ROTTERDAM CONVENTION

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

Country: CANADA

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Mirex
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Dodecachloropentacyclo [5.3.0.$0^{2,6}$.$0^{3,9}$.$0^{4,8}$] decane
1.3	**Trade names and names of preparations**	GC-1283; ENT 25719; Dechlorane; Dechlorane 4070; Dechlorane Plus; $C_{10}Cl_{12}$; Ferriamicide; HRS 1276; Bichlorendo

1.4	**Code numbers**	
1.4.1	CAS number	2385-85-5
1.4.2	Harmonized System customs code	Not Available
1.4.3	Other numbers (specify the numbering system)	RTECS PC8225000

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 notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: 2000/05/17

SECTION 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

The *Prohibition of Certain Toxic Substances Regulations, 2005* prohibit the manufacture, use, sale, offer for sale and import of toxic substances listed in Schedules 1 and 2 to the Regulations. Mirex is found in Schedule 1, which lists prohibited toxic substances subject to total prohibition, with the exception of incidental presence.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Prohibition of Certain Toxic Substances Regulations, 2005 (SOR/2005-41) under the *Canadian Environmental Protection Act, 1999*.

2.2.3 Date of entry into force of the final regulatory action

May 15, 2005

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Technical mirex contains approximately 95% mirex and 2.5% chlordecone. It has been used worldwide against fire ants, termites and other insect pests. However, mirex was never registered for use as an agricultural pesticide in Canada. It has mainly been used as a fire retardant agent in plastics, rubber, paint paper and electrical goods. It has also been used as a pyrotechnic for generating white smoke.

2.3.2 Final regulatory action has been taken for the category ☒ Industrial

Use or uses prohibited by the final regulatory action

The Regulations prohibit the manufacture, use, sale, offer for sale or import of mirex, with the exceptions listed below.

Use or uses that remain allowed (only in case of a severe restriction)

The Regulations do not apply to the incidental presence of mirex, or for use in a laboratory for scientific research purposes or as a laboratory analytical standard.

2.3.3 Final regulatory action has been taken for the category ☐ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

Formulation(s) and use or uses that remain allowed (only in case of a severe restriction)

2.4 Was the final regulatory action based on a risk or hazard evaluation? ☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Mirex, Environmental Health Criteria Document, Health and Welfare Canada, Health Protection Branch, 77-EHD-12, September 1977, 168 p.

Mirex in Canada, A report of the task force on mirex, April 1 1977 to the Environmental Contaminants Committee of Fisheries & Environment Canada and Health & Welfare Canada, Technical Report 77-1, 153 p.

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human ☒ Yes

health?

☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

Note: Mirex was assessed under the original *Canadian Environmental Protection Act* (CEPA). While the Act was updated in 1999, the conclusions of the assessment remain the same. This notification is based on the assessment and therefore references the original Act. Information provided here was current at the time of the original notification.

Mirex is specified on the List of Toxic Substances in Schedule I to the *Canadian Environmental Protection Act* (CEPA). The assessment of substances to determine if they are "toxic" under the CEPA is a shared responsibility of Environment Canada and Health Canada. Environment Canada assesses the environmental risks, and Health Canada assesses the human health risks. An assessment was conducted to determine if a substance is likely to harm the environment or the health of humans, taking into account the likelihood and magnitude of releases at levels occurring in the Canadian environment. Thus "toxic" in the context of CEPA is a function of both the inherent properties of a substance and the amounts, concentrations, or nature of entry of the substance in the Canadian environment.

The assessment process thus provides a framework for making science-based decisions on the effective management of toxic substances that are of concern. The determination of whether or not a substance is "toxic" must be based on sound, scientifically reliable data. Under CEPA, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(b) constitute or may constitute a danger to the environment on which life depends; or

(c) constitute or may constitute a danger in Canada to human life or health.

The main sources of mirex in Canada were located in New York State (U.S.) in the Niagara River and the Oswego River where chemical manufacturing and fire retardant production plants were located.

