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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 7 1998

MEMORANDUM

SUBJECT: Registration of Fortune Aza 3% EC® Containing 3% Azadirachtin (File Symbol 71038-U), Chemical No. 121701; Review of Product Chemistry Data; MRID Nos. 443655-01 and 443655-02; Submission No. S536030; DP Barcode No. 242258

FROM: Freshteh Toghrol, Ph.D., Senior Scientist F. Toghrol
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511W)

TO: Rita Kumar, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511W)

ACTION REQUESTED

Fortune Biotech Limited requests registration of Fortune Aza 3% EC® (File Symbol 71038-U). Fortune Aza 3% EC® is an end-use product containing 3% Azadirachtin as its active ingredient and 97% of inert ingredients or other ingredients.

To support this registration, Fortune Biotech Ltd., has submitted product chemistry data (MRID No. 443655-01 and -02), a proposed label a Confidential Statements of Formula dated August, 1997, for the end-use product (EPA Symbol No. 71038-U).

BPPD'S CONCLUSIONS AND RECOMMENDATIONS

1. An exemption from the requirement of a tolerance is established for the biochemical Azadirachtin, when used as a pesticide at application rates of 20 grams or less per acre on all raw agricultural commodities (40 CFR §180.1119).

2. The submitted product chemistry data satisfy the data requirements for Fortune Aza 3% EC® (EPA File Symbol 71038-U). The upper limit of aflatoxin was reported at [redacted] Neem seeds contain large amount of moisture, fungi will grow during

Manufacturing process information may be entitled to confidential treatment

the collection and storage of the seeds. If these fungi replicate and produce aflatoxin, the safety of the product will be compromised. Therefore, the registrant must develop a quality control (QC) and quality assurance (QA)program to be used during manufacturing of each batch of this product to examine the manufactured product for the presence of mycotoxin/aflatoxin producing fungi.

3. The submitted data satisfy the data requirement regarding product identity (151-10), manufacturing process (GLN 151-11), discussion of formation of unintentional ingredients (GLN 151-12), analysis of samples (151-13), certification of ingredient limit(151-15), and physical/chemical characteristics (151-17).

4. The submitted CSF for Fortune Aza 3% EC is acceptable. All inert ingredients used in the end-use product are cleared by the Agency for food-use.

Note To RAL

All CSF's for end-use products are subject to change based on the revised CSF for the technical, for example for Fortune 3% based on calculation (14X 18.7/100) is 2.61% and not 3%.

cc: F. Toghrol, Rita Kumar, BPPD Subject file.
F. Toghrol, CS#1 BPPD: Tel (703) 308-7014:7/7/98

DATA EVALUATION REPORT

FORTUNE AZA 3% EC

STUDY TYPE: Product Identity and Disclosure of Ingredients (§151-10)
Description of Beginning Materials and Manufacturing Process (§151-11)
Discussion of Formation of Impurities (§151-12)
Preliminary Analysis of Product Samples (§151-13)
Certification of Ingredient Limits (§151-15)

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Station I
2800 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 20

Primary Reviewer:
Robin Brothers, Ph.D.

Signature: Robin Brothers
Date: 5-11-98

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature:
Date: 5-11-98

Robert H. Ross, M.S., Group Leader

Signature: H T Bonga
Date: 5-11-98

Quality Assurance
Lee Ann Wilson, M.S.

Signature: L. A. Wilson
Date: 5-11-98

Disclaimer

This Data Evaluation Report may have been altered by the BPPD subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

FORTUNE AZA 3%EC
MRID 44365501

Product Identity and Disclosure of Ingredients (§151-10)
Description of Beginning Materials and Manufacturing Process (§151-11)
Discussion of Formation of Impurities (§151-12)
Preliminary Analysis of Product Samples (§151-13)
Certification of Ingredient Limits (§151-15)

EPA Reviewer: Freshteh Toghrol, Ph.D. F. Toghrol Date: 6/24/98
Biopesticide & Pollution Prevention Division (7511W)

DATA EVALUATION REPORT

STUDY TYPES: Product Identity and Disclosure of Ingredients (§151-10)
Description of Beginning Materials and Manufacturing Process (§151-11)
Discussion of Formation of Impurities (§151-12)
Preliminary Analysis of Product Samples (§151-13)
Certification of Ingredient Limits (§151-15)

