FAP 2215 SECTION H

FOOD ADDITIVE PETITION

ENVIRONMENTAL ASSESSMENT

1. Date: April 30, 1992

2. Name of applicant/petitioner: Anitox Corp.

3. Address:

P.O. Box 1929
1885 Anitox Drive
Buford, GA 30518

4. Description of the proposed action.

Approval of formaldehyde to be used on animal feed ingredients is requested in order to inhibit the growth of and proliferation of microorganisms, such as fungi, Salmonella, and other bacteria. Formaldehyde will be purchased in bulk on the open market from chemical manufacturers and packaged at Anitox Corp., 1885 Anitox Dr., Buford, GA.

This environmental assessment is prepared in association with the food additive petition for additional authorization for the use of formaldehyde in animal feeds, 21 CFR 573.460.

Formaldehyde will be used at rendering plants and in animal feed mills in various locations across the country. No hazardous waste products are to be generated at the site of packaging or at use locations for disposal. The environment present at the production site is open; adjacent to it is business/residential. The environments present at use locations would vary.

5. Identification of chemical substances that are the subject of the proposed action.

1) Generic Name: Formaldehyde

2) Trade Name: Formalin (37% solution)
Fannoform
Formalith
BFV
Fyde
Ivalon
Karsan
Lysoform
Superlysoform

3) Other Names: Formic aldehyde
Formol
HCHO
Methanal
Methyl aldehyde
Methylene oxide
Oxomethane
Oxymethylene
Paraform

4) Chemical Name: Formaldehyde

5) Chemical Structural Representatives:

CH_2O HCHO

6) Molecular Weight: 30.03

7) Chemical Abstract Service Registry Number: 50-00-0

8) USAN or Other Preferred Names: USAN Formaldehyde
Solution 21 CFR 573.460
Formaldehyde

9) Physical Descriptions:

Formaldehyde is a gas which readily polymerizes into a form called paraformaldehyde. The form most often used is a solution of 37% formaldehyde in water. This solution, often called formalin, has the following characteristics:

A) Form: Liquid/liquid solution
B) Appearance: Colorless to light yellow
C) Odor: Pungent
D) Boiling Point: 96°C
E) Flash Point: 141°C

10) Additives: None

11) Impurities: Iron, less than 0.5 ppm

6. Emission of formaldehyde into the environment.

1) Emissions at the manufacturing source of formaldehyde:

Bulk formaldehyde will be purchased on the open market. Formaldehyde is produced at several chemical plants located in various regions of the United States. The emissions for each one of these companies is regulated by state and federal authorities. Formaldehyde will be received in bulk tanker trailers. Relative to the

total formaldehyde produced our usage will be small, i.e., we will use less than 1% of the formaldehyde currently produced.

2) Emissions of formaldehyde from storage tanks.

The formaldehyde is transferred from the bulk tanker trailer to a storage tank through chemical resistant polypropylene pipe. These storage tanks are surrounded by a concrete dike capable of containing the contents of two full storage tanks.

The storage tanks for formaldehyde are composed of aluminum and are fixed roof. The lid seal is an air tight metal on metal seal. There will be a one-way vacuum valve on the top of the tank which allows through it only an inflow of air to the tank. Any air leaving the tank will pass through a scrubber consisting of water and a formaldehyde control agent, commercially known as Formalex™. This formaldehyde control agent has been demonstrated to neutralize formaldehyde upon treatment. Initial testing of the neutralized formaldehyde solution by an independent laboratory is summarized in the following table (Attachment H-1).

TABLE 1. NEUTRALIZATION OF A 10% BUFFERED FORMALDEHYDE SOLUTION WITH FORMALEX™

TREATMENT	VOLUME OF 10% BUFFERED FORMALIN (ml)	VOLUME OF FORMALEX™ (ml)	FORMALDEHYDE RESIDUE (% BY WEIGHT)
10% Buffered Formalin	100	10	1.66
10% Buffered Formalin	90	10	1.95
10% Buffered Formalin	80	20	0.04

These data show that formaldehyde solutions treated with this formaldehyde control agent results in a waste product that will have formaldehyde levels that are below the allowable limits as specified by 40 CFR 261.21 to 40 CFR 261.24.

In order to classify the neutralized formaldehyde solution as a non-hazardous waste, additional Environmental Protection Agency (EPA) toxicity tests were conducted by two certified laboratories (Attachment H-2 and H-3). The analysis of the waste product is presented in Tables 2 and 3.

