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**From:** JENKINS, DANIEL J [AG/1920] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=813004]  
**Sent:** 5/9/2014 2:10:26 PM  
**To:** AHLERS, ERIN M [AG/1000] [/O=MONSANTO/OU=NA-1630-01/cn=Recipients/cn=172788]  
**Subject:** RE: sodium sulfite/what is the resolution of this?

Got it, let me know...

Dan Jenkins  
U.S. Agency Lead

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**From:** AHLERS, ERIN M [AG/1000]  
**Sent:** Friday, May 09, 2014 10:01 AM  
**To:** JENKINS, DANIEL J [AG/1920]  
**Subject:** FW: sodium sulfite/what is the resolution of this?

Not to tattle, but you asked for real-time feedback.

I spoke with Erik on Wednesday and specifically ask that he NOT talk to the agency until he had a chance to discuss with Steve and collectively come up with a reasonable way to approach/state the issue/need without stirring up any unnecessary concern. The note Thursday appears to have been sent without that happening (Steve has not talked directly to Erik on the phone).

*I haven't had a chance to discuss with Erik*, but if it happened in the manner that I think it did, I am very disappointed. Hope to talk to Erik about this today.

**From:** ADAMS, STEPHEN A [AG/1000]  
**Sent:** Thursday, May 08, 2014 4:41 PM  
**To:** JANUS, ERIK [AG/1920]  
**Cc:** AHLERS, ERIN M [AG/1000]  
**Subject:** RE: sodium sulfite/what is the resolution of this?

Erik –

If you talk to Kerry, I wouldn't push the NNG issue too hard – don't want to draw attention to the toxicity of our product, but the idea of removing nitrates that could be transformed into nitroso compounds should be of interest to EPA.

Technology is anxious and needs to know how to proceed as quickly as possible, so as you hear anything, please pass it over the fence.

Thanks!

Steve

**From:** JANUS, ERIK [AG/1920]  
**Sent:** Thursday, May 08, 2014 2:41 PM  
**To:** ADAMS, STEPHEN A [AG/1000]  
**Cc:** AHLERS, ERIN M [AG/1000]  
**Subject:** RE: sodium sulfite/what is the resolution of this?

Steve,

Thanks for this add'l info. I have a note into Kerry Liefer following up on our last conversation and outlining some of the new info you present below. I did indeed use your highlighted points, not verbatim, but used. Apologies for the delay,

but I needed to go back and review the registration review documents he pointed me towards when we last spoke. These were of no help and I'm not sure why he pointed me towards them as they don't address issues with using a sulfite inert and don't address the FDA process. I hope to get an answer from him in the next few days.

Thanks, I'll be in touch,

- Erik

**From:** ADAMS, STEPHEN A [AG/1000]  
**Sent:** Tuesday, May 06, 2014 3:34 PM  
**To:** JANUS, ERIK [AG/1920]  
**Cc:** AHLERS, ERIN M [AG/1000]  
**Subject:** RE: sodium sulfite/what is the resolution of this?

Erik --

To follow up on our conversation the other day at our Team meeting, the Petition Monsanto filed asking EPA to grant an exemption from the requirement of a tolerance for sodium sulfite is still open/pending; however, EPA is not too anxious to grant such an exemption while FDA is reviewing the safety of sodium sulfite to humans.

The fact is that having sodium sulfite available for use in pesticides labeled for food-use PRIOR TO HARVEST would be of tremendous value to Monsanto to control nitrate levels in formulations containing the ethanolamine salt form of Glyphosate, which can be converted into N-nitroso-glyphosate (NNG), an impurity of toxicological significance with an upper concentration limit of 1 ppm in Glyphosate products. Do you think there is any way that we could successfully negotiate with EPA to allow the addition of sodium sulfite at a maximum concentration of 0.2% by weight of the total formulation? We don't need much!

Would you be willing to discuss this proposal with EPA? Of course, I would be happy to write up an argument that we could submit to support our request.

There are a couple of points that I would highlight:

1. Sodium sulfite (as far as I can tell) is still listed at 21 CFR 582.3798 as being generally recognized as safe when used in accordance with good manufacturing or feeding practices, except that it is not used in meats or in food consumed as a source of vitamin B1.
2. If we were to add sodium sulfite to our concentrated formulation at 0.2% by weight, it would roughly only represent a concentration of around 0.004% or so in the diluted spray solution (44 fl ounces applied in 20 gallons of water per acre, as an example) applied to the growing crop. By the time you consider exactly how much of that actually gets on the food commodity it is incredibly infinitesimal.
3. The use of low levels of sodium sulfite to ensure low levels of NNG, an impurity of known toxicological significance, is well worth the risk.
4. We are NOT asking that sodium sulfite be allowed in formulations labeled for application POST-HARVEST, only prior to harvest. Therefore, sodium sulfite would not be applied in any pesticide formulation that is applied directly to the raw agricultural commodity or processed food product.

Like I said, this use of sodium sulfite is of considerable importance right now to Monsanto's Roundup Xtend products. I think it is worth us trying a little harder to get this use out of EPA, if at all possible. The only other option we currently have to consider is the use of ascorbic acid that greatly increases the cost of goods of these crop protection products.

Let me know what you think and, if you agree, how you would like to approach EPA with this.

Thanks,

Steve

**From:** ADAMS, STEPHEN A [AG/1000]  
**Sent:** Thursday, April 10, 2014 12:18 PM  
**To:** JANUS, ERIK [AG/1920]  
**Subject:** RE: sodium sulfite/what is the resolution of this?

Here is the cover letter that went with the Petition for reinstatement of an exemption from the requirement of a tolerance for sodium sulfite. There was also a 2-volume set of administrative documents and tox summaries intended to

support the Petition. I can't find any correspondence in our Reg Affairs Library from EPA providing any evaluation of our Petition, so not sure where it ended up or how it got to where it is today – nowhere.

The data volumes are too big to send via email, but I can place them in my public folder on Finch and send you a link, if you want to look at them. I think at this point it would be just as well to find out what EPA did with our Petition and why they did not grant the exemption from the requirement of a tolerance.

Steve

**From:** JANUS, ERIK [AG/1920]  
**Sent:** Thursday, April 10, 2014 11:46 AM  
**To:** ADAMS, STEPHEN A [AG/1000]  
**Subject:** sodium sulfite/what is the resolution of this?

*PP 7E7261.* (EPA-HQ-OPP-2008-0043). Monsanto Company, 1300 "I" St., NW. Suite 450 East, Washington, DC 20005, proposes to amend 40 CFR 180 by establishing an exemption from the requirement of a tolerance for residues of sodium sulfite in or on any food or feed commodity when used as an inert ingredient in a pesticide product with the following limitations: Not to exceed 0.8% by weight in the formulated product. For use only in formulated products containing the active ingredient glyphosate and applied only to growing crops. Because this petition is a request for an exemption from the requirement of a tolerance, no analytical method is required. Contact: Karen Samek, telephone number: (703) 347-8825; e-mail address: [samek.karen@epa.gov](mailto:samek.karen@epa.gov).

<https://www.federalregister.gov/articles/2008/02/06/E8-2172/notice-of-filing-of-pesticide-petitions-for-residues-of-pesticide-chemicals-in-or-on-various>

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