Message

From: Crawford, Lydia [Crawford.Lydia@epa.gov]
Sent: 2/20/2020 6:30:37 PM
To: Milica Vogt [milica.vogt@bayer.com]
CC: James Nyangulu [james.nyangulu@bayer.com]; Schmid, Emily [Schmid.Emily@epa.gov]
Subject: RE: 524-ALO question
Attachments: MasterLabel_MON 301108_Final Label Submission January32020 LC comments.pdf

Dear Milica,
Please see the attached label comments for 524-ALO. I included the chemical compatibility statement in my comments just as a place holder until the chemistry review is finished.
Best,
Lydia

From: Milica Vogt <milica.vogt@bayer.com>
Sent: Wednesday, February 19, 2020 5:05 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: James Nyangulu <james.nyangulu@bayer.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: 524-ALO question

Dear Lydia,

I am following up on the review of 524-ALO submission and to check whether you have any questions that we can answer at this time. If Product Chemistry team is still in the process of reviewing attached "Justification for not including precautionary statement on chemical compatibility", would you please comment on the status of other items still under discussion on the label and whether you need anything else from that standpoint?

Thank you in advance for your response and we look forward to completing this review in the upcoming weeks.

Regards,

Milica

From: VOGT, MILICA [AG/1005]
Sent: Thursday, January 09, 2020 2:01 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: 524-ALO question

Hi Lydia,

Thanks for the follow up as I needed to discuss internally the new proposed deadline in regards to the overall launch of the product. Understanding your comments that Product Chemistry team is backlogged at the moment and that this additional time is to be on a safe side, we accept the new PRIA date with the expectation that we will be able to finalize by then.

EPA Reg. No. 524-ALO
Decision Number: 548837
Current PRIA date: January 13, 2020

New PRIA Date: March 16, 2020

Thank you and I look forward to hearing back from you soon on the next steps.

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Thursday, January 09, 2020 7:50 AM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: 524-ALO question

Hi Milica,
The PRIA date for this product is on Monday, 1/13, and I will be out of the office tomorrow. Please let me know by the end of today if the new PRIA date (3/16/2020) for 524-ALO decision # 548837 is acceptable.
Thank you,

Lydia Crawford
Biologist | Herbicide Branch | Registration Division
U.S. Environmental Protection Agency | Office of Pesticide Programs
(703) 347-0622 | Crawford.Lydia@epa.gov

From: Crawford, Lydia
Sent: Tuesday, January 7, 2020 11:58 AM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: james.m.nyangulu@monsanto.com; Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: 524-ALO question

Hi Milicia,
You'll have to wait and submit this as an amendment later after the registration is finished.

We're going to need to renegotiate the PRIA date because the justification you sent re:redox statement is with the chemistry team and they need time to review it. Since they're so backlogged, to be safe, I'm asking to renegotiate until March 16, 2020. Please let me know if you accept this new PRIA date for 524-ALO decision # 548837.

Best,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Tuesday, January 7, 2020 11:02 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Hi Lydia,

I would like to ask you the following question below for your comments and consideration if it would be feasible to include it at this time during the product registration phase instead of having to do it via amendment at a later time. However, if you foresee that this step would take a lot longer than the PRIA timeline, due to the commercial plans, we

may need to consider adding it later. If it can be done quickly now, then certainly it would be simpler for us and the agency to do it during this registration process. Looking forward to your response.

Current situation:
Submitted CSF contained the following line with the defoamer component in the Formulation.

Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name and CAS number.)	Supplier Name and Address	Each Component in Formulation a. Amount	b. % by Wt	Certified Limits % by Weight a. Upper	b. Lower	Purpose in Formulation
Dimethylpolypolysiloxane emulsion Agnique DFM 111s CAS # 63148-62-	BASF Mexicana S.A. de C.V. Av. Insurgentes Sur 975 Col. CD. De Los Deportes, C.P. 03710 Ciudad de México	0.10	0.01%	0.05 (b)	0.001(b)	Defoamer

In addition, we have identified another defoamer source that we would like to add as an additional option. The info is presented in the table below and the question is whether we can add this additional component source at this time?

Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name and CAS number.)	Supplier Name and Address	Each Component in Formulation a. Amount	b. % by Wt	Certified Limits % by Weight a. Upper	b. Lower	Purpose in Formulation
Polydimethylsiloxane antifoam emulsion (SAG 1572) No CAS # available for this blend	Momentive Performance Materials Inc. 260 Hudson River Road Waterford, NY 12188	0.05	0.005%	0.05 (b) (assume same as current)	0.001(b) (assume same as current)	Defoamer

Thank you in advance for your consideration.

Regards,

Milica

From: VOGT, MILICA [AG/1005]
Sent: Friday, January 03, 2020 8:57 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>; VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Lydia,

Please find attached the following information for your further consideration:

- Master Label with your most recent comments + my responses included for each comment + one new/additional comment
- Justification specific to MON 301108 Herbicide on reasons Physical/Chemical Hazards Statement requested in not warranted
- Updated Final Master Label
- Appendix 1- listing Tank Mix Partners and reg. no associated with each for Ag crops (let me know whether the way it is presented works. The label includes info in tank mix sections referring to these appendices)
- Appendix 2- listing Tank Mix Partners and reg. no associated with each for IT&O

I look forward to hearing back from you whether there is anything else needed.

Best regards,

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Tuesday, December 17, 2019 4:01 PM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Milica,
Yes, they can be included in an appendix at the end of the label, and just add a note in the tank mix section that the reg numbers can be found in that appendix.
Best,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Tuesday, December 17, 2019 2:02 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Hi Lydia,

Thanks for this confirmation. We will proceed forward with generating a document specific to 524-ALO.

