National Organic Standards Board,
c/o Robert Pooler, Agricultural Marketing Specialist,
USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268,
P.O. Box 96456, Washington, D.C. 20090-6456.

Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov.

National List Petition
Submitted: November 29, 2000

OCTADECYLAMINE

This Petition is submitted by the following:

Joseph Hall
Co-chair, MPPL Subcommittee, OTA
California Natural Products, Inc.
1250 E. Lanthrop Road
Lanthrop, CA 95330
phone (209)858-2525
email joehall@californianatural.com

Jim Pierce
Organic Valley / CROPP Cooperative
507 Main St. La Farge WI 54639
phone (608)625-2602 fax (608)625-4177
email jim.pierce@organicvalley.com website www.organicvalley.com.

Greg Cunningham
General Mills
201 General Mills BLvd
Minneapolis Mn 55426-1350
phone number 763 764 3058
email - greg.cunningham@genmills.com

Kelly Shea; Farm Relations Manager
Horizon Organic Dairy
6311 Horizon Lane
Boulder, CO 80308-7577
phone (719) 372-9233
email kellys@horizonorganic.com

Kim Burton
Smucker Quality Beverages, Inc.
Speedway Avenue
Chico, CA 95926
phone (530) 899-5058
email- kim.burton@jmsmucker.com

Clifford L. Jacobson
Spray Chem Chemical Company, Inc.
705 Keenan Court
Durham, CA 95938
phone (530) 895-3658
email – cliff@spraychem.com

OCTADECYLAMINE

Permitted for Processing
11-29-00

Category: Synthetic

Common Name: **Octadecylamine**

Intended Use: Boiler Water Additive used to prevent the corrosion of boiler equipment and their distribution lines.

CAS Registry Number: 124-30-1

RTECS Number: NIOSH/RG4150000

Synonyms:

1. 1-AMINOOCTADECANE
2. 1-OCTADECANAMINE
3. ADOGENEN 142
4. ALAMINE 7
5. ALAMINE 7D
6. ARMEEN 118D
7. ARMEEN 18D
8. ARMOFILM
9. KEMAMINE P 990
10. N-OCTADECYLAMINE
11. N-STEARYLAMINE
12. NISSAN AMINE AB
13. STEARAMINE
14. STEARYLAMINE

Molecular Formula: C18-H39-N (Eighteen Carbon Straight Chain Amine)

Regulatory Status: 21CFR Sec. 173.310 Boiler water additives: Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products.

Methods of Manufacturing: CATALYTIC HYDROGENATION OF STEARYL NITRILE

Manufacturers:

1. **Akzo Nobel Chemicals, Inc.,** 300 South Riverside Plaza, Chicago, IL 60606, (312)906-7500. Production sites: McCook, IL 60525; Morris, IL 60450. [Peer Reviewed] [SRI. 1997 Directory of Chemical Producers - United States of America. Menlo Park, CA: SRI International 1997. 925]
2. **Enenco, Inc.,** 3018 Bell Ave., Memphis, TN 38108, (901)320-5901. Production site: Memphis, TN 38108. [Peer Reviewed] [SRI. 1997 Directory of Chemical Producers - United States of America. Menlo Park, CA: SRI International 1997. 925]
3. **Witco Corp.,** 1 American Lane, Greenwich, CT 06831-2559. (202)552-2000. Production site: Mapleton, IL 61547. [Peer Reviewed] [SRI. 1997 Directory of Chemical Producers - United States of America. Menlo Park, CA: SRI

International 1997. 925]

Manufacturing Process: For the production of a primary amine the corresponding fatty acid or fatty ester is reacted with ammonia to produce a nitride and then the nitride is reacted with hydrogen gas to form the amine, a by-product of the reaction is two water molecules.

Mode of Action: Octadecylamine forms a molecularly thin film on the interior of steam lines. This boiler water additive's prevents corrosion by preventing the carbonic acid formed from the carbon dioxide captured within the steam from coming into contact with the steam lines.

Safety Information Attached

"The Chronic Toxicity of Octadecylamine"
Reprinted from the A.M.A. Archives of Industrial Health
December 1958, Vol 18, pp 483-487
Copy Right 1958, by American Medical Association

"No toxic effects were observed when, for two years, octadecylamine was fed to rats."

"No toxic effects were observed in dogs given octadecylamine at levels of 0.6 and 3.0 mg/kg per day on each of five days for a period of 12 months."

MSDS Attached

Attached Boiler Water Additives Estimation of Intake (CFSAN)

The maximum tolerance for octadecylamine in steam by Federal Standard is 3 ppm. For perspective, assume a product with 10% moisture, and assume all that moisture came from the steam. The residual level of octadecylamine would be .003 ppm.

However that .003 ppm radically overstates the true potential residue. First, the moisture of the vast majority of products does not come from the steam system. Second according to the literature adheres firmly to the surfaces of the steam lines making it un-available for in-corporation into finished products.

The true octadecylamine residual level is in orders of magnitude less than .003 ppm

Environmental Impact Reference Beratergremium fuer umweltrelevante Alstoffe (BUA); **177; 1997**
"Distribution Behaviour and Degradability"

"The calculated half-lives for the reaction of fatty amines with photochemically formed OH radicals are between 7 (1-ocatedecylamine) and 10 (1-octylamine) hours."

Justification: This is one of several substances available to prevent corrosion of steam lines. Saving the replacement cost of corroded parts of the steam system is a relatively small factor in value of this substance. Preventing unexpected failures of the steam system and the resulting unexpected down time and assuring the "quality"

of the steam upon which the "quality" of the product is dependent is of greater importance.

Industrial Plant Condensate Treatment- State of the Art

By P G Schmidt and D Simon
Cyrus Rice Water Consultants
Cyrus Rice Center
6500 Grand Avenue
Pittsburg, PA 155225-1221

Clinical Toxicology of Commercial Products 5th edition
Williams & Wilkins Baltimore/London

HSDB Hazardous Substance Data Bank

Final reports on the safety assessment of Lauramine and Stearamine
Anonymous
Source: J Am Coll Toxicol; 14(3); 1995; 196-203
Language: ENGLISH

OCTADECYLAMINE A NONTOXIC CORROSION INHIBITOR FOR STEAM PRODUCERS IN HOSPITALS
LUEDERITZ P; GROSSER J
Source: HYG MED; 11 (12). 1986 (RECD. 1987). 480-481. Coden: HYMED
Language: GERMAN
BIOSIS COPYRIGHT: BIOL ABS. RRM CARCINOGEN

The biological action of carbonate 4,4'-diaminodicyclohexylmethane and octadecylamine.
PAUSTOVSKAYA VV; ROZHKOVSKAYA GP; RAPPOPORT MB; ANINA IA; PASTERNAK GA
Source: GIG SANIT; 38 (11). 1973 (RECD 1974) 31-35 Coden: GISAA
Language: UNSPECIFIED

Primary fatty amines
Gesellschaft Deutscher Chemiker (GDCh) - Advisory Committee on Existing Chemicals of Environmental Relevance (BUA)
Source: S. Hirzel Verlag, P.O. Box 10 10 61, 70009 Stuttgart, Germany,
1997. xxi, 173p. 397 ref.
Language: ENGLISH
Document Type: MONOGRAPH

Primary Fatty Amines
Anonymous
Source: Beratergremium fuer umweltrelevante Altstoffe (BUA); 177; 1997; 185 p
Language: ENGLISH
Distribution Behaviour and Degradability.

LETTER FROM AKZO CHEMIE AMERICA TO US EPA REGARDING TEST OLEYLAMINE TEST RESULTS WITH ATTACHMENT
Source: EPA/OTS; Doc #40-8484007
Language: UNSPECIFIED
Contract Number: 40-8484007
Classification Code: TSCA Sect. 4 Rec 07/27/84

Order Info.: NTIS/OTS0526846

LETTER FROM AKZO CHEMIE AMERICA TO US EPA CONTAINING RISK EVALUATION OF OLEYLAMINE
Source: EPA/OTS; Doc #40-8484004
Language: UNSPECIFIED
Contract Number: 40-8484004
Classification Code: TSCA Sect. 4 Rec 00/00/00
Order Info.: NTIS/OTS0526843

LETTER FROM AKZO CHEMIE AMERICA TO US EPA REGARDING SUBMISSION OF OLEYLAMINE DATA WITH ATTACHMENTS
Source: EPA/OTS; Doc #40-8484002
Language: UNSPECIFIED
Contract Number: 40-8484002
Classification Code: TSCA Sect. 4 Rec 00/00/00
Order Info.: NTIS/OTS0526841

Toxicity of aliphatic amines: Structure-activity relationship.
GREIM H; BURY D; KLIMISCH H-J; OEBEN-NEGELE M; ZIEGLER-SKYLAKAKIS K
GSF--Inst. Toxikologie, Neuherberg Postfach 1129, 85758 Oberschleissheim, Germany.
Source: CHEMOSPHERE; 36 (2). 1998. 271-295. Coden: CMSHA
Language: ENGLISH
BIOSIS COPYRIGHT: BIOL ABS. SARs may enable the evaluation of the toxic

Effects of long-chain fatty amines on the growth of ras-transformed NIH 3T3 cells.
KOTHAPALLI R; LUI E MK; GUTHRIE N; CHAMBERS AF; CARROLL KK
Dep. Biochem., Univ. Western Ontario, London, ON, N6A 5C1, CAN.
Source: BIOCHEMICAL PHARMACOLOGY; 47 (10). 1994. 1909-1916. Coden: BCPCA
Language: ENGLISH
BIOSIS COPYRIGHT: BIOL ABS. A number of aliphatic primary amines were

Main results of the toxicological experimental studies of metal air corrosion inhibitors.
PAUSTOVSKAYA VV
Inst. Ind. Hyg. Occup. Dis., Kiev, USSR.
Source: GIG TR PROF ZABOL; 0 (3). 1990. 7-10. Coden: GTPZA
Language: RUSSIAN
BIOSIS COPYRIGHT: BIOL ABS. Basing on experimental toxicity research it

AN IN-VITRO MODEL FOR IDENTIFYING SKIN-CORROSIVE CHEMICALS I. INITIAL VALIDATION
OLIVER G JA; PEMBERTON MA; RHODES C
Source: TOXICOL IN VITRO; 2 (1). 1988. 7-18. Coden: TIVIE
Language: ENGLISH
BIOSIS COPYRIGHT: BIOL ABS. RRM PRE-SCREENING EPIDERMAL SLICE STRATUM

CORNEUM

THE BODY'S UPTAKE OF HIGHER ALIPHATIC AMINES THROUGH THE SKIN
TISHKEVICH GI; ASHEL'ROD AA; KOSYACHENKO GE; SHEVLYAKOV VA; POLYUSHITS RG
; KAPLUNOVA TA; BALAKIREVA SI
Source: GIG TR PROF ZABOL; 0 (8). 1987. 43-44. Coden: GTPZA
Language: RUSSIAN
BIOSIS COPYRIGHT: BIOL ABS. RRM RAT GUINEA-PIG HISTAMINOPEXIC INDEX
SENSITIZATION

Sampling and analysis of some corrosion-inhibiting amines in steam condensates.
MALAIYANDI M; THOMAS GH; MEEK ME
Monit. Criter. Div., Bur. Chem. Hazards, Environ. Health Dir., Health Protect. Branch, Natl. Health Welfare, Ottawa, Ont. K1A OL2, Can.
Source: J ENVIRON SCI HEALTH PART A ENVIRON SCI ENG; 14 (7). 1979 (RECD.1980). 609-628. Coden: JESED
Language: UNSPECIFIED
HEEP COPYRIGHT: BIOL ABS. The analysis of (polluting) corrosioninhibitors, e.g., morpholine (MOR), cyclohexylamine (CHA),diethylaminoethanol (DEAE) and octadecylamine (ODA) in steam condensates

