## Section A7.5.3.1.2 Short-term toxicity on birds (1)

**Annex Point IIIA XIII 1.2** *Anas platyrhynchos* (Mallard duck)

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | [redacted] 1998a): Five day dietary toxicity of YRC 2894 on mallard ducklings (Anas platyrhynchos) [redacted] Report No [redacted] VE 010, date: 1998-02-02, *revised: 1998-09-21.*<br>*PPP-Monograph Chapter: B.9.1 Effects on birds, B.9.1.2 Dietary toxicity - Active substance (Study 1)* |
| **1.2** | **Data protection** | [redacted] |
| 1.2.1 | Data owner | [redacted] |
| 1.2.2 | Companies with letter of access | [redacted] |
| 1.2.3 | Criteria for data protection | [redacted] |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes;<br>OECD guideline 205 and US-EPA guideline 71-2 |
| **2.2** | **GLP** | [redacted] |
| **2.3** | **Deviations** | [redacted] |

### 3 MATERIALS AND METHODS

In a study on the dietary toxicity of technical YRC 2894 (thiacloprid, purity [redacted]%) mallard ducks (10 day old chicks, 10 chicks per group, 1 group per test level, 2 control groups) were exposed for 5 days to dietary concentrations of 0, 313, 625, 1250, 2500 and 5000 ppm a.s. in feed. Exposure was followed by a 3-day observation period on untreated feed.

### 4 RESULTS

There were no treatment related mortalities at any test concentration. At test concentrations of 625 ppm or greater, some chicks exhibited signs of intoxication (uncoordinated movements, narcotic effects). Recovery from these effects was observed during the period on untreated feed. Statistically significantly lower body mass compared with controls was observed in treatment groups on days 5 and 8 at 1250 ppm, 2500 ppm, and 5000 ppm. On day 5 there was also a statistically significantly lower body mass in the 625 ppm group compared with the controls. Feed consumption was reduced (in a concentration-dependant manner) at 625 ppm and greater, compared with the controls. However, with increased starvation stress feed consumption rate in the treatment groups approached that in the controls. In the highest treatment level feed consumption was reduced for 4 days before it returned to control levels. The gross necropsy observations showed no pathological findings at test concentrations up to and including 1250 ppm. At the two highest test concentrations an anaemic pancreas was recorded for the majority of the

examined chicks.

The $LC_{50}$ was >5000 ppm. The NOEC was 313 ppm, based on clinical signs of toxicity and an effect on body mass development at 625 ppm.

## 5 CONCLUSION

**5.1 Conclusion**

[redacted]

5.1.1 Reliability [redacted] X

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 07/08/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

## Section A7.5.3.1.2 Short-term toxicity on birds (2)

**Annex Point IIIA XIII 1.2** *Colinus virginianus* (Bobwhite quail)

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | [redacted]1995b *[Monograph: 1995a]*): YRC 2894 (techn.): 5-day dietary $LC_{50}$ to bobwhite quail[redacted]Report No. VB-043, date: 1995-09-08, *revised: 1998-09-21.*<br>*PPP-Monograph Chapter: B.9.1 Effects on birds, B.9.1.2 Dietary toxicity - Active substance (Study 2)* |
| **1.2** | **Data protection** | [redacted] |
| 1.2.1 | Data owner | [redacted] |
| 1.2.2 | Companies with letter of access | [redacted] |
| 1.2.3 | Criteria for data protection | [redacted] |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes;<br>OECD guideline 205 and US-EPA 71-2 |
| **2.2** | **GLP** | [redacted] |
| **2.3** | **Deviations** | [redacted] |

### 3 MATERIALS AND METHODS

In a study on the dietary toxicity of technical YRC 2894 (thiacloprid, purity [redacted]%), bobwhite quail (14 days old, 10 birds per test group, 1 group per treatment level, 3 groups in the control) were exposed for 5 days to dietary concentrations of 625, 1250, 2500, 5000 or 10000 ppm a.s. in feed. This was followed by a 3 day observation period on untreated feed.

