OKADA ECOTECH PTE LTD (REG NO 199805584M)
55 Ayer Rajah Crescent
#03-19/23
Singapore 139949

5th Oct 2009

To whom it May Concern

Subject: Bioact- T™ WS500 and Biovectrol™ 500WS

Okada Ecotech Pte Ltd is the registered trademark owner of **Bioact- T™** and **Biovectrol™.**

Please also be informed that, for marketing reasons, we have decided to re-brand **Bioact- T™ WS 500** as **Biovectrol™ 500WS.**

We confirm herein that both **Bioact- T™ WS 500** and **Biovectrol™ 500WS** are identical products- manufactured under the same process and factory site, share the same formula and contain the same ingredients, strengths and packaging materials.

We trust the above clarifies our position vis-à-vis these two products, Should you require further clarifications, we would be very pleased to hear from you.

Yours Truly,
OKADA ECOTECH PTE LTD

KE TAN (MR)
Managing Director

Documents for Biovectrol 500WS

Registration of Pesticides Products with FPA Philippines

1. GENERAL

1.1 Name/Address of Applicant:

1.2 Product Trade/Brand Name : Biovectrol 500WS

1.3 Manufacturer of Technical Pesticide: EID Parry (India) Limited

1.4Description of Production Process: See Attached Production Flow Chart

2. SPECIFICATIONS

2.1 Common Name of Active Ingredient: Azadirachtin A & B

2.2 Chemical Name of Active Ingredient(IUPAC): NA

2.3 Chemical Abstract Service Number : NA

2.4 Formula (Empirical and structural) : NA

2.5Composition of Technical Including Impurities(all materials present at or over 0.10%) :NA

2.6 List of Ingredients and percent variations of each :

Azadirachtins	5.00%w/w
Neem Extracts	7.50%
Surfactants	50.00%
Glycols	37.50%

2.7 Appearance,color,state,odor : Dark Brown Liquid with Sweet Pleasant odor

2.8 Melting Point : NA

2.9Boiling Point : NA

2.10Vapor pressure : NA

2.11 Density and Specific Gravity : 1.10+/- 0.1

2.12Octanol Partition Coefficient-half life in soil, K_{oc} organic carbon partition coefficient: NA

2.13Formulation Type (GCFP code) : Water Soluble Formula

2.14 Storage Stability : Refer to Stability Test Reports at Ambient Temperature & Elevated Temperature (54 deg C)

2.15 Solubility in water and solvents : NA

2.16 Suspensibility/Emulsfying Characteristic: Soluble in Water

2.17 Known Capability/Incompatibility with other pesticide products or Active Ingredient: Compatible with other pesticide products

2.18 Flash point and other indicators of flammability : Non Flammable

2.19 pH : NA (System is non aqueous)

2.20 Methods of destruction or disposal : Waste must be disposed of in accordance with state/ local/National regulations

2.21Packaging type, sizes and materials : Packed in HDPE bottles, Capacity 1L & 5L

2.22 Assessment of Need of Child Resistant Packaging: Advise to keep product out of Reach of Children

2.23 Analytical Method of Constituents : See Assay Method of AZA A& B Biovectrol 500WS

2.24Submittal of Product samples : 500ml

3 BIOEFFICACY (TYPICAL FORMULATIONS)

3.1 Description of mode of Action or effect on pest for which control is claimed:

~Repellency

~ Antifeedant Activity- stimulates "deterent neurons" and inhibit "attractant neurons" located on the insect's mouth parts and thus suppress insect feeding

~Insect Growth Regulation (IGR) Effects- Disrupts molting hormone secretion and release in insects and prohibits insect growth

~ Reproduction Suppression- Lowers ecdysone titres resulting in a delay in oviposition and reduction in egg production

~Insect Fitness Disruption - Complex effects involving antifeedant effects, digestion, growth or reproductive disruption and other physiological impacts make insects weak, leading to natural mortality or predispose them to insecticide, biologicals and beneficials in an agroecosystem

~ Ovicial Activity – Alteration of embryo development

~ Systemic Effects – Exhibits systemic activity when applied through soil, tree injections and seed treatment

~ Insecticide Effect Enhancement- Pests exposed exhibit a greater level of susceptibility when treated with insecticides subsequently

~ Insecticide Synergism

~ Pest Resistance Suppression – Prevent or delay insect resistance by reducing Mixed Function Oxidase (MFO) levels in insects.

