

Section 7.5.1.3/1 **Terrestrial plant toxicity**
Annex Point IIIA XIII 3.4 **Seedling emergence test**

analysis

93.23.2 Preparation of TS solution for poorly soluble or volatile test substances	Please refer to Table A7.5.1.3/1-1.
93.33.3 Reference substance	None
93.3.13.3.1 Method of analysis for reference substance	Not applicable
93.43.4 Testing procedure	
93.4.13.4.1 Test plants	Please refer to Table A7.5.1.3/1-2.
93.4.23.4.2 Test system	Please refer to Table A7.5.1.3/1-3.
93.4.33.4.3 Test conditions	Please refer to Table A7.5.1.3/1-4.
93.4.43.4.4 Test duration	21 days following 50% emergence in the control
93.4.53.4.5 Test parameter	Emergence, phytotoxicity, shoot fresh and dry weight.
93.4.63.4.6 Observations	Observations of emergence and symptoms were made on days 7, 14 and 21 after 50% of control emergence. Observations of shoot fresh weight were made on day 21.
93.4.73.4.7 Sampling	Sampling of plant material for fresh weight and dry weight analysis took place on the final assessment day, (21 days after 50% control emergence).
93.4.83.4.8 Method of analysis of the plant material	For each replicate, the plants were clipped to soil level and weighed immediately. Dry weights were determined after oven-drying.
93.4.93.4.9 Quality control	Deionised water as negative control Acetone (99.4% pure) as solvent control.
93.4.103.4.10 Statistics	For the purpose of statistical analysis, emergence was defined as “the maximum number of emerged plants” and biomass was defined as “Total dry weight of plant above ground per replicate”. Outliers were identified using Dixon’s test (1953) and were excluded accordingly. The biomass measurements of the carrier control and treatment groups were compared with Dunnett’s t-test. Significance was determined at the levels of 0.01 and 0.05. Test data were evaluated to determine the LOER and NOER for shoot dry weight (using Dunnett’s test). The acetone control was compared to the water control to assess possible phytotoxic effects of acetone.

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [45]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [46]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [47]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [48]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [49]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [50]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [51]

Formatted: Bullets and Numbering

Section 7.5.1.3/1 **Terrestrial plant toxicity**
Annex Point IIIA XIII 3.4 **Seedling emergence test**

944 **RESULTS**

4.1 Results test substance

94.1.14.1.1 Applied initial concentration	Please refer to Table A7.5.1.3/1-5.
94.1.24.1.2 Phytotoxicity rating	No phytotoxic effects were observed in any of the species tested, with the exception of <i>Beta vulgaris</i> , for which only one instance of wilting was observed which did not require statistical analysis.
94.1.34.1.3 Number of dead plants	None
94.1.44.1.4 Effect data	Data on seedling emergence and plant biomass are presented in Tables A7.5.1.3/1-6 and A7.5.1.3/1-7. No effects on seedling emergence were noted for any species tested at any concentration level, with the exception of <i>Helianthus annuus</i> . Higher concentrations of Permethrin exhibited effects on plant biomass in four out of the six species.
94.1.54.1.5 Concentration / response curve	Not documented
94.1.64.1.6 Other effects	No other effects were observed.
94.2.2 Results of controls	
94.2.14.2.1 Number/percentage of plants showing adverse effects	None
94.2.24.2.2 Nature of adverse effects	Not applicable
94.3.3 Test with reference substance	Not performed
94.3.14.3.1 Concentration	Not applicable
94.3.24.3.2 Results	Not applicable

955 **APPLICANT'S SUMMARY AND CONCLUSION**

95.15.1 Materials and methods	The effect of Permethrin technical on seedling emergence was determined in a multi-rate test with two monocot and four dicot species. The study was conducted according to Draft Guideline OECD-208: Terrestrial (Non-Target) Plant Test 208A: Seedling emergence and seedling growth test (2000)
--------------------------------------	---

Formatted: Outline numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [52]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [53]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [54]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [55]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [56]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [57]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [58]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [59]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [60]

Formatted: Bullets and Numbering

Section 7.5.1.3/1 **Terrestrial plant toxicity**
Annex Point IIIA XIII 3.4 **Seedling emergence test**

95.2.5.2 Results and discussion

Please refer to Tables A7.5.1.3/1-6 and A7.5.1.3/1-7.

No effects on emergence were observed for any plant species at any of the test concentrations, with the exception of *Helianthus annuus* which demonstrated a sensitivity to soil treated with Permethrin. The NOER for this species was determined to be <0.0128.

No phytotoxic effects were observed in any plant species at any of the test concentrations, with the exception of *Beta vulgaris*, which demonstrated minor (but not statistically significant wilting at this test concentration.

Higher concentrations of Permethrin exhibited effects on plant biomass in four out of the six species (*Allium cepa*, *Avena sativa*, *Beta vulgaris* and *Helianthus annuus*). The most sensitive species was *Avena sativa*.

95.2.5.2.1 LOER

Please refer to Table A7.5.1.3/1-6.

95.2.5.2.2 NOER

Please refer to Table A7.5.1.3/1-6.

95.2.5.2.3 EC₂₅

Please refer to Table A7.5.1.3/1-6.

95.2.5.2.4 EC₅₀

Please refer to Table A7.5.1.3/1-6.

