	According to the Technical Guidance Document on Risk Assessment Part II (page 128), Secondary poisoning effects on bird populations rarely occurs over the short-term. Therefore, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth. Considering a one-generation study with the Northern Bobwhite (*Colinus virginianus*) ([redacted], 1992) performed to GLP standards according to FIFRA guideline 71-4, the lowest NOEC exceeds 500 ppm. Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a $PNEC_{bird}$ of 16.7 mg/kg food is obtained. According to the Technical Guidance Document on Risk Assessment Part II (page 128), Secondary poisoning effects on mammal populations rarely occurs over the short-term. Therefore, results from long-term studies are strongly preferred, such as NOECs for mortality, reproduction or growth. Considering the reproduction study conducted in rats with permethrin (3 generation study;), the NOAEL was set at 180 mg/kg bw/d . For the assessment of secondary poisoning, the results always have to be expressed as the concentration in food. Where toxicity data are presented only as NOAELs only, these NOAELs can be converted to NOECs with the following two formulae: $NOEC_{mammal\ food\_chr} = NOAEL_{mammal\ oral\_chr} \cdot CONV_{mammal}$ A conversion factor ($CONV_{mammal}$) of 20 is selected from table 22 p 129 as the 3 generation study was conducted with rats aged 6 weeks at the initiation of the study. The $NOEC_{mamalfood\_chr}$ is hence calculated to be 3600 ppm Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a $PNEC_{small\ mammal}$ of 120 mg/kg food is obtained. Therefore, by comparing the $PEC_{oral\ predator}$ obtained for the Fence DIP/SPRAY-TREATED WOOD scenario considering biodegradation (Tier 2) with the respective PNEC, PEC/PNEC ratios of 0.10 and 1,42E-02 are obtained for birds and small mammals respectively, indicating no unacceptable risk for earthworm-eating birds and small mammals. In annex I below, each scenario has been assessed; all the PEC/PNEC ratios are below 1, when biodegradation is considered, indicating no unacceptable risk for earthworm-eating birds and small mammals.	
Undertaking of intended data submission [ ]		

Calculation of:

$$C_{porewater} = PEClocal_{grw} = PEClocal_{soil,\ porew}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted environmental concentration in porewater	$PEClocal_{agr,soil,porew}$	[mg.l^{-1}]		Input
Predicted environmental concentration in groundwater	$PEClocal_{grw}$	[mg.l^{-1}]		Default

In order to estimate the concentration in pore water of soil a number of partition coefficients are derived:

Air water partition coefficient [-]

$$Kair - water = \frac{HENRY}{R \times TEMP}$$

Soil water partition coefficient (l.kg^{-1}):

$$Kpsoil = Koc \times Foc$$

Soil-water equilibrium partition distribution coefficient (m^3.m^{-3}):

$$K_{soil-water} = Fair \times K_{ai-water} + Fwater + Fsoil \times \frac{Kp_{soil}}{1000} \times RHOsolid$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source*
Henry's law constant	$HENRY$	[Pa.m^3.mol^{-1}]	> 4.5.10^{-2}	Input
Gas constant	R	[Pa.m^3.mol^{-1}.k^{-1}]	8.314	Default
Temperature at the air-water interface	$TEMP$	K	285	Default
Air-water partitioning coefficient	$K_{air-water}$	[-]		Output

Partition coefficient organic carbon -water	*Koc*	[L.kg^{-1}]	76880	Input
Fraction organic carbon in the soil	*Foc*	[-]	0.02	Default
Soil water partition coefficient	*Kpsoil*	[L.kg^{-1}]		Output
Fraction air in soil	*Fair*	[-]	0.2	Default
Fraction water in soil	*Fwater*	[-]	0.2	Default
Fraction solid in soil	*Fsolid*	[-]	0.6	Default
Bulk density of solids	*RHOsolid*	[kg.m^{-3}]	2500	Default
Soil-water equilibrium partition distribution coefficient	*Ksoil-water*	[m^3.m^{-3}]		Output

*All default values were taken from the Technical Guidance Document (European Commission, 2003)

Therefore:

Air water partition coefficient [-]:

$$Kair-water = \frac{>4.5.10-2}{8.314 \times 285} = 1.9 \times 10^{-5}$$

Soil water partition coefficient (L.kg^{-1}):

$$Kpsoil = 76880 \times 0.02 = 1537.6$$

Soil-water equilibrium partition distribution coefficient (m^3.m^{-3}):

$$K_{soil-water} = 0.2 \times 1.9 \times 10^{-5} + 0.2 + 0.6 \times \frac{1537.6}{1000} \times 2500 = 2306.6$$

