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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Second meeting
Geneva, 13–17 February 2006
Item 5 (b) of the provisional agenda*

Listing of chemicals in Annex III of the Rotterdam Convention: Review of notifications of final regulatory action to ban or severely restricted a chemical: Cyhexatin

Cyhexatin

Note by the Secretariat

1. Under article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, when the Secretariat has received at least one notification from each of two prior informed consent (PIC) regions that contain the information required in Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the documentation provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III and a decision guidance document drafted.

2. The Secretariat has received two notifications from two PIC regions relating to Cyhexatin which meet the information requirements of Annex I (North America– Canada and Asia – Japan). Summaries of those notifications were included in PIC Circular XX of December 2004 and PIC Circular XXII of December 2005. The notifications as they were received from the notifying countries are annexed to the present note.

3. The supporting documentation provided by Canada and Japan, where available, may be found in documents UNEP/FAO/RC/CRC.2/12/Add.1 and Add.2.

4. Cyhexatin was subject to the voluntary PIC procedure but was removed from that procedure in 1996. A fact sheet which explains the process followed and the revised decision guidance document which was issued in support that action may be found in document UNEP/FAO/RC/CRC.2/12/Add.3.

* UNEP/FAO/RC/CRC.2/1

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Annex

Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: CANADA

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	cyhexatin
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: tricyclohexyltin hydroxide CAS: tricyclohexylhydroxystannane
1.3	**Trade names and names of preparations**	Plictran 50W Miticide
1.4	**Code numbers**	
1.4.1	**CAS number**	13121-70-5
1.4.2	**Harmonized System customs code**	Not Applicable/Available
1.4.3	**Other numbers (specify the numbering system)**	RTECS #: WH8750000 EINECS/ELINCS #: 236-049-1
1.5	**Indication regarding previous notification on this chemical, if any**	
1.5.1	☒ This is a first time notification of final regulatory action on this chemical.	
1.5.2	❑ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ❑ This notification replaces all previously submitted notifications on this chemical.	
	Date of issue of the previous notification: _____	

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.6	Information on hazard classification where the chemical is subject to classification requirements	
International classification systems		**Hazard class**
WHO		III-229 - slightly hazardous
Other classification systems		**Hazard class**
EU		Xn;N - Harmful; Dangerous for the environment.

1.7	Use or uses of the chemical
1.7.1	☒ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Used in orchards and greenhouses to control mites on apples, pears, peaches, nectarines, strawberries, hops, non-bearing raspberries, and ornamentals
1.7.2	❑ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8	Properties	
1.8.1	**Description of physico-chemical properties of the chemical**	
	Appearance and Odour:	colourless to white crystalline powder; nearly odourless
	Molecular Weight:	385.02
	Melting Point:	195-198 deg C (383-388 deg F)
	Boiling Point:	228 deg C (442 deg F) (decomposes)
	Solubility:	Insoluble in water; soluble in acetone, chloroform, methanol
	Vapour Pressure:	Approximately zero
	REF: CHEMINFO, Canadian Centre for Occupational Health and Safety. 2000. CD library.	

1.8.2	**Description of toxicological properties of the chemical**	
	acceptable daily intake - 0.001 mg/kg FAO/WHO	
	Acute Toxicity	
	LD_{50} rat oral	85 to 820 mg/kg bw
	mouse, rabbit, guinea pig and chicken	500-1150\mg/kg bw
	LD50 Rat intraperitoneal	13 mg/kg
	LD50 Rabbit percutaneous	>2000 mg/kg
	Short Term	
	90-day dietary Wistar rat	NOAEL 25 ppm (~ 1.5 mg/kg bw)
	90-day dietary mouse	NOAEL 25 ppm (~ 3.75 mg/kg bw)
	90 day dietary dog.	NOEL 3 mg/kg bw (copper levels)
	Long Term	
	2-year dietary rat	NOAEL 6 mg/kg bw
	2-year dietary rat	NOEL for in-life parameters <1 mg/kg bw
	2-year dietary mouse	NOEL 3 mg/kg bw no evidence of an oncogenic effect at levels of up to 6\mg/kg bw
	Two-year dietary dog	failed to indicate a NOEL

