

US EPA ARCHIVE DOCUMENT

Data Evaluation Report on the contact and oral toxicity of BAS 510 F to the honey bee.

PMRA Submission Number: 2001-1027

EPA MRID Number: 454050-19

Data Requirement: PMRA DATA CODE: 9.2.4.1(acute contact); 9.2.4.2 (acute oral)
EPA DP Barcode: D278418
OECD Data Point: 8.7.2; 8.7.1
EPA Guideline: {non-guideline(oral);141-1
or 850.3020 (contact)}

Test material: BAS 510 F

Purity (%): 94.4 %

Common name: Nicobifen

Chemical name

IUPAC: 2-chloro-N-(4'-chlorobiphenyl-2-yl) nicotinamide

CAS name: 3-Pyridinecarboxamide, 2-chloro-N_(4'-chloro[1.1'-biphenyl]-2-yl)

CAS No.: 188425-85-6

Synonyms:

Primary Reviewer: Peter Takacs and Hemendra Mulye **Date:** January 21/02
{PMRA}

Secondary Reviewer(s): John Ravenscroft **Date:** June 06, 2002
{EPA}

Company Code: BAZ

Active Code: CHH-BAZ-4

Use Site Category: In Canada, this fungicide is proposed for use on USC 13, 14 and 30; agricultural feed, food and turf uses. BAS 510 F is to be used 2-6 times per growing season depending on the crop, at a maximum recommended application rate of 875 g a.i./ha/application.

EPA PC Code: 128008

CITATION: Dagmar Sack, July 1999. Effect of Reg. No. 300 355 (BAS 510 F) on the Honeybee (*Apis mellifera* L.) in Laboratory Trials. Ecology and Environmental Analytics BASF Aktiengesellschaft D-871 14 Limburgerhof, Germany. Study # 44156.



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EXECUTIVE SUMMARY:

For acute contact: In a 48 hr-acute contact toxicity study, honey bees *Apis mellifera* were exposed to BAS 510 F administered topically to the thorax at an application rate of 0 (negative control and solvent control), and 200 µg a. i./bee in accordance with the Bulletin OEPP/EPPO Bulletin 22 (1992); No. 170: Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. The NOEL and LD₅₀ values were 200 and >200 µg a. i./bee, respectively. The test material is classified as relatively non-toxic to honey bees in accordance with the classification of Atkins (1981).

There was no compound related mortality. The reference chemical dimethoate was highly toxic to bees.

This study is classified as acceptable and satisfies the guideline requirement for acute contact toxicity study for honey bees.

For acute oral: In a 48 hr-acute oral toxicity study, honey bees *Apis mellifera* were exposed to BAS 510 F administered in the feed solution at an application rate of 0 (negative control, solvent control) and 166 µg a. i./bee in accordance with the Bulletin OEPP/EPPO Bulletin 22 (1992); No. 170: Guideline on test methods for evaluating the side-effects of plant protection products on honeybees. The NOEC and LC₅₀ values were 166 and >166 µg a.i./bee, respectively. The test material is classified as relatively non-toxic to honey bees in accordance with the classification of Atkins (1981).

There was no compound related mortality. The reference chemical dimethoate was highly toxic to bees.

This study is classified as acceptable and satisfies the guideline requirement for acute oral toxicity study for honey bees.

Results Synopsis

Test organisms and test organism age: honey bee (not specified)

For acute contact

48 hr LD₅₀: >200 µg a. i./bee
48 hr NOEL: 200 µg a. i./bee
Endpoint(s) Effected: Mortality

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For acute oral

48hr LC₅₀: >166 µg a. i./bee
48hr NOEC: 166 µg a. i./bee
Endpoint(s) Effected: mortality

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

Appendix 1 to 5 19a, Section 1, Chemikaliengesetz of 25 July 1994 (Official Bulletin/Federal Republic of Germany, I 1994, P. 1703).
Bulletin OEPP/EPPO Bulletin 22 (1992); No. 170: Guideline on test methods for evaluating the side-effects of plant protection products on honeybees.