~ Anti fungal properties

3.2Pest controlled /fungi and names of crops, materials or premises to be protected:

Fusarium Etc
Root knot Nematodes

3.3 Application Rate (kg ai/Ha or % ai spray dilution for each site/pest listed:

Root Feeding via root dip : 1: 200~250 dilution
Root Feeding via soil : 1: 500 dilution
Foliar Spray : 1: 500 dilution
Chemigation via drip irrigation : 1: 2000~4000 dilution

3.4 Frequency and timing of application for each site/pest listed:

Root Feeding via root dip – Before transplanting
Root Feeding via soil - 15 to 30 days interval
Foliar Spray - 5 to 15 days interval
Chemication - 15 to 30 days interval

3.5Method of Application : Root Feeding, Foliar Spraying or Chemigation

3.6Phytotoxicity : Non phytotoxic

3.7Results of Laboratory Studies: See Bioefficacy Report from Dr Pedrosa

3.8 Complete description and data from local field trials or relevant test performed abroad or requested for waiver for each site/pest on label:

Not Available

3.9 Effects on Beneficial organisms: Effect on Honey Bees ~ Harmless

Effect on Earthworms (LC 50) >1000mg/kg- safe

4.TOXICOLOCY

4.1 Estimation of Acute Oral LD50 in Rats:

See Test Report on Acute Oral Toxicity of Etogrowth EC612 by A Prof Lee How Sung from National University of Singapore (Department of Pharmacology, Faculty of Medicine)

4.2 Estimation of Acute Dermal LD50 in Ratss:

See Test Report on Acute Dermal Toxicity of Etogrowth EC612 by A Prof Lee How Sung from National University of Singapore (Department of Pharmacology, Faculty of Medicine)

4.3 Inhalation LC50 : NA

4.4Skin Irritation/Corrosivity : NA

4.5 Eye Irritation : NA

4.5.1Dermal Sensitisation : NA

4.6 Allergic Sensitisation : NA

4.7 Subchronic toxicity (21 Days, Dermal) : NA

4.7.1 Subchronic toxicity (90 Days, Oral) : NA

4.7.2 Subchronic toxicity (90 Days, Dermal) : NA

4.8 Teratology : NA

4.9 Reproduction : NA

4.10 Chronix Toxicity : NA

4.11 Oncogenicity : NA

4.12 Mutagenicity : NA

4.13 Acute delayed neurotoxicity : NA

4.13.1 Subchronic neurotoxicity : NA

4.14 Pharmacokinetics (absorption, storage, metabolism & elimination: NA

4.15 Observation on Man, if any : NA

5. HUMAN EXPOSURE AND SAFETY

5.1 Assessment of applicator exposure : Dr Pedosa to advise

5.2 Assessment of farm workere exposure : Dr Pedosa to advise

5.3 Signs and symptoms of acute human poisoning : None

5.4 Recommended first aid procedure : Skin contact~ Immediately wash with soap & water
Eye contact~ Flush eyes immediately with steady running water
If Inhaled ~ Remove victims from areas of exposure and move to fresh air
If Swallowed~ Do not induce vomiting. Drink plenty of water. Seek medical treatment

5.5 Recommended medical treatment for poisoning, include antidote if any : NA

5.6 Proposed Acceptance Intake : NA

5.7 Protective equipment : Respiratory protection~ dust respirator
Hand protection ~ Protective gloves
Eye protection ~ Safety glasses of goggles
Protective clothing~ Protective clothing, safety boots

5.8 Other precautions : Do not smoke, drink or eat during handling and application

6. ENVIRONMENTAL EFFECTS

6.1 Avian acute oral toxicity : NA

6.2 Avian dietary acuty toxicity : NA

6.3 Fish acute toxicity : NA

6.4 Subacute fish Toxicity : NA

6.5 Aquatic acute toxicity : NA

6.6 Accumulation in fish : NA

6.7 Avian reproduction : NA

6.8 Fish reproduction : NA

6.9 Acute toxicity to honey bees: LC 50 >1000mg/kg

6.10 Contact toxicity to honeybees: NA

6.11Soil non-target microorganisms: Non hazardous to microflora

6.12 Soil Non Target macroorganism:

7. RESIDUE IN FOODS
for food use only

7.1 Identity of principal residues, metabolites, degradation products in edible crops, foods or feeds : Rapid decomposition in soil
Readily Biodegradable in Water

7.2 Residue decay curves for residues on crops to be treated: NA

7.3 Residues of active ingredient and principal metabolite in animal fed treated feeds or grazed on treated fields or pastures : NA

7.4 Effects of food processing or home preparations on residues: NA

7.5Analytical method for detection of principal residues, metabolites on treated commodities: NA