TABLE 2. FORMALDEHYDE REACTED WITH FORMALEX™

COMPOUND	CONCENTRATION
ACENAPHTHENE	<100 ppb
BENZIDINE	<100 ppb
BIS(CHLOROMETHYLETHER)	<100 ppb
BIS (2-CHLOROETHOXY) METHANE	<100 ppb
BIS (2-CHLOROETHYL) ETHER	<100 ppb
BIS (2-CHLOROISOPROPYL) ETHER	<100 ppb
BROMOPHENYL PHENYL ETHER	<100 ppb
CHLOROETHYL VINYL ETHER	<100 ppb
CHLOROPHENYL PHENYL ETHER	<100 ppb
CHLORONAPHTHANLENE (2)	<100 ppb
DICHLOROBENZIDINE (3,3')	<100 ppb
DINITROTOLUENE (2,4)	<100 ppb
DINITROTOLUENE (2,6)	<100 ppb
DIPHENYLHYDRAZINE (1,2)	<100 ppb
FLUORANTHENE	<100 ppb
HEXACHLOROBENZENE	<100 ppb
HEXACHLOROBUTADIENE	<100 ppb
HEXACHLOROCYCLOPENTADIENE	<100 ppb
HEXACHLOROETHANE	<100 ppb
ISOPHORONE	<100 ppb
NAPHTHALENE	<100 ppb
NITROBENZENE	<100 ppb
N-NITROSODIMETHYLAMINE	<100 ppb
N-NITROSODIPHENYLAMINE	<100 ppb
N-NITROSO-DI-N-PROPYLAMINE	<100 ppb
TRICHLOROBENZENE (1,2,4)	<100 ppb
BIS (2-ETHYLHEXYL) PHTHALATE	<100 ppb
BUTYL BENZYL PHTHALATE	<100 ppb
DIETHYL PHTHALATE	<100 ppb
DIMETHYL PHTHALATE	<100 ppb
DI-N-BUTYL PHTHALATE	<100 ppb
DI-N-OCTYL PHTHALATE	<100 ppb
ACENAPHTHYLENE	<100 ppb
ANTHRACENE	<100 ppb
BENZO (A) ANTHRACENE	<100 ppb
BENZO (B) FLUORANTHENE	<100 ppb
BENZO (K) FLUORANTHENE	<100 ppb

TABLE 2. FORMALDEHYDE REACTED WITH FORMALEX™ (CONT.)

COMPOUND	CONCENTRATION
BENZO (GHI) PERYLENE	<100 ppb
BENZO (A) PYRENE	<100 ppb
BENZOFLUORANTHENE (3,4)	<100 ppb
CHRYSENE	<100 ppb
DIBENZO (A,H) ANTHRACENE	<100 ppb
FLOURINE	<100 ppb
IDENO (1,2,3-CD) PYRENE	<100 ppb
PHENANTHRENE	<100 ppb
PYRENE	<100 ppb
ALDRIN	<100 ppb
DIELDRIN	<100 ppb
CHLORDANE (TECHNICAL)	<100 ppb
O,P'-DDE	<100 ppb
O,P'-DDD	<100 ppb
O,P'-DDT	<100 ppb
P,P'-DDE	<100 ppb
P,P'-DDD	<100 ppb
P,P'-DDT	<100 ppb
ENDOSULFAN I	<100 ppb
ENDOSULFAN II	<100 ppb
ENDOSULFAN SULFATE	<100 ppb
ENDRIN	<100 ppb
ENDRIN ALDEHYDE	<100 ppb
HEPTACHLOR	<100 ppb
HEPTACHLOR EPOXIDE	<100 ppb
A-BHC	<100 ppb
B-BHC	<100 ppb
LINDANE	<100 ppb
D-BHC	<100 ppb
TOXAPHENE	<100 ppb
AROCLOR 1016	NOT TESTED
AROCLOR 1221	NOT TESTED
AROCLOR 1232	NOT TESTED
AROCLOR 1242	NOT TESTED
AROCLOR 1248	NOT TESTED
AROCLOR 1254	NOT TESTED
AROCLOR 1260	NOT TESTED
AROCLOR 1262	NOT TESTED
SAMPLE PREP - B/N COMPOUNDS	YES

[1] Source: General Engineering Laboratories
Charleston, South Carolina

TABLE 3. CHEMICAL ANALYSIS OF FORMALDEHYDE-FORMALEX™ REACTION PRODUCT

COMPOUND	CONCENTRATION
2-CHLOROPHENOL	NON-DETECTABLE
2-NITROPHENOL	N.D.
PHENOL	N.D.
2, 4-DIMETHYLPHENOL	N.D.
2, 4-DICHLOROPHENOL	N.D.
2, 4, 6-TRICHLOROPHENOL	N.D.
4-CHLORO-3-METHYLPHENOL	N.D.
2, 4-DINITROPHENOL	N.D.
2-METHYL-4, 6-DINITROPHENOL	N.D.
PENTACHLOROPHENOL	N.D.
4-NITROPHENOL	N.D.
BENZIDINE	N.D.
B-BHC	N.D.
D-BHC	N.D.
ENDOSULFAN I	N.D.
ENDOSULFAN II	N.D.
ENDRIN	N.D.
HEXACHLOROCYLOPENTADIENE	N.D.
N-NITROSODIMETHYLAMINE	N.D.
SOLVENT SCAN	N.D.
PEST./HERB	N.D.
ENDRIN	N.D.
LINDANE	N.D.
ALDRIN	N.D.
DIELDRIN	N.D.
METHOXYCHLOR	N.D.
TOXAPHENE	N.D.
HEPTACHLOR	N.D.
CHLORDANE	N.D.
2, 4-D	N.D.
SILVEX	N.D.

[1] Source: Water Gas & Light Commission
Albany, Georgia

According to these test results, formaldehyde solutions treated with this control agent are not considered to be a hazardous waste and can be disposed of in an appropriate landfill. No other solid waste or waste water emissions is expected to be generated during the transfer or packaging of formaldehyde.

3) Emissions of formaldehyde at the packaging station.

For the drum-filling station, the following control measures are proposed:

Formaldehyde from the storage tanks will be transported to a drum-filling station and packaged in 55 gallon polypropylene drums or 275 gallon polypropylene bulk drums. During the packaging operation, an exhaust fan will remove the vapors from the top of the open container. The exhaust air will be filtered through a scrubber consisting of water and a formaldehyde control agent. Disposal of the waste product will be in the same fashion as from the storage tank scrubber.

