<table>
<thead>
<tr>
<th>Carbendazim</th>
<th>1.0 mg/kg</th>
<th>65</th>
<th>77</th>
<th>68</th>
<th>72</th>
<th>70.5 ± 5.2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.0 mg/kg</td>
<td>0</td>
<td>6</td>
<td>18</td>
<td>8</td>
<td>8.0 ± 7.5</td>
</tr>
<tr>
<td></td>
<td>5.0 mg/kg</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0 ± 0.0</td>
</tr>
</tbody>
</table>

**Table A7.5.2.1-10: Definitive test – EC50 Calculation**

<table>
<thead>
<tr>
<th>Lowest treatment group</th>
<th>5.2 mg a.i./kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest treatment group</td>
<td>100.0 mg a.i./kg</td>
</tr>
<tr>
<td>Regression slope</td>
<td>75.5</td>
</tr>
<tr>
<td>Regression constant</td>
<td>-55.9</td>
</tr>
<tr>
<td>Coefficient of determination</td>
<td>r² = 95 %</td>
</tr>
<tr>
<td>EC₅₀</td>
<td>25.2 mg a.i./kg</td>
</tr>
<tr>
<td>95% confidence limits</td>
<td>10.6 - 59.7</td>
</tr>
</tbody>
</table>
Section 7.5.3.1.2  
Annex Point IIIA XIII 1.2  
Short term (dietary) toxicity to birds  
Avian dietary toxicity test

1  REFERENCE


2  GUIDELINES AND QUALITY ASSURANCE

2.1  Guideline study

Yes,
US EPA OPPTS number 850.2200, FIFRA subdivision B - section 71-2;
OECD Guideline 205.

2.2  GLP

Yes

2.3  Deviations

No

3  METHOD

3.1  Test material

As given in section 2

3.1.1  Lot/Batch number

2001060167

3.1.2  Specification

As given in section 2

3.1.3  Purity

96.5% w/w

3.1.4  Composition of Product

Not applicable, test carried out on active substance

3.1.5  Further relevant properties

Due to the low water solubility of cypermethrin, the test substance was dissolved in acetone before being mixed into the diet.

3.1.6  Method of analysis in the diet

The method of analysis was developed by Wildlife International Ltd (study report available). Samples were extracted with ethyl acetate and the concentration of cypermethrin in the extracts determined by Gas Chromatography with Electron Capture Detection (GC-ECD).
Calibration samples were run alongside each sample set. The LOD was set at 0.10 ng on-column and the LOQ set at 100 ppm a.s. based on the lowest matrix fortification level.

Procedural recovery of the analytical method were 106% and 104% for samples taken on days 0 and 5, respectively. The measured concentrations of the dietary samples were not corrected for procedural recovery.

3.2  Administration of the test substance

Test substance was administered in the diet. Test diets were prepared by suspending the test article in solvent (acetone) prior to mixing with feed.
### Section 7.5.3.1.2

#### Short term (dietary) toxicity to birds

**Avian dietary toxicity test**

| 3.3 | Reference substance | No |
| 3.3.1 | Method of analysis for reference substance | Not applicable |

#### Testing procedure

| 3.4.1 | Test organisms | See table A7_5_3_1_1-1 |
| 3.4.2 | Test system | see table A7_5_3_1_1-2 |
| 3.4.3 | Diet | All birds were fed a game bird ration formulated to in-house specifications (full diet preparation is provided in the study report). An amount of diet sufficient to last the 5 day exposure period was prepared for each treatment and control group and presented to the birds at test initiation. Test diets were prepared by suspending the test article in solvent (acetone) prior to mixing with feed using a Hobart mixer. Samples of diet were collected at preparation (day 0) to verify the test concentration and to confirm the stability and homogeneity in the diets. Samples were also collected from feed troughs of the control, low and high dose groups on day 5 of the test to assess stability of the test substance under test conditions. |
| 3.4.4 | Test conditions | See table A7_5_3_1_1-3 |
| 3.4.5 | Duration of the test | 10 days acclimation + 5 days exposure + 3 days observation |
| 3.4.6 | Test parameter | Mortality, signs of toxic effects, food consumption, bodyweight. |
| 3.4.7 | Examination / Observation | Twice daily, with the exception of day 8 when birds were observed once before euthanasia. |
| 3.4.8 | Statistics | Not required as no mortality occurred during the study. Therefore the LC50 was based on the highest test concentration. No statistical analysis was applied to separate mean responses among treatment groups for the endpoints of food consumption and bodyweights. |

### RESULTS

| 4.1 | Limit Test / Range finding test | Not performed |
| 4.2 | Results test substance | Test diets from the 562 and 5620 ppm a.i. test concentrations were used to evaluate homogeneity. Means and standard deviations for the two test concentrations were 599±13.5 ppm a.i. and 5730±183 ppm a.i., representing 107% and 102% of nominal respectively. The coefficients of variation for these concentrations were 2.25% and 3.19% respectively. Samples collected during the test to verify test substance concentrations for the 1000, 1780 and 3160 ppm a.i. diets had means of 1020, 1900 and 3260 ppm a.i. respectively representing 102%, 107% and 103% of nominal. Stability of the test compound was verified by analysis of diet samples from feeders after being held at ambient for 5 days. Values averaged |

| 4.2.1 | Applied concentrations | |

| 4.2.1.1 | | |

| 4.2.1.2 | | |

| 4.2.1.3 | | |

| 4.2.1.4 | | |

| 4.2.1.5 | | |

| 4.2.1.6 | | |
### Section 7.5.3.1.2  
**Short term (dietary) toxicity to birds**  
**Avian dietary toxicity test**

| 4.2.2 | Effect data  
(Mortality) | 104% and 108% of the Day 0 values for the 562 and 5620 ppm a.i. test concentrations respectively. |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2.3</td>
<td>Body weight</td>
<td>No mortalities occurred during the test in any of the test groups or the controls</td>
</tr>
<tr>
<td></td>
<td></td>
<td>There was a decrease in mean body weight gain during the treatment period in birds receiving cypermethrin at 3160 and 5620 ppm a.i. test concentrations compared with untreated controls (see table A7_5_3_1-1-4).</td>
</tr>
<tr>
<td>4.2.4</td>
<td>Feed consumption</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>There were no apparent treatment-related effects on feed consumption at any of the test concentrations during the exposure period (see table A7_5_3_1-1-4).</td>
</tr>
</tbody>
</table>
| 4.2.5 | Concentration /  
response curve | Not applicable                                                                    |
|       |                   | There were no clinical signs of toxicity in the control group or in the treatment groups at 562 and 1000 ppm a.i. concentrations. All birds in these groups remained in good health throughout study. |
|       |                   | In the 1780 ppm a.i. treatment group signs of toxicity were noted on the morning of Day 1. These were wing droop, ruffled appearance and lethargy. These signs of toxicity were observed through to Day 7 for all except two birds which remained normal in appearance and behaviour. One bird continued to display a ruffled appearance until test termination but was nevertheless gaining weight and improving in condition. Lesions from toe picking were also noted in two birds during the course of the test. |
|       |                   | In the 3160 ppm a.i. treatment group signs of toxicity were first noted on the morning of Day 1. These were hyperexcitability, exhibited by all five birds in the first pen, and wing droop or ruffled appearance exhibited by two birds in the second pen. By the afternoon of Day 7 all birds were normal in appearance and behaviour. |
|       |                   | In the 5620 ppm a.i. treatment group signs of toxicity were first noted on the morning of Day 1. These were wing droop and ruffled appearance and were exhibited by up to seven birds. These signs of toxicity were observed only up to and through Day 7 for all except two birds which continued to display a ruffled appearance at test termination. These birds were nevertheless gaining weight and improving in condition. |
| 4.3   | Results of controls | None, all control birds remained in good health throughout the study. |
| 4.3.1 | Number/percentage of animals showing adverse effects | Not applicable |
| 4.3.2 | Nature of adverse effects | Not performed |
| 4.4   | Test with reference substance | Not performed |
Section 7.5.3.1.2  Short term (dietary) toxicity to birds
Annex Point IIIA XIII 1.2  Avian dietary toxicity test

