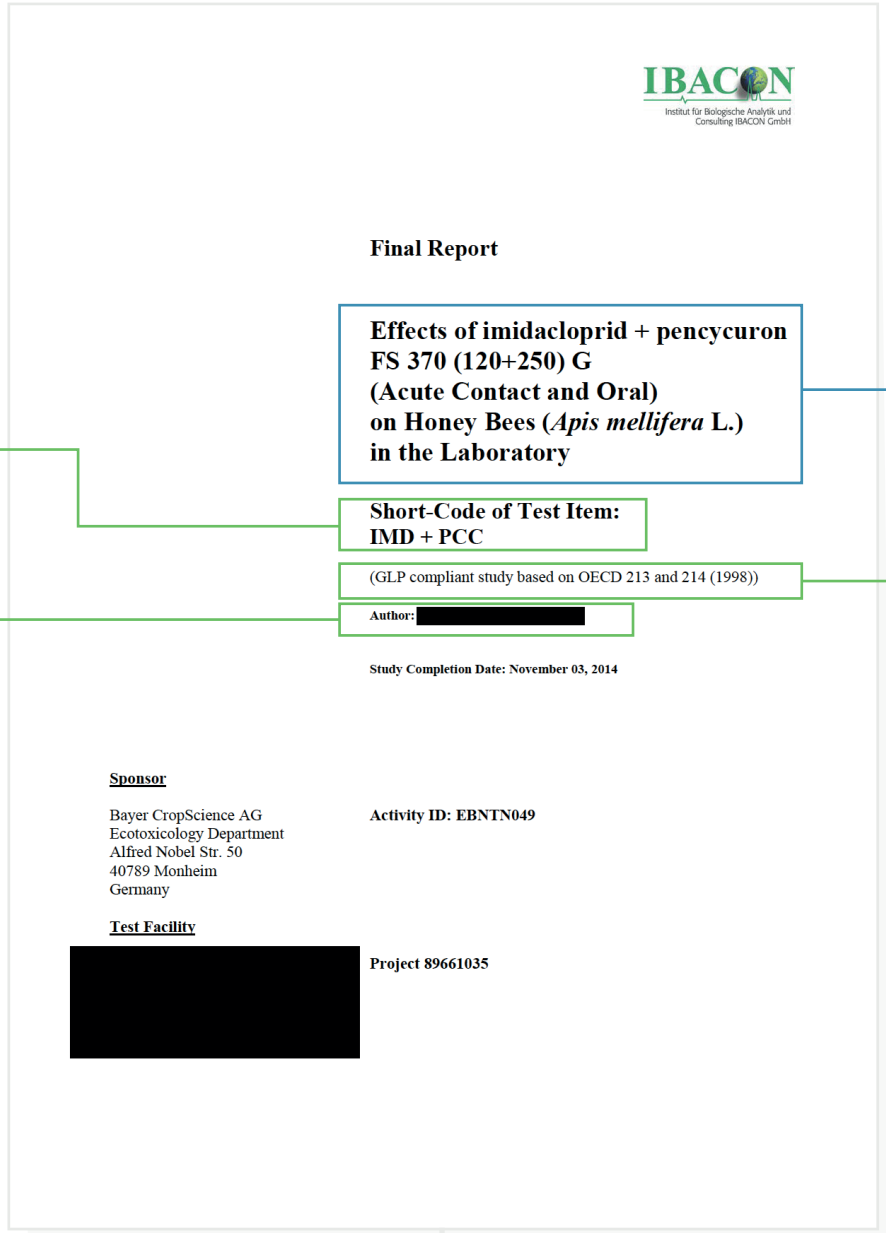
How to read a study report

Study reports can be quite long and not always easy to understand. To help you with reading and understanding, this guide will explain the most important parts and sections of a study report.

BAYER



IBACON
Institut für Biologische Analytik und Consulting IBACON GmbH

Final Report

Effects of imidacloprid + pencycuron FS 370 (120+250) G (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory

Short-Code of Test Item: IMD + PCC

(GLP compliant study based on OECD 213 and 214 (1998))

Author: [redacted]

Study Completion Date: November 03, 2014

Sponsor

Bayer CropScience AG
Ecotoxicology Department
Alfred Nobel Str. 50
40789 Monheim
Germany

Activity ID: EBNTN049

Test Facility

[redacted]

Project 89661035

SHORT-CODE

Abbreviation for the substances tested (3-letter-code)

AUTHOR

To respect our scientists' privacy we are not sharing their names and addresses. These parts are blacked out.

TITLE

What is investigated with *which* substance or product with *which* test organism.

GLP STATEMENT

GLP ("Good Labatory Practice") and refers to a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical non-clinical safety tests.

1. Summary

Author (year): [redacted] (2014)

Title: Effects of imidacloprid + pencycuron FS 370 (120+250) G (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory

Study Report Number and Date: IBACON Project: 89661035, Report Date: November 03, 2014

1. SUMMARY

Summary of the whole report, including the procedure, findings and the conclusion.