### 4 RESULTS

Mortalities occurred at concentrations of 5000 (40%) and 10000 (100%) ppm. Signs of toxicity (apathy, loss of equilibrium) were observed at 2500 ppm and higher. Reduced feed consumption (concentration-related) was also noted in these groups, which led to reduced bodyweight gain at 2500 ppm and higher compared with controls. *Post-mortem* examinations of all surviving birds showed no visible treatment related effects. Mortalities at 5000 and 10000 ppm exhibited discoloration of liver and spleen, which may have been *post-mortem* changes.

The $LC_{50}$ was 5459 ppm. The NOEC was 1250 ppm a.s., based on signs of toxicity and reduced bodyweight gain at 2500 ppm.

**Section A7.5.3.1.2** **Short-term toxicity on birds (2)**

**Annex Point IIIA XIII 1.2** *Colinus virginianus* (Bobwhite quail)

## 5 CONCLUSION

**5.1 Conclusion** [redacted]

5.1.1 Reliability [redacted] X

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 07/08/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

## Section A7.5.3.1.2 Short-term toxicity on birds (3)

**Annex Point IIIA XIII 1.2** *Coturnix coturnix japonica* (Japanese quail)

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| 1.1 | **Reference** | [redacted]1995c *[Monograph: 1995b]*): YRC 2894 (techn.): 5-Day Dietary $LC_{50}$ to Japanese quail[redacted]Report No[redacted]VW-176, date: 1995-09-29.<br>*PPP-Monograph Chapter: B.9.1 Effects on birds, B.9.1.2 Dietary toxicity - Active substance (Study 3)* |
| 1.2 | **Data protection** | [redacted] |
| 1.2.1 | Data owner | [redacted] |
| 1.2.2 | Companies with letter of access | [redacted] |
| 1.2.3 | Criteria for data protection | [redacted] |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| 2.1 | **Guideline study** | Yes;<br>OECD guideline 205 and US-EPA 71-2 |
| 2.2 | **GLP** | [redacted] |
| 2.3 | **Deviations** | [redacted] |

### 3 MATERIALS AND METHODS

In a study on the dietary toxicity of technical YRC 2894 (thiacloprid, purity [redacted]%), young Japanese quail (14 days old, 10 birds per test group, 1 group per treatment level, 3 groups in the control) were exposed for 5 days to dietary concentrations of 625, 1250, 2500, 5000 or 10000 ppm a.s. in feed. This was followed by a 3 day observation period on untreated feed.

### 4 RESULTS

Mortalities were observed at 2500 (50%), 5000 (100%) and 10000 (100%) ppm. Signs of toxicity (loss of equilibrium, apathy, narcosis, trembling, tumbling) were observed at all treatment levels. At 625 ppm, sublethal symptoms were less severe (loss of equilibrium, light apathy, tumbling) than at higher test levels, and no mortality was observed. A treatment-related reduction of feed consumption was detected at all test levels. This was associated with a treatment-related reduction in bodyweight gain at 625, 1250 and 2500 ppm (there was 100% mortality at higher test levels prior to weighing). Gross pathological investigation of mortalities at 5000 and 10000 ppm and surviving birds at 2500 ppm revealed no organ alterations. However, for mortalities at 2500 ppm there was a smaller spleen in two birds, and an enlarged gall bladder and anaemia of kidneys/pancreas in one bird.

The $LC_{50}$ was 2500 ppm. The NOEC was <625 ppm. (signs of toxicity

and reduced bodyweight gain were observed at this test level).

## 5 CONCLUSION

### 5.1 Conclusion

[redacted]

5.1.1 Reliability [redacted] X

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 07/08/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

## Section A7.5.3.1.3 Effects on reproduction of birds (2)

**Annex Point IIIA XIII 1.3** *Colinus virginianus* (Bobwhite quail)

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | [redacted] 1997 *[Monograph: 1997a]*): Effects of a subchronic dietary exposure of YRC 2894 (techn.) on bobwhite quail including effects on reproduction and health [redacted] Report No. SXR/REP 05, date: 1997-08-04.<br>*PPP-Monograph Chapter: B.9.1 Effects on birds. B.9.1.3 Long term/Reproductive toxicity (Study 2)* |
| **1.2** | **Data protection** | [redacted] |
| 1.2.1 | Data owner | [redacted] |
| 1.2.2 | Companies with letter of access | [redacted] |
| 1.2.3 | Criteria for data protection | [redacted] |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes;<br>OECD guideline 206 and US-EPA FIFRA 71-4 |
| **2.2** | **GLP** | [redacted] |
| **2.3** | **Deviations** | [redacted] |