5  APPLICANT’S SUMMARY AND CONCLUSION

5.1  Materials and methods
Cypermethrin technical active substance (purity 96.5%) was administered in the diet to 10-day old northern bobwhite quail (Colinus virginianus) at nominal doses of 0, 562, 1000, 1780, 3160 and 5620 ppm a.i. for five days according to OECD guideline 205 (10 birds of undetermined sex/treatment group).

Mortalities, health and clinical observations were recorded twice daily for seven days after the beginning of dosing, and once prior to euthanasia, on Day 8 of the test. Individual body weights were measured at Days 0 (test initiation), 5 and 8. Average food consumption was determined by measuring the change in weight of feed presented to the birds during the exposure period and the post-exposure period.

5.2  Results and discussion
No mortality observed in any treatment group. No clinical signs of toxicity nor modification of appearance and behaviour at 562 and 1000 g/kg food. Signs of toxicity (wing droop, ruffled appearance, lethargy, hyper excitability) were observed at 1780, 3160 and 5620 mg/kg food.

Treatment-related effect in bodyweight was observed during the exposure period at 3160 and 5620 mg/kg food.

Clinical signs/feed consumption: no apparent treatment-related effect during exposure period.

LC50 (5d) > 5620 mg a.s./kg feed or > 1376 mg a.s./kg bw/d, based on the mean body weight of 24.5 g and the food consumption of 6 g/day reported in the 5620 mg/kg treatment group.

The no observed effect concentration (NOEC) was 1000 ppm a.i. (1000 mg a.s./kg feed) based upon signs of toxicity in birds receiving the 1780 ppm a.i. test concentration.

5.2.1  LD50
> LC50 (5 days) = 5620 mg a.s./kg feed based on no mortality at the highest dose level

5.3  Conclusion
Validity criteria were fulfilled; no mortality was recorded in any of the three control groups.

LC50 (5d) > 5620 mg a.s./kg feed
NOEC 1000 mg a.s./kg feed

5.3.1  Reliability
1

Study was evaluated and accepted under directive 91/414/EC

5.3.2  Deficiencies
No

---

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

---

EVALUATION BY RAPPORTEUR MEMBER STATE

Date
May 2008

Materials and Methods
Applicant’s version is acceptable.

Results and discussion
Applicant’s version is a adopted.
### Short term (dietary) toxicity to birds

**Avian dietary toxicity test**

<table>
<thead>
<tr>
<th><strong>Conclusion</strong></th>
<th>Applicant's version is adopted.</th>
</tr>
</thead>
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<td><strong>Acceptability</strong></td>
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<tr>
<td><strong>Remarks</strong></td>
<td></td>
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**COMMENTS FROM ... (specify)**

**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.

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 A7.5.3.1-1:  Test animals

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species/strain</td>
<td>Northern bobwhite quail (Colinus virginianus)</td>
</tr>
<tr>
<td>Source</td>
<td>Wildlife International Ltd., Maryland</td>
</tr>
<tr>
<td>Sex</td>
<td>Undetermined as all birds were immature</td>
</tr>
<tr>
<td>Initial body weight (bw)</td>
<td>16-25 g at initiation of the test</td>
</tr>
<tr>
<td>Breeding population</td>
<td>Birds obtained from production flock. All birds were from the same hatch.</td>
</tr>
<tr>
<td>Amount of food</td>
<td>Ad libitum during acclimatization and during the test. Average feed consumption was determined by measuring the change in weight of feed presented to the birds during the exposure period and the post-exposure period. The accuracy of food consumption could be affected by wastage.</td>
</tr>
<tr>
<td>Age at time of first dosing</td>
<td>10 days</td>
</tr>
<tr>
<td>Health condition / medication</td>
<td>Birds appeared to be in good health at test initiation and received no form of antibiotic medication during acclimatization or test period.</td>
</tr>
<tr>
<td>Criteria</td>
<td>Details</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Test location</td>
<td>Indoor in thermostatically controlled brooding pens</td>
</tr>
<tr>
<td>Holding pens</td>
<td>Each pen had a floor space of approximately 72 x 90 cm and a ceiling height of 23 cm. External walls, ceilings and floors were made of galvanized steel wire and sheeting.</td>
</tr>
<tr>
<td>Number of animals</td>
<td>Total number of tested animals = 80</td>
</tr>
<tr>
<td>Number of animals per pen [cm²/bird]</td>
<td>5 birds/pen [1.3 cm²/bird]</td>
</tr>
<tr>
<td>Number of animals per dose</td>
<td>10 chicks per dose group (5 treatment groups plus 3 untreated control groups).</td>
</tr>
<tr>
<td>Pre-treatment / acclimation</td>
<td>All birds were acclimatised to the caging facilities from the day of hatch until initiation of the test. Throughout acclimatisation birds were fed the same bird ration and received a water soluble vitamin mix via their water. Water and feed were supplied <em>ad libitum</em>.</td>
</tr>
<tr>
<td>Diet during test</td>
<td>All birds were fed a game bird ration formulated to Wildlife International Ltd’s specifications. This comprised a minimum of 27% protein and 2.5% crude fat with a maximum of 5% crude fibre. The diet also contained vitamin and mineral pre-mix.</td>
</tr>
<tr>
<td>Dosage levels (of test substance)</td>
<td>Nominal dietary test concentrations were 0, 562, 1000, 1780, 3160, 5620 mg/kg feed. Sufficient quantity of test diet to last the 5 day exposure period were prepared at test initiation and administered at day 0.</td>
</tr>
<tr>
<td>Replicate/dosage level</td>
<td>Not applicable, only one preparation/dose.</td>
</tr>
<tr>
<td>Feed dosing method</td>
<td>Birds were allowed access to the feed <em>ad libitum</em></td>
</tr>
<tr>
<td>Dosing volume per application</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Frequency, duration and method of animal monitoring after dosing</td>
<td>Mortalities, health and clinical observations were recorded twice daily for seven days after the beginning of dosing, and once prior to euthanasia, on Day 8 of the test.</td>
</tr>
<tr>
<td>Time and intervals of body weight determination</td>
<td>Individual body weights were measured at Days 0 (test initiation), 5 and 8.</td>
</tr>
</tbody>
</table>
Table A7.5.3.1.1-3: Test conditions (housing)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test temperature</td>
<td>Average temperature in the brooding compartment of the pens was 39±2°C(SD) with the average room temperature for the study being 29.8±1.2°C(SD).</td>
</tr>
<tr>
<td>Shielding of the animals</td>
<td>Not specified</td>
</tr>
<tr>
<td>Ventilation</td>
<td>The air handling system was designed to vent up to 15 room air volumes per hour and replace them with fresh air.</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>Average relative humidity of 56±4°C(SD).</td>
</tr>
<tr>
<td>Photoperiod and lighting</td>
<td>16 hours of light per day (maintained by clock), with an average of 173 lux of illumination.</td>
</tr>
</tbody>
</table>

