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Comments Regarding the Agency for Toxic Substances and Disease Registry (ATSDR) Document Entitled "Substance-Specific Applied Research Program Priority Data Needs for Vinyl Chloride" (September, 1992)

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SUMMARY

A report was published by the Agency for Toxic Substances and Disease Registry (ATSDR) which outlined a number of areas in which the agency felt that there were gaps in the available scientific database relating to the compound vinyl chloride monomer (VCM) (ATSDR, 1992). The Chemical Manufacturers Association does not agree with many points made in the ATSDR report and is providing these comments in response.

Vinyl chloride monomer (VCM) is one of the most intensely studied chemicals in use today. The scientific literature contains a wealth of data describing both the short- and the long-term health effects of exposure to this chemical in humans and in a number of species of experimental animals. As such, the potential hazards associated with VCM are well known, yet ATSDR has called for further testing in its report, even though such information would not contribute any significant new information to the toxicological database on VCM.

The report prepared by ATSDR does not adequately acknowledge that the potential risk to humans of a chemical is a factor of both its hazard potential and the level of exposure. A chemical, regardless of its toxicological potential to affect the health of individuals in the vicinity of hazardous waste site, cannot pose a health hazard if there is no or negligible exposure. It is the level of potential exposure to VCM in the vicinity of hazardous waste sites that should be the focus of any future data gathering, and not items such as additional nonclinical testing, epidemiological studies, development of methods to mitigate toxicity, or the creation of a registry of exposed persons around such sites. Furthermore, it is not evident from the ATSDR document that there is recognition that VCM that may be present at waste sites is not the result of disposed of VCM itself or even discarded polyvinyl chloride materials, but rather is the result of degradation of commonly used solvents. Any attempts at reducing the potential risks associated with living near a hazardous waste site should be addressed through better waste disposal practices.

1.0 INTRODUCTION

The Agency for Toxic Substances and Disease Registry (ATSDR) released a document Entitled "Substance-Specific Applied Research Program Priority Data Needs for Vinyl Chloride" (ATSDR, 1992). The focus of this document was exposure from hazardous waste sites, vinyl chloride monomer (VCM) is one of the most intensely studies chemicals in use today, with the potential risks of this chemical well known, yet the ATSDR document does not accurately reflect this. The Chemical Manufacturers Association herein provides its comments regarding points made in the ATSDR document in order to clarify the issues.

2.0 SPECIFIC COMMENTS - DATA NEEDS

In order to respond to the ATSDR report regarding data needs, we have used the ATSDR framework for the sake of organization of these comments.

2.1 Exposure to VCM

2.1.1 Exposure Levels - Environmental Media

The purpose of Section III.A.1.c.i in the ATSDR report was to determine if adequate data on the levels of VCM in ambient and contaminated environments are available for the purposes of conducting meaningful follow-up exposure and health studies. The document provides a series of numbers describing concentrations of VCM detected in air and water media. It does not, however, provide the reader with a sense of what these values actually mean with respect to potential risks, and then concludes that there is a need for such data in environmental media at hazardous waste sites.

There is a considerable amount of data available concerning VCM concentrations in environmental media around PVC production facilities, and also concentrations of VCM in the indoor work environment at these facilities. In the work place, the data that are available are an excellent source of information with respect to determining the effects of VCM on humans

where the exposure to VCM has been documented. This, in turn, allows a more controlled way of determining potential risk to humans, as the exposure has been accurately defined. Such a situation does not exist with respect to hazardous waste sites, as there would be no indication of exposure to the multitude of other compounds that would confound any follow-up epidemiological studies or analyses.

Given the fact that the potential risk from VCM around hazardous waste sites is dependent upon the level of exposure, it is worth reviewing the available data from industrial exposure for the purpose of putting relevant exposure into perspective.

2.1.1.1 VCM in Workplace Air

Concentrations of VCM in the workplace prior to the 1960s were greater than 100 ppm and decreased to values less than 100 ppm between the 1960s and mid-1970s, then decreased again to an upper limit of 5 ppm [8 hour, time-weighted-average (TWA)] by 1975 (Doll, 1988; ACGIH, 1991). The current OSHA workplace standard in the United States is 1 ppm (8 hour TWA) with a 5 ppm short-term exposure limit (STEL) (29 CFR 1910.1017).

