PETITION

To the
U.S. Department of Agriculture
National Organic Program

To Amend 7 CFR §205.605(b)
To Include Taurine
As A Synthetic Substance Allowed
For Use in Organic Pet Food Production

Submitted September 2, 2010

Confidential Business Information Removed from this Copy

By
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September 2, 2010

Miles McEvoy
Deputy Administrator
USDA/AMS/TMP/NOP
1400 Independence Ave., S.W.
Room 2646-S
Ag Stop 0268
Washington, D.C. 20250-0201

Dear Mr. McEvoy,

The Pet Food Institute (PFI), a trade association comprised of pet product manufacturers and distributors in the United States, formally submits this petition to the U.S. Department of Agriculture's National Organic Program to request the amendment of §205.605(b) of the National Organic Standards to include taurine as a synthetic substance allowed for use in organic pet food production.

In accordance with the instructions on the National Organic Program website, we have provided answers to all of the questions below, and in a manner that satisfies the criteria in 7 USC 6517 and 6518, commonly known as the Organic Foods Production Act.

We, of course, are ready to provide any additional information that you, the National Organic Standards Board, or the Technical Advisory Panels may require to complete your review process.

Sincerely,

Nancy Cook
Pet Food Institute

Contents

Petition Information

Overview and Introduction

The U.S. Department of Agriculture's National Organic Standards recognized from the outset that vitamins, minerals and other required nutrients are essential in formulating certified organic products that will meet the nutritional requirements of humans and animals.

Specifically, §205.603(d)(2) and §205.603(d)(3) allow trace minerals and vitamins to be utilized in livestock for enrichment or fortification when FDA approved. Similarly, §205.605(b) allows food products labeled as "organic" or "made with organic" to contain nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Guidelines for Foods. Those nutrients are allowed for use in livestock feed and human food regardless of the method of manufacturing or handling.

Under the current regulations, pet food products seeking certification under the USDA Organic Standards must be produced in accordance with §205.605 and §205.606 of the National Organic Standards. Certain nutrients required by cats and/or dogs are not included in §205.605, §205.606, and are not referenced in 21 CFR 104.20(b).

On November 3, 2006, the USDA National Organic Program Notified Accredited Certifiers that they could allow additional nutrients to be utilized in products certified as "organic" or "made with organic" in accordance with 21 CFR 104.20(f). On April 26, 2010, the Deputy Administrator of the National Organic Program clarified the agency's interpretation, and announced that nutrient vitamins and minerals would only be allowed in products certified as "organic" or "made with organic" if those nutrients were allowed under CFR 104.20(b), or if those nutrients were listed under §205.605 or §205.606 of the national organic Standards.

Without the inclusion of those nutrients, however, pet foods cannot be labeled as *Complete and Balanced* under the model regulations developed by the Association of American Food Control Officials (AAFCO). These standards were developed in accordance with the National Research Council's (NRC) *Nutrient Requirements of Cats and Dogs* which represents the prevailing body of nutritional information and authority for these species.

Certain nutrients have been recognized by the National Research Council as required for inclusion in complete and balanced diets for cats and dogs. Hereafter those nutrients will be discussed as "required."

Inclusion of taurine in complete and balanced formulas is vital for pets because those formulas serve as the sole-source of nutrition for the pets. Unlike humans—who obtain our daily nutritional requirements from a variety of food consumed throughout the day—

pets obtain their entire nutritional requirements from that daily bowl of kibble or canned food.

Accordingly, this petition request approval for the use of taurine in commercially produced bet food products.

1. The substance's common name

Common Name: taurine
Chemical Name: 2-aminoethanesulfonic acid
Chemical Formula: $C_2H_7NO_3S$
Synonyms:
1-Aminoethane-2-sulfonic acid
2-Aminoethanesulfonic acid
2-Aminoethansulfonic acid
2-Aminoethylsulfonic acid
2-Sulfoethylamine
Ethanesulfonic acid, 2-amino-
NSC 32428
O-Due
Taufon
Taukard
Tauphon
Taurin
taurina
Taurine
β-Aminoethanesulfonic acid
β-Aminoethylsulfonic acid

As noted above, this substance has several synonyms. The term, "Taurine" will be used throughout this petition to refer to all forms of this material.

2. The official name, address, and telephone number for Pet Food Institute:

Pet Food Institute
2025 M St., NW
Suite 800
Washington, D.C. 20036
Tel: 202 367-1120
Fax: 202 367-1120
Website: www.petfood institute.org

Contact Persons: Dave Carter, de.carter@comcast.net
Nancy Cook, nancy@petfoodinstitute.org

3. The intended or current use of the substance:

Taurine will be included as a required nutrient in complete and balanced cat food formulations, and as a recommended nutrient in complete and balanced dog food formulations. It is being petitioned for use as a synthetic allowed substance under §205.605(b) of the National Organic Standards.

4. A list of activities for which the substance will be used – mode of action

Activities

Taurine is commonly discussed with the amino acids, but since it does not contain a carboxyl group it is in fact a β-amino sulfone. This amino sulfone is commonly found in animal tissues and proteins, but not vegetable source proteins. In the feline diet, taurine is a required nutrient. Although taurine is not classified as essential nutrient in complete and balanced dog foods by AAFCO (2006), scientific evidence exists that insufficient dietary taurine or its precursors in the diet can result in deficiencies with certain breeds, such as American Cocker Spaniels and Newfoundlands. Most breeds of dogs are able to produce adequate taurine from the sulfur amino acids methionine and cysteine; but, due to inconsistencies in ingredient composition and processing fortification with taurine is common.

Accordingly, taurine will be used as an ingredient in the following products to be manufactured as "organic" or "made with organic:"

- Wet cat food formulations labeled as complete and balanced for adult maintenance, and for growth and reproduction;
- Semi-moist cat food formulations labeled as complete and balanced for adult maintenance, and for growth and reproduction;
- Dry cat food formulations labeled as complete and balanced for adult maintenance, and for growth and reproduction;
- Wet dog food formulations labeled as complete and balanced for adult maintenance, and for growth and reproduction;Semi-moist dog food formulations labeled as complete and balanced for adult maintenance, and for growth and reproduction;
- Dry dog food formulations labeled as complete and balanced for adult maintenance, and for growth and reproduction; and
- Pet Treats.

Mode of Action

Taurine serves three primary functions in the body: 1) conjugate bile, 2) myocardium maintenance, and 3) retinal health. Dogs and cats conjugate bile exclusively with taurine and this represents a substantial sink for it's turnover. A deficiency of taurine results in dilated cardiomyopathy, and blindness in dogs and cats, respectively. Taurine is also involved in conjugation with a number of compounds to increase their hydrophilic properties for excretion. (National Research Council, 2006)

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.

Source:

Taurine was first isolated from ox bile in 1827 by German scientists Fredrich Tiedemann and Leopold Gmelin. The name, taurine, is a derivative of the Latin term, taurus.

Taurine occurs naturally in food, especially in seafood and meat, and it is a normal metabolite in humans. It is a metabolic product of sulphur-containing amino acids, and it is mainly biosynthesized from cysteine in the liver (SCF, 1999).

Today, a small amount taurine is still derived from bovine and ovine sources. This natural taurine, however, is essentially a by-product from the production of cholic acid, deoxycholic acid and other bile acids, and is therefore available in extremely limited supplies. New Zealand Pharmaceuticals, Ltd., for example, produces 800 tons of bile acids each year from oxen, cattle and sheep bile. Of that amount, only 20 tons consists of taurine for all markets.

Most taurine today is synthesized from methionine, Vitamin E and cysteine.

Manufacturing Process:

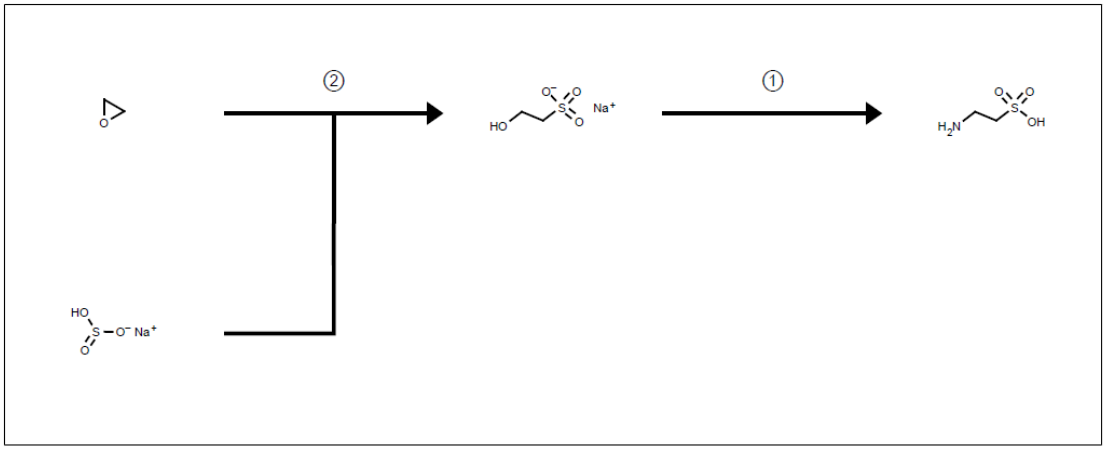
Synthetic taurine is produce in several methods. It is manufactured by several companies around the world. Here is a sample of the types of starting compounds used in various methods deployed for the syntheses of taurine.

