

Amino Acids

Processing

Identification

Chemical Names L-cysteine, Cys, L-cysteine monohydrochloride

Other Names: Cysteine is the model amino acid used for the purpose of this review. Much of the supporting data is for L-cysteine monohydrochloride. See attached list.

CAS Numbers:

L-cysteine monohydrochloride: 52-89-1

Other Codes:

L-Cysteine EU 920

[INS number expected to be the same, no separate number for the monohydrochloride salt].

Recommendation

Synthetic / Non-Synthetic:	National List:	Suggested Annotation:
<i>Synthetic (consensus)</i>	<i>Not Allowed 95%+ (consensus) Not Allowed 50% + (2-1-1)</i>	<i>Prohibited as an ingredient in organic food. (3-0-1). Prohibited as an ingredient in foods made with organic ingredients (2-1-1).</i>

Characterization

Composition:

Amino acids have an amino group (NH₂) adjacent to a carboxyl (COOH) group on a carbon. The formula for L-cysteine is H₂NSCH₂CHCOOH and for L-cysteine monohydrochloride is H₂NSCH₂CHCOOH • HCl • H₂O or C₃H₂NO₂S • HCl • H₂O

Properties:

Amino acids are the building blocks of proteins and peptides. As such, they are naturally occurring, but are rarely found in free form. Not all amino acids are associated with formation of proteins and there are a considerable and growing number of non-protein amino acids that are not found in nature. L-Cysteine monohydrochloride is a white odorless crystalline powder having a characteristic acid, slightly sweetish taste. Soluble in water and alcohol. Melting point 175°C.

How Made:

Amino acids can be produced from a number of different sources by a wide variety of means. One biological source is the extraction of keratin from human hair by use of hydrochloric acid and water. After several steps (not disclosed), keratin is hydrolyzed and purified into L-cystine (Sun-Orient Chemical Co., Ltd., 1998). L-cystine is then dissolved into a hydrochloric acid solution and converted by electrolysis to L-cysteine monohydrochloride in several steps (Sun-Orient Chemical Co., Ltd., 1998).

DL-cysteine hydrochloride can also be produced from the reaction of ammonia, hydrogen cyanide and mercaptaldehyde in the Strecker process (Ashford, 1994). DL-cysteine can then be resolved into L-cysteine and D-cysteine enantiomers (Streetweiser and Heathcock, 1985). L-cysteine can also be produced by the reaction of chloroacetaldehyde with hydrogen cyanide, ammonium bicarbonate, and sodium sulfide in the Bucherer-Berg reaction (Ashford, 1994). L-cysteine can be crystallized into the monohydrochloride form by reaction with a solution of hydrochloric acid. L-cysteine monohydrochloride can also be produced by an enzymatic process (Ashford, 1994).

In any case, the hydrochloride salt of L-cysteine would be considered synthetic given the crystallization product of reacting hydrochloric acid.

Furthermore, there are increasing numbers of cases where amino acids can be derived from genetically-engineered organisms; these products are to be considered synthetic, per NOSB determinations on genetic engineering. They also may be synthesized by a variety of other chemical means, and in these cases, would also be considered synthetic.

Specific Uses:

Amino acids have a wide range of uses in food processing and handling: as nutrients, dietary supplements, flavor enhancers, salt substitutes, coloring aids, anti-oxidants, preservatives, texturizers, dough conditioner or strengtheners. The model amino acid for this review, L-cysteine monohydrochloride, is used as a dough conditioner and as an anti-oxidant. When L-cysteine monohydrochloride is heated with sugar, it is used to form a broiled beef aroma extract (O'Hara, 1974). All protein and many non-protein amino acids are used in processing (see Winter, 1989; Food Chemicals Codex, 1996). The most used amino acids in processing are glutamic acid and its salt, monosodium glutamate (MSG) (Araki and Ozeki, 1991). Another familiar amino acid product is aspartame, the dipeptide ester formed as a combination of aspartic acid and phenylalanine. Aspartame is used as a sugar substitute (Winter, 1989).