### 3 MATERIALS AND METHODS

In a reproductive toxicity study technical YRC 2894, (thiacloprid, purity: [redacted] and [redacted] %) was administered *ad libitum* in the diet to groups of 20 pairs of sexually mature bobwhite quail (25 weeks old at test initiation) approaching their first breeding season. Nominal (mean measured) concentrations were: 60 (52), 173 (152) and 500 (467) ppm a.s. in the diet, administered for 23 weeks. There was also a control group (20 pairs) on untreated feed. Birds were observed for mortality, abnormal behaviour and signs of toxicity. Adult body weight and feed consumption was measured. Egg production and quality (eggshell measurements) and hatchling health and survival were examined. Results are summarised in Table A7_5_3_I_3-I.

### 4 RESULTS

There were no treatment related mortalities, overt signs of toxicity or treatment related adverse effects on adult body mass, at any test level. Statistically significant reduced feeding rates relative to the control group were recorded at all treatment levels during the photostimulation period. However, given that these differences were slight and were not associated with any effect on adult bodyweight and other parameters this was not considered to be a significant adverse effect. One bird in the 173 ppm group was sacrificed because of inflamed toes and an observed apathy, but this was not treatment related. No treatment

**Section A7.5.3.1.3** **Effects on reproduction of birds (2)**

**Annex Point IIIA XIII 1.3** *Colinus virginianus* (Bobwhite quail)

related effects were observed for any reproductive parameters or on the offspring. Gross pathological examination of adult birds at termination of the study showed some discoloration of different body organs and injuries on feet. Since these findings were distributed over all test and control groups, they were not considered to be treatment related.

The NOEC was 500 ppm a.s. (measured concentration: 467 ppm a.s.), which was the highest dietary concentration tested.

## 5 CONCLUSION

**5.1 Conclusion** [redacted]

5.1.1 Reliability [redacted] X

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 07/08/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Table A7_5_3_1_3-1 Results of a reproductive toxicity study on bobwhite quail**

| | |
|---|---|
| Test species | *Colinus virginianus* |
| Exposure | 23 weeks dietary |
| lowest observed concentration with effect (LOEC)(nominal conc.) | >500 ppm (n) |
| highest concentration without toxic effect (NOEC)(nominal conc.) | 500 ppm (n) |

## Section A7.5.3.1.3 Effects on reproduction of birds (3)

**Annex Point IIIA XIII 1.3** *Anas platyrhynchos* (Mallard duck)

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | [redacted] 1997 *[Monograph: 1997a]*: Effect of technical YRC 2894 on mallard reproduction [redacted] Report No. 107360, date: 1997-12-18.<br>*PPP-Monograph Chapter: B.9.1 Effects on birds. B.9.1.3 Long term/Reproductive toxicity (Study 3)* |
| **1.2** | **Data protection** | [redacted] |
| 1.2.1 | Data owner | [redacted] |
| 1.2.2 | Companies with letter of access | [redacted] |
| 1.2.3 | Criteria for data protection | [redacted] |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes;<br>US-EPA FIFRA 71-4 |
| **2.2** | **GLP** | [redacted] |
| **2.3** | **Deviations** | [redacted] |

### 3 MATERIALS AND METHODS

In a reproductive toxicity study technical YRC 2894 (thiacloprid, purity: [redacted]%) was administered *ad libitum* in the diet to groups of 15 pairs of sexually mature pen-reared mallard duck (*Anas platyrhynchos*) (19 weeks old at test initiation) approaching their first breeding season. Nominal (mean measured) dietary concentrations were: 60 (47.6), 173 (140) and 500 (418) ppm a.s. in the diet, administered for 20 weeks. There was one group of 15 pairs per treatment level, and one group of 15 pairs in a control. Birds were observed for mortality, abnormal behaviour and signs of toxicity. Adult body weight and feed consumption was measured. Egg production and quality (eggshell measurements), and hatchling health and survival were examined.

