Cyclohexylamine

Processing

Chemical Name(s):
Cyclohexylamine

CAS Number:
108-91-8

Other Names:
CHA, Cyclohexanamine, aminocyclohexane, hexahydroxyanaline, aminohexahydrobenzene, hexahydrobenzenamine

Other Codes:
NIOSH Registry Number: GX0700000
UN/ID Number: UN2357

Summary of Advised Recommendation*

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic	*Prohibited*	*None.*

Characterization

Composition:
$C_6H_{13}N$

Properties:
Strong fishy amine odor; colorless to yellow liquid; strong base; miscible with water and with common organic solvents: alcohol, ethers, ketones, esters, aliphatic hydrocarbons; completely miscible with aromatic hydrocarbons; soluble in chlorinated hydrocarbons, mineral oil, peanut oil, and soybean oil; molecular weight 99.17; boiling point 134.5 deg C at 760 mm Hg; melting point –17.7 deg C; specific gravity 0.8647 at 25 deg C; on distillation with water cyclohexylamine forms azeotropic mixture, boiling at 96.4 deg C at 76 mmHg; reacts with excess ammonia and zinc chloride at 350 deg C to produce alpha-picoline; reacts with organic compounds containing an active halogen atom, acid anhydrides and alkylene oxides, to replace one or both hydrogen atoms on the nitrogen atom; reacts with nitrous acid to form cyclohexanol.

How Made:
Prepared by the catalytic hydrogenation of aniline at elevated temperatures and pressures. Fractionation of the crude reaction product yields cyclohexylamine, unchanged aniline, and a high-boiling residue containing N-phenylcyclohexylamine (cyclohexylaniline) and dicyclohexylamine (Budavari, 1996). Also produced by a reaction of cyclohexanone and ammonia through reductive ammoniation. This reaction also co-produced dicyclohexylamine (Ashford, 1995).

Specific Uses:
Petititioned for use as a boiler water additive. It is also used to manufacture numerous synthetic chemicals, including insecticides, plasticizers, emulsifying agents, dyes, dry-cleaning soaps, and acid gas absorbents.

Action:
Goes into solution in boiler water and forms an azeotrope. This means that the substance cannot be separated from water by distillation or filtration and is carried over in the steam. Neutralizes carbonic acid in steam and steam condensates.

Combinations:
Used in combination with diethylaminoethanol (DEAE), morpholine, and octadecylamine (ODA) among other compounds. Often blended in proprietary mixtures that do not list solvents or carriers. It is also an inert ingredient in pesticides and has a wide range of industrial applications. Not compatible with strong oxidizers (such as chlorine, bromine, and fluorine), strong acids (such as hydrochloric, sulfuric, and nitric), acid chlorides and acid anhydrides.

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* *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed and commented on by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA (7 USC 6517(m)). The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and is not intended to incorporate commercial availability, socio-economic impact, or any other factor that the NOSB and the USDA may want to consider in making their decisions.*

Status

OFPA
Equipment cleaner [7 USC 6517(c)(1)(B)(i)].

Regulatory
FDA approved as a boiler water additive not to exceed 10 ppm in steam, and not approved for contact with milk and milk products [21CFR 173.310(d)].

EPA/NIEHS/Other Appropriate Sources
EPA - Cyclohexylamine (CHA) appears on the Superfund Amendments and Reauthorization Act (SARA) Title III and Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) List of Extremely Hazardous Substances (40 CFR 355 Appendix A). It is also subject to SARA reporting requirements contained in 40 CFR 311 and 40 CFR 312. Manufacturers of CHA are subject to Superfund requirements in 40 CFR 313.

The Reportable Quantity (RQ) is 10,000 lbs.
The Threshold Planning Quantity (TPQ) is 10,000 lbs.

CHA is classified as a Volatile Organic Compound (VOC) under §111 (subpart VV) of the Clean Air Act (40 CFR 60.489) and is subject to compliance with the emission standards set for VOCs.