Method One:

This method combines methionine, vitamin E and cysteine. Methionine is a non polar sulfur-containing proteogenic amino acid. Vitamin E is a naturally occcuring fat-soluble molecule important for regular reproduction. Vitamin E also acts as an antioxidant that will neutralize free radicals in the body. Cysteine is a conditionally-essential amino acid that can be synthesized. Depending on the scale of production either of the amino acids or vitamin E might prove limiting based on their availability.

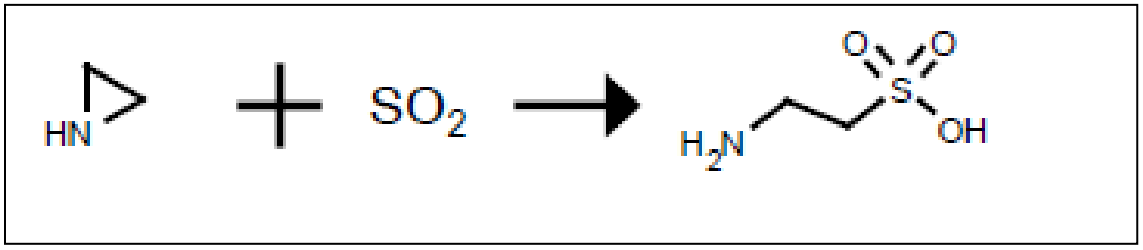
Method Two:

This method uses isethionic acid which results from the reaction of ethylene oxide and aqueous sodium bisulfite. Isethionic acid is an alkane sulfonic acid that contains a hydroxy group, and is often used in manufacturing high-foaming anionic surfactants. Ethylene oxide is a colorless gas, and contains one oxygen atom and two carbons. Aqueous sodium bisulfite is a chemical compound used as a food additive. This method is commercially viable; as all substrates are available in industrial quantities.



Method Three:

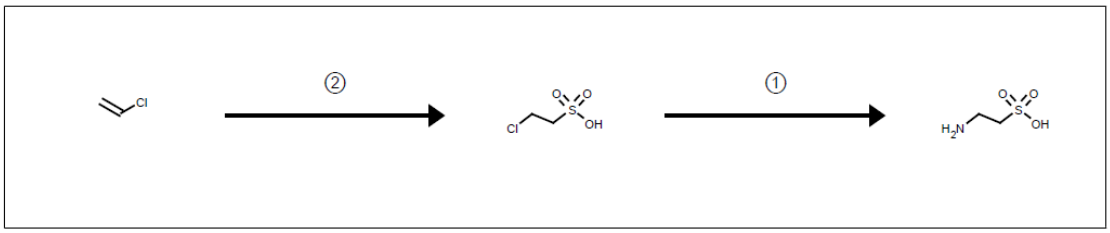
Taurine can also be synthesized through a reaction of sulfurous acid with aziridine. Sulfurous acid is a chemical compound that is detected in the gas phase. Aziridine is an organic compound that has three membered heterocyclic ring, one amine group and two methylene groups.

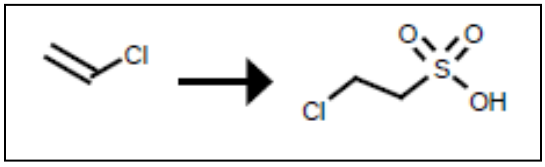


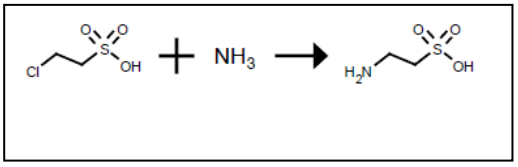
Method Four:

A fourth method is through sulfonation of ethylene chloride by sodium sulfite, followed by ammonolysis with either anhydrous ammonia or ammonium carbonate (Merck 2001).

Taurine is insoluble in the most common organic solvents, has a high melting point (ca. 328 ◦C) and temperature for decomposition (315 ◦C). Therefore, distillation to separate taurine from sodium sulfate containing mixtures is unrealistic. Moreover, simple recrystallization methods are impractical because the solubility of taurine in water is not sufficiently different from that of sodium sulfate. So far, the separation of taurine and sodium sulfate could be achieved through two methods: (1) reiterative recrystallization in water; and (2) reiterative electrodialysis. These two methods suffer from relatively low taurine yield (less than 75%), high energy consumption and complicated operations.

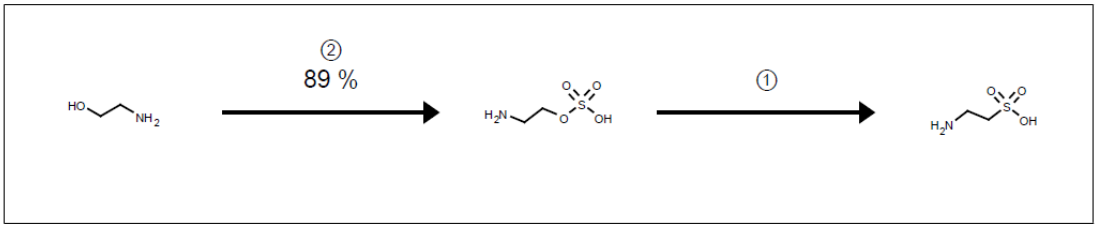




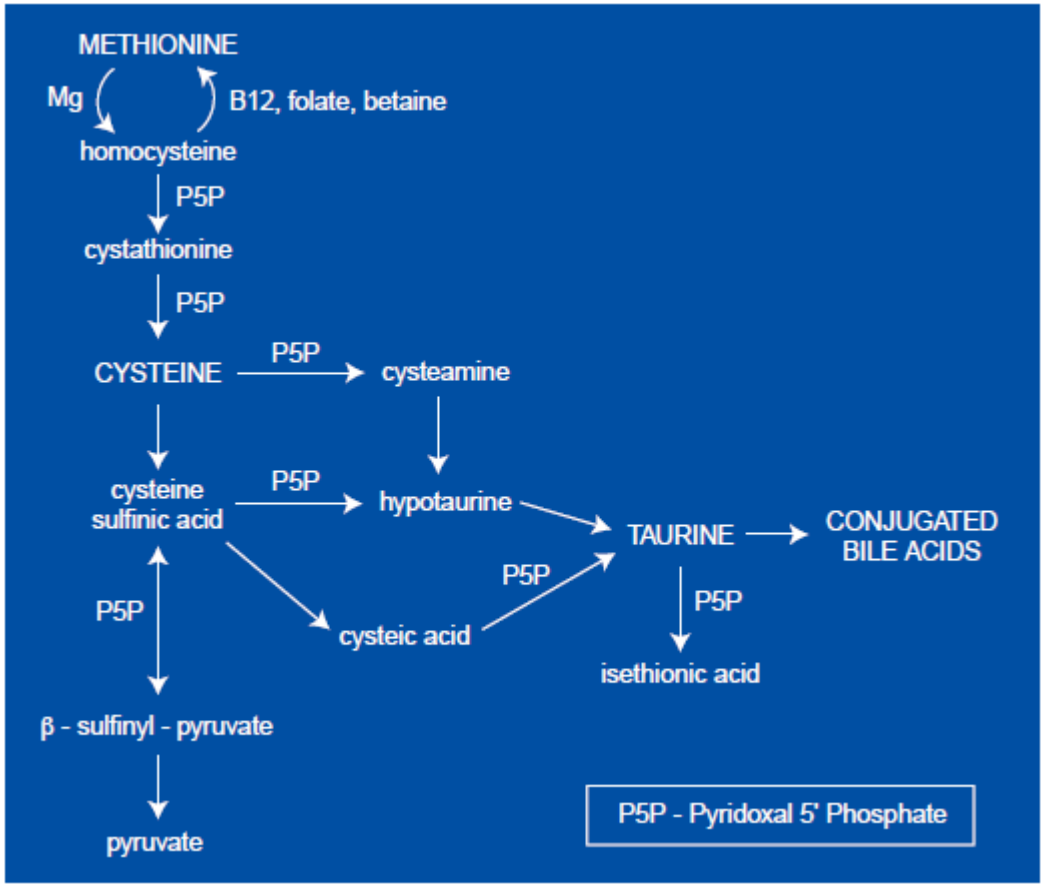


Method Five:

Finally, an alternate approach is salt formation with sulfuric acid and monoethanolamine followed by reduction with sodium carbonate and sodium sulfite. The resulting taurine is almost pure with a concentration commonly exceeding 98.5%.



The chart below illustrates a typical commercial process for synthesizing taurine.



Commercial Suppliers:

Taurine is among the bile acids that are relatively easy to synthesize industrially, and is therefore available from a multitude of manufacturers. One industry supply website, www.alibaba.com, contains listings for 1,085 synthetic taurine manufacturers.