### 4 RESULTS

Results are summarised in Table A7_5_3_1_3-1.

Female terminal bodyweight and bodyweight gain in the 173 and 500 ppm test groups were statistically significantly less than in the control. At 173 ppm there was an average 15.2% increase in female bodyweight over the exposure period, compared with a 26.0% increase in the control. In the 500 ppm group, the average increase in female bodyweight was 13.3%. Male bodyweight gain was statistically significantly less than the control at 173 ppm (there was an average 1.4% weight loss at this test level, compared with a 5.7% weight gain in

the controls). At 500 ppm, there was also a reduction in male bodyweight over the exposure period (average 3.0%) although this was not statistically significant. There was a trend for slightly reduced feed consumption (not statistically significant) over the treatment levels. This may have contributed to the reduced bodyweights. No treatment related clinical signs of toxicity were observed at any test level. No statistically significant differences in hatchling bodyweight or hatchling survival were recorded. However, the bodyweight of 14-day survivors at 500 ppm was statistically significantly less than the controls (averaging 12.6% less than control bodyweights). *Post mortem* observations of adult birds showed no treatment related findings.

The NOEC for reproductive parameters was 500 ppm a.s. (measured: 418 ppm a.s.) which was the highest dietary concentration tested. The overall NOEC for the study was 60 ppm a.s. (measured: 47.6 ppm a.s.), based on effects on bodyweights of adults at 173 ppm a.s. (measured: 140 ppm a.s.).

## 5 CONCLUSION

**5.1 Conclusion**

[redacted]

5.1.1 Reliability

[redacted] X

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 07/08/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Table A7_5_3_1_3-1 Results of a reproductive toxicity study on mallard duck**

| | |
|---|---|
| Test species | *Anas platyrhynchos* |
| Exposure | 20 weeks dietary |
| lowest observed concentration with effect (LOEC)(nominal conc.) based on reproductive parameters | >500 ppm |
| highest concentration without toxic effect (NOEC)(nominal conc.) based on reproductive parameters | 500 ppm |
| LOEC (nominal conc.) for effects on bodyweight of adult birds | 173 ppm |
| NOEC (nominal conc.) for effects on bodyweight of adult birds | 60 ppm |

## Section A7.5.3.1.3 Effects on reproduction of birds (1)

**Annex Point IIIA XIII 1.3** *Coturnix coturnix japonica* (Japanese quail)

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | [redacted] 1998b): Effects of a subchronic dietary exposure to YRC 2894 (techn.) on Japanese Quail including effects on reproduction and health [redacted] Report No [redacted] REP 07, date: 1998-02-16.<br>*PPP-Monograph Chapter: B.9.1 Effects on birds. B.9.1.3 Long term/Reproductive toxicity (Study 1)* |
| **1.2** | **Data protection** | [redacted] |
| 1.2.1 | Data owner | [redacted] |
| 1.2.2 | Companies with letter of access | [redacted] |
| 1.2.3 | Criteria for data protection | [redacted] |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes;<br>OECD guideline 206 |
| **2.2** | **GLP** | [redacted] |
| **2.3** | **Deviations** | [redacted] |

### 3 MATERIALS AND METHODS

In a reproductive toxicity study technical YRC 2894 (thiacloprid, purity [redacted]%) was administered in the diet to three groups of sexually mature Japanese quail (17 weeks old at test initiation) which were approaching their first breeding season. Each group consisted of 18-19 breeding pairs and received nominal dietary concentrations of 60, 173 or 500 ppm a.s. over a period of 6 weeks. A control group of 18 breeding pairs was maintained concurrently with the treatment groups. Before starting the study, all birds were acclimatised to test conditions (17 h photoperiod) for six weeks. During this time, birds stabilised their egg laying activity. After the breeding pairs had reached their peak egg laying activity, they were allowed to reproduce for a 2-week period without test compound influences (=pre-exposure period). Then, birds were subjected to the respective dietary treatments and monitored over further 6 weeks for their reproductive performance.

