

**Rotterdam Convention on the Prior
Informed Consent Procedure for
Certain Hazardous Chemicals and
Pesticides in International Trade**Distr.: General
28 June 2022

English only

Chemical Review Committee**Eighteenth meeting**

Rome, 19–23 September 2022

Item 5 (c) (viii) of the provisional agenda*

**Technical work: review of notifications of
final regulatory action: mirex****Mirex: notifications of final regulatory action****Note by the Secretariat****I. Introduction**

1. In accordance with paragraph 5 of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Secretariat had previously received notifications of final regulatory action for mirex that meet the requirements of Annex I to the Convention from Parties from at least two prior informed consent regions.¹
2. At its thirteenth meeting, the Chemical Review Committee reviewed the notifications and concluded that a notification from Canada in the industrial category² met the criteria set out in Annex II to the Convention. The notification from Canada and the rationale for the conclusion by the Committee are set out in document UNEP/FAO/RC/CRC.18/INF/27.
3. An additional notification for mirex that meets the requirements of Annex I was received from Ecuador in the pesticide category³ prior to the seventeenth meeting of the Committee. An intersessional task group was set up and undertook an initial assessment of whether the notification met the criteria set out in Annex II to the Convention, with a view to its full review during the seventeenth meeting of the Committee. However, taking into account the coronavirus disease (COVID-19) pandemic and the fact that the Committee could not meet in a face-to-face setting for its seventeenth meeting, as well as the challenges linked to online meetings, the Bureau agreed to prioritize certain items on the agenda of its seventeenth meeting. Consideration of the notification for mirex was thus deferred to a future meeting of the Committee.
4. The Secretariat has since received an additional notification of final regulatory action for mirex that meets the requirements of Annex I, from the following Party in the Asia prior informed consent region: Indonesia (industrial/pesticide).⁴

* UNEP/FAO/RC/CRC.18/1.

¹ See UNEP/FAO/RC/CRC.17/INF/6.

² See PIC Circular XII, Dec. 2000, and PIC Circular XXXVIII, Dec. 2013.

³ See PIC Circular LII, Dec. 2020.

⁴ See PIC Circular LIII, June 2021.

5. The notifications from Ecuador and Indonesia are set out in the annex to the present note. The supporting documentation provided by Ecuador and Indonesia is set out in document UNEP/FAO/RC/CRC.18/INF/25 and UNEP/FAO/RC/CRC.18/INF/26 respectively.

II. Proposed action

6. The Committee may wish:

(a) To review the information provided in the notifications and the supporting documentation from Indonesia and Ecuador related to mirex, in accordance with the criteria set out in Annex II to the Convention;

(b) If it concludes that at least one of the notifications mentioned in subparagraph (a) above meets the criteria set out in Annex II to the Convention, to recommend to the Conference of the Parties that the chemical in question be made subject to the prior informed consent procedure and, accordingly, be listed in Annex III to the Convention, and to agree on a workplan for the preparation of a draft decision guidance document on mirex.

Annex

Notifications of final regulatory action for mirex

- A. Notification of final regulatory action for mirex in the pesticide category submitted by Ecuador (in Spanish and English)**
- B. Notification of final regulatory action for mirex in the industrial/pesticide categories submitted by Indonesia**



CONVENIO DE ROTTERDAM

SECRETARÍA PARA EL CONVENIO DE ROTTERDAM SOBRE
EL PROCEDIMIENTO DE CONSENTIMIENTO FUNDAMENTADO
PREVIO APLICABLE A CIERTOS PLAGUICIDAS Y PRODUCTOS
QUÍMICOS PELIGROSOS OBJETO DE COMERCIO INTERNACIONAL



FORMULARIO DE NOTIFICACIÓN DE LA MEDIDA REGLAMENTARIA FIRME PARA PROHIBIR O RESTRINGIR RIGUROSAZMENTE UN PRODUCTO QUÍMICO

País:

ECUADOR

SECCIÓN 1 IDENTIDAD DEL PRODUCTO QUÍMICO SUJETO A LA MEDIDA REGLAMENTARIA FIRME

1.1	Nombre	MIREX
1.2	Nombre del producto químico en una nomenclatura internacionalmente reconocida (por ejemplo, la de UIQPA), si existe tal nomenclatura	dodecachloropentacyclodecane
1.3	Nombres comerciales y nombres de las preparaciones	No se dispone debido a que esta molécula se encuentra prohibida desde el año de 1992
1.4	Números de código	
1.4.1	Número de CAS	2385-85-5
1.4.2	Código aduanero del sistema armonizado	No se dispone
1.4.3	Otra nomenclatura (especificar el sistema de numeración)	219-196-6 (EC number) 375 (CIPAC number)

1.5 Indicación, si la hubiere, relativa a una notificación anterior sobre este producto químico

- 1.5.1 La presente es la primera notificación de una medida reglamentaria firme relativa a este producto químico.
- 1.5.2 Esta notificación sustituye todas las notificaciones presentadas con anterioridad relativas a este producto químico.

Fecha de emisión de la notificación anterior: _____

SECCIÓN 2

MEDIDA REGLAMENTARIA FIRME

2.1 El producto químico está:

prohibido O rigurosamente restringido

2.2 Información específica sobre la medida reglamentaria firme

2.2.1 Resumen de la medida reglamentaria firme

EL MINISTERIO DE AGRICULTURA

Acuerda:

Art. 1 - Prohíbese el registro, por parte del Programa Nacional de Sanidad Vegetal, por ser nocivos para la salud y haber sido prohibida su fabricación, comercialización o uso en varios países de los siguientes pesticidas: Aldrin, Dieldrin, Endrin, BHC, Campheclor (Toxafeno), Clordimeform (Galecron y Fundal), Chlordano, DDT, DBCP, Lindano, EDB, 2,4,5 T, Amitrole, Compuestos Mercuriales y de Plomo, Tetracloruro de Carbono, Leptophos, Heptachloro, Chlorobenzilato.