CHA also appears on a list of priority chemicals provided by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL), established by EPA under the Federal Advisory Committee Act (FACA). This substance is one of 85 industrial chemicals and pesticides selected for development of short-term exposure levels of airborne releases that will be used by federal, state, local and private institutions when responding to emergency situations involving accidental chemical releases. Additionally, the AEGLs can be used by various organizations that are involved in chemical manufacturing, processing, storing, and transporting, or for waste remediation processes. NAC/AEGL encourages the submission of acute toxicity data or other toxicity studies on any of the substances listed (62 *Fed. Reg.* 27733).

NIEHS - National Toxicology Program database:

Acute Toxicity: (Abbreviations)

Dose	Mode	Specie	Amount	Unit
LD_{50}	ORL	RAT	710	MG/KG
LD_{50}	IPR	RAT	200	MG/KG
LD_{50}	IPR	MUS	300	MG/KG
LD_{50}	SCU	MUS	1150	MG/KG
LD_{50}	SKN	RBT	320	MG/KG
LDLO	PAR	RBT	500	MG/KG

AQTX/TLM96: 1000-100 PPM

Sax Toxicity Evaluation: Moderate via oral and inhalation routes; high via intraperitoneal routes.

Carcinogenicity: Not Available

Mutagenicity:

CYT-HMN:LEU	10 UMOL/L/5H
CYT-RAT-UNK	50 MG/KG
SPM-RAT-IPR	5 MG/KG/5D
DLT-MUS-IPR	500 MG/KG/5D-I
CYT-HAM: FBR	10 MG/L
CYT-DOM-UNK	50 MG/KG

Teratogenicity: Not Available. [See discussion below]

Standards, Regulations & Recommendations:

OSHA: Final Limit: Permissible Exposure Level (PEL) Time Weighted Average (TWA): 10 ppm [610] (Federal Register (1/19/89))

ACGIH: Threshold Limit Value (TLV) TWA 10 ppm [610]
NIOSH Criteria Document: None
NFPA Hazard Rating: Health (H): 2
Flammability (F): 3
Reactivity (R): 0
H2: Materials hazardous to health, but areas may be entered freely with full-faced mask self-contained breathing apparatus which provides eye protection (see NFPA for details).
F3: Materials which can be ignited under almost all normal temperature conditions (see NFPA for details).
R0: Materials which are normally stable even under fire exposure conditions and which are not reactive with water (see NFPA for details).

Other Toxicity Data:
Skin and Eye Irritation Data: skn-hmn 125 mg/48H SEV
Review: Toxicology Review-2

Other Data (Regulatory)
Hazard Class: 8; Subsidiary Risk: 3; Packing Group: II

Labels Required: Corrosive and Flammable liquid

Acute/Chronic Hazards:
Toxic. Causes irritation on contact. Highly toxic decomposition products. Mutagen.

Minimum Protective Clothing: If Tyvek-type disposable protective clothing is not worn during handling of this chemical, wear disposable Tyvek-type sleeves taped to your gloves.

Recommended Glove Materials: The following gloves show the best resistance based on permeation testing. It is recommended that two different glove types be used for best protection. However, if this chemical makes direct contact with your glove, or if a tear, puncture or hole develops, remove them at once. Butyl rubber (to 160 min.)

Recommended Respirator: Where the neat test chemical is weighed and diluted, wear a NIOSH-approved half face respirator equipped with a combination filter cartridge, i.e. organic vapor/acid gas/HEPA (specific for organic vapors, HCl, acid gas, SO2 and a high efficiency particulate filter).

Storage Precautions: You should store this chemical in a freezer and away from all mineral acids and bases.