The equation for deriving the concentration in porewater is:

$$C\,porewater = \frac{PEClocal_{soil} \times RHOsoil}{K_{soil\text{-}water} \times 1000}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted environmental concentration in soil	$PEClocal_{soil}$	[mg.kg^{-1}]	0.168	Input
Soil-water partitioning coefficient	*Ksoil-water*	[mg.l^{-1}]	2306.6	Calculated
Bulk density of wet soil	*RHOsoil*	[kg.m^{-3}]	1700	Default
Predicted environmental concentration in porewater	$PEClocal_{agr.soil,porew}$	[mg.l^{-1}]		Output

Therefore, in the case of permethrin:

$$PEClocal_{.soil,porew} = \frac{0.168 \times 1700}{2306.6 \times 1000} = 1.24 \times 10^{-4}\,mg.L^{-1}$$

Scenario	$Clocal_{soil,leach,time2}$	$C_{earthworm}$ (mg/kg wet worm)	PEC/PNEC birds	PEC/PNEC mammals
Scenario: Fence: Dip/Spray Treated Wood				
Tier 1 (no biodegradation)	4.71E+00	4.76E+01	2.85	3,97E-01
Tier 2 (worst case biodegradation)	1.68E-01	1.70E+00	0.10	1,42E-02
Tier 3 (typical biodegradation)	-			
Scenario: Fence: Penetration Treated Wood	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	2.94E+00	2.97E+01	1.78	2,48E-01
Tier 2 (worst case biodegradation)	1.06E-01	1.07E+00	0.06	8,92E-03
Tier 3 (typical biodegradation)	8.27E-02	8.35E-01	0.05	6,96E-03
Scenario: Fence: In Situ Treatment (Brushing) Professional	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	2.35E+00	2.38E+01	1.43	1,98E-01
Tier 2 (worst case biodegradation)	2.41E-01	2.43E+00	0.15	2,03E-02
Tier 3 (typical biodegradation)	-			
Scenario: Fence: In Situ Treatment (Brushing) Non-Professional	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	2.35E+00	2.38E+01	1.43	1,98E-01
Tier 2 (worst case biodegradation)	2.46E-01	2.49E+00	0.15	2,08E-02
Tier 3 (typical biodegradation)	-			
Scenario: Noise Barrier: Dip/Spray Treated Wood	$Clocal_{comp,leach,time2}$			
PEC Soil Tier 1 (no biodegradation)	1.32E+00	1.34E+01	0.80	1,12E-01
PEC Soil Tier 2 (worst case biodegradation)	4.73E-02	4.78E-01	0.03	3,98E-03
Scenario: Noise Barrier: Penetration Treated Wood	$Clocal_{comp,leach,time2}$			
PEC Soil Tier 1 (no biodegradation)	1.32E+00	1.34E+01	0.80	1,12E-01
PEC Soil Tier 2 (worst case biodegradation)	3.59E-02	3.62E-01	0.02	3,02E-03
Scenario: House: Dip/Spray Treated Wood	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	3.54E+00	3.57E+01	2.14	2,98E-01
Tier 2 (worst case biodegradation)	1.26E-01	1.28E+00	0.08	1,07E-02
Tier 3 (typical biodegradation)	-			
Scenario: House: Penetration Treated Wood	$Clocal_{soil,Leach,Time2}$			
Tier 1 (no biodegradation)	3.54E+00	3.57E+01	2.14	2,98E-01
Tier 2 (worst case biodegradation)	9.58E-02	9.68E-01	0.06	8,07E-03
Tier 3 (typical biodegradation)	7.45E-02	7.53E-01	0.05	6,28E-03
Scenario: House: In Situ Treatment (Brushing) Professional	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	2.83E+00	2.86E+01	1.71	2,38E-01
Tier 2 (worst case biodegradation)	2.90E-01	2.93E+00	0.18	2,44E-02
Tier 3 (typical biodegradation)	2.30E-01	2.32E+00	0.14	1,93E-02
Scenario: House: In Situ Treatment (Brushing) Non-Professional	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	2.83E+00	2.86E+01	1.71	2,38E-01
Tier 2 (worst case biodegradation)	2.96E-01	2.99E+00	0.18	2,49E-02
Tier 3 (typical biodegradation)	2.35E-01	2.37E+00	0.14	1,98E-02
Scenario: Transmission Pole: Dip-Treated Wood	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	8.79E-01	8.88E+00	0.53	7,40E-02
Tier 2 (worst case biodegradation)	3.14E-02	3.18E-01	0.02	2,65E-03
Scenario: Transmission Pole: Penetration Treated Wood	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	8.79E-01	8.88E+00	0.53	7,40E-02
Tier 2 (worst case biodegradation)	2.38E-02	2.41E-01	0.01	2,01E-03
Scenario: Fence Post: Dip/Spray Treated Wood	$Clocal_{soil,leach,time2}$			
Tier 1 (no biodegradation)	3.05E-01	3.08E+00	0.18	2,57E-02
Tier 2 (worst case biodegradation)	1.09E-02	1.10E-01	0.01	9,17E-04

