



Water Talk

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Amine Regulations

Selecting the amines to use when treating steam and condensate systems, requires more than a review of the makeup water analysis or the steam system design. FDA limits, and OSHA limits should also be considered if the use of the amine will be in food contact processes, space heating, sterilization or humidification.

While neutralizing amines are safe to use, the concentrations are regulated. The Food and Drug Administration (FDA) only allows certain amines, at specific use concentrations, in systems where the treated steam will contact food or food packaging. OSHA has separate guidelines for the use and concentrations of amines that become airborne. This Water Talk will serve as a means to clarify

some of the regulatory concerns, as well as to review the seminal event that spurred some of the limitations we deal with when using amines.

FDA/USDA Limits

The USDA no longer issues separate regulations for the plants under its jurisdiction (meat, poultry, egg and fish processing facilities). These limitations were previously listed under older USDA guidelines, as “G6” and “G7” compounds. These older USDA limitations have all been replaced by the limits found in Title 21, Sections 173.310 and 184.1139 of the Code of Federal Regulations. 21 CFR 173.310 lists the various boiler water additives, approved by the FDA, for use in the

preparation of steam, when the steam will contact food or food packaging. This regulation also spells out the conditions where these approvals are applicable.

21 CFR 184.1 lists the various substances generally regarded as safe (GRAS).

FDA Amine Standards – Title 21 CFR 173.310.d	
Cyclohexylamine	Not to exceed 10 ppm in steam No milk or milk products
Diethylaminoethanol (DEAE)	Not to exceed 15 ppm in steam No milk or milk products
Morpholine	Not to exceed 10 ppm in steam No milk or milk products
Octadecylamine (ODA)	Not to exceed 3 ppm No milk or milk products
FDA GRAS Standards – Title 21 CFR 184.1139	
Ammonium Hydroxide (NH ₄ OH)	No Limitations in steam, except not used in excessive amounts OK with milk or milk products

Thus all 3 common amines, and the filming amine, Octadecylamine can all be used in steam, where the steam contacts food or food packaging. These are conditional approvals, requiring that the concentration limits are adhered to, and that the steam not be in contact with milk or milk products.

There are other conditional limits on the use, including:

1. The amount used is not in excess of what is needed to produce the intended effect.

2. The containers are properly labeled with the names of the additives.
3. Adequate directions are promulgated to assure compliance with the provisions of the CFR.

Ammonium Hydroxide limits are specified in 21 CFR 184.1139. These limits specify that it be used as a boiler water additive at levels not to exceed current good manufacturing practices.

Blended Amines, a Misconception

A commonly held belief is that 21 CFR 173.310 places a limit of 25 ppm on the blended combination of amines in steam. This is incorrect, 21 CFR 173.310 has no such limit. When using a blended amine or when using combinations of amines fed separately, the limit is still on the amines, individually. A strict adherence to the limits found in the above table would imply that the total amines present in a system when using a tri-amine (Cyclo, DEAE, Morph) would be the sum of the maximums of each of the amines...35 ppm.

This would be valid so long as each individual

amine concentration is at or below its individual limit. Thus a system containing 10 ppm cyclohexylamine, 15 ppm DEAE and 10 ppm morpholine, for 35 ppm of total amine, would meet the limits of 21 CFR 173.310.

Humidification

The use of amines in steam humidification is less clear. There are no Federal regulations mandating specific maximum amine concentrations within the steam used in direct steam humidification systems. One place to start is 29 CFR 1910.1000. This code lists the limits for various Air Contaminants. The limits for amines in this section are:

Air Contaminant Limits - Title 29 CFR 1910.1000		
Chemical	ppm	mg/m³
Cyclohexylamine	Not Listed	Not Listed
Diethylaminoethanol (DEAE)	10	50
Morpholine	20	70

The above permissible exposure limits (PEL) are 8 hour time weighted averages (TWA). Water treaters typically do not have the expertise or equipment to take breathing zone air samples in order to determine actual exposures rates. Thus, the water treatment industry has chosen to limit the

use of amines to those limits as spelled out in 21 CFR 173.310.

Background - Cornell University Museum

Where did all of the concern over the use of amines in steam humidification come from? In October 1982, The National Institute for Occupational Safety and Health (NIOSH), received a request from workers at the Herbert F Johnson Museum of Art, Cornell University, Ithaca, New York, to investigate exposure to Diethylaminoethanol (DEAE). DEAE was added to the steam used to humidify the air in the museum.

The request expressed concern that exposure to DEAE caused eye irritation and dermatitis in the workers. The subsequent testing by NIOSH representatives found DEAE in only two of 14 air samples taken. These two with positive results showed levels of 0.05 and 0.04 milligrams per cubic meter of air (mg/m³). Both of these were 1/1000 of the PEL for DEAE, well below the OSHA permissible exposure limit for DEAE of 50 mg/m³. The investigators then went on to identify traces of

DEAE on two samples of plastic material which had been exposed to the atmosphere for several years.

These findings, coupled with interviews of employees, led NIOSH to conclude that employees at the Johnson Museum were not exposed to excessive concentrations of airborne DEAE.

However, the report continued to state that sporadic contact with surfaces containing DEAE may have been associated with some of the irritant symptoms reported. This led NIOSH to the inevitable conclusion that DEAE was the culprit, and therefore the report went on to recommend that exposure to DEAE be eliminated.

The impact of the Cornell incident

The Cornell University incident set the precedent for all future suspected amine exposure events.

While the use of amines in direct humidification systems isn't outright banned, the NIOSH recommendations, in every subsequent event, are quite clear...eliminate the exposure to DEAE. This of course has come to mean, eliminate the use of

DEAE in direct steam injected humidification systems.

Common Recommendations

In cases where a customer has asked for a recommendation, many water treaters will rely on a proven approach. They give their customer the correct information, and let the customer decide the best course of action that works for their facility.

Treating the system with amines is the best approach from a system preservation standpoint, but various stake holders in the customer hierarchy may feel the most conservative approach to employee comfort is the primary concern.

Conclusion

A thorough system review, coupled with careful product selection and application techniques are vital to optimum system production. The proper treatment choices should take into account, not only these system mechanics and chemistries, but also any regulatory limitations as well as local limitations governing the use of amines.