95.3.5.3 Conclusion

Based on the results of this study (conducted under worst-case greenhouse conditions), it can be concluded that Permethrin technical may affect the emergence of *Helianthus annuus* above concentrations of 0.0128 mg/kg dry soil. Biomass reduction can occur for non-target plants like *Avena sativa* above 8 mg/kg dry soil.

95.3.5.3.1 Reliability 1

95.3.5.3.2 Deficiencies No

es

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Section 7.5.1.3/1 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4 Seedling emergence test

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	9 April 2009
Materials and Methods	Applicants version acceptable.
Results and discussion	According to Tables A7.5.1.3/1-6 and A7.5.1.3/1-7, the following endpoints can be derived from the study: NOERemergence < 0.0128 (<i>H. annuus</i>) LOERemergence = 0.0128 (<i>H. annuus</i>) ER ₅₀ emergence = not determined NOERbiomass = 1.6 (<i>A. sativa</i>) LOERbiomass = 8 (<i>A. sativa</i>) ER ₅₀ biomass = 1034 (<i>A. sativa</i>)

However, the RMS believes that no reliable quantitative endpoint values can be derived from the data provided because measurement of actual dose concentrations were only taken for three nominal dose levels: 100, 40 and 0.32 mg/kg dry soil. The corresponding measured concentrations (and % of nominal concentration) for these three dose levels were 696 (69.6%), 11.6 (29%) and 0.015 (4.7%) respectively. Therefore the endpoint values specified in Table A7.5.1.3/1-6 and Table A7.5.1.3/1-7 may be significantly overestimated i.e. actual NOER/LOER values may be much lower than the nominal values indicated. This fact needs to be highlighted to the reader.

In any case though – the observed effect of permethrin on emergence in sunflower did not follow a continuous dose-responsive pattern and emergence was not affected in any of the other 5 plant species tested at permethrin concentrations as high as 696 mg/kg dry soil (actual measured value). The LOER and NOER were thus considered tentative anyway.

The study is only considered to be useful in showing that emergence in *Helianthus annuus* (sunflower) MAY be affected by permethrin exposure at concentrations even lower than 0.0128 mg/kg dry soil (nominal). The actual NOER for these effects on emergence in sunflowers needs to be further investigated – is it a species-specific phenomenon?

Section 7.5.1.3/1 **Terrestrial plant toxicity**
Annex Point IIIA XIII 3.4 **Seedling emergence test**

Conclusion	<p>Disagree with the Notifiers conclusion that “Based on the results of this study (conducted under worst-case greenhouse conditions), it can be concluded that Permethrin technical may affect the emergence of <i>Helianthus annuus</i> above concentrations of 0.0128 mg/kg dry soil“. This value of 0.0128 was the LOER (as effects on emergence occurred at this concentration) so in fact permethrin may also affect the emergence of <i>Helianthus annuus</i> <u>below</u> concentrations of 0.0128 mg/kg dry soil. Furthermore, as highlighted above – the endpoint is based on nominal concentrations of permethrin – the actual value of the NOERemergence cannot be calculated based on the information provided in the report but is likely to be <u>significantly-significantly</u> lower than this.</p> <p>Agree with the Notifiers conclusion that “Biomass reduction can occur for non-target plants like <i>Avena sativa</i> above 8 mg/kg dry soil“. However, as discussed above – it should be highlighted that the endpoint is based on nominal concentrations of permethrin – the actual value of the NOERbiomass cannot be calculated based on the information provided in the report but is likely to be <u>significantly-significantly</u> lower than this.</p>
Reliability	Disagree with Notifiers reliability score of 1 – RMS is of the opinion that the reliability score should be 2-3, as no definitive endpoints (based on actual measured concentrations) can be derived from the data provided.
Acceptability	Acceptable as supplementary information.
Remarks	
Date	COMMENTS FROM ... (<i>specify</i>) <i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Table A7.5.1.3/1-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Not documented
Vehicle	Acetone (99.4% pure)
Concentration of vehicle	Not documented
Vehicle control performed	Yes
Other procedures	No

Table A7.5.1.3/1-2: Test plants

	Family	Species	Common name	Source
Dicotyledonae	Chenopodiaceae	<i>Beta vulgaris</i>	Sugarbeet	Unknown
	Cucurbitaceae	<i>Cucumis sativus</i>	Cucumber	Supermarketer
	Fabaceae	<i>Glycine max</i>	Soybean	Die Saat
	Asteraceae	<i>Helianthus annuus</i>	Sunflower	Peredovick
Monocotyledonae	Liliaceae	<i>Allium cepa</i>	Onion	Sturon
	Poaceae	<i>Avena sativa</i>	Oat	Prevision

Table A7.5.1.3/1-3: Test system

Criteria	Details
Test type	Greenhouse (polycarbonate)
Pot size	15 cm diameter
Identification of the plant species	Please refer to Table A7.5.1.3/1-2
Number of replicates	Dicotyledons: 10 Monocotyledons: 6 (1 pot per replicate in each case)
Numbers of plants per replicate per dose	Dicotyledons: 5 planted, 3 retained / replicate / dose Monocotyledons: 7 planted, 5 retained / replicate / dose
Date of test substance application	Soil was treated on 30 th June 2006
Date of phytotoxicity rating	7, 14 and 21 days after 50% of the seeds in the control had emerged