Scenario	$Clocal_{soil,leach,time2}$	$C_{earthworm}$ (mg/kg wet worm)	PEC/PNEC birds	PEC/PNEC mammals
Scenario: Fence Post: Penetration Treated Wood	**$Clocal_{soil,leach,time2}$**			
Tier 1 (no biodegradation)	3.05E-01	3.08E+00	0.18	2,57E-02
Tier 2 (worst case biodegradation)	8.26E-03	8.35E-02	0.01	6,96E-04

Section A7.5.5.1 **Annex Point IIA, VII.7.5**	**Bioconcentration, terrestrial : Bioconcentration, further study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	As demonstrated under Point 7.5.5 and explained in the Environmental Risk Assessment, permethrin does not present a risk of secondary poisoning in the environment. Therefore, further studies should not be required.	
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	*15/1/09*	
Evaluation of applicant's justification	*Applicants justification has been robustly defended*	
Conclusion	*Accept Applicants justification – no further studies required*	
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		

Section A7.5.6	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The Technical Guidance on Data Requirements for Active Substances states that this is required when the preliminary risk assessment indicates additional testing may be required. The terrestrial data available are sufficient to characterise the risk to the terrestrial environment. Permethrin is of low toxicity to terrestrial organisms other than insects, and the exposure to terrestrial insects is minimal, based upon use patterns. Any impact will be transient and localised. Therefore a justification for non-submission of data is proposed based upon limited exposure and sufficient confidence in available data to accurately predict terrestrial impact.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11/05/05	
Evaluation of applicant's justification	Applicant's justification is adequate	
Conclusion	Adopt applicant's justification	
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*	

Section A7.5.6	Effects on other terrestrial non-target organisms
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.5.7.1.1	Effects on mammals: Acute oral toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	The acute toxicity of permethrin has been suitably addressed in the mammalian toxicity Sections. The only scenario which may require some additional understanding of impact is exposure of bats to treated beams. IUCLID Section 7.3 details reference; Racey, P.A & Swift, S.M; 1986; The residual effects of remedial timber treatments on bats. Biological conservation, **35**, 215-214 In this investigation, A 0.3% permethrin (25:75 *cis:trans*) product was applied at a rate of 0.5 litres m-2 according to manufacturers specifications. Other products (gammaHCH+PCP, Copper, Borester, Deltamethrin, Napthenate, TBTO, Zinc octoate) were also tested. The permethrin product was applied to the plywood lining of a steel cage 6 weeks to 14 months before bats (*Pipistrellus pipistrellus*) were introduced. The plywood was grooved to allow bats to climb and hang. Negative (solvent) controls were included in the experimental design. Wild caught bats (10 per cage) were introduced and fed ad libitum. No obvious harm was caused to the bats roosting for 16 to 22 weeks in cages lined with permethrin treated plywood. gammaHCH+PCP treated plywood caused 100% mortality. Therefore a non-submission of data is proposed based upon an understanding of permethrin toxicity to mammals which is possible to extrapolate from existing mammalian data.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Date	EVALUATION BY RAPPORTEUR MEMBER STATE 11/05/05	

Section A7.5.7.1.1	Effects on mammals: Acute oral toxicity
Evaluation of applicant's justification	Applicant' s invocation of study is acceptable and evaluation is justified.
Conclusion	Adopt applicant's justification
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	

Section A7.5.7.1.2	Effects on mammals: Short term toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The short term toxicity of permethrin has been suitably addressed in the mammalian toxicity Sections. The only scenario which may require some additional understanding of impact is exposure of bats to treated beams. IUCLID Section 7.3 details reference; Racey, P.A & Swift, S.M; 1986; The residual effects of remedial timber treatments on bats. Biological conservation, **35**, 215-214 In this investigation, A 0.3% permethrin (25:75 *cis*:*trans*) product was applied at a rate of 0.5 litres m-2 according to manufacturers specifications. Other products (gammaHCH+PCP, Copper, Borester, Deltamethrin, Napthenate, TBTO, Zinc octoate) were also tested. The permethrin product was applied to the plywood lining of a steel cage 6 weeks to 14 months before bats (*Pipistrellus pipistrellus*) were introduced. The plywood was grooved to allow bats to climb and hang. Negative (solvent) controls were included in the experimental design. Wild caught bats (10 per cage) were introduced and fed ad libitum. No obvious harm was caused to the bats roosting for 16 to 22 weeks in cages lined with permethrin treated plywood. gammaHCH+PCP treated plywood caused 100% mortality. Therefore a non-submission of data is proposed based upon an understanding of permethrin toxicity to mammals which is possible to extrapolate from existing mammalian data.	
Undertaking of intended data submission [ ]		

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/05/05
Evaluation of applicant's justification	Applicant's invocation of study is acceptable and justification is acceptable
Conclusion	Adopt applicant's justification
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	

