Message

From: Ozmen, Shamus [Ozmen.Shamus@epa.gov]
Sent: 3/3/2021 8:35:36 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]
CC: Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Lara, Rhina [Lara.Rhina@epa.gov]
Subject: RE: CDX PSP Package Transmitted to OPP
Attachments: PFAS Pesticide Packaging, Web clean.docx; PFAS Pesticide Packaging, Web tracked changes.docx; Q&As PFAS in Packaging internal.docx

Thanks Mike.

Ex. 5 Deliberative Process (DP)

Thanks,
Shamus

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Wednesday, March 3, 2021 1:51 PM
To: Ozmen, Shamus <Ozmen.Shamus@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>
Subject: FW: CDX PSP Package Transmitted to OPP

Hi Shamus

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Tuesday, March 02, 2021 7:19 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Rosenblatt,

Daniel <Rosenblatt.Dan@epa.gov>
Cc: Goodis, Michael <Goodis.Michael@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Shamus Ozmen <shamusozmen@gmail.com>
Subject: FW: CDX PSP Package Transmitted to OPP

fyi

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Karen Larson <klarson@clarke.com>
Sent: Friday, February 26, 2021 3:46 PM
To: Messina, Edward <Messina.Edward@epa.gov>
Subject: RE: CDX PSP Package Transmitted to OPP

Hi Ed,

I want to thank you for encouraging the team to proceed with our PRIA submissions with expediency. We are in quality review of the next round of submissions to RD next week, have sourced steel containers for early season demand, and have the new 2.5-gallon and 55-gallon plastic containers (Baritainers®) en route. As we begin to receive approvals from your office, we are ready to commercialize.

Now that I can see the light in that tunnel, wondered if you had insight as to what Clarke should be doing to collect the Anvil 10+10 product that is red tagged at our customer warehouses? Our commitment to EPA in January included that we would collaborate with EPA to make sure the Anvil 10+10 is appropriately handled.

Also, Lynn suggested you might appreciate an update on Clarke activities, other than Anvil 10+10. Below is a summary we've shared with our customers and industry partners.

1. **Clarke voluntarily ceased all sales and shipments of its products in fluorinated plastic containers.**
2. We are **transitioning all of our liquid mosquito control product packaging to a next generation technology** of non-fluorinated plastic with an improved environmental profile. We are presently completing storage stability evaluations for US EPA submission.
3. We **analytically confirmed the new container to be free of PFAS**. In making our container selection, it was also key that the containers be returnable, refillable and, at end of life, recyclable.
4. We are working with our suppliers of distributed products to understand their container solutions.
5. We have implemented a **voluntary product exchange program.** Any U.S. customer with inventory of any liquid Clarke Mosquito Control product in a fluorinated container can exchange this material for fresh material in non-fluorinated packaging. The decision to steward in this way was easy; the implementation is difficult. Clarke is doing this to allow our customers to conduct important mosquito control operations during the 2021 season without potential distraction related to Clarke product packaging.

Thank you & stay well,
Karen

From: Messina, Edward <Messina.Edward@epa.gov>
Sent: Thursday, February 18, 2021 4:26 PM
To: Karen Larson <klarson@clarke.com>; Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>
Cc: Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Subject: RE: CDX PSP Package Transmitted to OPP

Thanks. Happy to chat further. Do you want to set something up for next week?

Ed

Ed Messina, Esq.
Acting Office Director
Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Karen Larson <klarson@clarke.com>
Sent: Tuesday, February 16, 2021 10:01 AM
To: Herrick, Jacquelyn <Herrick.Jacquelyn@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Subject: RE: CDX PSP Package Transmitted to OPP

Good morning, Jackie & Ed

I know that Jackie was out of office on the day of our submission, and yesterday was a Federal holiday – so I'm checking in again to confirm that our submission made it past front end. Will the agency (is it possible to) begin the review of the submission and provide feedback/questions ahead of the completion of a 21-day screen?