03389773 Subfile: RISKLINE-96110022
Primary Fatty Amines
Anonymous
Source: Beratergremium fuer umweltrelevante Altstoffe (BUA); 177; 1997; 185 p
Language: ENGLISH
Distribution Behaviour and Degradability. The homologues 1-octylamine to 1-tetradecylamine, based on the calculated values of their Henry's Law constants and in so far as they occur in their free form, are classified as being moderately volatile from aqueous solution. Similar estimates for higher homologues are not possible, since no data are available on their saturation concentrations in water at room temperature. The experimentally determined n-octanol/water partition coefficients (log Pow) at pH 7 for 1-octylamine and 1-dodecylamine are 0.76 and 1.85, respectively. It can be assumed that the contribution of corresponding ammonium cations to the total concentration at this pH value is already considerable, leading to an increased polarity of the substances. Due to the interface- active character of the higher homologues, no experimental data are available. Calculated values of log Pow for the free amines are between 3.0 (1-octylamine) and 8.3 (**1-octadecylamine**). Experimental data on the bioaccumulation of fatty amines are not available. A reliable estimation of bioaccumulation on the basis of the conventional relationship between bioaccumulation factor and n-octanol/water partition coefficient is not possible, due to the interface-active properties of primary fatty amines and their conjugated acids Experimental data on soil sorption coefficients are not available. For this class of substances, in respect to soil sorption, one may assume the existence of two competing processes: adsorption onto inorganic soil components (bentonites, silicates) and absorption by organic soil substances. Cationic surfactants, to which the fatty amines belong, are strongly adsorbed by inorganic soil components. The sorption of primary fatty amines by organic soil substances, on the other hand, based on measurements of the n-octanol/water partition coefficients of the lower homologues, is low to very low. The Koc values are between 62 (1-octylamine) and 242 (1-dodecylamine). Experimental data on the geoaccumulation of fatty amines are not available. Due to the marked tendency of fatty amines to physi- and chemisorption on inorganic soil components, a high potential for geoaccumulation can be expected. In a model experiment involving incubation with an adapted mixed culture of soil (loam) microorganisms, 1-octylamine and 1-decylamine, which were adsorbed onto bentonite, were subject to rapid primary degradation. Thus, it may be assumed that at least the short-chain fatty amines, which have accumulated in the soil, will be biologically degraded following termination of their application to the soil. Experimental data on the photochemical degradation of primary fatty amines in the atmosphere are not available. The calculated half-lives for the reaction of fatty amines with photochemically formed OH radicals are between 7 (**1-ocatedecylamine**) and 10 (1-octylamine) hours.

Under environmental conditions, primary fatty amines are stable to hydrolysis. Since the substances show practically no absorption of ultraviolet light at wavelengths above 240 nm, their direct photolysis is not to be expected. Information on indirect photolysis is not available. Primary fatty amines are inherently biodegradable. Some experimental evidence suggests that they are readily biodegradable at non-bacteriotoxic concentrations. Ecotoxic Effects Concerning Aquatic Organisms. On account of their bacteriostatic and fungistatic properties, numerous studies, in which usually the EC100 values were determined, are available particularly on the toxicity of fatty amines towards bacteria and fungi. From these values alone one can draw only limited conclusions on the toxic effect, since the course of the toxicity curve (concentration against effect) is not known. The data show that fatty amines with chain lengths between 12 and 16 C-atoms (1-dodecylamine, 1-tetradecylamine and 1-hexadecylamine) possess the greatest toxicity towards both bacteria and fungi. The following EC0 and EC50 values are reported: Streptococcus mutans: 24-hr EC0: 0.2 mg/1 (1-dodecylamine) - 31 mg/l (**1-octadecylamine**); 120-hr EC50: 2 mg/l (1-dodecylamine) - 257 mg/l (1-octylamine). Streptococcus faecalis; 8-hr EC50: 0.7 mg/l (1-hexadecylamine) - 298 mg/l (1-octylamine). Photobacterium phosphoreum: 5-min EC50: 577 mg/l (1-octadecylamine). For the mixed chain-length fatty amines the following data are available in respect to inhibition of growth or gas production in mixed cultures of bacteria (activated sludge) (period of exposure in brackets): For the lysis of the protozoan, Amoeba proteus, an EC0 of 4.4 mg/l and an EC50 of 11.1 mg/l were determined for. At a concentration of 22.2 mg/l, all the cells were lysed after one hour. The ECl00 for the formation of polar filaments in the eel parasite, Plistophora anguillarum, was found to be 10 mg/l for all substances of the homologues series, with the exception of (EC100 = 100 mg/l). For the algal species, Chlorella vulgaris and Stige

BWAs are added to boiler systems to inhibit adverse effects such as corrosion of surfaces and buildup of mineral scale. The total scope of substances added to boiler water is broad: alkaline substances for pH control (such as sodium hydroxide), phosphates to control water hardness, sludge conditioners to keep solids in solution, antifoam agents, neutralizing amines, filming amines,

Overview of Boiler-Generated Steam

Boiler-generated steam is used in numerous industrial operations for the purpose of transmitting heat to a process. In food processing, boiler steam has many indirect uses (such as heating of retorts) in which steam does not contact food. Consideration of BWAs as direct addition additives in food derives from those uses in which steam directly contacts food. Some examples are blanching of vegetables and steam cooking of food.

BWA intake (as fraction of the daily solid food diet) =

(BWA level in steam) x 0.625% x 0.5

where the 0.625 factor (i.e., 62.5%) accounts for uptake of moisture during cooking of food and the 0.5 factor (i.e., 50%) is the fraction of an individual's daily intake of solid food that may contact steam. These factors will be discussed individually, below.

The Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA) has used an estimation approach for carry-over of boiler water additives (BWAs) into food since the mid-1960's when the first petitions for regulation of BWAs were reviewed. As part of its on-going appraisal of review procedures for food additives, the Division of Food Chemistry and Technology (DFCT) researched the data sources from which the BWA intake calculation is derived.

The estimation procedure for BWA intake is written:

BOILER WATER ADDITIVES
ESTIMATION OF INTAKE
USE OF BOILER WATER ADDITIVES FOR
PRODUCTION OF STEAM THAT CONTACTS FOOD

Data for these factors were developed by Pennwalt Chemicals for FAP 3A1157, which requested use of diethylaminoethanol (DEAE) as a filming amine.

The 62.5% factor derives from the petitioner's study of a "transfer factor" to account for an observed change from level in steam to level in steam-cooked food. The firm studied two subparts of this transfer factor: (1) the ratio of steam to

Review of Data

Data to support factors used in our BWA intake estimate were derived from Food Additive Petitions (FAPs) submitted shortly after implementation of the 1958 Food Additives Amendment to the FD&C Act. In the following sections we discuss the data submitted and our current evaluation.

Sources of the 62.5% and 50% Factors

the "blowdown" tube. The time between blowdowns can be [illegible] in number of cycles of concentration of feed water solids. Typical boilers go through five to thirty cycles of concentration, with the number of cycles dependent on total solids in feed water and boiler pressure. A trend in recent years is to pretreat feed water to remove impurities so that boiler water can operate through more cycles or operate at higher pressures. BWAs are added to the feed water and their level in boiler water may increase in proportion to the number of cycles of concentration.

The typical boiler operation is a dynamic system in which fresh feed water is continuously added to the boiler to account for the loss of water vapor and the loss of boiler sludge. The boiler operates at approximately constant volume with approximately 90% of the feed water lost as steam and 10% in the removal of boiler sludge. In the removal of boiler sludge, components such as water hardness salts and other precipitable impurities in the feed water are concentrated in the bottom of the boiler and occasionally forced out of the boiler by a blast of air through

oxygen scavengers and chelants. The levels of these BWAs are adjusted to maintain an equilibrium of dissolved solids in boiler water, and the specific BWAs added to a boiler system are dependent on the quality of input water. Some of the BWAs have "self-limiting" concentrations at which point their function in boiler water becomes adverse. (For example, excessive amounts of chelant will lead to increased corrosion.)

approximated as 1% of the level in boiler water, and the level in boiler water is the level in feed water times a concentration factor for number of cycles of operation between "blowdowns." The number of cycles of operation generally varies between five and thirty, depending on the boiler system.

The estimation procedure is written:

BHA intake = (BHA level in boiler water) x 0.01 x 0.625 x 0.5

Level of Additive in Steam

For volatile BHAs, whose functionality requires carry-over into steam, the level in steam is assumed to be identical to the level in boiler water and the level in boiler water is that in the feed water after accounting for any loss due to degradation. The residual level in boiler water is used as the level volatilizing into steam.

For most nonvolatile BHAs, the level in steam may be [illegible] there is a special population group whose diets contain more steam-cooked food than the typical consumer, viz., people in institutions, such as prisons, boarding schools, rest homes and orphanages. The survey undertaken by the petitioner of FAP 3A1187 found that for ten institutions the fraction of food steam-cooked "... in any one institution is well below 50%. In no case was a figure higher than 50% reported." The agency agreed with the petitioner that 50% should be used "... (to) error on the side of safety..."

over 100% for DEAE used at a very exaggerated use level. In further analyses were done at the intended use level. For this and subsequent BHA petitions, we have assumed that the efficiency of transfer will be 100%.

The 50% factor derives from a small-scale survey of ten institutions undertaken by the petitioner of FAP 3A1187. We realize that the vast majority of consumers will be exposed to BHAs through use of boiler steam to prepare processed foods, such as blanching vegetables before canning or freezing. However, [illegible]

food, measured as total condensed steam used to cook a given quantity of food, and (2) efficiency of transfer of DEAE from steam to food. For the first sub-factor, the ratio of steam to food was measured for two foods: potatoes and beef brisket. The ratios were 0.45 for potatoes and 1.03 for beef brisket. To derive a factor for total diet, a weighted average of these two numbers, 0.625, was computed for a solid food diet containing 70% vegetables and 30% meat. The second sub-factor, to account for efficiency of transfer from steam to food, was analyzed to be [illegible] use level. No

near 0.1%, ... If foaming or priming occurs (mechanisms (1) and (2)) carry-over will be many times greater."

Some of these opinions related to data on carry-over of common boiler ingredients as measured in typical boiler quality control. Depending on the indicator substance examined, the factor for carry-over varied from 0.01% to 5%. Considering all of the data and opinions, we concluded that 1% is a reasonable figure to use because it represents the "guaranteed" maximum for efficiently run boiler systems.

(1) Foaming
(2) Priming
(3) Spray Carryover

Mechanisms (1) and (2) do not occur in a well-operated boiler but are possible in problem boilers. Mechanism (3) results when steam bubbles break at the water's surface (in the steam drum) and account for most of the boiler water carry-over into the steam. Boilers are equipped with steam purifiers or separators for removing a portion of the entrained boiler water. It is [illegible] carry-over but it is somewhere in the petition FAP 3A2365, the 5 percent figure was used in order to greatly exaggerate conditions. To our knowledge, no boiler manufacturer would allow an entrainment of five percent of boiler water in the steam from his boiler."

