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Please deliver the following

TO: Has Shah**FAX NO.:** 703-741-6091**FROM:** Tom Downs**DATE:** February 26, 1996**TOTAL NUMBER OF PAGES** (including cover page):7

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COMMENTS: This fax transmits draft comments on the ATSDR Medical Management Guidelines for Vinyl Chloride. Let me know if you have comments or proposed revisions. Thank you.

CMA 113544

February 26, 1996

Ms. Jennifer Heise
Peer Review Coordinator
ERG
110 Hartwell Avenue
Lexington, MA 02173

Re: ATSDR Medical Management Guidelines for Vinyl Chloride

Dear Ms. Heise:

This letter transmits the Chemical Manufacturers Association (CMA) Vinyl Chloride Panel's comments on the Medical Management Guidelines for Vinyl Chloride under development by the Agency for Toxic Substances and Disease Registry (ATSDR). At the request of Scott Wright of ATSDR, CMA is submitting these comments directly to you.

Please call me at (703) 741-5637 if you have questions or need additional information on the enclosed comments.

Very truly yours,

Hasmukh C. Shah, Ph.D.
Manager, 
(Vinyl Chloride Panel)

Enclosure

CC: Scott Wright

CMA 113545

**BEFORE THE AGENCY FOR TOXIC SUBSTANCES
AND DISEASE REGISTRY**

MEDICAL GUIDELINES FOR VINYL CHLORIDE

**Comments of the
Chemical Manufacturers Association
1300 Wilson Boulevard
Arlington, VA 22209**

**Langley A. Spurlock
Vice President -- CHEMSTAR**

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2550 M Street, N.W.
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March 4,
February 23, 1996

CMA 113546

**Comments of the
Chemical Manufacturers Association
on the Agency for Toxic Substances and Disease Registry's
Proposed Medical Guidelines for Vinyl Chloride**

Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) recently requested review and comment on proposed Medical Management Guidelines for Vinyl Chloride. The Chemical Manufacturers Association (CMA) Vinyl Chloride Panel, which represents producers of vinyl chloride, is pleased to provide these comments.

appreciates ATSDR's desire to develop for the most part

CMA acknowledges that the proposed Medical Management Guidelines for Vinyl Chloride represent a substantial effort by ATSDR to produce a useful reference document which reads clearly and accurately from a scientific and medical standpoint, and is nearly complete in its draft form. ATSDR's final product should prove quite helpful to emergency medical personnel and others in need of a medical reference on vinyl chloride. CMA's specific suggestions for refining the Medical Management Guidelines are presented below.

various chemicals that read

and are useful reference documents,

Page 1, Route of Exposure, Inhalation

The fifth sentence (beginning "Occupational exposures have resulted") should be revised to read as follows: "Occupational exposures well above the current threshold limit value (TLV®) have resulted in the occurrence of a syndrome consisting of acroosteolysis, scleroderma-like skin changes, and Raynaud's phenomenon."

The last sentence (beginning "Chronic exposures have led to cancer") should be revised to read as follows: "Chronic exposures (well above the current TLV®) have led to increased risk of cancer, particularly of angiosarcoma of the liver. Increased risks of cancer of the lung and brain have been reported but not substantiated."

Page 3, Health Effects, boxed text

The third sentence (beginning "Vinyl chloride has been shown") should be revised to read as follows: "Vinyl chloride has been shown to induce

angiosarcoma of the liver in humans and in laboratory animals with chronic exposure."

The fourth sentence (beginning "Immunological effects") should be revised to read as follows: "Immunological effects and effects on reproduction have not been conclusively demonstrated in humans or animals."

Page 3, Acute Exposure, Cardiovascular

The last sentence (beginning "Chronic exposure to vinyl chloride") should be removed from the Acute Exposure section and placed under Chronic Exposure, on page 4. The sentence also should be revised to read as follows: "Chronic exposure to vinyl chloride (well above the current TLV®) can cause a syndrome consisting of acroosteolysis (dissolution of the bones of the terminal phalanges of the fingers, toes, and sacroiliac joints), Raynaud's phenomenon, and scleroderma-like skin changes."

Page 4, Chronic Exposure, Carcinogenicity

This paragraph should be revised to read as follows:

"The Environmental Protection Agency has classified vinyl chloride as a known human carcinogen. Vinyl chloride has been shown to induce cancer of the liver (angiosarcoma) in humans and laboratory animals when they are exposed for long durations above the current TLV®. There is inconsistent and inconclusive evidence suggesting that vinyl chloride exposure also may be associated with cancer of the lung, brain, and central nervous system."

Page 5, Reproductive and Developmental Effects

The first paragraph should be revised to read as follows:

"Occupational vinyl chloride exposure has been reported to result in decreased sexual performance both in men and women, although this theory has not been substantiated in controlled epidemiologic studies. In men, occupational exposure has been reported to be associated with decreased libido, impotence, and decreased testosterone production. In women, vinyl chloride exposure has been reported to result in decreased sexual function and elevated blood pressure and edema during pregnancy (i.e., pre-eclampsia). The reports of these findings largely have been based on individual random cases, and are not considered strongly suggestive of vinyl chloride's health effects. Animal studies have not conclusively demonstrated the presence or absence of vinyl chloride reproductive toxicity, but additional studies currently under way should clarify these issues."

*Header***Supplementary material**

The information that follows should be added to the Chronic Exposure section or possibly to a new section entitled "Occupational Exposure":

- ◆ **ANGIONEUROTIC DISORDERS IN THE HANDS AND FEET
(RAYNAUD'S PHENOMENON)**
exposure criteria:
minimum intensity of exposure:
confirmed occupational exposure, assessed if possible by:
 - anamnesis and study of exposure conditions
 - and, if appropriate, atmospheric sampling

- ◆ **ACRO-OSTEOLYSIS IN THE UNGUAL PHALANGES OF THE HANDS
AND FEET**
May accompany angioneurotic disorders confirmed by X-ray (loss of
substance from bones)
exposure criteria:
minimum intensity of exposure:
confirmed occupational exposure, assessed if possible by:
 - anamnesis and study of exposure conditions
 - and, if appropriate, atmospheric sampling

- ◆ **DISTAL SKIN DISORDERS**
Pseudoscleroderma syndrome with penetration of the skin, possibly
accompanied by general symptoms (arthralgia, myalgia); follows on from
angioneurotic disorders.

exposure criteria:
minimum intensity of exposure:
confirmed occupational exposure, assessed if possible by:
 - anamnesis and study of exposure conditions
 - and, if appropriate, atmospheric sampling

- ◆ **LIVER FIBROSIS WITH PORTAL HYPERTENSION**
Portal Hypertension syndrome fibrosis confirmed by endoscopy or
histology or indirectly by echography.
exposure criteria:
minimum intensity of exposure:
confirmed occupational exposure, assessed if possible by:
 - anamnesis and study of exposure conditions
 - and, if appropriate, atmospheric sampling

Header

- ◆ **ANGIOSARCOMA**
angiosarcoma, usually hepatic
exposure criteria:
minimum intensity of exposure:
confirmed occupational exposure, assessed if possible by:
 - anamnesis and study of exposure conditions
 - and, if appropriate, atmospheric sampling