COMPLIANCE:

This study was conducted in compliance with the Good Laboratory Practice Regulations; Appendix 1 to §19a, Section 1, Chemikaliengesetz of 25 July 1994 (Official Bulletin/Federal Republic of Germany, I 1994, P. 1703).

A. MATERIALS:

1. Test Material

BAS 510 F

Description: Solid
Lot No./Batch No. : N37
Purity: 94.4%
Stability of Compound
Under Test Conditions: Stable at least for the period of investigations (PCP 04672)
Storage conditions of test chemicals: Not stated

Physicochemical properties of BAS 510 F.

Parameter	Values	Comments
Water solubility at 20°C	4.69 mg/L	
Vapour pressure	7x10 ⁻⁹ mbar @ 20 °C	

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Parameter	Values	Comments
UV absorption	UV molecular extinction: 1.53x10 ³ at 290 nm	
pKa	does not dissociate in water	
log Kow	2.96	

2. Test organism:

Species: honey bee, *Apis mellifera*

Age at test initiation: Not specified.

Source: Purchase of 5 colonies in April 1998 from: Imkerei Nengel Bruckenstr. 12 56348 Dahlheim, FRG

Date of collection: Not specified.

Cultural Background: Colonies of *Apis mellifera* are kept continuously by an experienced bee keeper at the BASF Agricultural Research Center, Limburgerhof, FRG. These bee colonies are kept in a normal beekeepers manner. Details of keeping are reported in a separate journal.

B. STUDY DESIGN:

1. Experimental Conditions

b) Definitive Study:

The 48 hr study was carried out as a limit test at 200 µg ai./bee with a sugar water control for the oral test and an acetone control for the contact test.

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Table 1 . Experimental Parameters/Design

Parameter	Value	Remarks Criteria
<u>Acclimation:</u> Duration: Feeding: Health of bees	Bees were not acclimated.	Bees were removed from the hives shortly before the start of the experiment The health of bees was not described.
Cage - description and size	The bee cages are made of stainless steel with the dimensions about 10 cm (breadth), 8.5 cm (height) and 5.5 cm (depth).	<i>EPA : Test chambers may be constructed of metal, plastic, wire mesh, or cardboard. A vial containing sugar water must be attached.</i>
<u>Test conditions</u> Temperature: Humidity: Lighting:	23.6-25.9 °C Not stated Not stated	<u>Temperature:</u> EPA requires 25-35°C OECD requires 25±2°C <u>Humidity</u> EPA requires 50 - 80% humidity OECD requires 50 - 70% humidity <u>Lighting</u> EPA/OECD recommend darkness except during dosing and observation.
<u>Solvent/dispersant control, if used</u> Name: Concentration:	acetone not stated	<i>EPA/OECD prefer acetone as a solvent EPA: negative and solvent controls required. Positive control not required.</i>
Number of bees per cage	10	<i>EPA requires at least 25 bees per treatment OECD prefers 10 bees per cage</i>
Number of cages per treatment	5	<i>EPA: One cage per each treatment level and each control.</i>
<u>Number of replicates</u> Negative control: Solvent/dispersant control, if used: Treated:	5 5 5	<i>OECD requires at least three replicate, each of ten bees EPA: Replications are not required.</i>