7.6 Proposed Maximum residue level for each crops, food, feed or animal expected to contain residue : NA

8. ENVIRONMENT FATE AND TRANSPORT

8.1 Volatility : NA

8.2 Adsorption/Absorption: NA

8.3 Leaching : NA

8.4 Degradation in Soil : Rapid decomposition in Soil

8.5 Biodegradation : Readily biodegradable

8.6 Hydrolysis : NA

8.7 Aqueous photolysis : NA

8.8 Analytical Method-residue in Soil : NA

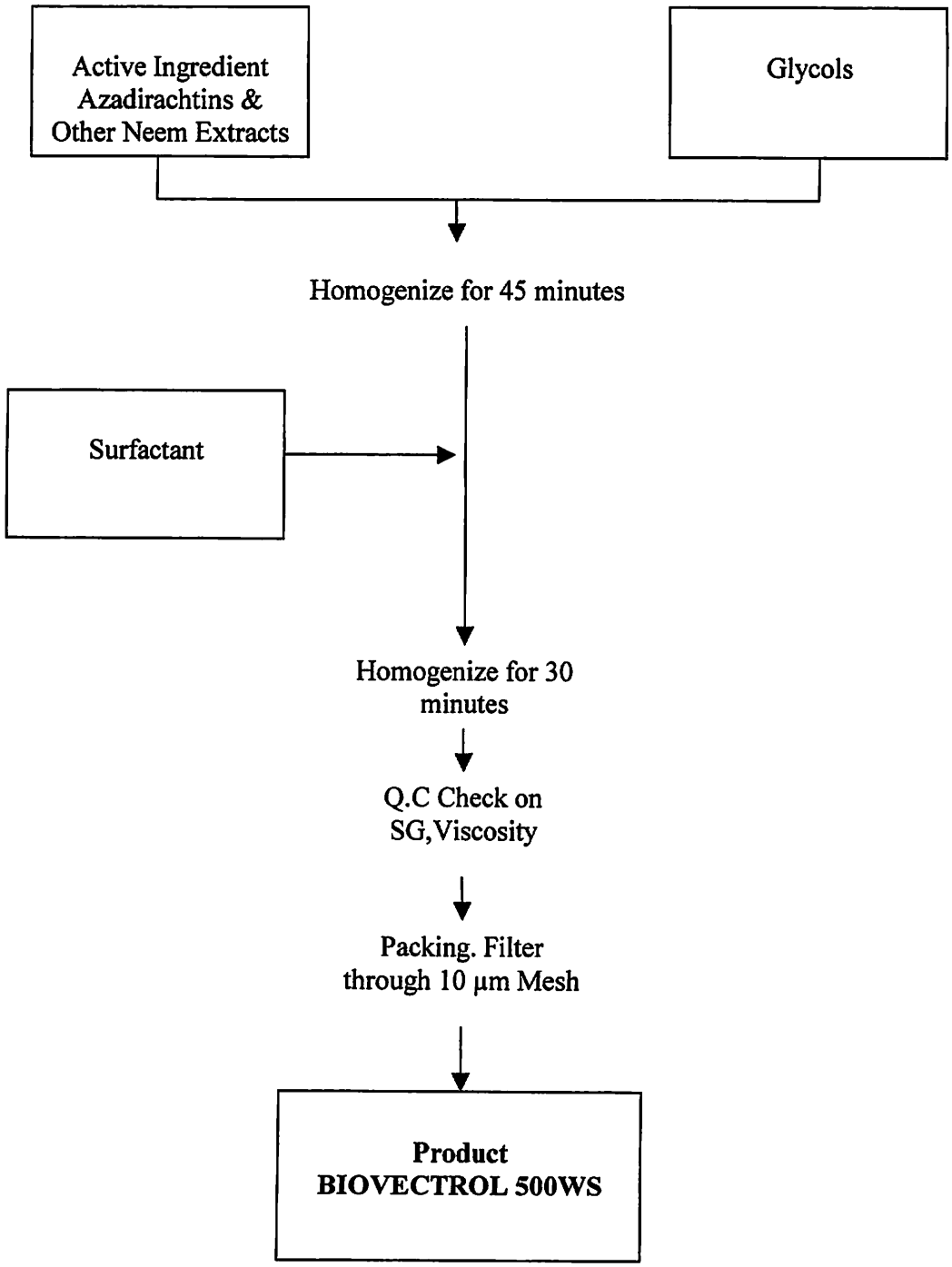
8. Analytical Method- residue in water : NA

9. LABELLING

9.1 Proposed toxicity category : Not classified in WHO Pesticide Classification

9.2 Draft Label (3 copies) : See Attached copies of Label of Biovectrol 500WS

PRODUCTION FLOWCHART
BIOVECTROL™ 500WS



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Test Data On Storage Stability of Biovectrol™ 500WS

1. Product : Biovectrol 500WS
   Batch No: 2006082201 Mfg Date : 22 Aug 2006

2. Test Results :

   Test Conditions : Stored at 54 ± 2 Deg C in 500ml wide mouth Glass Bottle

   Analytical Method :HPLC

	Starting Point	1 Week
Effective Quantity (Azadirachtins)	Initial Value	Analyzed Value
	5.12%	4.89%
	5.20	4.81
	5.18	4.92
Average	5.16	4.87
Appearance	Clear Brown Liquid	No Change

3. Conclusion: After testing for 1 week at 54 ± deg C, Azadirachtins resolution is within limits of 5 ± 0.5%. There is no visible change in appearance and color . 1 week stability of Azadirachtins in Biovectrol 500WS is equivalent to at least 1 year of shelf life at ambient temperature (30 Deg C)

Yap Mee Fah (Ms)
Technical Consultant

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STORAGE STABILITY TEST REPORT FOR BIOVECTROL™ 500WS

1. Objective

To conduct stability test of **BIOAVECTROL™ 500WS** based on national standards
(Batch No: 2006082201)

2. Materials & Methods

Stability Test should be conducted in accordance with the FAO Accelerated Storage Test Procedures usually at 54 ±2 deg C for 7 days or at ambient temperature for 1 years.