	Teratogenicity Rabbit — NOEL 1.0 mg/kg bw; NOEL for embryo/ fetotoxicity 0.5mg/kg bw Rats — NOAEL 1.0\mg/kg bw Reproduction Rats — NOEL of 12.5 ppm (~ 0.75 mg/kg bw) Rabbit — NOAEL ≥3 mg/kg bw REF: Decision Document E89-01, June 1989. Canada. CHEMINFO, Canadian Centre for Occupational Health and Safety. 2000. CD library.
1.8.3	**Description of ecotoxicological properties of the chemical** LC50 Large mouth bass — 2.1 UG/L/96 HR LC50 Scud — 5 UG/L/96 HR LC50 Bluegill sunfish — 6.7 UG/L/96 HR LD50 Bobwhite quail — 520 mg/kg 8 day dietary REF: CHEMINFO, Canadian Centre for Occupational Health and Safety. 2000. CD library.

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**
2.1	**The chemical is:** ☒ **banned** **OR** ☐ **severely restricted**
2.2	**Information specific to the final regulatory action**
2.2.1	**Summary of the final regulatory action** • No pest control uses are allowed • Dow announced voluntary withdrawal of the product from the market, supported by a stock return and refund program coordinated through local dealers. • CAPCO Note in August 1987 cautioned women who are or may be pregnant against working in treated orchards or fields. • Dow took corporate decision to abandon further interest in Plictran and asked for original registration to be cancelled • Agriculture Canada put growers on notice that Health and Welfare Canada has revoked residue tolerances, effective January 29, 1989.
2.2.2	**Reference to the regulatory document** Decision Document E89-01 CAPCO Note C87-11
2.2.3	**Date of entry into force of the final regulatory action** December 31, 1989

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☒ Yes ☐ No
	If yes, give information on such evaluation	
	A review of teratology studies in rats and rabbits indicated chemical to be teratogenic; margins of safety were considered to be low even in cases where a rubber suit and gloves were utilized	
	Reference to the relevant documentation	
	Decision Document E89-01 CAPCO Note C87-11	

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☒ Yes ☐ No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	• teratogenic in rats and rabbits at low doses (see S 1.8.2) • margin of safety low even in cases where a rubber suit and gloves were utilized	
	Reference to the relevant documentation	
	Decision Document E89-01 CAPCO Note C87-11	
	Expected effect of the final regulatory action	
	Removal of risk to orchard/field workers where Piclam was used.	
2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☐ Yes ☒ No
	If yes, give summary of the known hazards and risks to the environment	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.5	**Category or categories where the final regulatory action has been taken**	
2.5.1	**Final regulatory action has been taken for the chemical category**	☐ **Industrial**
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	
2.5.2	**Final regulatory action has been taken for the chemical category**	☒ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All formulations prohibited from import, sale or use.	
	Formulation(s) and use or uses that remain allowed	
	None	

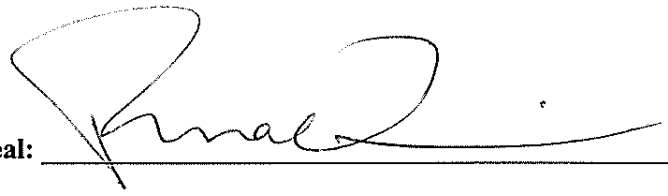
2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	**Year**
Produced		
Imported		
Exported		
Used		

2.6	**Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions**
	Conditions of exposure are may occur in other regions where cyhexatin is used.