It is the current environmental conservation policy of Anitox Corp. to recycle 55 gallon drums and 275 gallon bulk drums. Customers receiving liquid products in reusable drums are economically encouraged to return undamaged drums to Anitox Corp. Upon receipt of the drum containers, the drums are visually inspected for damage and if undamaged are refilled with the same product. Damaged drums returned to Anitox Corp. will be triple rinsed to remove any residual formaldehyde and disposed in compliance with local regulations. The rinse water containing any residual formaldehyde will be treated with a formaldehyde control agent and suspended on vermiculite for proper disposal. No other solid or liquid waste is expected to be generated.

These processes to control the environmental emissions of formaldehyde will result in levels of formaldehyde that are in compliance with the following state and federal emission requirements.

29 CFR 1910.1048	(Attachment H-4)
40 CFR 355	(Attachment H-5)
40 CFR 370	(Attachment H-6)
40 CFR 372	(Attachment H-7)
Georgia's Rules for Air Quality Control	(Attachment H-8)

Formaldehyde emissions during the transfer of formaldehyde from the bulk tanker trailer to the storage tank and the packaging of formaldehyde in 55 gallon and 275 gallon bulk drums is currently being monitored. These results are presented in the following table.

SAMPLE DATE	DESCRIPTION	TIME	OPERATING CONDITIONS	HCHO CONC.
6/25/91	Tank Farm Area Sample	22 min.	Scrubber	1.9
6/25/91	Tank Farm Area Sample	15 min.	Scrubber w/ 15 gal water	1.7
6/25/91	Tank Farm Area Sample	13 min.	Scrubber w/ 15 gal water and 1000ml of Formalex™	1.1
9/05/91	Tank Farm	45 min.	Scrubber w/ 15 gal water and 1500ml of Formalex™	0.31
10/24/91	Drumming Station	16 min.	Drumming bulk drums	0.47
10/24/91	Drumming Station	152 min.	Drumming bulk drums	0.43

The formaldehyde emissions at the scrubber in tank farm area were determined by an impinger containing liquid as described in 29 CFR 1910.1048 (Attachment H-4). The intake for the monitoring device was placed directly over the vent of the scrubber. These measurements were taken as a bulk tanker trailer was unloading 40,000 lbs. of formaldehyde. During the process of unloading, the solution in the scrubber was changed to test the effectiveness of water or an aqueous solution of Formalex™ in reducing formaldehyde emissions. Additional monitoring of formaldehyde emissions from the scrubber were taken using a more concentrated solution of Formalex™. Monitoring was conducted by placing the intake of the monitoring device over the vent of the scrubber for the entire amount of time required to unload 40,000 lb. of formaldehyde. Monitoring at the drumming station during the filling of 275 gallon bulk drums was determined by passive dosimeter as described in 29 CFR 1910.1048 (Attachment H-4).

Based on the emissions from the tank farm and drumming station, the quantity of formaldehyde being released into the environment each year can be calculated.

The density of formaldehyde is 1.101 g/ml. Based on an average bulk tanker weight of 40,000 lbs. (18,143.9 kg), the transfer of formaldehyde to the storage tank would result in the displacement of 16,479.46 l of air. This air was found to contain 0.31 ppm (20.31 mg/l of air) of formaldehyde. This would calculate to be 5.1086 g of formaldehyde being released for each truckload transferred to the storage tank (16,479.46 l x 0.31 mg/l = 5108.6 mg).

$$\frac{18,143.9 \text{ kg}}{1.101 \text{ g/ml}} = 16,479.46 \text{ l}$$

16,479.46 l x 0.31 mg/l = 5108.6 mg of formaldehyde released per truckload.

Based on an annual usage of 2,000,000 lb. of formaldehyde, 255.43g of formaldehyde would be released during the transfer of formaldehyde to the storage tank per year.

The quantity of formaldehyde released during packaging can be calculated in a similar manner.

$$\frac{18,143.9 \text{ kg}}{1.101 \text{ g/ml}} = 16,479.46 \text{ l}$$

16,479.46 l x 0.43 mg/l = 7086.17 mg of formaldehyde released per truckload packaged

Based on a annual usage of 2,000,000 lbs. of formaldehyde, 354.31g of formaldehyde would be released during the packaging operation per year.

These results show that the proposed control processes will result in less than ten pounds of formaldehyde being released from all emission sources each year.

In compliance with local, state and federal regulations, an air quality permit for formaldehyde was approved by the state of Georgia on December 6, 1991 (Attachment H-9).

4) Concentration of formaldehyde expected to enter the environment as a result of use.

Formaldehyde will be applied to feeds or feedstuffs in a closed system by a liquid dispensing system. In the typical feed mill, feed ingredients are blended in a closed system feed mixer. Formaldehyde will be added by a liquid dispensing system at this stage of the feed manufacturing process. Upon complete mixing, the feed is transported from the mixer by a closed auger system to either a feed storage tank, a feed pelletizer or a bagging operation. Concentrations of formaldehyde entering the environment at the site of use are below the 0.5 ppm threshold limit value level (TLV). However, monitoring will be necessary to determine if additional modifications need to be taken.

In the typical rendering plant operation, animal by products are ground and cooked at high temperatures by moist or dry heat. The final product is transferred from the cooker by a closed auger system through a cooler to storage tanks by bagging operations. Formaldehyde will be added by a liquid dispensing system to the rendered animal by-product in the closed auger system after the rendered animal by-product is transported out of the cooker-cooler. Monitoring will be necessary to determine actual emissions at each location.

Application of the product to feedstuffs, such as meat and bone meal, in an open system will result in higher formaldehyde levels immediately after treatment. However these levels decrease quite rapidly to below the TLV level.

