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GDCh-Advisory Committee
on Existing Chemicals of
Environmental Relevance (BUA)

Ethylene oxide

BUA Report 141
(February 1993)

S. Hirzel
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on Existing Chemicals of Environmental Relevance (BUA)

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Foreword

The German Chemicals Act (Chemikaliengesetz - ChemG) of 1980 stipulates that certain existing chemicals must be reported to the competent authority, if they exhibit properties which indicate that they may be hazardous, either alone or in combination with other substances.

In the summer of 1982, an Advisory Committee on Existing Chemicals of Environmental Relevance (BUA) was set up by the German Chemical Society (Gesellschaft Deutscher Chemiker - GDCh). It brings together representatives from the scientific community, the chemical industry and the governmental authorities. This Advisory Committee is responsible for elaborating appropriate solutions for substances of relevance for health and the environment on the basis of voluntary measures. It selects and examines existing chemicals from the aforementioned angles. The testing and evaluation are based on scientific criteria alone.

It was, therefore, necessary to develop priority setting procedures. In a first phase reports were only prepared for priority chemicals. Within the framework of a first priority setting procedure, chemicals were compiled from several priority lists and 135 chemicals were selected for detailed substance reports.

In a second priority setting procedure the survey of the German Chemical Industry Association (VCI) on all substances with a production volume of more than 10 tons per year was used as a starting list. Since this survey covered 4,600 chemicals, BUA decided to process the corresponding list in several stages. The first stage included approx. 1,050 substances with a production volume of more than 1,000 tons per year.

Detailed reports are drawn up on chemicals suspected of having a hazard potential and abridged reports on those presenting only a minor hazard potential, according to the current state of knowledge.

The detailed BUA reports take in both the published literature and data from industry. If data for the evaluation of the chemicals are not available, additional studies are recommended and the results are published as updates to the reports. The reports serve as a basis for the instigation of administrative measures, when there are indications of risks to health or the environment.

Tübingen, May 1993

Ernst Bayer
Chairman of the Advisory Committee
on Existing Chemicals
of Environmental Relevance

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BUA Report on Ethylene oxide

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The world production capacity for ethylene oxide (EO) was approximately 9.5 million tonnes in 1990. The production capacity in the Federal Republic of Germany was about 83 5,000 tonnes in 1990. Production quantities, export and overall consumption have been estimated for the year 1990 as follows:

	Germany	
	old federal states	GDR, new federal states
Production	596 000	78 000
Sales	43 000	-
Consumption	553 000	78 000

EO is a starting product for a series of secondary and derivative products which are used in various application areas. The most important secondary products in terms of quantity are ethylene glycol (27 %), ethanolamines (13 %), ethoxylates (35 %) and glycol ethers (9 %). EO is used at about 0.1 % directly as a fumigant for sterilization purposes.

Introduction into the atmosphere occurs during manufacture, storage, processing and during use as a fumigant.

In 1990, in the Federal Republic of Germany (old federal states), approximately 33 t passed into the atmosphere in production and storage and < 1 t during further processing. The manufacturers‘ data

from the former GDR and of some EO-processing companies (about 20 % of EO consumption) in this context are unknown.

Data on emissions in the sterilization sector are not available. In the worst case, approximately 600 t must be expected, the entire estimated quantity used.

Both in production and in further processing, EO is introduced into untreated industrial waste water. Since EO, on account of its physical and chemical properties, is decreased by stripping processes and in part by hydrolysis, a significant introduction into the receiving stream is not to be expected.

The introduction of EO from residual contents in liquid detergents is estimated as a maximum of 1 t/year. In this case also, the EO arising primarily with the waste water will volatilize.

EO has not been detected in the atmosphere or in surface waters. EO has been detected in traces (not detectable to 12.6 µg/m^3 in landfill pollution measurements.

In workplace measurements, EO concentrations of < 0.02 to 15 mg/m^3 have been reported in the production sector and concentrations of < 0.02 to 477 mg/m^3 have been reported in sterilization processes. Most of the data relate to relatively old publications which do not describe German plants.

In addition, EO occurs in fumigated materials (medical equipment, foodstuffs, tobacco). Immediately after fumigation, high concentrations in the gram per kilogram range are sometimes found. After the following treatment specified in the fumigation, these values substantially decrease to below the detection limit.

EO is synthesized by plants, bacteria and fungi; as an intermediate in the decomposition of ethene, it is found both in bacteria and in some plants.

Degradability

Studies on the biodegradation show a degree of degradation of 3 % rsp. 5 % after 5 days. After 20 days, the degree of degradation, measured as the ratio of biological O_2 demand to the theoretical O_2 demand, is 52 (± 16) %.

In a study period of 20 days, a slow hydrolysis of the EO to form ethylene glycol (half life approximately 12 days) takes place. To what extent the biodegradation of EO is due to hydrolysis to form ethylene glycol and metabolism of this readily degradable hydrolysis product has not been determined.

Under environmental conditions, it can likewise be assumed that EO is also eliminated by abiotic processes or at least part of it is hydrolyzed to form ethylene glycol.

The half lives of EO hydrolysis to ethylene glycol at 25°C are 12.9 days for distilled river water, 14.2 days for untreated river water and approximately 9 days for salt water (3 % NaCl). In salt water, in addition to ethylene glycol, 2-chloroethanol is formed as a further reaction product.