Canadian human exposure to mirex was generally minimal except in the group partially or wholly dependent on a diet of fish or fish-eating birds from Lake

Ontario and the St. Lawrence River. A second, very small, group at risk were those hunters that occasionally ate meals of game birds.

In humans, mirex is stored mainly in fat tissue, where it is not broken down. Mirex has been demonstrated to cause cancer in experimental animals and possibly carcinogenic to humans.

International

In response to the increasing international awareness concerning the environmental and human health risks associated with certain persistent organic pollutants (POPs) mirex was identified as one of the priority substances for consideration in the negotiation of a Protocol for POPs under the United Nations Economic Commission for Europe Convention on Long-range Transboundary Air Pollution.

Due to increasing concern about the risks to human health and the environment posed by persistent organic pollutants, the United Nation Environment Program (UNEP) has initiated a process to evaluate the need to develop a global legally-binding instrument for managing these substances. At the invitation of the UNEP Governing Council the Intergovernmental Forum for Chemical Safety (IFCS) submitted a report to the Governing Council for consideration in 1997. The report concluded that there was sufficient scientific knowledge to warrant immediate international action to protect human health and the environment and to develop a global legally binding instrument to that effect. Mirex was one of the initial 12 substances to be considered under this initiative.

Expected effect of the final regulatory action

Mirex was found to meet the criteria for Track 1 substance under Canada's Toxic Substance Management Policy and as such is to be virtually eliminated from the environment. The prohibition on manufacture, use, sale, offer for, sale, or import of mirex, will work towards the objective of virtual elimination.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

Note: Mirex was assessed under the original *Canadian Environmental Protection Act* (CEPA). While the Act was updated in 1999, the conclusions of the assessment remain the same. This notification is based on the assessment and therefore references the original Act. Information provided here was current at the time of the original notification.

Mirex is specified on the List of Toxic Substances in Schedule I to the *Canadian Environmental Protection Act* (CEPA). The assessment of substances to determine if they are "toxic" under the CEPA is a shared responsibility of Environment Canada and Health Canada. Environment Canada assesses the environmental risks, and Health Canada assesses the human health risks. An assessment was conducted to determine if a substance is likely to harm the environment or the health of humans, taking into account the likelihood and magnitude of releases at levels occurring in the Canadian environment. Thus "toxic" in the context of CEPA is a function of both the inherent properties of a substance and the amounts, concentrations, or nature of entry of the substance in the Canadian environment.

The assessment process thus provides a framework for making science-based decisions on the effective management of toxic substances that are of concern. The determination of whether or not a substance is "toxic" must be based on sound, scientifically reliable data. Under CEPA, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

(d) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(e) constitute or may constitute a danger to the environment on which life depends; or

(f) constitute or may constitute a danger in Canada to human life or health.

The main sources of mirex in Canada were located in New York State (U.S.) in the Niagara River and the Oswego River where chemical manufacturing and fire retardant production plants were located. This transboundary movement of mirex into Canadian waters resulted in contamination of fish and fish-feeding birds with the results that mirex contaminated several ecosystems in Canada. Mirex is biologically active, accumulates in food chains, is extremely persistent and is dispersed in the environment.

Sufficient data were not available to enable a meaningful calculation of either an acceptable or tolerable level of mirex in the Canadian environment with respect to wildlife and aquatic life. It should be noted that the U.S. EPA set the maximum concentration of mirex permissible in water for fresh water and marine aquatic life at 0.001 µg/L. This value was obtained through the use of an application factor of 0.01 times the lowest concentration at which effects have been noted in crayfish, the most sensitive species tested.

Quantitative information describing the persistence of mirex was limited. However, the available information consistently indicated that the substance is persistent in the environment. For example, 12 years after its application to clay soil, 50% of the mirex originally applied was recovered as mirex and mirex-related compounds with mirex representing between 65-70% of the total residues. Mirex decomposition in the environment takes place chiefly by photolysis. Anaerobic decomposition by microorganisms can occur, but it is not extensive. Mirex is also recognized to be subject to long-range transport and has been demonstrated to persist in sediment.