Action:

In general, amino acids have many modes of action based on their ability to form proteins and impart flavors. L-cysteine hydrochloride acts as an antioxidant by a reduction reaction in ascorbic acid fortified foods (O'Hara, 1974). Ascorbic acid need not be present to prevent browning, but the two antioxidants act synergistically.

Combinations:

Amino acids are used in literally hundreds of combinations. The model amino acid used in this review, L-cysteine monohydrochloride, is most effective in low-pH solutions with a food grade acid.

Status**OFPA**

Amino acids, generally and specifically, would be considered non-synthetic, non-organic ingredients used as a direct food additive (7 U.S.C. 6518(c)(1)(B)(iii)).

Regulatory

Regulated by the Food and Drug Administration. See discussion of GRAS listing below.

Status among Certifiers

In general, amino acids have been a gray area in organic processing standards. While most would prohibit MSG or aspartame as clearly synthetic, various certifiers have considered some amino acids to be non-synthetic and allowed for post-harvest handling uses, as processing aids or as non-organic ingredients. For example, L-cysteine monohydrochloride was implicitly allowed by California Certified Organic Farmers, Oregon Tilth, and other certifiers for post-harvest handling of fresh produce between 1994 and 1997. The substance was removed from their lists and placed under consideration in 1997.

Historic Use

Provisionally allowed by various certifiers under the assumption that they were 'natural' and not available from an organic source.

International

The Codex Alimentarius Commission organic food guidelines say that amino acids may be used as a food additive "[o]nly approved in so far as their used is legally required in the food products in which they are incorporated" [sic] (Joint FAO/WHO Food Standards Programme, 1999). L-cysteine was added the European Union list of approved food additives--for all foods, not just organic foods--in October 1998 by Directive 98/72. Does not appear on the EU list of approved substances to be used as direct food additives in organic foods. IFOAM does not list amino acids as allowed in processing, either individually or collectively (IFOAM, 1998).

OFPA 2119(m) Criteria

- (1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems. As this is a processing material, the substance is not used in organic farming systems.
- (2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment. See processor criteria 3 below.
- (3) The probability of environmental contamination during manufacture, use, misuse or disposal of such substance. This is considered below under item (2).
- (4) The effect of the substance on human health. This is considered in the context of the effect on nutrition (3) below as well as consideration of GRAS and residues (5) below.
- (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. As this is not released into the agroecosystem, there is no direct effect.
- (6) The alternatives to using the substance in terms of practices or other available materials. See discussion of alternatives in (1) below.
- (7) Its compatibility with a system of sustainable agriculture. This is considered more specifically in the context of organic handling in (6) below.

NOSB Processing Criteria

A SYNTHETIC PROCESSING AID OR ADJUVANT may be used if;

1. An equivalent substance cannot be produced from a natural source and has no substitutes that are organic ingredients.

Fresh organic produce does not necessarily need preservative or anti-oxidant additives. Picking to order, more frequent and more timely shipment, tighter inventory management, better management of product flow, maintaining temperatures, and rotating stock can compensate for shorter shelf life.

The anti-oxidants ascorbic acid, citric acid, and tocopherols (Kays, 1991) are already recommended to be added to the National List. Other antioxidants not yet reviewed by the NOSB include the following GRAS substances: sulfites, cinnamic acid, benzoic acid, carbon monoxide, EDTA, glutathione, N-acetylcysteine and inorganic halides.

There are a number of potential alternatives to the use of L-cysteine monohydrochloride that can be used to prevent browning in potato processing. Some approaches include variety selection, quality assurance of lower reducing sugars, and holding the potatoes longer at elevated temperatures to convert more sugars to starch may all be viable alternatives. Ascorbic acid and citric acid are used as anti-browning agents, most widely for enzymatic browning in fruit and vegetable processing. Additionally, exclusion of oxygen also helps in reducing the rate of enzymatic browning.

Tocopherol, derived from non-GMO, non-solvent extracted soybeans, can be used in a wide variety of cereal and bakery products as an anti-oxidant (i.e., slow down the rate of lipid oxidation) as a function of processing and storage. Again, exclusion of O₂ can also slow down the rate of lipid oxidation (i.e., muscle foods, foods with high level of unsaturated fatty acids).