Table A7.5.3.1.1-4: Effect Data

<table>
<thead>
<tr>
<th>Treatment Group (ppm a.i.)</th>
<th>Mean body weight (g)</th>
<th>Mean food consumption (g/bird/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 0</td>
<td>Day 5</td>
</tr>
<tr>
<td>0</td>
<td>21</td>
<td>32 (11)</td>
</tr>
<tr>
<td>562</td>
<td>20</td>
<td>31 (11)</td>
</tr>
<tr>
<td>1000</td>
<td>20</td>
<td>32 (12)</td>
</tr>
<tr>
<td>1780</td>
<td>21</td>
<td>31 (10)</td>
</tr>
<tr>
<td>3160</td>
<td>21</td>
<td>31 (9)</td>
</tr>
<tr>
<td>5620</td>
<td>21</td>
<td>28 (7)</td>
</tr>
</tbody>
</table>

Bracketed figures are the mean change, calculated using individual body weights.

Reported figures have been rounded to the nearest whole number.
Section 7.5.3.1.3  Effects on reproduction of birds
Annex Point IIIA XIII 1.3

1  REFERENCE


2  GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study
Yes,
FIFRA guideline 71-4
OECD guideline 206

2.2 GLP
Yes

2.3 Deviations
No

3  METHOD

3.1 Test material
As given in section 2

3.1.1 Lot/Batch number
2001060167

3.1.2 Specification
As given in section 2

3.1.3 Purity
96.5% w/w

3.1.4 Composition of Product
Not applicable, study was performed on the technical grade active substance

3.1.5 Further relevant properties

3.1.6 Method of analysis
The method of analysis was developed by Wildlife International Ltd (study report available). Samples were extracted with ethyl acetate and the concentration of cypermethrin in the extracts determined by Gas Chromatography with Electron Capture Detection (GC-ECD). Calibration samples were run alongside each sample set. The LOD was set at 0.10 ng on-column and the LOQ set at 100 ppm a.s. based on the lowest matrix fortification level.

The individual procedural recoveries were in the range 88-107%. The measured concentrations of the dietary samples were not corrected for procedural recovery.

3.2 Administration of the test substance
Test substance was administered in the diet. Test diets were prepared by mixing cypermethrin (dissolved in acetone) into a premix which was then used for weekly preparation of the final diet.
Section 7.5.3.1.3  
Effects on reproduction of birds

Annex Point IIIA XIII 1.3

3.3 Testing procedure

3.3.1 Test organisms  
See table A7.5.3.1.3-1

3.3.2 Test system  
See table A7.5.3.1.3-2

3.3.3 Diet  
See table A7.5.3.1.3-2

3.3.4 Test conditions  
See table A7.5.3.1.3-3

3.3.5 Duration of the test  
21 days

3.3.6 Test parameter  
Adult bodyweight, adult feed consumption, eggs laid, eggs cracked, viable embryos, live embryos, hatchlings, 14 day old survivors, eggshell thickness and offspring bodyweight.

3.3.7 Examination / Observation  
All birds were observed daily. Body weights of the adults were recorded before dosing and at two week intervals up to eight weeks after dosing, and then at the end of the study. Food consumption per pen was recorded weekly.

During egg laying, eggshell thickness was measured on one egg from odd numbered pens during odd numbered weeks and from even numbered pens during even numbered weeks, when available. Eggs were examined for embryo viability, on day 11-12 of incubation, and survival, on day 21 of incubation.

The group body weight (by parental pen) of hatchlings was determined after hatching and after an additional 14 days. Macroscopic examinations were recorded at post-mortem on birds which died during the study and on all surviving birds at the end of the exposure period.

3.3.8 Statistics  
Not applicable, the NOEC was determined based on no-effects at the highest dose tested.

4 RESULTS

4.1 Limit Test / Range finding test

4.1.1 Concentration  
Performed (38 day pilot study)

Three treatment groups (5 pairs/group) were fed diets containing 160, 400 and 1000 ppm cypermethrin respectively. A non-treated diet was also fed to a fourth control group.

4.1.2 Number/percentage of animals showing adverse effects  
No treatment related mortalities occurred in the control, 400 or 1000 ppm dose groups. One incidental mortality did occur in the 160 ppm group, however following observations at necropsy this single mortality was considered to be unrelated to treatment.

Additionally there were no signs of toxicity nor any treatment-related effects on feed consumption, bodyweight or egg production at any of the concentrations tested.

4.1.3 Nature of adverse effects  
No treatment-related effects were observed in the pilot study.
Section 7.5.3.1.3
Annex Point IIIA XIII 1.3

Effects on reproduction of birds

4.2 Results test substance

4.2.1 Applied concentrations

Dietary analysis: The absence of test substance or co-eluting substance was confirmed for control samples. Homogeneity testing was carried out for the 160 and 1000 ppm a.i. test concentrations (six samples at each concentration, from top, middle and bottom of left and right sections of the mixing vessel). Means and standard deviations were 178±10.2 and 972±12.9 ppm a.i. respectively, with coefficients of variation of 5.73 and 1.33% respectively.

Measured concentrations of cypermethrin in the freshly prepared then frozen diet ranged from 93 to 104% of the nominal values. Measured concentrations in diet samples collected from feeders after seven days at ambient also ranged from 93 to 104% of the Day 0 values.

4.2.2 Effect data (Mortality and reproductivity)

Mortality: No treatment-related mortalities occurred during the study. Two incidental mortalities occurred, one in the 160 ppm a.i. treatment group and the other in the 400 ppm a.i. treatment group.

The mortality in the 160 ppm a.i. treatment group was a female found dead on Day 2 of Week 12. Prior to death, the female was noted to have extensive head and neck lesions and appeared weak. At necropsy the bird was well muscled, with a body weight of 210 g. Yolk remnants were found in the abdominal cavity. The spleen was pale and slightly enlarged, the kidneys were pale, the cecal contents were pasty, and the ovary was developing. At necropsy, the female’s pen mate was noted to have a slightly enlarged spleen, but was otherwise unremarkable.

The mortality in the 400 ppm a.i. treatment group was a female that was euthanized on Day 2 of Week 19 due to her debilitated condition. Prior to death the female was noted as thin and exhibited depression, a ruffled appearance, lethargy, foot lesions and associated lameness. At necropsy, the bird was emaciated, with a body weight of 136 g. There was a loss of muscle mass with the keel prominent. The liver and kidneys were pale and the ovary was regressed. At necropsy, the female’s pen mate was noted to have areas of hyperemia in the small intestine, but was otherwise unremarkable.

Reproductive effects: There were no treatment-related effects upon reproductive performance at any of the concentrations tested. When compared to the control group, there were no statistically significant differences in any of the reproductive parameters measured in the 160, 400, or 1000 ppm a.i. treatment groups.

The NOEC was determined to be 1000 ppm (1000 mg a.s./kg feed) based on the highest dose level tested.

See Table A7_5_3_1_3-4
### Section 7.5.3.1.3 Effects on reproduction of birds

#### 4.2.3 Body weight
There was a slight, but statistically significant (p < 0.05) increase in the mean body weight of the males in the 400 ppm a.i. treatment group at termination of the adult portion of the study. Since the difference observed was small, not concentration dependant, and represented an increase in body weight, it was not considered to be related to treatment. Thus it was concluded that there were no treatment-related effects on the body weight of adult birds during the study.

See Table A7.5.3.1.3-4

#### 4.2.4 Food consumption
There were inconsistent, but statistically significant, increases in food consumption for different dose groups at different times during the study. In all cases the differences from the control were very small and were not considered to be treatment-related.

See Table A7.5.3.1.3-4

#### 4.2.5 Results of residue analysis
Not performed

#### 4.2.6 Other effects
Clinical signs: There were no treatment-related effects on behaviour or appearance of adult birds during the study. No overt signs of toxicity were observed at any of the concentrations tested. Incidental clinical observations noted during the test included those normally associated with injuries and penwear.

Autopsy: No treatment-related macroscopic abnormalities were observed in any birds examined.

### 4.3 Results of controls

#### 4.3.1 Number/percentage of animals showing adverse effects
No adverse effects shown by any animals in the control group

#### 4.3.2 Nature of adverse effects
None found
5. **APPLICANT’S SUMMARY AND CONCLUSION**

Cypermethrin technical active substance (96.5% purity) was administered in the diet to twenty-nine week old northern bobwhite quail (*Colinus virginianus*) at nominal doses of 0, 160, 400 and 1,000 ppm a.i. for 21 weeks. There were two birds housed in each pen (one male and one female) and 16 pens for each dose level of cypermethrin and the untreated control.

Body weights of the adults were recorded before dosing and at two week intervals up to eight weeks after dosing, and then at the end of the study. Food consumption per pen was recorded weekly.

Any eggs were collected daily and examined for cracking and eggshell thickness measured. Eggs were incubated and examined for embryo viability and survival and allowed to hatch.

Macroscopic examinations were recorded at *post-mortem* on birds which died during the study and on all surviving birds at the end of the exposure period.

5.2 **Results and discussion**

No treatment-related mortalities occurred during the study. There were no treatment-related effects on behaviour or appearance of adult birds and no overt signs of toxicity were observed at any of the concentrations tested. It was concluded that there were no treatment-related effects on the body weight of adult birds and any small differences in feed consumption were not considered to be treatment-related.

There were no treatment-related effects upon reproductive performance at any of the concentrations tested and no treatment-related macroscopic abnormalities were observed in any birds examined at autopsy.

5.2.1 **NOEC**

The NOEC (21 weeks) = 1000 mg a.s./kg feed or 92.0 mg a.s./kg bw/d

5.3 **Conclusion**

Validity criteria can be considered as fulfilled.

See table A7_5_3_1_3-5.

5.3.1 **Reliability**

1

5.3.2 **Deficiencies**

No

Study was evaluated and accepted under Directive 91/414/EC

---

### Evaluation by Competent Authorities

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<thead>
<tr>
<th>Date</th>
<th>May 2008</th>
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<td><strong>Materials and Methods</strong></td>
<td>Applicant’s version is acceptable.</td>
</tr>
<tr>
<td><strong>Results and discussion</strong></td>
<td>Applicant’s version is adopted.</td>
</tr>
<tr>
<td><strong>Conclusion</strong></td>
<td>Applicant’s version is adopted.</td>
</tr>
<tr>
<td><strong>Reliability</strong></td>
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<tr>
<td><strong>Acceptability</strong></td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
### Section 7.5.3.1.3  
#### Effects on reproduction of birds

<table>
<thead>
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<th>Remarks</th>
<th>COMMENTS FROM ... (specify)</th>
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</thead>
<tbody>
<tr>
<td>Date</td>
<td>Give date of comments submitted</td>
</tr>
</tbody>
</table>
| Materials and Methods | Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant’s summary and conclusion.  
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>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species/strain</td>
<td>Northern bobwhite quail (Colinus virginianus)</td>
</tr>
<tr>
<td>Source</td>
<td>K&amp;L Quail, Oroville, CA</td>
</tr>
<tr>
<td>Sex</td>
<td>Males an females (determined by visual examination of plumage)</td>
</tr>
<tr>
<td>Initial body weight (bw)</td>
<td>187-249 g at initiation of the test</td>
</tr>
<tr>
<td>Breeding population</td>
<td>All birds were from the same hatch, approaching their first breeding season and had not been used in any previous testing.</td>
</tr>
<tr>
<td>Amount of food</td>
<td>Ad libitum during acclimatisation and during the test. Average feed consumption was determined per pen per week by weighing the freshly filled feeder on day 0 and recording the amount of additional diet added during the week before re-weighing the feeder on day 7 of each week.</td>
</tr>
<tr>
<td>Age at time of first dosing</td>
<td>29 weeks</td>
</tr>
<tr>
<td>Health condition / medication</td>
<td>Birds were examined prior to test initiation for physical injuries and appeared to be in good health. Neither the adults nor offspring were given any medication during the study.</td>
</tr>
<tr>
<td>Criteria</td>
<td>Details</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Test location</td>
<td>Indoors in holding pens</td>
</tr>
<tr>
<td>Holding pens</td>
<td>Georgia Quail Farm Manufacturing model no. 0330 with a floor area of 1377 cm², measuring approximately 27 x 51 cm. Pens had sloping rooves with a ceiling height of 20-25 cm and were constructed of galvanised wire mesh and sheathing.</td>
</tr>
<tr>
<td>Number of animals (male/female)</td>
<td>64 pairs (1 male, 1 female per pen, 16 pens per treatment group)</td>
</tr>
<tr>
<td>Number of animals per pen [cm²/bird]</td>
<td>1 male and 1 female per pen [688.5 cm²/bird]</td>
</tr>
<tr>
<td>Number of animals per dose</td>
<td>16 pens (16 males, 16 females) per treatment group</td>
</tr>
<tr>
<td>Pre-treatment / acclimation</td>
<td>All birds were acclimatised to the caging facilities for 16 weeks prior to study initiation and were observed daily during this period. Throughout acclimatisation birds were given water and feed ad libitum.</td>
</tr>
<tr>
<td>Diet during test</td>
<td>The basal diet was formulated to Wildlife International’s specifications by Agway Inc. and contained at least 27% protein, 2.5% fat and no more than 5% fibre. Although the basal diet contained approximately 1.1% calcium, an additional 5% of limestone (38.5% calcium) was added to the basal diets of adults for the purpose of shell formation. Offspring received basal diet without test substance and without the limestone supplement.</td>
</tr>
<tr>
<td>Dosage levels (of test substance)</td>
<td>Untreated control, 160, 400, 1000 mg a.s./kg feed (adjusted for purity of test substance). Dose levels were based on results of a range-finder study. Control diet and each treated diet were prepared weekly and presented to the birds once per week.</td>
</tr>
<tr>
<td>Replicate/dosage level</td>
<td>16 pens (1 pair of birds) per dose level</td>
</tr>
<tr>
<td>Dosing method</td>
<td>Ad libitum</td>
</tr>
<tr>
<td>Dosing volume per application</td>
<td>As required</td>
</tr>
<tr>
<td>Frequency, duration and method of animal monitoring after dosing</td>
<td>All birds were observed daily throughout the study for signs of toxicity or abnormal effects. Additionally all offspring were observed daily from hatching until 14 days of age.</td>
</tr>
<tr>
<td>Time and intervals of body weight determination</td>
<td>Measured at test initiation, at the end of test weeks 2, 4, 6, 8 and at adult termination. Bodyweights were not measured during egg laying so as to avoid any adverse effects of handling on egg production.</td>
</tr>
</tbody>
</table>
Incubation, storing and hatching