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Parameter		Value	Remarks ----- Criteria
For Acute contact study	<u>Doses used</u>		
	Nominal:	200 µg ai./bee	<i>EPA requires at least five dosage levels, spaced geometrically at least 60% of the next higher level OECD requires five doses in a geometric series, with a factor not exceeding 2.2</i>
	Method of test material application including the body part and volume of test solution applied	single 1 µl drop on thorax of bees.	<i>EPA: Test material administered as single topical dose (topical drop) or whole body exposure to impregnated dust.</i>
	Time of test material application	Not stated	
For Acute oral study	<u>Doses used</u>		
	Nominal:	166 µg ai./bee	test material was dissolved in 0.2 mL of invert sugar and fed to the bees via a feeding tube.
	Details of the food source		
Method of feeding during the study		Sugar solution: Api-invert sugar syrup The syrup is diluted with deionized water (50%) (v/v)	<i>EPA: A 50% sugar/water solution will be provided ad libitum throughout the holding and test periods. A vial containing solution must be attached to each cage.</i>
Duration of the study		48 hr	<i>EPA: 48 hours with observation for mortality and signs of intoxication at 4, 24, and 48 hours after exposure to test material.</i>
<u>Reference chemical, if used</u>			
Name: Dimethoate Concentration(s):		BAS 152 11 I, batch 96-3 0.1, 0.125, 0.15, 0.2, 0.25, 0.5 µg/bee.	

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2. Observations:

Table 2: Observations

Parameters	Details	Remarks
		Criteria
Parameters measured including sublethal effects/toxicity symptoms	mortality	<i>EPA requires less than 20% mortality in the controls OECD requires less than 10% mortality in the controls</i>
Observation intervals	3, 24 and 48 hours	<i>EPA/OECD require observation intervals of 4, 24 and 48 h after dosing</i>
Amount of treated diet consumed per group (For acute oral)	165.9 µg ai./bee	
Were raw data included?	Yes	
Other observations, if any	-	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

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Table 3: Effect of BAS 510 F on cumulative mortality of honey bees in acute oral test.

Treatments ($\mu\text{g a.i./bee}$) measured conc.		No. of bees	Observation period					
			3 hr		24 hr		48hr	
			No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Negative control		50	0	0	0	0	0	0
166		50	0	0	0	0	1	2
NOEC		166 $\mu\text{g a.i./bee}$						
LD ₅₀ /LC ₅₀		> 166 $\mu\text{g a.i./bee}$						
<u>Reference chemical</u>	mortality (% or No.)	30	1	3.3	10	33	20	66
dimethoate	LD ₅₀ /LC ₅₀ :	Contact, 48 hr: 0.38 $\mu\text{g a.i./bee}$						
	NOEC	not stated						

Table 4: Effect of BAS 510 F on cumulative mortality of honey bees in acute contact test.

Treatments ($\mu\text{g a.i./bee}$) measured conc.		No. of bees	Observation period					
			3 hr		24 hr		48hr	
			No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Negative control		50	0	0	0	0	0	0
200		50	0	0	0	0	0	0
NOEC		200 $\mu\text{g a.i./bee}$						
LD ₅₀ /LC ₅₀		> 200 $\mu\text{g a.i./bee}$						
<u>Reference chemical</u>	mortality (% or No.)	30	0	0	24	80	29	96.6
dimethoate	LD ₅₀ /LC ₅₀ :	48 hr: 0.36 $\mu\text{g a.i./bee}$						
	NOEC	not stated						

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B. SUB-LETHAL TOXICITY EFFECTS:

Sublethal effects were not evaluated in the tests.

C. REPORTED STATISTICS:

No statistical procedures were used due to lack of mortality.

D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

Not applicable.

E. STUDY DEFICIENCIES:

No major deficiencies were noted in this study.

F. REVIEWER'S COMMENTS:

G. CONCLUSIONS:

The test chemical is considered relatively non toxic to bees via both oral and contact routes of exposure. This study is considered acceptable.

For acute contact

LD50: > 200 µg/bee
NOEC: 200 µg/bee

For acute oral

LC50: >166 µg/bee
NOEC: 166 µg/bee

III. REFERENCES:

1) Atkins, E. L., Kellum, D. and Atkins, K. W. 1981. Reducing pesticide hazards to honey bees: Mortality prediction techniques and integrated management strategies. University of California, Division of Agriculture Science, Leaflet 2883. P 22.

Approved 04/01/01 C.K.

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