Message

From: Schmid, Emily [Schmid.Emily@epa.gov]
Sent: 10/27/2020 3:09:17 PM
To: Schmid, Emily [Schmid.Emily@epa.gov]
Subject: FW: Tavium Label
Attachments: ATT00001.txt

Importance: High

Make sure this makes it into the jacket.

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Tuesday, October 27, 2020 11:01 AM
To: Kenny, Daniel <Kenny.Dan@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label
Importance: High

Hi Dan,

Thanks for the chance to review. We accept these additional clarifications/tweeks. We noticed on place where an additional "of" is required. Please see snip below, page 10, A.4.

Also, in your message, you indicate the "training requirements" are identical, did you mean the Evaluation components as shown in the highlights below. If these are the same for all three registrants, Syngenta provides its concurrence.

Thanks
Monty

From: Kenny, Daniel <Kenny.Dan@epa.gov>
Sent: Tuesday, October 27, 2020 10:09 AM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Thank you, Monty. I had no problems with the clarifications, so they are all in there. I can also confirm that the training requirements are identical for the other two registrants.

Unfortunately, a few more clarifications have created the need for a few more tweaks in Appendix D. Otherwise, this is unchanged from your previous document. To make it easy to spot and consider the changes, I am sending a redline copy as well as a clean copy. Please review and respond to this by 11:00 this morning.

Sorry for the rush, things are crazy today.

Thanks,
Dan

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Tuesday, October 27, 2020 9:32 AM
To: Kenny, Daniel <Kenny.Dan@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label
Importance: High

Hi Dan,

Please find the draft terms. We have made a few edits that we believe help with the readability…i.e. after the first instance of A21472 referring indicating that that to Tavium throughout. To address this, we modified the introduction to read "The previously approved labeling of A21472 Plus VaporGrip Technology [herein referred to by the alternate brand name: Tavium® Plus VaporGrip® Technology]" and then made sure all subsequent references were consistently referred to as Tavium. We also found a few typos/missing areas that were address.

Please note that in once section on page 12, Syngenta wants to ensure consistency with the other products. We are supportive of these points if required of all three (Engenia, Xtendimax and Tavium).

Syngenta therefore concurs with these draft terms of registration if the aforementioned consistency is achieved for the highlighted sections below. Please let me know if this requires additional discussion or consideration by the Agency.

Please feel free to contact me at any time today if I can be of assistance,

Thanks
Monty

C. Evaluation Component:

1. Syngenta will annually conduct a survey directed to users of ~~A21472~~Tavium Plus VaporGrip Technology for use over-the-top of dicamba tolerant soybean or cotton. This survey must be based on a statistically representative sample. The sample size and geographical resolution should be adequate to allow analysis of responses within regions, between regions, and across the United States. Syngenta must submit the draft survey to EPA as well as the survey results. This survey shall evaluate, at a minimum, the following:
   a. Growers' and users' adherence to the terms of the ~~A21472~~Tavium Plus VaporGrip Technology Use Directions and Label Restrictions, if ~~A21472~~Tavium Plus VaporGrip Technology is used, and
   b. Whether growers have encountered any perceived issue with non-performance or lack of efficacy of ~~A21472~~Tavium Plus VaporGrip Technology and, if so, how growers have responded.
   c. Whether growers have reported any issues with non-performance of lack of efficacy of ~~A21472~~Tavium Plus VaporGrip Technology and how the company representatives have responded.
   d. A question asking about awareness of public records of resistance (e.g., any awareness of popular press or industry publications on dicamba resistance or suspected resistant biotypes).
   e. A question directed to asking about awareness of personal/neighbor reports of resistance.
   f. Application practices for dicamba product applied (rate, time, amount, etc.) to the fields planted with dicamba-resistant seed.
2. Utilize the results from the survey described in paragraph 1 of this section to annually review, and modify as appropriate for the upcoming growing season, the following elements of Syngenta's resistance management plan:
   a. Efforts aimed at achieving adoption of BMP's;
   b. Responses to incidents of likely resistance and confirmed resistance; and
   c. The education program and effectiveness of information dissemination. At the initiative of either EPA or Syngenta, EPA and Syngenta shall consult about possible modifications of the education program.

Dixon Monty USGR
Syngenta will support these points C.1.c – C.1.f if consistent requirement on all dicamba tolerant products (Engenia, Xtendimax and Tavium)

From: Kenny, Daniel <Kenny.Dan@epa.gov>
Sent: Monday, October 26, 2020 10:58 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Hi Monty. Please see the attached updated terms. We'd appreciate it if you could have your folks go through it and indicate Syngenta's concurrence. This reflects the most recent changes from all of the discussions, but if you see something that you don't think is appropriate for your product, please point it out to us and we'll take a look. We'll hope to hear from you all sometime tomorrow morning.