2.7	**Other relevant information that may cover:**
2.7.1	**Assessment of socio-economic effects of the final regulatory action** Plictran was an effective miticide which generated high returns to fruit producers. Apple growers could expect $8.50 for every dollar spent on Plictran, while strawberry and hops growers in British Columbia could expect anywhere from $17 to $74. "It is difficult to anticipate the long-term consequences of removing Plictran from the market. In the short term, it is evident that the use of other chemicals such as Apollo, Omite, Dicofol and Superior Oil will increase. However, in the long run, alternating these chemicals might not be sufficient to prevent pest resistance. In this case, unless other pesticides are introduced onto the market, some industries like raspberry, strawberry and hop production would likely become too vulnerable to mite damage to remain viable." REF: Decision Document E89-01, June 1989. Canada.
2.7.2	**Information on alternatives and their relative risks** - dicofol - mite resistance - omite (propargite) - less effective, some resistance, some phytotoxicity - carzol (formetanate hydrochloride) - mite resistance - ethion - high toxicity - dienochlor - fenbutatin oxide - clofentezine -chinomethionat - dormant oils
2.7.3	**Relevant additional information**

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Telephone	+1 613-736-3660
Telefax	+1 613-736-3659
E-mail address	Trish_MacQuarrie@hc-sc.gc.ca
Designated National Authority	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Name of person in charge	Trish MacQuarrie
Position of person in charge	Director, Alternative Strategies and Regulatory Affairs Division
Telephone	+1 613-736-3660
Telefax	+1 613-736-3659
E-mail address	Trish_MacQuarrie@hc-sc.gc.ca

Date, signature of DNA and official seal: 

Interim Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

UNEP

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: JAPAN

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	IDENTITY OF CHEMICAL	
1.1	**Common name**	Cyhexatin
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Tricyclohexyltin hydroxide
1.3	**Trade names and names of preparations**	Plictran, Acarstin, Mitacid, Pennstyl
1.4	**Code numbers**	
1.4.1	**CAS number**	13121-70-5
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	RTECS：WH8750000

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	☑ This is a first time notification of final regulatory action on this chemical.
1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☐ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
The WTO Recommended Classification of Pesticides by Hazard	III
Other classification systems	**Hazard class**

1.7	Use or uses of the chemical
1.7.1	☑ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Agricultural insecticides until 1987.
1.7.2	☐ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8	**Properties**
1.8.1	**Description of physico-chemical properties of the chemical**

description of the form :
Molecular formula：C18H34OSN
Molecular weight：385.16
melting point：195～198℃

References
"Saishin nouyaku data book", 1989 (Pesticide data book revised edition, Soft Science, Tokyo, 1989)

solubility in water：trouble solubility
organic solvents ： non-solubility

CAS Number : 013121-70-5
Chem Name : TRICYCLOHEXYLHYDROXYSTANNANE
Mol Formula: C18H34OSn
Mol Weight : 385.16
Melting Pt : 196 deg C
Boiling Pt :
Water Solubility:
  Value : 0.00824 mg/L
  Temp : 25 deg C
  Type : EST
  Ref : MEYLAN,WM ET AL. (1996)
Log P (octanol-water):
  Value : 6.63
  Type : EST
  Ref : MEYLAN,WM & HOWARD,PH (1995)
Vapor Pressure:
  Value : 8.64E-009 mm Hg
  Temp : 25 deg C
  Type : EST
  Ref : NEELY,WB & BLAU,GE (1985)
Henry's Law Constant:
  Value : 0.000418 atm-m3/mole
  Temp : 25 deg C
  Type : EST
  Ref : MEYLAN,WM & HOWARD,PH (1991)
Atmospheric OH Rate Constant:
  Value : 1.09E-010 cm3/molecule-sec
  Temp : 25 deg C
  Type : EST
  Ref : MEYLAN,WM & HOWARD,PH (1993)

Source; Syracuse Research Corporation (SRC)
http://esc.syrres.com/interkow/webprop.exe?CAS=13121-70-5&submit=Submit+CAS

1.8.2	**Description of toxicological properties of the chemical**

Acute toxicity

The LD_{50} of micronized cyhexatin (purity, 96%) in Sprague-Dawley CD rats treated by gavage was 265 mg/kg bw (95% confidence interval, 124-569) in females and 501 (192-1307) mg/kg bw in males (Denton, 1993a). Higher LD_{50}s were found for technical-grade cyhexatin, i.e. 654 (446-1454) mg/kg bw in females and 627 (478-1120) mg/kg bw in males (Denton, 1993b).