In 1988, the concentrations of VCM (8 hour TWA based on individual personnel monitoring) in the work environment ranged from approximately <0.25 to 10.5 mg/m^3 (<0.1 to 4.1 ppm) in four PVC resin production facilities in the United States. Reactor operators, loading personnel and laboratory technicians showed the greatest potential exposures for 8 hour exposures. TWA air concentrations ranged from 0.5 to 11 mg/m^3 (0.2 to 4.1 ppm); these air concentrations had decreased to 0.5 to 2 mg/m^3 (0.2 to 0.77 ppm) in 1992. In 1990, one facility reported 8 hour TWA concentrations in air for instrument technicians and process operators of 35 and 26.5 mg/m^3 (13.5 and 10.3 ppm), respectively. By 1992 (January to September data only), the work-place concentrations in these facilities had decreased to a range of approximately <0.25 to 2 mg/m^3 (<0.1 to 0.8 ppm). These data represent the greatest concentrations of VCM in air reported for these four facilities over the five year period 1988 through 1992 (Vinyl Institute, personal communication). Localized releases of VCM to the natural environment can

occur around production and manufacturing facilities; therefore, the concentrations of VCM are highest near such facilities.

2.1.1.2 VCM in Environmental Emissions from Production Facilities

Decreases in concentrations of VCM in the work environment discussed above would also be indicative of corresponding decreases in environmental releases from production/manufacturing facilities. VCM has been measured in air around suspected "hot spots" (i.e., in areas near production and manufacturing facilities) in the United States. Prior to the implementation of VCM emission regulations in 1978, the average air concentrations of VCM at production facilities in the United States was 0.04 mg/m³ (0.017 ppm) (IARC, 1979). In Houston, Texas, where large quantities of VCM are produced, air concentrations ranged from 0.008 mg/m³ (0.003 ppm) to peak values of 3.2 mg/m³ (1.2 ppm) (Gordon and Meeks, 1977). In Long Beach, California, ambient air concentrations of VCM near two VCM plants ranged from 0.3 to 8.8 mg/m³ (0.1 to 3.4 ppm) (National Field Investigations Center, 1974). However, within approximately one kilometer of VCM production/manufacturing facilities, reported air concentrations of VCM ranged from approximately 0.03 to 0.1 mg/m³ (0.01 to 0.04 ppm) (EPA, 1975b; Baxter *et al.*, 1977). More recent information based on sampling near production/manufacturing facilities since standards for the work environment were reduced to about 13 mg/m³ (5 ppm) in 1975, showed that air concentrations of VCM were near the analytical detection limit (about 0.013 mg/m³ or 0.005 ppm) in three out of five British plants. For two other facilities, the VCM air concentrations were approximately 0.05 mg/m³ (0.02 ppm) at a location 100 m outside the facility boundary, and 0.2 mg/m³ (0.09 ppm) just inside the boundary fence (Turner *et al.*, 1984).

2.1.1.3 Risk from VCM in Workplace Air

The best available epidemiological data regarding exposure to VCM were critically reviewed by Sir Richard Doll (Doll, 1988). This review clearly illustrated the current understanding that the potential risk associated with VCM is a factor of the level of exposure, with there being no significant risk to humans below certain levels. The review, which incorporated well-

documented levels of exposure of humans to VCM had two major conclusions: (i) Apart from liver cancer, VCM/PVC workers exposed between the 1940s/1950s and mid-1970s did not have unusual hazards of accident or disease, and (ii) workers exposed to VCM concentrations of "several hundred parts per million or more" clearly showed an increased risk of contracting angiosarcoma of the liver, normally an extremely rare disease (annual incidence of 1 to 2×10^{-7} in the general population; Byren and Holmberg, 1975).

Doll (1988) concluded that it was "difficult to decide whether vinyl chloride produces a risk of developing cancer other than angiosarcoma of the liver which might be small compared to the risks produced by nonoccupational causes, at sites other than the liver" (Doll, 1988). He also concluded that there was no evidence to support the association between exposure to VCM and any other digestive tract cancer. Doll's review did not support a significant association between VCM exposure and the risk of brain cancer when the combined data from four major epidemiological studies were analyzed (Doll, 1988). An apparent excess risk of brain cancer among VCM workers in the United States, reported in a study conducted by Wong *et al.* (1991), was subsequently attributed to chance or diagnostic bias by the authors (Wong and Whorton, 1993). With respect to the association of exposure to VCM and lung cancer, Doll (1988) concluded that a small hazard may have existed when occupational exposures to VCM were extreme, but that the study data did not conclusively demonstrate this risk and that the increased risk would in any case be negligible at the current small exposures to VCM.

2.1.1.4 Risk from Environmental Emissions of VCM in Air

In his review, Doll concluded that the minute exposures that would result from emissions escaping from VCM facilities must cause comparably minute risks to the general public. The concentrations of VCM measured near VCM/PVC production/manufacturing facilities are in the order of 0.01 to 0.04 ppm (EPA, 1975b; Baxter *et al.*, 1977), or some 10,000-fold less than the "several hundred parts per million or more" exposures that resulted in measurable occupational hazards. Therefore, an increased risk of cancer to the general public could not possibly be detected, with the possible exception of an increased risk of angiosarcoma of the liver. Any inference that angiosarcoma incidence in the general population is related to VCM exposure,

however, could be misleading because angiosarcoma may also be caused by thorium dioxide and arsenic in pesticides and by certain medicines (Doll, 1988).