FINDINGS

Summary of the testing results, including description of the statistic used.

Findings:

Table 1. Toxicity to Honey Bees; laboratory tests

Test Item	Imidacloprid + pencycuron FS 370 (120+250) G	
Test Species	*Apis mellifera*	
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (50 % w/v sucrose solution)

INTERESTING TO KNOW

Safety studies are specifically designed to evaluate toxicity across a range of doses to understand, which doses cause which effect. The studies are used for the determination of doses with no observed adverse effect (the so-called: No Observed Adverse Effect Level or NOAEL), doses where first adverse effects are seen (the so-called Lowest Observed Adverse Effect Level or LOAEL) and doses which show significant effects. By testing the full range of toxicity and by applying additional safety factors regulators have certainty that the product is safe when used according to the approved label.

For example, a product is considered safe, when the maximum exposure of a human is at least 100 times lower than the NOAEL in the safety studies (e.g. NOAEL = 10 mg/kg/day and the maximum human exposure is 0.1 mg/kg/day).

MATERIAL AND METHODS

Detailed description and identification of the test item, the test system, treatment levels.

Material and Methods:

Imidacloprid + pencycuron FS 370 (120+250) G: imidacloprid (NTN 33893): 10.4 % w/w (119.8 g/L), pencycuron (NTN 19701): 21.9 % w/w (252.0 g/L), (all values analytical); Batch ID.: ECE4101025; Sample Description: TOX09865-00; Material No.: 05866316; Specification No.: 102000008024 - 02; density: 1.151 g/mL (20°C).

OBSERVATION

Description of observed effects during the test.

Observations:

Contact Test:

The contact test was prolonged for a further 48 hours up to 96 hours due to increasing mortality between 24 and 72 hours. Application of 4.0, 2.0, 1.0, 0.50, 0.25 and 0.13 µg/bee of imidacloprid + pencycuron FS 370 (120+250) G on the honey bee thorax led to mortalities of 100.0 % to 10.0 % at the end of the test (*i.e.* after 96 hours). No mortality occurred in the control group (water + 0.5 % Adhäsit).

CONCLUSION

Scientific interpretation of the study results and the statistics and conclusion on which toxicity value results from this study (=which amount of a substance caused which effect).

Conclusion:

The toxicity of imidacloprid + pencycuron FS 370 (120+250) G was tested in both, an acute contact toxicity test and an acute oral toxicity test on honey bees.
The LD_{50} (24, 48, 72 and 96 h) of the test item was determined to be 2.50, 0.54, 0.42 and 0.38 µg product/bee (equivalent to 0.260, 0.056, 0.044 and 0.040 µg a.i. imidacloprid/bee) in the contact toxicity test, respectively.

2. SURVEY OF THE STUDY

The survey summarizes the general frame conditions of the study and the persons involved.

2. Survey of the Study

2.1 General Information

Sponsor:

Bayer CropScience AG
Ecotoxicology Department
Alfred Nobel Str. 50
40789 Monheim
Germany

3. Quality Assurance unit statement

4. Statement of compliance

3. QUALITY ASSURANCE UNIT STATEMENT
4. STATEMENT OF COMPLIANCE

These parts are blackened to invalidate reports for submission by 3rd party companies.

5. Objectives of the Study

5.1 Title

Effects of imidacloprid + pencycuron FS 370 (120+250) G (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory

5.2 Purpose

The purpose of this study was to determine the acute contact and oral toxicity of imidacloprid + pencycuron FS 370 (120+250) G to the honey bee (*A. mellifera* L.).

5. OBJECTIVES OF THE STUDY

The objectives of the study provide a detailed description of the intention of the study.

INTERESTING TO KNOW

Authorities get the full text study reports for their assessment (and can demand access to the raw data). In the evaluation reports then created by authorities the summaries of the studies are presented.

6. Materials and Methods

6.1 Test Item, Control, Wetting Agent and Reference Item

Test Item

The test item and the information concerning the test item were provided by the Sponsor:

Name:	Imidacloprid + pencycuron FS 370 (120+250) G
Short Code:	IMD + PCC

6. MATERIALS AND METHODS

This overview shows a more detailed description of material and methods.

REFERENCE ITEM

In studies often a so called „reference item“ is used. A reference item is a substance, of which effects are known. The purpose of using a reference item is to prove that the effects that are shown in the test systems are valid.

Reference Item

The information concerning the reference item according to the substance container label and data sheet:

Name:	Perfekthion EC (BAS 152 11 I)
Manufacturer:	BASF SE, Crop Protection, [redacted]
Batch No.:	FRE-000926
Active Ingredient / Content:	dimethoate: 400.0 g/L (nominal)

APPLICATIONS

In most of the test systems a control (equal to the treatment with the test and the reference item, but containing no test substance), a test item and a reference are used.

The results for the test item are compared to the control, the reference is necessary to check whether your test system works.