(a) FAO Accelerated Storage Test Procedure

Fill a 500ml wide-mouth glass bottle to within 1 cm of the top with the sample. Seal the bottle with a phenolic cap having a soft liner. Turn the cap firmly to ensure a a tight seal and place in an oven maintained at 54 ±2 deg C for 7 days.At the end of the heating period, remove the bottle from the oven and allow it to come to room temperature before removing the cap.

After completion of the heat stability treatment, the sample should not be exposed to heat, bright sunshine or high atmospheric humidity.

(b) Observation

Any changes in phenomenon of the tested sample, maintained at 54± 2 deg C, in the oven was monitored for 7 days. Observations were recorded daily.

3. Results & Discussion

There were no visible change in the **BIOAVECTROL™ 500WS** sample.

BIOAVECTROL™ 500WS passed the Stability Test conducted in accordance with the FAO Specifications

4. References

Interim Specifications for Pesticides used in Public Health, World Health Organization, Division of Control of Tropical Diseases, WHO Pesticide Evaluation Scheme.

Guidelines on Product Chemistry Data Requirements for Pesticide Registration, Pesticides Board, Malaysia 1993 (GP 1/93).

Guidelines on Good Labeling Practice for Pesticides, Food & Agriculture Organization of the United Nations.

Guidelines for Registration of Pesticide (Under the Control of Plants (Registration of Pesticides) Rules 1994, Veterinary Public Health & Food Supply Division, Republic of Singapore.

International Code of Conduct on the Distribution and Use of Pesticides, Food & Agriculture Organization of the United Nations, 1990.

Pesticide Analytical Manual Volume II (PAM II), February 1997.

Environment Research Foundation, Rachel's Environment & Health Weekly #469, Nov 1995.

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of the Nation's Pesticide Control Law.

U.S. EPA Office of the Inspector General, INERT INGREDIENTS OF PESTICIDES, Sept 1991.

ENVIRONMENT HEALTH PERSPECTIVES, Dangers of Household Pesticides, Vol 103 No. 6 , June 1995

Yap Mee Fah (Ms)
Technical Consultant

22/8/06
Date of Test

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Procedure for the determination of Azadirachtin (AZA)

1. The sample was well shakened and an appropriate amount was taken for analysis

2. Analysis by HPLC technique

2.1 HPLC Operating Conditions

Column : Inertsil ODS-3 4.6 x 150mm
UV detector : 215nm
Mobile Phase : Acetonitrile: Water (35:65)
Injection Volume: 20 µl
Flow rate : 1.0 ml/min

2.2 Determination

1. One point calibration (150ppm) was prepared using the CRM material
2. The standard solution was injected into the HPLC and the area of the standard peak was recorded.
3. The sample solution was prepared and injected into the HPLC under the same condition.
4. The result of AZA was calculated by direct proportion of the area of sample versus area of standard.

REPORT ON ACUTE ORAL TOXICITY TEST: FIXED DOSE PROCEDURE – Bioact-T WS500
Batch no: BN2006082801
Manufacture Date: 28/08/2006
Sponsor: OKADA ECOTECH PTE LTD, Blk 1 Pasir Panjang Road #07-15/17, Alexandra Distripark, Singapore 118478.
Tel (65) 68723515, Fax (65) 68726558

Materials and Methods

Test substance: Bioact-T WS500, Batch no.BN2006082801.
Manufacture Date: 28/08/2006
Test was conducted from 30 Oct to13 Nov 2006
Sample received was a concentrate brownish in colour clear viscous solution, with a characteristic aroma. Test was conducted on the undiluted liquid.

The procedure was a modification of the OECD 420, GUIDELINE FOR TESTING OF CHEMICALS - Acute Oral Toxicity – Fixed Dose Procedure. Adopted 17th December 2001.

A dose of 2ml/kg (approx 2000 mg/kg) body weight was used for oral administration.

