This Statement was prepared to give you information about ethylene oxide and to emphasize the human health effects that may result from exposure to it. The Environmental Protection Agency (EPA) has identified 1,177 sites on its National Priorities List (NPL). Ethylene oxide has not been definitely identified at any NPL site. However, it has been tentatively identified at three of these sites. As EPA evaluates more sites, the number of sites at which ethylene oxide is found may change. This information is important for you to know because ethylene oxide may cause harmful health effects and because these sites are potential or actual sources of human exposure to ethylene oxide.

When a chemical is released from a large area, such as an industrial plant, or from a container, such as a drum or bottle, it enters the environment as a chemical emission. This emission, which is also called a release, does not always lead to exposure. You can be exposed to a chemical only when you come into contact with the chemical. You may be exposed to it in the environment by breathing, eating, or drinking substances containing the chemical or from skin contact with it.

If you are exposed to a hazardous substance such as ethylene oxide, several factors will determine whether harmful health effects will occur and what the type and severity of those health effects will be. These factors include the dose (how much), the duration (how long), the route or pathway by which you are exposed (breathing, eating, drinking, or skin contact), the other chemicals to which you are exposed, and your individual characteristics such as age, sex, nutritional status, family traits, life style, and state of health.

1.1 WHAT IS ETHYLENE OXIDE?

Ethylene oxide (also known as ETO or oxirane) is a flammable gas with a somewhat sweet odor. It dissolves easily in water, alcohol, and most organic solvents.

Ethylene oxide is produced in large volumes and is used to make other chemicals, especially ethylene glycol, a chemical used to make antifreeze and polyester. Most ethylene oxide is used up in the factories where it is produced. A very small amount (less than 1%) is used to control insects on stored agricultural products such as nuts and spices. Ethylene oxide is also used in very small amounts in hospitals to sterilize medical equipment and supplies.

When ethylene oxide is produced or used, some of the gas is released to air and water. If it is released into the air, humidity and sunlight

cause it to break down within a few days. In water, ethylene oxide will either break down or be destroyed by bacteria within a few days.

Further information on the properties and uses of ethylene oxide can be found in Chapters 3, 4 and 5.

1.2 HOW MIGHT I BE EXPOSED TO ETHYLENE OXIDE?

You are not likely to be exposed to ethylene in the general environment. In studies of the air quality in Texas and California, no ethylene oxide was found. There is also no evidence that ethylene oxide is commonly found in water. Because of the limited information about ethylene oxide in air, water, or soil at hazardous waste sites, we do not know how likely it is that you might be exposed to ethylene oxide at or near these sites.

You may be exposed to ethylene oxide if you work where it is produced or used. Health care workers, such as technicians, nurses, and physicians in hospitals and clinics, may have contact with ethylene oxide because it is used to sterilize medical equipment and supplies. Since ethylene oxide is used as a fumigant to spray agricultural products, if you are a farmer or work on a farm where ethylene oxide is used, you may also be exposed to this substance.

It is not known if food crops are a source of exposure to ethylene oxide for the general public. Ethylene oxide has been found at levels up to 3.5 parts of ethylene oxide per one million parts of food (3.5 ppm) in some foods shortly after being sprayed with pesticide that contains it. These levels decrease with time as ethylene oxide evaporates or breaks down into other substances, and thus little or none may remain when the food is eaten.

Further information on the ways that you can be exposed to ethylene oxide is presented in Chapter 5.

1.3 HOW CAN ETHYLENE OXIDE ENTER AND LEAVE MY BODY?

Ethylene oxide can enter your body when air containing this substance is breathed into your lungs. Because ethylene oxide evaporates very easily, it is unlikely that it remains in or on food or remains dissolved in water long enough to be eaten or swallowed, although this is not known for certain. It is not known if ethylene oxide can enter the body through the skin.

After a person has been exposed to ethylene oxide, it leaves the body through the urine or feces or by breathing it out through the lungs. This probably occurs very rapidly, perhaps within 2 or 3 days.