Section A7.5.7.1.3	Effects on mammals: Effects on reproduction	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	Technically not feasible [ ] Scientifically unjustified [ ]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification:	Permethrin has been tested for toxicity in a comprehensive package of studies including acute toxicity, genotoxicity, short- and long-term toxicity/carcinogenicity, developmental toxicity studies, reproductive toxicity and neurotoxicity. The most relevant studies for assessing any endocrine disruption potential for permethrin are summarised below: Multi-generation reproduction study in the rat ([redacted]) In a 3-generation reproduction study, groups of 20 male and 20 female Wistar COBS rats received permethrin (25% *cis*/75% *trans*) in the diet at 0, 5, 30, and 180 mg/kg body weight per day during growth, mating, gestation, parturition, and lactation for three generations, each with two litters. Foetal toxicity and teratogenicity were assessed in the second pregnancy of the F2 generation. Treatment with permethrin had no effect on general behaviour or condition, food intake, body weight gain, or pregnancy rate of the dams, or on parturition, sex ratio, or pup weight. A small number of rats of each group (including controls) developed eye abnormalities, including ocular haemorrhage and chronic glaucoma, but this were not related to the treatment. Examination of F3b foetuses showed no treatment-related effect on sex ratio, body weight, or the occurrence of visceral or skeletal abnormalities. This study indicated that permethrin has no effect on the reproduction ability of rats at doses up to 180 mg/kg body weight per day. Teratogenicity study in the rat ([redacted]) Groups of 22/23 female Wistar rats received permethrin (25% *cis*/75% *trans*) at 0 or 200 mg/kg body weight in corn oil by daily oral gavage on days 6-16 (inclusive) of pregnancy. Treatment was without apparent effect on maternal body weight gain or general conditions. The animals were sacrificed on Day 20 so and their uterine contents were examined. Treatment had no effect on the number of corpora lutea, implantations, live foetuses, early and late foetal deaths, or foetal abnormalities. Examination of the foetuses, which included dissection and skeletal staining, showed no morphological effects of treatment. These results indicate that permethrin at 200 mg/kg body weight per day is not foetotoxic to rats Teratogenicity study in the rabbit ([redacted])	

Section A7.5.7.1.3	Effects on mammals: Effects on reproduction

[redacted])

Groups of 18-24 female New Zealand White rabbits received permethrin (25% *cis*/75% *trans*) at 0, 100, 200 or 400 mg/kg body weight in corn oil by daily oral gavage on days 6-18 (inclusive) of pregnancy. Treatment was without significant maternal effect. General health and condition of treated animals remained comparable with that of controls. An initial depression in body weight was observed in all groups, the effect in Group 4 (400 mg/kg/day) being slightly more pronounced. Subsequently, the rates of weight gain were comparable for all groups. The animals were sacrificed on Day 29 so that their uterine contents were examined. All other litter parameters of treated groups were comparable with those of the controls with the exception a slight not dosage-related increase in pre-implantation loss that was recorded in all treated groups. However, all values were within the background control range of 16.5% ± 8.7%.

External, internal and skeletal examination of foetuses revealed a number of anomalies in both treated and control groups, the majority of which were of types and incidences previously recorded in control rabbits of this strain. There was no indication of any treatment-related response. These results indicate that permethrin at up to 400 mg/kg body weight per day is not foetotoxic to rabbits.

An apparent reduction in pregnancy rate was recorded in all treated groups. For this result to have been related to treatment (which commenced on Day 6) it would have had to be due to failure of the late stages of implantation or to early post-implantation death of embryos which would resorb leaving no detectable remains on Day 29 of gestation. However, in females which carried viable young to term, no reduction in the number of implantations or consistent increase in pre- or post-implantation losses was recorded in any group. Therefore, on the basis of information obtained in this study it was considered unlikely that the effect was treatment-related.There were no indications that permethrin gave rise to any teratogenic response.

In addition, two limit test studies conducted in mice and rabbits respectively are available. In both studies, 400 mg/kg/d was without any adverse effects in either dams or foetuses.

Chronic toxicity and carcinogenicity in the rat [redacted])

Diets containing permethrin (25% *cis*/75% *trans*) at concentrations sufficient to provide dosagesof 10, 50 or 250 mg/kg body weight/day were fed to groups of 60 male and 60 female Wistar rats for 103 consecutive weeks. Clinical effects observed at 250 mg/kg per day were increased mortality in males, occasional body tremors in males and females towards the end of the study.

Liver was the main target organ with an increased weight in males, hepatocyte hypertrophy in males and females at 250 mg/kg per day.

