

July 6, 2001

Administrator
US Environmental Protection Agency
Attn: Chemical Right to Know Program
P. O. Box 1473
Merrifield, VA 22116

Dear Administrator:

The American Methanol Institute Testing Group (AMITG) has previously submitted the robust summary for methanol for the HPV Challenge Program, AR-201 on behalf of the consortium identified in our commitment letter dated March 18, 1999. As requested by your staff, enclosed please find a Test Plan for Methanol. As stated in the previously submitted robust summary, the enclosed document further supports the conclusion that **no further testing is needed for methanol**. The information submitted adequately addresses all SIDS endpoints in the HPV program and no data gaps exist.

Sincerely,

John E. Lynn
President & CEO

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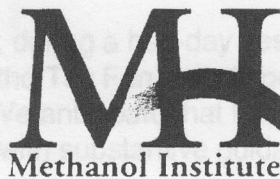
*National Toxicology Program
U.S. Department of Health and Human Services*



Center For The Evaluation Of Risks To Human Reproduction

PUBLIC COMMENTS ON THE METHANOL EXPERT PANEL REPORT

that will take place on July 9th, 2002 at a public meeting titled "Methanol - Is it a Developmental Toxicant?" at the University of Colorado, Boulder, Colorado, as part of the public record for this report. Your comments will be included in the report. The National Toxicology Program will provide the scientific basis for preparing the final report on this topic.



July 3, 2002

Dr. Michael Shelby
CERHR
PO Box 12233
MD EC-32
Research Triangle Park, NC 27709

JUL - 9 2002

Dear Dr. Shelby:

The Methanol Institute appreciates this additional opportunity to comment on the draft final report of the Expert Panel on the Developmental and Reproductive Toxicity of Methanol. As you know, the Methanol Institute provided written comments on the initial draft report (Sections 1-4) on September 5, 2001, and Dr. John Clary of BioRisk provided expert oral testimony on behalf of the methanol industry at the October 15, 2001 public meeting.

Our attached comments provide a few additional remarks directed at Sections 1-4, while the majority of our comments have focused on the summary and conclusions contained in Section 5. We believe that Sections 1-4 of the Expert Panel report provide a useful summary and analysis of the available data on the reproductive and developmental effects of exposure to methanol. However, further clarification seems needed with several of the conclusions stated by the Expert Panel. We believe the Panel inappropriately employed rodent data in assuming a developmental effect to exposure of low levels of methanol to pregnant women. Further, the Panel's arbitrary setting of an unnecessarily low "safe level" for methanol is not justified by the available data.

We also remain concerned - and somewhat mystified - by the undue length of time it took the CERHR to release its final draft report. The report's Section 5 was written during an open public meeting in October, but it took until May to publish the Federal Register notice. This delay will add to the public's perception that the CERHR's consensus process appears to have been breached with this report.

While the comment period for this final draft report closes on July 8th, we would strongly urge the CERHR to include the presentations and discussions

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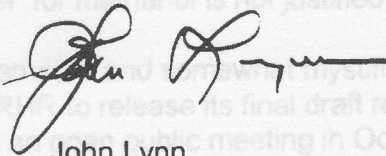
that will take place on July 9th, during a half-day session titled "Methanol – Is it a Developmental Toxicant?" at the Tox Forum in Aspen, Colorado, as part of the public record for this report. We anticipate that this program will provide the National Toxicology Program with substantive guidance for preparing the final report on this topic.

The charter of the CERHR does not take into account the very real economic implications of its findings, but as the trade association for the global methanol industry, we are obligated to do so. In reviewing the current and future potential for consumer exposure to methanol, the report cites the use of a wide array of methanol-containing products (windshield washer fluid, paints, varnishes, and Sterno heaters), dietary exposure from fruits and diet soft drinks, and the potential for the broader use of methanol fuels in motor vehicles. Further, methanol is a leading candidate hydrogen carrier fuel for a range of fuel cell technology applications.

We were quite pleased to be involved in this process. We also have high hopes that the Expert Panel's conclusions ultimately will provide guidance in determining the potential for developmental or reproductive effects from exposure to methanol. Such guidance would be useful in helping the methanol industry to limit the potential for any harmful exposures. As the Panel's preliminary conclusions stand today, we find the ultimate utility of this report to be less than we had hoped. In choosing an arbitrary "safe level" for methanol and raising concerns about the potential for developmental effects in women exposed to "high levels" of methanol based on rodent data, the Panel's conclusions may serve as a detriment to a better understanding of this issue.

We would certainly appreciate the opportunity to keep this dialogue open as the NTP and NIEHS prepare their final report for publication. We would be happy to meet with representatives of NTP/NEIHS to discuss our concerns.