Good baking techniques will produce acceptable quality dough for most uses. Increased mixing time will yield comparable results (Sai Manohar, R. and Rao Haridas, P, 1997). Other compounds that are more acceptable exist, be they oils, natural emulsifiers, or other agricultural products, such as gluten (Saiz, et al. 1997).

2. Its manufacture, use and disposal does not contaminate the environment.
Depending on the amino acid in question, and the particular process to produce it, there may be some environmental and/or human safety hazards associated with the manufacture of these materials.

For the case of cysteine, hydrochloric acid is hazardous to handle and use; synthetic alternatives for production of this amino acid are even more hazardous (involves hydrogen cyanide). The degree of negative impact(s) of amino acid production varies, and these may have to be evaluated on a case-by-case basis, if they are to be allowed at all. The main concern with manufacturing from human hair is the use of hydrochloric acid. Hydrochloric acid is highly corrosive (Sax, 1984). Hazards when working with the substance include explosions, lung injury, edema, severe burns, and death (NIEHS, 1991). The by-products of processing the human hair is disposed of in a manner similar to other biological wastes (Skymart Enterprises, 1994).

Hydrogen cyanide is produced by further processing of methane and ammonia. Hydrogen cyanide is a gas that is highly toxic. Exposure causes paralysis, unconsciousness, convulsions, and respiratory arrest. Death usually results from exposure at 300 ppm concentrations for a few minutes (Clayton and Clayton, 1982). Hydrogen cyanide has a toxicity rating of 6 and is one of the fastest poisons known to man (Gosselin, 1984). Manufacture of hydrogen cyanide is a significant source of atmospheric release of cyanide (Midwest Research Institute, 1993).

Misuse of amino acids, as far as undue levels accidentally being ingested, can be a concern; toxicity varies from one to another and affects some people more than others. Overall, the risks of overexposure to amino acids themselves, however, should be minimal, as long as good manufacturing practices are used and quality assurance and HACCP programs verify that such practices are maintained.

Disposal of amino acids into the environment should not pose any significant risk.

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have any adverse effect on human health.

The introduction of essential amino acids could potentially enhance the nutritional quality of the food from a narrow, empirical perspective. The model amino acid, L-cysteine monohydrochloride, is not considered essential, and is easily synthesized. The LD50 of L-cysteine monohydrochloride is 1250 mg/kg (mouse) (Areki and Ozaki, 1991). Lethal doses fed to rats and mice caused ataxia, sedation, decreased activity, reflex reduction, muscle relaxation, respiratory depression, hypothermia, and apparent congestion of several organs (Takasaki, et al., 1973 quoted in Environ, 1987). Cysteine treated mice developed retinal and hypothalamic lesions identical to those associated with MSG (Olney and Ho, 1970).

Exposure to free amino acids in pure available form have been long been linked to a number of genetic disorders and food allergies. The most widely studied are those related to glutamic acid and glutamates, in particular MSG. Also, the link between phenylalanine and phenylketonuria has also been the subject of much study. While such problems associated with the cysteine are less common and have not been exhaustively studied, they are nonetheless documented. Free cysteine can cause problems in a segment of the population. Cystine--a metabolic product of cysteine--has been linked to cystinuria (Meister, 1965). Individuals who suffer from cystinuria accumulate amino acids in the urine and the formation of kidney stones composed of cystine (Environ, 1987). More common in the literature are allergies to cysteine-based proteins that are activated by cysteine proteases, such as bromelain (see, for example, Pike, Bagarozzi and Travis, 1997).

Addition of amino acids to food products could conceivably boost nutritional value, from a purely analytical viewpoint, as certain amino acids are lacking in certain foods (or certain regional diets). However, in the absence of solid evidence that there is a real nutritional deficiency in the target population for the food product(s) in question, precautionary action on the part of the food manufacturer is warranted.