Section A7.5.7.1.3	Effects on mammals: Effects on reproduction

This effect was associated with focal changes of the thyroid follicles in males and females which are most likely secondary effects to liver toxicity.
The microscopic liver and thyroid changes were also observed at 50 mg/kg per day in both sexes. With respect to tumours (including rare, unusual, or malignant neoplasms), none of the tumour types observed in this study were considered to be related to the ingestion of permethrin.
The NO(A)EL was determined to be 10 mg/kg bw/day

Chronic toxicity and carcinogenicity in the rat and the mouse ([redacted]

Four groups of 96 Wistar rats (48 males and 48 females) were maintained for 104 weeks on diets containing 0, 500, 1000, or 2500 ppm permethrin (40% *cis*/60% *trans*). In addition, four groups of 100 Swiss mice (50 males and 50 females) were maintained for a lifetime study (80% mortality) on diets containing 0, 250, 1000, or 2500 ppm permethrin (40% *cis*/60% *trans*).
Changes of toxicological significance were confined to the dose level of 2500 ppm permethrin in both species. Tremors and hypersensitivity to noise were noted in rats at this dose during the first 2 weeks of study but such signs were not seen in mice. Pathological examination of the central and peripheral nervous systems did not reveal abnormalities attributable to permethrin administration. The effect on mice at 2500 ppm permethrin was shown by decreased body weight gain. Liver hypertrophy, associated with increase in liver weight, microsomal enzyme activity, and proliferation of smooth endoplasmic reticulum occurred in the rat with similar but less marked changes in the mouse. This was considered to be an adaptive response of no toxicological significance.
No evidence of a carcinogenic effect was seen in the rat study. In the mouse study a slight elevation in benign lung tumour incidence in males only at 2500 ppm permethrin was observed but was not considered to represent a carcinogenic effect. No effect to any endocrine or reproductive organ was observed.
Therefore, the following conclusions can be drawn from these studies:

- · Permethrin has no effects on reproductive indices nor fertility nor reproductive tissues and organs as shown in the multi-generation study in rats.
- · No teratogenic effects were reported in rats or rabbits.
- · No effects on any endocrine organs or reproductive tissues were observed in rats or mice in long term studies.

These results support the conclusion that permethrin is not a teratogen, reproductive toxin or endocrine disrupter. No concerns over issues of endocrine disruption were raised neither by EPA in the

Section A7.5.7.1.3	Effects on mammals: Effects on reproduction
	RED (2006, "In the available toxicity studies on permethrin, there was no toxicologically significant evidence of endocrine disruptor effects") nor within the JMPR toxicological evaluation in 1999.
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	28/05/2009
Evaluation of applicant's justification	Acceptable
Conclusion	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	

Appendix 1 to Doc III-A7

Bayer Environmental Science is a an affiliated company of Bayer CropScience, therefore the studies submitted by Bayer Environmental Science are owned by Bayer CropScience AG.

Reference List Doc. III-A7 sorted by reference no.

Reference No	AUTHOR (S)	Year	Title. Source, Report No. Glp /(Un) Published	Data Protection Claimed (Yes/No)	Owner
7,4(1)	Solomon, K.R., Giddings, J.M., Maund, S.J.	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: I. Distributional analysis of Laboratory Aquatic Toxicity Data. Environmental Toxicology and Chemistry, 20, 3, 652-659; Not GLP; Published	No	N/A
7,4(2)	Giddings, J.M., Solomon, K.R., Maund, S.J.	2001	Probabilistic Risk Assessment of Cotton Pyrethroids: II. Aquatic mesocosm and Field Studies. Environmental Toxicology and Chemistry, 20, 3, 660-668; Not GLP; Published	No	N/A
7,4,1,1(1)	[redacted]	1978c	Determination of the Acute Toxicity of Compound 21z (WRL) to Rainbow Trout (Salmo gairdneri) Using Dimethyl Sulphoxide as the Solvent. [redacted]; Not GLP; Unpublished	Yes	Sumitomo Chemical
7,4,1,1(1)	[redacted]		Analytical report :; Analysis of test concentrations of. the compound 21Z (Wellcome Research Laboratories) in acute toxicity flow-through tests with Bluegill Sunfish (*Lepomis macrochirus*) and Rainbow Trout (*Salmo gairdneri*) using dimethyl sulphoxide as a solvent aid.. [redacted], unpublished	Yes	Sumitomo Chemical
7,4,1,1(2)	[redacted]	1984	Acute toxicity of dichlorovinylcarboxylic acid to rainbow trout., [redacted] unpublished	Yes	Bayer CropScience AG
7,4,1,2(1)	Thompson, R.S. & Williams, T.D.	1978	Determination of the Acute Toxicity of Compound 21z (WRL) to Daphnia magna Using Acetone as the Solvent. The Wellcome Foundation, Ltd. Report No. HEFG 78-10; Not GLP; Unpublished	Yes	Sumitomo Chemical
7,4,1,2(1)	Bowles F.P		Analysis of the test compound Z21 (Wellcome Research Laboratories) in acute toxicity study static tests with daphnia magna. ICI Brixham Laboratory BL/B/1897, unpublished.	Yes	Sumitomo Chemical