Table A7.5.1.3/1-4: Test conditions

Criteria	Details
Method of application	The spray solution was distributed on sand with a kitchen stirrer. This was then mixed with soil (saturated to approx 50% of the water holding capacity) placed in pots.
Test Substrate	Heat treated soil mixed with sand and clay, adjusted to pH 7.31 and sieved to a particle size of 5 mm after slight drying. (TOC of 0.88%) Soil composition: Sand – 86% Silt – 4% Clay – 10%
Watering of the plants	Pots were irrigated with a water and nutrient source located at the bottom of each pot. A cotton strip connected soil and water source. Consumed water was controlled and replaced when necessary.
Temperature	21 - 39°C
Thermoperiod	Not documented
Light regime	16 h natural light and high pressure sodium lamps to maintain a minimum intensity of 5000 lux.
Relative humidity	50 - 94%
Wind volatility	Not applicable
Observation periods and duration of test	Observations were made 7, 14 and 21 days after 50% of the seeds in the control had emerged.
Pest control	No plant protection measures were performed
Any other treatments and procedures	Fertilisation took place for all species on 12 th , 18 th and 21 st of July 2006.

Table A7.5.1.3/1-5: Test concentrations

Nominal Concentrations (mg/kg dry soil)	Mean measured concentrations and % of nominal concentration (mg/kg dry soil)	Estimated Corrected ^a concentrations (mg/kg)	Deviation of estimated from determined concentration (%)
1000	696 (69.6%)	754	8.3
200	NA	-	
40	11.6 (29.0%)	10.1	-12.9
8	NA	-	
1.6	NA	-	
0.32	0.015 (4.7%)	0.0158	5.3
0.064	NA	-	
0.0128	NA	-	

NA = not analysed

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

~~August 2009~~ March
2011

^a = corrected by linear trend estimations

Table A7.5.1.3/1-6: Effect data – effects on biomass (mg/kg dry soil, nominal concentration)

Species	Endpoint			
	LOER	NOER	ER ₂₅	ER ₅₀
<i>Allium cepa</i>	1000	200	99.94	- ^a
<i>Avena sativa</i>	8	1.6	62.18	1034
<i>Beta vulgaris</i>	200	40	1313	- ^a
<i>Cucumis sativus</i> ^b	>1000	1000	ND	ND
<i>Glycine max</i>	>1000	1000	ND	ND
<i>Helianthus annuus</i>	40	8	201.16	- ^a

^a = ER₅₀ not determined because confidence interval was too wide

ND = Not determined as only minimum inhibitory effects visible

Table A7.5.1.3/1-7: Effect data – effects on emergence (mg/kg dry soil, nominal concentration)

Species	Final seedling emergence (21 days after 50% emergence in control)	
	LOER	NOER
<i>Allium cepa</i>	ND	ND
<i>Avena sativa</i>	ND	ND
<i>Beta vulgaris</i>	ND	ND
<i>Cucumis sativus</i>	ND	ND
<i>Glycine max</i>	ND	ND
<i>Helianthus annuus</i> ^a	0.0128	<0.0128

^a = LOER/NOER are tentative as no continuous dose-response reaction was observed

ND – Not determined (ER₅₀ value above maximum dosage)

Table A7.5.1.3/1-8: Validity criteria for terrestrial plant toxicity according to Seedling Emergence proposed test guideline 208

	Fulfilled
The seedling emergence should be at least 80% for crop and 65% for non-crop species	Yes
The mean control seedling growth does not exhibit visible phytotoxic effects	Yes
The mean control survival is at least 90% for the duration of the study	Yes
For any species, all organisms in a test must be from the same source	Yes
All test chambers or rooms used for a particular species should be identical and should have same conditions and contain same amount of soil matrix, support media, or substrate from the same source.	Yes

Section 7.5.1.3/2 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4 **Vegetative vigour test**

96.21.1 Reference

961 REFERENCE

Balluff, M. (2006b), A greenhouse limit test to determine the effects of Permethrin Technical 25/75 on the vegetative vigour of six species of plants, eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany, unpublished report No.: 20064034/S1-FGVV.

Dates of experimental work: June 22, 2006 – July 14, 2006.

96.21.2 Data protection

Yes

96.21.2.1 Data owner

Tagros Chemicals India Ltd.

96.21.2.2 Companies with letter of access

Not applicable.

96.21.2.3 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/IA.

972 GUIDELINES AND QUALITY ASSURANCE

97.12.1 Guideline study

Yes

Draft Guideline OECD-208: Terrestrial (Non-Target) Plant Test: (208B) Vegetative Vigour Test (2000)

97.22.2 GLP

Yes

97.32.3 Deviations

Yes

The guideline used has been superseded by the OECD draft proposal for a new guideline 227 “Terrestrial Plant Test: Vegetative Vigour Test”,

Official
use only

Formatted: Outline numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Section 7.5.1.3/2 **Terrestrial plant toxicity**
Annex Point IIIA XIII 3.4 **Vegetative vigour test**

published in 2003. The study deviated from this guideline in the following respect:

The in-life phase of the study was 21 days, however according to OECD Guideline 227, the study duration should be 28 days.

However, this deviation is not considered to compromise the scientific validity of the study.