Doll (1988) also concluded that there may have been a minute hazard to the general public from the VCM concentrations historically observed around manufacturing facilities. However, the concentrations of VCM around production facilities has decreased substantially since the 1970s. VCM air concentrations within a few hundred meters of VCM areas were below analytical detection limits (< 0.005 ppm) for three of five facilities in the United Kingdom, and the concentrations for the other two facilities were about 0.02 ppm (100 m outside the boundary fence), and 0.09 ppm (just inside the boundary fence). However, accidents and production start-ups were associated with higher concentrations (Turner *et al.*, 1984). Based on this evidence, Doll (1988) concluded that "according to any reasonable criterion, the hazard to the general public (if there is any at all) must be negligible."

2.1.1.5 VCM in Water

Vinyl chloride also has been measured in both groundwater and drinking water in the United States. The greatest concentration of VCM measured in drinking water was 0.01 mg/L near a production facility (Safe Drinking Water Committee, 1977; IARC, 1979). Vinyl chloride monomer has also been reported in groundwater in the United States. Measurable levels in California wells averaged 0.02 mg/L and were as high as 0.023 mg/L (Kizer, 1986). In the Los Angeles area, groundwater contained less than 0.001 mg/L of VCM (Baird *et al.*, 1983), while in non-specified areas of Nebraska and California groundwater concentrations ranged from 0.75 to 0.023 mg/L (Goodenkauf and Atkinson, 1986; CSDHS, 1990).

As described in the preceding sections, there are good data available from which to predict potential risks of individuals from VCM. In the opinion of the Chemical Manufacturers Association, the ATSDR appears to not be utilizing the exposure-response data of VCM that already are available for humans.

See corrected pg
attached

2.1.2 Exposure Levels - Humans

Section III.A.1.c.ii of the ATSDR report states that there is a lack of data regarding levels of vinyl chloride in body tissues or fluids. ATSDR considers these data important for conducting meaningful follow-up exposure and health studies with individuals exposed to VCM and points out that there is no validated biomarker of VCM exposure currently available from which to use for the purposes of dosimetry. The development of the database as described is considered by the Chemical Manufacturers Association to be unnecessary and would appear to be a waste of resources.

ATSDR is correct in its view that thiodiglycolic acid, a major metabolite of VCM, is of limited value for the monitoring of VCM exposure due to confounding factors such as variable metabolism between individuals, influences of disease states, and the fact that this metabolite is not unique to VCM exposure. There is currently work going on that involves biomarkers of exposure (Ciroussel *et al.*, 1990; Swenberg *et al.*, 1992), although it is not yet at the stage where it is a reliable predictor of quantitative exposure. Any type of methodology that ATSDR puts forward to monitor human exposure to VCM must be specific and it must be quantitative. There is no mention in the document that ATSDR acknowledges the work that is currently being undertaken in this area.

In addition, ATSDR considers that modeling cannot reliably predict levels of VCM in human tissues for the purposes of further studies, yet it does not give an explanation for this statement. As indicated in the report, there is currently an effort underway at ATSDR to examine data from 245 National Priorities List (NPL) sites at which VCM has been found. This database, when completed, will include the concentrations in on-site and off-site media, the sizes of the potentially exposed populations, and an indication of relevant exposure routes. From these concentrations determined by ATSDR, it would be possible to predict potential exposure to VCM and assess the risk, if any, to persons nearby without the need to (a) develop and validate methods for quantifying exposure and (b) actually apply these methods to untold numbers of individuals living within predetermined distances from hazardous waste sites, as is alluded to by ATSDR.

As discussed above, the current epidemiological information that was critically reviewed by Doll (1988) has indicated clearly that for individuals living around production facilities, where VCM concentrations in ambient air have ranged from approximately 0.005 to 0.09 ppm since the introduction of standards, the hazard is negligible. Such a conclusion is based upon well documented exposure in industrial workers, where concomitant exposure to other agents/chemicals have been addressed in a way not possible in the recommendation of ATSDR.