7,4,1,2(3)	Forbis A.D, Burgess, D	1984	Static Acute toxicity report : Acute toxicity of DCVA to Daphnia magna. Mobay chemical corporation, Stillwel, Kansas; Report N°505 BES Ref : M-034747-01-1;Report date : 25 June 1984:unpublished	Yes	Bayer CropScience AG
7.4.1.3(1)	Dorgerloh, M	2008	*Pseudokirchneriella subcapitata* growth inhibition test with permethrin (techn.).Report No. E323 3265-4; GLP; Unpublished	Yes	Bayer CropScience AG
7.4.1.3(2)	Stratton, G.W. and C.T. Corke	1982	Toxicity of the insecticide permethrin and some degradation products towards algae and cyanobacteria. Environ. Pollut., Ser. A 29:71-80.	No	N/A
7,4,1,4	Dengler, D.	1999	Testing of Toxic Effects of Permethrin Technical Insecticide on Activated Sludge with the Respiration Inhibition Test. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH. Report No. 99385/01-AAHT; GLP; Unpublished	Yes	Sumitomo Chemical
7,4,2(1)	[redacted]	1989	Uptake, depuration and bioconcentration of carbon-14-permethrin by Bluegill Sunfish *(Lepomis macrochirus)*; [redacted]; GLP; Unpublished study prepared by [redacted]	Yes	Sumitomo Chemical
7,4,2(2)	Muir, D.C.G., Rawn, G.P, Townsend, B.E., Lockhart, W.L., and Greenhalgh, R.	1985	Bioconcentration of cypermethrin, deltamethrin, fenvalerate, and permethrin by Chironomus tentans larvae in sediment and water. Environmental Toxicology and Chemistry. 4:51-61; Not GLP; Published	No	N/A
7,4,3,2(1)	Spehar, R.L, Tanner, D.K., Nordling, B.R.;	1983	Toxicity of the synthetic pyrethroids, permethrin and AC222,705 and their accumulation in early life stages of fathead minnows and snails; Aquatic toxicology; 3; 171-182; not GLP; Published	No	N/A
7,4,3,2(2)	Hansen D.J., Goodman L.R, Moore J.C., Higdon P.K	1983	Effect of the synthetic pyrethroids AC222,705, permethrin and Fenvalerate on Sheepshead minnows in early life stages toxicity test ; Environmental Toxicology and Chemistry; 2; pp 251-258; not GLP;	No	N/A
7,4,3,4	Kent, S; Williams, N.; Gillings, E.; Morris D. S.;	1995	Permethrin: Chronic toxicity to Daphnia magna; Zeneca Brixham Environmental Lab; Project No. BL5443/B; GLP; Unpublished	Yes	Sumitomo Chemical

7,4,3,5,1(1)	Conrad, A.U., Fleming, R.J., Crane, M.	1999	Laboratory and field response of chironomus riparius to a pyrethroid insecticide. Water Research, 33, 7, 1603-1610; Not GLP; Published	No	N/A
7,4,3,5,1(2)	Fleming, R.J., Holmes, D., Nixon S.J.	1998	Toxicity of permethrin to Chironommus reparius in artificial and natural sediments. Environmental Toxicology and Chemistry, 17, 7, 1332 - 1337; Not GLP; Published	No	N/A
7,5,1,1	Johnen, B.G, Slinger, J.M, Bridgman, P.A.	1977	P557: Effect on carbon and nitrogen turnover by soil microorganisms. ICI internal report AR2659/B; Not GLP; Unpublished	Yes	Syngenta
7,5,1,2	Kumar, A.	1997	Permethrin Technical Acute toxicity in Earthworm. Jai Research Foundation Report 1054/JRF/ECO/97; GLP; Unpublished	Yes	Sumitomo Chemical
7,5,2,1(2)	Moser, Th., Scheffczyk, A.,	2005	Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1)., ECT Oekotoxikologie GmbH, Germany. Report No. P15HR BES N° M-259607-01-127 October 2005 unpublished	Yes	Bayer CropScience AG
7,5,2,1(3)	Moser, T, Scheffczyk, A.,	2005	Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1). ECT Oekotoxikologie GmbH, Germany. Bayer AG, Report No. P14HR BES Ref M-258697-01-1 12 October 2005 Unpublished	Yes	Bayer CropScience AG
7,5,3,1,1	[redacted]	1975a	Acute oral LD50 in Mallard Duck with FMC33297. [redacted]0; Not GLP; Unpublished	Yes	Sumitomo Chemical
7,5,3,1,2	[redacted]	1975b	Eight-day dietary LC50 in Bobwhite Quail and Mallard Duck with FMC33297. [redacted]; Not GLP; Unpublished	Yes	Sumitomo Chemical
7,5,3,1,3	[redacted]	1992	.Permethrin: A one-generation study with the Northern Bobwhite *(Colinus virginianus)*; [redacted]; GLP; Unpublished	Yes	Sumitomo Chemical
7,5,4,1	Gough, H.J, Jackson, D, Lewis, G.B	1993	Permethrin: Acute Contact and Oral toxicity to Honey Bees (Apis mellifera) of technical material; Jealott's Hill Research Station; Report No. RJ1344B; 18 Jan 1993; GLP; Unpublished	Yes	Sumitomo Chemical