During the test, adult birds were held under a 17 h photoperiod and observed daily for mortality, abnormal behaviour, and signs of toxicity. Adult body mass was determined at the beginning of the acclimatisation period and at adult sacrifice. Feed consumption was measured weekly for each pen. Eggs laid during the acclimatisation period were counted and discarded. Starting with pre-exposure week 1, all eggs laid were collected, candled for eggshell cracks and incubated until chicks hatched. Biweekly throughout the egg laying period, all eggs laid on a distinct day were taken for eggshell measurements. Eggs set were examined for fertility, embryo development and hatchability. Hatched

**Section A7.5.3.1.3** **Effects on reproduction of birds (1)**

**Annex Point IIIA XIII 1.3** *Coturnix coturnix japonica* (Japanese quail)

chicks were raised over a further 2 week period during which they were fed with untreated diet. During that time they were observed for body mass development and general appearance. At study termination, all birds/chicks were asphyxiated with $CO_2$. All adult birds were necropsied at study termination.

**4 RESULTS**

Results for reproductive parameters are presented in Table A7_5_3_1_3-1.

Each batch of treated diet used was checked separately for its YRC 2894 concentration. On average, birds of the 60, 173, and 500 ppm treatment groups received mean dietary YRC 2894 concentrations of 51 ± 2.8 ppm, 157 ± 19.1 ppm and 485 ± 17.7 ppm, respectively.

There were no treatment-related mortalities or overt signs of toxicity with either the parental birds or their offspring. Feed consumption rates, body mass at study termination, and fresh masses of liver (both sexes) and heart (females only) of the parental birds were statistically significantly lower in the 500 ppm treatment group relative to the control group. None of the examined reproductive parameters was adversely affected in any treatment group compared with the control birds. However, there was a significantly lower average body mass of the 14-day surviving chicks from the 500 ppm treatment group when compared with the controls. Gross pathology revealed no treatment related findings.

The overall NOEC was 173 ppm a.s. in the diet (measured concentration: 157 ppm a.s.), based on a statistically significant effect on adult body mass, adult food consumption, and body mass of 14 day surviving chicks at 500 ppm a.s. (measured concentration: 485 ppm a.s.).

**5 CONCLUSION**

**5.1 Conclusion** [redacted]

5.1.1 Reliability [redacted] X

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 07/08/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Table A7_5_3_1_3-1 Results of a reproductive toxicity study on Japanese quail**

| Test Species | *Coturnix coturnix japonica* | | | |
|---|---|---|---|---|
| Exposure | Dietary treatment with YRC 2894 techn. (thiacloprid) | | | |
| Nominal dietary concentrations | 0 ppm | 60 ppm | 173 ppm | 500 ppm |
| Analytically verified dietary concentr. | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean number of eggs laid per hen | [redacted] | [redacted] | [redacted] | [redacted] |
| Average egg mass [g] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean number of cracked eggs per hen | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean eggshell thickness [mm] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean number of eggs set per hen | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean number of fertile eggs per hen | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean number of hatchlings per hen | [redacted] | [redacted] | [redacted] | [redacted] |
| Avg. mass of hatchlings [g] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean no. of 14 day survivors per hen * | [redacted] | [redacted] | [redacted] | [redacted] |
| Avg. mass of 14 day survivors | [redacted] | [redacted] | [redacted] | [redacted] |

* This number was very adversely affected by a coccidioses caught by the chicks during the last two study weeks

## Section A7.5.4.1

**Annex Point IIIA XIII 3.1**

## Acute toxicity to honeybees and other beneficial arthopods, for example predators

*Apis mellifera* (honeybee)