Eggs were collected daily and stored in a cold room until incubation, with all eggs hied in a weekly interval being considered as one lot. Prior to incubation the eggs were weighed and examined for cracking. During egg laying, eggshell thickness was measured on one egg from odd numbered pens during odd numbered weeks and from even numbered pens during even numbered weeks, when available. Eggs were incubated at 37.4°C and examined for embryo viability, on day 11-12 of incubation, and survival, on day 21 of incubation, before allowing them to hatch. The temperature and humidity of the incubator were kept constant by forced air currents and the eggs were rotated through an arc of 90° each hour.

Test period after egg-laying

The egg laying phase of the study lasted approximately 11 weeks and was followed by a post-adult termination phase (incubation, hatching and 14 day offspring rearing period) lasting 6 weeks.

Turning of eggs

Yes, the incubator was equipped with an automatic egg rotation device.

Collection period for eggs

The egg laying phase of the study lasted approximately 11 weeks.

---

**Table A7_5_3_1_3-3: Test conditions (housing)**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test temperature</td>
<td>The study room was maintained at 20.6±1.6°C(SD)</td>
</tr>
<tr>
<td>Shelding of the animals</td>
<td>Yes, only birds associated with this study were kept in the study room to avoid excessive disturbance</td>
</tr>
<tr>
<td>Ventilation</td>
<td>15 room air volumes every hour were vented and replaced with fresh air</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>relative humidity 34 ±13%(SD)</td>
</tr>
<tr>
<td>Photoperiod and lighting</td>
<td>8:16 hour light/dark regime for the first seven weeks followed by a 17.7 light/dark regime until termination.</td>
</tr>
<tr>
<td>Storing, incubation and hatching conditions for eggs</td>
<td>Eggs were incubated at 37.4°C. The temperature and humidity of the incubator were kept constant by forced air currents and the eggs were rotated through an arc of 90° each hour.</td>
</tr>
<tr>
<td>Environmental conditions for young birds</td>
<td>On day 21 of incubation eggs were transferred to a Petersime Hatcher. Wire mesh baskets were used to keep hatchlings separated by parental pen of origin. Eggs were not rotated in the hatcher. The average temperature in the hatching compartment was 37.2±0.0°C (SD) and a relative humidity of approximately 77% (recorded daily).</td>
</tr>
</tbody>
</table>
Table A7.5.3.1.3-4: Values of reproduction ability

<table>
<thead>
<tr>
<th>Reproductive parameter</th>
<th>Control</th>
<th>Test Group (ppm)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
<td>15</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>No. of Replicates</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean adult food consumption (g/bird/day)</td>
<td>18.57</td>
<td>19.29</td>
<td>18.67</td>
<td>20.05</td>
</tr>
<tr>
<td>Mean adult body weight at term, males (g)</td>
<td>216</td>
<td>219</td>
<td>229*</td>
<td>212</td>
</tr>
<tr>
<td>Mean adult body weight at term, females (g)</td>
<td>244</td>
<td>236</td>
<td>234</td>
<td>246</td>
</tr>
<tr>
<td>No. eggs laid</td>
<td>812</td>
<td>755</td>
<td>613</td>
<td>808</td>
</tr>
<tr>
<td>Eggs laid (% of maximum laid)</td>
<td>72</td>
<td>72</td>
<td>58</td>
<td>72</td>
</tr>
<tr>
<td>Eggs cracked (% of total laid)</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>No. eggs set</td>
<td>715</td>
<td>663</td>
<td>539</td>
<td>723</td>
</tr>
<tr>
<td>Viable embryos (% of eggs set)</td>
<td>86</td>
<td>92</td>
<td>96</td>
<td>97</td>
</tr>
<tr>
<td>Live three-week embryos (% of viable embryos)</td>
<td>99</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Hatchlings (% of live three-week embryos)</td>
<td>96</td>
<td>96</td>
<td>96</td>
<td>95</td>
</tr>
<tr>
<td>No. of hatchlings</td>
<td>596</td>
<td>586</td>
<td>502</td>
<td>661</td>
</tr>
<tr>
<td>No. of 14 day survivors</td>
<td>574</td>
<td>556</td>
<td>489</td>
<td>622</td>
</tr>
<tr>
<td>14-day old survivors (% of hatchlings)</td>
<td>96</td>
<td>94</td>
<td>96</td>
<td>93</td>
</tr>
<tr>
<td>Mean body weight of hatchlings ± SD (g)</td>
<td>6 ± 1</td>
<td>6 ± 0</td>
<td>6 ± 1</td>
<td>6 ± 1</td>
</tr>
<tr>
<td>Mean body weight of 14-day old survivors ± SD (g)</td>
<td>28 ± 3</td>
<td>26 ± 3</td>
<td>27 ± 2</td>
<td>26 ± 3</td>
</tr>
<tr>
<td>Hatchlings (% of eggs set)</td>
<td>82</td>
<td>87</td>
<td>92</td>
<td>91</td>
</tr>
<tr>
<td>14 day old survivors (% of eggs set)</td>
<td>79</td>
<td>83</td>
<td>88</td>
<td>85</td>
</tr>
<tr>
<td>Mean egg shell thickness ± SD (mm)</td>
<td>0.230 ± 0.013</td>
<td>0.228 ± 0.013</td>
<td>0.228 ± 0.017</td>
<td>0.228 ± 0.014</td>
</tr>
<tr>
<td>Eggs laid/hen</td>
<td>51</td>
<td>50</td>
<td>41</td>
<td>51</td>
</tr>
<tr>
<td>Eggs laid/hen/day</td>
<td>0.51</td>
<td>0.51</td>
<td>0.41</td>
<td>0.51</td>
</tr>
<tr>
<td>14 day old survivors/hen</td>
<td>36</td>
<td>37</td>
<td>33</td>
<td>39</td>
</tr>
<tr>
<td>Hatchlings (% of maximum set)</td>
<td>57</td>
<td>60</td>
<td>52</td>
<td>64</td>
</tr>
<tr>
<td>14 day old survivors (% of maximum set)</td>
<td>55</td>
<td>57</td>
<td>50</td>
<td>60</td>
</tr>
</tbody>
</table>

1 Represents the total number of eggs laid in each group.

2 Based on 99 days of egg production.

3 Hatchlings found dead were not weighed.

4 Maximum laid is defined as the largest number of eggs laid by any one hen.

Differences between the control and each treatment groups were not significant (p > 0.05) except for *.

% values represent pen means for each experimental group.
<table>
<thead>
<tr>
<th></th>
<th>Fulfilled</th>
<th>Not fulfilled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality of control animals &lt;10%</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Average number of 14-day-old survivors per hen in controls ≥ 14, 12 and 24 for mallard duck, bobwhite quail and Japanese quail</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Average eggshell thickness for the control group ≥ 0.34, 0.19 and 0.19 mm for mallard duck, bobwhite quail and Japanese quail</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Concentration of the test substance in the diet ≥ 80% of the nominal concentration throughout the test period</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>
Section 7.5.4.1
Annex Point IIIA XIII 3.1

Acute toxicity to honeybees and other beneficial
arthropods, for example predators

Acute toxicity to honeybees

1 REFERENCE

1.1 Reference
Badmin, J.S., Twydell, T.S. (1976), Evaluation of the insecticide WL
43467 (cypermethrin) against the honeybee Aphis mellifera; Woodstock
Laboratory, Shell Research Ltd, report no. WK61/S/B/0137 (CYP/T7),
(unpublished)

1.2 Data protection
1.2.1 Data owner
Chimuc Agriphar s.a

1.2.2 Criteria for data
protection
Data submitted to the MS after 13 May 2000 on existing a.s. for the
purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study
Guideline not specified

2.2 GLP
No, GLP was not compulsory at the time the study was performed

2.3 Deviations
No raw data, the report is a summary of laboratory investigations.

3 METHOD

3.1 Test material
WL 43467 (cypermethrin)

3.1.1 Lot/Batch number
Not specified

3.1.2 Specification
Deviating from the specification given in section 2

3.1.3 Purity
Not specified, however the report mentions that the study was
conducted using technical material and also a 400 g/L EC formulation
(FX 3315)

3.1.4 Composition of
Product
Not specified

3.1.5 Further relevant
properties
Due to the low water solubility of the technical material, the test
substance was dissolved in acetone.

3.2 Administration of
the test substance
Oral test: the formulation and the a.s. (in acetone) were added to the
20% honey suspension. 200μl of honey solution containing the a.s. were
offered to each replicate of 10 bees.

Contact test: CO2 immobilized bees were treated by topical applications
of 1μL suspension of the ventral side of the thorax.

3.3 Reference
substance
Parathion

3.4 Testing procedure

3.4.1 Test organisms
Honeybees (Apis mellifera L.); worker bees

3.4.2 Collection and
Acclimatisation
20 bees (mean weight 138 mg in total) were collected from the upper
combs of the hive on the afternoon prior to testing. They were held
under laboratory conditions (23°C ±2°C, ambient humidity) in muslin
cages prior to testing and were fed a 20% honey solution ad libitum.
Section 7.5.4.1
Annex Point IIIA XIII 3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators

Acute toxicity to honeybees

3.4.3 Test system

Bees were treated with the appropriate test concentration and then transferred to 10 x 3.5 cm metal gauze cylinders placed in the airstream of an electric fan and fed a 20% honey solution ad libitum.

Bees were examined for mortality after 24 hours.

3.4.4 Test concentrations

Topical applications were made by applying 1 µl of test substance in acetone to the ventral abdomen of CO₂ immobilised bees using a micrometer syringe.

Oral administration was carried out by dispersing the test substance in a 20% honey solution and presenting 0.2 ml in a glass feeding vial to a group of 10 bees.

An 8-fold range of concentrations were used to obtain a dose response curve (raw data not reported) and the test repeated at least twice.

3.4.5 Number of replicates

10 bees x 2 replicates/ concentration.

3.4.6 Test conditions

23 ± 2 °C, ambient humidity

3.4.7 Duration of the test

24 hours

3.4.8 Test parameter

Mortality

3.4.9 Examination / Observation

All bees were examined for mortality after 24 hours

4 RESULTS

4.1 Results test substance

4.1.1 LD₅₀

LD₅₀ (cypermethrin, 24h) contact = 0.020 µg a.s./bee

LD₅₀ (cypermethrin, 24h) oral = 0.035 µg a.s./bee

[LD₅₀ (400g/L EC formulation, 24h) oral = 0.031 µg a.s./bee ]

4.2 Test with reference substance

LD₅₀ (parathion, 24h) contact = 0.16 µg a.s./bee

LD₅₀ (parathion, 24h) oral = 0.14 µg a.s./bee

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Cypermethrin was administered both topically and orally to groups of 10 worker bees and mortality recorded after 24 hours.

5.2 Results and discussion

Individual mortality data is not presented, however the report states that a dose response curve was used to obtain the LD₅₀ for cypermethrin.

5.2.1 LD₅₀

LD₅₀ (cypermethrin, 24h) contact = 0.020 µg a.s./bee

LD₅₀ (cypermethrin, 24h) oral = 0.035 µg a.s./bee

5.3 Conclusion

Cypermethrin can be considered as very toxic to bees.

5.3.1 Reliability

2
Section 7.5.4.1
Annex Point IIIA XIII 3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators

Acute toxicity to honeybees

5.3.2 Deficiencies

No raw data presented and the test concentrations used in the study are not reported. However the results appear to be valid in terms of published LD50 values for cypermethrin. This study was reviewed under Directive 91/414/EC.

In addition, higher tier field studies on non-target arthropods are available (see Doc IIIA 7.5.6). Therefore it was considered that further laboratory tests on bees are not required.

Evaluation by Competent Authorities

<table>
<thead>
<tr>
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<th>May 2008</th>
</tr>
</thead>
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<td>Results and discussion</td>
<td>Applicant's version is adopted.</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Applicant's version is adopted.</td>
</tr>
<tr>
<td>Reliability</td>
<td>4</td>
</tr>
<tr>
<td>Acceptability</td>
<td>non acceptable</td>
</tr>
</tbody>
</table>

The test only provides indicative information about the toxicity of the active substance cypermethrin. No guideline is refered to and no raw data is provided. It is therefore impossible to check the accuracy of the results. However, the results fit the toxicity value available in the pesticide manual (11th edition CDS Tomlin ISBN 1 901396 11 8)

Remarks

The applicant version o the summary is accepted because it is a good summary of the respective Doc IV. However the quality of the Doc IV is not acceptable.

Comments from ...

Give date of comments submitted

Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.