Competent Authority Report

Programme for Inclusion of Active Substances in Annex I to Council Directive 98/8/EC

Permethrin (PT 8)

CAS-No. 52645-53-1

DOCUMENT IIIA (A8 – A9)

Evaluation Report

Rapporteur: Ireland

August 2009

Permethrin PT8

Document IIIA (A8 – A9)

CONTENTS

Section A8 IUCLID: 8.1-8.8	Measures necessary to protect man, animals and the environment	
Subsection (Annex Point)		**Official use only**
8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)	**GENERAL PROCEDURES:** Store in a cool, dry, well-ventilated place. To avoid product decomposition, do not use or store near heat, open flame or hot surfaces. Do not heat product above 170°C. Store in original containers only. Keep out of reach of children and animals. Do not contaminate other pesticides, fertilizers, water, food or feed by storage or disposal.	
8.2 In case of fire, nature of reaction products, combustion gases, etc (IIA8.2)	Under fire conditions, material is subject to rapid decomposition with gas generation that may result in container rupture. Thermal decomposition and burning may form toxic by-products.	

Section A8 IUCLID: 8.1-8.8		Measures necessary to protect man, animals and the environment
8.3	Emergency measures in case of an accident (IIA8.3)	**FIRST AID MEASURES** **EYES:** Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention. **SKIN:** Wash with plenty of soap and water. **INGESTION:** Drink 1 or 2 glasses of water and induce vomiting by touching the back of the throat with a finger or by giving syrup of ipecac. Never induce vomiting or give anything by mouth to an unconscious person. Contact a medical doctor. **INHALATION:** Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention. **NOTES TO MEDICAL DOCTOR:** Permethrin has low oral, dermal and inhalation toxicity. It is minimally irritating to the eyes and practically non-irritating to the skin. Reversible skin sensations (paresthesia) may occur and ordinary skin salves have been found useful in reducing discomfort. Treatment is otherwise controlled removal of exposure followed by symptomatic and supportive care. **FIRE FIGHTING MEASURES** EXTINGUISHING MEDIA: Foam, CO_2 or dry chemical. Soft stream water fog only if necessary. Contain all runoff. FIRE / EXPLOSION HAZARDS: Slightly combustible. This material may support combustion at elevated temperatures. CAUTION: Overheated containers may rupture due to product decomposition under fire conditions. FIRE FIGHTING PROCEDURES: Isolate fire area. Evacuate downwind. Wear full protective clothing and self-contained breathing apparatus. Do not breathe smoke, gases or vapors generated. HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide and/or carbon dioxide. Chlorine and hydrogen chloride may be formed. **ACCIDENTAL RELEASE MEASURES** RELEASE NOTES: Isolate and post spill area. Wear protective clothing and personal protective equipment. Keep unprotected persons and animals out of the area. Keep material out of lakes, streams, ponds and sewer drains. Dike to confine spill and absorb with a non-combustible absorbent such as clay, sand or soil. Vacuum, shovel or pump waste into a drum and label contents for disposal.

Section A8 IUCLID: 8.1-8.8	Measures necessary to protect man, animals and the environment
	To clean and neutralize spill area, tools and equipment, wash with a suitable solution (i.e., bleach or caustic/soda ash and either ethylene glycol or an appropriate alcohol, i.e., methanol, ethanol or isopropanol). Follow this by washing with a strong soap and water solution. Absorb as above, any excess liquid and add to the drums of waste already collected. Repeat if necessary. Dispose of drummed waste according to national legislation.
8.4 Possibility of destruction or decontamination following release in or on the following: air, water, including drinking water and soil (IIA8.4)	Open dumping or burning of this material or its packaging is prohibited. Spilled material should be soaked up with an inert material (eg. Sand, silica, sawdust, acid binder, universal binder). Transfer collected material to heavy duty plastic drums and keep safe for disposal. An acceptable method of disposal is to incinerate in accordance with local, state and national environmental laws, rules, standards and regulations
8.5 Procedures for waste management of the active substance for industry or professional users (IIA8.5)	DISPOSAL METHOD: In accordance with current regulations may be taken to waste disposal site or incineration plant, after consultation with site operator and/or with the responsible authority. Can be land-filled or incinerated. However, because acceptable methods of disposal may vary by location and regulatory requirements may change, the appropriate agencies should be contacted prior to disposal. EMPTY CONTAINER: Non-returnable containers which held this material should be cleaned, prior to disposal, by triple rinsing. Containers which held this material may be cleaned by being triple-rinsed, and recycled, with the rinsate being incinerated. Do not cut or weld metal containers. Vapours that form may create an explosion hazard. Packaging that cannot be cleaned should be disposed of as product waste.
8.5.1 Possibility of re-use or recycling (IIA8.5.1)	None
8.5.2 Possibility of neutralisation of effects (IIA8.5.2)	To clean and neutralize spill area, tools and equipment, wash with a suitable solution (i.e., bleach or caustic/soda ash and either ethylene glycol or an appropriate alcohol, i.e., methanol, ethanol or isopropanol). Follow this by washing with a strong soap and water solution. Absorb as above, any excess liquid and add to the drums of waste already collected. Repeat if necessary. Dispose of drummed waste according to national legislation.