Spills And Leakage: If you should spill this chemical, use absorbent paper to pick up all liquid spill material. Seal the absorbent paper, as well as any of your clothing which may be contaminated, in a vapor-tight plastic bag for eventual disposal. Wash any surfaces you may have contaminated with a strong soap and water solution. Do not reenter the contaminated area until the Safety Officer (or other responsible person) has verified that the area has been properly cleaned.

Disposal And Waste Treatment: You should dispose of all waste and contaminated materials associated with this chemical as specified by existing local, state and federal regulations concerning hazardous waste disposal. It is suggested that your contaminated materials should be destroyed by incineration in a special, high temperature (>2000 degrees F), chemical incinerator facility.

Emergency Procedures

Skin Contact:
IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water.
IMMEDIATELY call a hospital or poison control center even if no symptoms (such as redness or irritation) develop.
IMMEDIATELY transport the victim to a hospital for treatment after washing the affected areas.
Inhalation:
IMMEDIATELY leave the contaminated area; take deep breaths of fresh air.

IMMEDIATELY call a physician and be prepared to transport the victim to a hospital even if no symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop.

Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Respirator Recommendation.

Eye Contact:
First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center.

Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.

Ingestion:
If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center.

Generally, the induction of vomiting is NOT recommended outside of a physician's care due to the risk of aspirating the chemical into the victim's lungs. However, if the victim is conscious and not convulsing and if medical help is not readily available, consider the risk of inducing vomiting because of the high toxicity of the chemical ingested. Ipecac syrup or salt water may be used in such an emergency. IMMEDIATELY transport the victim to a hospital. If the victim is convulsing or unconscious, do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. IMMEDIATELY transport the victim to a hospital.

Symptoms: May cause irritation on contact. Causes nausea and narcotic effects.

Firefighting:
This compound is not very flammable but any fire involving this compound may produce dangerous vapors. You should evacuate the area. All firefighters should wear full-body protective clothing and use self-contained breathing apparatuses. You should extinguish any fires involving this chemical with a dry chemical, carbon dioxide, foam, or halon extinguisher.

Other sources
US Department of Transportation - Contained on the DOT Hazardous Materials Table (59 *Fed. Reg.* 67395).

State Right-to-Know Lists: Illinois (1991), Massachussets (1994), New Jersey (1989), Pennsylvania (1989).

Status Among U.S. Certifiers
Not allowed by any U.S. Certifier. See the discussion regarding boiler water additives in the background paper Steam Generation in Organic Food Processing Systems (Steam Paper).

International
Canada – Not included in the list of permitted non-organic additives substances for organic food products (CGSB, 1999).

CODEX- Not in Annex 2, Table 4, 'Processing Aids' (FAO/WHO, 1999).

EU 2092/91 – Not in Annex VI, 'Processing Aids' (EU 2092/91).

IFOAM – Not on Appendix IV, approved processing aids and other products (IFOAM, 2000).

Japan — Not on the list of approved food additives (Woolsey, 2000).

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. Chemical interactions within a processing environment is discussed in the Steam Paper.

(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.
Cyclohexylamine is a severe eye, skin, and respiratory irritant, and is toxic when taken in by any route, including dermal, ingestion, inhalation, mucous membranes (IPCS, 1993). It causes second- and third-degree burns on short contact, and is very injurious to the eyes. It is strongly caustic, and inhalation can cause severe burns. Recommended protection for handling this material involves gloves, goggles, and respirators (Cheremishinoff, 1999; NTP, 2001). Some references advise wearing a self-contained breathing apparatus when handling cyclohexylamine (Toxnet, 2001). Systemic affects on humans include nausea and vomiting, anxiety, restlessness and drowsiness; spinal-type convulsions occur in rabbits (Gosselin, et.al., 1984). The LD_{50} value in rats (oral) is 156 mg/kg, and in rabbits (skin) is 277 mg/kg (Patnaik, 1992).

This is further considered in the context of the effect on nutrition (3) below as well as the 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 the Steam Paper, and the comments of the reviewers below.