1. Ten female Sprague Dawley (SD) rats, 8-10 weeks old, were obtained from the Laboratory Animals Centre, NUS and acclimatized at Animal Holding Unit, Kent Ridge, for 5 days. Animals were caged individually. Room was kept at 22-26°C, humidity at 40-70% with 12 hour light and 12 hour dark cycle. They were fed a conventional laboratory diet with unlimited supply of drinking water. Before test substance was orally administered, food was withheld overnight.
2. Initial Sighting test with 1 female rat was carried out on 4 Oct 2006 with a gavage of 2ml/kg rat of **Bioact-T WS500**. For this Main study, 5 female rats were randomly chosen and allocated as treatment group. Body weights were recorded just before dosing. They were dosed by gavage with **Bioact-T WS500** at a dose of **2ml/kg rat.**
3. The other 5 female rats were used as Control and dosed with water, at 2ml/kg rat.
4. All animals were observed over 2 hours in the first instance after dosing, and then every hour for the next 2 hours. Thereafter, observations were made at least once daily during working days until day 15. Body weights, feed and water consumption were also monitored.
5. At day 15, body weights were recorded and the rats euthanised. Post mortem was performed and gross pathology observations made.

Results - for details, please refer to tables below.

Mortality: None of the rats died over the testing period

Observations: After oral administration of **Bioact-T WS500**, rats were slightly subdued but did not show any signs of being unwell. No other untoward clinical signs were observed during the rest of the test period.

Raw Data: Weight gain and food and water consumption after dosing of **Bioact-T WS500** were similar when compared to control.

Necropsy: All rats survived to Day 15. Euthanasia was carried out by overdose of CO_2 inhalation. Necropsy of Rat B4 showed bleeding in the small intestine. No abnormality was observed in other rats.

Conclusion

The LD_{50} for **Bioact-T WS500** in rats cannot be determined accurately from this method but is considered to be much greater than 2 ml/kg (approximately equivalent to 2000 mg/kg) body weight.

Bioact-T WS500 *is considered to have acute oral toxicity of the least hazard category,* ***category 5/Unclassified*** *in the Globally Harmonised System (GHS) classification of chemicals to cause acute toxicity.*

"TESTING AT DOSES ABOVE 2000 MG/KG
2. Exceptionally, and only when justified by specific regulatory needs, the use of an additional upper fixed dose level of 5000 mg/kg may be considered. Recognising the need to protect animal welfare, testing of 5000 mg/kg is discouraged and should only be considered when there is a strong likelihood that the results of such a test would have a direct relevance for protecting animal or human health." (OECD 420 Annex 4, page 13/14)

Acute oral toxicity tests on animal species do not provide information on chronic toxicity or other adverse effects of the chemical in other species and human.

LEE How Sung B.Pharm(Hons), M.Pharm, PhD
Associate Professor
Department of Pharmacology
National University of Singapore

Date 20th Dec 2006

Acute Oral Toxicity Test of Bioact-T WS500

Summary

Dosage: 2 ml/kg
Date: Start 30/10/2006; End 13/11/2006
Route of administration: Oral gavage
Animals used: Female SD rats (8-10 weeks)
Operators: JL, LEY, TYQ

Rats	Body Weight (g)	Dose (ml)	Weight on 15 day (g)	Observations	
				1st Day	2-15th day
Control (water)					
C1	173	0.35	240	All slightly	All normal
C2	194	0.39	239	subdued	
C3	183	0.37	239		
C4	193	0.39	228		
C5	207	0.41	256		
Test (Bioact-T WS500)					
B1	195	0.39	243		
B2	177	0.35	230	All subdued	All normal
B3	178	0.36	225		
B4	216	0.43	264		
B5	192	0.38	243		
Mean for Control	190	0.38	240		
Mean for Bioact-T WS500	192	0.38	241		

Records of Body Weights, food intake and water intake in Rats for Day 1 – Day 3 after gavage of water (C1-C5) and Bioact-T WS500 (B1-B5)

Rats*	day1 (30-10-06)			day 2 (31-10-06)					day 3 (1-11-06)				
	body wt (g)	food (g)	water (g)	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)	body wt (g)	food (g)	food intake(g)	water (g)	water Intake (g)
C1	173	324	642	186	307	17	600	42	188	290	17	572	28
C2	194	347	636	206	329	18	606	30	212	304	25	579	27
C3	183	336	672	196	314	22	641	31	200	294	20	620	21
C4	193	350	677	199	339	11	644	33	202	322	17	620	24
C5	207	367	682	218	341	26	653	29	221	325	16	636	17
B1	195	361	673	204	337	24	642	31	208	321	16	622	20
B2	177	344	675	189	328	16	637	38	195	306	22	616	21
B3	178	370	680	188	340	30	647	33	187	323	17	628	19
B4	216	345	678	230	326	19	626	52	233	303	23	589	37
B5	192	377	687	205	359	18	649	38	206	340	19	628	21

	body wt (g)			body wt (g)		food intake(g)		water intake (g)	body wt (g)		food intake(g)		water intake (g)
mean for control	190			201		19		33	205		19		23
mean for B	192			203		21		38	206		19		24

		mean food intake 5-15day		mean water intake 5 - 15 day
mean for control		20		23
mean for B		20		23

*** C is for rats given Control (water) and B is for rats given Bioact-T WS500**

Records of Body Weights, food intake and water intake in Rats for Day 4 – Day 9 after gavage of water (C1-C5) and Bioact-T WS500 (B1-B5)