On the basis of the available information, it was concluded that mirex is persistent in the environment. Mirex can accumulate in living tissues. In experimental work with aquatic organisms, all species at all trophic levels have been found to accumulate this substance. Bioaccumulation factors of 15,000 and 51,000 have been observed in lake trout captured in Lake Ontario and fathead minnows.

A comparison of concentrations of mirex in lake trout, a predator species, with those in smelt, a prey species, gives a ratio of 1.26, indicating that biomagnification is occurring. A biomagnification factor of 10^6 for mirex between its concentration in water of Lake Ontario and the St. Lawrence River and in beluga whale oil has been reported.

In experimental studies with birds, mirex has been shown to accumulate, particularly in fatty tissues. A study showed that mirex fed to roosters accumulated to about 100 times the concentration in the feed in thirty-two weeks. When the roosters were given clean food the mirex residues slowly decreased. Similar studies were conducted on mammals with similar findings. On the basis of the available information, it was concluded that mirex is a bioaccumulative substance.

Expected effect of the final regulatory action

Mirex was found to meet the criteria for Track 1 substance under Canada's Toxic Substance Management Policy and as such is to be virtually eliminated from the environment. The prohibition on manufacture, use, sale, offer for, sale, or import of mirex, will work towards the objective of virtual elimination.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	Never manufactured in Canada	Not

		Applicable
imported	146	1963-1976
exported	Not Available	Not Available
used	Not Available	Not Available

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

Any state and region in a similar situation may find these Regulations relevant.

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

For the original prohibition, the Task Force on mirex recommended formal control for the importation and use of mirex. The Task Force considered there were no uses for which mirex was indispensable in Canada. There were substitute materials for the main uses of mirex. In fact, at the time of the investigation, mirex was probably no longer marketed in Canada nor stockpiled. Therefore its use could be prohibited, as a preventative measure, without major economic or social disruption and without increasing the risk of fire hazard to the public from products that require fire retardant additives.

The amended Regulations continue previous prohibitions and therefore represent no change in Canadian activities related to this substance.

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

Fire retardancy in compositions formerly including mirex has been achieved through the use of substitutes or through the use of alternative plastics technology. The Task Force on mirex recognized however that there was a need to assess the hazard of substitute materials particularly the other organochlorine Dechloranes and their transformation products. No information on such assessment was found since the publication of the Task Force's report (April 1977).

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

Not applicable.

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

Not available.

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems e.g. WHO, IARC, etc.	**Hazard class**
IARC	Group 2B: possible human carcinogen

Other classification systems e.g. EU, USEPA	**Hazard class**
Not Available	Not Available
Not Available	Not Available

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Mirex occurs as white, odorless crystals with the flowing properties: Melting point: 485 °C Vapour pressure: $3x10^{-7}$ mm Hg at 25 °C Practically insoluble in water. Soluble in dioxane, xylene, benzene, carbon tetrachloride, and methyl ethyl ketone.

Reference

Contaminant Profiles, Mirex, Health Canada (http://www.hc-sc.gc.ca/ehp/ehd/catalogue/bch_pubs/98ehd211/con_profiles.pdf)

3.2.2 Description of toxicological properties of the chemical

Data on the human health effects are not available. The primary organs affected by mirex in experimental animals are the liver, kidney, eyes, and thyroid.

Acute Effects

- Diarrhea due to hemorrhagic intestines.
- Increase in hematocrit.
- Hepatic effects (adaptive and toxic effects).
- Dermal/ocular effects (hair loss, production of cataracts in very young, mild epidermal proliferation; in mice).
- Toxic effects to the thyroid.
- Adrenal gland hypertrophies and releases increased levels of corticosterone.
- Decreases in serum glucose levels.
- Decreases in body weight or body weight gain greater than 10 percent.
- Abnormal behaviour (lethargy, weakness, hyper-excitability, tremors, convulsions).