Discuss if deviating from view of rapporteur member state

Discuss if deviating from view of rapporteur member state

Discuss if deviating from view of rapporteur member state

Discuss if deviating from view of rapporteur member state

Discuss if deviating from view of rapporteur member state
### Section 7.5.5
Annex Point II.A.VII.7.5

**Bioconcentration, terrestrial**

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<td>Other existing data [✓]</td>
<td>Technically not feasible [ ]</td>
</tr>
<tr>
<td></td>
<td>Scientifically unjustified [✓]</td>
</tr>
<tr>
<td>Limited exposure [ ]</td>
<td>Other justification [ ]</td>
</tr>
</tbody>
</table>

**Detailed justification:**
The log Pow for cypermethrin was found to be in the range 3.3-3.6 initially indicating potential bioaccumulation in the food chain. However, an experimental bioaccumulation factor of 373+/−45 in fish indicates it has a low bioaccumulation potential at least in the aquatic compartment. In addition, the risk of secondary poisoning through the food chain from the aquatic environment is unlikely to be a problem, as the bioavailability of cypermethrin will be poor due to its rapid dissipation from water and strong adhesion to sediment.

The substance has a high Koc value which ranges from 80653 to 574360 (see DocIII.A7.2.3.1) which indicates its non-mobile character. Cypermethrin will therefore adhere strongly to soil/sediment making it very difficult for organisms to uptake and accumulate it. In addition, degradation in soil is rapid with t₁₂ <52 days and an acute toxicity study in earthworm indicated no effects at the test concentration limit of 100mg/kg soil.

It can be concluded therefore that there is no concern for bioaccumulation in the terrestrial compartment due to a very limited bioavailability.

| 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: May 2008

Evaluation of applicant's justification:
Log Pow ranges from 5.3 to 5.6 according to Bates 2002a.

Conclusion:
Applicant’s justification is accepted.

Remarks:

**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
<table>
<thead>
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<th>Section 7.5.5</th>
<th>Bioconcentration, terrestrial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annex Point HA.VII.7.5</td>
<td></td>
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</tbody>
</table>

Remarks
### Measures necessary to protect man, animals and the environment

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<tbody>
<tr>
<td><strong>Section A8</strong></td>
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<tr>
<td><strong>Measures necessary to protect man, animals and the environment</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Subsection (Annex Point)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>8.1</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)</strong></td>
<td></td>
</tr>
<tr>
<td>All formulated cypermethrin products are subject to regulations such as the Plant Protection Products Regulations as well as the Biocidal Products Regulation. Therefore all uses must be approved by the competent authorities before the product can be placed on the market. Each type of product carries an approved label detailing the specific conditions of use and associated hazards. Cypermethrin has been approved for use in agriculture for over 20 years and is listed in Annex I of Directive 91/414/EC.</td>
<td></td>
</tr>
<tr>
<td>Cypermethrin is very toxic to aquatic organisms and should therefore not enter the drainage system or watercourses.</td>
<td></td>
</tr>
<tr>
<td><strong>8.1.0 Methods and precautions concerning placing on the market</strong></td>
<td></td>
</tr>
<tr>
<td>Appropriate engineering controls should be employed during the formulation process, including local exhaust ventilation and the use of personal protective equipment (overalls, gloves and respirator). All workers must be fully trained to handle hazardous substances on the plant.</td>
<td></td>
</tr>
<tr>
<td>Provide local exhaust or general room ventilation when handling the active substance.</td>
<td></td>
</tr>
<tr>
<td>Handle in accordance with good industrial hygiene practises. Do not eat, drink or smoke. Wash hands and exposed skin after work and particularly before meals. If splashes do occur, remove any contaminated clothing immediately and wash skin with mild soap and water. Wash splashes to eyes with copious amounts of water immediately.</td>
<td></td>
</tr>
<tr>
<td>Wear suitable respiratory equipment, chemical-resistant gloves, overalls and chemical goggles/face shield with safety glasses.</td>
<td></td>
</tr>
<tr>
<td><strong>8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations</strong></td>
<td></td>
</tr>
<tr>
<td>Store only in the original container in a cool, well ventilated place away from all possible sources of ignition and away from food, drink and animal feedingstuffs. Keep out of the reach of children.</td>
<td></td>
</tr>
<tr>
<td><strong>8.1.2 Methods and precautions concerning storage of the active substance and its formulations</strong></td>
<td></td>
</tr>
<tr>
<td>When transporting by road, ensure the driver is aware of the potential hazards and is trained in the actions to be taken in case of an accident or emergency.</td>
<td></td>
</tr>
<tr>
<td><strong>UN 3352 PYRETHROID PESTICIDE, LIQUID, TOXIC (Cypermethrin)</strong></td>
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<td>Class 6.1, packing group III</td>
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<td>H.I. no. 60 (ADR)</td>
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<tr>
<td>Marine Pollutant (IMDG)</td>
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</tbody>
</table>
### Measures necessary to protect man, animals and the environment

#### Subsection (Annex Point)

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

For small fires, use carbon dioxide or dry chemical to extinguish flames. Use fluxing salts or dry sand to surround and smother the fire. For large fires use water fog or spray or alcohol foam. Do not use water jet or heavy water stream. Cool exposed containers with water spray or fog.

Wear full protective equipment when dealing with fire, including breathing apparatus. Ensure area is cleared of all personnel.

Do not empty fire control water into drains.

**8.2 In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)**

When heated to decomposition, the evolution of carbon monoxide, carbon dioxide, nitrogen oxides, hydrochloric acid and hydrogen cyanide must be anticipated (information derived from chemical structure).

**8.3 Emergency measures in case of an accident (IIA8.3)**

- **Inhalation:** Move casualty to fresh air and allow to rest. If breathing is difficult administer oxygen. If breathing has stopped, apply artificial respiration. Seek medical advice.

- **Skin contact:** Remove contaminated clothing immediately and wash exposed skin thoroughly with mild soap and water. If symptoms are severe, seek medical advice.

- **Eye contact:** Rinse immediately with copious amounts of clean water for 10-15 minutes. Obtain immediate medical advice.

- **Ingestion:** Do not induce vomiting. If conscious, rinse mouth with water ensuring the casualty does not swallow. If swallowed seek medical advice immediately and show the container or label.

No specific antidote is known, treatment should be symptomatic.

**8.3.2 Emergency measures to protect the environment**

Spillages should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Ensure the area is cleared of all other persons.

Soak up spillage onto suitable inert material (e.g. clay or diatomaceous earth) as soon as possible. Collect spillage and place in an appropriate container, tightly closed and properly labelled.

Prevent spillage from entering the drainage system or watercourses. If contamination of drains or public waters occurs, notify the appropriate authorities immediately.
Section A8  Measures necessary to protect man, animals and the environment

Subsection (Annex Point)  

8.4  Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA.8.4) 

8.4.1 Possibility of destruction or decontamination following release in the air 
Cypermethrin is non-volatile, therefore there should be no potential hazard to the atmosphere.

8.4.2 Possibility of destruction or decontamination following release in water, including drinking water 
Cypermethrin is a viscous liquid/semi-solid with low water solubility. Therefore it is likely that any material entering water will form an immobile mass which can be removed by mechanical means. Activated carbon can be used on any material that has dissolved and the precipitate removed by mechanical means.

