

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD (HSRB)  
PUBLIC TELECONFERENCE/WEBINAR  
MEETING AGENDA**

**Tuesday, October 25, 2022  
1:00 pm – 4:00 pm (Eastern Time\*)**

**Internet Virtual Meeting**

The meeting will be conducted at the following website:

**Join Zoom Meeting**

<https://us02web.zoom.us/j/87497909624>

**Meeting ID: 874 9790 9624**

**Passcode: 944460**

**HSRB WEB SITE <https://www.epa.gov/osa/human-studies-review-board>**

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|-----------------|---|
| <b>12:50 PM</b> | <b>HSRB members login online and call in on the phone</b>   |
| <b>1:00 PM</b>  | <b>Convene Meeting and Introduction of Members</b> – Tom Tracy (Designated Federal Officer, EPA HSRB)   |
| <b>1:05 PM</b>  | <b>Welcome and Updates</b> – Monique Tadeo (HSRB Official and Director)   |
| <b>1:10 PM</b>  | <b>Opening Remarks</b> – Lisa Corey (HSRB Co-Chair)<br>Julia Sharp (HSRB Co-Chair)  |
| <b>1:15 PM</b>  | <b>Updates from OPP</b> – Michelle Arling (Office of Pesticide Programs)  |
|                 | <b>Topic: Anderson and Molhave (1983): Chapter 14: Controlled Human Studies with Formaldehyde. In: Formaldehyde Toxicity, James E. Gibson ed. Hemisphere Publishing Group, Washington D.C. Open literature study.</b> |
| <b>1:20 PM</b>  | <b>EPA Science Review Highlights</b> – Dr. Timothy McMahon, OPP Antimicrobials Division   |
| <b>2:00 PM</b>  | <b>Board Questions of Clarification</b>   |
| <b>2:10 PM</b>  | <b>EPA Ethics Review Highlights</b> – Michelle Arling, OPP  |

**2:30 PM      Board Questions of Clarification**

**2:40 PM      Public Comments**

**2:50 PM      Break**

**3:05 PM      Board Discussion**

**Charge to the Board – Science:**

*Is the research described in Formaldehyde Toxicity, Chapter 14 (Controlled Human Studies with Formaldehyde) by Ib Andersen and Lars Molhave, under the section titled “A Five-H Exposure Study” scientifically sound, providing reliable data for use in a weight-of-evidence to determine a point of departure for acute inhalation exposures to formaldehyde?*

**Charge to the Board – Ethics:**

*Does available information support a determination that there is no clear and convincing evidence that the conduct of the research was fundamentally unethical or deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm or impaired their informed consent?*

**4:00 PM      Adjournment – Tom Tracy, DFO**

\*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Tom Tracy at [tracy.tom@epa.gov](mailto:tracy.tom@epa.gov)

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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**Wednesday, October 26, 2022  
1:00 pm – 4:00 pm (Eastern Time\*)**

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| <b>12:50 PM</b> | <b>HSRB members login online and call in on the phone</b>   |
| <b>1:00 PM</b>  | <b>Convene Meeting</b> – Tom Tracy (Designated Federal Officer, EPA HSRB)<br><br>Topic: Kulle, T.J.; Sauder, L.R.; Hebel, J.R.; Green, D.J.; Chatham, M.D. (1987): Formaldehyde Dose-Response in Healthy Non-Smokers. JAPCA 37: 919-924. DOI: 10.1080/08940630.1987.10466285<br>Kulle, T.J. (1993). Acute Odor and Irritation Response in Healthy Nonsmokers with Formaldehyde Exposure. Inhalation Toxicology 5(3): 323-332. DOI: 10.3109/08958379308998389 (statistical re-analysis of data from Kulle et al. 1987 paper) |
| <b>1:10 PM</b>  | <b>EPA Science Review Highlights</b> – Dr. Timothy McMahon, OPP Antimicrobials Division   |
| <b>1:50 PM</b>  | <b>Board Questions of Clarification</b>   |
| <b>2:00 PM</b>  | <b>EPA Ethics Review Highlights</b> – Michelle Arling, OPP  |
| <b>2:20 PM</b>  | <b>Board Questions of Clarification</b>   |
| <b>2:30 PM</b>  | <b>Public Comments</b>  |

**2:40 PM      Break**

**2:55 PM      Board Discussion**

**Charge to the Board – Science:**

*Is the research by Thomas J. Kulle et al described in the 1987 publication “Formaldehyde Dose-Response in Healthy Nonsmokers” and the 1993 publication “Acute Odor and Irritation Response in Healthy Nonsmokers with Formaldehyde Exposure” scientifically sound, providing reliable data for use in a weight-of-evidence to determine a point of departure for acute inhalation exposure to formaldehyde?*

**Charge to the Board – Ethics:**

*Does available information support a determination that there is no clear and convincing evidence that the conduct of the research was fundamentally unethical or deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm or impaired their informed consent?*

**4:00 PM      Adjournment – Tom Tracy, DFO**

\*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Tom Tracy at [tracy.tom@epa.gov](mailto:tracy.tom@epa.gov)

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| <b>12:50 PM</b> | <b>HSRB members login online and call in on the phone</b>  |
| <b>1:00 PM</b>  | <b>Convene Meeting</b> – Tom Tracy (Designated Federal Officer, EPA HSRB)<br><br><b>Topic: Study Report: Field Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-Based Repellent Spray Against Mosquitoes. Study Report MIM-006. May 12, 2022.</b> |
| <b>1:10 PM</b>  | <b>EPA Science Review Highlights</b> – Clara Fuentes, OPP Biopesticides and Pollution Prevention Division  |
| <b>2:00 PM</b>  | <b>Board Questions of Clarification</b>  |
| <b>2:10 PM</b>  | <b>EPA Ethics Review Highlights</b> – Michelle Arling, OPP   |
| <b>2:35 PM</b>  | <b>Board Questions of Clarification</b>  |
| <b>2:45 PM</b>  | <b>Public Comments</b>   |
| <b>2:50 PM</b>  | <b>Break</b>   |
| <b>3:05 PM</b>  | <b>Board Discussion</b>  |

**Charge to the Board – Science:**

*Did the research summarized in “Field Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray Against Mosquitoes” generate scientifically reliable data, useful for estimating the amount of time that product tested repels mosquitoes?*

**Charge to the Board – Ethics:**

*Does the available information support a determination that the research was conducted in substantial compliance with the applicable requirements of 40 CFR part 26, subparts K and L?*

**3:55 PM**      **Closing Comments and Next Steps -**      Lisa Corey (HSRB Co-Chair)  
Julia Sharp (HSRB Co-Chair)

**4:00 PM**      **Adjournment – Tom Tracy, DFO**

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