Rats*	day 4 (2-11-06)					day 9 (7-11-06)						
	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)	body wt (g)	old food (g)	new food (g)	food intake (g)	old water (g)	new water (g)	water intake (g)
C1	190	274	16	542	30	214	167	382	107	363	682	179
C2	215	281	23	552	27	239	173	377	108	437	687	115
C3	199	278	16	600	20	214	179	379	99	493	666	107
C4	205	302	20	596	24	209	215	372	87	474	688	122
C5	219	308	17	623	13	236	213	375	95	534	680	89
B1	208	307	14	603	19	220	213	385	94	503	688	100
B2	192	292	14	596	20	205	201	401	91	495	674	101
B3	185	309	14	611	17	205	216	382	93	495	676	116
B4	232	285	18	550	39	242	188	397	97	398	677	152
B5	207	325	15	607	21	220	219	408	106	498	675	109

	body wt (g)		food intake(g)		water intake (g)	body wt (g)			food intake(g)			water intake (g)
mean for control	206		18		23	222			99			122
mean for B	205		15		23	218			96			116

Records of Body Weights, food intake and water intake in Rats for Day 12 – Day 15 after gavage of water (C1-C5) and Bioact-T WS500 (B1-B5)

Rats*	day 12 (10-11-06)					day 15 (13-11-06)				
	body wt (g)	food (g)	food intake (g)	water (g)	water intake (g)	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)
C1	225	320	62	565	117	240	252	68	476	89
C2	245	318	59	629	58	239	271	47	604	25
C3	221	326	53	604	62	239	259	67	536	68
C4	224	312	60	612	76	228	262	50	539	73
C5	241	319	56	621	59	256	261	58	568	53
B1	230	327	58	626	62	243	267	60	564	62
B2	216	346	55	598	76	230	288	58	531	67
B3	207	328	54	619	57	225	266	62	557	62
B4	252	334	63	597	80	264	269	65	526	71
B5	234	340	68	602	73	243	276	64	540	62

	body wt (g)		food intake(g)		water intake (g)	body wt (g)		food intake(g)		water intake (g)
mean for control	231		58		74	240		58		62
mean for B	228		60		70	241		62		65

Lee How Sung

From: MeeFah [yapmf@okada-ecotech.com]
Sent: Tuesday, December 19, 2006 8:56 AM
To: Lee How Sung
Subject: Re: Bioact-T WS500 and Etogrowth EC612 Acute Tox

Lee How Sung wrote:

Hi Mee Fah,
Did you take a look at the reports?
I have agreed that our charges will be the same as before.

Here is the breakdown:

Acute Oral Tox for 2 test substances
$2100 (without animals) x2 = $4200
20% discount -$ 840
$3360
Acute Dermal Tox for 2 test substances
$2400 (without animals) x2 = $4800
15% discount - $ 720
$4080

Total will be S$ 7440

This is not an invoice. Will be sending it to your office after you have o.ked the reports.

Best Wishes of the Season and the Coming New Year 2007
hs
-----Original Message-----
From: Lee How Sung
Sent: Friday, December 15, 2006 11:54 AM
To: 'MeeFah'
Cc: Lee How Sung
Subject: Bioact-T WS500 and Etogrowth EC612 Acute Tox

Hi Mee Fah,

I have sent you the raw data in excel.
Here are the 4 reports.
Please let me know if these are o.k.

Have a Nice Day!
hs

All 4 Reports endorsed.
Will send Invoice to Robinson Rd Address
hls 20/12/2006

Been pretty busy lately. Will be looking at the reports today and revert.

Thanks.

12/20/2006

REPORT ON ACUTE DERMAL TOXICITY TEST: FIXED DOSE PROCEDURE – Bioact-T WS500
Batch no: BN2006082801
Manufacture Date: 28/08/2006
Sponsor: OKADA ECOTECH PTE LTD, Blk 1 Pasir Panjang Road #07-15/17, Alexandra Distripark, Singapore 118478.
Tel (65) 68723515, Fax (65) 68726558

Materials and Methods

Test substance: Bioact-T WS500, Batch no.BN2006082801.
Manufacture Date: 28/08/2006
Test was conducted from 30 Oct to 13 Nov 2006
Sample received was a concentrate brownish in colour clear viscous solution, with a characteristic aroma. Test was conducted on the undiluted liquid.

The procedure was a modification of the OECD GUIDELINE FOR TESTING OF CHEMICALS – Proposal for a New DRAFT GUIDELINE 434: Acute Dermal Toxicity – Fixed Dose Procedure. DRAFT GUIDELINE 14 May 2004 (1st Version).

A dose of 5ml/kg (approx 5000 mg/kg) body weight was used for dermal application.