| | | | Official use only |
|---|---|---|---|
| | | **1 REFERENCE** | |
| **1.1** | **Reference** | Nengel, S. (1995): Assessment of side effects of YRC 2894 (techn.) to the honey bee, *Apis mellifera* L. in the laboratory following the EPPO Guideline No. 170. Source: GAB Biotechnologie GmbH. Bayer AG, Report No. 95087/ 01-BLEU, date: 1995-10-13.<br>*PPP-Monograph Chapter: B.9.4 Effects on bees. B.9.4.1 Toxicity-Active substance* | |
| **1.2** | **Data protection** | [redacted] | |
| 1.2.1 | Data owner | [redacted] | |
| 1.2.2 | Companies with letter of access | [redacted] | |
| 1.2.3 | Criteria for data protection | [redacted] | X |
| | | **2 GUIDELINES AND QUALITY ASSURANCE** | |
| **2.1** | **Guideline study** | Yes;<br>EPPO method 170 | |
| **2.2** | **GLP** | [redacted] | |
| **2.3** | **Deviations** | [redacted] | X |
| | | **3 MATERIALS AND METHODS** | |
| | | The acute toxicity of thiacloprid (purity [redacted] %) to the honeybee *Apis mellifera* was studied for 48 h under laboratory conditions to concentrations of 9.4 to 150.0 µg as/bee for feeding (oral application, solution in acetone/sugar) and for topical application (contact, solution in acetone) with 12.5 to 200 µg as/bee. Reference substance was dimethoate. | X |
| | | **4 RESULTS** | |
| | | A $LD_{50}$ of 17.32 µg/bee was reported for acute oral toxicity and 38.82 µg/bee for the endpoint acute contact. | X |
| | | **5 CONCLUSION** | |
| **5.1** | **Conclusion** | [redacted] | X |
| 5.1.1 | Reliability | [redacted] | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 10/11/06 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |

| | |
|---|---|
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

| Section 7.5.5<br>Annex Point IIIA 13.3 | Bioconcentration, terrestrial / further studies | |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| Other existing data [ ]<br>Limited exposure [ ] | Technically not feasible [ ] Scientifically unjustified [ ]<br>Other justification [X] | |
| Detailed justification: | Studies on bioconcentration of thiacloprid in soil organisms were not submitted. There is no data requirement on such data for actives used in PT 8. | |
| Undertaking of intended data submission [ ] | – | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| Date | 08/08/06 | |
| Evaluation of applicant's justification | [redacted] | |
| Conclusion | [redacted] | |
| Remarks | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| Date | *Give date of comments submitted* | |
| Evaluation of applicant's justification | *Discuss if deviating from view of rapporteur member state* | |
| Conclusion | *Discuss if deviating from view of rapporteur member state* | |
| Remarks | | |

| Section 7.5.6<br>Annex Point IIIA 13.3 | Effects on other terrestrial non-target organisms | |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data** [ ] | **Technically not feasible** [ ] **Scientifically unjustified** [ ] | |
| **Limited exposure** [ ] | **Other justification** [X] | |
| **Detailed justification:** | Such studies are not a data requirement for actives used in PT 8. | |
| **Undertaking of intended data submission** [ ] | – | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | 08/08/06 | |
| **Evaluation of applicant's justification** | [redacted] | |
| **Conclusion** | [redacted] | |
| **Remarks** | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| Section 7.5.7.1<br>Annex Point IIIA 13.3 | **Effects on mammals: acute oral toxicity, short term toxicity, effects on reproduction** | |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data** [ ] | **Technically not feasible** [ ] **Scientifically unjustified** [ ] | |
| **Limited exposure** [ ] | **Other justification** [X] | |
| **Detailed justification:** | Such studies are not a data requirement for actives used in PT 8 | |
| **Undertaking of intended data submission** [ ] | – | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | 08/08/06 | |
| **Evaluation of applicant's justification** | [redacted] | |
| **Conclusion** | [redacted] | |
| **Remarks** | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

## Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

| Subsection (Annex point) | | | Official use only |
|---|---|---|---|
| REFERENCE | | Anonymous (2005): Safety Data Sheet of Preventol TX. Lanxess Deutschland GmbH, MSDS No. 161040/04, date: 2005-02-10 | |
| 8.1 (IIA, VIII 8.1) | | **Recommended methods and precautions concerning handling, use, storage, transport or fire** | |
| 8.1.0 | **Methods and precautions concerning placing on the market** | Please refer to information given below. | |
| 8.1.1 | **Methods and precautions concerning handling and use of the active substance** | Labelling according to Directive 67/548/EEC: harmful by inhalation and if swallowed and limited evidence of a carcinogenic effect (Xn, R20/22, R40). Therefore, if product is handled while not enclosed, and if skin contact may occur:<br><br>Use respiratory protection: Fine dust mask (Class P1). Respiratory protection instructions ZH1/701 issued by the German Confederation of Commercial Employers' Accident Liability Insurance Associations must be observed.<br><br>Eye protection: goggle.<br><br>Hand protection: Wear suitable protective gloves (e.g. of rubber, Polyvinyl chloride – PVC). After contamination with product change the gloves immediately and remove them according to relevant national and local regulations.<br><br>Keep away from sources of ignition – NO smoking.<br><br>Follow the explosion protection guidelines of the "Berufsgenossenschaft der Chemischen Industrie" (Employers' Accident Liability insurance Association for the German Chemical industry)<br><br>The product may cause dust explosion. Observe the usual precautionary measures required for chemicals with dust-explosive properties. Observe national regulations.<br><br>Do not breathe dust. Avoid contact with eyes and skin. Keep away from food and drink stuffs. Do not eat, drink or smoke at work. Wash hands before breaks and at end of work and use skin-protecting ointment. | |
| 8.1.2 | **Methods and precautions concerning storage of the active substance** | German storage class: 11 Combustible Solids.<br><br>Keep container tightly closed.<br><br>Store in original container. For reasons of quality assurance, keep dry at temperatures under 50 °C. Store so that unauthorised persons do not have access. Keep away from food, drink and animal feeding stuffs.<br><br>Only use containers that are approved specifically for the substance/product. Suitable container materials: plain steel, aluminium, stainless steel #316, copper, brass and HDPE (high density polyethylene) (Reference: Swan, 1997).<br><br>Based on experience by the packaging of thiacloprid technical, the following packaging materials are recommended for the direct contact with this substance: HDPE, LDPE and Polypropylene (Reference: Wittmann, 2006). | |

## Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

**8.1.3 Methods and precautions concerning transport of the active substance**

**ADR/RID/ADNR**

| | |
|---|---|
| UN-No.: | 2811 |
| Labels: | 6.1 |
| Packaging group: | III |
| Hazard No. | 60 |
| Description of the goods | UN 2811 Toxic solid, organic, N.O.S. (chloronicotinyl-compound) |

**IMDG**

| | |
|---|---|
| UN-No.: | 2811 |
| Labels: | 6.1 |
| Packaging group: | III |
| Description of the goods | Toxic solid, organic, N.O.S. (chloronicotinyl-compound) |

**IATA**

| | |
|---|---|
| UN-No.: | 2811 |
| Labels: | 6.1 |
| Packaging group: | III |
| Description of the goods | Toxic solid, organic, N.O.S. (chloronicotinyl-compound) |

Transport information: Slightly toxic. Keep dry. Keep separated from foodstuffs.

**8.1.4 Methods and precautions concerning fire of the active substance**

Extinguishing media: sprayed water jet, foam, extinguishing powder, $CO_2$, sand. Fight fire in early stages if safe to do so. Do not breathe fumes. Use breathing apparatus:

- In well ventilated areas: full face mask with combination filter, e.g. ABEK-P2 (but this offers no protection from carbon monoxide!)
- Enclosed premises: respirator with independent air supply

In the event of fire, the formation of hydrogen chloride, hydrogen cyanide, carbon monoxide, sulphur dioxide and nitrogen oxides must be anticipated.

Contain fire fighting water. Do not allow run-off from the fighting to enter drains or water courses.

**8.2 (IIA, VIII 8.2) In case of fire, nature of reaction products, combustion gases, etc.**

In the event of fire, formation of hydrogen chloride, hydrogen cyanide, carbon monoxide, sulphur dioxide and nitrogen oxides.