(7) Its compatibility with a system of sustainable agriculture.
This is considered more specifically below in the context of organic handling in (6) below.

Criteria from the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if;

1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
CHA cannot be produced from natural sources and has no organic ingredients as substitutes. Steam can be produced from water without the addition of boiler water additives. A list of substances that are FDA approved for boiler water contact is attached. While these are not direct substitutes, these are available options. The NOSB has already recommended that several of these be listed. When considering chemical means to condition steam lines in boiler systems, the additives to the steam lines must be volatile, so that they purposely travel along with the steam. There are no known non-synthetic boiler additives that can serve this purpose. See the Steam Paper for more discussion.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling.*
Cyclohexylamine is made from aniline, which is a coal tar derivative (Budavari, 1996) that is regarded as highly toxic and can be absorbed into the skin in fatal amounts (Archer, 1996). The environmental impacts of coal tar production, from mining to refining, are extensive, and are beyond the scope of this review. N-phenylcyclohexylamine (cyclohexylaniline) and dicyclohexylamine are also volatile amines. Dicyclohexylamine's rat LD_{50} is 200-373 mg/kg (Greim, 1997) , which would normally be considered 'very toxic' (Gosselin, Smith, and Hodges, 1984).

   In general, volatile amines are highly reactive, and they are acknowledged to be hazardous materials to handle. Extra precautions in handling and disposal are required (Archer, 1996).

   Amines react with carbon dioxide and water to form carbamic acid (NH_2COOH). Carbamic acid is itself unstable and highly reactive in water, but readily form members of the large family of chemicals known as 'carbamates' (Streitweiser and Heathcock, 1985).

   As noted above, it is listed as an Extremely Hazardous Substance under Superfund. Disposal must be in compliance with EPA Hazardous Substance regulations.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
Cyclohexylamine (CHA) functions on steam, not on the food. It is a poison by ingestion, skin contact, and intraperitoneal routes (Lewis, 1989).

   Most of the studies on the adverse health effects of CHA are based on its properties as a metabolite of the artificial sweeteners, the cyclamates (Bopp, Sonders, and Kesterson, 1985). Sodium cyclamate directly metabolizes into CHA in all mammalian species (NRC, 1985). The rate and frequency of this conversion is a matter of scientific debate (Bopp, Sonders, and Kesterson, 1985). The FDA banned cyclamates in 1970 under the Delaney clause because it was suspected of being a carcinogen (35 *Fed. Reg.* 13644). Cyclamates in combination with saccharin and cyclohexylamine were reported to cause bladder cancer in rodents (Bryan, G.T. and E. Erturk, 1970; Price et al., 1970). Subsequent studies have failed to replicate these earlier findings (for example, Gaunt, et al., 1976; Hardy, et al., 1976). The National Research Council also concluded that there was no clear evidence that cyclamates or cyclohexylamine cause cancer (NRC, 1985).

   These studies consistently recognize and note that CHA is 20 to 50 times more toxic than cyclamates, that CHA is more biologically active than cyclamates, and that CHA consistently shows other adverse health effects not exhibited by cyclamates. A comprehensive review of the studies and a summary of the findings is contained in Bopp, Sonders, and Kesterson (1985). That review concludes that neither cyclamates nor cyclohexylamine are carcinogenic or teratogenic. More recent sources report that cyclohexylamine may be mutagenic to animal models (Patnaik, 1992) and there is evidence that it is a human mutagen (Lewis, 1989). In a number of studies, the adverse health effects of CHA were conceded, and the researchers questioned the frequency of conversion of cyclamate to CHA. In particular, studies consistently show that CHA causes testicular atrophy in test animals (Bopp, Sonders, and Kesterson, 1985; Patnaik, 1992).

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
The primary use is to prevent corrosion of boiler and steam line equipment. It does not serve as a preservative, or to recreate/improve flavors, colors, textures, or nutritive value lost during processing. The use is not intended to have any technical or functional affect on the food product. The material comes into direct contact with organic foods though, which is the reason for the petition.

5. *Is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
The FDA does not classify cyclohexylamine as Generally Recognized as Safe (GRAS). The FDA sets a threshold for its use in steam is not to exceed 10 parts per million (ppm), and excludes use in milk and milk products (21 CFR 173.310). CHA is on the FDA Priority-Based Assessment of Food Additives (PAFA) File (CFSAN, 1998). Cyclohexylamine does not contain any heavy metals.

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

Organic standards are precautionary when evaluating synthetic substances used in food. Volatile amines in general, and cyclohexylamine in particular, do not appear to be compatible with the principles of organic handling. They are synthetic, toxic, and are not necessary to produce any food. Given the environmental impacts of the manufacturing process and the adverse health effects from exposure, they do not fit within organic principles. Food processors generated and used steam for a long time without these chemicals. Many organic food processors have already adopted viable and practical ways to address corrosion. The reviewers also comment on the availability of alternatives.

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.* Again, culinary steam can be produced without the use of this chemical. See the Steam Paper and the reviewers' comments for further discussion.

TAP Reviewer Discussion*

Reviewer 1 *[Food Science and Nutrition Professor with inspection and certification experience]*
Cyclohexylamine is a neutralizing amine which acts as an azeotrope to neutralize carbonic acid produced from dissolved CO_2 in the steam which reacts with water to form the carbonic acid as the corrosive agent. It is widely used as a volatile amine type boiler additive for both its effectiveness and generally low cost . . . It has an acute oral toxicity of LD_{50} of 360 mg/kg ranking it the most toxic of cycloaliphatic amines. It is also used in the manufacture and synthesis of Siduron, a crab grass and weed control agent.

Cyclohexylamine is a major metabolite of cyclamate, a class of artificial sweeteners that was banned by the FDA. Acute LD_{50} values are 20 to 50 times lower than those of cyclamate meaning 20 to 50 times as toxic as cyclamates. The literature is replete with studies showing the toxicity of cyclohexylamine and further studies . . . have failed to confirm earlier findings. Therefore toxicity of cyclohexylamine remains controversial.

. . . *[C]*yclohexylamine is synthetic . . . manufactured from highly toxic aniline. Overall because of its potential toxicity the FDA has not approved its use as GRAS and has set a threshold for its use in steam at 10 ppm. It cannot be used in milk and dairy processing where there is direct contact with milk.

Use of cyclohexylamine on the basis of all the adverse health information provided in the scientific literature is not consistent with organic principles and practices. Its use, either by itself or with other neutralizing volatile amines, is based on its anti-corrosion properties as a boiler additive. There are many other means of reduction of steam and boiler corrosion such as boiler feed water treatments and/or installation of stainless steel steam lines. . .

Therefore on the basis of its synthetic properties, non-GRAS status, controversial worker safety and health issues I recommend that use of cyclohexylamine as a boiler additive be prohibited for all organic process operations where there is direct steam contact with food. I feel the food processing industry has a significant number of alternatives to insure steam and boiler integrity *[as well as]* energy efficiency as outlined in previous discussions.

Advised Recommendations to the NOSB
Synthetic
Prohibited
Suggested annotation: prohibited for processing operations where there is direct steam to food contact.

**OMRI's information is enclosed in square brackets in italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are edited for identifying comments, redundant statements, and typographical errors. Any text removed is identified by ellipses [. . .] Statements expressed by reviewers are their own, and do not reflect the opinions of any other individual or organization.*

Reviewer 2 *[Consultant to organic certifiers]*
Cyclohexylamine is a synthetic material. . . An equivalent substance cannot be produced from a natural source and has no substitutes that are organic ingredients. . . Cyclohexylamine is derived from aniline, which itself is highly poisonous, derived from a number of sources. Alternatively, synthesis of cyclohexylamine from cyclohexanone (see above) relies on benzene as a reaction component, and therefore also involves highly toxic materials (Budavari, 1996). . . Cyclohexylamine is heavier than air and can travel a considerable distance to a source of ignition and flash back. Its vapors form explosive mixtures with air. Vigorous reactions may occur when the amine is mixed with strong acids or oxidizers (Patnaik, 1992). . . *[C]*yclohexylamine raises significant concerns regarding its toxicological affects on humans, animals, and the environment.