8.4.3 Possibility of destruction or decontamination following release in or on soil 
Cypermethrin adsorbs strongly to soil, therefore any material accidentally released to soil should be relatively localised. Contaminated soil should be removed and placed in appropriate containers for safe disposal or incineration.

8.5 Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA.8.5)

8.5.1 Possibility of re-use or recycling 
Empty containers should not be re-used for any purpose. Dispose of in accordance with local regulations. Destroy or puncture empty containers to prevent re-use.

8.5.2 Possibility of neutralisation of effects 
In the event of accidental spillage, chemical absorbents and collected spilled material should be disposed of in accordance with local regulations and by a suitable waste contractor.

The preferred method of disposal is incineration, however if this is not possible cypermethrin can be decomposed by hydrolysis at pH 12 or above. For emulsifiable material, 5% sodium hydroxide solution or saturated (7-10%) sodium carbonate can be used. For non-emulsifiable material, a 1:1 v/v mixture of either of these solutions and a water/oil soluble solvent (e.g. denatured alcohol, monoethylene glycol, hexylene glycol or isopropanol) can be used. The material should be covered with hydrolysing agent and left to stand for 7 days. The material should be analysed to ensure the active ingredient has been degraded to a safe level before being disposed of.

8.5.3 Conditions for controlled discharge including leachate qualities on disposal 
Cypermethrin is toxic to fish and other aquatic organisms and should not be discharged into surface waters under any circumstances. Disposal by controlled incineration is preferred.
8.5.4 Conditions for controlled incineration

Cypermethrin can be destroyed by controlled high temperature incineration (≥1000°C) with effluent scrubbing.

8.6 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)

Cypermethrin is highly toxic to aquatic organisms (fish, daphnia) with the exception of green algae.

Cypermethrin is a broad spectrum insecticide and will kill beneficial insects, honeybees and other non-target arthropods. Cypermethrin has a low toxicity to earthworms. Comprehensive field studies on the effects of agricultural spray operations on non-target beneficial insects have been carried out and are detailed in DocIIIA_7.5.6.

Cypermethrin has low mammalian toxicity and should therefore not pose a risk to roosting bats. It also has a low toxicity to birds. However, a full study on the toxicity to birds is provided in DocIIIA_7.5.3.

8.7 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 groundwater against pollution caused by certain dangerous substances (IIA8.7)

Cypermethrin is a list I substance according to Directive 80/68/EEC (organohalogen) and should not be indirectly discharged to groundwater.

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**Evaluation by Competent Authorities**

**CONDITIONS FOR CONTROLLED INCINERATION (8.5.4)**

**EVALUATION BY RAPPORTEUR MEMBER STATE**

**Date**

July 2007

**Materials and methods**

Destruction of cypermethrin by controlled incineration

**Results and discussion**

The criteria as given by the applicant ("halogen content of cypermethrin < 60°C; therefore no specific information about the pyrolytic behaviour is required") are not in relation to the proposed criteria in the TGD. The TGD states that if the waste disposal method suggested is incineration, the compounds generated by burning (e.g. whether polychlorinated dioxins and furans or other halogen compounds can be formed), the recommended burning conditions (temperature, reaction time and oxygen content) and other information needed for the safe incineration of the waste must be given.

**Conclusion**

The applicant must complete this part (8.5.4) with the required data, conform with TGD

**Acceptability**

Not acceptable
### Section A8

**Measures necessary to protect man, animals and the environment**

#### Subsection

(Annex Point)

#### Remarks

*None*

#### EVALUATION BY INDUSTRY

- **Date**: End of 2008
- **Results and discussion**: Has been completed

#### Evaluation by Rapporteur Member State

- **Final conclusion**: Agreed

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#### Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

#### EVALUATION BY RAPPORTEUR MEMBER STATE

- **Date**: March, 2008
- **Materials and methods**: 
- **Results and discussion**: 
- **Conclusion**: 
- **Reliability**: 
- **Acceptability**: Human Health Part: Acceptable
- **Remarks**: 

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#### EVALUATION BY RAPPORTEUR MEMBER STATE

- **Date**: July, 2009
- **Materials and methods**: 
- **Results and discussion**: 
- **Conclusion**: 
- **Reliability**: 
- **Acceptability**: Environment Part: Acceptable
- **Remarks**: 

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<tr>
<td>Hazard Symbols</td>
<td>Harmful, Dangerous for the Environment</td>
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<tr>
<td>Indication of danger</td>
<td>R20/22 – Harmful by inhalation and if swallowed</td>
</tr>
<tr>
<td>Risk phrases</td>
<td>R37 – Irritating to respiratory system</td>
</tr>
<tr>
<td></td>
<td>R50/53 – Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment</td>
</tr>
<tr>
<td>Safety phrases</td>
<td>S2 – Keep out of the reach of children</td>
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<tr>
<td></td>
<td>S24 – Avoid contact with skin</td>
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<tr>
<td></td>
<td>S36/37/39 – Wear suitable protective clothing, gloves and eye/face protection</td>
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<tr>
<td></td>
<td>S60 – This material and its container must be disposed of as hazardous waste</td>
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<tr>
<td></td>
<td>S61 – Avoid release to the environment. Refer to special instructions/Safety data sheets</td>
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<tr>
<td>Justification for proposed classification</td>
<td>The classification of Cypermethrin was agreed at the 29th ATP and appears in Annex I of Directive 67/548/EEC containing the list of harmonised classifications and labelling for substances which are legally binding within the EU</td>
</tr>
</tbody>
</table>
## Classification and Labelling

### Section A9

#### Annex Point II.A.IX

**Proposal and justification for the classification and labelling of the active substance according to Directive 67/548/EEC**

## Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

### Evaluation by Rapporteur Member State

- **Date**: March, 2008; July 2009

### Results and discussion

**Materials and methods**

**Results and discussion**

**Conclusion**

**Reliability**

**Acceptability**

- Human Health: Acceptable.
- Environment part acceptable

### Remarks

- **Date**: June 2011

**Results and discussion**

**TM II 2011 Conclusions:**
- Conclusions 29th ATP:
  - Xn; R20/R22
  - Xi; R37
  - N, R50/53

According to CLP regulation 1272/2008:
- Acute Tox. 4, H332
- Acute Tox. 4, H401
- STOT SE3, H335
- Aquatic Acute 1, H400
- Aquatic Chronic 1, H410

The guidance values in the CLP regulation are changed for specific target organ toxicity – repeated exposure.

Guidance values for oral, 90d, rat, cat. 2: 10 mg/kg bw/d < C ≤ 100 mg/kg bw/d.

Taking the new criteria into consideration:

- STOT RE2, H373 Should be added
## Section A9 (IX)

### Classification and Labelling

#### Proposal and justification for the classification and labelling of the active substance according to Directive 67/548/EEC

- **Conclusion**
  
  BE will get into contact with ECHA and discuss how to proceed as change in dose/concentration guidance values may lead to revision of classification.

  The classification according to CLP 1272/2008 2nd ATP should be:

  - Acute Tox. 4, H332
  - Acute Tox. 4, H301
  - STOT SE3, H335
  - Aquatic Acute 1, H400
  - Aquatic Chronic 1, H410
  - STOT RE2, H373

#### Reliability

#### Acceptability

#### Remarks