Part 3 **Evaluation Form 3 -**

for use in checking that all test and study reports required in accordance with Annex IIP have been provided

Active substance: PHEROMONE

Applicant:

Date: APRIL 2001

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N#	Justification provided L/N#	Undertaking provided Date/N#	Official use only* Data Gap Y/N#
Point 1	**Identity of the Active Substance**				
1.1	Applicant (name, address, contact, telephone and telefax numbers) - R	—	—	—	—
1.2	Manufacturer(s) (name, address, contact, telephone and telefax numbers) - R	—	—	—	—
1.3	ISO common name proposed or accepted, and synonyms - R	—	—	—	—
1.4	Pheromone or Semiochemical name as in Annex I to Directive 67/548/EEC, if not included in that Annex, in accordance with IUPAC and CA nomenclature if applicable - R	—	—	—	—
1.5.1	Manufacturer's code number(s), for the pheromone and semiochemical active substance and formulations, materials concerned, countries in which used and periods for which used - R	—	—	—	—
1.5.2	Trade Name(s) - R	—	—	—	—
1.5.3	Patent Status - R	—	—	—	—
1.7	Molecular formula, molecular mass and structural formula - R	—	—	—	—
1.8.1	Method of manufacture (pathways, by-products and impurities) for each plant, whether or not relevant to a pilot plant - R	—	—	—	—
1.8.2	Description of starting materials - R	—	—	—	—

* To be completed by the Competent Authority of the Member State to which application is made

Y = yes; P = in part; N = no; L = location (volume and page) where justification can be found; Date = date report to be submitted

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
1.9.3	Control Product Specification Form or Confidential Statement of Formula - R	—	—	—	—
1.10.2	Impurities nad additives				
	* IUPAC and CA names	—	—	—	—
	* ISO common name proposed or accepted	—	—	—	—
	* CAS, CIPAC, EINECS and ELINCS numbers	—	—	—	—
	* Molecular and structural formula	—	—	—	—
	* Molecular mass	—	—	—	—
	* Maximum content in g/kg	—	—	—	—
	* Whether or not relevant to a pilot plant	—	—	—	—
	* In the case of additives, their function and trade names	—	—	—	—
	* In the case of impurities and by-products of particular environmental concern, details of the analytical methods	—	—	—	—
	* Guidance in identifying impurities of toxicological concern - R	—	—	—	—
1.11.1	Analytical profile of batches - R	—	—	—	—
1.11.2	Results of analyses of batches produced in laboratory or pilot scale production systems and used in toxicological testing - R	—	—	—	—
1.12	Other/special studies - CR	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
Point 2	**Physical and Chemical Properties of the Active Substance**				
2.1.1	Melting point, freezing point or solidification point of purified active substance - R	—	—	—	—
2.1.2	Boiling Point of purified active substance - R	—	—	—	—
2.2	Relative density of purified active substance - R	—	—	—	—
2.3.1	Vapour pressure of purified active substance - R	—	—	—	—
2.3.2	Henry's law constant - R	—	—	—	—
2.4.1	Description of the physical state and colour of both the purified active substance and active substance as manufactured (or technical grade active ingredient) - R	—	—	—	—
2.4.2	Description of the odour of the purified active substance and active substance as manufactured - R	—	—	—	—
2.5.1.1	* Ultraviolet/visible (UV/VIS) - R	—	—	—	—
2.5.1.2	* Infrared (IR) - R	—	—	—	—
2.5.1.3	* Nuclear magnetic resonance (NMR) - R	—	—	—	—
2.5.1.4	* Mass spectra (MS) - R	—	—	—	—
2.5.2.1	Spectra for impurities * Ultraviolet/visible (UV/VIS) See 2.5.1.1	—	—	—	—
2.5.2.2	Spectra for impurities				