Other petitioners have suggested carry-over factors of about 0.1%. For example, Dearborn Chemical in FAP 9A2365 states: "Boiler water gains entrance to the steam by three mechanisms, namely:

basis, to show a maximum figure...." Nalco subsequently clarified this: "The manufacturers of boilers guarantee less than one percent boiler water in the steam produced. The typical industrial boiler water contains total dissolved solids in the range of 1,000 to 2,000 ppm. This is equivalent to 0.1-0.2 percent. With a guarantee of less than one percent entrainment of boiler water in the steam, therefore, the dissolved solids in the steam would amount to a maximum of 20 ppm.

The 0.01 factor (i.e., 1%) derives from a series of opinions and indirect data on carryover of non-volatile substances from boiler water into steam. For example, Nalco Chemical in FAP 3A0967 stated "A very high percentage of boilers, operated in feed plants, are so controlled that the steam contains less than one percent (1%) of boiler water. While it is unusual, or accidental, for the steam to contain as much as five percent (5%) boiler water, we have calculated concentrations in steam on this

Boiler water [illegible]
The ratios of level in steam to level in boiler water for such substances are indicators of carry-over of non-volatile substances. However, even the latest data submitted to DFCT give ratios of 0.001 to 0.05 (i.e., 0.1% to 5% carry-over) depending on the substance analyzed. Our evaluation of these data is the same as previous, i.e., the assured minimum rate of carry-over is 1%.

[illegible] gathered before or during [illegible] processing has changed from 1967 to the present. To date, there have been no new data on use of boiler steam for cooking at institutions.

The other assumption that has been questioned by BWA petitioners is the 1% carry-over of BWA from boiler water into steam. We have received data on operating boilers relative to levels of [illegible] in boiler water and in condensed steam. DFCT concludes that the principles and [illegible] estimate intake of BWAs remain valid.

The assumption that has the greatest impact on BWA intake is that 50% of some individuals' daily food intake may be processed with boiler steam. We have asked petitioners of new BWAs to provide updated data on frequency of use of boiler steam for cooking food in institutions. The survey data in FAP 3A1157 were [illegible] the chelant, which would likely be of greater concern. There is no question that food concern. Some volatile BWAs are intended to react with oxygen in boiler systems. For such additives the substances present in steam are a mixture of residual additive and its reaction products.

1988 Evaluation

[illegible] technical efficacy of each particular BWA.

Chemical form of the BWA

Some BWAs change chemical form during use. For example, some non-volatile BWAs are used to chelate with calcium or iron. For such substances, the chemical form of the BWA when it contacts food is probably a stable complex rather than a "free" form of [illegible] account for evolution of steam. BWAs are generally added to feed water at a constant rate. Non-volatile BWAs will concentrate in boiler water until the total solids are great enough to affect boiler efficiency; then, solids are removed from the bottom of the boiler in a "blowdown" operation. The BWA concentration in boiler water may be up to 30 times the level added through feed water. Such concentration of BWA in boiler water is included in our estimation of BWA intake based on the

Boiler systems operate with a continuous influx of feed water to

TEC00045

of the food consumed by each animal. Body weights were determined weekly. Hematological studies were conducted on animals

Received for publication April 8, 1958.

From the Departments of Pharmacology (Drs. Deichmann, Radomski, and MacDonald) and Pathology (Drs. Kascht and Erdmann) University of Miami School of Medicine.

the groups.

The compound dissolved in corn oil was added to ground Purina Laboratory Chow supplemented with 1% cod-liver oil. One group of 24 rats was fed the control diet, the second group received 20 ppm, the third 100 ppm, the fourth 200 ppm, and the fifth 500 ppm octadecylamine. A record was kept

Two-Year Rat-Feeding Experiment

Experimental.—One hundred twenty healthy, weanling, Sprague-Dawley rats, housed in individual cages, were used in this experiment. They were divided into five groups of 24 each (12 males and 12 females) with randomization of litter mates among

The chronic toxicity studies consisted of a two-year rat-feeding experiment and a one-year dog-feeding experiment. In addition to the chronic studies, a short-term experiment comparing the subacute toxicity of octadecylamine with that of stearic acid was conducted, using rats.

portance as an anticorrosive agent in live steam, which may be used to cook food. It has been estimated that the rate of addition of this chemical to steam is 2.5 ppm, and that the maximum concentration of octadecylamine to be expected in food may range from 0.25 to 0.50 ppm.

trols in either the percentage mortality or the mean survival time. In both control and experimental rats there was a higher than expected rate of mortality due to acute respiratory infections. Numerous attempts were made to culture the organisms responsible for these deaths. However, only normal bacterial inhabitants of a rat's respiratory

Results.—There was no significant difference observed between the mean daily consumption of experimental and control diets (Table 1). The mean weight gains were also essentially the same for all groups. There was no significant difference between the animals fed octadecylamine and the con-

0	M	15.9	348.0	67	601.1
	F	14.5	209.4	83	472.4
20	M	17.0	319.5	75	528.6
	F	15.0	193.0	79	540.4
100	M	16.2	281.7	75	508.5
	F	14.5	201.9	88	553.3
200	M	17.8	324.5	75	535.6
	F	12.6	210.2	83	475.5
500	M	18.1	258.5	67	549.9
	F	14.1	204.4	92	504.5

TABLE 1.—*Food Consumption, Weight Gain, Mortality, and Survival of Rats Fed Octadecylamine for Two Years*

Dietary Concentration Ppm	Sex	Diet Consumption Gm/Day	Mean Weight Gain Gm.	Mortality, per Cent	Mean Survival Days

termination of the experiment and from a few rats killed in extremis. Tissues taken for micropathological examination included brain, pituitary, adrenals, skeletal muscle, bone marrow, heart, lungs, liver, spleen, kidneys, gastroenteric tract (three levels), pancreas, lymph nodes, and ovary or testis.

WILLIAM B. DEICHMANN, Ph.D.; J. L. RADOMSKI, Ph.D.; WILLIAM E. MacDONALD, M.S.; ROBERT L. KASCHT, M.D., and R. L. ERDMANN, M.D., Coral Gables, Fla.

The purpose of this investigation was to determine the chronic toxicity of commercial octadecylamine (containing 20% hexadecylamine). This material is of im-

picked at random from each of the groups. All animals surviving at the end of two years were killed. Pathological examinations were made on the tissues of all animals killed at

Reprinted from the A. M. A. Archives of Industrial Health
December 1958, Vol. 18, pp. 483-487

The Chronic Toxicity of Octadecylamine

TABLE 2.—*The Effects on the Peripheral Blood of Feeding Octadecylamine to Rats for Two Years*

(Average values and standard deviations of counts taken on groups of five or six rats after 96 weeks of feeding)

Dietary Concentration Ppm	Hemoglobin Gm/100 Ml. Mean±S. D.	Red Blood Cells Millions/Cu. Mm. Mean±S. D.	White Blood Cells Thousands/Cu. Mm. Mean±S. D.	Neutrophils Thousands/Cu. Mm. Mean±S. D.	Lymphocytes Thousands/Cu. Mm. Mean±S. D.
0	11.4±1.1	6.2±1.0	21.8±3.3	8.0±3.3	13.7±3.7
20	13.3±0.3	8.3±1.7	21.4±6.6	6.7±2.6	14.0±4.3
100	12.8±1.0	8.1±0.7	23.0±6.9	7.8±1.8	14.0±5.3
200	13.5±1.0	8.4±0.7	17.0±4.2	6.2±2.0	13.7±6.0
500	14.5±0.4	8.6±1.3	19.6±3.3	6.3±0.4	13.7±6.3

tract were found. The impression was gained that these deaths were the result of a nonspecific endemic pulmonary infection occasionally observed in rat colonies.

The blood studies were conducted on all groups of rats after 4, 8, 13, 16, 20, 25, 28, 43, 55, 66, 86, and 96 weeks of feeding. The only significant change that was noted was a slight upward trend in the total white and total neutrophil count. This may have been associated with the prevalence of respiratory disease in the colony. The final (96-week) values shown in Table 2 reveal no significant differences in hemoglobin concentration, red count, white count, absolute neutrophil count, and absolute lymphocyte count between any of the groups fed octadecylamine and the controls.

Inasmuch as a preliminary study (to be reported below) with doses of 3000 ppm of octadecylamine had shown a constant and striking change in the gastroenteric tract and mesenteric lymph nodes, particular attention was focused on these organs as the sites of expected micropathologic change. However, no change, either quantitatively or even qualitatively similar, was observed.

There were no significant pathologic differences between the control group and the groups of rats fed 20, 100, 200, and 500 ppm octadecylamine. Lesions encountered in all groups included pyelonephritis, hyaline casts in the renal tubules, occasional renal abscesses, and bronchitis or pneumonia. One animal in the control group showed a mild endocarditis and valvulitis; one animal in the 100 ppm octadecylamine group developed a brain abscess, and one animal receiving 500 ppm showed histocytic hyperplasia of a mesenteric lymph node. The changes observed were not considered significant or related to the ingestion of octadecylamine.

One-Year Dog-Feeding Experiment

Twelve young mongrel dogs were selected for the one-year dog feeding experiment. They were housed in individual cages and fed once daily. The diet consisted of a mixture of Purina Kibbled Meal and canned horse meat. In addition, they had access at all times to Hunt Club Bones (a dog biscuit). The twelve dogs were divided into four groups of three animals each. One group (two males and one female) served as control; a second group (one male and two females) received octadecylamine at a dose level of 0.6 mg/kg/day; the third group (two males and one female) 3.0 mg/kg/day, and the fourth group (one male and two females) 15.0 mg/kg/day. Throughout the experiment, octadecylamine in corn-oil solution was administered by capsule once daily except Saturdays and Sundays. The dogs were weighed once a month and the doses recalculated on the basis of the new weights. Hematological examinations consisting of total red blood cell count, hemoglobin concentration, and total and differential white cell counts were performed on the 12 dogs at the start of the experiment and 1, 2, 3, 6, 8, 11, and 12 months thereafter. All surviving animals were killed at the end of the year for gross and microscopic examination.

Results.—With one exception, all dogs survived the experiment in obvious good

				Daily Dose: 15.0 Mg/Kg.						
D-96	11.4	15.4 *	6.1	5.8 *	8.5	8.2 *	4.0	5.2 *	2.2	1.8 *
D-94	12.8	16.0	6.3	5.2	6.4	33.8	5.0	0.8	1.1	5.3
D-100	11.4	17.0	6.0	5.6	7.4	7.8	3.7	5.0	3.0	1.7

* These final counts after 8 months of feeding (dog died subsequently).

D-97	11.0	14.4	6.2	7.6	10.4	6.4	3.9	4.0	5.6	2.8
				Daily Dose: 0.6 Mg/Kg.						
D-95	12.4	15.4	5.4	7.8	5.8	9.9	4.1	6.3	1.3	3.9
D-96	12.8	15.3	5.9	6.4	9.4	17.6	5.9	9.4	0.6	7.4
D-98	13.0	14.6	6.2	7.0	10.9	11.9	4.8	7.9	4.4	3.3
				Daily Dose: 3.0 Mg/Kg.						
D-92	11.0	13.6	6.0	7.2	8.9	12.8	7.6	6.7	0.7	5.9
D-93	10.2	14.6	5.3	7.6	13.6	9.9	9.0	5.3	3.5	4.1
D-99	11.0	14.6	6.2	8.2	7.5	10.2	3.6	6.9	3.2	3.5

(Blood counts after 1, 2, 3, 6, 8, and 12 months of feeding)

Identification No.	Hemoglobin Gm/100 Ml.		Red Blood Cells Millions/Cu. Mm.		White Blood Cells Thousands/Cu. Mm.		Neutrophils Thousands/Cu. Mm.		Lymphocytes Thousands/Cu. Mm.	
	Initial	Final	Initial	Final	Initial	Final	Initial	Final	Initial	Final
					Control Dogs					
D-90	10.4	11.5	5.2	5.6	10.9	13.8	6.5	8.7	3.9	3.9
D-91	11.4	13.9	6.4	6.8	12.2	9.4	9.4	4.1	2.8	4.0

from anorexia during the last three weeks of life, and exhibited bloody diarrhea during the three days prior to death. The animal did not show a severe loss in weight, but

Gross pathological organ changes were not observed. The organs examined microscopically included the heart, lungs, liver, spleen, kidneys, gastroenteric tract (three

TABLE 4.—*Effect of Feeding Octadecylamine to Dogs for One Year*
(Only initial and final counts are given; complete blood counts

D-96	F	13.0	7.0	7.2	+0.2
D-100	F	15.0	8.3	9.7	+1.4
				Average gain	0.4

* Died after 22 weeks.

dogs, and were expected since the dogs used for the experiment were young and attained maturity as the experiment progressed. The initial and final values are shown in Table 4. There are no significant differences between the animals receiving octadecylamine and the controls.

health. One dog, at the 15 mg/kg. level, died after 22 weeks. This animal suffered

D-95	M	0.6	8.7	11.5	+1.8
D-98	F	0.6	6.7	10.8	+4.0
				Average gain	2.9
D-94	F	3.0	8.1	12.8	+4.7
D-92	M	3.0	6.0	7.9	+1.9
D-99	M	3.0	7.9	12.0	+4.1
				Average gain	4.2
D-90 *	M	15.0	9.4	9.0	−0.4

beginning of the experiment and after 1, 2, 3, 6, 8, 11, and 12 months of drug administration. A slight gradual increase in the total number of red blood cells and concentration of hemoglobin was observed as the experiment progressed. These changes were noted in all control and experimental

Identification No.	Sex	Dose of Octadecylamine Mg/Kg.	Initial Weight of Dog Kg.	Final Weight of Dog Kg.	Change of Weight Kg.
D-89	M	0	10.2	12.5	+2.3
D-91	F	0	4.3	9.8	+4.5
D-97	M	0	7.6	12.2	+4.6
				Average gain	4.0
D-96	F	0.6	10.4	11.7	+0.7

ceiving 15 mg/kg. was less than that gained by the control dogs or those fed lower levels of octadecylamine. The weight gain of the dogs on both of the lower levels was essentially the same as that of the control dogs (Table 3).

Blood studies were performed at the

CHRONIC TOXICITY OF OCTADECYLAMINE

TABLE 3.—*Weight Changes of Dogs Fed Octadecylamine for One Year*

Daily		

the impression was gained that it was suffering from gastroenteric irritation.

The mean weight gain of the dogs re-

bone marrow, heart, lungs, liver, spleen, kidneys, gastroenteric tract (three levels), pancreas, and lymph nodes.

including the heart, liver, kidneys, pancreas, and adrenals, did not show significant abnormalities.

microscopic pathological examinations were made on tissues taken from all animals killed at termination of the experiment and from certain animals killed in extremis while the experiment was in progress. Tissues taken for micropathological examination included brain, viscera, gonads, skeletal muscle, [illegible] terminal primary amino group). These experimental diets were fed for a total of 209 days. A record was kept of the food consumed by each animal. Individual body weights were determined weekly throughout the experiment. All animals surviving at the end of 209 days were killed. Gross and

One group of 10 Sprague-Dawley rats (5 males and 5 females), housed in individual cages, was fed 3000 ppm of octadecylamine in the basic diet. A similar group received the basic diet containing 3000 ppm of stearic acid (a straight-chain fatty acid differing from octadecylamine only in that it contains a carboxyl group in place of the [illegible] nodes were filled with pale, "foamy" histiocytes.

Comparison of Subacute Toxicity of Octadecylamine with That of Stearic Acid

The intestines of these dogs had a different appearance from the intestines of the other dogs and were slightly similar to those of rats fed 3000 ppm octadecylamine, suggesting the possibility of some absorption of a nonstaining material into the mucosa of the small intestine. Also, in both of these animals the sinuses of the mesenteric lymph tract was identified. However, in the two surviving animals of the group that received 15.0 mg./kg. of octadecylamine, the tips of the villi of the mucosa of the small intestine were pale-staining. This appeared in the superficial substantia propria. No foam cells or deposits of lipid material were identified.

[illegible] showed severe pulmonary infection consisting of tracheobronchitis, lobular pneumonia, lipoid histiocyte response, and abscess formation. No retention or imbibition of this ingested material was noted in sections of the gastroenteric tract. Abundant iron-containing pigment was found in the spleens; the other organs examined microscopically [illegible] ever, those which survived began to gain midway during the course of the experiment. This was not true of the rats on stearic acid; throughout the experiment these animals showed a gradual but somewhat erratic tendency to gain.

Tissues from rats fed 3000 ppm stearic acid showed [illegible] and females receiving octadecylamine was shorter than that for the rats receiving stearic acid. On the other hand, the mortality ratio of the rats on stearic acid was slightly greater for both males and females. It is interesting to note that all of the rats on octadecylamine lost weight initially. However, [illegible] decylamine showed a mean weight loss of 31 gm. while those fed stearic acid gained 30 gm. Although the females on octadecylamine showed a mean gain of 30 gm., it was significantly less than the gain of the females on stearic acid, which was 58 gm. The mean period of survival of both males

	Females	3/5	137	+58	12.5

Results.—Both groups exhibited anorexia, but the rats that received octadecylamine had a significantly lower mean daily intake of food than those receiving stearic acid in their diet (Table 5). The males on octa-

Compound	Sex	Mortality Ratio	Average Survival Time, Days	Average Weight Change, Gm.	Average Diet Consumption per Day, Gm.
Octadecylamine	Males	4/5	87	−31	8.3
	Females	1/5	118	+30	11.5
Stearic acid	Males	1/5	107	+12	18.9

levels), pancreas, lymph nodes, bone marrow, brain, pituitary, adrenals, and ovary or testis. No definite lesion of the intestinal

TABLE 5.—*Effect of Feeding to Rats 3000 Ppm of Octadecylamine and 3000 Ppm of Stearic Acid for a Period of 209 Days*

Department of Pharmacology, University of Miami School of Medicine.

No toxic effects were observed in dogs given octadecylamine at levels of 0.6 and

including 500 ppm. The weight changes, blood counts, percentage and distribution of mortality, and food consumption of the rats fed octadecylamine were similar to those noted in the controls. Octadecylamine at this level produced no micropathological changes in rats.

spleen, pancreas, kidneys, and adrenals—were normal.

Summary and Conclusions

No toxic effects were observed when, for a period of two years, octadecylamine was fed to rats in the diet at levels up to and of time (118 and 133 days). In the third animal (137 days) only one such nodule was seen. Although the mesenteric nodes of all five animals showed a granulomatous response, this likewise appeared more intense in rats fed octadecylamine for 118 and 133 days. The other organs examined—heart, ...dn, necrosis, and fibrosis. These lymph node sections stained weakly positive with Sudan IV. Sections of the livers of three of five animals showed nodular aggregates of histiocytes, with slight necrosis. This feature was most pronounced in the two animals that survived for the shortest period. Histiocytes within the mucosa of the small intestine in each animal. These were not stained by Sudan IV. The mesenteric lymph nodes were grossly enlarged and matted. Microscopic examination of them revealed a marked granulomatous reaction with abundant histiocytes, nodule or tubercle forma-

...significant pathological lesions, but those fed octadecylamine showed an accumulation of histiocytes with pale or foamy cytoplasm in the mucosa of the small intestine and mesenteric lymph nodes. Focal granulomas were seen in the livers of some of these latter animals.

substituted for the terminal primary amine group) demonstrated that at a level of 3000 ppm in the diet the two compounds elicited similar toxic reactions. Both compounds produced anorexia and increased rate of mortality. Rats fed stearic acid showed no ...are 500 ppm for the rat, and 3.0 mg/kg/day (equivalent to approximately 100 ppm in the diet) for the dog.

The preliminary experiment on the comparative subacute toxicity of octadecylamine and stearic acid (a compound with the same carbon skeleton but having a carboxyl group ... no pathology. While the death of the one dog might be fortuitous, the bulk of the evidence indicates that octadecylamine has some toxic effects (primarily on the gastroenteric tract when fed at a level of 15.0/kg/day). Thus it appears that the maximum nontoxic levels of octadecylamine ...less weight than controls of the dogs receiving the lower levels of octadecylamine. Two of the three animals fed 15.0 mg/kg. (including the one which died) showed slight changes of an equivocal nature in the mucosa of the small intestine. Otherwise, microscopic examination of the tissues showed

CHRONIC TOXICITY OF OCTADECYLAMINE

Tissues from rats fed 3000 octadecylamine showed varying degrees of pulmonary infection. Sections from the gastroenteric tract revealed a diffuse aggregation of foamy ...

3.0 mg/kg. per day on each of five days of a week for a period of 12 months. One of the three dogs receiving 15 mg/kg/day died after 22 weeks. The other two dogs gained ...

OCTADECYLAMINE
HSDB - Hazardous Substances Data Bank

0.0 ADMINISTRATIVE INFORMATION
Hazardous Substances Data Bank Number: 1194
Last Revision Date: 20000612

1.0 SUBSTANCE IDENTIFICATION
Name of Substance: OCTADECYLAMINE
CAS Registry Number: 124-30-1
Synonyms:
1. 1-AMINOOCTADECANE [Peer Reviewed]
2. 1-OCTADECANAMINE [Peer Reviewed]
3. ADOGENEN 142 [Peer Reviewed] [U.S. Department of Health, Education & Welfare, Public Health Service. Center for Disease Control, National Institute for Occupational Safety & Health. Registryof Toxic Effects of Chemical Substances. 1977 edition. Washington, D. C.: U.S. Government Printing Office, 1977. 602]
4. ALAMINE 7 [Peer Reviewed] [U.S. Department of Health, Education & Welfare, Public Health Service. Center for Disease Control, National Institute for Occupational Safety & Health. Registryof Toxic Effects of Chemical Substances. 1977 edition. Washington, D. C.: U.S. Government Printing Office, 1977. 602]
5. ALAMINE 7D [Peer Reviewed]
6. ARMEEN 118D [Peer Reviewed] [U.S. Department of Health, Education & Welfare, Public Health Service. Center for Disease Control, National Institute for Occupational Safety & Health. Registryof Toxic Effects of Chemical Substances. 1977 edition. Washington, D. C.: U.S. Government Printing Office, 1977. 602]
7. ARMEEN 18D [Peer Reviewed]
8. ARMOFILM [Peer Reviewed]
9. KEMAMINE P 990 [Peer Reviewed]
10. N-OCTADECYLAMINE [Peer Reviewed] [U.S. Department of Health, Education & Welfare, Public Health Service. Center for Disease Control, National Institute for Occupational Safety & Health. Registryof Toxic Effects of Chemical Substances. 1977 edition. Washington, D. C.: U.S. Government Printing Office, 1977. 602]
11. N-STEARYLAMINE [Peer Reviewed]
12. NISSAN AMINE AB [Peer Reviewed]
13. STEARAMINE [Peer Reviewed]
14. STEARYLAMINE [Peer Reviewed] [U.S. Department of Health, Education & Welfare, Public Health Service. Center for Disease Control, National Institute for Occupational Safety & Health. Registryof Toxic Effects of Chemical Substances. 1977 edition. Washington, D. C.: U.S. Government Printing Office, 1977. 602]

Molecular Formula: C18-H39-N [Peer Reviewed]
RTECS Number: NIOSH/RG4150000
2.0 MANUFACTURING/USE INFORMATION
Methods of Manufacturing:
CATALYTIC HYDROGENATION OF STEARYL NITRILE [Peer Reviewed] [SRI]

Manufacturers:

1. Akzo Nobel Chemicals, Inc., 300 South Riverside Plaza, Chicago, IL 60606, (312)906-7500. Production sites: McCook, IL 60525; Morris, IL 60450. [Peer Reviewed] [SRI. 1997 Directory of Chemical Producers - United States of America. Menlo Park, CA: SRI International 1997. 925]
2. Enenco, Inc., 3018 Bell Ave., Memphis, TN 38108, (901)320-5901. Production site: Memphis, TN 38108. [Peer Reviewed] [SRI. 1997 Directory of Chemical Producers - United States of America. Menlo Park, CA: SRI International 1997. 925]
3. Witco Corp., 1 American Lane, Greenwich, CT 06831-2559. (202)552-2000. Production site: Mapleton, IL 61547. [Peer Reviewed] [SRI. 1997 Directory of Chemical Producers - United States of America. Menlo Park, CA: SRI International 1997. 925]

Other Manufacturing Information:

EIGHTEEN CARBON STRAIGHT CHAIN AMINE SOMETIMES USED AS ANTICORROSIVE AGENT IN LIVE STEAM LINES. [Peer Reviewed] [Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-139]

Major Uses:

1. ANTICORROSIVE AGENT [Peer Reviewed] [Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-139]
2. MOLD RELEASE AGENT IN MFR OF BATTERY CASES; CORROSION INHIBITOR IN STEAM PLANTS; CHEMICAL INTERMEDIATE FOR OCTADECYL ISOCYANATE; CHEMICAL INTERMEDIATE FOR OTHER SURFACE-ACTIVE AGENTS; ANTICAKING AGENT; FLOTATION AGENT; AGENT IN VARIOUS ASPECTS OF PETROLEUM INDUSTRY; ANTISTRIPPING AGENT IN ASPHALT EMULSIONS FOR HIGHWAYS [Peer Reviewed] [SRI]
3. Surface protection against condensate corrosion in steam systems. [Peer Reviewed] [Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present.,p. V22 740]

U.S. Production:

1. (1972) 2.46X10+8 GRAMS [Peer Reviewed] [SRI]
2. (1975) PROBABLY GREATER THAN 1.36X10+6 GRAMS [Peer Reviewed] [SRI]
3. (1984) 1.11X10+9 g [Peer Reviewed] [USITC. SYN ORG CHEM-U.S. PROD/SALES 1984 p.177]

3.0 CHEMICAL AND PHYSICAL PROPERTIES

Boiling Point: 346.8 deg C @ 760 mm Hg [Peer Reviewed] [Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996.,p. 3-226]

Melting Point: 52.9 deg C [Peer Reviewed] [Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996.,p. 3-226]

Molecular Weight: 269.51 [Peer Reviewed] [Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996.,p. 3-226]

Density/Specific Gravity: 0.8618 @ 20 deg C/4 deg C [Peer Reviewed] [Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed.

Boca Raton, FL: CRC Press Inc., 1995-1996.,p. 3-226]
Dissociation Constants: pKa = 10.65 [Peer Reviewed] [Barratt MD; Toxicol In Vitro 10: 85-94 (1996)]
Solubilities: Insol in water; sol in alcohol, ether, benzene; very sol in chloroform; miscible in acetone [Peer Reviewed] [Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996.,p. 3-226]
Spectral Properties:

1. Index of refraction: 1.4522 @ 20 deg C [Peer Reviewed] [Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996.,p. 3-226]
2. IR: 20374 (Sadtler Research Laboratories Prism Collection) [Peer Reviewed] [Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985.,p. V1 926]
3. NMR: 16084 (Sadtler Research Laboratories Spectral Collection) [Peer Reviewed] [Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985.,p. V1 926]
4. MASS: 212 (Aldermaston, Eight Peak Index of Mass Spectra, UK) [Peer Reviewed] [Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985.,p. V1 926]
5. MASS: 4716 (National Bureau of Standards EPA-NIH Mass Spectra Data Base, NSRDS-NBS-63) [Peer Reviewed] [Weast, R.C. and M.J. Astle. CRC Handbook of Data on Organic Compounds. Volumes I and II. Boca Raton, FL: CRC Press Inc. 1985.,p. V2 298]

4.0 SAFETY AND HANDLING

HAZARDOUS REACTIONS

Decomposition:
When heated to decomposition it emits toxic fumes of nitroxides. [Peer Reviewed] [Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 2515]

OTHER SAFETY AND HANDLING

Disposal Methods:
SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices. [Peer Reviewed]

5.0 TOXICITY/BIOMEDICAL EFFECTS

TOXICITY EXCERPTS

Human Toxicity Excerpts:

1. SAID TO BE PRIMARY SKIN SENSITIZER. [Peer Reviewed] [Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-139]
2. The effects of non-drug-containing liposomes of different compositions and sizes on the proliferation of nine

cancer-derived and one normal cultured human cell lines were determined. Stearylamine- and cardiolipin-containing liposomes were toxic (ID50) at 200 uM liposomal lipid concentrations or less ... [Peer Reviewed] [Mayhew E et al; Exp Cell Res 171 (1): 195-202 (1987)]

Non-Human Toxicity Excerpts:

1. /RATS/ AT LEVELS OF 3000 PPM FOR FROM 89-209 DAYS, /DEVELOPED/ ANOREXIA, WT LOSS & SOME HISTOLOGIC CHANGES IN MESENTERIC LYMPH NODES, GASTROINTESTINAL MUCOSA & LIVER. [Peer Reviewed] [Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-139]
2. OCTADECYLAMINE CAUSED LOCAL IRRITATION & A GENERAL RESORPTION EFFECT ON SKIN OF MICE, RATS, & GUINEA PIGS. [Peer Reviewed] [PAUSTOVSKAYA VV ET AL; GIG SANIT 38(11) 31-35 (1973)]
3. Rats fed levels of 0 to 500 ppm in the diet for 2 years showed no detectable effects on growth, food consumption, hematology, or microscopic pathology. At 3000 ppm there was anorexia, weight loss, and some histological changes in the gastrointestinal tract, mesenteric nodes, and liver. Octadecylamine is a primary skin irritant. [Peer Reviewed] [Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994. 1132]
4. The results of safety assessment testing of ... stearamine ... for use in cosmetic products were reported. ... Stearamine /has/ been formulated for use as antistatic agents, although no current uses have been reported. Alterations including weight loss, increased mortality, and intestinal and mesenteric lymph node histiocyte accumulation have been reported in a study following treatment of experimental animals with 3,000 ppm stearamine, but these effects were not seen after exposure to 500 ppm. Chronic stearamine exposure has not been reported to induce tumor formation, although 0.01% stearamine in the presence of a high fat diet promoted the carcinogenic effects of 7,12-dimethylbenz(a)anthracene, while 0.1% inhibited tumor production. This compound was also reported to induce severe hyperplasia in the skin of albino-mice concentrations as low as 3 mg. ... [Peer Reviewed] [Pang S; Journal of the American College of Toxicology 14 (3): 196-203 (1995)]

TOXICITY VALUES

Non-Human Toxicity Values:

1. LD50 RAT ORAL 1000 MG/KG, ACUTE [Peer Reviewed] [Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994. 1132]
2. LD50 Mouse oral 3 g/kg [Peer Reviewed] [Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996.

2515]
3. LD50 Mouse ip 250 mg/kg [Peer Reviewed] [Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 2515]

PHARMACOKINETICS

Interactions:

IF (3)H-METHOTREXATE IS COMPLETELY ENTRAPPED IN LIPOSOMES CONCN OF DRUG IN LIVER & SPLEEN INCR. IF DICETYL PHOSPHATE IN LIPOSOMES IS REPLACED BY STEARYLAMINE GREATER PROP OF LIPOSOMES IS TAKEN UP BY LIVER & SPLEEN. [Peer Reviewed] [COLLEY CM ET AL; BIOCHEM SOC TRANS 3(1) 157-9 (1975)]

7.0 ENVIRONMENTAL FATE/EXPOSURE POTENTIAL

SUMMARY

Environmental Fate/Exposure Summary:

Octadecylamine's production and use as a corrosion protection agent in steam plants may result in its release to the environment through various waste streams. If released to air, an estimated vapor pressure of 4.4X10-5 mm Hg at 25 deg C indicates octadecylamine will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase octadecylamine will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 7 hours. Particulate-phase octadecylamine will be removed from the atmosphere by wet and dry deposition. If released to soil, octadecylamine is expected to be immobile based upon an estimated log Koc of 5.5. A pKa value of 10.65 indicates octadecylamine will exist primarily in the protonated form in the environment. Volatilization from moist soil surfaces is not expected to be important because the protonated form of octadecylamine is not expected to volatilize. Octadecylamine is not expected to volatilize from dry soil surfaces based upon its vapor pressure. A 32% of theoretical BOD in an activated sludge inoculum was observed over a 15-day incubation period, suggesting that biodegradation may be rapid in the environment. If released into water, octadecylamine's pKa value indicates that the protonated form will be the dominant species under most environmental conditions. Both the neutral species and the cation are expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is not expected to be an important fate process because the protonated form is the dominant species in water and is not expected to volatilize. An estimated log BCF of 5.6 suggests the potential for bioconcentration in aquatic organisms is very high. Occupational exposure to octadecylamine may occur through inhalation and dermal contact with this compound at workplaces where octadecylamine is produced or used. (SRC) [Peer Reviewed]

POLLUTION SOURCES

Artificial Sources:

Octadecylamine's production and use as a corrosion protection agent in steam plants(1) may result in its release to the environment through various waste streams(SRC). [Peer Reviewed] [(1) Bellows J; Kirk-Othmer Encycl Chem Technol. 4th ed.

Kroschwitz JI ed. NY,NY: John Wiley & Sons 22: 749 (1997)]

ENVIRONMENTAL FATE

1. TERRESTRIAL FATE: Based on a classification scheme(1), an estimated log Koc value of 5.5(SRC), determined from an estimated log Kow of 7.7(2,SRC) and a regression-derived equation(3), indicates that octadecylamine is expected to be immobile in soil(SRC). A pKa value of 10.65(4) indicates that the protonated form will be the dominant species in moist soil surfaces and cationic molecules generally adsorb strongly to soils(SRC). Volatilization of octadecylamine from moist soil surfaces is not expected to be an important fate process since the protonated form is expected to be the dominant species based on the pKa value(4). Volatilization of octadecylamine from dry soil surfaces is not expected(SRC) based upon the estimated vapor pressure of 4.4X10-5 mm Hg at 25 deg C(5). A 32% of theoretical BOD in an activated sludge inoculum was observed over a 15-day incubation period(6), suggesting that biodegradation may be rapid in the environment(SRC). [Peer Reviewed] [(1) Swann RL et al; Res Rev 85: 23 (1983) (2) Meylan WM, Howard PH; J Pharm Sci 84: 83-92 (1995) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington,DC: Amer Chem Soc pp. 4-9 (1990) (4) Barratt MD; Toxicol In Vitro 10: 85-94 (1996) (5) Lyman WJ; p 31 in Environmental Exposure From Chemicals Vol I, Neely WB, Blau GE (eds), Boca Raton,FL: CRC Press (1985) (6) Yoshimura K et al; J Amer Oil Chem Soc 57: 238-41 (1980)]
2. AQUATIC FATE: Based on a classification scheme(1), an estimated log Koc value of 5.5(SRC), determined from an estimated log Kow of 7.7(2,SRC) and a regression-derived equation(3), indicates that octadecylamine is expected to adsorb to suspended solids and sediment in water(SRC). A pKa value of 10.65(4) indicates that the protonated form will be the dominant species in water and volatilization from water surfaces is not expected to be an important fate process(SRC). According to a classification scheme(5), an estimated log BCF of 5.6(3,SRC), from its estimated log Kow(2,SRC), suggests the potential for bioconcentration in aquatic organisms is very high(SRC). A 32% of theoretical BOD in an activated sludge inoculum was observed over a 15-day incubation period(6), suggesting that biodegradation may be rapid in the environment(SRC). [Peer Reviewed] [(1) Swann RL et al; Res Rev 85: 23 (1983) (2) Meylan WM, Howard PH; J Pharm Sci 84: 83-92 (1995) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington,DC: Amer Chem Soc pp. 4-9, 5-4, 5-10, 15-1 to 15-29 (1990) (4) Barratt MD; Toxicol In Vitro 10: 85-94 (1996) (5) Franke C et al; Chemosphere 29: 1501-14 (1994) (6) Yoshimura K et al; J Amer Oil Chem Soc 57: 238-41 (1980)]
3. ATMOSPHERIC FATE: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere(1), octadecylamine, which has an estimated vapor pressure of 4.4X10-5 mm Hg at 25 deg C(2), is

expected to exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase octadecylamine is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals(SRC); the half-life for this reaction in air is estimated to be 10 hours(SRC) from its estimated rate constant of 3.4X10-11 cu cm/molecule-sec at 25 deg C(SRC), determined from a structure estimation method(3). Particulate-phase octadecylamine will be removed from the atmosphere by wet and dry depostion(SRC). [Peer Reviewed] [(1) Bidleman TF; Environ Sci Technol 22: 361-367 (1988) (2) Lyman WJ; p. 31 in Environmental Exposure From Chemicals Vol I, Neely WB, Blau GE (eds), Boca Raton,FL: CRC Press (1985) (3) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993)]

ENVIRONMENTAL TRANSFORMATIONS

Biodegradation:

A 32& of theoretical BOD using an activated sludge inoculum was observed for octadecylamine over a 15-day incubation period(1), suggesting that biodegradation may be rapid in the environment(SRC). [Peer Reviewed] [(1) Yoshimura K et al; J Amer Oil Chem Soc 57: 238-41 (1980)]

Abiotic Degradation:

The rate constant for the vapor-phase reaction of octadecylamine with photochemically-produced hydroxyl radicals has been estimated as 3.4X10-11 cu cm/molecule-sec at 25 deg C(SRC) using a structure estimation method(1). This corresponds to an atmospheric half-life of about 11 hours at an atmospheric concentration of 5X10+5 hydroxyl radicals per cu cm(1). Octadecylamine is not expected to undergo hydrolysis due to the lack of hydrolyzable functional groups(2) nor to directly photolyze due to the lack of absorption in the environmental UV spectrum. [Peer Reviewed] [(1) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington,DC: Amer Chem Soc pp. 7-4, 7-5 (1990)]

ENVIRONMENTAL TRANSPORT

Bioconcentration:

An estimated log BCF of 5.6 was calculated for octadecylamine(SRC), using an estimated log Kow of 7.7(1,SRC) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC). [Peer Reviewed] [(1) Meylan WM, Howard PH; J Pharm Sci 84: 83-92 (1995) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington,DC: Amer Chem Soc pp. 5-4, 5-10 (1990) (3) Franke C et al; Chemosphere 29: 1501-14 (1994)]

Soil Adsorption/Mobility:

The Koc of octadecylamine is estimated as approximately 3.198X10+5(SRC), using an estimated log Kow of 7.7(1,SRC) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that octadecylamine is expected to be immobile in soil(SRC). [Peer Reviewed] [(1) Meylan WM, Howard PH; J Pharm Sci 84: 83-92 (1995) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington,DC: Amer Chem Soc pp. 4-9 (1990) (3) Swann RL et al;

Res Rev 85: 23 (1983)]
Volatilization from Soil/Water:
The Henry's Law constant for octadecylamine is estimated as 9.4X10-4 atm-cu m/mole(SRC), using a fragment constant estimation method(1). This Henry's Law constant indicates that the neutral form of octadecylamine is expected to volatilize from water surfaces(2). Based on this Henry's Law constant, the volatilization half-life from a model river (1 m deep, flowing 1 m/sec, wind velocity of 3 m/sec)(2) is estimated as approximately 6 hours(SRC). The volatilization half-life from a model lake (1 m deep, flowing 0.05 m/sec, wind velocity of 0.5 m/sec)(2) is estimated as approximately 167 hours(SRC). A pKa of 10.65(3) indicates octadecylamine will exist predominately in the protonated form at environmental pHs and therefore volatilization from water and moist soil surfaces is not expected to be an important fate process(SRC). Octadecylamine is not expected to volatilize from dry soil surfaces(SRC) based upon an estimated vapor pressure of 4.4X10-5 mm Hg at 25 deg C(4). [Peer Reviewed]
[(1) Meylan WM, Howard PH; Environ Toxicol Chem 10: 1283-93 (1991) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington,DC: Amer Chem Soc pp. 15-1 to 15-29 (1990) (3) Barratt MD; Toxicol In Vitro 10: 85-94 (1996) (4) Lyman WJ; p. 31 in Environmental Exposure From Chemicals Vol I, Neely WB, Blau GE (eds), Boca Raton,FL: CRC Press (1985)]

HUMAN EXPOSURE
Probable Routes of Human Exposure:
NIOSH (NOES Survey 1981-1983) has statistically estimated that 2,303 workers are potentially exposed to octadecylamine in the US(1). Occupational exposure to octadecylamine may occur through inhalation and dermal contact with this compound at workplaces where octadecylamine is produced or used(SRC). [Peer Reviewed]
[(1) NIOSH; National Occupational Exposure Survey (NOES) (1983)]

EXPLOSION HAZARDS	
SPECIAL FIRE FIGHTING PROCEDURES	
EXTINGUISHING MEDIA	Foam, dry chemical, water spray, carbon dioxide
UNUSUAL FIRE AND EXPLOSION HAZARDS	

III. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (test method) COC	320°F	AUTOIGNITION TEMPERATURE	
FLAMMABLE LIMITS IN AIR, % by volume	LOWER		UPPER
APPEARANCE AND ODOR	White solid, ammoniacal odor		

II. HAZARDOUS INGREDIENTS

MATERIAL	%	TLV (Units)
Armeen 18 or Armeen 18D	100	

SPECIFIC GRAVITY (H_2O=1)	0.791 (60°C)	VAPOR PRESSURE at 20° C.	< 1mmHg
VAPOR DENSITY (air = 1)	--	SOLUBILITY IN WATER, % by wt. at 20° C.	insoluble
PER CENT VOLATILES BY VOLUME	~ 1	EVAPORATION RATE (Butyl Acetate = 1)	
APPEARANCE AND ODOR	White solid, ammoniacal odor		

FORMULA: RNH_2 MOLECULAR WEIGHT: ~ 269

TRADE NAME AND SYNONYMS: ARMEEN 18 and 18D

I. PHYSICAL DATA

BOILING POINT, 760 mm. Hg	~ 320-344°C.	FREEZING POINT	~132°F

MATERIAL SAFETY DATA SHEET

CHEMICAL NAME: n-Octadecylamine

SYNONYMS: stearylamine; 1-aminooctadecane CHEMICAL FAMILY: Amine

Akzo Chemie America

300 SOUTH WACKER DRIVE • CHICAGO, ILLINOIS 60606 • (312) 786-0400

PRECAUTIONARY LABELING	Corrosive
OTHER HANDLING AND STORAGE CONDITIONS	

EMERGENCY PHONE NUMBERS

PROTECTIVE GLOVES	Neoprene	EYE PROTECTION	Face shield Splash goggles
OTHER PROTECTIVE EQUIPMENT	Eye wash, emergency showers		

VIII. SPECIAL PRECAUTIONS

VII. SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION (specify type)			
VENTILATION	LOCAL EXHAUST		SPECIAL
	MECHANICAL (general)		OTHER
STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED	Avoid contact with skin.		
WASTE DISPOSAL METHOD	Absorb spilled material on floor with cleaning compounds or saw dust; dispose of this solid waste to conform with local regulations.		

HAZARDOUS POLYMERIZATION			
May Occur	Will not Occur	CONDITIONS TO AVOID	
	X		
HAZARDOUS DECOMPOSITION PRODUCTS			

VI. SPILL OR LEAK PROCEDURES

V. REACTIVITY DATA

STABILITY			
UNSTABLE	STABLE	CONDITIONS TO AVOID	Strong oxidizing agent - Strong acids
	X		
INCOMPATIBILTY (materials to avoid)			

OVEREXPOSURE	
EMERGENCY AND FIRST AID PROCEDURES	Remove contaminated clothing Wash area with soap and water Wash eyes with water for 15 minutes
EYE IRRITATION	Severe eye irritant
THRESHOLD LIMIT VALUE	
EFFECTS OF OVEREXPOSURE	

IV. HEALTH HAZARD DATA

ACUTE ORAL TOXICITY LD_{50}	
DERMAL IRRITATION	Primary skin irritant

EVAPORATION RATE..... ND
APPEARANCE AND ODOR..... Opaque, off-white liquid with ammoniacal odor.

BOILING/FREEZING POINT @760 mmHg... 210°F (99°C) / ND
pH..... ND
VAPOR PRESSURE mm Hg @20° C..... ND
VAPOR DENSITY (Air = 1)..... >1
PERCENT VOLATILE BY WEIGHT (%)..... 100
SPECIFIC GRAVITY @20°C..... 0.99
SOLUBILITY IN WATER..... Substantial
D.O.T. LABELS REQUIRED..... NA
UN/NA I.D. NUMBER..... NA
PACKAGING GROUP..... NA
NON-BULK SHIPPING NAME..... Compound, Boiler Cleansing, Liquid
BULK SHIPPING NAME..... Same

SECTION 5 — PHYSICAL DATA

CHEMICAL NAME(S)	CAS NUMBER	% WT	TLV-TWA	PEL	SEC.313	CARCINOGENT
?	?	<15	?	?	?	?
OCTADECYL AMINE ACETATE	61790-59-8	<10	NOT ESTABLISHED	NOT ESTABLISHED	No	No

SECTION 4 — SHIPPING DATA

D.O.T. PROPER SHIPPING NAME... NA
D.O.T. HAZARD CLASS..... NA
NFPA - HEALTH HAZARD..... 2
FIRE HAZARD..... 0
REACTIVITY HAZARD..... 0
NFPA SCALE..... 4=Extreme 3=High 2=Moderate 1=Slight 0=Insignificant
KEY..... NA= Not Applicable ND= Not Determined

SECTION 3 — HAZARDOUS INGREDIENTS

SECTION 2 — PRODUCT IDENTIFICATION

PRODUCT NUMBER..... Q-1126
TRADE NAME OR CHEMICAL NAME... CONDENSATE LINE TREATMENT Q-1126
SYNONYMS..... NA
CHEMICAL FAMILY..... Condensate Line Treatment

SECTION 1 — MANUFACTURER INFORMATION

QUES INDUSTRIES, INC.
5420 W. 140TH STREET
CLEVELAND, OH 44142
(216) 267-8989

EMERGENCY RESPONSE: (800) 255-3924

CONDENSATE LINE TREATMENT Q-1126

Latest Revision Date...09/18/95 Print Date.....10/29/9

MATERIAL SAFETY DATA SHEET

OTHER PRECAUTIONS.....Safety shower and eyewash fountains should be easily accessible.

SECTION 12 SUPPLIER INFORMATION

This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of manufacturer. The data on this sheet relates only to the specific material designated herein. Manufacturer assumes no legal responsibility for use or reliance upon this data.

disposal in accordance with all regulations.

SECTION 11 SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION.....NIOSH/MSHA approved can or cartridge respirator for gas and vapor as needed to maintain P.E.L.

VENTILATION.....Local and/or mechanical exhaust to maintain exposure below P.E.L.

PROTECTIVE CLOTHING.....Neoprene gloves, apron, boots - as necessary to prevent skin contact.

EYE PROTECTION.....Chemical goggles.

SECTION 10 ENVIRONMENTAL DATA

SPILL OR LEAK PROCEDURES... Keep upwind. Avoid skin contact. Absorb with sand or inert material and place in suitable container for disposal. Do not flush into waterways.

WASTE DISPOSAL METHOD..... Dispose of in accordance with all federal, state and local regulations.

HAZARDOUS WASTE 40CFR261... NA

CONTAINER DISPOSAL..... Empty containers may contain residuals. Thoroughly clean, then offer for recycling , reuse or

SECTION 9 EMERGENCY AND FIRST AID PROCEDURES

SKIN.....Remove contaminated clothing and flush exposed skin with soap and water. If irritation persists or develops, get medical attention. Launder contaminated clothing before reuse.

EYES.....Immediately flush eyes with large amounts of water for 15 minutes and get medical attention.

INGESTION....If swallowed, DO NOT INDUCE VOMITING. Get medical attention immediately. Never give anything by mouth to an unconscious person.

INHALATION.....Move to fresh air. Aid in breathing, if necessary, and get medical attention.

HAZARDOUS POLYMERIZATION..... Will not occur

SECTION 8 HEALTH HAZARD DATA

SKIN CONTACT... May cause skin irritation upon prolonged contact.

EYE CONTACT.... May cause irritation upon contact.

INHALATION..... Mists may cause respiratory irritation.

INGESTION..... May cause irritation.

UNUSUAL FIRE & EXPLOSION HAZARDS... Cool drums exposed to fire or heat to prevent steam rupture.

SECTION 7 REACTIVITY DATA

PRODUCT STABILITY..... Stable

Conditions to Avoid..... NA

CHEMICAL INCOMPATIBILITY..... Strong acids

HAZARDOUS DECOMPOSITION PRODUCTS... Oxides of carbon and nitrogen may form in burning conditions.

SECTION 6 FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (Test Method)..... >200°F (93°C) C.O.C.

AUTOIGNITION TEMPERATURE..... ND

FLAMMABILITY LIMITS IN AIR (% V)... ND

EXTINGUISHING MEDIA..... Not Combustible

SPECIAL FIRE FIGHTING PROCEDURES... NA

CONDENSATE LINE TREATMENT Q-1126

Daniel M. Cicero

Nalco Chemical Company

Regulatory Issues in Condensate Treatment

Diethylaminoethanol: A Descriptive Study," *Journal of Occupational Medicine*, 36 (June 1994):623-626.

[1] Margaret E. Gadon, MD, James M. Melius, MD, Gerald J. McDonald, AS and David Orgel, MD, "New-Onset Asthma after Exposure to the Steam System Additive 2-

evacuation, 13 employees stated they did not feel well and were eventually transported to local hospital emergency rooms. The following Monday, ... an employee of the 2nd floor felt ill and directly contacted Albany police, who contacted the local paramedics. The paramedics treated 70 employees and transported 19 to local hospitals. A total of 32 people were transported to

"The nurse was called to the 2nd floor to evaluate an employee complaining of nausea and dizziness and, upon her arrival, was informed of another employee who had vomited. She called for paramedics to transport the employees to local emergency rooms. When the paramedics learned of a third employee who was not feeling well, they evacuated the 2nd floor. After the

Further investigation correlated the release of DEAE to seven cases of new-onset asthma at this facility, Building 8, New York State Department of Taxation and Finance. But this was not the only amine-caused problem at this facility. Four months later, as recorded in a report issued by the National Institute of Occupational Safety and Health (NIOSH):

building. The leak resulted in the release of an additive to the steam system, diethylaminoethanol (DEAE), into the building air. Within hours, many employees complained of irritative symptoms of the respiratory tract and ear, nose and throat. Forty-nine of the approximately 2500 employees were sent to local emergency rooms."[1]

Further investigation correlated the release of DEAE to

amines in steam systems, how risks can be managed and what can be done to document compliance with the regulations.

In the June 1994 issue of the *Journal of Occupational Medicine*, the following incident was reported. "A steam leak occurred in the heating system of a State office

Under ordinary circumstances, only facility managers and engineering staffs concern themselves with the implications of improper boiler water treatment. With respect to condensate treatment, however, awareness is also necessary for individuals not historically involved in plant operations. The purpose of this paper is to examine the regulations and guidelines governing the use of

INTRODUCTION

p10.
[1] Ibid. p.14

exposures are usually labeled as odor complaints.

[2] U.S. National Institute for Occupational Safety and Health, *Health Hazard Evaluation Report HETA 91-978-2242, New York State Department of Taxation and Finance, Albany, New York*, (Cincinnati, OH, July 1992)

inhalation, ingestion, absorption through the skin, and skin and eye contact. Obviously, the higher the exposure, the higher the potential for serious, adverse health effects. Most commonly, exposure to small amounts of amines results in the types of symptoms experienced in the case history cited in the introduction: nausea, vomiting, dizziness, etc. In less serious cases, these types of

Most condensate treatment involves neutralizing and filming amines; substances which generate some inherent environmental and health concerns. Before looking at the regulations governing their safe use, it is important to understand the nature of these products.

The symptoms of exposure to several amines are listed in Table 1. Neutralizing amines can be introduced through

existing in a building to the on-set of a chronic health problem, water treatment is no longer simply an engineering concern.

GENERAL HEALTH EFFECTS OF AMINES

This case is extreme, but not unique. And it illustrates why facility managers, risk managers, plant engineers and maintenance managers have become increasingly concerned with the application of condensate system corrosion inhibitors. When employees become ill, a public building is evacuated, paramedics and the police are called, NIOSH conducts a formal investigation, and a

have been responsible for an outbreak of symptoms in the building including headache, nausea, dizziness and eye irritation. These symptoms are consistent with DEAE exposures as reported in other NIOSH Health Hazard Evaluations..., where steam-containing DEAE was used to humidify the buildings."[2]

In the discussion portion of their report, the NIOSH investigators characterized the employees' hypothesis — that the cause of the health problems at Building 8 was exposure to DEAE and pesticides — was "reasonable and well thought out, and warranted further evaluation." They further noted that, "[t]he DEAE leak ... appeared to

hospitals over these 2 days and all 32 were released by the hospitals, with some being given oxygen."[2]

this is considered accidental contact. The FDA has ruled that these cases are beyond regulation. Also, if the FDA would be conservative that a small amount of the steam actually contacts the food.

ACCIDENTAL CONTACT

The FDA recognizes that, although not intended, steam may come into contact with food because of the failure of a mechanical barrier between the food and the steam.

Although not specifically listed in Title 21, the FDA recognizes that there are some items that come into contact with the food, but to an even lesser extent than those recognized as indirect food additives. In the case of steam, this might mean a process where steam is used although not in direct contact with the food, where it could be considered "manufacturing" aids or ingredients character and are not directly injected into the food in any way. Food simply comes into contact with these substances during its processing or packaging. An example of this might be an adhesive that is used in making a cereal box.

INCIDENTAL CONTACT

	contact with milk and milk products.

INDIRECT FOOD ADDITIVES

These compounds, like Secondary Direct Food Additives, come into contact with the product as a result

Octadecylamine	Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Trisodium nitrilotriacetate	Not to exceed 5 parts per million in boiler feedwater; not be used where steam will be in million in steam, and excluding use of such steam in contact with milk and milk products.
Hydrazine	Zero in steam
Morpholine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products

Substances	Limitations
Cyclohexylamine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
DEAE	Not to exceed 15 parts per

1419, page ii, January 1, 1997, U.S. Government Printing Office, Washington, DC.

used in such treatment should not remain in the water in

[9] ibid.

[10] U.S. Department of Agriculture, Food Safety and Inspection Service, *List of Proprietary Substances and Nonfood Compounds*, Miscellaneous Publication Number publication of the name of the approved substance. There are special cases, however, where certain products require a letter to be provided to the inspector when the product is not listed.

Another difference between the FDA and USDA approvals is the listing by the USDA of the category code under which the substance may be used. "Compounds Food Safety and Inspection Service (FSIS)]. Copies of the letters must be supplied to Federal inspectors as proof of authorization until the substances and compounds appear in the subsequent revision of [the *List of Proprietary Substances and Non-Food Compounds*]."[10] It is also important to keep in mind that the approval letters from the USDA are generally not valid after the

When a product has been approved by the USDA for use in facilities under its jurisdiction, "letters indicating acceptability of the substances and compounds are issued to suppliers by [the Facilities, Equipment, Labeling, and Compounds Review Division (FELCRD), Office of Policy Program Development and Evaluation (OPPDE), — Boiler Water Additives — which lists the components of the product.[9] The USDA will not list a boiler water additive product unless its components are in compliance with the appropriate FDA paragraph. If a product is approved for use in boilers by the USDA, that fact should be stated in the product's Material Safety Data Sheet (MSDS).

approves specific *products* for use in federally inspected meat, poultry, shell egg grading, rabbit and egg product processing facilities. For instance, Nalco® 1820, a condensate system corrosion inhibitor, is listed by name in the USDA publication *List of Proprietary Substances and Non-Food Compounds*, Part II — Nonfood Compounds Used in the Plant Environment. In Title 21, this product is acceptable for use under 21 CFR 173.310 subject to the Good Manufacturing Practices Procedures of the FDA regulations.

MEAT & POULTRY PROCESSING

Unlike the FDA, which lists specific *chemical compounds* acceptable for use in the processing of food, the USDA

[14] Nalco Chemical Company, *Amine Safety Initiative*, 1994, p3.2

an Acceptable Ambient Air Concentration for Diethylaminoethanol,Report prepared for the Alkyl Amines Council, September 1, 1993, p.10.

[17] Burton, D. Jeff, "Humidification: What About Water Additives?" *Occupational Health & Safety*, Vol. 64, No. 10, p28.

