

Docket ID NO. EPA-HQ-ORD-2009-0229

PUBLIC COMMENTS BY JPEC
FOR TOXICOLOGICAL REVIEW OF ETHYL TERTIARY
BUTYL ETHER [PUBLIC COMMENT DRAFT]

IRIS Public Science Meeting
EPA Conference Center, Arlington, Virginia
October 26, 2016

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JPEC Comments

ETBE is synthesized from bio-ethanol and used as an bio-fuel added to gasoline in Japan to reduce CO₂ emissions and support the objectives of the Kyoto Protocol.

JPEC conducted many studies to evaluate the toxicity, carcinogenicity, and potential health risks of ETBE, between 2006 and 2010, commissioned by and under the guidance of Ministry of Economy, Trade & Industry of Japan (METI).

The resulting risk assessment, performed under the guidance of an independent committee of academic and government experts, concluded that the use of 7% ETBE-blended gasoline does not pose a human health risk by either the oral or inhalation route of exposure.

JPEC Comments

We assure credibility of the data of all studies conducted in JPEC ETBE projects.

- **The 2-year carcinogenicity studies [Drinking water and Inhalation], 2-stage carcinogenicity studies and genotoxicity studies were implemented in accordance with the OECD principles of GLP(OECD1998).**

JPEC Comments

- In “Toxicological review of ETBE (Public Comments Draft)”, there are some differences on aspect of ETBE hepatotumorigenicity MOA with JPEC. Base on our MOA studies we concluded hepatotumorigenicity in rats is not relevant to human.
- ETBE Genotoxicity studies conducted by JPEC were negative in the results.

ETBE Inhalation Exposure Level and Health Risk in Humans

(based on "ETBE risk assessment report" in ETBE Risk Assessment Study by JPEC (March 2008))

Opened at JPEC English home page; <http://www.pecj.or.jp/english/news/pdf/b-2-8.pdf>

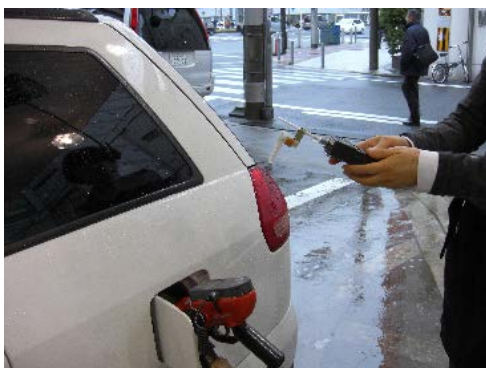
ETBE Exposure level and Health Risks	7% ETBE blended with gasoline
Exposure level: ETBE concentration in environment estimated by simulation ● <u>C_{air}</u> = Maximum atmospheric ETBE concentration	<u>C_{air}</u> = 38 µg/m³ (≒0.009ppm)
● <u>NOAEL in rats</u> ① Kidney, urothelial hyperplasia (2-year inhalation carcinogenicity) • NOAEL = 500ppm =2,090mg/m³ ② Liver adenoma (2-year inhalation carcinogenicity study) • NOAEL =1500ppm =6,270mg/m³	<u>NOAEL :</u> ① Kidney, urothelial hyperplasia =2,090,000µg/m³ ② Liver adenoma = 6,270,000µg/m³
● <u>MOE</u> (Margin of Exposure) = NOAEL[*] /C_{air}	① <u>MOE</u> = 55,000 ② <u>MOE</u> =165,000
CONCLUSION : Inhalation exposure to ETBE does not pose a health risk to humans.	

Personal exposure level of ETBE at a gasoline stations*

*Yoko Nagataki et al (Keio University Medical School):Annual Meeting of Japan Society of Occupational Health (2010), Vol 83, P614

	Job	TWA(ppm)	Notes
A. Gas station crews	Fueling	8h-TWA:0.071 (Max 0.246)	Gasoline blended with 7%ETBE
B. Tank truck drivers	Unloading	STEL:0.298 (Max 1.098)	

A



B



**Thank you very much
for your attention.**