UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

February 22, 2016

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 91399-E
Product Name: Biotab7
DP Barcode: 429875

Lynette T. Umez-Eronini

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Demson Fuller PM #32/Srinivas Gowda
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Advanced Biocide Technologies Inc.

CODE: A540 New Product; Non-Fast Track;

DATE DUE: March 23, 2016

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium chlorite	20
Other Ingredients:	80
Total:	100

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DP BARCODE:	429875
MRID:	49742100, 49742101, and 49742102
SUBJECT:	Biotab7
REG. NO.:	91399-E
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
020502	7758-19-2	Sodium chlorite

TEST LAB:	Case Consulting Laboratories, Inc.
SUBMITTER:	Technology Sciences Group Inc.
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	February 22, 2016
COMMENT:	This product is for non-food use.

BACKGROUND:

The consultant, Technology Sciences Group Inc., on behalf of the registrant, Advanced Biocide Technologies Inc. has submitted an application for registration of an end-use non-integrated product called Biotab7. The application was initially submitted under the product name, Oxytab. Advanced Biocide submitted a request via email on August 26, 2015 to change the name. This product is a cleaner, disinfectant and deodorant for use on hard non-porous and non-food contact surfaces. The product is for non-food use.

The product chemist reviewed the following documents:

1. Cover letter from the registrant to EPA, 10/23/2015.
2. EPA Form 8570-1- Application for Pesticide Registration, 10/23/2015.
3. EPA Form 8570-4 - Basic Confidential Statement of Formula (CSF), 10/23/2015.
4. EPA Form 8570-34 - Certification with Respect to Citation of Data, 10/23/2015.
5. EPA Form 8570-27 - Formulator's Exemption Statement, 10/23/2015.
6. EPA Form 8570-35 – Data Matrix (confidential and releasable versions), 10/23/2015, 3 pages each.
7. Product Label, 10/23/2015.
8.

MRID	Citation
49742100	Advanced Biocide Technologies, Inc. (2015) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Biotab7. Transmittal of 11 Studies.
49742101	Velea, L. (2015) Product Chemistry of Biotab7 - Group A. Unpublished study prepared by Technology Sciences Group Inc. 145p.
49742102	Velea, L. (2015) Product Properties of Biotab7 - Group B. Project Number: 5920/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 14p.

FINDINGS:

1. The nominal concentration of the active ingredient on the Basic CSF is consistent with the label.
2. All ingredients in this formulation are approved for use in pesticide formulations.
3. The active source is EPA registered.
4. Certified limits of all the ingredients are within the EPA Standard Certified Limits.
5. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 49742101 and Table A below).

6. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 49742102 and Table B below), with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) studies. Said studies are pending.

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Basic CSF, 10/23/2015 to be acceptable. Group A Product Chemistry data requirements have been met. Group B Product Chemistry data requirements have been met, with the exception of with the exception of OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) studies. The unmet requirement must be sent upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes [X] No [ ]
- Are all TGAIs used registered? Yes [ ] No [X]
- Integrated formulation system Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Solid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Sodium chlorite	20	19.00	21.00

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [X]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49742101
830.1600 Description of Materials	A	49742101
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	49742101
830.1670 Formation of Impurities[4]	NA	
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	A	49742101
830.1800 Enforcement Analytical Method[7]	A	49742101
830.1900 Submittal of Samples	A	49742101

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Solid	49742102
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Product is reactive to water and potassium permanganate and results in bubbling and noxious fumes; After 24h, product is not reactive to water and potassium permanganate. Product is nonreactive to monoammonium phosphate and powdered iron.	49742102
830.6315 Flammability/ Flame Extension	A	Not Applicable - Product contains no ingredients that are flammable or that will support combustion.	49742102
830.6316 Explodability	A	Not Applicable – Product does not contain any functional groups, such as nitro groups, that would confer explosive potential.	49742102
830.6317 Storage Stability	G	Study is underway and results will be reported when the study is complete.	49742102

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6319 Miscibility[1]	A	Not Applicable – Guideline is applicable when product is an emulsifiable liquid to be used with petroleum solvents. Product is miscible with water so this parameter is not relevant.	49742102
830.6320 Corrosion Characteristics	G	Study is underway and results will be reported when the study is complete.	49742102
830.6321 Dielectric Breakdown Voltage	A	Not Applicable - Product is not intended to be used on or in the vicinity of electrical equipment or electrical conduits.	49742102
830.7000 pH[2]	A	2.30, 1% solution at 25°C	49742102
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity (Kinematic)	A	Waiver: Guideline is required when the product is a liquid. Product is a solid, so this parameter is not relevant.	49742102
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	2.21 g/ml (18.47 lbs/gallon) at 25°C	49742102
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water