The reaction of this synthetic material with organic foodstuffs may create a variety of synthetic by-products, the health implications of which are not completely known, especially over the long-term. There is no indication that addition of cyclohexylamine to the processing stream has a beneficial affect on the nutritional quality of food.

Historically, NOSB recommendations have been against the contact of any synthetic boiler additives with organic foods. All organic production and processing standards are in agreement that toxic substances should not contaminate organic foods. Organic certifiers in the United States, if they take a position at all on this issue, are consistent in repeating the prohibition recommended by the NOSB. . .

Many studies have provided assessments of the toxicity of cyclohexylamine, as a corollary to investigations made on the affect of cyclamates on mammalian species. [*The studies that show that c]*yclamates . . . could be metabolized to cyclohexylamine. Cyclohexylamine was in turn discovered to be considerably more toxic than cyclamate, the acute LD_{50} values being 20 to 50 times lower than for cyclamates, and that cyclohexylamine may be a carcinogen (Bopp, et. al, 1985). While the studies undertaken have not produced absolutely consistent results, and the carcinogenicity has not been fully reproducible, the risk involved with ingestion of cyclohexylamine (and cyclamates) remains a serious concern. . .

Live steam can be and is produced in many processing systems without the use of any boiler additives that carry over onto the food products. Boiler water can be treated in advance of use in the system by a variety of methods to soften, deionize, filter, and otherwise purify it. These steps reduce the need for addition of synthetic materials not on the National List to the boiler system. In some applications, the steam or heating system for the food may be changed to one where live steam is not the active agent, but rather heating (of food contents directly, or of steam in contact with food) is done via a heat exchange system. The wide variety and individuality of processing systems which exist is indicative of the many ways in which the full range of processed food products can be made, without the need for toxic boiler additives to be used in contact with organic foods. This reviewer does not know of any food product type that absolutely requires cyclohexylamine in steam which contacts organic food.

Justification of use of cyclohexylamine by the petitioners is based on the constraints of their particular boiler and steam systems as they currently exist, and on the financial and/or logistical challenges involved with changing those systems so as to avoid contact of the organic food by the cyclohexylamine. However, economic considerations are clearly not one of the criteria (either in OFPA or the final NOP rule) for determining the suitability of materials used in organic production systems.

History shows that quite often it has been the case that an organic operator (producer or handler) has had to make substantial changes to their system in order to be compliant with organic standards. These changes often involved redesigning of systems, practices, and techniques. In many cases, such changes resulted in the need for financial investment, as well as an investment in time. Some creativity on the part of the operator was often needed, to devise a new system. This has indeed been the case for certain processors, who made adjustments to their boiler systems or manufacturing practices in order to comply with the prohibition of contact of organic foodstuffs by synthetic boiler chemicals. The inconvenience of having to retool or readjust systems should not be the determining factor in whether or not such materials are added to the National List.

For certain processors, where organic processing events are not frequent, the boiler may be operated without the cyclohexylamine for a limited time, without significant affect on the boiler or steam line system. For these operations, no retooling may be needed; instead, a procedure can be designed whereby it is verifiable that the volatile boiler chemical has been exhausted from the system prior to handling the organic goods.