It is safer to avoid addition of amino acids under normal circumstances. Research is incomplete on the role free amino acids play in the human system. They can serve as neurotransmitters or precursors of neurotransmitters, and altering the balance of them as compared to a natural human diet may have

unknown or negative effects. A common example is the effect of monosodium glutamate and D-glutamate on certain individuals (Coyle and Puttfarcken, 1993). High bloodstream levels of tryptophan can alter sleep cycles due to its impingement on serotonin production. Other amino acids have been linked to genetic disorders, such as phenylalanine in phenylketonuria, and cystine in cystinuria. These are only some of the possible range of action of amino acids in the human system. A related example is aspartame, a dipeptide of aspartic acid and phenylalanine used as a sweetener; health questions have been raised about the safety of this food additive (Winter, 1989).

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

By delaying oxidation and extending product shelf life, L-cysteine monohydrochloride could be considered a preservative. It is debatable whether cysteine used as an anti-browning agent in dehydrated potatoes could qualify it as a preservative, or at least as a means of retaining color otherwise lost during processing. Decomposing cysteine used as beef aroma / flavoring agent would be considered a way to artificially recreate flavors. Cysteine improves dough quality by working on the gluten as an antioxidant (Koh, et al, 1997).

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

The Food, Drug, and Cosmetic Act, 21 CFR Sec. 172.320(a) lists that food additive amino acids may be safely used as nutrients added to foods. The list includes both L-Cysteine and L-Cysteine Monohydrochloride. Section 172.320(c) establishes that amino acids used as an additive “intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source, provided that:

- (1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the reference adult male recommended by the National Academy of Sciences in Recommended Dietary Allowances . . .
- (2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.
- (3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily-intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

“The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form cannot following levels of amino acids expressed as percent by weight of the total protein of the finished food [sic]. For example, the maximum percent by weight of total protein in a given food expressed as free L-cysteine and L-cystine expressed as free amino acid is 2.3%.”

The regulations further state that “[e]ach manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.” The regulations go on to state the specific content of the records required to be kept.

Additionally, specific regulations regarding L-Cysteine monohydrochloride are found at 21 CFR 184.1272. These state that the ingredient may be used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener . . . in yeast-leavened baked goods and baking mixes. This

regulation was issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named. Use as an antioxidant in fresh produce is not mentioned but appears to be covered as part of the general evaluation.

Food Chemicals Codex limits: Must contain not less than 98.0% and not more than 102.0% of $C_3H_2NO_2S \cdot HCl \cdot H_2O$ after drying. Arsenic as As not more than 3 ppm; heavy metals as lead (Pb) of not more than 0.002% and lead not more than 10 ppm, loss on drying not less than 8% and not more than 12% (National Academy of Sciences, 1981 et seq).

6. Is compatible with the principles of organic handling.

In general, the use of isolated amino acids does not appear to be compatible with organic handling to most if not all of the reviewers. Use to extend shelf-life appears to be counter to consumer expectations that organic produce is fresh and does not have any artificial preservatives. Use to fortify foods also does not appear to be compatible. There is no product formulation or recipe known that absolutely requires their inclusion, and no process that is rendered impossible by their exclusion. Preservative action, mimicking of flavors, creation of non-essential food product characteristics, or re-creation of sensory qualities by such isolated, non-organically-produced materials runs counter to the principles of organic handling. Additionally, organic foods should not contain artificial flavors or synthetic flavor potentiators. On that basis, L-cysteine and other amino acids are not compatible as organic flavor enhancers. Supplement of diet by amino acids runs counter to the principle that proper nutrition can be achieved through a varied, wholesome diet.

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

For L-Cysteine: Use of an antioxidant is not essential for fresh produce. Dough conditioners are not essential for flour. Artificial beef aroma is not essential for any food. Because L-cysteine is not an essential amino acid, no food needs to be fortified with it. As nutritional supplements in general, isolated amino acids are not organic ingredients, and so should not be added to foods labeled as organic. Therefore the minimum amount required for use in such foods would be zero. In general: the reviewers could find no food product, legal requirements, or standards of identity where amino acids were required to produce a given food.

Discussion

Condensed Reviewer Comments

None of the reviewers had a commercial or financial interest in L-cysteine monohydrochloride or any other amino acid.