In another country, the product is used to treat fishmeal in an open system at a treatment level of 12.5 kg/ton (Attachment H-10). The open system was a mobile treatment unit that consisted of a hopper and screw conveyer. The ingredient was treated with formaldehyde solution as it moved through the screw conveyer at a treatment rate of 12.5 kg/ton. After treatment, the ingredient was stored in an open warehouse. Formaldehyde levels were monitored with detector tubes and passive dosimeters at various times. Levels of formaldehyde measured are reported in the table below.

Location	Concentration of Formaldehyde (ppm)[1]
Center of warehouse, during treatment process	2 - 5
At treatment equipment, during treatment	>5
Furthest wall from treatment equipment, during treatment	2
At treated fishmeal, day after treatment	<0.5
At treated fishmeal, 2 days after treatment	0

[1] Concentrations of formaldehyde are reported as time weighted averages (TWAs).

5) Occupational exposures to formaldehyde emissions.

a) Occupational exposures to humans manufacturing formaldehyde.

Control measures to limit formaldehyde emissions at the site of manufacture reduce the occupational exposure of humans to below the 0.5 ppm level. This data is presented in Part 6, Item 3 of the Environmental Assessment (EA).

b) Occupational exposure to humans packaging formaldehyde.

Control measures to limit formaldehyde emissions at the site of packaging reduce the occupational exposure of humans to below the 0.5 ppm TLV level. This data is presented in Section H Part 6, Item 3. Under the current safety program at Anitox Corp., humans packaging formaldehyde in drums or bulk container drums are required to wear rubber or neoprene gloves, safety glasses, a hard hat with a face shield and protective clothing. A full-face respirator or gas mask with cartridge or canister specifically approved for formaldehyde is required to be at the packaging station. During the packaging operation, warning signs indicating formaldehyde use are posted on the access doors to the facility.

c) During application of formaldehyde to animal feeds or feedstuffs the following controls will be used to protect workers:

Application of formaldehyde to feeds or feedstuffs will be in a closed system by a liquid dispensing system. The same type of filtration apparatus may be used as suggested for the drum-filling operation.

If the products is applied in an open system the proper personal protective equipment must be provided and used.

All operations should be in compliance with OSHA regulations.

d) Human exposure to those handling feed that has been treated with formaldehyde:

Complete feedstuffs treated with 0.74 to 1.48 lb/ton of formaldehyde will have low levels of formaldehyde gas, but those workers, such as baggers who fill bags with feed will need to be monitored to determine if they need to wear approved masks to remove formaldehyde vapors. Due to changing conditions like ventilation, length of time feed is held and varying treatment rates, it is necessary to monitor each situation to see what the levels of formaldehyde vapors are in various work areas. Our actual field experience has been that formaldehyde vapors seldom exceed the permissible TLV limit of 0.5 ppm.

Fishmeal and other type of meals that normally have high bacteria loads may be treated with up to 5.92 lb/ton of formaldehyde. Again individual monitoring will be necessary to determine worker protection needs.

7. Fate of emitted substances in the environment.

During manufacture and application of formaldehyde, the environmental concentration of formaldehyde in air is expected to be below 0.5 ppm. The concentration of formaldehyde in freshwater, estuarine, marine, and terrestrial ecosystems as a direct results of these processes is 0 ppm. There should be no waste produced through use of the product. Any waste product disposed of would be as a result of an accident.

The accumulation of formaldehyde in the atmosphere is suppressed by several natural removal processes. These include photodecomposition of formaldehyde, reactions of formaldehyde with reactive intermediates in the environment and the transfer of formaldehyde in the atmosphere to rain water and surface water. (Attachment H-11).

In the process of photodecomposition, formaldehyde absorbs ultraviolet light. This absorption of energy from ultraviolet light electronically excites molecules of formaldehyde. The excited molecules undergo molecular fragmentation

or rearrangement. The rearrangement of formaldehyde will result in the generation of hydrogen and carbon monoxide. The half-life of formaldehyde decay by photodecomposition in the atmosphere near sea level is expected to be between 3.0 and 4.2 hours. The effective disappearance is, therefore, in 36 hours.

A second removal process of formaldehyde from the atmosphere involves the reaction of formaldehyde with reactive intermediates present in the atmosphere. Reactive species in sunlight irradiated, NO_x - and hydrocarbon polluted atmospheres react with formaldehyde. These include HO, HO_2, $O(^3P)$, NO_3 and O_3. Of these reactive species, HO radicals react more readily with formaldehyde to form water and a CHO radical. The CHO radical undergo further degradation to HO_2 and carbon monoxide. The approximate rate constant for this removal of formaldehyde from the atmosphere is 1.1×10^{-11} cc. molecules $^{-1}$ second $^{-1}$. The reaction of atmospheric formaldehyde with atmospheric NO_3 results in the formation of $HONO_2$ and HCO. The approximate rate constant for this reaction is 1.2×10^{-15} cc molecules^{-1} second^{-1}.

The combined removal of atmospheric formaldehyde by these two processes, photodecomposition and reactions with reactive intermediates, shortens the half life of formaldehyde in the atmosphere to 2.6 hours. The half life of formaldehyde in the atmosphere is further shortened by rainout and entrapment in aqueous media. In this case, microorganisms play an important role in the degradation of formaldehyde.

