Message

**From:** Herrick, Jacquelyn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40DA8860B1DD43D9B006AC1E0E9E04CE-MARCHESE, J]
**Sent:** 4/6/2021 12:47:08 PM
**To:** Duan, Dehui [Duan.Dehui@epa.gov]; Leifer, Kerry [Leifer.Kerry@epa.gov]; Mathur, Shyam [Mathur.Shyam@epa.gov]
**Subject:** RE: Spinosad SC ML Revised Packaging

Ok thank you Dehui!

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herrick.jacquelyn@epa.gov

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**From:** Duan, Dehui <Duan.Dehui@epa.gov>
**Sent:** Tuesday, April 06, 2021 8:20 AM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Leifer, Kerry <Leifer.Kerry@epa.gov>; Mathur, Shyam <Mathur.Shyam@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Jackie,
I found that 8329-61 is similar to 1021-1687 (not 1688 as the registrant said). No SS and CC are associated to either of them.
Dehui

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Tuesday, April 6, 2021 6:56 AM
**To:** Leifer, Kerry <Leifer.Kerry@epa.gov>; Duan, Dehui <Duan.Dehui@epa.gov>; Mathur, Shyam <Mathur.Shyam@epa.gov>
**Subject:** FW: Spinosad SC ML Revised Packaging

Hi PC Team,

Please see Clarke's note below regarding 8329-61 (and the referenced document attached). Does this provide enough information for -61?

Please let me know.

Thank you,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Monday, April 05, 2021 10:40 AM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Leisha Schumacher <lschumacher@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Jackie,

Thank you. Eurofins TestAmerica has forwarded the PR Notice instructions to their Quality Assurance and technical staff. I have given them your email and phone number for any questions specific to the submission requirements.

In our first phase of submissions, we included the bridging rationales in the transmittal document. After discussion with the RD team, we've begun to include that in a formatted "report" within the submission package for subsequent submissions instead of on the transmittal.

- For 8329-61, the tested product is MGK's 1021-1688 (which is produced by Clarke), which is substantially similar, contains the active ingredients in the same ratio, and contains an identical inert composition.
- For 8329-82, the product tested is 8329-106 which is a substantially similar product (me-too of each other), with a minor change in one inert ingredient.

Best regards,
Karen

**Karen J. Larson**
Vice President, Product innovation & Government Affairs

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**Email:** klarson@clarke.com

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Friday, April 2, 2021 2:15 PM
**To:** Karen Larson <klarson@clarke.com>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Leisha Schumacher <lschumacher@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen,

Kerry and I spoke further with our General Counsel yesterday regarding the Eurofins submission. They agree that the Eurofins document should be submitted per PRN 11-3. I would be happy to set up a call with a Eurofins representative and our Counsel if needed to address their concerns directly.

I would like reiterate, this formatting is not holding up the review. I received word from Kerry's team this afternoon that their report is almost complete. I think we should be able to get you an approval letter for 8329-62, -106, and -108 early next week. There is question on the SS/CC data on 8329-61 and -82. SS/CC data should be product specific, and at the moment those data appear to not be. Can you confirm what was submitted for SS/CC on those products?

Thanks,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Wednesday, March 31, 2021 1:24 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Leisha Schumacher <lschumacher@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Agree, and yes I will make time. I can be available until 5 Eastern.

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Wednesday, March 31, 2021 12:22 PM
**To:** Karen Larson <klarson@clarke.com>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Leisha Schumacher <lschumacher@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen,

You have quite a few questions below. I think it might be better if we have a quick chat. I have a meeting with Kerry at 3 that shouldn't take long and then have a meeting at 4. Would you be available sometime between then?

Thanks,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Wednesday, March 31, 2021 12:05 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Leisha Schumacher <lschumacher@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Jackie,

Clarke has already granted letter of access to MGK (see attached). Can you clarify whether this was submitted by MGK?

I continue to be confused over this and suspect it has been unnecessarily jumbled into a bureaucratic mess. MGK and other basics will be relying exclusively on the information Clarke has provided for Clarke's newly sourced

container. Clarke's supplemental registrations are of minor consideration to their business, and we appreciate greatly their cooperation to expedite submissions on our behalf. However, given your request earlier this week for a resubmission from Eurofins, what direction can Clarke provide them now?

It is still not clear whether a Eurofins submission of a *reformatted appendix to Clarke's report* will require a new MRID and submitter assignment or whether it will be a supplement to the existing MRID. Since RD is requiring MGK (and others) to cite Clarke's submitted report, inclusive of the appendix, will they need a letter of access from Eurofins as well? This seems unnecessarily complex and bears a low probability of success in a short timeframe. What of the existing submissions and data matrixes? Do these also require resubmission? This all seems unnecessarily burdensome given the nature of the review!