1. Eight female Sprague Dawley (SD) rats, 8-10weeks old, were obtained from the Laboratory Animals Centre, NUS and acclimatized at Animal Holding Unit, Kent Ridge, for 5 days. Animals were caged individually. Room was kept at 22-26°C, humidity at 40-70% with 12 hour light and 12 hour dark cycle. They were fed a conventional laboratory diet with unlimited supply of drinking water.
2. After the initial Sighting test using 1 female rat with **Bioact-T WS500** at dose 5ml/kg rat on 4 Oct 2006, 5 female rats were randomly chosen and allocated as treatment group and the other 3 female rats were to act as control group.
3. Each rat was anesthetized with an approximate dose of 0.2ml per 100 g rat of a cocktail (20 ml working solution) containing 4.8 ml ketamine (2mg/ml), 3.2 ml medetomidine (1mg/ml) and 12ml sterile water.
4. When the rat was sedated, its weight was recorded, hair on its back was shaved to expose an area of 4 x 5 cm skin for dermal application of the test substance.
5. Five female rats were treated with **Bioact-T WS500** at a dose of **5ml/kg rat** being applied on to exposed skin. The other 3 female rats were used as Control and dosed with water, at 5ml/kg rat. A specially constructed Elizabethan collar was used to prevent rats from ingesting the test substance.
6. All animals recovered from anesthesia in about an hour and were monitored. At the end of 24 h exposure period, the collar was detached and the test substance was washed off with water. The rats were observed at least once daily during working days until day 15.

Body weights, feed and water consumption were also monitored every 2-4 days.

7. At day 15, body weights were recorded and the rats euthanised. Post mortem was performed and gross pathology observations made.

Results - for details, please refer to tables below.

Mortality: None of the rats died over the testing period

Observations: Dermal application of **Bioact-T WS500** did not seem to affect the rats much after they recovered from anesthesia. No other untoward clinical signs were observed during the rest of the test period.

Raw Data: Weight gain and food and water consumption after dosing of **Bioact-T WS500** were comparable between the test group and the control.

Necropsy: All rats survived to Day 15. Euthanasia was carried out by overdose of CO_2 inhalation. No abnormality was observed during gross necropsy of rats.

Conclusion

The Acute Dermal LD_{50} for **Bioact-T WS500** in rats cannot be determined accurately from this method but is considered to be much greater than 5 ml/kg body weight (approximately equivalent to 5000 mg/kg body weight).

Bioact-T WS500 *is considered to have acute dermal toxicity of the least hazard category,* ***category 5/Unclassified*** *in the Globally Harmonised System (GHS) classification of chemicals to cause acute toxicity.*

"TESTING AT DOSES ABOVE 2000 MG/KG
2. Exceptionally, and only when justified by specific regulatory needs, the use of an additional upper fixed dose level of 5000 mg/kg may be considered. Recognising the need to protect animal welfare, testing in animals in Category 5 ranges is discouraged and should only be considered when there is a strong likelihood that results of such a test would have a direct relevance for protecting human health." (OECD New Draft Guideline 434, 14 May 2004 (1st version) Annex 4, page 13)

Acute dermal toxicity tests on animal species do not provide information on chronic toxicity or other adverse effects of the chemical in other species and human.

LEE How Sung B.Pharm(Hons), M.Pharm, PhD
Associate Professor
Department of Pharmacology
National University of Singapore

Date 20th Dec 2006

Acute Dermal Toxicity Test of Bioact-T WS500

Summary

Dosage: 5 ml/kg
Date: Start 6/2/2006; End 20/2/2006
Route of administration: Dermal
Animals used: Female SD rats (8-10 weeks)
Operators: JL, LEY, TYQ

Rats	Body Weight (g)	Dose (ml)	Weight on 15 day (g)	Observations	
				1st Day	2-15th day
Control (water)					
C1	**233**	1.15	**259**	Sedated but	All normal
C2	**200**	1.00	**229**	awake after	
C3	**191**	1.00	**230**	about an hour	
Test (Bioact-T WS500)					
B1	**215**	1.08	**248**		
B2	**220**	1.10	**238**	Sedated but	All normal
B3	**222**	1.11	**255**	awake after	
B4	**240**	1.20	**277**	about an hour	
B5	**241**	1.20	**274**		
Mean for Control	**208**	**1.05**	**239**		
Mean for Bioact-T WS500	**228**	**1.14**	**258**		

Records of Body Weights, food intake and water intake in Rats for Day 1 – Day 3 after dermal application of water (C1-C3) and Bioact-T WS500 (B1-B5)

