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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Novaluron:** Transmittal of Data Evaluation Records (DERs) for Four Environmental Chemistry Method Studies

FROM: He Zhong, Ph.D., Biologist HE ZHONG Digitally signed by HE ZHONG Date: 2021.09.22 14:21:31 -04'00'
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

THRU: Sujatha Sankula, Branch Chief 2021.09.24 10:59:31 -04'00'
Gregory Orrick, Risk Assessment Process Leader 2021.09.23 16:30:46 -04'00'
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

TO: Robert Little, Chemical Review Manager
Nicole Zinn, Team Leader
Kevin Costello, Branch Chief
Risk Management and Implementation Branch 2
Pesticide Re-evaluation Division (7508P)

This memorandum finalizes Data Evaluation Records (DER) for four Environmental Chemistry Method (ECM) and Independent Laboratory Validation (ILV) studies for analytical methods in water for novaluron (MRID 51561792 and 51561601) and its degradates phenyl urea (CPU) and aniline (CLA) (MRID 50610215 and 51561701). These methods were submitted to the EPA in support of registration review. The chemistry methods analyze novaluron and its degradates by LC-MS/MS with ion pair transitions *m/z* 493.0→158.1 for novaluron quantitation (Q) and *m/z* 493.0→141.0 for novaluron confirmation (C), with ion pair transitions *m/z* 353.0→275.2 (Q) and *m/z* 353.0→108.1 (C) for CPU, and with ion pair transitions *m/z* 310.1→108.0 (Q) and *m/z* 310.1→127.2 (C) for CLA. Reported retention times are *ca.* 3.4, 2.9 and 3.2 minutes for novaluron, CPU and CLA, respectively in the ECM studies and 4.1, 2.5, 2.9 minutes for novaluron, CPU and CLA, respectively in the ILV studies.

The limit of quantification (LOQ) is 0.010 µg/L in water for novaluron, which is less than the lowest toxicological level of concern of 0.026 µg/L for estuarine/marine invertebrates (MRID 45638212). The degradates CPU and CLA are residues of concern (ROCs) for human health drinking water exposure assessment but not for ecological risk assessment. The LOQs for CPU and CLA in water are 0.10 µg/L, which are less than the human health benchmark for novaluron, 65 µg/L. EFED concludes that the analytical methods in water for novaluron and its degradates were validated by the corresponding ILVs and the studies are classified as **acceptable**. The classification and results of each study are summarized in **Table 1**.

Table 1. Summary of Analytical Method Studies for Novaluron, CPU, and CLA

MRID		Analytes	Matrices	Limit of Detection (LOD)	Limit of Quantitation (LOQ)	Study Classification
Environmental Chemistry Method	Independent Laboratory Validation					
51561702	51561601	Novaluron	Water	0.004 µg/L	0.010 µg/L	**Acceptable**
50610215	51561701	CPU	Water	0.072 µg/L	0.10 µg/L	**Acceptable**
		CLA	Water	0.011 µg/L	0.10 µg/L	

References

MRID 51561702 Cashmore, A., and O. Idialu. 2020. Validation of the Analytical Method for the Determination of Novaluron in Aqueous matrices by LC-MS/MS. Report prepared by Smithers ERS Limited, North Yorkshire, United Kingdom, sponsored by ADAMA Makhteshim Ltd., Beer Sheva, Israel, and submitted by Agan Chemical Manufacturers, Ltd., c/o Makhteshim-Agan of North America, Inc. (d/b/a ADAMA), Raleigh, North Carolina; 66 pages. Study No.: 3202771. Sponsor Reference No.: 000106386. Final report issued December 1, 2020.

MRID 51561601 Dwamena, A.K. 2021. Independent Laboratory Validation of the Analytical Method For Determination of Novaluron in Aqueous Matrices by LC-MS/MS. Report prepared by Smithers, Wareham, Massachusetts, sponsored by ADAMA Makhteshim Ltd., Beer-Sheva, Israel, and submitted by Agan Chemical Manufacturers, Ltd., c/o Makhteshim-Agan of North America, Inc. (d/b/a ADAMA), Raleigh, North Carolina; 65 pages. Smithers Study No.: 14125.6133. Final report issued April 29, 2021.

MRID 50610215 Reibach, P. 2018. Validation of the Analytical Method for the Determination of Novaluron and its Degradates in Aqueous Matrices by LC-MS/MS. Report prepared by Smithers Viscient, Wareham, Massachusetts, sponsored by ADAMA Agricultural Solutions, Ltd., Israel, and submitted by Agan Chemical Manufacturers, Ltd., c/o Makhteshim-Agan of North America, Inc. (d/b/a ADAMA), Raleigh, North Carolina; 121 pages. Smithers Viscient Study No.: 14125.6100. Sponsor Protocol/Project No.: R-38356. Final report issued May 22, 2018.

MRID 51561701 Cashmore, A., and O. Idialu. 2020. Independent Laboratory Validation of Analytical Method 14125.6100 for the Determination of Novaluron Degradates CPU and CLA in Water. Report prepared by Smithers ERS Limited, North Yorkshire, United Kingdom, sponsored by ADAMA Makhteshim Ltd., Beer Sheva, Israel, and submitted by Agan Chemical Manufacturers, Ltd., c/o Makhteshim-Agan of North America, Inc. (d/b/a ADAMA), Raleigh, North Carolina; 95 pages. Study No.: 3202770. Final report issued November 10, 2020.