The container evaluation data does not in any way describe any testing on any pesticide product and was submitted *voluntarily* in response to an *informal* inquiry from RD. It is not specific, even, to the container that is being evaluated! It simply reveals a proprietary method which complies with all EPA Office of Water and DoD guidance for the testing of PFAS in water and other media. Will RD now be requiring the same container testing and submission requirements of every registrant proposing a new container, or a new registration in any container whether or not new, or is this a standard applied only to Clarke?

I do understand these are unprecedented questions for industry and OPP to be grappling with, but while RD delays a review over administrative issues Clarke continues to be unable to meet customer demand for product packaged in small containers and refillable plastic drums, *and* alternative products remain commercially available in traditionally fluorinated packaging.

I submit again my offer to resubmit the container evaluation with the same MRID and absent the voluntarily included SOP in the appendix.

Karen

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Wednesday, March 31, 2021 9:19 AM
**To:** Leisha Schumacher <lschumacher@clarke.com>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Thanks Leisha.

Regarding the MGK submissions, I'm wondering if they have the container evaluation data outside of the SS/CC and enforcement analytical methodologies that were submitted. If they area relying on additional data that Clarke has submitted, we need indication from them that they are relying on your data.

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**From:** Leisha Schumacher <lschumacher@clarke.com>
**Sent:** Tuesday, March 30, 2021 3:54 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hello Jackie,

Yes, those are the products that we have not yet submitted. Karen has been working with Bayer and can provide an update when she returns.

For the MGK submissions, do they need to send a courtesy copy of the CSFs, or are you referring to the container evaluation data? If the latter is the case, MGK did not perform any data and would cite the information we submitted.

If you need anything else, please let me know.

Sincerely,

**Leisha Schumacher** (Abel)
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St. Charles, IL 60174

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** March 30, 2021 7:43 AM
**To:** Karen Larson <klarson@clarke.com>
**Cc:** Leisha Schumacher <lschumacher@clarke.com>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen and Leisha:

I have some people looking into Karen's question, I'm not sure offhand.

Also, I went through all of the submissions yesterday and it looks like we are still waiting on the following. Can you confirm?

8329-105
8329-18
8329-20
8329-24
8329-93
1021-2562
*432-1132 – has an anticipated submission date of 3/15. Do you know if Bayer made this submission? If so can you provide us with the submission number so that we can get it to the top of the processing line?

Also, MGK made a few submissions (1021-1687, 1021-1688, 1021-1807) earlier on in the process. After a quick glance it did not look like they included the supplemental information we requested after the first batch of Clarke submissions. Do you know if they have similar information available for review?

Please do not hesitate to reach out to me with any questions or concerns.

Many thanks,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Monday, March 29, 2021 5:13 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Leisha Schumacher <lschumacher@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Jackie,

I am out of the office through Tuesday, but will send along the PR Notice guidance to Eurofins. Will they be re-submitting by email and maintaining the same MRID?

I was hoping to avoid this confusion, since this is a method wholly unrelated to FIFRA and independent of Clarke's pesticide formulations and registrations, how do claims of confidentiality under FIFRA 10(d)(1)(A), (B), or (C) apply?

Karen

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Monday, March 29, 2021 12:37 PM
**To:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen,

Thank you for coordinating this submission with Eurofins. Per the voicemail I just left, can you ask that they format the document abiding by the format outlined in PRN 2011-3 that includes the first few cover pages so we may get this document officially uploaded in our system? FYI Kerry's team is working on the review now.

Thank you,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Thursday, March 25, 2021 1:51 PM
**To:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>
**Cc:** Leifer, Kerry <Leifer.Kerry@epa.gov>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Jennifer,
Laura Turpen of Eurofins confirmed she just sent the un-redacted SOP to the three of you.

Thank you,
Karen

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**From:** Saunders, Jennifer <Saunders.Jennifer@epa.gov>
**Sent:** Wednesday, March 24, 2021 12:14 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Karen Larson <klarson@clarke.com>
**Cc:** Leifer, Kerry <Leifer.Kerry@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen, Jackie is out, and I wanted to touch base on the possibility of getting Eurofins to submit the unredacted version directly to EPA. Thanks!