Regarding the inclusion of the Reg numbers for the brand names, would it be feasible to include an appendix with all brand names of the tank mix partners across all sections of the label and associated reg numbers of those or is the request to include reg numbers throughout the label after each brand name is listed. I look forward to receiving this clarification from you.

Thank you and best regards,

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Monday, December 16, 2019 10:02 AM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Milica,
Thank you for sending the rebuttal information from 71995-52; this is something we will consider. If you could write up a similar document for 524-ALO as you suggested, then the agency can start processing that request. I anticipate that this will take longer than the renegotiated PRIA date, but I'd like to wait until the Chemistry team has the rebuttal documents to renegotiate.
I don't think a meeting will be necessary for this, just the similar justification documents.
Best,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Thursday, December 12, 2019 4:03 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>; VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Hi Lydia,

Sounds good. I look forward to your further comments on the Physical and Chemical Hazards statement.

Best regards,

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Thursday, December 12, 2019 2:30 PM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Milica,
Yes, let's extend the PRIA date.

I will have to take a look at these documents and consult with CHEM and get back to you on the Physical and Chemical Hazards statement. I'll get back to you about that tomorrow or early next week.
Best,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Thursday, December 12, 2019 1:35 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>; VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Hi Lydia,

Thank you for your prompt response. With the requirement to include the EPA Reg. # for the brand names and additional comment regarding Physical and Chemical Hazard statement, I am afraid that those items would not be resolved by tomorrow's PRIA date. In that respect, can the PRIA deadline be extended to January 13th. Below is the information on this PRIA action.

EPA Reg. No. 524-ALO

Decision Number: 548837
Current PRIA date: December 13, 2019
New PRIA Date: January 13, 2020

Regarding Physical and Chemical Hazard statement, I am attaching documents that were previously submitted to the agency for the labeling of EPA Reg. No. 71995-52 with similar Physical and Chemical Hazard statement. Included are the justification that explains why there is no hazard and the EPA's final decision regarding that Reg. No. Would this information be sufficient as a proof why the statement is not needed on the 524-ALO label, would you suggest we develop a justification document specific to 524-ALO or if necessary, could the meeting/teleconference be organized with the Product Chemistry reviewer?

Thank you and I look forward to your prompt response.

Regards,

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Wednesday, December 11, 2019 1:50 PM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Milica,
Thanks. I transferred over the remaining comments to the updated label with agency responses.
Best,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Tuesday, December 10, 2019 11:18 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Dear Lydia,

Thanks again for reviewing this product label and providing your comments. I am attaching for your review and consideration the following documents:

- Updated label
- Version of the label with your comments and my direct responses included to each of your comment which in some cases require your further consideration.
- PRN 95-3 referenced in my comments regarding the reduction in the REI to 4 hours.

Please let me know if you have any questions and feel free to call me at the number included below. I look forward to your prompt input and feedback so that we can finalize this as soon as possible.

Thank you for your further consideration.

Milica
314-343-7328

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Tuesday, December 10, 2019 1:40 PM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>

Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Milica,
That sounds good. I'm fine keeping the PRIA date as is; we're trying to renegotiate a few days before the PRIA date when possible, so that's the only reason I asked.
Talk to you soon,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Tuesday, December 10, 2019 2:31 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Hi Lydia,

Thanks for the follow up email. I plan to respond back later today so I suggest to leave it as is at this time. Perhaps, we can touch base tomorrow afternoon if you have any additional comments. Hope this works for you.

Thank you,

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Tuesday, December 10, 2019 12:45 PM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: 524-ALO question

Hi Milica,
The PRIA date is coming up on Friday (12/13), and I know we just got the label back to you to review and there are quite a few comments. Do you think we need to extend the PRIA date?

Best,
Lydia

From: Crawford, Lydia
Sent: Thursday, December 5, 2019 2:45 PM
To: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: 524-ALO question

Hi Milica,
Perfect timing; I was just about to send the label comments over. Here it is; let me know if you have any questions.
Best,
Lydia

From: VOGT, MILICA [AG/1005] <milica.vogt@bayer.com>
Sent: Thursday, December 5, 2019 2:31 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>

Cc: james.m.nyangulu@monsanto.com
Subject: Re: 524-ALO question

Dear Lydia,

Since the PRIA timeline is approaching soon, I wanted to following up with you on the status of the review and whether you have any questions.

Please don't hesitate to reach out and we look forward to receiving any updates from you.

Best regards,

Milica

On Nov 14, 2019, at 11:16 AM, VOGT, MILICA [AG/1005] <milica.vogt@monsanto.com> wrote:

Dear Lydia,

Thank you for your email and inquiry. Master Label for EPA Registration No. 524-539 was utilized as a template to create proposed Master Label for 524-ALO. That was one of the most recent Master Labels that was accepted by the EPA for a Monsanto glyphosate product registration. However, we recently provided an updated label for consideration and I am attaching that email exchange to ensure you have the most up to date information submitted for your review.

Please don't hesitate to let me know if you have any additional questions or need anything else.

Thank you and best regards,

Milica

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Thursday, November 14, 2019 2:01 PM
To: milica.vogt@bayer.com
Subject: 524-ALO question

Dear Milica,
I'm starting the label review for reg symbol 524-ALO. Could you let me know what label(s) you used as a framework to create this proposed label?
Thanks!

Lydia Crawford
Biologist | Herbicide Branch | Registration Division
U.S. Environmental Protection Agency | Office of Pesticide Programs
(703) 347-0622 | Crawford.Lydia@epa.gov

<mime-attachment>

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