983 **MATERIALS AND METHODS**

98.13.1 **Test material** As given in section 2 (Permethrin 25:75)

98.1.13.1.1 Lot/Batch number P - 165

98.1.23.1.2 Specification As given in section 2 (Permethrin 25:75)

98.1.33.1.3 Purity 93.07%

98.1.43.1.4 Composition of Product Not applicable

98.1.53.1.5 Further relevant properties None

98.1.63.1.6 Method of analysis Not applicable

98.23.2 Preparation of TS solution for poorly soluble or volatile test substances Please refer to Table A7.5.1.3/2-1.

98.33.3 Reference substance None

98.3.13.3.1 Method of analysis for reference substance Not applicable

98.43.4 **Testing procedure**

98.4.13.4.1 Test plants Please refer to Table A7.5.1.3/2-2.

98.4.23.4.2 Test system Please refer to Table A7.5.1.3/2-3.

98.4.33.4.3 Test conditions Please refer to Table A7.5.1.3/2-4.

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [61]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [62]

Formatted: Bullets and Numbering

Section 7.5.1.3/2 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4 Vegetative vigour test

98.4.43.4.4	Test duration	21 days
98.4.53.4.5	Test parameter	Phytotoxicity, shoot fresh and dry weight.
98.4.63.4.6	Observations	Observations of symptoms were made 7, 14 and 21 days after applications. Observations of height and shoot fresh weight were made only on day 21.
98.4.73.4.7	Sampling	Sampling of plant material for shoot fresh and dry weight took place on the final assessment day, (21 days after application).
98.4.83.4.8	Method of analysis of the plant material	For each replicate, the plants were clipped to soil level and weighed immediately. Dry weights were determined after oven-drying.
98.4.93.4.9	Quality control	Deionised water as negative control Acetone (99.4% pure) as solvent control
98.4.103.4.10	Statistics	Statistical analysis was used to evaluate effects of test item application on plant dry biomass. Before analysis, potential outliers were selected and tested using Dixon's test (1953). No outliers were identified. Statistical analysis was carried out using the program SAS. Homogeneity of variance was tested prior to analysis of variance by application of Barlett's test and Shapiro-Wilks-test for normality of values. Because one or both of these tests indicated the preconditions of parametrical analysis, the Student's t-test within the SAS GLM procedure was used. The level of significance was 0.05.

99.4 RESULTS

4.1 Results test substance

99.1.44.1.1	Applied initial concentration	Please refer to Table A7.5.1.3/2-5.
99.1.44.1.2	Phytotoxicity rating	No symptoms of phytotoxicity were observed in any plant species.
99.1.44.1.3	Plant height	BBCH 12 – 14 for all species.
99.1.44.1.4	Plant dry weights	Please refer to Table A7.5.1.3/2-6.
99.1.54.1.5	Root dry weights	Not documented
99.1.64.1.6	Number of dead plants	None
99.1.74.1.7	Effect data	Please refer to Table A7.5.1.3/2-6.

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [63]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [64]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [65]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [66]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [67]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [68]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [69]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [70]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [71]

Formatted: Bullets and Numbering

Section 7.5.1.3/2 **Terrestrial plant toxicity**
Annex Point IIIA XIII 3.4 **Vegetative vigour test**

99.1.94.1.8	Concentration / response curve	Not applicable as the study is a limit test
99.1.94.1.9	Other effects	No other effects were observed.
99.2.4.2 Results of controls		
99.2.4.2.1	Number/percentage of plants showing adverse effects	None
99.2.4.2.2	Nature of adverse effects	Not applicable
99.3.4.3	Test with reference substance	Not performed
99.3.14.3.1	Concentration	Not applicable
99.3.24.3.2	Results	Not applicable
1005 APPLICANT'S SUMMARY AND CONCLUSION		
100.15.1	Materials and methods	The effect of Permethrin technical on vegetative vigour was determined in a limit test with two monocot and four dicot species. The study was conducted according to Draft Guideline OECD-208: Terrestrial (Non-Target) Plant Test: (208B) Vegetative Vigour Test (2000).
100.25.2	Results and discussion	Please refer to Table A7.5.1.3/1-6. No phytotoxic effects were observed in any plant species during the course of the study. Permethrin caused significant effects on the inhibition of biomass, but these were only significant for <i>Avena sativa</i> , and <i>Allium cepa</i> . The most sensitive species was <i>Allium cepa</i> .
100.35.3	Conclusion	Based on the results of this study (conducted under worst-case greenhouse conditions), it can be concluded that since the effects on biomass for all species was < 20%, Permethrin can be classified as a low risk to terrestrial plants.
100.3.15.3.1	Reliability	2
100.3.25.3.2	Deficiencies	Yes The guideline used has been superseded by the OECD draft proposal for

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 2 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Outline numbered + Level: 3 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0 cm + Tab after: 1.25 cm + Indent at: 1.25 cm

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [72]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [73]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [74]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [75]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [76]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [77]

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering ... [78]

Formatted: Bullets and Numbering

Section 7.5.1.3/2 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4 Vegetative vigour test

a new guideline 227 "Terrestrial Plant Test: Vegetative Vigour Test", published in 2003. The study deviated from this guideline in the following respect:

The in-life phase of the study was 21 days, however according to OECD Guideline 227, the study duration should be 28 days.

