Table 4. Supply Chain Risk Evaluation for Citric Acid

Risk Parameter Ratings and Drivers		
Criticality: High	**Likelihood: Moderate-Low**	**Vulnerability: Moderate-Low**
Citric acid is widely used for membrane cleaning.	The water sector has experienced significant price increases, but has not experienced citric acid supply chain disruptions between 2000 and 2022.	Domestic manufacturing is limited and meeting domestic demand depends on imports.
Risk Rating: Moderate-Low		



References

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