The LD_{50}s in CD(SD)BR rats after gavage of technical-grade and micronized cyhexatin (purity, 95-96%) from another source were 274 (189-397) mg/kg bw for technical-grade and 411 (293-577) mg/kg bw for micronized cyhexatin in females and 425 (260-693) mg/kg bw for technical-grade and 407 mg/kg bw (confidence interval not calculable) for micronized cyhexatin in males (Longobardi, 1994a,b).

References :

IPCS INCHEM JMPR-Monographs & Evaluations
http://www.inchem.org/documents/jmpr/jmpmono/v94pr06.htm

1.8.3	**Description of ecotoxicological properties of the chemical**

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**			
2.1	**The chemical is:**	☑ **banned**	**OR**	☐ **severely restricted**
2.2	**Information specific to the final regulatory action**			
2.2.1	**Summary of the final regulatory action**			

Ban on sale and use of agricultural chemicals.

2.2.2	**Reference to the regulatory document**

Agricultural Chemicals Regulation Law and Ministerial ordinance of Ministry of Agriculture, Forestry and Fisheries, Ministerial Order of March 5, 2003.

2.2.3	**Date of entry into force of the final regulatory action**

Ministerial ordinance of Ministry of Agriculture, Forestry and Fisheries: March 10, 2003.

2.3	Was the final regulatory action based on a risk or hazard evaluation?	☑ Yes ☐ No
	If yes, give information on such evaluation	
	As part of an Environmental Protection Agency (EPA) "Data Call-In" requirement on cyhexatin in the United States, "Manufacture" undertook teratology studies in rats and rabbits. These new oral teratology studies indicated that cyhexatin was teratogenic. http://www.hc-sc.gc.ca/pmra-arla/english/pdf/rdd/rdd_e8901-e.pdf	
	Reference to the relevant documentation	
	Decision Document E89-01: Agriculture Canada, Food Production and Inspection Branch, Plant Industry Directorate Bulletin concerning tolerance for pesticide residue of Ministry of Health, Labour and Welfare: June 6, 1994.	

2.4	Reasons for the final regulatory action	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☑Yes ☐ No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	
	It is based on the result that existing toxic data were evaluated synthetically.	
	Reference to the relevant documentation	
	Internal documents at the time of the examination.	
	Expected effect of the final regulatory action	
	Should result in reduced human exposure to this substance as its use is phased out.	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☐Yes ☑ No
	If yes, give summary of the known hazards and risks to the environment	
	Reference to the relevant documentation	
	Expected effect of the final regulatory action	

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	☐ Industrial
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	

2.5.2	Final regulatory action has been taken for the chemical category	☑ Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Uses for agricultural chemicals.	
	Formulation(s) and use or uses that remain allowed	
	n/a	

2.5.3	Estimated quantity of the chemical produced, imported, exported and used, where available.	
	Quantity per year (MT)	Year
Produced	1,966 t (Total)	1984-1987 As agricultural Chemicals (Wettable Powder: a.i.50%)
Imported	n/a	
Exported	n/a	
Used	n/a	

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action

2.7.2	**Information on alternatives and their relative risks**	
2.7.3	**Relevant additional information**	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Ministry of Agriculture , Forestry and Fisheries (MAFF)
Address	MAFF : 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8950, JAPAN
Telephone	MAFF :+81-3-3501-3965
Telefax	MAFF :+81-3-3501-3774
E-mail address	
Designated National Authority	
Institution	Global Environment Division Ministry of Foreign Affairs
Address	2-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8919, Japan
Name of person in charge	Mr. Koichi Ito
Position of person in charge	Director
Telephone	+81-3-5501-8245
Telefax	+81-3-5501-8244
E-mail address	koichi.ito@mofa.go.jp

Date, signature of DNA and official seal: 01.09.2004. 伊藤康