Best,
Jenn

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Thursday, March 18, 2021 8:14 PM
**To:** Karen Larson <klarson@clarke.com>
**Cc:** Leifer, Kerry <Leifer.Kerry@epa.gov>; Saunders, Jennifer <Saunders.Jennifer@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen,

Thanks for the response. I'll circle back to the chem team with this information. In the meantime, please reach out to the laboratory to gauge their willingness to answer questions that may arise per your suggestion.

Many thanks,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Thursday, March 18, 2021 4:56 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Jackie,

The only redactions within the document occur in the appendix that includes Eurofins TestAmerica's analytical test method. It is not within the body of the test reports which were provided to Clarke under the standard protocol of the laboratory.

Eurofins claims the method is proprietary business information and has not disclosed that information to Clarke. Clarke requested the method for inclusion as an appendix to the report because we expected that although the method is well understood by the Office of Water and DoD, it is likely new methodology to OPP. The information is not proprietary to Clarke, it is proprietary to the laboratory in the same way that the method used by Alpha Analytical (for Massachusetts DEP) to test Clarke's product is proprietary to that lab and to date has not been disclosed. We would not expect that the redactions would influence the results of the study.

I don't expect that Eurofins will provide an un-redacted report to Clarke to submit to EPA (and thus own the rights to waive CBI at a later date), but I can inquire with the lab as to their availability to answer questions from the Agency if that is something your team needs. Alternatively, since the method is already in an appendix, would it be more appropriate to resubmit the study without that appendix?

Best regards,
Karen

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Thursday, March 18, 2021 1:36 PM
**To:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen,

CITAB noted that MRID 51436403 contains what appears to be redacted information in various locations throughout the document. Can you provide us with an unredacted version of the document and, if appropriate, include any CBI in a confidential appendix per PR Notice 2011-3?

Thanks,
Jackie

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**From:** Herrick, Jacquelyn
**Sent:** Wednesday, March 17, 2021 11:58 AM
**To:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Karen,

I'll reach out to the team reviewing the data and will let you know.

Thanks,
Jackie

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**From:** Karen Larson <klarson@clarke.com>
**Sent:** Wednesday, March 17, 2021 11:54 AM

**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Jackie,

Are you able to provide an estimated timeline for completed review of the earlier of Clarke's and MGK's submissions? I know some were received just last week, but can you provide any feedback on the container test report and the first wave of submissions?

Thank you,
Karen

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** Tuesday, March 16, 2021 6:23 AM
**To:** Leisha Schumacher <lschumacher@clarke.com>
**Cc:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Thank you Leisha. I do have those -RRI documents, my mistake on not including the update in the chart.

Thank you,
Jackie

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**From:** Leisha Schumacher <lschumacher@clarke.com>
**Sent:** Monday, March 15, 2021 3:07 PM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hello Jackie,

Below is an updated timeline with any changes highlighted. The revised Anvil 4.5+4.5 documents were sent to your email on Thursday. If you need any additional information, please let me know.

Do you have a rough timeline for when you expect the first round of products (sent on 2/10-2/15) to be reviewed?

| Product Name | EPA Reg. No. | Submission Target | EPA Notes |
|---|---|---|---|
| **Natular 20EC** | **8329-106** | **02/10/21** | **Submitted** |
| NATULAR 2EC | 8329-82 | 02/10/21 | Submitted |
| Clarke Anvil 10+10 | 8329-62 | 02/10/21 | Submitted |
| Clarke Anvil 2+2 | 8329-61 | 02/10/21 | Submitted |
| **Merus 3.0** | **8329-108** | **02/15/21** | **Submitted** |
| **Anvil 2+2** | **1021-1687-8329** | **03/02/21** | **Submitted** |
| **Anvil 10+10** | **1021-1688-8329** | **03/02/21** | **Submitted** |

| | | | |
|---|---|---|---|
| **Aqua Anvil** | **1021-1807-8329** | **03/02/21** | **Submitted** |
| Biomist 3+15 ULV | 8329-33 | 03/09/21 | Submitted |
| Biomist 4 + 12 ULV | 8329-34 | 03/09/21 | Submitted |
| Biomist 4+4 ULV | 8329-35 | 03/09/21 | Submitted |
| Biomist 1.5 + 7.5 ULV | 8329-40 | 03/09/21 | Submitted |
| **Biomist 30+30 ULV** | **8329-42** | **03/09/21** | Submitted |
| **ULV Mosquito Master 412** | **8329-36** | **03/19/21** | |
| **Permethrin 57% OS** | **8329-44** | **03/19/21** | |
| **Flit 10 EC (repack)** | **432-1132 (8329-67)** | **03/19/21** | |
| **Natular SC Sub Reg/Spinosad SC ML** | **62719-748-8329 (8329-117)** | **03/12/21** | **Submitted** |
| **Duet** | **1021-1795-8329** | **03/11/21** | **Submitted** |
| **Aqua Halt** | **1021-1803-8329** | **03/11/21** | **Submitted** |
| Anvil 4.5+4.5 ULV | 8329-RRI | 03/11/21 | Submitted |
| **Duet HD** | **8329-105** | **03/31/21** | |
| **Mosquitomist TWO ULV** | **8329-18** | **03/31/21** | |
| Mosquitomist 1.5 ULV | 8329-20 | 03/31/21 | |
| Mosquitomist One ULV | 8329-24 | 03/31/21 | |
| **Cocobear** | **8329-93** | **03/31/21** | |
| **Aqua Duet** | **1021-2562-8329** | **04/07/21** | |