**8.3 (IIA, VIII 8.3) Emergency measures in case of an accident**

## Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

| | | |
|---|---|---|
| 8.3.1 | **Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment, if available** | GENERAL ADVICE: Move out of dangerous area. If the patient is likely to become unconscious, place and transport in stable sideways position. Also heed the risks to your own person. Remove soiled or soaked clothing immediately.<br>UPON INHALATION: Take the patient into the fresh air; if there is difficulty in breathing, medical advice is required.<br>FOLLOWING SKIN CONTACT: Cleaning with plenty of water, soap or other non-irritating cleansing agent.<br>FOLLOWING EYE CONTACT: Contamination of the eyes must be treated by thorough irrigation with water, with the eyelids held open. Eventually a doctor (or eye specialist) should be consulted.<br>UPON SWALLOWING: Call emergency doctor immediately.<br><br>INFORMATION FOR THE PHYSICIAN: The active ingredient belongs to the following chemical group: thiazolidine derivative. Therapeutic measures: Basic aid, decontamination, symptomatic treatment. |
| 8.3.2 | **Emergency measures to protect the environment** | Use the personal equipment listed in Chapter 8.1. Do not empty into drains or waters. Take up spilled product with dust-binding material or suitable vacuum cleaner. Avoid formation of dust. Fill materials taken up into closable container. To clean the floor and all objects contaminated by this material, use damp cloth. Also place used cleaning materials into closable receptacles. |
| **8.4 (IIA, VIII 8.4)** | | **Possibility of destruction or decontamination following release in or on the following: (a) air, (b) water, including drinking water, and (c) soil** |
| 8.4.1 | **Possibility of destruction or decontamination following release in the air** | The vapour pressure of thiacloprid is very low. Therefore a contamination of the environmental compartment air by thiacloprid is negligible after its release into the environment due to an accidental misuse.<br><br>If dusting occurs, wear an approved respirator. |
| 8.4.2 | **Possibility of destruction or decontamination following release in water, including drinking water** | Do not discharge into the drains/surface water/groundwater.<br><br>From water or drinking water thiacloprid should be removed with adsorptive material like charcoal. |
| 8.4.3 | **Possibility of destruction or decontamination following release in or on soil** | Use mechanical handling equipment. Take up avoiding formation of dust.<br><br>Pack spilled material in suitable containers for recovery or disposal.<br><br>Clean contaminated floors and objects thoroughly, observing environmental regulations. |
| **8.5 (IIA, VIII 8.5)** | | **Procedures for waste management of the active substance for industry or professional users** |
| 8.5.1 | **Possibility of re-use or recycling (IIA, VIII 8.5.1)** | Detailed instructions for safe disposal:<br><br>In cases where larger amounts of the product have become unusable, it should be established whether material utilisation is possible. Small amounts of the product and uncleaned empty packaging should be packaged and sealed, labelled and transferred to a suitable incinerator in accordance with the local regulations. |
| 8.5.2 | **Possibility of neutralisation of effects (IIA, VIII 8.5.2)** | |

## Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

| | | |
|---|---|---|
| 8.5.3 | **Conditions for controlled discharge including leachate qualities on disposal (IIA, VIII 8.5.3)** | For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used. It is among the tasks of the polluter to assign the waste to waste codes specific to industrial sectors and processes according to the European Waste Catalogue. |
| 8.5.4 | **Conditions for controlled incineration (IIA, VIII 8.5.4)** | |
| **8.6 (IIA, VIII 8.6)** | | **Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms**<br><br>No observations on undesirable or unintended side-effects on beneficial and other non-target organisms. |
| **8.7 (IIIA, VIII 1)** | | **Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances**<br><br>Organohalogen compounds are covered by List I of the Annex to Directive 80/68/EEC.<br><br>Biocides and their derivatives are covered by List II of the Annex to Directive 80/68/EEC. |

## Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 11/04/2007 |
| **Materials and Methods** | [redacted] |
| **Results and discussion** | [redacted] |
| **Conclusion** | [redacted] |
| **Reliability** | [redacted] |
| **Acceptability** | [redacted] |
| **Remarks** | [redacted] |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

| | | |
|---|---|---|
| **Section A8**<br>**Subsection A8.6** | **Measures necessary to protect man, animals and the environment** | |
| **Annex Point IIA, VIII 8.6** | OBSERVATIONS ON UNDESIRABLE OR UNINTENDED SIDE-EFFECTS | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [...]** | **Technically not feasible [ ]** **Scientifically unjustified [ ]**<br>**Other justification [X]** | |
| **Detailed justification:** | There are no observations on undesirable or unintended side-effects on beneficial and other non-target organisms. | |
| **Undertaking of intended data submission [ ]** | – | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | 11/04/2007 | |
| **Evaluation of applicant's justification** | [redacted] | |
| **Conclusion** | [redacted] | |
| **Remarks** | [redacted] | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |