Message

From: Jared Rothstein [jrothstein@socma.org]
Sent: 9/30/2020 4:47:25 PM
To: Feustel, Ingrid [feustel.ingrid@epa.gov]; Kramek, Niva [kramek.niva@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]
CC: Wheeler, Cindy [Wheeler.Cindy@epa.gov]
Subject: RE: TSCA MCL Use Inquiry

Hi Ingrid,

Do you have any times available to chat next week about the MCL risk evaluation? I would like to get a better understanding of this catch-all use category and how well it corresponds to my member's specific use of the substance.

Best regards,
Jared

-----Original Message-----
From: Feustel, Ingrid <feustel.ingrid@epa.gov>
Sent: Tuesday, September 29, 2020 4:41 PM
To: Jared Rothstein <jrothstein@socma.org>; Kramek, Niva <kramek.niva@epa.gov>; Wolf, Joel <Wolf.Joel@epa.gov>
Cc: Wheeler, Cindy <Wheeler.Cindy@epa.gov>
Subject: RE: TSCA MCL Use Inquiry

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Thank you Jared,

Based on the information provided, the use you describe would fall under industrial and commercial use as a processing aid not otherwise listed in multiple manufacturing sectors, which presents an unreasonable risk to workers and occupational non users. As Niva said, we welcome your member's participation in the SBAR process.

Best,
Ingrid

Ingrid S. Feustel
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Pronouns: she, her, hers

-----Original Message-----
From: Jared Rothstein [mailto:jrothstein@socma.org]
Sent: Tuesday, September 29, 2020 10:07 AM
To: Kramek, Niva <kramek.niva@epa.gov>; Wolf, Joel <Wolf.Joel@epa.gov>
Cc: Wheeler, Cindy <Wheeler.Cindy@epa.gov>; Feustel, Ingrid <feustel.ingrid@epa.gov>
Subject: RE: TSCA MCL Use Inquiry

Hi Niva,

Thanks you for the additional clarity regarding the SBAR panels and risk management. Would you be able to provide me with any determination whether using methylene chloride as a cooling medium in a closed system, for say chemical intermediates, presents an unreasonable risk, or whether that use is excluded from the risk evaluation?

The Agency excluded the use of methylene chloride as a functional fluid in a closed system during pharmaceutical manufacturing (due to the FFDCA statutory exclusion). The risk evaluation did not seem to contemplate however that methylene chloride might be used as a functional fluid in a closed system for other chemical manufacturing processes outside of the pharma space.

Based on your feedback, it sounds like my member's activities do not have a connection to any of the finalized conditions of use that present an unreasonable risk in the risk evaluation, but I just wanted to confirm. I am happy to discuss the circumstances further or provide any additional detail that might be helpful.

Best regards,
Jared

From: Kramek, Niva <kramek.niva@epa.gov>
Sent: Monday, September 28, 2020 12:56 PM
To: Wolf, Joel <Wolf.Joel@epa.gov>; Jared Rothstein <jrothstein@socma.org>
Cc: Wheeler, Cindy <Wheeler.Cindy@epa.gov>; Feustel, Ingrid <feustel.ingrid@epa.gov>
Subject: RE: TSCA MCL Use Inquiry

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.
Hi Jared -

For the self-nominations for small entity representatives to participate in the SBAR panel process, we are looking for small firms or other organizations that would be impacted by the upcoming risk management action. The rulemaking will be addressing the unreasonable risks identified in the risk evaluation. It might be easiest for you and your member to identify which of the conditions of use that present an unreasonable risk apply to them. (The conditions of use are listed in section 5.4 of the final risk evaluation (and also repeated in the executive summary). If none of those conditions of use determined to present an unreasonable risk describe their processes or use, they are likely not eligible to serve as a SER. Please note, however, if one of the downstream uses has been determined to present an unreasonable risk, there is the potential for impacts on the upstream formulator (as well as distributors and others), and we would encourage that formulator to participate as a SER.

We have been asking small businesses to think about whether they make, sell, or use the formulations or products that EPA has determined present an unreasonable risk, or if they engage directly in the processes EPA has determined present an unreasonable risk. If there is no connection between the small business's activities and the conditions of use that present an unreasonable risk, they are likely not to be directly impacted and not eligible to be a SER.