For processors who intend to process frequently enough, or for long enough run times, redesigning of the system will be necessary, in one way or another. Prohibition on the use of volatile boiler chemicals can exist without consigning

processors to premature deterioration of their equipment. It is often the case in industry that the creative process involved in redesigning systems has unpredicted benefits (short- and long-term) to the operator and the environment, in terms of long-tern cost-effectiveness and sustainability; efforts in this direction should be encouraged, especially if not doing so results in a compromise of organic principles.

In fact, running boiler equipment designed for use with synthetic additives without the additives in place does lead to deterioration, and consequent lower efficiency of the system, which generally means greater energy consumption (Kohan, 1997). While greater efficiency of energy consumption seems undoubtedly to be desirable (both economically and ecologically), energy balance as a whole has not been considered as factor by the NOSB or certifiers when making determinations on the compatibility or allowability of materials or methods. To use such a factor as a criterion in the case for the volatile boiler additive is therefore inconsistent with the rest of the paradigm, and should not be a determining factor at this time.

Advised Recommendations to the NOSB
Cyclohexylamine should be deemed a synthetic, prohibited material, and not be added to the National List for any purpose.

Reviewer 3 *[University staff in Food Science with inspection, consulting, and certification experience]*
Cyclohexylamine (CHA) is petitioned for use as a steam additive chemical to reduce corrosion in pipes. There could be direct food contact in many processing operations when steam is used to cook or heat food, such as in a blancher, cooker, canner, or other operations. CHA has no functionality toward the food.

In the petition, page C-3 has the structure incorrect. There is no oxygen in the ring, it's a CH_2 group. . .

Response to Criteria
CHA is on the EPA List of Extremely Hazardous Substances. This would make its use of serious concern to the organic industry.

There is mixed information about this. Sodium cyclamate (from which CHA is a metabolite) was once approved as an artificial sweetener, but subsequent studies which pointed to its carcinogenesis caused it to be banned in the US. Subsequent studies seem to indicate that it isn't carcinogenic, but it has retained its banned status in the US. In spite of cyclamate's use as a sweetener, it is still categorized as an Extremely Hazardous Substance by EPA based on its irritation and fire hazards. With this mixed message, there is sufficient evidence of potential adverse effects that precautionary action does not warrant allowing its use. . .

The justification for use of CHA is no different than trying to justify the use of a synthetic herbicide like Round-Up for organic farming, just because it provides a cheaper alternative to weed control and does not leave any detectable residue. Organic handling isn't about economics or end product testing, it's the process that's critical when evaluating compatibility with organic principles. Food processors generated and used steam for a long time without these chemicals. Many organic food processors have already adopted viable and practical ways to address corrosion without the use of CHA.

There are other solutions that could be used to produce the desired result (no corrosion of piping). To summarize many of the citations reviewed, 'use of stainless steel piping completely solves the problem of corrosion.' The justification statement in the petition and the alternative control methods do not mention this as a possible solution. They do mention the costs of capital equipment and provide anecdotal evidence of the life expectancy and replacement needs should boiler water additives not be used, but provide no data to support this. There are numerous tests that can and should be performed periodically to determine the corrosion rates, (even with the use of inhibitors) to insure that equipment is being operated and maintained in a safe and efficient manner. Without confirming studies to show the differences in corrosion rates with and without the use of corrosion inhibitors, it appears that these petitioners are using anecdotal evidence to justify their continued use of cheap toxic chemicals instead of more expensive, but viable alternatives. There are several cited alternatives: stainless steel piping (suitable for all operations); discontinued use during organic processing (suitable for some operations); steam to steam heat exchanger (suitable for some operations); secondary boiler for food contact application only (suitable for all operations) that could be used. None of these are necessarily cheap, but all offer a viable alternative to the use of toxic chemicals

Advised Recommendations to the NOSB
CHA should not be approved for use as a boiler chemical for organic production.

Conclusion

The reviewers unanimously consider cyclohexylamine to be synthetic, and unanimously advise the NOSB to not add it to the National List. Use should remain prohibited in organic handling.

References

See the Steam Paper.