In aquatic environments, formaldehyde may undergo hydration at the carbonyl group to form a gem-diol. However, biodegradation by aquatic organisms is considered to be the major route of formaldehyde removal from aqueous media. It has been observed that aquatic microorganisms in lake water would completely degrade formaldehyde in 30 hours at 20°C under aerobic conditions. Under anaerobic conditions, formaldehyde is completely degraded in 48 hours.

8. Environmental effects of released substances.

Little or no formaldehyde is expected to be introduced into the environment with proper use and disposal of the product. However, data on the effects to the environment is reviewed below.

1) Effects on Humans:

Formaldehyde is a normal metabolite and a vital ingredient in the synthesis of essential biochemical substances in man and thus in small quantities is not toxic. Small amounts of formaldehyde are readily metabolized to formic

acid in the bloodstream. Formic acid may be further oxidized to carbon dioxide and water. Formaldehyde is eliminated from the blood with a half-life of 1-2 minutes (Attachment H-12).

However, formaldehyde exposure at high concentrations (above the TLV) is acutely toxic as described in 29 CFR 1910.1048 (Attachment H-4). Acute effects of exposure in humans are described as follows:

a. Ingestion - Liquids containing 10 to 40% formaldehyde cause severe irritation and inflammation of the mouth, throat, and stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03-0.04%) may cause discomfort in the stomach and pharynx.

b. Inhalation - Formaldehyde is highly irritating to the upper respiratory tract and eyes. Concentrations of 0.5 to 2.0 ppm may irritate the eyes, nose, and throat of some individuals. Concentrations of 3 to 5 ppm also cause tearing of the eyes and are intolerable to some persons. Concentrations of 10 to 20 ppm cause difficulty in breathing, burning of the nose and throat, cough, and heavy tearing of the eyes, and 25 to 30 ppm causes severe respiratory tract injury leading to pulmonary edema and pneumonitis. A concentration of 100 ppm is immediately dangerous to life and health. Deaths from accidental exposure to high concentrations of formaldehyde have been reported.

c. Skin - Formalin is a severe skin irritant and a sensitizer. Contact with formalin causes white discoloration, smarting, drying, cracking, and scaling. Prolonged and repeated contact can cause numbness and a hardening or tanning of the skin. Previously exposed persons may react to future exposure with an allergic eczematous dermatitis or hives.

d. Eye Contact - Formaldehyde solutions splashed in the eye can cause injuries ranging from transient discomfort to severe, permanent cornmeal clouding and loss of vision. The severity of the effect depends on the concentration of formaldehyde in the solution and whether or not the eyes are flushed with water immediately after the accident.

Under 29 CFR 1910.1048 (Attachment H-4) formaldehyde is considered to have the potential to cause cancer in humans based on animal carcinogenicity studies.

Rats exposed to formaldehyde at 2 ppm develop benign nasal tumors and changes of the cell structure in the nose as well as inflamed mucous membranes of the nose. Repeated and prolonged exposure increases risk.

Formaldehyde has been the subject of several epidemiologic studies to determine its effect on humans when exposed to low levels of formaldehyde and formaldehyde vapors over long period of time. The most comprehensive of these studies was conducted by the National Cancer Institute and the Formaldehyde Association (Attachment H-13). In this study 26,561 workers who had been exposed to formaldehyde were studied. The researchers concluded that the risk of lung cancer did not increase with cumulative levels of formaldehyde. Individuals exposed to other hazardous substances had a higher mortality rate associated with lung cancer than those exposed to formaldehyde alone (slightly negative trend). In other words, formaldehyde did not seem to cause any increase in the risk of lung cancer in workers in formaldehyde manufacturing plants.

2) Effects on Animals:

a) Acute oral toxicity:

Formaldehyde is slightly toxic to laboratory animals when administered orally. The LD_{50} values in rats given formaldehyde (formalin solution) was reported in the range of 500-800 mg/kg (Attachments H-12 and H-14).

b) Acute inhalation toxicity and skin irritancy:

When administered by inhalation, formaldehyde is moderately toxic in rats. Three minute LC_{50} values were in the range of 815-820 ppm, while four hour LC_{50} values were in the range of 479 - 482 ppm (Attachments H-12 and H-14). The four hour LC_{50} valve of formaldehyde has also been reported for mice (LC_{50} - 414 ppm; Attachment H-12). The most predominant pathological change was pulmonary edema.

Due to the use of formaldehyde in cosmetic products considerable information has been generated on skin irritation and sensitization. Formaldehyde produces a mild to moderate response when applied to the skin of rabbits or guinea pigs at a dose of 0.1 - 20% (Attachment H-12).

c) Mutagenicity

Formaldehyde has exhibited mutagenic activity in Pseudomonas fluorescens and Escherichia coli, however no mutagenic activity was detected in the Ames strains of Salmonella typhimurium (Attachments H-12 and H-14). In fungi, formaldehyde was observed to be slightly mutagenic. These mutations were primarily mitotic recombination. The exposure of Drosophila to formaldehyde vapors did not produce mutations in adults or larva (Attachments H-13 and H-14).