However, this deviation is not considered to compromise the scientific validity of the study.

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	9 April 2009
Materials and Methods	The in-life phase of the study was 21 days, however according to OECD Guideline 227, the study duration should be 28 days. Applicants version acceptable.
Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	Acceptable.
Remarks	

COMMENTS FROM ... (specify)	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Table A7.5.1.3/2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Not documented
Vehicle	Acetone (99.4% pure)
Concentration of vehicle	Not documented
Vehicle control performed	Yes
Other procedures	No

Table A7.5.1.3/2-2: Test plants

	Family	Species	Common name	Source
Dicotyledonae	Chenopodiaceae	<i>Beta vulgaris</i>	Sugarbeet	Unknown
	Cucurbitaceae	<i>Cucumis sativus</i>	Cucumber	Supermarketer
	Fabaceae	<i>Glycine max</i>	Soybean	Die Saat
	Asteraceae	<i>Helianthus annuus</i>	Sunflower	Peredovick
Monocotyledonae	Liliaceae	<i>Allium cepa</i>	Onion	Sturon
	Poaceae	<i>Avena sativa</i>	Oat	Prevision

Table A7.5.1.3/2-3: Test system

Criteria	Details
Test type	Greenhouse (polycarbonate)
Pot size	15 cm diameter
Identification of the plant species	Please refer to Table A7.5.1.3/2-2
Number of replicates	Dicotyledons: 15 Monocotyledons: 6 (1 pot per replicate in each case)
Numbers of plants per replicate per dose	Dicotyledons: 2 plants / replicate / dose Monocotyledons: 5 plants / replicate / dose
Date of test substance application	All crops were sprayed on 22 nd June 2006
Height of plants at application	BBCH 12-14
Date of phytotoxicity rating	7, 14 and 21 days after application

Table A7.5.1.3/2-4: Test conditions

Criteria	Details
Method of application	Application was carried out in a closed spray cabin with a spray surface of 10880 cm ² . All test replicates were treated with a flat fan nozzle at a spray pressure of 2.0 bar and at a distance of approximately 35 cm.
Dose rates	A single nominal dose rate of 6875 g/ha (solved in 300 litres acetone/ha).
Test Substrate	Heat treated soil mixed with sand and clay, adjusted to pH 7.31 and sieved to a particle size of 5 mm after slight drying. (TOC of 0.88%) Soil composition: Sand – 86% Silt – 4% Clay – 10%
Watering of the plants	Pots were irrigated with a water and nutrient source located at the bottom of each pot. A cotton strip connected soil and water source. Consumed water was controlled and replaced when necessary.
Temperature	24 - 27°C
Thermoperiod	Not documented
Light regime	16 h natural light and high pressure sodium lamps to maintain a minimum intensity of 5000 lux.
Relative humidity	50 - 94%
Wind volatility	Not applicable
Observation periods and duration of test	Observations of symptoms were made 7, 14 and 21 days after application. Observations of height and shoot fresh weight were made only on day 21.
Pest control	No plant protection measures were performed
Any other treatments and procedures	Fertilisation took place for all species from 9 th May 2006 – 12 th July 2006.

Table A7.5.1.3/2-5: Test concentrations

Test item	Nominal test item concentration (g/l)	Calculated test item concentration (g/l)	Mean measured test item concentrations (g/l)
Permethrin Technical (25:75)	22.92	24.688	24.227
		24.046	
		23.947	

Table A7.5.1.3/1-6: Effect data – effects on biomass (dry weight of plants [g]) 21 days after post-emergence application of Permethrin at 6875 g product/ha

Species	Test substance					
	Water control		Acetone control		Permethrin	
	Mean shoot biomass	% Inhibition	Mean shoot biomass	% Inhibition	Mean shoot biomass	% Inhibition
<i>Allium cepa</i>	2.09	-	1.91	9.00	1.64*	14.09
<i>Avena sativa</i>	1.86	-	1.83	1.70	1.66*	9.37
<i>Beta vulgaris</i>	1.91	-	2.06	-7.99	1.98	4.26
<i>Cucumis sativus</i>	4.58	-	4.68	-2.24	5.30***	-13.14
<i>Glycine max</i>	4.61	-	4.63	-0.38	5.10	-10.17
<i>Helianthus annuus</i>	8.89	-	7.60	14.50	6.25	17.82

* = significant compared to carrier control ($\alpha = 0.05$)

** = significant, but determination of negative inhibition was not objective to this study

Table A7.5.1.3/1-7: Validity criteria for terrestrial plant toxicity according to Vegetative Vigour draft test guideline 227

	Fulfilled
The plant growth does not exhibit visible phytotoxic effects	Yes
The mean plant survival is at least 90% at the end of the test	Yes
For any species, all organisms in a test must be from the same source	Yes
All test chambers or rooms used for a particular species should be identical and should have same conditions and contain same amount of soil matrix, support media, or substrate from the same source.	Yes

Section 7.5.2.1 Terrestrial Tests, Long-Term Tests		
Annex Point IIIA, XIII.3.2 Reproduction Study with Other Soil Non-Target Macro-Organisms		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure [X]	Other justification []	
Detailed justification:	It is proposed that this point is not relevant for Permethrin, as the product is intended for application directly to the wood surface in low volumes and is not recommended for use on soil or watercourses during its normal use pattern.	
	A study carried out on the acute toxicity of Permethrin to earthworms	