Four individual manufacturers have provided information utilized in the preparation of this petition:

Qianjiang Yongan Pharmaceutical Co., LTD
No. 16 Zhuze Road
Qianjiang, China
Tel: + 86-728-6202727/6201636
Fax: +86-728-6202797
E-mail: yasales@chinataurine.com
Website: www.chinataurine.com

Changshu Yudong Chemical Company
Wangshi Haiyu Town
Changshu City

Jungshu Province, China PC 215519
Tel +86-512-52565808
Fax +86-512-52561808
E-mail: yonglida@public1.sz.js.cn
Website: www.yudongchem.com

Zone Industrielle Grasbesch
L-3370 Leudelange
G.D. de Lusombourg
Tel: +352-49-89-770
Fax: +352-49-89-771
Email: sales@taurinepffg.com
Website: www.taurinepffg.com

New Zealand Pharmaceuticals Ltd.
Po Box 1869, Palmerston North, 4440,
New Zealand
+64 6 9523840
market@nzp.co.nz
www.nzp.co.nz

The manufacturing processes provided by these companies is included in Attachment A, Confidential Business Information.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance

Taurine has not been previously petitioned, but has been allowed for use in pet food products certified as "organic", or" made with organic," since October 2002.

Following the 2004 directive by NOP that pet food products could be certified under 7 CFR § 205.605 and §205.606, certifiers have relied upon the guidance from the NOP regarding the use of taurine and other required nutrients for pet food products. In November 2006, the NOP issued a notice in response to a complaint, reading, in part:

> *"The complaint that resulted in the opening of this case questioned the use of the nutrients docosahexenoic acid (DHA) and arachidonic acid (ARA) in an organic (redacted). The resulting investigation led to questions concerning the use of the nutrients nucleotices and taurine. FDA permits the use of all four in (redacted). Accordingly, provided the nutrients in question are in full compliance with FDA*

rules and regulations, they would comply with the NOP National List as currently written." (underlines added)

Certifiers have relied upon this guidance as approval for allowing the use of taurine in pet food products certified as "organic" and "made with organic."

In addition, the NOSB in November 2008 unanimously adopted a recommendation regarding changes in the organic regulations to support labeling of organic pet food. An appendix to that report specifically lists taurine as a material suitable for petition for addition to the National List.

In February, 2010, Taurine was included among the materials reviewed in the TAP Report "Overview of Accessory/Voluntary Nutrients," which was prepared for the National Organic Program and the National Organic Standards Board by the Cornucopia Institute, a consumer advocacy organization. The Cornucopia Institute reviewed these materials exclusively from the standpoint of their utilization in human foods, and did not include an analysis of taurine as a nutrient in pet food. This is significant because taurine is a required nutrient for cats, and not an accessory nutrient.

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers

U.S. Environmental Protection Agency (EPA)

The U.S. Environmental Protection Agency does not regulate taurine. The material is not listed on the EPA List 4 list of inert pesticide ingredients. Some pesticides include taurine compounds as inert ingredients. N-methyl taurine (CAS No. 107-68-6)

A complete EPA Substance Registry Sheet is included with this petition as Attachment C.

U.S. Food and Drug Administration (FDA)

21 CFR 205.605(b) specifies that nutrient vitamin and minerals are allowed in accordance with 21 CFR 104.20. Taurine is not included in 21 CFR 104.20(d)(3) (―Food for Human Consumption‖).

Taurine is used as food additives permitted in feed and drinking water of animals. The following is quoted from 21 CFR 573.980:

> The food additive taurine (2-amino-ethanesulfonic acid) may be safely used in feed in accordance with the following prescribed conditions:
>
> (a) It is used as a nutritional supplement in the feed of growing chickens.
> (b) It is added to complete feeds so that the total taurine content does not exceed 0.054 percent of the feed.

While FDA does not specifically regulate the use of taurine as a pet food ingredient, the agency's website contains advice to consumers regarding "Selecting Nutritious Pet Food." The article on that website references the American Association of Feed Control Officials model regulations that require a minimum of 0.10% taurine in extruded cat food formulations, and a minimum of 0.20% in canned cat food formulations.

Taurine compounds are also used as ―Substances for Use only as Components of Paper and Paperboard., *N* -methyl- *N* -(tall oil acyl) taurine, sodium salt (CAS Reg. No. 61791–41–1) is used as ―Components of paper and paperboard in contact with aqueous and fatty foods.‖ (21 CFR 176.170). Methyl taurine-oleic acid condensate (molecular weight 486) is used as ―Defoaming agents used in the manufacture of paper and paperboard.‖ (21 CFR 176.210).

U.S. Department of Agriculture (USDA)

Taurine is not specifically regulated by USDA

Clean Air Act

Taurine does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.

Clean Water Act

Taurine is not listed as Hazardous Substances under the CWA, nor is it listed as Priority or Toxic Pollutants under the CWA.

OSHA

Taurine is not considered highly hazardous by OSHA.

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance

CAS Number: **107-35-7**

ACX Registry Number: X1007629-4

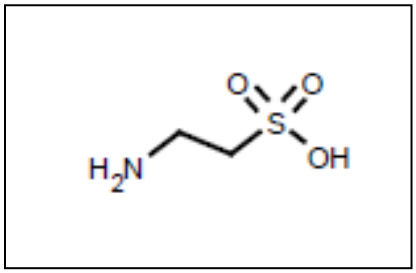
9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d)

effects on human health; and, (e) effects on soil organisms, crops, or livestock.

Physical Properties

Synthetic or crystalline taurine is a white, crystalline powder freely soluble in water.

Molecular Formula: $C_2H_7NO_3S$, structured as: NH_2-CH_2-CH_2-SO_3H



Molecular Weight: 125.146880 [g/mol]

Melting Point: 305-310

Characteristics

Pure white needle crystal, odorless, chemically stable, soluble in water and insoluble in ethanol, ether and other organic solvents.

Taurine is a β-aminosulfonic acid (2-aminoethanesulfonic acid), an essential dietary nutrient for cats. It is considered by the National Research Council as dispensable for dogs fed adequate quantities of sulfur-containing amino acids (National research Council 2006), However, some independent research over the past five years has documented the occurrence of health issues in some breeds of dogs, including American Cocker Spaniel and Newfoundlands, related to taurine deficiency. (Cavaghan, 2008)

Taurine occurs naturally in food, especially in seafood and meat, and it is a normal metabolite in humans. It is a metabolic product of sulphur-containing amino acids, and it is mainly biosynthesized from cysteine in the liver (SCF, 1999).

Mammalian taurine synthesis occurs in the pancreas via the cysteine sulfinic acid pathway. In this pathway, the sulfhydryl group of cysteine is first oxidized to cysteine sulfinic acid by the enzyme cysteine dioxygenase. Cysteine sulfinic acid, in turn, is decarboxylated by sulfinoalanine decarboxylase to form hypotaurine. It is unclear whether hypotaurine is then spontaneously or enzymatically oxidized to yield taurine.

Taurine differs structurally from other amino acids in that a sulfonic acid group (SOOH) replaces the customary carboxylic acid (COOH) group; thus imparting different properties to this β-sulfonic amino acid. It is concentrated in the myocardium, retina and neutrophils. Taurine, while not oxidized for fuel by mammals, has numerous functions including bile acid conjugation, osmotic regulation, cell membrane stabilization, modulation of cellular calcium flux, neuronal excitability modulation, metabolic antioxidant capacity and xenobiotic elimination.

Synthesis of taurine occurs in the liver from cysteine and methionine and is dependent upon vitamin B6 (pyridoxal-5-phosphate) as a co-enzyme. Two key enzymes in taurine synthesis are cysteine dioxygenase and cysteine sulphinic acid decarboxylase which are responsible for the conversion of cysteine to cysteine sulphinic acid and hypotaurine, respectively. The activity of these two enzymes is very low in the cat, but adequate in the dog. Further, the cat and dog cannot conjugate bile acids with glycine; rather, taurine is used exclusively. Thus, a constant dietary supply of taurine or its precursors is necessary because of this substantial turnover or drain on taurine stores. (Aldrich, 2008)

Chemical Mode of Action

The major reaction of taurine is its conjugation with bile acids in the liver. It is also involved in conjugation with a number of compounds to increase their hydrophilic properties for excretion.

Since taurine does not contain a carboxyl and is a β-amino acid, it is not found in vegetable proteins and is made in most animal species from cysteine. (National Research Council, 2006)

Chemical interactions with other substances, especially substances used in organic production;

Taurine dust is potentially explosive if exposed to heat or ignition sources Because of the nature of use of this material the risk of explosion is extremely low.

Taurine may evolve toxic gases (carbon oxides and hydrocarbons) if heated to decomposition. It may also evolve sulphur oxides and nitrogen oxides when heated to decomposition.

Taurine is incompatible with oxidizing agents (eg. peroxides) and acids (eg. hydrochloric acid).

Toxicity and environmental persistence

Taurine is insoluble in the most common organic solvents, and its temperature of melting point (ca. 328 ◦C) and decomposition (315 ◦C) are very close. (Gu, 2003)

Taurine is Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, or OSHA. Extremely high amounts may cause toxicity, which could lead to diarrhea, depression, short-term memory loss, and ulcers.