Sincerely,



John Lynn
President & CEO

Enclosure



METHANOL HEALTH EFFECTS



Methanol is a colorless liquid with a mild alcohol odor. It is widely used as a chemical feedstock to produce a variety of consumer products, including windshield washer fluid. Methanol also is an excellent hydrogen carrier for a range of fuel cell technology applications. While consumer exposure to methanol should be avoided and will continue to be minimized with the use of well-engineered fuel containers meeting stringent requirements, it is useful to review the health effects of exposure to methanol.

Methanol is toxic to humans, and is readily absorbed by ingestion and inhalation, and more slowly by skin exposure. However, methanol is already present within the human body in small quantities from eating fruits and vegetables, and drinking diet soda containing artificial sweeteners. According to the FDA, as much as 500 milligrams per day of methanol is safe in an adult's diet. In the body, methanol is metabolized in the liver, converted first to formaldehyde, and then to formate. As a building block for many biological molecules, formate is essential for survival. However, high levels of formate buildup after excessive methanol intake can cause severe toxicity and even death. Refueling a fuel cell car with methanol will only give low-dose exposures (23-38 ppm for a few minutes), with a small intake of 3 milligrams of methanol. This is less than drinking a single can of diet soda containing 200 milligrams of aspartame which would produce 20 milligrams of methanol in the body.



The initial symptoms of methanol poisoning (drinking one to four ounces) may be delayed for as long as 12 to 18 hours as the body metabolizes methanol to formate, and can consist of weakness, dizziness, headache, nausea and vomiting, and blurred vision. In severe cases of accidental or reckless ingestion, methanol poisoning may lead to permanent blindness or death, although complete recovery is the rule in patients admitted early to a hospital. There are several treatments available to combat methanol poisoning, including early treatment with sodium bicarbonate to help prevent visual impairment. In a hospital setting, hemodialysis is effective in removing both methanol and formate from the blood, and co-exposure to ethanol has been shown to reduce formate levels. In case of skin exposure to methanol, washing immediately with soap and plenty of water can prevent further skin absorption.



Methanol exposure should be avoided and can be managed safely through the proper design of fuel containers and fueling systems. A spill-free nozzle has been developed by Identic of Sweden that features a dry-connection to the fuel cell car that makes it virtually impossible for the consumer to contact methanol from the pump or the vehicle. Similarly stringent standards are now being developed for methanol fuel cartridges

that will be used in a broad range of micro-fuel cell devices for consumer electronics.

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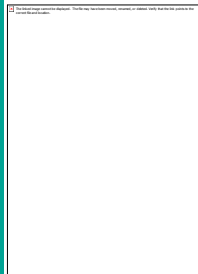
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The Methanol Institute (MI) and its research arm, the Methanol Foundation, represent the global methanol industry. Our mission is to expand markets for the use of methanol as a chemical commodity building block, a hydrogen carrier for fuel cell applications, and an alternative fuel. MI was formed in 1989, during the height of the Clean Air Act debate, and worked to help create the highly successful reformulated gasoline program.

Today, methanol is one of the world's most widely distributed chemical commodities. As a basic building block for hundreds of chemical products, methanol is being used safely and effectively in everything from plastics and paints, to construction materials and windshield washer fluid.

The emergence of fuel cell technologies has the potential to create vast new markets for methanol as the hydrogen carrier of choice. Methanol fuel cell technologies can be used to power zero and near-zero emissions cars, buses and trucks. In the growing market for distributed power, stationary fuel cell systems for residential and commercial applications can also be fueled with methanol, particularly in rural locations that do not have access to natural gas lines. The earliest consumer markets for methanol fuel cell technology will power everything from laptop computers and cellular phones, to lawnmowers and portable power generators.



MI is encouraging the development of several emerging markets for methanol. Wastewater treatment plants are using methanol to reduce nitrates that can

literally kill small and large water bodies. Methanol is also considered a “superior” fuel for electric power turbines, providing an alternative to natural gas and distillate fuels that significantly reduces nitrogen oxide emissions.

Promoting the development of innovative technologies to produce methanol from renewable resources is a central focus of MI. Landfill methanol gas is being purified into a synthesis gas for the production of methanol at pilot plants in New Jersey and New York, and full commercial demonstrations in Ohio and elsewhere.

MI directs international efforts relating to methanol product stewardship and regulatory affairs. For example, MI formed a testing team to respond to the U.S. EPA’s High Production Volume Chemical Testing Challenge Program, completing a rigorous analysis of the health and environmental research available on methanol. This work will form the basis for a review of methanol by the international community.

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Last Modified: July 20, 2008

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