Rats*	day1 (30-10-06)			day 2 (31-10-06)					day 3 (1-11-06)				
	body wt (g)	food (g)	water (g)	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)
C1	233	330	663	224	327	3	648	15	225	314	13	639	9
C2	200	334	676	198	326	8	648	28	200	312	14	628	20
C3	191	356	680	195	344	12	642	38	196	332	12	608	34
B1	215	336	638	213	320	16	603	35	214	299	21	579	24
B2	220	335	680	215	320	15	646	34	217	300	20	619	27
B3	222	373	676	224	363	10	646	30	221	345	18	625	21
B4	240	328	680	242	321	7	639	41	244	302	19	612	27
B5	241	346	684	238	341	5	645	39	236	336	5	606	39

	body wt (g)			body wt (g)		food intake(g)		water intake (g)	body wt (g)		food intake(g)		water intake (g)
mean for control	208			206		8		27	207		13		21
mean for B	228			226		11		36	226		17		28

		mean food intake day 5-15 (g)		mean water intake day 5-15 (g)
mean for control		23		26
mean for B		24		27

*** C is for rats given Control (water) and B is for rats given Bioact-T WS500**

Records of Body Weights, food intake and water intake in Rats for Day 4 – Day 9 after dermal application of water (C1-C3) and Bioact-T WS500 (B1-B5)

Rats*	day 4 (2-11-06)					day 9 (7-11-06)						
	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)	body wt (g)	old food (g)	new food (g)	food intake (g)	old water (g)	new water (g)	water intake (g)
C1	225	294	20	604	35	236	176	328	118	475	684	129
C2	203	295	17	606	22	206	209	387	86	513	648	93
C3	194	314	18	570	38	204	172	368	142	407	677	163
B1	216	277	22	551	28	224	155	381	122	425	650	126
B2	215	282	18	596	23	224	172	382	110	477	689	119
B3	223	324	21	599	26	238	214	372	110	488	643	111
B4	240	284	18	585	27	251	175	363	109	450	680	135
B5	238	317	19	566	40	249	198	360	119	409	675	157

	body wt (g)		food intake(g)		water intake (g)	body wt (g)			food intake(g)			water intake (g)
mean for control	207		18		32	215			115			128
mean for B	226		20		29	237			114			130

Records of Body Weights, food intake and water intake in Rats for Day 12 – Day 15 after dermal application of water (C1-C3) and Bioact-T WS500 (B1-B5)

Rats*	day 12 (10-11-06)						day 15 (13-11-06)				
	body wt (g)	food (g)	food intake (g)	old water (g)	new water (g)	water intake (g)	body wt (g)	food (g)	food intake(g)	water (g)	water intake (g)
C1	252	258	70	599	633	85	259	184	74	558	75
C2	215	326	61	583	583	65	229	270	56	526	57
C3	213	301	67	582	582	95	230	220	81	490	92
B1	238	309	72	571	571	79	248	239	70	502	69
B2	229	334	48	625	625	64	238	268	66	552	73
B3	244	309	63	572	572	71	255	242	67	500	72
B4	267	285	78	579	579	101	277	205	80	491	88
B5	262	237	123	539	539	136	274	163	74	430	109

	body wt (g)		food intake(g)			water intake (g)	body wt (g)		food intake(g)		water intake (g)
mean for control	227		66			82	239		70		75
mean for B	248		77			90	258		71		82

KEEP OUT OF REACH OF CHILDREN. SHAKE WELL BEFORE USE

STORAGE
Store in a cool, dry place. Avoid exposure to direct sunlight and high temperature.

DIRECTIONS FOR USE
Dilute **BIOVECTROL 500WS** with water and mix homogenously.

APPLICATIONS / DILUTION RATIOS:

Root Feeding via root dip	1: 200~250	Before transplanting
Root Feeding via soil	1:500	15~30 days' interval
Foliar Spray	1:500	5~15 days' interval
Chemigation via drip irrigation	1:2000~4000	15~30 days' interval

Manufacturer : **OKADA ECOTECH PTE LTD**
55 Ayer Rajah Crescent , #03-19/23
Singapore 139949
Tel: 6872 3515, Fax: 6872 6558
Homepage: www.okada-ecotech.com

Date of Manufacture :
Expiry Date : 12 months from Date of Manufacture

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BIOVECTROL™ 500WS

Water Soluble Concentrate
For Crop Protection & Plant Growth Promotion

- High penetrability and systemic effects with various application techniques
- Recommended for agriculture, horticulture and silviculture plants
- Non-hazardous. Ecology and Environmental Friendly. Safe for mammals, avian and aquatic wildlife. Low impact on beneficials (honeybees, earthworms, etc) and natural predators (spiders, etc).
- Highly effective insect control agent with multiple modes of activities such as antifeedant activities, insect growth regulation (IGR) effects, ovicidal activities, repellency, etc for crop protection.
- Improves photosynthesis and assimilate translocation to promote healthy growth of produce from disease-free crops
- Prevention and protection against fungal, bacterial and plant virus infections
- Highly effective against root knot nematodes and other common plant diseases.
- Non-phytotoxic
- Improvement of Soil Conditions and Farming Environment

CONTENTS
Azadirachtin A, B 5.0%
Other Neem Extracts ..... 7.5% (w/w)
Inert Ingredients (Surfactants and blends of glycols) 87.5%

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