In the manufacturing process, adverse health effects are not anticipated under normal conditions. This product is generally considered to be of low toxicity, however over exposure to any dust should be avoided. Over exposure via inhalation at high levels may

result in mucous membrane irritation of the nose and throat with coughing. Ingestion may result in gastrointestinal irritation, however due to product form, ingestion is considered highly unlikely.

According to the National Research Council's Nutrient Requirements of Dogs and Cats "No reports could be found on acute or chronic toxicity related to feeding large quantities of free taurine to dogs (National Research Council, 2006)

Environmental impacts from its use or manufacture;

Use:

There is no significant detrimental environmental impact from the use of taurine.

Manufacture

The primary consideration is the impact of the chemicals utilized to synthesize taurine. The following chemicals are utilized in one or more of the synthesis methods described in Section 5: Manufacturing Process:

Ammonium hydroxide is a nonsynthetic material, and is corrosive.

Aziridine is highly flammable and is a severe irritant, causing burns, and death. The occupational exposure limit is set at 0.5 ppm; 0.88 mg/m3 (skin) (ACGIH 1993-1994).

Ethylene chloride poses an environmental threat upon release; it is regulated by the EPA.

Ethylene oxide is relatively stable to heating—in the absence of a catalyst, it does not dissociate up to 300°C, and only above 570°C there is a major exothermic decomposition, which proceeds through the radical processes. They result in a gas mixture containing acetaldehyde, ethane, ethyl, methane, hydrogen, carbon dioxide, ketene and formaldehyde.

Isethionic acid is found naturally and poses no hazards.

Methionine, vitamin E, and cysteine are all naturally occurring substances and thus should pose no significant threat to the environment or human health,

Monoethanolamine does not pose a significant environmental threat.

Sulfuric acid is corrosive but poses no environmental risk

Sulfurous acid is hazardous, though in the liquid form and managed should pose no significant environmental threat.

Effects on human health

In 1975 the significance of taurine in human nutrition was identified, when it was discovered that formula-fed, pre-term infants were not able to sustain normal plasma or urinary taurine levels. (Raiha, 1975)

Taurine is the most abundant free *(not protein bound)* amino acid, which is needed in human organs including heart, brain and liver, and is involved in a number of crucial physiological processes. Recently taurine is considered to play an important role during fetal life and appears to be vital for the growth of fetus in general and for development of central nervous system of fetus in particular. Therefore, it was widely used as food additive in daily food industry. (Gu 2003)

Taurine is beneficial to human health. Taurine has been shown to be essential in certain aspects of mammalian development, and *in vitro* studies in various species have demonstrated that low levels of taurine are associated with various pathological lesions, including cardiomyopathy, retinal degeneration, and growth retardation, especially if deficiency occurs during development. Metabolic actions of taurine include: bile acid conjugation, detoxification, membrane stabilization, osmoregulation, and modulation of cellular calcium levels. Clinically, taurine has been used with varying degrees of success in the treatment of a wide variety of conditions, including: cardiovascular diseases, hypercholesterolemia, epilepsy and other seizure disorders, macular degeneration, Alzheimer's disease, hepatic disorders, alcoholism, and cystic fibrosis. (Alt Med Rev 1998;)

Several recent studies have been conducted on the effect of Taurine on human health, particularly because if its growing popularity as an ingredient in commercially-marketed energy drinks. One recent study was conducted by the European Food Safety Authority (EFSA).

Human studies showed significant increases in plasma taurine 90 minutes after consumption of a taurine-rich meal with levels declining to background within 180-270 minutes (Trautwein and Hayes, 1995). The SCF indicates that these results also corroborate those from an unpublished human study using radiolabelled taurine, which showed peak serum levels at 1-2 hours after oral administration, declining by 7 hours (SCF, 2003). Other human data suggest that taurine is absorbed orally via an active transport mechanism in the gut wall (Ahlman *et al.,* 1993; 1995a, b).

Results from one study on absorption, tissue distribution, metabolism and elimination of taurine given orally to rats were provided by the petitioner. In this study (Sved *et al.,* 2007) three biodisposition studies with taurine were performed in male and female adult rats at dosages of 30 and 300 mg/kg bw. A single dose of ^{14}C taurine was rapidly absorbed, distributed to tissues and excreted unchanged in the urine. Elimination of radioactivity from intracellular pools was slow. Pre-treatment of animals for 14 days with unlabelled taurine did not significantly affect the fate of ^{14}C taurine. Daily administration

of unlabelled taurine for 14 days did not result in an increase in total taurine in the brain. It was concluded that the data indicated that exogenous taurine rapidly equilibrates with endogenous body pools and that any excess is rapidly eliminated by the kidneys.

Based on these data which revealed that brain taurine levels did not increase after dosing, the study concluded that the possibility that taurine may exhibit acute, central pharmacological effects mediated by an action on the central nervous system was scientifically improbable. (EFSA)

In separate studies, taurine has been administered, mostly by oral ingestion on a daily basis for periods up to one year, and with daily doses generally in the 3-6 g range, to a large number of patients (adults, children and even infants) suffering from a wide variety of serious diseases. Taurine has also been administered parenterally at a daily dose of 0.64 g for 20 months or by intravenous administration at daily doses of 12 g for 15 days and 18 g for 60 days. Although the principal aim of these clinical studies was not to evaluate potential adverse effects of chronic administration of taurine it is apparent that these doses produced no adverse health effects. Such information has revealed that oral daily ingestion of taurine doses in the 3-6 g range for periods up to one year did not produce adverse health effects. (EFSA, 2009)

In other studies, it was found that diabetes mellitus (DM) is associated with taurine, and many *in vivo* experimental studies showed that taurine administration is able to reduce the alterations induced by DM in the retina, lens, and peripheral nerve, although its effects on diabetic kidney are dubious. (Franconi, Flava, et. al. 2004)

Effects on soil organisms, crops or livestock

Soil Organisms

One study conducted in 1970 by biologists at Rutgers University isolated streptomycetes and aerobic bacteria able to utilize cysteic acid and taurine as sole sources of energy, nitrogen and sulphur from soil materials. None of the isolated fungi did this. The bacterium which was used in most experiments grew on both compounds. The sulphur of the compounds was recovered as sulphate and most of the nitrogen as ammonia after breakdown by growing or pregrown organisms. A significant portion of the nitrogen was assimilated by the growing organisms. Sulphite appeared as a transitory sulphur product. Deamination preceded desulphuration in early periods of incubation; the reactions were brought about by adaptive enzyme systems.

Dissimilation of cysteic acid by pregrown organisms was maximum at reactions close to neutrality. During development of pregrown organisms at pH **8.5** and **9.0** appreciable amounts of sulphite were detected. Acid reactions which inhibited development of the cultures were produced during decomposition of taurine. (Stapley, 1970)

Table 1. *Breakdown of taurine and cysteic acid by mixed soil populations*

The culture media containing cysteic acid or taurine and inoculated with soil suspensions were tested for changes in reaction and sulphate production after incubation for 10 days.

Inoculum	Organic compound	pH values		Sulphate S, % of initial organic S
		Initial	Final	
Compost	Cysteic acid	4·0	3·7	7
Barnyard soil		4·0	4·5	1
Pine forest soil		4·0	3·5	8
Compost		7·0	6·5	93
Barnyard soil		7·0	6·7	4
Pine forest soil		7·0	6·6	1
Compost	Taurine	4·0	2·8	3
Barnyard soil		4·0	3·0	0
Pine forest soil		4·0	2·7	7
Compost		7·0	2·8	30
Barnyard soil		7·0	3·8	25
Pine forest soil		7·0	2·7	33

With complete breakdown of taurine by, agrobacterium species, most of the nitrogen and sulphur of the compounds was released as ammonia and inorganic sulphate (Ikeda ***et al.* 1963).**

Taurine is a natural part of animal manures, and is therefore a part of the natural ecosystem. Cattle manure contains the average content of taurine as a percent of the dry base:

Dairy:	0.06%
Beef	0.06%
Feedlot”	0.06%

For poultry, the percentage of taurine in manure dry matter is:

Chick Starter:	0.21%
Pullet Grower:	0.21%
17-40 weeks:	0.06%
Post-Molt	0.04%

For swine, the content of taurine in dry manure is:

Nursery:	0.08%
Grower:	0.06%
Finisher:	0.07%

(Chen, 2003)

Crops or Livestock

There is no known impact of taurine on crops or livestock.

In 1989, however, The United States Patent Office granted Patent No. 4,877,447 for a process of utilizing taurine to increase crop production. The patent covered a method of increasing the harvest of a crop which comprises applying an effective amount of taurine to the crop or its seeds, or a composition therefor. (U.S. Patent Office, 1989)

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.

The following Material Safety Data Sheets are included in Attachment B.

Sheet No. 1, Fischer Scientific
Sheet No. 2 Qianjiiang. Yongan Pharmadeutical co., Ltd.
Sheet No. 3 New Zealand Pharmaceuticals, Ltd.

The Food and Drug Administration (FDA) does not require a National Institute of Environmental Health Studies report for taurine. Therefore a NIEHS report has not been developed. The information contained in this petition under Section 9 covers the safety of human health and environment.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

A listing of relevant research information and literature concerning taurine is included as **Attachment C** with this petition.

12. A “Petition Justification Statement" which provides justification for inclusion of the substance on the National List. The petition should state why the synthetic substance is

necessary for the production of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.

Overview

The U.S. Department of Agriculture's National Organic Standards recognized from the outset that vitamins, minerals and other required nutrients are essential in formulating certified organic products that will meet the nutritional requirements of humans and animals.

Specifically, §205.603(d)(2) and §205.603(d)(3) allow trace minerals and vitamins to be utilized in livestock for enrichment or fortification when FDA approved. Similarly, §205.605(b) allows food products labeled as "organic" or "made with organic" to contain nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Guidelines for Foods. Those nutrients are allowed for use in livestock feed and human food regardless of the method of manufacturing or handling.

Under the current regulations, pet food products seeking certification under the USDA Organic Standards must be produced in accordance with §205.605 and §205.606 of the National Organic Standards. Certain nutrients required by cats and/or dogs are not included in §205.605, §205.606, and are not referenced in 21 CFR 104.20(b). Without the inclusion of those nutrients, however, commercially-produced pet foods cannot be labeled as *Complete and Balanced* under the model regulations developed by the Association of American Food Control Officials in accordance with the National Research Council's *Nutritive Requirements of Cats and Dogs*.

For adult cats, the National Research Council lists 0.0079 kg. of taurine as the minimal nutritional requirement per kilogram of the animal's body weight. The National Research Council specifies that the recommended allowance of taurine for adult cats is 0.0099 kg. per kilogram of body weight. For kittens, the National Research Council lists 0.017 kg. of taurine as the minimum requirement per kilogram of bodyweight, and specifies a recommended allowance of 0.33 kg. of taurine per kilogram of body weight.

Taurine is involved in dog and cat fetal development, growth, reproduction, neuro-modulation, sight, hearing, heart function, immune response, antioxidation, and bile acid and xenobiotic conjugation and acts as an anticonvulsant (Huxtable, 1992).

In cats, taurine deficiency results in feline central retinal degeneration (FCRD) and blindness; dilated cardiomyopahy and heart failure; inadequate immune response; poor neonatal growth; reduced auditory brain stem evoked potentials resulting in deafness; poor reproduction resulting in a low number of fetuses, resorptions, abortions, decreased birth weight, and low survival rate of kittens; and congenital defects including hydrocephalus and anencephaly. (National Research Council, 2006)

Taurine is an essential nutrient of cats because the state of taurine synthesis from its dietary sulfur amino acid precursors, cysteine and methionine, is much less than the extent of loss through fecal bile acids and urine. (Knopf et al., 1978)

In cats, inadequate provision of dietary taurine clearly results in deficiency. A deficiency of taurine results in clinical diseases including feline central retinal degeneration and dilated cardiomyopathy (Hayes et al., 1975; Pion et al., 1987). Taurine deficiency also adversely affects reproductive performance, growth and motor function and the immune system (Sturman et al., 1985; Schuller-Levis and Sturman, 1990). Taurine is an essential nutrient of cats because the rate of taurine synthesis from its dietary sulphur amino acid precursors, cysteine and methionine, is much less than the extent of loss through fecal bile acids and urine (Knopf et al., 1978).

Historically, a need for dietary taurine is not generally recognized in dogs. This is because dogs are known, like many species, to have the metabolic capacity to synthesize taurine from the dietary sulfur amino acids, cysteine and methionine. Recently, however, nutritional paradigms have been recognized to result in taurine deficiency in dogs. In many cases, taurine deficiency was also associated with dilated cardiomyopathy (Bakus, et al. 2001). Diet-induced (taurine deficiency) dilated cardiomyopathy is reported more in large than small dogs possibly because taurine biosynthesis rate (TBR) is lower in large than small dogs (Ko, 2007).

Dilated cardiomyopathy is defined as any disease involving primarily and predominantly the heart muscle. The cardiomyopathies of animals are idiopathic diseases that are not the result of any systemic or primary cardiac disease. In animals (primarily dogs and cats), they have been classified as dilated cardiomyopathy, hypertrophic cardiomyopathy, and restrictive or unclassified cardiomyopathy. If a disease process has been identified as the cause of myocardial dysfunction, these are more correctly identified as secondary myocardial diseases or a descriptive term precedes the term cardiomyopathy (eg, taurine-responsive cardiomyopathy; Merck, 2010).

Pion et al. (1987) were the first to report the association of dilated cardiomyopathy with taurine deficiency in cats (NRC, 2006). Since then, taurine levels have been increased to acceptable levels in all commercial cat foods. Most cases today are not taurine responsive and reflect primary (or idiopathic) disease.

Dilated cardiomyopathy is one of the most prevalent acquired heart diseases of dogs, only surpassed by degenerative valve disease and, in some parts of the world, heartworm disease as a major cardiovascular cause of morbidity and mortality. It most commonly

affects large-breed dogs and far less commonly small-breed dogs (with a few exceptions such as American Cocker Spaniels, Springer Spaniels, and English Cocker Spaniels). Doberman Pinschers, Boxers, Great Danes, German Shepherds, Irish Wolfhounds, Scottish Deerhounds, Newfoundland, Saint Bernards, and Labrador Retrievers, among other large-breed dogs, are particularly at risk. The disease is typically seen in middle-aged dogs; males are affected more than females.

There is breed variation in the presenting history and clinical signs. Up to 35% of Boxers demonstrate episodes of weakness or collapse as the presenting clinical sign and most demonstrate no myocardial failure at the time of presentation. The syncope typically results from severe ventricular arrhythmias. In those Boxers that do not succumb to sudden death, signs of left-sided Copngenetive Heart Failure (eg, cough, dyspnea) eventually develop as a result of myocardial failure. Doberman Pinschers typically develop concurrent and progressive ventricular arrhythmias along with progressive systolic dysfunction. As with Boxers, collapse and sudden death occur (in up to 20% of Doberman Pinschers), and signs of left-sided CHF eventually develop. Most Doberman Pinschers demonstrate evidence of myocardial failure at the time syncopal episodes are noted, in contrast to Boxers. In other breeds, such as Great Danes and Newfoundlands, sudden death and collapse are far less likely. Signs of right-sided CHF predominate, including weakness, exercise intolerance, pleural effusion, and ascites. Ascites was noted in 35% of Newfoundlands with dilated cardiomyopathy in one study. Cats with dilated cardiomyopathy typically present with severe signs of pleural effusion and dyspnea, and clinical signs are usually rapidly progressive and refractory to therapy. (Merck, 2010)

Dietary requirements for taurine are also greater for high-moisture processed pet foods (e.g., cans, pouches). Heat treatment does not destroy taurine; rather, its loss is thought to be due to an increased taurine degradation by intestinal bacteria and/or loss through increased bile acid conjugation. Vegetable proteins and grains have very low to non-detectable levels of taurine. Some have even been implicated in lowering circulating taurine (e.g., rice bran, barley, isolated soy protein). Given these challenges and ingredient options, synthetic taurine (2-aminoethanesulfonic acid) is often required. (Aldrich, 2008)

Administration of taurine to a cat suffering from naturally occurring chronic (about 3 years) epilepsy caused disappearance of the clinical manifestation of the seizures as well as a marked improvement in the previously grossly abnormal EEG. The treatment consisted of injections of taurine initially, followed by a more prolonged administration of the amino acid by mouth. The combined methods of administration seemed essential for the success of the trial. By the date of publication (5 months post-taurine) the animal has suffered only one "grand mal" type seizure which occurred 3 months after the last dose of taurine was administered. Disappearance of the seizures preceded by several weeks the improvement in the EEG. In accordance with previous findings by a number of investigators, the results of this study suggest an immediate depressant action of taurine on hyperexcitable cortical neurons, followed by a more long-lasting, ameliorative influence on cerebral metabolism contributing to an increased resistance to epileptic discharge.(Van Gelder, 2007)

Why the synthetic substance is necessary for the production of an organic product.

First, the synthesis of taurine appears to be severely limiting for strict obligate carnivores. (National Research Council, 2006) Obligate carnivores, therefore, must obtain adequate taurine levels through their diets. This is why taurine must be considered a "required nutrient", and not an accessory nutrient for those carnivores.

Because dogs and cats rely on commercially-prepared foods as their sole source of nutrition, it is vital that those commercial food products contain all of the nutrients required for healthy growth and adult maintenance. Accordingly, the American Association of Feed Control Officials (AAFCO) have developed model regulations, based upon the National Research council's *Nutrient Requirements of Dogs and Cats*, regarding the level of nutrients for a commercially-produced pet food to be labeled as *complete and balanced*. The term *complete and balanced* means that the formula supplies a nutritionally adequate diet when fed according to label instructions. Under the AAFCO model regulations, canned cat food products must contain a minimum of 0.10 percent taurine for both growth and reproduction, and for adult maintenance to be labeled as complete and balanced.