Section 7.5.2.1 Terrestrial Tests, Long-Term Tests	
Annex Point IIIA, XIII.3.2 Reproduction Study with Other Soil Non-Target Macro-Organisms	
	<p>showed minimal risk to terrestrial macro-organisms. In this study the LC₅₀ was determined to be >1200 mg/kg. An investigation was carried out in order to assess the risk to the terrestrial compartment (Document IIC 2.3). The outcome of this assessment initially indicates that the use of Permethrin 10 EC poses a potential risk to the terrestrial compartment. However, calculations of PECs in soil are grossly exaggerated and cannot be relied upon to give a realistic assessment of risk to the terrestrial environment. An investigation into the potential for secondary poisoning in mammals following consumption of earthworms exposed to Permethrin indicated a maximum potential concentration of 41.75 mg/kg Permethrin in whole earthworms (including gut contents) and an ultimate risk quotient of 21.86 for mammalian species. Although, this result is above the trigger value of 1, considering the exaggerated PEC_{soil} and C_{porewater} values used in the estimation of bioaccumulation, it can be assumed that there is negligible risk to the terrestrial compartment as a result of exposure to Permethrin.</p> <p>On this basis therefore, it is proposed that long-term terrestrial tests are not required.</p>
Undertaking of intended data submission []	Not applicable
Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	9 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.5.2.2 Terrestrial Tests, Long-Term Tests		
Long-Term Test with Terrestrial Plants		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/>	
Limited exposure <input checked="" type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	<p>It is proposed that this point is not relevant to Permethrin as the product is a wood preservative and is not intended for direct application to plants. The biocidal product, Permethrin 10 EC is applied as a liquid wood-preservative in low volumes directly to the wood surface and exposure of the terrestrial environment is considered unlikely assuming the product is used as per the label instructions.</p> <p>Studies were carried out on the toxicity of Permethrin to terrestrial plants in seedling emergence and vegetative vigour studies. In the seedling emergence study, Permethrin was found to potentially affect the emergence of species such as <i>Helianthus annuus</i> above concentrations of 0.0128 mg/kg dry soil and it was found that biomass reduction can occur for non-target plants like <i>Avena sativa</i> above 8 mg/kg dry soil. However, the results of the vegetative vigour study indicated that since the effects on biomass for all species was < 20%, Permethrin can be classified as a low risk to terrestrial plants.</p> <p>On the basis of these results it is proposed that long-term testing of terrestrial plants is not required.</p>	
Undertaking of intended data submission <input type="checkbox"/>	Not applicable	
Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	15 April 2009	
Evaluation of applicant's justification	Justification acceptable.	
Conclusion	Justification acceptable.	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

~~August 2009~~ March
2011

Section 7.5.2.2	Terrestrial Tests, Long-Term Tests Long-Term Test with Terrestrial Plants
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.5.3.1.1 Effects on Birds		
Annex Point IIIA, XIII.1.1 Acute Oral Toxicity		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	<p>According to the "Data requirements for biocidal product types, Version 4.3.2 (October 2000)", these data are only required if the product is applied outdoors in the form of baits, granulates or powder. As the product, Permethrin 10 EC is applied as a liquid in low volumes directly to the wood surface, it is proposed that a study to address this point is not required</p> <p>It is also worth noting that Permethrin has a very low toxicity to birds. The acute LD₅₀ is >3,000 mg/kg bw and the dietary toxicity is >5,000 mg/kg diet according to the WHO Permethrin EHC 94, (1990).</p>	
Undertaking of intended data submission <input type="checkbox"/>	Not applicable	
Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPporteur MEMBER STATE		
Date	14 April 2009	
Evaluation of applicant's justification	Applicant's version acceptable.	
Conclusion	Applicant's version acceptable.	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section 7.5.3.1.2 Effects on Birds	
Annex Point IIIA, XIII.1.2 Short-Term Toxicity	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
Official use only	
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>
Detailed justification:	<p>According to the "Data requirements for biocidal product types, Version 4.3.2 (October 2000)", these data are only required if the product is applied outdoors in the form of baits, granulates or powder. As the product, Permethrin 10 EC is applied as a liquid in low volumes directly to the wood surface, it is proposed that a study to address this point is not required.</p> <p>It is also worth noting that Permethrin has a very low toxicity to birds. The acute LD₅₀ is >3,000 mg/kg bw and the dietary toxicity is >5,000 mg/kg diet according to the WHO Permethrin EHC 94, (1990).</p>
Undertaking of intended data submission <input type="checkbox"/>	Not applicable
Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	14 April 2009
Evaluation of applicant's justification	Applicant's version acceptable.
Conclusion	Applicant's version acceptable.
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Permethrin
(Tagros Chemicals India Ltd.)