Reviewer 1

Amino acids may be synthetic or non-synthetic, depending on their source, means of isolation, and final molecular structure. Classification as synthetic or non-synthetic therefore needs to be determined on a case-by-case basis.

In all cases, it is recommended that amino acids be PROHIBITED for inclusion in any foods labeled as organic. In foods which are labeled as "made with organic ingredients," it may be possible to allow non-synthetic amino acids to be used as non-organic ingredients, but with the restriction that the product label specifically explains the purpose of their use in the product. Otherwise, the likelihood of confusing the consumer is too high. This restriction should be added to the proposed annotation given in the NOSB database, which otherwise seems complete.

It should be reiterated that the above allowance only applies to non-synthetic amino acids. Synthetic amino acids, including those which are products of genetic engineering should be PROHIBITED in any foods containing organic ingredients.

Reviewer 2

I would consider that all manufacturing processes for L-cysteine result in the formation of synthetic L-cysteine and/or the hydrochloride form. Even though hydrochloric acid is used, probably at a 6 normal or greater concentration, it is not produced by enzymatic proteolysis as cysteine is released *in vivo*. For example, humans have approximately 2N hydrochloric acid in their stomach that maintains the optimum pH for enzymes like pepsin and others to hydrolyze food proteins into their constituent amino acids so that they can be absorbed.

When conducting amino acid analysis in the laboratory, many methods use 6 Normal hydrochloric acid to hydrolyze the protein with no enzymes because the process is much faster and less expensive. Therefore, any amino acid produced as a function of 6N Hydrochloric acid hydrolysis is synthetic.

In summary, I feel that all commercial methods as provided by the NOSB database and from my sources indicate that L-cysteine is synthetic. Because of the issues of alternatives, incompatibility with organic process criteria, potential for loss of vitamin B6, as well as NOSB processing criteria 3, I recommend that L-cysteine or L-cysteine hydrochloride not be added to the National List of Allowed Non-organic Ingredients.

Reviewer 3

I believe that the NOSB should recommend that amino acids be restricted for usage in foods made with organic ingredients, only in a case-by-case basis for specific uses. There may be cases of essential amino acid fortification, for example, that may make sense for certain population groups. The NOSB should also specifically restrict the usage of any amino acids made from genetic engineering, racemic mixtures, and D-enantiomers. The use of monosodium glutamate and other "free" glutamates should be prohibited in organic foods.

Reviewer 4

L-cysteine hydrochloride and ascorbic acid are both antioxidants (preventing browning) and do not need to be used together. They often are, but this is not required. L-cysteine hydrochloride is a sulfhydryl containing amino acid which prevents browning by reacting with quinone intermediates in the browning reaction catalyzed by the enzyme, polyphenol oxidase.

Alternatives to L-cysteine as an antioxidant include the following (all are GRAS): ascorbic acid, citric acid, sulfites, cinnamic acid, benzoic acid, carbon monoxide, EDTA, glutathione, N-acetylcysteine and inorganic halides. Use of cysteine to prevent browning is not considered a preservative, it's more of a processing aid.

Conclusion

Unlike vitamins and minerals, the reviewers could find or cite no guidelines or laws that mandate the fortification of certain food products with amino acids at this point. Even if there were, it is highly unlikely that they would apply to a non-essential amino acid like L-cysteine monohydrochloride.

If the NOSB chooses to add amino acids to the National List, those foods that are artificially fortified may need to be labeled as "Made from organically grown ingredients and fortified with ____." The more difficult decision will be to determine whether or not amino acids in any form qualify to be used in foods labeled as made with organic ingredients. The NOSB might want to consider several different options. The most conservative approach would be to not allow such usage and require a case-by-case review. The most permissive would be to allow all amino acids from any source to be used in foods labeled as made with organic ingredients and as incidental ingredients of the non-organic ingredients on the National List. Amino acids essential for human nutrition are readily available in organically grown food. Restricted use of non-synthetic amino acids might be the most prudent course. The NOSB may want to explicitly exclude in the annotation those amino acids that are derived from genetic engineering, racemic mixtures, D-enantiomers, and monosodium glutamate.

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