Chronic Effects (Noncancer)

- Renal effects.
- Decreases in body weight or body weight gain greater than 10 percent.
- Non-precancerous lesions of the liver

Reproductive/Developmental Effects

- Reproductive and developmental effects in female and male rats.

Genotoxicity

- No information available.

Carcinogenicity

- An increased incidence of hepatocellular adenomas have been noted, but only in animals having hepatotoxicity.
- IARC has classified mirex as possibly carcinogenic to humans, based on sufficient evidence in animals, but inadequate evidence of carcinogenicity in humans.

Data

LD_{50} (rabbit, dermal): 800 mg/kg

LD_{50} (male & female rat, dermal): > 2,000 mg/kg

LD_{50} (rat, intraperitoneal): 365 mg/kg

LD_{50} (rat, intraperitoneal (corn oil)): 700 ppm

LD_{50} (mouse, intraperitoneal (corn oil)): 330 ppm

LD_{50} (female rat, oral): 365 mg/kg to 600 ± 102 mg/kg

LD_{50} (female rat, oral (corn oil)): 600 mg/kg

LD_{50} (male rat, oral (corn oil)): 740 mg/kg

LD_{50} (male rat, oral): 306 ± 71 mg/kg

LD_{50} (male & female rat, oral (peanut oil)): > 3,000 mg/kg

LD_{50} (mouse, oral): 15 - 30 ppm (90 days)

LD_{50} (female rat, oral): 6 mg/kg (90 days)

LD_{50} (rat, oral): 100 ppm

LC_{50} (female rat, oral): 275 ppm (30 days)

LC_{50} (male rat, oral): 607 ppm (30 days)

Reference

Contaminant Profiles, Mirex, Health Canada
(http://www.hc-sc.gc.ca/ehp/ehd/catalogue/bch_pubs/98ehd211/con_profiles.pdf)
Mirex, Environmental Health Criteria Document, Health and Welfare Canada, Health Protection Branch, 77-EHD-12, September 1977, 168 p.

3.2.3 Description of ecotoxicological properties of the chemical

Acute Effects

- Data available suggest that mirex can be toxic to plants and unicellular organisms but probably at relatively high concentrations.
- Avian species as a group appear to be relatively insensitive to the toxic effects of mirex.
- Several marine species are extremely sensitive to mirex, particularly crayfish, crabs and shrimps. At concentrations of mirex as low as 0.1 µg/L toxic effects were noted in crayfish, shrimp and crab juveniles exposed for 3 weeks experimentally.

Data

LD_{50} (mallard duck, oral): 2,400 mg/kg

LD_{50} (coturnix quail, oral): 10,000 ppm

LD_{50} (pheasant, oral): 1,400 - 1,600 ppm

LD_{50} (young male grackle, oral): 750 ppm (12 days)

LD_{50} (adult male cowbird, oral): 750 ppm (12 days)

LD_{50} (adult female red-winged blackbird, oral): 750 ppm (11 days)

LD_{50} (young female starling, oral): 750 ppm (9 days)

LD_{50} (quail, intraperitoneal): 300 mg/kg

Reference
Mirex, Environmental Health Criteria Document, Health and Welfare Canada, Health Protection Branch, 77-EHD-12, September 1977, 168 p.

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Environment Canada Environmental Stewardship Branch Chemical Sectors Directorate Chemical Management Division
Address	Place Vincent Massey 351 St. Joseph Blvd., 17th Floor Gatineau, Quebec, K1A 0H3 CANADA
Name of person in charge	France Jacovella
Position of person in charge	Executive Director, Chemical Management Division
Telephone	(819) 956-5263
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Date, signature of DNA and official seal: France Jacovella

PLEASE RETURN THE COMPLETED FORM TO:

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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.