CASE NO.: 062088

PC CODE: 121701

DP BARCODE: D242258

MRID NO.: 44365501

TEST MATERIAL: FORTUNE AZA 3%EC (active ingredient, Azadirachtin 3%)

SYNONYMS: Not provided

STUDY NUMBER: Not provided

SPONSOR: Fortune Biotech Limited, 6-6-125, Annam Gardens, Kavadiguda, Secunderabad, 500 380, India

TESTING FACILITY: Not provided

TITLE OF REPORT: FORTUNE AZA 3% EC: Manufacturing Data Volume

AUTHORS: D.J. Brookman and K.K. Curry

REPORT ISSUED: August 1, 1997

EXECUTIVE SUMMARY: The product identity, ingredients, certified ingredient limits, manufacturing process, and discussion of formation of impurities of FORTUNE AZA 3% EC are given in MRID 44365501. The active ingredient of FORTUNE AZA 3% is Azadirachtin which consists of Azadirachtin A and Azadirachtin B. The source for Azadirachtin is the manufacturing-use product, FORTUNE AZA Technical, which is a natural product derived from neem seeds. FORTUNE AZA 3% EC is a formulationconsisting of Azadirachtin, and the inert ingredients [redacted] The impurities listed are naturally occurring compounds likely to occur with the neem seed extract. The certified limits (weight %, upper, lower) for the ingredients are: Azadirachtin-active ingredient, (3.75%, 2.25%), inert ingredients from manufacturing-use product [redacted]

Inert ingredient information may be entitled to confidential treatment

FORTUNE AZA 3%EC
MRID 44365501

Product Identity and Disclosure of Ingredients (§151-10)
Description of Beginning Materials and Manufacturing Process (§151-11)
Discussion of Formation of Impurities (§151-12)
Preliminary Analysis of Product Samples (§151-13)
Certification of Ingredient Limits (§151-15)

[redacted] Aflatoxins may be present in neem seeds and are restricted to an upper limit in FORTUNE AZA 3% EC of [redacted] A method for the certification of the limits of Azadirachtin by HPLC is given. The potential for the formation of unintentional ingredients is unlikely. Preliminary analysis of FORTUNE AZA 3% was not performed because it is produced from a characterized manufacturing-use product, FORTUNE AZA Technical.

Classification of the study - Acceptable.

COMPLIANCE: Signed and dated Data Confidentiality and GLP Statements were provided. GLP requirements were not met because the data are descriptive and do not report laboratory work, and there was no study director assigned to this work. No Quality Assurance Statement was provided.

A. PRODUCT IDENTITY AND DISCLOSURE OF INGREDIENTS (151-10)

FORTUNE AZA 3% EC is an emulsifiable liquid end-use product with activity as an insecticide, nematicide and fungicide. The active ingredient of Azadirachtin, consists of Azadirachtin A and Azadirachtin B. Azadirachtin is supplied from the manufacturing-use product, FORTUNE AZA Technical, a natural product derived from neem seeds. The relative amounts of Azadirachtin A and Azadirachtin B may vary from batch to batch therefore, the sum of both Azadirachtins is used for active ingredient identity. [redacted] intentionally-added inert ingredients are used: [redacted]

B. DESCRIPTION OF BEGINNING MATERIALS AND MANUFACTURING PROCESS (151-11)

[redacted]

C. DISCUSSION OF FORMATION OF IMPURITIES (151-12)

[redacted]

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

D. PRELIMINARY ANALYSIS OF PRODUCT SAMPLES (151-13)

The end-use product is made from a characterized manufacturing-use product and was not required.

E. CERTIFICATION OF LIMITS (151-15)

Ingredient	Certified Limits (% w/w) Upper	Lower
Azadirachtin [CAS Nos. 11141-17-6, 95507-03-2]	3.75	2.25
[redacted]		

An HPLC method using a reversed-phase column and an external standard is described. The mobile phase was methanol:water (60:40 v/v). Methanol is the solvent for weighed samples of FORTUNE AZA 3% EC. The analysis was for Azadirachtin, the active ingredient.