The mutagenic potential of formaldehyde in mammalian systems has not resulted in generating a significant dose response relationship (Attachment H-12). In the L5178Y mouse lymphoma assay, formaldehyde was observed to be mutagenic. However, in the Chinese hamster ovary cell/HGPRT assay, formaldehyde was observed to be non-mutagenic.

d) Subchronic toxicity:

The effect of formaldehyde in the rat and dog following oral exposure has been investigated (Attachment H-15). Formaldehyde was fed to beagle dogs at a treatment rate of 0, 50, 75 and 100 mg formaldehyde/kg body wt/day. No differences were observed in hematology, clinical chemistry, or pathology among the treatment groups. However, the 100 mg/kg/day treatment group was observed to have a decreased body weight gain. In a similar study in rats, formaldehyde caused a decrease in body weight gain at the 150 mg/kg/day treatment level. In additional toxicity studies in rats, formaldehyde was observed to cause an increase in the thickness of the forestomach and a slight discoloration of the mucosal lining at the 125 mg/kg/day treatment level.

e) Chronic toxicity and carcinogenicity:

Early animal studies addressing the chronic toxicity and carcinogenicity of formaldehyde were feeding studies with hexamethylenetetramine (HMT). Hexamethylenetetramine is a food preservative that is metabolized to formaldehyde and ammonia under acidic conditions in the stomach of the animal (Attachment H-18). In feeding studies, no treatment related tumors or toxic effects were observed in rats or mice

exposed to hexamethylenetetramine (up to 5% in the drinking water) for 1-2 years (Attachments H-19 and H-20).

In a 24 month study, formaldehyde was administered to rats in the drinking water (Attachment H-16). Treatment levels were 0, 1.2, 15 or 82 mg/kg of body weight/day for male rats and 0, 1.8, 21 or 109 mg/kg of body weight for female rats. No adverse effects on general health, hematology or chemical chemistry were observed in any of the treatment levels. In the high dose group, the consumption of formaldehyde treated water was observed to be 40% lower than water consumption in the controls. This resulted in decreased feed consumption and body weight. Histopathological examination revealed hyperplasia and ulceration in the forestomach and stomach.

The majority of the chronic toxicity and carcinogenicity studies on formaldehyde have centered on inhalation exposure data. This is due to the considerable amount of concern about human exposure to formaldehyde in the environment. Long-term inhalation experiments in rats and mice are presented in Attachments H-18 through H-20. Formaldehyde vapors at a level of 15 ppm have been observed to cause lesions and squamous cell carcinomas in the nasal cavity of rats after 24 months of exposure (6 hours/day; 5 day/week). There is a regression of the rhinitis, dysplasia and metaplasia when the animals were removed from formaldehyde vapors. Similar studies were performed in mice which were observed to be less sensitive to formaldehyde.

The chronic toxicity and carcinogenicity of formaldehyde in animals exposed by inhalation and by exposure to water containing formaldehyde (drinking water or gavage) are based on DNA-protein crosslinking. This evidence indicates that the carcinogenic effect of formaldehyde is limited to tissues that come into direct effect with free formaldehyde at high levels. In the case where animal feedingstuff is treated with formaldehyde, cross-linking with the protein in the feedingstuffs greatly reduces the carcinogenic potential. This conclusion is substantiated by the fact that formaldehyde has been safely used in certain animal feedingstuffs since the early 1960's and that hexamethylenetetramine, which is metabolized to formaldehyde, is still being used as a food preservative.

f) Reproductive toxicity:

The effects of formaldehyde on reproduction, embryotoxicity and teratotoxicity are presented in Attachments H-12 and H-14. In gavage studies, pregnant mice were intubated with a stock solution of formaldehyde (37% formaldehyde solution) on days 6 through 15 of gestation. Treatment rates were 0, 74, 148 or 185 mg of formaldehyde/kg body weight/day. At the highest dose level 22 of the 34 (64.7%) pregnant mice died. The incidence of fetal reabsorption in this treatment group were observed to be greater. However, this increased incidence was not significantly different from the control group or any other treatment group. There were no treatment related differences in the incidence of malformation, mean number of implantation, stunted fetuses, live fetuses per litter or average fetal body weight per litter. It was concluded from this study that formaldehyde did not affect reproduction.

Formaldehyde is very rapidly metabolized in animals (half life of 1-1.5 minutes). When low levels of formaldehyde are fed to pregnant animals, it is very unlikely that the embryos are exposed to formaldehyde. If higher levels of formaldehyde are used for embryotoxicity, these levels are usually lethal to the dam. An approach that has been utilized for assessing the embryotoxicity/teratotoxicity of formaldehyde is to feed the pregnant animals hexamethylenetetramine (HMT) which is metabolized to formaldehyde in vivo. In beagles consuming 0, 600 or 1250 mg/kg of HMT during days 4 through 56 of gestation, only the 1250 mg/kg treatment level was observed to have a toxic effect. At 1250 mg/kg, there was an increase in the rate of stillborn (17.85%), a decrease in growth rate between birth and weaning and an increase in postnatal mortality. No malformed pups were observed in any of the treatments.

In a separate study, rats were exposed to 1% hexamethylenetetramine in their drinking water from two weeks before mating through pregnancy and lactation. No malformations of histological changes were observed. Although the body weight of the pups were suppressed for the first 9-13 weeks post partum.

g) Toxicology of metabolites:

In laboratory animals, formaldehyde maybe metabolized to formic acid or carbon dioxide. These metabolites are considered to be nontoxic.

3) Effects of formaldehyde on vegetation:

In fumigation experiments designed to determine the cause of smog damage in plants, formaldehyde was tested at atmospheric concentrations of 0.7 ppm and 2.0 ppm (Attachment H-21). Formaldehyde was observed to have no effect on spinach, endive, beets, oats or alfalfa when these plants were exposed to 2.0 ppm for 2 hours. However, when these plants were exposed to formaldehyde at 0.7 ppm for 5 hours, and atypical symptom was observed in alfalfa.