Although taurine is not classified as essential in complete and balanced dog food formulas, scientific evidence exists that taurine deficiency in diets can be detrimental to certain breeds of dogs. Although AAFCO has no regulatory authority, the model regulations serve as the basis for enforcement by most state feed control officials.

Cats fed canned foods require a higher concentration of taurine in their diet than those fed dry food. This difference was initially thought to be related to the more severe processing conditions used in the preparation of canned diets and a consequent reduction in the bioavailability of taurine due to the formation of Maillard reaction products. Whereas heat processing may indeed explain some of the difference, this is not believed to be related to de creased absorption of dietary taurine but rather to an increased excretion of tauroconjugated bile acids (Hickman et al. 1990). Further, based on recent reports, it is now believed that when canned diets are fed there is an increase in taurine degradation by the intestinal flora.

Nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance

Taurine is a naturally-occurring substance found in the bile of oxen, cattle, and other bovine and ovine animals. However, the concentration of taurine in pure bile is too low to be utilized commercially.

From an evolutionary standpoint, taurine was plentiful in the diet of a true carnivore, as high concentrations of taurine are found in muscle tissue. However, as most domesticated

felines normally do not consume living prey, they are at risk to become taurine-deficient if not adequately supplied in the diet. (Spitze, Wong, Rogers and Fascetti, 2003)

Several companies manufacture taurine synthesized from synthetic sources, and a few companies offer taurine synthesized from bovine and ovine bile. The processes replicate in large part the naturally occurring process that occurs in the herbivore mammalian biological system.

The taurine synthesized from natural sources is produced primarily as a byproduct in the manufacturers' primary products, cholic acid, deoxycholic acid, and other bile acids. New Zealand Pharmaceuticals, Ltd., for example, produces 800 tones of bile acids each year from oxen, cattle and sheep bile. Of that amount, only 20 tons consists of taurine for all markets.

Beneficial effects to the environment, human health (pet health), or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.

Effect on the Environment

Taurine is a sulphonated beta amino acid, thus taurine is neither incorporated into proteins, nor degraded by mammalian tissues. Most herbivores and omnivores synthesize all the taurine they need from the dietary sulphur amino acids, methionine and cysteine. In carnivores, dietary intake of taurine is essential to maintain normal taurine concentrations in the body. Most animal tissues contain high concentrations of taurine, particularly muscle, viscera and brain, whereas higher plants contain no measurable taurine.(Spitze, Wong, Rogers and Fascetti, 2003)

As a naturally occurring substance. There is no perceptible effect on the environment, either positive or negative.

Effect on Human (and Animal) Health

As mentioned previously, taurine is a conditionally essential amino acid that is found in the tissues of most animal species. Low levels of taurine have been associated with retinal degeneration, growth retardation, and cardiomyopathy. Taurine has been used clinically in the treatment of cardiovascular diseases, hypercholesterolemia, seizure disorders, ocular disorders, diabetes, Alzheimer's' disease, hepatic disorders, cystic fibrosis, and alcoholism. (Alternative Medicine Review, 2001)

In pets, taurine is a required nutrient for cats, and may be conditionally essential for dogs.

In cats, adequate intake of taurine is required to prevent feline central retinal degeneration and blindness; dilated cardiomyopathy and heart failure; inadequate immune response; poor neonatal growth; reduced auditory brain stem evoked potentials (resulting in

deafness); poor reproduction, (resorptions, abortions, decreased birth weight, and low survival rate of kittens); and congenital defects including hydrocephalus and anencephaly.

In dogs, adequate levels of taurine are required to prevent dilated cardiomyopathy. Some dogs with low plasma taurine also have bilaterally symmetrical hyper reflective retinal lesions, which is similar to classic feline central retinal degeneration. (National Research Council, 2006)

Taurine has been administered, mostly by oral ingestion on a daily basis for periods up to one year, and with daily doses generally in the 3-6 g range, to a large number of patients (adults, children and even infants) suffering from a wide variety of serious diseases. Taurine has also been administered parenterally at a daily dose of 0.64 g for 20 months or by intravenous administration at daily doses of 12 g for 15 days and 18 g for 60 days. Although the principal aim of these clinical studies was not to evaluate potential adverse effects of chronic administration of taurine it is apparent that these doses produced no adverse health effects. Such information has revealed that oral daily ingestion of taurine doses in the 3-6 g range for periods up to one year did not produce adverse health effects. (EFSA, 2009)

References for Justification Statement

Alternative Medicine Review (2001) Taurine Monograph. Alternative Medicine Review. Vol. 6, No. 1

Association of American Feed Control Officials (2010) "Model Regulations for Pet Food and Specialty Pet Food." Official Publication. Oxford, IN. pp133-180

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Van Gelder, N.M; Koyama, I; Jasper, H.H. (2007) "Taurine Treatment of Spontaneous Epilepsy in a Cat." Epilepsia, Vol 18, Issue 1 pp 46-44.

Huxtable, R.J. (1992) the physiological actions of taurine. Physiol. Rev. 72:101-163.

Knopf, K.;Sturman, J.A.; Armstrong, M; Hayes K.C., (1978) Journal of Nutrition. 108, 773

Ko KS, Backus RC, Berg JR, Lame MW, Rogers QR. (2007) "Differences in taurine synthesis rate among dogs relate to differences in their maintenance energy requirement." Journal of Nutrition, May.

Merck (2010) "Dialated Cardiomyopathy." Merck Manuals, Online Medical Library" http://www.merck.com/mmpe/sec07/ch084666/ch084666b.html

National Research Council (2006) Nutrient Requirements of Dogs and Cats, Ad Hoc Committee on Dog and Cat Nutrition, Committee on Animal Nutrition, Board on Agriculture and Natural Resources, Division on Earth and Life Studies, Washington, D.C.

Pion, PD; Kittleson, MD; Rogers QR; Morris, JG (1987) Myocardial failure in cats associated with low plasma taurine: a reversible cardiomyopathy. Science. Vol. 237, No. 4816. Pp 764-768. August

Spitze, A.R.; Wong, D.L.; Rogers, Q.R.; and Fascetti, A.J. (2003) Taurine concentrations in animal feed ingredients; cooking influences taurine content." J. Anim. Physiol. A. Anim. Nutr. 87. Pp 251-262.

13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

Two manufacturers who have cooperated with the applicant in developing material for this petition have provided the applicant with a description of their manufacturing process that they consider to be proprietary knowledge, and therefore considers this information confidential business information. Those companies, Qianjiang Yongan Pharmaceutical Co., LTD, and New Zealand Pharmeceuticals, Ltd. expended significant financial resources in the development and refinement of their manufacturing processes, and maintain these records as trade secrets. Accordingly, this information is 1) commercially valuable, 2) used in the applicant's business, 3) maintained in secrecy. The release of this information outside of the company would be injurious to the company.

Attachment A
Confidential Business Information

CBI Removed

CBI Removed

CBI Removed

CBI Removed

CBI Removed

CBI Removed

CBI Removed

CBI Removed

Attachment B
Material Safety Data Sheets

Sheet No. 1 Fischer Scientific
Sheet No. 2 Qianjiiang. Yongan Pharmadeutical Co., Ltd.
Sheet No. 3 New Zealand Pharmaceuticals', Ltd.

Material Safety Data Sheet

Taurine, 99%

ACC# 94400

Section 1 - Chemical Product and Company Identification

MSDS Name: Taurine, 99%
Catalog Numbers: AC166540000, AC166541000, AC166545000
Synonyms: 2-Aminoethanesulfonic Acid.
Company Identification:

Acros Organics N.V.
One Reagent Lane
Fair Lawn, NJ 07410

For information in North America, call: 800-ACROS-01
For emergencies in the US, call CHEMTREC: 800-424-9300

Section 2 - Composition, Information on Ingredients

CAS#	Chemical Name	Percent	EINECS/ELINCS
107-35-7	Taurine	99%	203-483-8

Hazard Symbols: None listed.
Risk Phrases: None listed.

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Appearance: white solid. **Caution!** The toxicological properties of this material have not been fully investigated. May cause eye and skin irritation. May cause respiratory and digestive tract irritation.
Target Organs: No data found.

Potential Health Effects
Eye: May cause eye irritation.
Skin: May cause skin irritation.
Ingestion: May cause irritation of the digestive tract. The toxicological properties of this substance have not been fully investigated.
Inhalation: May cause respiratory tract irritation. The toxicological properties of this substance have not been fully investigated.
Chronic: No information found.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.
Skin: Get medical aid. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.
Ingestion: Never give anything by mouth to an unconscious person. Get medical aid. Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.

Inhalation: Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.
Notes to Physician: Treat symptomatically and supportively.

Section 5 - Fire Fighting Measures

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Runoff from fire control or dilution water may cause pollution.
Extinguishing Media: In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam. Use agent most appropriate to extinguish fire. Use water spray, dry chemical, carbon dioxide, or appropriate foam.
Flash Point: 300 deg C (572.00 deg F)
Autoignition Temperature: Not applicable.
Explosion Limits, Lower: Not available.
Upper: Not available.
NFPA Rating: (estimated) Health: 1; Flammability: 1; Instability: 0

Section 6 - Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.
Spills/Leaks: Vacuum or sweep up material and place into a suitable disposal container. Clean up spills immediately, observing precautions in the Protective Equipment section. Avoid generating dusty conditions. Provide ventilation.