6.6 Application of the Test Item, the Control and the Reference Item

Application in the Contact Test:	A single 5 µL droplet of imidacloprid + pencycuron FS 370 (120+250) G in an appropriate carrier (tap water + 0.5 % Adhäsit*) was placed on the dorsal bee thorax using a calibrated pipette (Burkard – Applicator). For the control one 5 µL droplet of tap water containing 0.5 % Adhäsit* was used. The reference item was also applied in 5 µL tap water (dimethoate made up in tap water containing 0.5 % Adhäsit)

VALIDITY CRITERIA OF THE STUDY

Validity criteria for studies are set in the respective guidelines. Only if they are fulfilled, the results of a study can be considered scientifically reliable. In case a study is not valid, it cannot be used in the risk assessment.

6.10 Validity Criteria of the Study

Control Mortality:	Should not exceed 10 % at test end (see 7.1)
LD_{50} of Reference Item:	Contact test: should be in the range of 0.10 - 0.30 µg a.i./bee (24 h) (see 7.1) Oral test: should be in the range of 0.10 - 0.35 µg a.i./bee (24 h) (see 7.1)

7. Results and Discussion

7.1 Validity Criteria of the Study

Control Mortality:	Contact Test water control:	0.0 %
	Oral Test sugar control:	6.7 %
LD_{50} of Reference Item (24 hrs):	Contact Test:	0.22 µg a.i./bee
	Oral Test:	0.23 µg a.i./bee
Validity of the Tests:	The contact and oral test are considered valid as the control mortality in each case was < 10% and the LD_{50} values obtained with the reference item (dimethoate), were within the required ranges.	

7. RESULTS AND DISCUSSION

Here you will find the results of the tests conducted in the study as tables and descriptive text summaries.

INTERESTING TO KNOW

Also control groups may show some mortality (i.e. also in the absence of a test item, tested organisms may die due to other reasons. That's why e.g. mortality is compared between control group and test group

DETAILED STUDY RESULTS

Detailed presentation of all study results.

Table 2. Mortality and behavioural abnormalities of the bees in the contact toxicity test

	after 4 hours		after 24 hours		after 48 hours		after 72 hours		after 96 hours	
	mortality	behav. abnorm.	mortality	behav. abnorm.	mortality	behav. abnorm.	mortality	behav. abnorm.	mortality	behav. abnorm.
dosage	mean %	mean %	mean %	mean %	mean %	mean %	mean %	mean %	mean %	mean %
test item µg product/bee										
4.0	6.7	93.3	46.7	53.3	80.0	20.0	96.7	3.3	100.0	0.0
2.0	0.0	86.7	50.0	50.0	90.0	10.0	96.7	0.0	96.7	3.3
1.0	0.0	96.7	43.3	53.3	80.0	0.0	90.0	0.0	90.0	6.7
0.50	0.0	70.0	36.7	53.3	73.3	0.0	76.7	6.7	80.0	6.7
0.25	3.3	26.7	10.0	26.7	10.0	0.0	10.0	0.0	10.0	3.3

8. References

Abbott W.S. 1925: A method of computing the effectiveness of an insecticide. J. econ. Entomol. 18: 265 - 267

Chemikaliengesetz der Bundesrepublik Deutschland (ChemG), Anhang 1, in der Fassung der Bekanntmachung vom 28. August 2013 (BGBl. I S. 3498)

Directive 2004/10/EC of 11 February 2004 amending Council Directive 87/18/EEC, Official Journal of the European Union N° L 50: 44 - 59

Finney D.J. 1971: Probit Analysis. 3rd Edition, Cambridge University Press, London

8. REFERENCES

In the end of each study report a list of all references is provided, including guidelines used, regulations and scientific articles.

9. Distribution of the Final Report

Sponsor:	1x (original)
IBACON:	1x (one certified copy of the final report)

9. DISTRIBUTION OF THE FINAL REPORT

Here you can see where and how often the final report was distributed.

RAW DATA

RAW data is defined as the original data as they were taken during the study, i.e. before summarizing them for analysis. They are usually provided in the appendix.

Table 6. Mortality and behavioural abnormalities of the bees in the oral toxicity test (raw data)

			after 4 hours			after 24 hours			after 48 hours			after 72 hours			after 96 hours		
unit no.:	treatment	consumed dosage	dead #	beh. abnor. #	abnor. symp.	dead #	beh. abnor. #	abnor. symp.	dead #	beh. abnor. #	abnor. symp.	dead #	beh. abnor. #	abnor. symp.	dead #	beh. abnor. #	abnor. symp.
1		0.76	0	10	m, ap	4	4	a, ap	5	3	ap, a	5	0		5	0	
2	test item	0.84	0	10	ap, a	1	2	ap	6	2	a	8	1	a	9	1	a
3	[µg product/bee]	0.66	0	10	n, ap, a	0	4	ap	1	3	a	2	4	a	2	0	
1		0.39	0	10	ap, a	0	1	a	1	1	a	1	0		1	0	
2	test item	0.39	0	10	n, ap, a	3	2	a	3	1	a	3	0		3	0	