The objective of this investigation was to determine the typical type of damage in plants that was associated with smog (Attachment H-22). This damage (described as typical damage) included the metabolic sheen or silvering of plant leaves, speckled necrosis or marginal bleaching. Atypical damage in plants was usually in the form of wilting, the appearance of large necrotic areas, tip, burning, chlorosis, bleaching or minute pitting of the leaves (Attachment H-22). The criteria worked well except for in alfalfa and it was concluded that alfalfa was not a good differential test plant for determining the presence of smog producing chemicals.

EFFECTS OF FUMIGATION WITH FORMALDEHYDE GASES ON PLANTS[a,b]

Plant Type	Injury at different concentrations of formaldehyde (ppm)	
	0.7	2.0
Spinach	0	0
Endive	0	0
Beet	0	0
Oats	0	0
Alfalfa	A	O

[a] Plants were fumigated with 0.7 ppm for five hours or 2.0 ppm for 2 hours.

[b] 0, no injury; A, injury that is atypical of smog damage in Los Angeles area;

In similar studies, formaldehyde at levels of 6.5 ppm was observed to have no effect on petunias or pinto beans after 1 hour exposure (Attachment H-21). Laboratory data from these experiments is presented in the following two tables.

PLANT DAMAGE CAUSED BY IRRADIATED FORMALDEHYDE[a]

Duration of Fumigation, h	PLANT INJURY		
	14-d-old Pinto	8-d-old Pinto	Petunia
0.25	Atypical	0	0
1.0	Atypical	0	0

[a] The concentrate of formaldehyde in the fumigant at the beginning depts were 14.4 - 16.0 ppm. The concentration of HCHO at the end of the exposure times were 1.5 - 1.6 ppm.

In a separate study, formaldehyde was observed to have no effect on petunias, pinto beans or tobacco leaf surfaces after 4 hours of exposure (Attachment H-21).

PINTO BEAN, TOBACCO AND PETUNIA DAMAGE CAUSED BY IRRADIATED FORMALDEHYDE AFTER 4 HOURS OF EXPOSURE

Concentration of HCHO (ppm)	Injury		
	Tobacco	Pinto Beans	Petunias
5.6	0	0	0
6.1	0	0	0

Formaldehyde has been investigated for its effect on photosynthesis and respiration. An alga (Euglena gracilis) was exposed to air containing 0.075 ppm for 1 hour. The rates of photosynthesis and respiration were slightly but not statistically significantly reduced. In fasted cells, formaldehyde was observed to slightly increase the rate of photosynthesis and respiration. This data is presented in the following table.

EFFECT OF TO FORMALDEHYDE (AT 0.075 PPM FOR 1 H) ON RATES OF PHOTOSYNTHESIS AND RESPIRATION OF EUGLENA GRACILIS

	Rate[a]	
	Control	Formaldehyde Exposure
Unfasted cells		
Photosynthesis	5.25	4.54
Respiration	2.26	1.83
Fasted Cells		
Photosynthesis	4.22	4.61
Respiration	1.47	1.54

[a] For photosynthesis, micromoles of oxygen given off by 6.3×10^6 cells in 10 min; for respiration, micromoles of oxygen absorbed by 6.3×10^6 cells in 10 min.

The effect of formaldehyde on pollen germination has been investigated. Lily pollen was exposed to formaldehyde at 0.37, 1.40 or 2.40 ppm for 5 hours. Pollen tube length was observed to be reduced after one hour of exposure to 1.40 ppm. After 5 hours of exposure to 0.37 ppm, pollen tube length was also observed to be reduced. This data is presented in the following table.

POLLEN-TUBE LENGTH IN LILIUM LONGIFLORUM AFTER EXPOSURE OF POLLEN GRAINS TO FORMALDEHYDE

Formaldehyde Concentrations	Pollen-Tube Length, (% of control) at different exposure duration		
(ppm)	1h	2h	5h
0.37	100.0	100.0	27.7
1.40	86.5	67.3	0.0
2.40	62.5	41.6	0.0

4) Effects of formaldehyde on aquatic life:

a) Effects on flora:

Formaldehyde was observed not to effect the aquatic algae Aphanothece sp., Oscillatoria sp., and Rhizoclonium sp. after exposure to 37 mg formaldehyde per liter for seven days (Attachment H-23). However, cultures of Scenedesmus sp., Sirogonium sp., Spyrogyra sp., and Stigeoclonium sp. did not survive at formaldehyde concentration of 5.6 mg formaldehyde per liter.

b) Toxicity in non-vertebrates:

Formaldehyde has observed to be lethal to Daphnia magna at levels of 5 mg formaldehyde per liter or greater. The median threshold level for a 48 hour exposure was estimated to be 2 mg formaldehyde per liter (Attachment H-22). Other invertebrates, such as crayfish (Procambrus blandingi), did not exhibit any toxic effects when exposed to 40 ug formaldehyde/liter for 72 hours. Lethal concentrations of formaldehyde in other species are summarized in the following Table.

LETHAL CONCENTRATIONS OF FORMALDEHYDE IN INVERTEBRATES AFTER 96 HOURS OF EXPOSURE[a]

Species of Invertebrates	LC_{50}
Freshwater prawn (Palaemonetes kadiakensis)	465 ul/l
Seed Shrimp (Cypridopsis sp.)	1.05 ul/l
Asiatic clam (Corbicula leana)	126 ul/l
Snail (Helisoma sp.)	93 ul/l
Backswimmer (Notonecta sp.)	835 ul/l

[a] LC_{50} values summarized from Attachment H-24 and H-25.

c) Toxicity of formaldehyde in fish:

Formaldehyde has been used as a therapeutic agent (16% - 250 ppm) in controlling external parasites in commercial hatcheries. A review of the literature summarizing the toxicity of formaldehyde is freshwater and saltwater fish is presented in the following table.