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
	* Infrared (IR) See 2.5.1.2	—	—	—	—
2.5.2.3	Spectra for impurities				
	* Nuclear magnetic resonance (NMR) See 2.5.1.3	—	—	—	—
2.5.2.4	Spectra for impurities				
	* Mass spectra (MS) See 2.5.1.4	—	—	—	—
2.6	Solubility of purified active substance in water				
	• determined in the neutral range	—	—	—	—
	• determined in the acidic range (pH 4 to 6)	—	—	—	—
	• determined in the alkaline range (pH 8 to 10) - R	—	—	—	—
2.7	Solubility in organic solvents at 15 to 25° C - R	—	—	—	—
2.8.1	n-octanol/water partition coefficient - R	—	—	—	—
2.9.1	Hydrolysis rate of purified active substance at pH values 4, 7 and 9 under sterile conditions, in the absence of light				
	• Identity of hydrolysis products	—	—	—	—
	• Rate constant observed	—	—	—	—
	• Estimated DT_{50} value - CR	—	—	—	—
2.9.2	Direct phototransformation of purified active substance in water using artificial light (simulating sunlight and excluding wavelengths $\lambda < 290$ nm) under sterile conditions, to include				
	• Photochemical halflife	—	—	—	—
	• Mass balance to account for 90 % of the applied radioactivity	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
	• Identity of breakdown products	—	—	—	—
	• Dissociation constant(s) (pKa values) - R	—	—	—	—
	• Identity of dissociated species formed	—	—	—	—
	• Dissociation constant(s) (pKa values) of the active principle - CR	—	—	—	—
2.17.2	Stability (temperature, metals) - R	—	—	—	—
2.18	Other/special studies - CR	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
Point 3	**Further Information on the Active Substance (Function, Mode of action, Handling)**				
3.1	Function *e.g.* fungicide - R	—	—	—	—
3.3	Fields of use *e.g.* forestry - R	—	—	—	—
3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected) - R	—	—	—	—
3.5.1	Statement of the mode of action of the active substance in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved - R	—	—	—	—
3.8.1.2	Detailed instructions for sage disposal - R	—	—	—	—
3.10	Other/special studies - CR	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
Point 4	**Analytical Methods**				
4.1.1	Analytical standards for pure active substance - R	—	—	—	—
4.2.1	Description of analytical methods for the analysis of the active substance as manufactured - R				
	For each method submitted:				
	• Specificity	—	—	—	—
	• Extent of interference by other substances present	—	—	—	—
	• Explantation of interferences which contribute more than ± 3 % of the total quantity determined	—	—	—	—
	For each method submitted, linearity over an appropriate range:				
	• Equation of the calibration line	—	—	—	—
	• Correlation co-efficient	—	—	—	—
	• Representative labelled	—	—	—	—
	• documentation *e.g.* chromatograms	—	—	—	—
	For each method submitted, accuracy:				
	• Pure active substance	—	—	—	—
	• Impurities	—	—	—	—
	For each method submitted, repeatability (at least 5 determinations):				
	• % relative standard deviation (RSD)	—	—	—	—
	• Indication as to whether outliers identified have been discarded	—	—	—	—
	• reasons for the occurrence of outliers	—	—	—	—
4.2.3	Description of analytical methods for the determination of impurities (non-active components arising from the manufacturing process or from degradation during storage) which are of toxicological, ecotoxicological or environmental concern or which are present in quantities ≥ 1g/kg in the active substance as manufactured				

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
	- CR				
	For each method submitted: • Specificity	—	—	—	—
	• Extent of interference by other substances present	—	—	—	—
	• Explantation of interferences which contribute more than ± 3 % of the total quantity determined	—	—	—	—
	For each method submitted, linearity over an appropriate range: • Equation of the calibration line	—	—	—	—
	• Correlation co-efficient	—	—	—	—
	• Representative labelled	—	—	—	—
	• documentation *e.g.* chromatograms	—	—	—	—
	For each method submitted, accuracy: • Pure active substance	—	—	—	—
	• Impurities	—	—	—	—
	For each method submitted, repeatability (at least 5 determinations): • % relative standard deviation (RSD)	—	—	—	—
	• Indication as to whether outliers identified have been discarded	—	—	—	—
	• reasons for the occurrence of outliers	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
4.3	Description of analytical methods for the determination of residues (all components included in the residue definition proposed (see point 6) to enable compliance with MRLs to be determined or to determine dislogeable residues - always required	—	—	—	—
	For each method and representative matrix:				
	• Specificity (using a confirmatory method, if appropriate)	—	—	—	—
	• Repeatability	—	—	—	—
	• Validation - independent laboratory	—	—	—	—
	• Limit of determination	—	—	—	—
	• Individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level - CR	—	—	—	—
4.9	Other/special studies - CR	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIA Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
Point 5	**Toxicological and Toxicokinetic Studies on the Active Substance**				
5.1.1	Toxicokinetic studies - Single dose, oral route, in rats - CR	—	—	—	—
5.2.1	Acute oral toxicity - R	—	—	—	—
5.2.2	Acute percutaneous toxicity - R See 5.2.1	—	—	—	—
5.2.3	Acute inhalation toxicity - R See 5.2.1	—	—	—	—
5.2.4	Skin irritation - R See 5.2.1	—	—	—	—
5.2.5	Eye Irritation - R See 5.2.1	—	—	—	—
5.2.6	Skin sensitization - R See 5.2.1	—	—	—	—
5.3.2	Oral 90-day toxicity (rodents) - CR/R	—	—	—	—
5.3.6	90-day inhalation toxicity (rodents) - CR/R See 5.3.2	—	—	—	—
5.3.8	Percutaneous 90-day toxicity (rodents) - CR/R See 5.3.2	—	—	—	—
5.4.1	*In vitro* genotoxicity testing - Bacterial assay for gene mutation - R	—	—	—	—
5.4.3	*In vitro* genotoxicity testing - Test for gene mutation in mammalian cells - R	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