1.4 HOW CAN ETHYLENE OXIDE AFFECT MY HEALTH?

Ethylene oxide can cause a wide variety of harmful health effects in exposed persons. In general, with higher levels of exposure to this chemical, more severe effects will occur. The major effects seen in workers exposed to ethylene oxide at low levels for several months or years are irritation of the eyes, skin, and mucous membranes and problems in the functioning of the brain and nerves. At higher levels of exposure to ethylene oxide, which may result from accidents or equipment breakdown, the types of effects are similar, but they are more severe and harmful. There is also some evidence that exposure to ethylene oxide can cause an increased rate of miscarriages in female workers exposed to ethylene oxide.

Studies in animals have shown that breathing ethylene oxide at high levels can interfere with their ability to reproduce. Litter sizes have been smaller than usual, and the babies of exposed animals have weighed less than normal and have had delayed bone formation.

Some studies of workers exposed to ethylene oxide in ethylene oxide factories or hospital sterilizing rooms have shown an increased incidence of leukemia, stomach cancer, cancer of the pancreas and Hodgkin's disease. Ethylene oxide has also been shown to cause cancer in laboratory animals. Leukemia, brain tumors, lung tumors and tumors of the tear glands of the eye have been found.

Further information on the health effects of ethylene oxide is presented in Chapter 2.

1.5 WHAT LEVELS OF EXPOSURE HAVE RESULTED IN HARMFUL HEALTH EFFECTS?

Tables 1-1 through 1-4 show the relationship between exposure to ethylene oxide and known health effects. Skin contact with ethylene oxide can result in blisters and burns that may appear to be similar to frostbite. With longer times of contact, there is a more severe reaction. Eye damage can also result from ethylene oxide contact.

It is possible to smell ethylene oxide if it is present in water at or above 140 mg per liter (about one quart) of water. It can also be smelled in air if it is present at or above 430 ppm (430 parts of ethylene oxide per million parts of air).

A Minimal Risk Level (MRL) is also included in Table 1-1. This MRL was derived from animal data for long-term exposure, as described in Chapter 2 and in Table 2-1. The MRL provides a basis for comparison with levels that people might encounter in the air. If a person is exposed to ethylene oxide at an amount below the MRL, it is not expected that harmful (noncancer) health effects will occur. Because this level

TABLE 1-1. Human Health Effects from Breathing Ethylene Oxide*

Short-term Exposure (less than or equal to 14 days)				
Levels in Air	<u>Length of Exposure</u>	Description of Effects The health effects resulting from short-term exposure of humans to air containing specific levels of ethylene oxide are not known.		
Long-term Exposure (greater than 14 days)				
Levels in Air (ppm) 0.09	<u>Length of Exposure</u> 14 weeks	Description of Effects** Minimum risk level (MRL) for intermediate exposure to ethylene oxide. Based on a study in mice.		
3-430	5-20 years	Problems with hand/eye coordination.		
10-400 700	2 years 2 months	Eye and nose irritation. Seizures, cataracts.		

^{*}See Section 1.2 for a discussion of exposures encountered in daily life. **These effects are listed at the lowest level at which they were first observed. They may also be seen at higher levels.

TABLE 1-2. Animal Health Effects from Breathing Ethylene Oxide

Short-term Exposure (less than or equal to 14 days)				
Levels in Air (ppm) 100	Length of Exposure 10 days of pregnancy	Description of Effects* Decreased litter size and smaller newborn rats.		
800	4 days	Death in mice.		
Long-term Exposure (greater than 14 days)				
Levels in Air (ppm)	Length of Exposure	Description of Effects*		
50	10-11 weeks	Decreased physical activity in mice.		
100	14 weeks	Kidney damage in mice.		
200	14 weeks	Nasal inflammation in mice.		
400	14 weeks	Death in mice.		