Product type 8

August 2009/March
2011

Section 7.5.3.1.3 Effects on Birds		
Annex Point IIIA, XIII.1.3 Effects on Reproduction		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input checked="" type="checkbox"/>	
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	<p>According to the "Data requirements for biocidal product types, Version 4.3.2 (October 2000)", these data are only required if the product is applied outdoors in the form of baits, granulates or powder. As the product, Permethrin 10 EC is applied as a liquid in low volumes directly to the wood surface it is proposed that a study to address this point is not required.</p> <p>It is also worth noting that Permethrin has a very low toxicity to birds. The acute LD₅₀ is >3,000 mg/kg bw and the dietary toxicity is >5,000 mg/kg diet according to the WHO Permethrin EHC 94, (1990).</p>	
Undertaking of intended data submission <input type="checkbox"/>	Not applicable	
Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPporteur MEMBER STATE		
Date	14 th April 2009	
Evaluation of applicant's justification	Justification acceptable.	
Conclusion	Justification acceptable.	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

~~August 2009~~ March 2011

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

August 2009/March
2011

Section 7.5.4.1 Effects on Honeybees	
Annex Point IIIA, XIII.3.1 Acute Toxicity to Honeybees and Other Beneficial Arthropods, for Example Predators	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
Official use only	
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/>
Limited exposure <input checked="" type="checkbox"/>	Other justification <input type="checkbox"/>
Detailed justification:	<p>According to the "Data requirements for biocidal product types, Version 4.3.2 (October 2000)", this test may only be required for certain product types and is not recommended for Product Type 8.</p> <p>The product Permethrin 10 EC is applied as a liquid in low volumes directly to the wood surface. It is not intended for direct application to plants or flowers where bees may be actively foraging. Based on this information, it is therefore proposed that a study to address this point is not required.</p>
Undertaking of intended data submission <input type="checkbox"/>	Not applicable
Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

~~August 2009~~ March
2011

Section 7.5.4.1

Effects on Honeybees

Annex Point IIIA, XIII.3.1 **Acute Toxicity to Honeybees and Other Beneficial Arthropods, for Example Predators**

Conclusion

Discuss if deviating from view of rapporteur member state

Remarks

<p>Section 7.5.5 Annex Point IIA 7.5</p>	<p>Bioconcentration, terrestrial Bioconcentration, further studies</p>	<p>Official use only</p>
<p>JUSTIFICATION FOR NON-SUBMISSION OF DATA</p>		
<p>Other existing data <input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Limited exposure <input type="checkbox"/> <input type="checkbox"/></p>	<p>Technically not feasible <input type="checkbox"/> <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/> <input type="checkbox"/></p> <p>Other justification <input type="checkbox"/> <input type="checkbox"/></p>	
<p>Detailed justification:</p>	<p>It is proposed that this point is not relevant to Permethrin as the product is intended for direct application to the wood surface and is not applied directly to the soil or to watercourses. Consequently, exposure of terrestrial organisms to Permethrin is considered to be unlikely.</p> <p>Permethrin has an estimated log K_{ow} of 5.9, indicating the potential to bioaccumulate. The BCF for earthworms estimated by the environmental fate modelling system USES 4.0 is 23.8 l/kg. However, in the unlikely event that the product enters the terrestrial compartment by accidental discharge, an investigation into the potential for secondary poisoning in mammals following consumption of earthworms exposed to Permethrin indicated a maximum potential concentration of 41.75 mg/kg Permethrin in whole earthworms (including gut contents) and an ultimate risk quotient of 21.86 for mammalian species. Although, this result is above the trigger value of 1, considering the exaggerated PEC_{soil} and $C_{porewater}$ values used in the estimation of bioaccumulation, it can be assumed that there is little risk of bioaccumulation in the terrestrial compartment as a result of exposure to Permethrin.</p> <p>In an investigation into bioaccumulation in avian species, Permethrin and its metabolites are found not to accumulate in birds (WHO Permethrin EHC 94, 1990; Leahey <i>et al.</i>, 1977). During repeated dosing to quails and to mallard ducks, very similar patterns and levels of both the appearance and depletion of radioactive residue in tissues were found. The level in fat, which was minimal, reached a plateau during a 28-day period. In all tissues, residues declined extensively during a 14-day period after the final dose.</p> <p>Based on the information provided above, it can be concluded that further studies are not required in this case.</p>	
<p>Undertaking of intended data submission <input type="checkbox"/> <input type="checkbox"/></p>	<p>Not applicable</p>	
<p>Evaluation by Competent Authorities</p>		
<p>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</p>		

Section 7.5.5	
Bioconcentration, terrestrial	
Annex Point IIA 7.5	
Bioconcentration, further studies	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Formatted

Formatted

Formatted

Formatted

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

~~August-2009~~March
2011

Section 7.5.6 Effects on Other Terrestrial Non-Target Organisms	
Annex Point IIIA, XIII.3	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
Official use only	
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/>
Limited exposure <input checked="" type="checkbox"/>	Other justification <input type="checkbox"/>
Detailed justification:	<p>The product Permethrin 10 EC is intended for low-volume, localised application, directly to the wood surface and is not applied directly to plants or soil. As a result the exposure of terrestrial non-target organisms to Permethrin is unlikely to occur.</p> <p>Adverse effects on the terrestrial compartment from the use of Permethrin in Permethrin 10 EC are deemed unlikely. An investigation was carried out in order to assess this risk to the terrestrial compartment (Document IIC 2.3). The outcome of this assessment initially indicates that the use of Permethrin 10 EC poses a potential risk to the terrestrial compartment. However, it was concluded that this calculation represented a worst-case scenario that is unlikely to occur as exposure of the terrestrial compartment is highly unlikely when the product is used according to the label instructions (Please see point IIIA 7.5.5 for further details).</p> <p>An investigation into the toxic effects of Permethrin to terrestrial plants indicated that Permethrin has no significant adverse effects on terrestrial plants (Please see Document IIIA 7.5.1.3-1 and IIIA 7.5.1.3-2 for further details).</p> <p>Based on the information above, it is therefore proposed that due to limited exposure and the expected absence of adverse effects, further studies on non-target organisms are not required.</p>
Undertaking of intended data submission <input type="checkbox"/>	Not applicable
Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPporteur MEMBER STATE	
Date	16 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
Remarks	