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**From:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Sent:** March 15, 2021 1:34 PM
**To:** Leisha Schumacher <lschumacher@clarke.com>
**Cc:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Hi Leisha and Karen,

I'm going through all of my notes and trying to keep all of your submissions organized. Please confirm the column I added to your tracking table is correct.

Many thanks,
Jackie

| Product Name | EPA Reg. No. | Submission Target | EPA Notes |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Natular 20EC** | **8329-106** | **02/10/21** | **Submitted** |
| NATULAR 2EC | 8329-82 | 02/10/21 | Submitted |
| Clarke Anvil 10+10 | 8329-62 | 02/10/21 | Submitted |
| Clarke Anvil 2+2 | 8329-61 | 02/10/21 | Submitted |
| **Merus 3.0** | **8329-108** | **02/15/21** | **Submitted** |
| **Anvil 2+2** | **1021-1687-8329** | **03/02/21** | **Submitted** |
| **Anvil 10+10** | **1021-1688-8329** | **03/02/21** | **Submitted** |
| **Aqua Anvil** | **1021-1807-8329** | **03/02/21** | **Submitted** |
| Biomist 3+15 ULV | 8329-33 | 03/08/21 | Submitted |
| Biomist 4 + 12 ULV | 8329-34 | 03/08/21 | Submitted |
| Biomist 4+4 ULV | 8329-35 | 03/08/21 | Submitted |
| Biomist 1.5 + 7.5 ULV | 8329-40 | 03/08/21 | Submitted |
| **Biomist 30+30 ULV** | **8329-42** | **03/08/21** | Submitted |
| **ULV Mosquito Master 412** | **8329-36** | **03/12/21** | |
| **Permethrin 57% OS** | **8329-44** | **03/12/21** | |
| **Flit 10 EC (repack)** | **432-1132 (8329-67)** | **03/15/21** | |
| **Natular SC Sub Reg/Spinosad SC ML** | **62719-748-8329 (8329-117)** | **03/19/21** | **Submitted** |
| **Duet** | **1021-1795-8329** | **03/15/21** | **Submitted** |
| **Aqua Halt** | **1021-1803-8329** | **03/15/21** | **Submitted** |
| Anvil 4.5+4.5 | 8329-RRI | 03/26/21 | |
| **Duet HD** | **8329-105** | **03/31/21** | |
| **Mosquitomist TWO ULV** | **8329-18** | **03/31/21** | |
| Mosquitomist 1.5 ULV | 8329-20 | 03/31/21 | |
| Mosquitomist One ULV | 8329-24 | 03/31/21 | |
| **Cocobear** | **8329-93** | **03/31/21** | |
| **Aqua Duet** | **1021-2562-8329** | **04/07/21** | |

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**From:** Herrick, Jacquelyn
**Sent:** Monday, March 15, 2021 11:48 AM
**To:** Leisha Schumacher <lschumacher@clarke.com>
**Cc:** Karen Larson <klarson@clarke.com>
**Subject:** RE: Spinosad SC ML Revised Packaging

Thank you for the notice Leisha!

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**From:** Leisha Schumacher <lschumacher@clarke.com>
**Sent:** Monday, March 15, 2021 9:17 AM
**To:** Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
**Cc:** Karen Larson <klarson@clarke.com>
**Subject:** Spinosad SC ML Revised Packaging

Good morning Jackie,

Corteva submitted an R340 amendment for Spinosad SC ML (62719-748) on Friday March 12th. The submission reference is CDX_2021002855; BU-1033868. This is for support of Clarke's registrations for Natular SC (62719-748-8329) and Natular SC Mosquito Larvicide (8329-117).

Sincerely,

**Leisha Schumacher** (Abel)
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