Photochemical/oxidative degradation in the atmosphere represents a relatively unimportant degradation pathway. The half lives determined from measurements and Computer programs are between 72 days and 321 days.

Accumulation

Because of the low log P_{OW} of -0.3, accumulation of EO in biological material and in soils is not to be expected.

Ecotoxicological effect

1. Effects on aquatic organisms

Under environmental conditions, EO generally occurs in the gaseous state, and dissolved in water it shows a high volatility. The significance of results determined in the laboratory system for the

effects on aquatic organisms is therefore restricted.

Because of the high volatility of EO from water bodies, the following ecotoxicological values were primarily determined in non-aerated or only minimally aerated test systems.

EO concentrations between 10 and 100 mg/l effect a 50 % inhibition of the propagation of the community of organisms of activated sludge after a test period of 16 hours at 22 °C.

Measurement of acute toxicity to *Daphnia magna* and *Artemia salina*, measured in the static test method, gave the following values:

	LC_{50} (24h) in mg/l	LC_{50} (48h) in mg/l
D. magna	260 to > 300	137 to 300
A. salina	350 to > 500	490 to 1000

For acute toxicity to fathead minnows (*Pimephales promelas*) and goldfish (*Carassius auratus*) LC_{50} values between 84 and 90 mg/l were determined after 24, 48 and 96 h.

In all the aquatic test organisms mentioned, no effect was seen with the hydrolysis product ethylene glycol up to the highest concentration tested of 10,000 mg/l.

For the hydrolysis product ethylene chlorohydrin (2-chloroethanol), in the case of *Artemia salina* a 24 h LC_0 of > 1000 mg/l and a 48 h LC_{50} of 680 mg/l were determined.

No data are available for the effect on aquatic plants.

2. Effects on terrestrial organisms

As a sterilizing agent, EO has insecticidal, fungicidal and bactericidal activity.

Studies on various microorganisms show the relationship of the activity of EO both to the fumigation conditions (EO concentration, air humidity, duration of exposure, fumigation temperature) and to the generation phase of the microorganisms studied.

The EO concentrations used for sterilization varied between 150 and 1200 mg/l.

Sterilization of soil samples with EO lead to an impairment of the subsequent development of microorganisms and nematodes, combined inter alia with pH elevation and reduction of the phosphate content in the soil.

In the case of English ryegrass, the effects of sterilization of the soil with EO (1200 mg/l) are a reduction of the plant dry weight and chloroses with necrotic lesions.

After 24 hours‘ fumigation (1000 - 3000 mg of EO/m^3 of larvae of the khapra beetle *Trogoderma granarium* although mortality of the adults was exhibited within the 15 day observation period (9 8.6 % at 3000 mg/m^3 there was no significant difference in the reproduction rates of surviving insects.

Similar studies with the lesser grain borer *Rhyzopertha dominica* showed significant effects on the reproduction rates of surviving insects from a concentration of > 500 mg of EO/m^3.

Studies on free-living terrestrial vertebrates and on effects in ecosystems are not available.

Toxicological aspect

EO is a readily volatile substance, which after inhalatory, dermal or oral uptake can be distributed in all body tissues. Because of its alkylating activity, it can initiate both germ-line mutations and somatic mutations in all tissues and other cell damage (for instance with the consequence of fetotoxic or neurotoxic effects).

The breakdown of EO in the body essentially proceeds by hydrolysis to ethane-1,2-diol or via binding to glutathione to form mercapturic acids.

After acute exposure, EO primarily exhibits central nervous system effects and a high irritation potential. Also in humans, acute intoxication appears to show irritation of the mucous membranes. Several cases of sensitization to EO have been described in the literature.

At repeated exposure, peripheral neurotoxic effects occur. The no adverse effect level for this is approximately 10 ppm.

EO shows genotoxic effects in virtually all experimental models. Chromosomal aberrations in peripheral lymphocytes are observed. Even in small doses the germ cells are targeted and potentially be prone to inheritable defects. Dominant-lethal effects have been repeatedly observed. Significant increases in chromosomal aberrations, sister chromatide exchange rates and micronuclei rates have been observed in exposed workers. The degree of alkylation of haemoglobin has been used as a suitable parameter for exposure to EO.

EO is a typical genotoxic carcinogen in animal experiments. After long-term inhalation exposure, primarily leukemias and brain tumors have been observed in rats; lung carcinomas, uterus carcinomas and lymphomas have been observed in mice. The available epidemiological data do not show an unambiguous correlation between exposure to EO and the tumor rates observed.

EO has a highly fetotoxic effect immediately after fertilization (on the zygotes); fetotoxic effects are less recognizable in later stages of gravidity. Adverse effects on male fertility are only found at dose levels in which also dominant-lethal effects occur. An increased spontaneous abortion rate and increased frequency of pregnancy complications have been observed in exposed women.

No study has hitherto been made in order to determine specifically immunotoxic effects.

Neurotoxic effects occur generally after longer term exposure.

Recommendations

Ecological aspect

The findings presented on the occurrence of EO in the environment and on its ecotoxicology must be regarded as sufficient for an environmental relevance evaluation. Further studies on the ecotoxicology are not deemed to be necessary.

Toxicological aspect

All toxicological end points of the effects of EO have been studied and are evaluable.

Further tests are not necessary.