Our 2nd submission, for our Merus 3.0 was submitted yesterday (MERUS 3.0: CDX_2021_001618), and we hope to have a batch of a dozen more early next week. All of these products in the early submissions have demand in the small-volume containers (2.5 gal, 10L), for which a steel drum option is not viable. Those that are available only in drums have more commercial flexibility and will be submitted later (in about 3 weeks). To date, we have been very impressed with the performance of the all of the containers tested.

In full transparency, Clarke has initiated a voluntary exchange program for all of its products packaged in fluorinated HDPE, and we aim to replenish material in the field for our users before the season's start. This week's snow storm has helped, but only by a wisp. We expect we will need to fill packages and get these ready for distribution in 4 weeks' time if we are to meet the needs of the mosquito control districts and programs in the south.

If you or the team have any questions about the submission packages, or feedback on what we might do differently to streamline the next submission, I am all in and will be available to a phone call or meeting at any time. The best number is always the cell# 630-675-0936.

(Ed – the COO of the company providing the packaging Clarke has been evaluating attended the CLA/RISE webinar last week and may reach out to you)

Thank you & Stay warm,
Karen

Karen Larson
Vice President
Product Innovation & Government Affairs

clarke
675 Sidwell Court
St. Charles, Illinois 60174
U.S.A.
Office: 630-671-3123
www.clarke.com

From: Karen Larson
Sent: Wednesday, February 10, 2021 1:57 PM
To: Herrick, Jacquelyn (Herrick.Jacquelyn@epa.gov) <Herrick.Jacquelyn@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>
Subject: FW: CDX PSP Package Transmitted to OPP

Good afternoon, Jackie

I am forwarding the submission record and tracking numbers for the first bundled Clarke submission with the new alternative packaging. We will have another submitted early next week, and hope to complete the submissions by end of month.

McLaughlin Gormley King (EPA Co. No. 1021) will be submitting within the next day or two 3 submissions citing (with permission, of course) the study included in this package.

I look forward to your feedback on the submission format. If there is anything Clarke can do differently in the formatting of the submission to streamline the reviews, please let us know. We are anxious to onboard the new packaging that has, so far, met all of our needs and expectations.

Thank you, and stay well
Karen

Karen Larson
Vice President
Product Innovation & Government Affairs

clarke
675 Sidwell Court
St. Charles, Illinois 60174
U.S.A.
Office: 630-671-3123
www.clarke.com

From: Leisha Schumacher <lschumacher@clarke.com>
Sent: Wednesday, February 10, 2021 12:32 PM

To: Karen Larson <klarson@clarke.com>
Cc: Nandita Chowdhury <nchowdhury@clarke.com>; Josie Belter <jbelter@clarke.com>
Subject: FW: CDX PSP Package Transmitted to OPP

It is done! Phase 1 (a) has been submitted ☺

Leisha Schumacher (Abel)
Senior Regulatory Specialist
label@clarke.com
630-671-3152
675 Sidwell Court
St. Charles, IL 60174

From: helpdesk@epacdx.net <helpdesk@epacdx.net>
Sent: February 10, 2021 12:07 PM
To: Leisha Schumacher <lschumacher@clarke.com>
Subject: CDX PSP Package Transmitted to OPP

Your PSP package (Packaging Phase 1) for Clarke Mosquito Control Products, Inc. (8329) has been successfully transmitted to OPP.

Below are the application(s) included in this package and their tracking number(s):
CLARKE ANVIL 10-10 ULV: CDX_2021_001466
CLARKE ANVIL 2-2 ULV: CDX_2021_001467
NATULAR 2 EC: CDX_2021_001468
NATULAR 20 EC: CDX_2021_001469
NATULAR SC Mosquito Larvicide: CDX_2021_001470

Company Name: Clarke Mosquito Control Products, Inc.
Company Number: 8329

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
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