Thanks,
Dan

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 8:19 PM
To: Kenny, Daniel <Kenny.Dan@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

Hi Sarah,

Please find version G (000100-01623.20200812G.A21472_PLUS_VAPORGRIP_TECHNOLOGY.AMEND.AUG2020-CL.pdf) that contains edits on page adds the points 1 and 2 below as shown highlighted in the snip.

Thanks and please let me know if any additional edits are needed.

Monty

From: Kenny, Daniel <Kenny.Dan@epa.gov>
Sent: Monday, October 26, 2020 7:49 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Thank you Monty. I did a quick scan, and there are a couple things I saw. We'll need to have the team to a final sweep to make sure nothing from before was inadvertently changes, but in the meantime we can/should do just a couple things:

1) Sarah had mentioned a late breaking addition to the buffer exclusions if you were interested, and it just came through. If you'd like, you can expand the first exclusion to the buffer area that currently discusses mowed grass fields to read "…mowed grass areas, and areas of bare ground from recent plowing or grading that are contiguous to the treated field."
2) We need to change the heading from that section from "Sensitive Areas". That has been causing huge confusion on whether they need to always observe the buffer or only if it's considered a sensitive area. Please change the heading to read something like "Spray Buffers", or something like that. That would improve the issue quite a bit.

Thanks very much,
Dan

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 7:32 PM
To: Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label
Importance: High

Hello Sarah,

Please find the revised label for Tavium (000100-01623.20200812F.A21472_PLUS_VAPORGRIP_TECHNOLOGY.AMEND.AUG2020-CL.pdf). The only change from the earlier version was the rewording of section 4.7 (page 16) as discussed below. Please let me know if any further changes are needed, I will be available at anytime.

With Kind Regards,

Monty

From: Meadows, Sarah <Meadows.Sarah@epa.gov>
Sent: Monday, October 26, 2020 7:11 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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That's right. Thanks, Monty.

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 7:05 PM
To: Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

Hi Sarah,

I realize our emails of 6:54 crossed paths. For clarity and based upon the note below, and the attached email…we are going to add back the language that is aligned/the same as Bayers label. Please let me know if that is not correct.

Thanks
Monty

From: Meadows, Sarah <Meadows.Sarah@epa.gov>
Sent: Monday, October 26, 2020 6:54 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia

<Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Hi, Monty. Yes, you can include that language. Sorry for the confusion.

Thanks,

Sarah

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 6:24 PM
To: Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

HI Sarah,

Thanks. One last question to hopefully ensure consistency, Bayer shared their label with us which has the following:

[redacted]

We were instructed to remove this in our label comments received Friday (see below)

[redacted]

May we include the struck language back?

Thanks
Monty

From: Meadows, Sarah <Meadows.Sarah@epa.gov>
Sent: Monday, October 26, 2020 6:10 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Hi, Monty. You can go ahead and send me the new version now just in case we don't need another change. And there's no need for a highlighted copy, just a clean copy.

Thanks,

Sarah

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 6:08 PM
To: Meadows, Sarah <Meadows.Sarah@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

Hi Sarah,

I will have that put back and we can send it back in the event there the other change ends up not being required unless you prefer me to wait for the final label change.

Also, for ease of these final reviews, would you prefer I only include version highlighting these last changes or is it better to include the version with all changes in the earlier iterations highlighted..

Thanks
Monty

From: Meadows, Sarah <Meadows.Sarah@epa.gov>
Sent: Monday, October 26, 2020 5:37 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Hi, Monty. I noticed one statement has been removed that we'll need you to add back. I have noted it in the attached file. There may be one other label change needed tonight, but I wanted to go ahead and give you the heads up on this.

Thanks,

Sarah

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 5:02 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

Hi Emily,

Thanks and again apologies for sending multiple version so quickly. I am available at anytime the rest of the day/evening if needed.

Best Regards,
Monty

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, October 26, 2020 4:34 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Tavium Label

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Hi Monty,

Sarah is helping me check the label so I forwarded this latest version to her.

Thank you,
Emily

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 4:21 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: Kenny, Daniel <Kenny.Dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: RE: Tavium Label
Importance: High

Hi Emily,

I was just alerted to one change that will be needed for a smoc maximum rate in the cotton sections. Specifically, section 8.1.1 section 3.b. should read as follows:

- DO NO exceed ~~3.71~~ 2.48 lb ai/A/year of S-metolachlor-containing products on medium- or fine -textured soils.