Section A8 IUCLID: 8.1-8.8		Measures necessary to protect man, animals and the environment
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal (IIA8.5.3)**	Keep material out of lakes, streams, ponds and sewer drains.
	Conditions for controlled incineration	Incinerate in accordance with local, state and national environmental laws, rules, standards and regulations. However, because acceptable methods of disposal may vary by location and regulatory requirements may change, the appropriate agencies should be contacted prior to disposal.
8.6	**Observations on undesirable or unintended side-effects e.g. on beneficial and other non-target organisms (IIA8.6)**	Permethrin is highly toxic to aquatic and terrestrial arthropods. Care should be taken to avoid contamination of the aquatic environment. Permethrin is slightly toxic to birds and oral LD50 values are greater than 3600 mg/kg. Longer dietary studies showed that concentrations of up to 500 ppm in the diet had no effect on bird reproduction.
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**	None

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	5 November 2008
Materials and methods	The applicant's version is acceptable.
Conclusion	Adopt applicant's version
Reliability	1
Acceptability	acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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	

1.1. CLASSIFICATION AND LABELLING

1.1.1. Current Classification

Directive 67/548/EEC

Hazard symbol: (for labelling)	Xn N	Harmful Dangerous for the environment
Indication of danger:		
Risk Phrases: (for labelling)	R20/22 R43 R50 R53	Harmful by inhalation and if swallowed May cause sensitisation by skin contact Very toxic to aquatic organisms May cause long-term adverse effects in the aquatic environment
Safety Phrases: (for labelling)	S 2 S 13 S 24 S 36/37/39 S 60 S 61	Keep out of the reach of children Keep away from food, drink and animal feedingstuffs Avoid contact with skin Wear suitable protective clothing, gloves and eye/face protection This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheets
Specific concentration limits	C ≥ 25 %: Xn, N; R20/22-43-50-53 1 % ≤ C < 25 %: N; R43-50-53 0,025 % ≤ C < 1 %: N; R50-53 0,0025 % ≤ C < 0,025 %: N; R51-53 0,00025 % ≤ C < 0,0025 %: R52-53	

Regulation (EC) No 1272/2008

Pictogram: (for labelling)	
Signal word:	Warning
Hazard Statements: (forclassification and labelling)	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects. H302+H332: Harmful if inhaled and swallowed H317: May cause an allergic skin reaction
Precautionary Statements: (for labelling)	P102: Keep out of reach of children P220: Keep away from food, drink and animal feedingstuffs P280: Wear protective gloves and clothing and eye/face protection P305+351+313: IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention. P273: Avoid release to the Environment P391: Collect spillage P501: Dispose of contents/container to hazardous waste

2.

The active substance, Permethrin, is not classified from a physical/chemical viewpoint.

Physical-Chemical Properties:
The active substance permethrin will not classify as being flammable, explosive or oxidising. No further data required.

Toxicology:
No changes proposed. However, under the CLP Regulation the classification of permethrin as a skin sensitizer needs to be distinguished between category 1A and 1B. This was not required under the previous dangerous substances legislation. On the basis of the data that comprises five studies three from the biocide process and two from the pesticide process. However, as the substance is currently classified sensitizer R43 and there are two positive studies we would advocate retaining the classification as sensitizer according to the CLP Regulation and propose the classification of permethrin as a skin sensitizer category 1B ('skin sens. Cat. 1B').

Environment:
Change proposed according to the amendment No: 286/2011 of Commission Regulation (EU) No: 1272/2008.

H400 will be changed to H400 (Acute Cat 1), very toxic to aquatic life. H410 will be changed to H410 (Acute Cat 1; Chronic Cat 1): Very toxic to aquatic life with long lasting effects.
M-Factor added: Acute M-Factor: 100 Chronic M-Factor: 10000 (based on $0.001<L(E)C50\leq0.01$) and ($0.000001<NOEC\leq0.00001$, NRD).

Additional information:
A full data package (including: physical/chemical properties, toxicology, environment) for biocidal products containing permethrin will be required at Member State level when applying for authorisation and results of that evaluation will determine the classification of the product.

2.1.1. Proposed Classification

There is no proposal by the RMS to change the classification proposal for the active substance, permethrin. Please see above the classification of permethrin.