[18] 29 CFR 1910.1000

[19] ppm No Observed Adverse Effect Level (NOAEL)

[15] Edgerton, Sylvia A., Kenny, Donald V., Joseph, Darrell W., *Determination of Amines in Indoor Air from Steam Humidification*, Environmental Science & Technology, Vol. 23, No. 4, 1989

[16] ENVIRON Corporation, Arlington, VA, *Assessment of* Alkyl Amines Council and conducted by a third party consulting firm, ENVIRON Corporation, has resulted in the development of an Acceptable Ambient Air Concentration (AAAC) for DEAE of 0.1 ppm. This concentration is significantly lower than the OSHA PEL, but only slightly higher than the odor threshold for the substance. The AAAC for DEAE was based on the 10 [illegible] that odors become airborne in the workplace. These limits are based on results from toxicological studies, medical surveillance and built-in safety factors. PEL's are expressed as 8-Hour (TWA), 15-minute (Short Term Exposure Limits (STEL)) or Ceiling (C) limits. If there is a contact hazard, a "skin" designation is given.[19]

Recent risk assessment work on DEAE sponsored by the limits, plus the limits for other commonly used amines, are listed in Table 7. To date, no major agency or association has prohibited the use of steam treated with chemical additives for humidification, but questions and concerns about such use are common.[17] OSHA Subpart Z — Air Contaminants — has established Permissible Exposure Limits (PEL's) for approximately 600 [illegible][18] irritative properties. The TLV-TWA is the time-weighted average concentration to which nearly all workers may be exposed for eight hours per day, forty hours per week, without adverse effect. The Occupational Safety and Health Administration (29 CFR 1910.1000) has also established a time-weighted average permissible exposure limit (PEL) of 10 ppm (50 mg/m3) for DEAE.[16] These room air during normal operation of the boiler and humidification systems remained very low compared with any established health standards."[15]

The American Conference of Governmental Industrial Hygienists (ACGIH) adopted in 1980 a standard of 10 ppm as the Threshold Limit Value — Time Weighted Average (TLV-TWA) for DEAE in air, based on its

[20] The American Conference of Governmental Industrial Hygienists (ACGIH) has proposed a reduction of the TWA for morpholine to 2 ppm.

[21] U.S. National Institute for Occupational Safety and Health, *Health Hazard Evaluation Report HEAT 89-057-2005 Cincinnati Electronics Corp., Cincinnati, OH.*

[22] ibid, p1.

[illegible] diethylaminoethanol and cyclohexylamine-containing steam be eliminated by using alternative humidification methods..."[22]

It is not uncommon for employees to complain of amine odors. The relationship between the OSHA PEL, the odor threshold for the amine and the concentration of

The conclusion drawn by the NIOSH investigators was: "The acute outbreak of illness experienced by the employees on December 5-7, 1988, coincided with the introduction of steam from boiler number 2 and, therefore, was most likely the result of workers' exposure to diethylaminoethanol and cyclohexylamine. The [illegible] recommend that [illegible] illness among employees of Cincinnati Electronics Corporation in Cincinnati, Ohio which had occurred on December 5-7, 1988. The corrosion inhibitors diethylaminoethanol and cyclohexylamine had been added to the boiler water, which was used to humidify the work area. These amines were suspected as a cause of the employees' symptoms."[21]

ODOR COMPLAINTS

"On December 8, 1988, the National Institute for Occupational Safety and Health (NIOSH) received a request from a management representative and from the local representative of the International Brotherhood of Electrical Workers (IBEW), to investigate an outbreak of [illegible]

	TWA ppm	PEL/TWA ppm	Threshold ppm in air
Morpholine	20 (71)	20 (70)	0.14
DEAE	10 (48)	10 (50)	0.04
Cyclo-hexylamine	10 (41)	10 (40)	0.90

observed in a 14-week subchronic inhalation study in rats. A safety factor of 10 was applied to the NOAEL for extrapolation from animals to humans, and an additional safety factor of 10 was incorporated to protect unusually sensitive individuals.

Table 6: Amine PEL and Odor Threshold Summary

For regulatory compliance measurements, samples of condensed *steam* must be obtained. The sample should be drawn off the top of the pipe. This differs from performance measurements which should be made on liquid-phase samples.

their products into blends of a number of amines for exactly this reason: to ensure proper distribution through the condensate system.

Sampling procedure is critical. A sample collection station similar to the one shown in Figure 5 is required.

With all of these methods, it is critical that steam and condensate sampling occur at a variety of locations around the system especially at critical locations. Because of their distributive nature, concentrations of amines will vary across the system. It is common practice among water treatment companies to formulate

best method is gas chromatography done in a capable laboratory. Unfortunately, this method requires fixed samples to be sent to the laboratory, with the associated lead times and costs. Testing should be done for every amine in a blended product. On-site chromatography is possible, but the equipment is costly and requires routine

PROPER TESTING AND MONITORING

Measurement of amines is problematic. The choice of which monitoring method to use comes down to the required accuracy of the test and how much a facility is willing to pay for the information. Simple, drop-wise

condensate system was continuously monitored. At the point indicated, the amine feed was discontinued. As is obvious from inspection, the soluble iron level increased dramatically and quickly, an indication of an increase in corrosion. Any interruption in feed, as is experienced when batch feeding, will cause this effect.

Obviously, the continuous feed method is preferable because it maintains a constant treatment level in the system. In Figure 4, the Fe(II) concentration in a

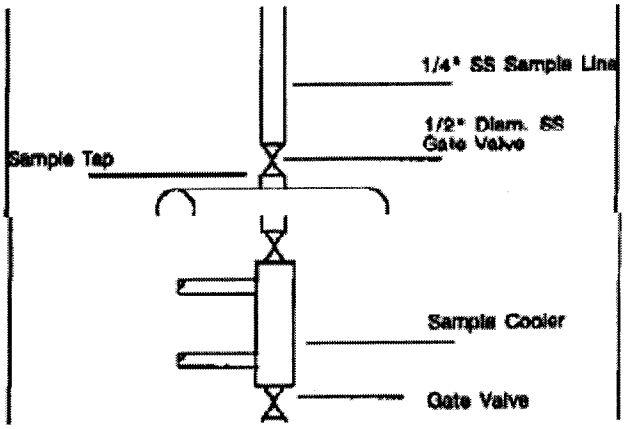
should be supplemented with more accurate laboratory analysis on a periodic basis.

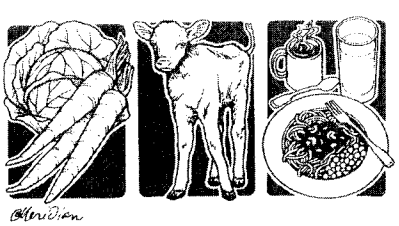
Also, it is important to periodically monitor the concentration of amines in several locations around the steam system. This aids in ensuring proper application of the products for corrosion inhibition and in documenting regulatory compliance. Use of a simple, inexpensive amine titration test is useful on a day-to-day basis, but

In common use since the 1940's, neutralizing amines have proven their ability to minimize condensate system corrosion. When used in accordance with published guidelines, their use is safe. Because improper use of amines can result in the kinds of problems discussed in this paper, awareness is the key to resolving problems, should they arise.

Figure 5: Sampling Equipment

CONCLUSIONS AND RECOMMENDATIONS





March 26, 2001
Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Dear FDA FOIA Staff:

The Organic Materials Review Institute (OMRI) requests, pursuant to the Freedom of Information Act (FOIA), 5 USC 552, information on the following substance that is approved for use by FDA as boiler water additives:

Substance	CAS #	21 CFR	Federal Register Notice	Date
Octadecylamine	**124-30-1**	**173.310(d)**	**27 FR 6232**	**June 30, 1962**

The appropriate *Federal Register* notice is attached for your convenience.

Please provide any data or information used by FDA to issue regulations regarding the safe use of the boiler compound listed above when used in the preparation of steam that contacts food. In particular, please provide the basis for the determination of the limitation found in 21 CFR 173.310(d). OMRI specifically requests any data submitted by the petitioners regarding the amount of this chemical found in steam and food. OMRI also requests data submitted by those who may have objected to the original notice, and any data submitted subsequent to the establishment of the regulation regarding the use of this compound as a boiler water additives.

Also, please provide any information on verification of compliance with the limitations set forth in that section. This would include test methods employed by FDA, the sampling procedure, the results from the analysis of the samples taken, and any actions taken against violators from 1962 to the most recent date for which information is available. Please provide any record of investigation and reports of measures taken by companies found out of compliance or in violation of these limitations, including any product recalls related to this compound.

OMRI respectfully requests that any and all fees for this request be waived because it meets both tests of FDA's FOIA Implementation Policy for Waivers contained in 21 CFR 20.43:

(1) Is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government
OMRI is tendering this request as part of research under contract for the US Department of Agriculture's National Organic Program as the Technical Advisory Panel to the National Organic Standards Board (NOSB). The results

Pooler, Bob

File: Bioler Chem

From: KBurton@jmsmucker.com%inter2
Sent: Friday, September 14, 2001 10:32 AM
To: Mathews, Richard
Cc: Pooler, Bob; steven.harper@smallplanetfoods.com%inter2; bb@omri.org%inter2; kdowney@omri.org%inter2
Subject: TAP Boiler Chemical FOIA Request

called Judy Kidwell go out 7th - Brian Baker

Richard,
Per our conversation this morning please have someone from NOP call FDA regarding the status of the FOIA's on diethyaminoethanol, cyclohexlamine, morpholine, and octadecylamine. Michael Howard, who was our original contact, suggested calling Judith Kidwell (202-418-3354) or Parvin Yasaei (202-418-3023) for the status of these FOIA request. If we can choose an order of preference the processing committee would like to have diethyaminoethanol as the highest priority and the others to follow. Please update Steve, Brian and I with the outcome of the conversation. Again, congrats on your promotion.....

go out

Thanks,

Kim

----- Forwarded by Kim Burton/Chico/JMS on 09/14/2001 06:50 AM -----

Brian Baker <bb@omri.org> 09/12/2001 01:46 PM

To: "Kim Burton" <kim.burton@jmsmucker.com>
cc: ebr@guppy.pond.net, kdowney@guppy.pond.net, "Steven Harper" <stevenh@smallplanetfoods.com>
Subject: TAP Boiler Chemical FOIA Request

Hi Kim--

I talked to Steve Harper today about the October TAP reviews, and also about the boiler water additive TAP reviews and the criteria used to determine when a petition is needed. Steve and I briefly discussed the ammonium hydroxide information. Immediately following the conversation with Steve, I called Judith Kidwell, the FOIA officer for diethyaminoethanol, morpholine, and octadecylamine. She said that she will try to find out the status of those FOIAs, but confirmed that they were still in the system and had not been sent. I asked her when FDA would send the files, and she would not give an estimate. She indicated that yesterday's events have changed staff availability and schedules for all Federal agencies in Washington, DC. I gave her our deadline for mailing TAPs to the NOSB and the dates of the NOSB meeting, indicating that if it was appropriate and would help, I was willing to meet the staff in person while in Washington before the meeting, and provide whatever assistance was needed to expedite the release of the information. She will call tomorrow if she has any new information. I will let you know as soon as I learn anything about the fulfillment of that request. Please let me know if I can be of further assistance.

Be well,
bb

Pooler, Bob

To: Mathews, Richard; Strother, Toni
Cc: KBurton@jmsmucker.com; ebr@OMRI.org
Subject: FDA FOIA Information, response

File: Biobased chem. →

Rick,

Judy Kidwell of FDA informed me that the FOIA material for octadecylamine went out on September 7th to B. Baker (OMRI) and the information on diethylaminoentanol, cyclohexlamine and morpholine was sent yesterday (09/18/01) to B. Baker. OMRI needs to forward the information to NOP for distribution to the NOSB ASAP.

Bob Pooler