

Meeting Summary

Chloroprene: PBPK Model Peer Review Discussion

Representatives of USEPA and Denka Performance Elastomers

December 15, 2020 11-12 EDT

Virtual Meeting

Attendees:

ORD:

- Jennifer Orme-Zavaleta
- David Dunlap
- Bruce Rodan
- Wayne Cascio
- Samantha Jones
- Kris Thayer
- John Vandenberg
- Paul White
- Paul Schlosser
- Dustin Kapraun
- Vicki Soto
- Dahnish Shams
- Emily Trentacoste

OAR:

- Kelly Rimer
- Erika Sasser

OMS

- Robert Tallent

Denka Performance Elastomer LLC/Ramboll:

- Patrick Walsh (Denka)
- Robinan Gentry (Ramboll)
- Harvey Clewell (Ramboll)
- Mel Anderson (Ramboll)

Agenda: Denka and Ramboll, their contractor, present their views about the peer reviewer recommendations to EPA.

Discussion of the peer review report on the Ramboll Chloroprene PBPK Model

- Welcome and introductions. EPA indicated the purpose of the meeting was to hear from Denka and Ramboll, their contractor, on their views about the peer reviewer recommendations.

- Denka/Ramboll noted that the written comments provided by the reviewers was largely in line with what was discussed during the peer review meeting. Denka/Ramboll have worked to evaluate the comments and have broadly categorized the substantive comments received (e.g., Kgl sensitivity, A1 approach and support, metabolite (epoxide) kinetics).
- Denka/Ramboll summarized their overall impressions of the report and provided their judgments on high-level issues highlighted by peer reviewers. Based on an early evaluation of the peer review comments, responses may vary from conducting additional analysis to increasing clarity and documentation within the Ramboll/Denka report.
- Because the model is a Ramboll/Denka product, EPA outlined expectations that Ramboll will provide a written planning document generally describing their proposed approach to resolving peer review comments. The document will include general attribution information describing the comment and which reviewers provided them. Denka/Ramboll agreed to provide this documentation as soon as possible.
- For both EPA and Denka/Ramboll, chloroprene remains a high priority. Denka/Ramboll encouraged both parties to continue to have open lines of communication. Follow up meetings or conversations should be scheduled as needed to ensure the process continues to move expeditiously given the high interest from several parties (e.g., public, Denka, EPA).

Action Items:

- Denka/Ramboll will generate a planning document that generally outlines responses to Tier 1 and Tier 2 peer reviewer comments. The organization of this document will incorporate the reviewer name and relevant peer review charge questions. Denka/Ramboll expect to have this information ready no later than the beginning of 2021. Ramboll will outline LOE and a proposed timeline for making such revisions, if warranted, following input from EPA.
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- Notes from this meeting will be circulated for posting on the IRIS website