APPENDIX 4

FORMAT FOR COMPILATION OF *Tier I* QUALITY CHECKS FOR PHEROMONES AND OTHER SEMIOCHEMICALS

PART 1

SUMMARY REPORT - APPROPRIATE FOR STUDIES CONDUCTED IN ACCORDANCE WITH THE TEST GUIDELINES CURRENTLY SPECIFIED

EXAMPLE 1

1.	**Data point number**	IIP 5.2.3 Acute inhalation toxicity
2.	**Reference point (location) in dossier**	PHEROMX, Data point number IIP 5.2.3
3.	**Author**	U.N. Known
	Title	Acute inhalation toxicity of PHEROMX in rats
	Owner, Date	Owner, unpublished report No.xxx-000, May 1, 1998
4.	**Testing Facility**	N.N. Laboratories, River road, London
5.	**Dates of work**	December 5, 1997 to January 23, 1998
6.	**Test Substance**	PHEROMX
7.	**Test Method**	according to OECD guideline 403: No Deviations from the protocol with respect to… * LC50 not determined * concentration - not clearly reported * administration by intatracheal instillation * observation period of 14 days * histopathology of lungs
8.	**GLP**	No

Appendix 4 **Format for Compilation of *Tier I* Quality Checks** **Part 1** **Summary Report - appropriate for studies conducted in accordance with the test guidelines currently specified**

EXAMPLE 2

Data Point Number IIP 5.3.2	**Oral 90-day toxicity of the active substance to rodents**
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Waiver of data for oral 90-day toxicity study, based on limited exposure.
Technically not feasible [ ] Limited exposure [x]	Scientifically unjustified, Other justification [ ] based on existing data [ ] *(check, as appropriate)*

Detailed justification:	The request for waiver for oral 90-day toxicity study (rodents) is based upon the following rationale. · Application rates of up to 375 g SCLP/ha/yr are generally understood not to result in significant exposure levels. · Repeated dose toxicity of SCLPs is described.
Undertaking of intended data submission [ ]	

EXAMPLE 3

Data Point Number IIP 5.4.1	**In vitro genotoxicity testing - Bacterial assay for gene mutation**
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Waiver of genotoxicity, based on limited exposure.
Technically not feasible [ ] Limited exposure [x]	Scientifically unjustified, Other justification [ ] based on existing data [ ] *(check, as appropriate)*

Detailed justification:	The request for waiver for genotoxicity data -bacterial assay for gene mutation- is based upon the following rationale. · Application rates of up to 375 g SCLP/ha/yr are generally understood not to result in significant exposure levels. · Mutagenicity of SCLPs is described.
Undertaking of intended data submission [ ]	

Appendix 4 **Format for Compilation of *Tier I* Quality Checks** **Part 1** **Summary Report - appropriate for studies conducted in accordance with the test guidelines currently specified**

EXAMPLE 4

Data Point Number IIP 6.3	**Residue trials**
	JUSTIFICATION FOR NON-SUBMISSION OF DATA
	Waiver of residue data, based on low potential risk of any residues on a treated crop.
Technically not feasible [ ] Scientifically unjustified, Other justification [ ] Limited exposure [x] based on existing data [ ] *(check, as appropriate)*	
Detailed justification:	No residue data need to be submitted because the product will be used: • in retrievably-sized polymeric dispensers used at a rate no more than 375 g ai/ha/yr (150 g ai/acre/yr); • at rate no more than 50 g ai/ha (20 g ai/acre) per application and no potentially adverse effects are observed during the Tier I toxicity testing; • at rates up to 375 g ai/ha/yr and because it is a SCLP.
Undertaking of intended data submission [ ]	

EXAMPLE 5

1	**Data point number**	**IIP 7.13 Environmental fate – Other/Special studies: public literature**
2.	**Reference point (location) in dossier**	PHEROMX, Data point number IIP 7.13
3.	**Author** **Title** **Owner, Date**	Shaver, T.N Environmental fate of (Z)-11-hexadecanal and (Z)-9-tetradecanal, components of a sex pheromone of the taboacco budworm (Lepidotera: Noctuidae). Environmental entomology. 1983; 12: 1802-1804
4.	**Testing Facility**	University of Atlanta, Department of entomology, USA
5.	**Dates of work**	May 15, 1981 to August 3, 1981
6.	**Test Substance**	(Z)-11-hexadecanal and (Z)-9-tetradecanal
7	**Test Method**	The test method used is described briefly. Results on the persistence of (Z)-11-hexadecanal and (Z)-9-tetradecanal and their transport from the site of application to another site or medium are descibed. These data indicate that no significant persistence and transport of these agents in any part of the environment occurs.
8.	**GLP**	No

Appendix 4	Format for Compilation of *Tier I* Quality Checks	Part 1	Summary Report - appropriate for studies conducted in accordance with the test guidelines currently specified

EXAMPLE 6

Data Point Number **IIP 8.2.1**	**Acute toxicity of the active substance to fish**
	JUSTIFICATION FOR NON-SUBMISSION OF DATA
	Waiver of data on toxicity to fish, based on low potential risk.
Technically not feasible [ ] Limited exposure [x]	Scientifically unjustified, Other justification [ ] based on existing data [ ] *(check, as appropriate)*
Detailed justification:	The request for waiver of non-target data (fish) is based upon the following rationale. • Application rates of up to 375 g SCLP/ha/yr are generally understood to result in exposure levels which are comparable to natural emissions and safe for nontarget species. • A worst-case scenario exposure of aquatic animals to the technical active ingredient estimates if all of the active ingredient were released at one time from microcapsules, the resultant total concentration would be 10,000 times less than the published LC50 for Bluegill Sunfish. • An overspray onto water of 50 g ai/ha would result in only 0.044 in^2 of water surface being covered. • The microcapsules exhibit poor film formation properties, thus an overspray onto water surfaces is be expected to significantly reduce the transmission of oxygen. • A literature search yielded no information that microcapsules of the size intended for use with this product would interfere with fish respiration.
Undertaking of intended data submission [ ]	

EXAMPLE 7

1	**Data point (s)**	**IIIP 7.1.4 Skin irritation**
2.	**Reference point (location) in dossier**	OEC_PHE_EX, Data point number IIIP 7.1.4
3.	**Author** **Title** **Owner, Date**	U.N. Known Primary dermal irritation test of OEC_PHE_EX in rabbits. Owner, unpublished report No.xxx-000, May 1, 1998
4.	**Testing Facility**	N.N. Laboratories, River road, London
5.	**Dates of work**	January 30, 1998 to February 3, 1998
6.	**Test Substance**	OEC_PHE_EX
7.	**Test Method**	according OECD 403: No Deviations form the protocol with respect to…
		• number of tested animals (6 rabbits)
		• minimal edema in 1 rabbit with abraded skin
		• scores of edema and erythema at 1, 24, 48 and 72 hours
8.	**GLP**	No