LETHAL CONCENTRATIONS OF FORMALDEHYDE IN FISH AFTER 96 HOURS OF EXPOSURE[a]

SPECIES	LC_{50}
Largemouth bass (Micropterus salmoides)	143 ul/l
Rainbow trout (Salmo gairdneri)	118 ul/l
Atlantic Salmon (Salmo salar)	173 ul/l
Lake trout (Salvelinus namaycush)	100 ul/l
Black bullhead (Ictalurus melas)	62.1 ul/l
Channel catfish (Ictalurus punctatus)	65.8 ul/l
Green sunfish (Lepomis cyanellus)	173 ul/l
Bluegill (Lepomis macrochirus)	100 ul/l
Smallmouth bass (Micropterus dolomieui)	136 ul/l

[a] LC_{50} values summarized from Attachment H-24.

Of the twenty species of fish tested for acute toxicity, striped bass were observed to be the most sensitive (24 hr LC_{50} was from 3.7 - 11.1 mg/l; Attachment H-25). In addition, formaldehyde has been found to occur naturally and in shrimp during postmortem change (0-4.8 ppm) and cod fish (1-150 ppm) (Attachment H-26).

Currently, a formalin solution (37% formaldehyde) is approved for use as a drug to control external parasites on salmon, trout, catfish, largemouth bass, and bluegill fish and to control fungi on salmon, trout and esocid eggs (21 CFR 529.1030; Attachment H-27).

9. Uses of resources and energy.

Natural resources required to:

Produce: Only a small tract of land is required for storage tanks and a building for drum-filling. No energy is required except electricity for pumps.

Transport: The product will be transported by truck and ship and therefore will require fuel.

Use: Use of the product will require a small tract of land for storage and treatment in a building. Energy required is electricity for a pump.

Dispose: Disposal consists only of disposal of used to reduce formaldehyde vapors. This may be disposed of in a landfill.

There will be no effects on endangered or threatened species of on property listed in the National Register of Historic Places.

10. Mitigation measures.

The Occupational Safety and Health Administration (OSHA) requires as stated in 29 CFR 1910.1048 that the following safety and health measures be implemented when employees are exposed to formaldehyde.

a) Exposure monitoring - Each employer who has a workspace in which formaldehyde is used, shall monitor employees to determine their exposure to formaldehyde. If the exposure level is below the action level or the short term exposure limit (STEL), the employer will not be required to monitor for formaldehyde. If the exposure level is above the action level or the STEL, additional precautions must be taken. These include:

1) Initial Monitoring - The employer shall identify all employees which may be exposed at or above the action level or at or above the STEL and accurately determine the exposure of each employee. The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may results in new or additional exposure to formaldehyde.

2) Periodic Monitoring - The employer shall periodically measure and determine the employee exposure to formaldehyde at least every six months.

b) Limited Access - The employer shall limit access to areas in which the hazards of formaldehyde are recognized or have been determined. The employer shall communicate the access restrictions and location to other employers with work operations at that work site.

c) Engineering Control and Work Practice - The employer shall institute engineering and work practice controls to reduce and maintain employee exposure to formaldehyde at or below the TWA and the STEL. When the employer has established that feasible engineering and work practice controls cannot reduce employee exposure to or below either of the Personal Exposure Limits (PELs), the employer shall apply these controls to reduce employee exposures to the extent feasible and shall supplement them with respirators which satisfy this standard.

d) Under 29 CFR 1910.1048, additional safety measures are required in situations in which the employee exposure limit of formaldehyde has been determined to be above the PELs. These include the following:

   1) The employer shall institute a written respirator program as described under 29 CFR 1910.134 (Attachment H-4).

   2) The employer shall provide protective equipment and clothing in compliance with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133.

   3) For each workspace where the is possibility of an emergency involving formaldehyde, the employer shall assure appropriate procedures are adopted to minimize injury and loss of life. Appropriate procedures shall be implemented in the event of an emergency.

   4) The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or exceeding the STEL. As described under 29 CFR 1910.1048.

e) Hazard Communication - Each employer who has a workspace in which formaldehyde is used shall comply with the requirements of 29 CFR 1910.1200 in establishing a hazard communication program. Under these guidelines a Material Safety Data Sheet for formaldehyde has been written and includes the information listed in 29 CFR 1910.1048 (Attachment H-4).

Under the hazard communication guidelines listed in 29 CFR 1910.1048 a training program for the use of hazardous materials is to be implemented. This includes training at the time of the initial assignment and whenever a new hazard from formaldehyde is introduced into the work area.

Warning labels will be placed on formaldehyde containers (55 gallon drums, 275 gallon bulk drums, and bulk tanks) in accordance with the National Fire Protection Association (NFPA) Code for Hazardous Materials (NFPA 704-1980) and Federal Standard Number 313-B. This code will list the flammability hazard, the health hazard, reactivity hazard, and any other special hazards associated with formaldehyde.

It is the intent of Anitox Corp. to assist customers in complying with these OSHA standards.

11. Alternatives to the proposed action.

No potential adverse environmental impacts are expected.

12. List of preparers.

Diane Burrell: Quality Control Manager and Safety Coordinator for Anitox Corp. for 8 years.

Kurt Richardson, Ph.D.: Research Director for Anitox Corp. for 4 years. Doctorate in Toxicology and Physiology.

13. Certification.

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

Date April 30, 1992

Signature of responsible official BJ Bland

Title President