Section 7 - Handling and Storage

Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.
Storage: Store in a tightly closed container. Store in a cool, dry, well-ventilated area away from incompatible substances.

Section 8 - Exposure Controls, Personal Protection

Engineering Controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.
Exposure Limits

Chemical Name	ACGIH	NIOSH	OSHA - Final PELs
Taurine	none listed	none listed	none listed

OSHA Vacated PELs: Taurine: No OSHA Vacated PELs are listed for this chemical.
Personal Protective Equipment
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Skin: Wear appropriate protective gloves to prevent skin exposure.
Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

Section 9 - Physical and Chemical Properties

Physical State: Solid
Appearance: white
Odor: None reported.
pH: Not available.
Vapor Pressure: Not available.
Vapor Density: Not available.
Evaporation Rate: Not available.
Viscosity: Not available.
Boiling Point: Not available.
Freezing/Melting Point:300 deg C
Decomposition Temperature:300 deg C
Solubility: 65 g/l (12 c)
Specific Gravity/Density: Not available.
Molecular Formula:C2H7NO3S
Molecular Weight:125.14

Section 10 - Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures.
Conditions to Avoid: Incompatible materials, dust generation, excess heat, strong oxidants.
Incompatibilities with Other Materials: Oxidizing agents.
Hazardous Decomposition Products: Nitrogen oxides, carbon monoxide, oxides of sulfur, irritating and toxic fumes and gases, carbon dioxide, nitrogen.
Hazardous Polymerization: Has not been reported.

Section 11 - Toxicological Information

RTECS#:
CAS# 107-35-7: WX0175000
LD50/LC50:
CAS# 107-35-7:
Oral, mouse: LD50 = >7 gm/kg;
Oral, rat: LD50 = >5 gm/kg;
Carcinogenicity:
CAS# 107-35-7: Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.
Epidemiology: No information available.
Teratogenicity: No information available.
Reproductive Effects: No information available.
Neurotoxicity: No information available.
Mutagenicity: No information available.
Other Studies: See actual entry in RTECS for complete information.

Section 12 - Ecological Information

No information available.

Section 13 - Disposal Considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.
RCRA P-Series: None listed.
RCRA U-Series: None listed.

Section 14 - Transport Information

	US DOT	IATA	RID/ADR	IMO	Canada TDG
Shipping Name:	No information available.				No information available.
Hazard Class:					
UN Number:					
Packing Group:					

Section 15 - Regulatory Information

US FEDERAL

TSCA
CAS# 107-35-7 is listed on the TSCA inventory.
Health & Safety Reporting List
None of the chemicals are on the Health & Safety Reporting List.
Chemical Test Rules
None of the chemicals in this product are under a Chemical Test Rule.
Section 12b
None of the chemicals are listed under TSCA Section 12b.
TSCA Significant New Use Rule
None of the chemicals in this material have a SNUR under TSCA.
SARA

CERCLA Hazardous Substances and corresponding RQs
None of the chemicals in this material have an RQ.
SARA Section 302 Extremely Hazardous Substances
None of the chemicals in this product have a TPQ.
Section 313
No chemicals are reportable under Section 313.
Clean Air Act:
This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.
Clean Water Act:
None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.
OSHA:
None of the chemicals in this product are considered highly hazardous by OSHA.
STATE

CAS# 107-35-7 is not present on state lists from CA, PA, MN, MA, FL, or NJ.
California No Significant Risk Level: None of the chemicals in this product are listed.

European/International Regulations

European Labeling in Accordance with EC Directives
Hazard Symbols:
Not available.
Risk Phrases:

Safety Phrases:
S 24/25 Avoid contact with skin and eyes.
S 37 Wear suitable gloves.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S 28A After contact with skin, wash immediately with plenty of water.

WGK (Water Danger/Protection)
CAS# 107-35-7: 1
Canada - DSL/NDSL
CAS# 107-35-7 is listed on Canada's DSL List.
Canada - WHMIS
WHMIS: Not available.
Canadian Ingredient Disclosure List
Exposure Limits

Section 16 - Additional Information

MSDS Creation Date: 9/02/1997
Revision #5 Date: 3/18/2003

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Fisher be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Fisher has been advised of the possibility of such damages.

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Tel: +86-27-50701737 Fax: +86-27-87339689
E-mail: yapharmh@hi2000.com Http:// www.ChinaTaurine.com

Material Safety Data Sheet

Product Name: Taurine
Catalog Codes: SLT2014
CAS#: 107-35-7
RTECS: 1012186TE
TSCA: TSCA 8(b) inventory: Taurine
CI#: Not available.
Synonym: 2-Aminoethanesulfonic acid; 2-Aminoethylsulfonic acid; 2-Sulfoethylamine
Chemical Name: Taurine
Chemical Formula: C2-H7-N-O3-S

Contact Information:
Qianjiang Yongan Pharmaceutical Co.,Ltd
No.16 Zhuze Road, Qianjiang, Hubei, PRC 433132
Internal Sales call & Fax:
86-728-6201636/86-728-6204008
International Sales:
86-27-50701757/50701767/50701737
Order Online: www.chinataurine.com

Composition:

Name	CAS #	% by Weight
Taurine	107-35-7	99

Toxicological Data on Ingredients: Not applicable.

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.
Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
Repeated or prolonged exposure is not known to aggravate medical condition.

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.
Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.Cold water may be used.
Serious Skin Contact: Not available.
Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

QIANJIANG YONGAN PHARMACEUTICAL CO., LTD
Address: No.16 Zhuze Road, Qianjiang, Hubei, China
Tel: +86-27-50701737 Fax: +86-27-87339689
E-mail: yapharmh@hi2000.com Http:// www.ChinaTaurine.com

Material Safety Data Sheet

Product Name: Taurine
Catalog Codes: SLT2014
CAS#: 107-35-7
RTECS: 1012186TE
TSCA: TSCA 8(b) inventory: Taurine
CI#: Not available.
Synonym: 2-Aminoethanesulfonic acid; 2-Aminoethylsulfonic acid; 2-Sulfoethylamine
Chemical Name: Taurine
Chemical Formula: C2-H7-N-O3-S

Contact Information:
Qianjiang Yongan Pharmaceutical Co.,Ltd
No.16 Zhuze Road, Qianjiang, Hubei, PRC 433132
Internal Sales call & Fax:
86-728-6201636/86-728-6204008
International Sales:
86-27-50701757/50701767/50701737
Order Online: www.chinataurine.com

Composition:

Name	CAS #	% by Weight
Taurine	107-35-7	99

Toxicological Data on Ingredients: Not applicable.

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

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Catalog Codes: SLT2014
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RTECS: 1012186TE
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Contact Information:
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Serious Skin Contact: Not available.
Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

NEW ZEALAND PHARMACEUTICALS NZP LTD

NEW ZEALAND

Material Safety Data Sheet

PRODUCT NAME TAURINE

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Supplier Name	**NEW ZEALAND PHARMACEUTICALS LTD**
Address	68 Weld Street, Palmerston North, NEW ZEALAND
Telephone	+64 6 952 3800
Fax	+64 6 952 3801
Emergency	+64 6 952 3800
Email	markets@nzp.co.nz
Web Site	http://www.nzp.co.nz
Synonym(s)	
Use(s)	DIETARY SUPPLEMENT

2. HAZARDS IDENTIFICATION

NOT CLASSIFIED AS HAZARDOUS ACCORDING TO THE CRITERIA IN THE HS (MIN DEG OF HAZ) REGS 2001

NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO NZS 5433

UN No.	None Allocated	**Hazchem Code**	None Allocated	**Pkg Group**	None Allocated
DG Class	None Allocated	**Subsidiary Risk(s)**	None Allocated	**EPG**	None Allocated

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Formula	Conc.	CAS No.
TAURINE	C2-H7-N-O3-S	100%	107-35-7

4. FIRST AID MEASURES

Eye	Flush gently with running water for 15 minutes.
Inhalation	If over exposure occurs leave exposure area immediately. If irritation persists, seek medical attention.
Skin	Gently flush affected areas with water. Seek medical attention if irritation develops.
Ingestion	For advice, contact a Poisons Information Centre on 0800 764 766 (0800 POISON) or +643 479 7248 (New Zealand) or a doctor. If swallowed, do not induce vomiting. Ingestion is considered unlikely due to product form.
Advice to Doctor	Treat symptomatically
First Aid Facilities	Eye wash facilities and safety shower should be available.