F. DISCUSSION

All of the necessary information was presented to fulfill the appropriate guideline requirements. Preliminary analysis of FORTUNE AZA 3% was not performed because it is produced from a characterized manufacturing-use product, FORTUNE AZA Technical.

G. STUDY DEFICIENCIES

GLP requirements were not met and no Quality Assurance Statement was provided; these do not invalidate the study results.

Classification: Acceptable

DATA EVALUATION REPORT

FORTUNE AZA 3% EC

STUDY TYPE: PHYSICAL AND CHEMICAL CHARACTERISTICS (§151-16)

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Station 1
2800 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37930
Task Order No. 20

Primary Reviewer: Robin Brothers, Ph.D.	Signature: Date:	Robin Brothers 9-11-98
Secondary Reviewers: Sylvia Milanez, Ph.D., D.A.B.T.	Signature: Date:	9-11-98
Robert H. Ross, M.S., Group Leader	Signature: Date:	9-11-98
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson 9-11-98

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

FORTUNE AZA 3%EC **Physical and Chemical Characteristics (§151-16)**
MRID 444365502

EPA Reviewer: Freshteh Toghrol, Ph.D.
Biopesticides and Pollution Prevention (7511W)

F. Toghrol, Date 6/24/98

DATA EVALUATION REPORT

STUDY TYPE: Physical and Chemical Characteristics (§151-16) OPPTS 8300.6302 - 830.7050

P.C. CODE: 121701

DP BARCODE: D242258

CASE: 062088

SUBMISSION: S536030

MRID NO.: 44365502

TEST MATERIAL: Fortune AZA 3% EC (active ingredient, Azadirachtin 3%)

SYNONYMS: Not given

SPONSOR: Fortune Biotech Limited, 6-6-125, Annam Gardens, Kavadiguda, Secunderabad, 500 380 India

TESTING FACILITY: Not provided

TITLE OF REPORT: Fortune AZA 3% EC: Physical and Chemical Characteristics

AUTHORS: D J. Brookman and K.K. Curry

STUDY COMPLETED ON: August 1,1997

EXECUTIVE SUMMARY: The physical and chemical characteristics of Fortune AZA 3% EC were reported in MRID 44365502. Fortune AZA 3% EC is an end-use product which contains Azadirachtin as the active ingredient. Azadirachtin consists of the biologically active-ingredients Azadirachtin A and Azadirachtin B. The analytical methods used to determine the physical and chemical characteristics were appropriate for the purposes of this study.

Classification of the Study: Acceptable

COMPLIANCE: *Good Laboratory Practices were not followed. The study was not intended to support* product registration. Data Confidentiality statements were provided.

A. PHYSICAL AND CHEMICAL CHARACTERISTICS (§151-16)

Physical State: liquid, observed at 30°C.

Density, Bulk Density, Specific Gravity :1.064 g/mL determined at 27°C

pH: 5.3, *temperature of test not given.*

Oxidizing or Reducing Action: None of the components of Fortune AZA 3% EC are expected to have any particular ability to act as an oxidant or reductant.

Flammability: Flash point greater than 100°C.

Explodability: No explosive potential.

Storage Stability: The active ingredient will be stable for at least 12 months of storage under ambient conditions.

Viscosity: 530 cP at 27°C

Miscibility: The end-use product was miscible with crop oil and water when prepared according to label directions (Fortune AZA 3.0%EC : crop oil :water, 1.76:1.0:97.24 (v/v/v).

Corrosion Characteristics: Fortune AZA 3% EC and other end-use products similar to Fortune AZA 3% have been stored in HDPE containers for one year. No deterioration of the containers was reported.

Dielectric Breakdown Voltage: Not applicable (product is not expected to be used for electrical products).

B. DISCUSSION

All of the necessary information was presented.

C. STUDY DEFICIENCIES

GLP were not used. No temperature was given for the pH test.

Classification of Study: Acceptable

Confidential Statement of Formula may be entitled to confidential treatment

13544

R142060

Chemical:	**Azadirachtin**
	PC Code: 121701
HED File Code:	**41500 BPPD Tox/Chem**
Memo Date:	**7/7/1998**
File ID:	**DPD242258**
Accession #:	**000-00-9002**

HED Records Reference Center
4/13/2007