This is the only needed change.

I am very sorry for this needed correction and hope this does not create too much inconvenience.

Thanks
Monty

From: Dixon Monty USGR
Sent: Monday, October 26, 2020 4:03 PM
To: 'Schmid, Emily' <Schmid.Emily@epa.gov>; 'Crawford, Lydia' <Crawford.Lydia@epa.gov>
Cc: kenny.dan@epa.gov <kenny.dan@epa.gov>; 'Echeverria, Marietta' <Echeverria.Marietta@epa.gov>
Subject: RE: Tavium Label

Hello Emily,

My label team just provided this version that highights all changes made today including adding the typographical edits as well as those mentioned below. This version may be easier for your review. Please therefore find the clean and this version with only todays edits added.

Thanks
Monty

From: Dixon Monty USGR
Sent: Monday, October 26, 2020 3:56 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>; Crawford, Lydia <Crawford.Lydia@epa.gov>
Cc: kenny.dan@epa.gov <kenny.dan@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>
Subject: RE: Tavium Label

Hi Emily,

Please find attached the revised labels. As requested, we have added page numbers and made the following changes:

Section (Page)	Previous Version	New Version
4.7 (16)	Applications of this product may qualify for reduced use restrictions, such as a reduced downwind buffer distance, provided a **qualified DRT** listed on www.TaviumTankMix.com is used and operated according to the directions and limitations provided at www.TaviumTankMix.com.	*Deleted based upon guidance below*
4.7.1 (16)	*Requirements for Reduced Use Restrictions with Optional Hooded/Shielded Sprayer:* ONLY **qualified** hooded/shielded sprayers listed on www.TaviumTankMix.com. are eligible for reduced use restrictions when applying this product. Refer to the website for specific application requirements when using a **qualified** hooded/shielded sprayer. While this	*Requirements for Reduced Use Restrictions with Optional Hooded/Shielded Sprayer:* **ONLY qualified** hooded/shielded sprayers listed on www.TaviumTankMix.com are eligible for reduced use restrictions when applying this product. If a **qualified** hooded/shielded sprayer is used for applications to dicamba-tolerant soybeans, the downwind buffer is 110 feet. While this product

	product may be applied with other (non-qualified) hooded/shielded sprayers, no reduction in use restrictions is associated with their use.	may be applied with other (non-qualified) hooded/shielded sprayers, no reduction in use restrictions is associated with their use.
6.3.7 (23)	Roads, paved or gravel surfaces, mowed and/or managed areas adjacent to fieldsuch as rights-of-ways.	Roads, paved or gravel surfaces, mowed grass areas adjacent to treated fields.

In addition, we corrected a couple of typos and removed the – from 240-foot to read 240 foot.

I have included a clean, highlighted (blue new edits) that includes all previous changes and then a single edit that shows the points in the chart above. Note the deletion in section 4.7 page 16 is not shown in the single edit but is in the hightlighted version with all edits.

Please let me know if can do anything else on my end.

Thanks
Monty

From: Dixon Monty USGR
Sent: Monday, October 26, 2020 3:16 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: Tavium Label

Hi Emily,

Just an update, hope to have label to you in next 15 to 20 minutes.

Thanks
Monty

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, October 26, 2020 1:45 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>
Subject: RE: Tavium Label

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Hi Monty,

Yes, I believe this is what he was talking about.

Add to "4.7 Optional Use of Drift Reduction Technology" (Page 15):
If approved hooded sprayer is used, the downwind buffer is 110'.

Let me know if I'm misunderstanding and you are looking for something else.

Thanks,

Emily

From: Dixon Monty USGR <monty.dixon@syngenta.com>
Sent: Monday, October 26, 2020 1:39 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: Tavium Label

Hi Emily,

Yes, happy to do so. He had mentioned you were working on hooded sprayer language that we could incorporate. Do you have that by chance...if so we can add it to this version.

Thanks
Monty

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, October 26, 2020 1:37 PM
To: Dixon Monty USGR <monty.dixon@syngenta.com>
Subject: Tavium Label

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Hi Monty,

Dan let me know that you were working on last edits to the label. I noticed it doesn't have page numbers. Could you add those? It will fail QAQC without them and I don't want to risk that.

You can go ahead and send the revised label to me as soon as you have it ready.

Thanks!
Emily

Emily Schmid
Product Manager 25
Herbicide Branch
Registration Division, Office of Pesticide Programs
U.S. Environmental Protection Agency

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