5. FIRE FIGHTING MEASURES

Flammability	Combustible - potentially explosive dust if exposed to heat or ignition sources, however due to the nature of use the risk is extremely low. May evolve toxic gases (carbon oxides and hydrocarbons) if heated to decomposition. May also evolve sulphur oxides and nitrogen oxides when heated to decomposition.
Fire and Explosion	Combustible solid - explosive dust at high concentrations. Evacuate area and contact emergency services. Toxic gases (carbon oxides and hydrocarbons) may be evolved when heated. Remain upwind and notify those downwind of hazard. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire. Use waterfog to cool intact containers & nearby storage areas.
Extinguishing	Dry agent, carbon dioxide, foam or water fog. Prevent contamination of drains or waterways, absorb runoff with sand or similar.
Hazchem Code	None Allocated

6. ACCIDENTAL RELEASE MEASURES

Spillage If spill (bulk), contact emergency services if appropriate. Wear dust-proof goggles, PVA/rubber gloves, a Class P1 (Particulate) respirator (where an inhalation risk exists), coveralls and rubber boots. Clear area of all unprotected personnel. Prevent spill entering drains or waterways. Collect and place in sealable containers for disposal or reuse. Avoid generating dust.

7. STORAGE AND HANDLING

Storage Store in cool, dry, well ventilated area, removed from oxidising agents, acids and foodstuffs. Ensure product is adequately labelled.

Handling Before use carefully read the product label. Use of safe work practices are recommended to avoid eye or skin contact and inhalation. Observe good personal hygiene, including washing hands before eating. Prohibit eating, drinking and smoking in contaminated areas.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ventilation Ensure adequate natural ventilation. Maintain dust levels below the recommended exposure standard.

PPE Wear dust-proof goggles and rubber or PVC gloves. Where an inhalation risk exists, wear a Class P1 (Particulate) Respirator. When using large quantities or where heavy contamination is likely, wear coveralls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	WHITE POWDER	**Solubility (water)**	SOLUBLE
Odour	ODOURLESS	**Specific Gravity**	NOT AVAILABLE
pH	NOT AVAILABLE	**% Volatiles**	NOT AVAILABLE
Vapour Pressure	NOT AVAILABLE	**Flammability**	COMBUSTIBLE
Vapour Density	NOT AVAILABLE	**Flash Point**	NOT AVAILABLE
Melting Point	> 300°C	**Upper Explosion Limit**	NOT AVAILABLE
Boiling Point	NOT AVAILABLE	**Lower Explosion Limit**	NOT AVAILABLE
Evaporation Rate	NOT AVAILABLE	**Autoignition Temperature**	NOT AVAILABLE

10. STABILITY AND REACTIVITY

Reactivity Incompatible with oxidising agents (eg. peroxides) and acids (eg. hydrochloric acid).

Decomposition Products May evolve toxic gases (carbon oxides and hydrocarbons) if heated to decomposition. May also evolve sulphur oxides and nitrogen oxides when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

Health Hazard Summary Under normal conditions of use adverse health effects are not anticipated. This product is generally considered to be of low toxicity, however over exposure to any dust should be avoided. Use safe work practices to avoid direct eye contact or prolonged skin contact and dust generation or inhalation.

Eye Exposure may result in irritation, pain and redness.

Inhalation Over exposure at high levels may result in mucous membrane irritation of the nose and throat with coughing.

Skin Prolonged contact may result in irritation.

Ingestion Ingestion may result in gastrointestinal irritation, however due to product form, ingestion is considered highly unlikely. Maintain good personal hygiene standards.

Toxicity Data TAURINE (107-35-7)
LD50 (ingestion): > 5 g/kg (rat)

12. ECOLOGICAL INFORMATION

Environment This product is not anticipated to cause adverse effects to animal or plant life if released to the environment in small quantities. Not expected to bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Ensure product is covered with moist soil to prevent dust generation and dispose of to approved Council landfill. Contact the manufacturer if additional information is required.

Legislation Dispose of in accordance with relevant local legislation.

14. TRANSPORT INFORMATION

NOT CLASSIFIED AS A DANGEROUS GOOD ACCORDING TO NZS 5433

Shipping Name	None Allocated				
UN No.	None Allocated	**DG Class**	None Allocated	**Subsidiary Risk(s)**	None Allocated
Pkg Group	None Allocated	**Hazchem Code**	None Allocated	**EPG**	None Allocated

15. REGULATORY INFORMATION

16. OTHER INFORMATION

RESPIRATORS: In general the use of respirators should be limited and engineering controls employed to avoid exposure. If respiratory equipment must be worn ensure correct respirator selection and training is undertaken. Remember that some respirators may be extremely uncomfortable when used for long periods. The use of air powered or air supplied respirators should be considered where prolonged or repeated use is necessary.

ABBREVIATIONS:
mg/m3 - Milligrams per cubic metre
ppm - Parts Per Million
TWA/ES - Time Weighted Average or Exposure Standard.
CNS - Central Nervous System
NOS - Not Otherwise Specified
pH - relates to hydrogen ion concentration - this value will relate to a scale of 0 - 14, where 0 is highly acidic and 14 is highly alkaline.
CAS# - Chemical Abstract Service number - used to uniquely identify chemical compounds.
M - moles per litre, a unit of concentration.
IARC - International Agency for Research on Cancer.

PERSONAL PROTECTIVE EQUIPMENT GUIDELINES:
The recommendation for protective equipment contained within this Chem Alert report is provided as a guide only. Factors such as method of application, working environment, quantity used, product concentration and the availability of engineering controls should be considered before final selection of personal protective equipment is made.

HEALTH EFFECTS FROM EXPOSURE:
It should be noted that the effects from exposure to this product will depend on several factors including: frequency and duration of use; quantity used; effectiveness of control measures; protective equipment used and method of application. Given that it is impractical to prepare a Chem Alert report which would encompass all possible scenarios, it is anticipated that users will assess the risks and apply control methods where appropriate.

Report Status This document has been compiled by RMT on behalf of the manufacturer of the product and serves as the manufacturer's Material Safety Data Sheet ('MSDS').

It is based on information concerning the product which has been provided to RMT by the manufacturer or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer.

While RMT has taken all due care to include accurate and up-to-date information in this MSDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, RMT accepts no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this MSDS.

Prepared By Risk Management Technologies
5 Ventnor Ave, West Perth
Western Australia 6005

Phone: +61 8 9322 1711
Fax: +61 8 9322 1794
Email: info@rmt.com.au
Web: www.rmt.com.au

MSDS Date: 08 May 2007

End of Report

Attachment C
EPA Substance Registry

http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search.do?details=displayDetails

Last updated on Tuesday, July 20, 2010

Substance Registry Services

You are here: EPA Home SoR Home Substance Registry Services Home Search and Retrieve Substance Search

Home Search & Retrieve Automated Services Outreach & Education Training

Substance Search Search By List Advanced Search

Substance Details - Taurine

Back to Substance Search Results

Export Substance Details (PDF)

Core Metadata

Substance Type
Chemical Substance
EPA Registry Name
Taurine
EPA Registry Name List
Chemical Identification
Systematic Name
Ethanesulfonic acid, 2-amino-
Systematic Name List
Chemical Abstracts Index Name
Preferred Acronym
CAS Number
107-35-7
EPA Identification Number
Molecular Formula
C2H7NO3S
Molecular Weight
125.15
Definition
Comment/Description
Classifications

Internal Tracking Number: 24315
Substance Status: Approved

Associated Identifiers

This section provides other identifiers associated with this substance, including former CAS numbers, incorrectly used CAS numbers, and retired EPA Identifiers.

Former CAS Number(s)
91105-79-2

Structure

Structure Notation Type	Notation
SMILES	O=S(=O)(O)CCN

Synonym

Below are the EPA applications/systems, statutes/regulations, or other sources that track or regulate this substance. This table shows how each list refers to the substance. To view more metadata about the specific Synonym, click on the Synonym.

Statutes/Regulations

Statutes/Regulations	Synonym	Synonym Quality	Effective Date	End Date
TSCA Inv	Ethanesulfonic acid, 2-amino-	Valid		

EPA Applications/Systems

EPA Applications/Systems	Synonym	Synonym Quality	Effective Date	End Date
AFS	L-Taurine	Valid		
CAMEO	L-Taurine	Valid		
AFS	Taurine, L-	Valid		
GCES	Ethanesulfonic acid, 2-amino-	Valid		
eIUR	Ethanesulfonic acid, 2-amino-	Valid		
eIUR	Taurine	Valid		
ECOTOX	Taurine	Valid		

Other Sources

Other Sources	Synonym	Synonym Quality	Effective Date	End Date
CUS02	Ethanesulfonic acid, 2-amino-	Valid		
CUS98	Ethanesulfonic acid, 2-amino-	Valid		
CA Index	Ethanesulfonic acid, 2-amino-	Valid		
CUS94	Taurine	Valid		
ChemIDStd	Taurine	Valid		
NTP Chemical Repository	L-Taurine	Valid		

Ad Hoc List

There are no Synonyms of this type.

EPA Synonyms

There are no Synonyms of this type.

Related References

Below are links to other sources of information about this substance.

The following list includes links related to the selected metadata item. A link may lead to resources within the SRS, to another site within EPA, or go to a site outside EPA. A link may be another Web site or a document. For additional information on links to external Web sites, see SoR Disclaimer.

There are no related references for this substance.

Back to Substance Search Results

http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/substancesearch/search

Attachment D
References and Research Information

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