I'm happy to discuss more if you'd like. It is also appropriate for someone to submit a self-nomination if they are in doubt. EPA and SBA will be reviewing the nominations and even if an entity is not eligible to be a SER, we'd still like to engage with them more generally on risk management. For self-nominations, it is very helpful to identify which condition of use they feel is relevant, in addition to the information described on the website (name of firm, NAICS code, etc).

Thanks -

Niva

Niva Kramek
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Kramek.niva@epa.gov<mailto:Kramek.niva@epa.gov>

From: Wolf, Joel <Wolf.Joel@epa.gov>
Sent: Monday, September 28, 2020 9:45 AM
To: Jared Rothstein <jrothstein@socma.org>
Cc: Kramek, Niva <kramek.niva@epa.gov>; Wheeler, Cindy <Wheeler.Cindy@epa.gov>; Feustel, Ingrid <feustel.ingrid@epa.gov>
Subject: Re: TSCA MCL Use Inquiry

Hi Jared,

Thanks for reaching out regarding SBAR. I'm out as well today, but am copying Niva Kramek and Cindy Wheeler. One of them will get back to you.

Thanks, Joel
Sent from my iPhone

On Sep 28, 2020, at 9:36 AM, Jared Rothstein <jrothstein@socma.org<mailto:jrothstein@socma.org>> wrote:

Hi Joel,

I was wondering if you might be able to assist me with my inquiry below, I received an out-of-office note from Ingrid and am trying to get an answer before the deadline for self-nominations for the methylene chloride SBAR panel, which is September 30. Thank you for any assistance you may be able to provide.

Best regards,
Jared

Jared Rothstein
Senior Manager, Regulatory Affairs
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From: Jared Rothstein
Sent: Monday, September 28, 2020 9:31 AM
To: Feustel.ingrid@epa.gov<mailto:Feustel.ingrid@epa.gov>
Subject: TSCA MCL Use Inquiry

Hi Ingrid,

I am reaching out regarding the TSCA methylene chloride risk evaluation. One of my members is interested in participating in the SBAR Panel for risk management of MCL but are uncertain if their use has applicability - they use methylene chloride as a cooling medium in a closed system during the manufacture of a variety of chemistries.

Under the Agency's typology of uses, use of MCL as a coolant in a closed industrial system would be captured under "functional fluids (closed systems)," under "industrial, commercial, and consumer uses, per the life cycle diagram for MCL on page 21 of the original 2017 scope document for the rule. This is repeated on p. 23 of the scope. As the Agency fleshed this use out, it seems to have concluded that the only "functional fluids (closed systems)" use of MCL was in the manufacture of drugs and medicines.

This was all distinct from use as a coolant in automobile refrigeration, classified under "automotive care products," separately from "other use"s – That use was ultimately found to pose unreasonable risk, presumably due to exposure of auto mechanics.

Then, in the final risk analysis, EPA concluded that use of MCL as a functional fluid in pharmaceutical manufacture was excluded from the RE as a non-TSCA use:

While use of methylene chloride as a functional fluid in a closed system during pharmaceutical manufacturing was included in the problem formulation and draft risk evaluation, upon further analysis of the details of this process, EPA has determined that this use falls outside TSCA's definition of "chemical substance." Under TSCA § 3(2)(B)(vi), the definition of "chemical substance" does not include any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. EPA has found that methylene chloride use as a functional fluid in a closed system during pharmaceutical manufacturing entails use as an extraction solvent in the purification of pharmaceutical products, and has concluded that this use falls within the aforementioned definitional exclusion and is not a "chemical substance" under TSCA.

Since my members use of MCL as a coolant medium in a closed system is equivalent to the use of a functional fluid in a closed system, would that mean it is excluded from the risk evaluation?

Thank you for any clarification you might be able to provide regarding this use and its applicability to the TSCA risk evaluation / risk management activities for MCL.

Best regards,
Jared

Jared Rothstein
Senior Manager, Regulatory Affairs
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