^{*}These effects are listed at the lowest level at which they were first observed. They may also be seen at higher levels.

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TABLE 1-3. Human Health Effects from Eating or Drinking Ethylene Oxide*

Short-term Exposure (less than or equal to 14 days)				
Levels in Food Levels in Water	Length of Exposure	Description of Effects The health effects resulting from short-term exposure of humans to food containing specific levels of ethylene oxide are not known. The health effects resulting from short-term exposure of humans to water containing specific levels of ethylene oxide are not known.		
Long-term Exposure (greater than 14 days)				
Levels in Food Levels in Water	Length of Exposure	Description of Effects The health effects resulting from long-term exposure of humans to food containing specific levels of ethylene oxide are not known. The health effects resulting from long-term exposure of humans to water containing specific levels of ethylene oxide are not known.		

^{*}See Section 1.2 for a discussion of exposures encountered in daily life.

TABLE 1-4. Animal Health Effects from Eating or Drinking Ethylene Oxide

Short-term Exposure (less than or equal to 14 days)				
Levels in Food (ppm)	Length of Exposure	Description of Effects*		
4,000	1 day	Death in rats.		
Levels in Water		The health effects result- ing from short-term exposure of animals to water containing specific levels of ethylene oxide are not known.		
	Long-term Exposur (greater than 14 day			
Levels in Food 2,000	Length of Exposure 21-30 days	Description of Effects Liver damage and stomach irritation in rats.		
Levels in Water		The health effects result- ing from long-term exposure of animals to water containing specific levels of ethylene oxide are not known.		

^{*}These effects are listed at the lowest level at which they were first observed. They may also be seen at higher levels.

is based only on information currently available, some uncertainty is always associated with it. Also, because the method for deriving MRLs does not use any information about cancer, an MRL does not imply anything about the presence, absence, or level of risk for cancer.

Further information on exposure levels of ethylene oxide that cause health effects in humans and animals is presented in Chapter 2.

1.6 IS THERE A MEDICAL TEST TO DETERMINE WHETHER I HAVE BEEN EXPOSED TO ETHYLENE OXIDE?

There are two kinds of tests that can determine if you have been exposed to ethylene oxide within the last couple of days. These tests are not routinely done in a doctor's office, but can be done in a special laboratory. One test measures this substance in blood, the other measures it in air that you breathe out of your lungs. If you were exposed to ethylene oxide more than two or three days ago, there may be no ethylene oxide remaining in your body. In addition, if you have been exposed to very low levels of ethylene oxide, these tests may not detect it. The results of these tests cannot be used to predict the type or severity of health effects resulting from exposure.

Further information on this topic is presented in Chapter 2 and 6.

1.7 WHAT RECOMMENDATIONS HAS THE FEDERAL GOVERNMENT MADE TO PROTECT HUMAN HEALTH?

In order to protect the general population from exposure to ethylene oxide, the federal government has established a number of guidelines and regulations related to its use and disposal.

The EPA is considering listing ethylene oxide as a hazardous air pollutant and regulating industrial emissions. The Food and Drug Administration (FDA) has set limits on the levels of ethylene oxide that may remain on food products fumigated with this chemical. In order to protect workers who use ethylene oxide while on the job, the Occupational Safety and Health Administration (OSHA) has established a limit of 1 ppm in workplace air for an 8-hour work day and a limit of 5 ppm for a 15-minute period.

More detailed information on federal and state regulations regarding ethylene oxide is given in Chapter 7.

1.8 WHERE CAN I GET MORE INFORMATION?

If you have any more questions or concerns not covered here, please contact your State Health or Environmental Department or:

Agency for Toxic Substances and Disease Registry Division of Toxicology 1600 Clifton Road, E-29 Atlanta, Georgia 30333

This agency can also give you information on the location of the nearest occupational and environmental health clinics. Such clinics specialize in recognizing, evaluating, and treating illnesses that result from exposure to hazardous substances.