Formatted

Formatted

Formatted

Formatted

Section 7.5.6 Effects on Other Terrestrial Non-Target Organisms

Annex Point IIIA, XIII.3

	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.5.7.1.1 Effects on Mammals	
Annex Point IIIA, XIII.3.4 Acute Oral Toxicity	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
Official use only	
Other existing data <input checked="" type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>
Detailed justification:	Data from the study "Acute Oral Toxicity Study of Permethrin Technical in Rats", Desai, N.B., 1998, is presented under point IIIA 6.1.1. The acute oral LD ₅₀ of Permethrin in rats was found to be 544 mg/kg bw. It would be expected that terrestrial vertebrates would exhibit similar toxic responses on exposure to Permethrin, as the mammals tested in the above named study.
Undertaking of intended data submission <input type="checkbox"/>	Not applicable
Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
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
Remarks	

Formatted

Formatted

Formatted

Formatted

Section 7.5.7.1.2 Effects on Mammals	
Annex Point IIIA, XIII.3.4 Short Term Toxicity	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
	Official use only
Other existing data <input checked="" type="checkbox"/> [X]	Technically not feasible <input type="checkbox"/> [] Scientifically unjustified <input type="checkbox"/> []
Limited exposure <input type="checkbox"/> []	Other justification <input type="checkbox"/> []
Detailed justification:	Data from the study "Repeated Dose (90-Day) Oral Toxicity Study with Permethrin in Wistar Rats", Ramesh, E., 2003, is presented under point IIIA 6.4.1. The NOEL of Permethrin in rats was found to be 8.6 mg/kg bw/day. It would be expected that terrestrial vertebrates would exhibit similar toxic responses on exposure to Permethrin, as the mammals tested in the above named study.
Undertaking of intended data submission <input type="checkbox"/> []	Not applicable
Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
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

Formatted

Formatted

Formatted

Formatted

Permethrin
(Tagros Chemicals India Ltd.)

Product-type 8

~~August 2009~~ March
2011

Section 7.5.7.1.2 Effects on Mammals

Annex Point IIIA, XIII.3.4 Short Term Toxicity

Conclusion

Discuss if deviating from view of rapporteur member state

Remarks

Section 7.5.7.1.3 Effects on Mammals		
Annex Point IIIA, XIII.3.4 Effects on Reproduction		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input checked="" type="checkbox"/>	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/>	
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	<p>This point is not relevant to Permethrin as the product is intended for direct application to the wood surface and is not applied directly to plants or soil. Exposure of mammals to Permethrin is therefore considered to be unlikely as the product is intended for low volume, localised application.</p> <p>Studies addressing the long-term toxicity and carcinogenicity (combined study), teratogenicity and effects on reproduction in mammals have been summarised under points IIIA 6.5/6.7, 6.8.1 and 6.8.2, respectively. A 90-day study in the rat is available and is summarised under Doc IIIA, 6.4.1. Only minimal signs of toxicity such as liver weights associated with hepatocellular hypertrophy were noted in this study. In a 90 day oral study in mice, animals exhibited, at the highest dose tested, signs of toxicity such as respiratory distress, hyperactivity and tremor. A 90 day dermal study in the rat is also available and is summarised under Doc IIIA, 6.4.2. Clinical signs such as piloerection and tremors were noted. A 90-day inhalation study was also conducted in the rat and is summarised under Doc IIIA, 6.4.3. Rats exhibited nasal irritation and mild tremors at the highest dose tested (0.4363 mg/l). A two year combined chronic/carcinogenicity study in rats is currently ongoing which should provide further information in a second species. Furthermore, Permethrin is neither genotoxic, nor teratogenic. In a two generation study in the rat no treatment related effects were reported.</p> <p>It would be expected that terrestrial vertebrates would exhibit similar toxic responses on exposure to Permethrin as the mammals tested in the above named studies.</p>	
Undertaking of intended data submission <input type="checkbox"/>	Not applicable	

Section 7.5.7.1.3 Effects on Mammals	
Annex Point IIIA, XIII.3.4 Effects on Reproduction	
Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
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
Remarks	

Formatted

Formatted

Formatted

Formatted

Section 7.6 Annex Point IIA 7.8		Summary of Ecotoxicological Effects and Fate and Behaviour in the Environment	
		JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified []	
Limited exposure []	Other justification [X]		
Detailed justification:	Please refer to Document IIA.		
Undertaking of intended data submission []	Not applicable		

Section 7.6 Annex Point IIA 7.8	Summary of Ecotoxicological Effects and Fate and Behaviour in 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	16 April 2009
Evaluation of applicant's justification	Justification acceptable.
Conclusion	Justification acceptable.
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
Remarks	

Formatted

Formatted

Formatted

Formatted