2.2 Registry of Exposed Persons

The ATSDR document states that a registry of individuals exposed to VCM in the environment would provide an important reference tool to aid in assessing long-term health consequences of such exposure (Section III.2.a). In the opinion of the Chemical Manufacturers Association, it is believed that no significant information would be gleaned regarding the human health effects of VCM, from the setting up of such a registry, that is not already available from the numerous epidemiological reports available that have been based upon occupational exposure to this chemical (see review by Doll, 1988). Such data regarding occupational exposure to VCM also has the advantage that concomitant exposure to other chemicals is minimized when compared to exposure via a hazardous waste site, where it may not be possible or economically feasible to analyze the various media for all possible chemicals that could influence the health of humans in areas adjacent to hazardous waste sites. To open a registry, as ATSDR is recommending, would be prohibitively time-consuming and expensive, and, in the opinion of the Chemical Manufacturers Association, would not provide any significant new information. It would have to take into account and pay considerable attention to case histories, the long-term exposure history, and confounding factors such as smoking. Interestingly, VCM has itself been found in tobacco smoke (Hoffmann *et al.*, 1976). Even if establishment of a registry was undertaken, the fact that it would be impossible to quantitatively document the past exposure to VCM from hazardous waste sites and to consider all the possible confounding factors would make this information of little practical use.

As indicated previously, even in the case of industrial workers exposed, for all practical purposes to pure VCM, there are levels of exposure that have been found to have no significant

effects upon the health of the individuals (Doll, 1988). Only angiosarcoma of the liver has been definitively linked to VCM exposure, except possibly for a possible risk of lung cancer when exposure has been large (Doll, 1988). Based upon these data, even if ATSDR were able to solicit the cooperation of all the people potentially exposed to VCM from living near hazardous waste sites, and had unlimited access to funding, no new information would be generated regarding the potential hazards of VCM. Also, it should be noted that when considering the potential risk of VCM, the production, use, and transportation of VCM provide the more critical areas for monitoring of exposure as compared to disposal sites.

2.3 Toxicity of VCM

2.3.1 Acute Exposure

In Section III.B.1.a of the ATSDR report, it is stated that acute duration nonclinical studies are a priority data need in order to identify target organs and levels of exposure which present a significant risk to human health following acute exposure. It is unclear what the relevance of conducting such a study(ies) would be, considering that exposure to VCM at or near a waste disposal site would be expected to be long-term at low concentrations. The effects of longer term exposure in laboratory animals has been previously reviewed by ATSDR in its toxicological profiles on VCM (ATSDR, 1989; ATSDR, 1993).

It is typical for acute exposure studies to essentially measure lethality in the test animal, while it seems to be the intent of ATSDR to obtain data regarding more subtle endpoints and no-effect doses for effects that are characteristically obtained from longer term investigations. The Chemical Manufacturers Association cannot see what new or additional data, generated as a result of this proposed data need, would add to what is currently available in the literature.

2.3.2 Reproductive and Developmental Toxicity

Animal and human studies with VCM do not indicate effects upon reproduction and/or development, effects suggested in the ATSDR report (Sections III.B.1.e and f). This lack of

potential effects of VCM on human offspring was the focus of a 1987 report prepared by the Vinyl Institute and included with these comments as Appendix A (Vinyl Institute, 1987). The ATSDR seems to have incorrectly confused the effects of maternal toxicity at high doses of VCM with reproductive and/or developmental effects in its report. This is particularly evident in ATSDR's review of the studies reported by John *et al.* (1977; 1981), where groups of pregnant rats, mice and rabbits were exposed via inhalation to VCM at concentrations of 0, 50, 500 or 2,500 ppm for seven hours per day during the critical period of organogenesis. Although the high levels of VCM caused maternal toxicity, there was no significant embryonal or fetal toxicity observed nor were there any teratogenic effects produced in the offspring.

2.4 Biomarkers

Biomarkers, in effect, relate directly to other areas discussed in the ATSDR report and in these comments; namely the monitoring of exposure to VCM and the creation of a registry of exposed persons. These items would require sensitive and specific methods of quantitatively documenting exposure to VCM. Such a biomarker would essentially provide dosimetry data for a particular individual, although the use of such data in comparisons to potential risks would have to be exhaustively validated in order for them to be of any potential use. The Chemical Manufacturers Association believes that information related to adducts formed by the interaction between industrial chemicals and macromolecules is important with respect to exposure and the assessment of risk, and currently supports work in this area for a number of compounds. There is a considerable amount of work presently being conducted with VCM related to adduct formation, adduct stability, and the effects of these upon specific genes (Jacobsen and Humayun, 1989; Ciroussel *et al.* 1990; Swenberg *et al.*, 1992). As such, the Chemical Manufacturers Association feels that the development of suitable biomarkers for VCM exposure and for subsequent risk assessment is currently being addressed.

2.5 Clinical Methods of Mitigating Toxicity

These comments on clinical methods made by ATSDR (Section III.B.2.d) do not provide meaningful guidance as they could be taken to mean everything from the development of early

diagnostic methods to finding a cure for angiosarcoma of the liver. Essentially, toxicity due to VCM could be reduced or eliminated altogether through reduction in exposure. Such results have been clearly demonstrated for industrial exposure (see comment 2.1.1). The reduction or elimination of exposure of individuals to VCM near NPL sites is a factor of better waste management practices and monitoring by federal authorities.

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