Active Substance: **Applicant:** **Date:**

Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
5.5.1	Long-term (2 years) oral toxicity in the rat (can be a combined long-term and carcinogenicity study) - CR	—	—	—	—
5.5.2	Carcinogenicity study in the rat (can be a combined long-term and carcinogenicity study) - CR See 5.5.1	—	—	—	—
5.5.4	Mechanism of action and supporting data - R	—	—	—	—
5.6.1	Two generation reproductive toxicity in the rat - CR	—	—	—	—
5.6.2.1	Teratogenicity test by the oral route in the rat - CR/R	—	—	—	—
5.6.2.2	Teratogenicity test by the oral route in the rabbit - CR	—	—	—	—
5.7.1	Acute neurotoxicity - rat - CR	—	—	—	—
5.9.7	Demal penetration - CR	—	—	—	—
5.10	Other/special studies - CR	—	—	—	—
5.11	Summary of mammalian toxicity and overall evaluation - R	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

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Annex IIP point	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N	Justification provided L/N	Undertaking provided Date/N	Official use only Data Gap Y/N
Point 6	**Metabolism and Residue Data (not normally required)**				
6.3	Residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed or where residues from soil can be taken up - CR	—	—	—	—
6.3.4	Tobacco - CR	—	—	—	—
6.4.1	Poultry and/or lactating ruminants (goat or cow) - CR	—	—	—	—
6.6	Residues in succeeding crops - CR	—	—	—	—
6.6.2	Metabolism and distribution studies on representative crops - CR	—	—	—	—
6.8.1	Pre-harvest interval (in days) for each relevant crop - CR	—	—	—	—
6.10	Other/special studies - CR	—	—	—	—

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 3** **Evaluation Form 3 Annex IIP Test and Study Reports**

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Point 7	**Fate and Behaviour in the Environment**				
7.4.1	Adsorption and desorption of the active substance - CR	—	—	—	—
7.4.3	Column leaching studies with the active substance - CR	—	—	—	—
7.4.9	Volatility - laboratory study - CR	—	—	—	—
7.6	Direct phototransformation of relevant metabolites, degradation and reaction products in water using artificial light (simulating sunlight and excluding wavelengths $\lambda < 290$ nm) under sterile conditions, to include	—	—	—	—
	• Photochemical halflife	—	—	—	—
	• Mass balance to account for 90 % of the applied radioactivity	—	—	—	—
	• Identity of breakdown products	—	—	—	—
	• Quantum yield of direct phototransformation	—	—	—	—
	• Calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the substance added	—	—	—	—
	- CR				
7.4	Monitoring data concerning fate and behaviour of the active substance and of relevant metabolites, degradation and reaction products - R	—	—	—	—
7.13	Other/special studies - CR	—	—	—	—

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Point 8	**Ecotoxicological Studies on the Active Substance**				
8.1.2	Avian dietary toxicity (5-day) test in a quail species or in mallard duck - CR	—	—	—	—
8.2.1	Acute toxicity of the active substance to fish - CR/R - Prefer EP	—	—	—	—
8.3	Aquatic species other than fish and aquatic species field testing - CR	—	—	—	—
8.3.1	Acute toxicity to aquatic invertebrates - CR/R - Prefer EP	—	—	—	—
8.4	Effects on algal growth and growth rate (2 species)	—	—	—	—
	Analytical data on concentrations in the test media - CR/R - Prefer EP	—	—	—	—
8.6	Effects on aquatic plants - CR/R	—	—	—	—
	Analytical data on concentrations in the test media See 8.3	—	—	—	—
8.7	Bees - CR/R	—	—	—	—
	- Prefer EP	—	—	—	—
8.8	Non-target terrestrial arthropods - CR/R	—	—	—	—
	- Prefer EP	—	—	—	—

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8.8.2	Effects on non-target terrestrial arthropods in extended laboratory/semi-field tests See 8.3	—	—	—	—
8.8.2.5	Other terrestrial invertebrates - CR	—	—	—	—
8.9	Earthworms - CR/R	—	—	—	—
8.10	Soil microbial activity - CR/R	—	—	—	—
8.12	Terrestrial vascular plants See 8.3 - CR	—	—	—	—
8.13	Effects on terrestrial vertebrates other than birds/wild mammal toxicty - CR	—	—	—	—
8.16.1	Other/special studies - laboratory studies - CR	—	—	—	—
8.16.2	Other/special studies - field studies - CR	—	—	—	—