Art. 2 – Igualmente se prohíbe el registro en razón de producir contaminación ambiental, efectos tóxicos; y, por haberse cancelado el mismo en varios países, de los siguientes productos: Methyl, Diethyl y Ethyl Parathion, Mirex y Dinoseb.

2.2.2 Referencia al documento reglamentario, p.e., dónde está registrada o publicada la decisión

Acuerdo Ministerial No 0112.- publicado en el Registro Oficial No. 64 con fecha 12 de noviembre de 1992. Art. 2

2.2.3 Fecha de la entrada en vigor de la medida reglamentaria firme

12 de noviembre de 1992

2.3 Categoría o categorías respecto a las cuales se ha adoptado la medida reglamentaria firme

2.3.1 Uso o usos del producto químico en su país antes de adoptar la medida reglamentaria firme

Insecticida

2.3.2 La medida reglamentaria firme se ha adoptado para la categoría del producto químico

Industrial

Uso o usos prohibidos por la medida reglamentaria firme

No aplica

Uso o usos que se siguen autorizando (sólo en caso de rigurosamente restringido)

No aplica

2.3.3 La medida reglamentaria firme se ha adoptado para la categoría del producto químico

Plaguicida

Formulación(es) y uso o usos prohibidos por la medida reglamentaria firme

Se prohíbe totalmente el uso de Mirex

Formulación(es) y uso o usos que se siguen autorizando (sólo en caso de rigurosamente restringido)

No aplica

2.4 ¿La medida reglamentaria firme se adoptó sobre la base de una evaluación de los riesgos o peligros?

Sí

No (En caso de respuesta negativa, completar también la sección 2.5.3.3)

2.4.1 En caso afirmativo, proporcione la documentación pertinente, que describe la evaluación de riesgos o peligros

No aplica

2.4.2 Resumen descriptivo de la evaluación de riesgos o peligros sobre los que se ha basado la prohibición o la rigurosa restricción

2.4.2.1 ¿El motivo por el que se adoptó la medida reglamentaria firme guarda relación con la salud humana?

Sí

No

En caso afirmativo, proporcione un resumen de los peligros o riesgos relacionados con la salud humana, incluida la salud de los consumidores y de los trabajadores

Posibles efectos cancerígenos, puede perjudicar a los niños alimentados con leche materna.
Nocivo en contacto con la piel y por ingestión.

Efecto previsto de la medida reglamentaria firme

La Medida Reglamentaria tiene como efecto previsto la eliminación de la exposición a este plaguicida y por consecuencia la disminución de generación de riesgos para la salud

- 2.4.2.2 ¿El motivo por el que se adoptó la medida reglamentaria firme guarda relación con el medio ambiente? Sí No

En caso afirmativo, proporcione un resumen de los peligros y riesgos relacionados con el medio ambiente

Bioacumulable, persistente, contaminante orgánicos persistente (COP).

H400. Muy tóxico para los organismos acuáticos. Acuático agudo (CAt. 1): Peligroso para el medio ambiente acuático.

H410: Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos. Acuático crónico (Cat:1): Peligroso para el medio ambiente acuático.

Efecto previsto de la medida reglamentaria firme

La Medida Reglamentaria tiene como efecto previsto la eliminación de la exposición a este plaguicida y por consecuencia la disminución de generación de riesgos para el ambiente.

2.5 Otra información pertinente relativa a la medida reglamentaria firme

- 2.5.1 Cantidad estimada del producto químico producido, importado, exportado y utilizado

	Cantidad por año (toneladas)	Año
Producida	No aplica	No aplica
Importada	No aplica	No aplica
Exportada	No aplica	No aplica
Utilizada	No aplica	No aplica

- 2.5.2 Indicar, en la medida de lo posible, la probabilidad de que la medida reglamentaria firme afecte a otros estados o regiones

Ecuador no exporta esta sustancia, por ende, no existiría afectación a otros países.

- 2.5.3 Información adicional pertinente que pueda incluir:

2.5.3.1 Evaluación de los efectos socioeconómicos de la medida reglamentaria firme

No se han presentado efectos socioeconómicos.

2.5.3.2 Información sobre alternativas y sus riesgos relativos, p.ej., el MIP alternativas químicas y no químicas

La alternativa que se propuso es la aplicación del manejo integrado de plagas, lo que implica el uso de controles preventivos, mecánicos, biológicos y la adopción de un control químico; este último basado en plaguicidas aprobados en el país.

Debido a que la normativa de prohibición de uso de esta molécula data de 1992, no se dispone de información de cuales fueron los usos aprobados, por tanto, no se posee información sobre alternativas químicas.

2.5.3.3 Bases para la medida reglamentaria firme con excepción de la evaluación de riesgos y peligros

Por ser nocivos para la salud, el ambiente y por haberse cancelado en varios países.

2.5.3.4 Información adicional, si la hubiere, relativa al producto químico o a la medida reglamentaria firme

No disponible

SECCIÓN 3

PROPIEDADES

3.1 Información sobre clasificación de peligros si el producto químico está sujeto a requisitos de clasificación

Sistemas de clasificación internacionales
p.e., OMS, CIIC, etc.

Categoría de peligro

OMS	O obsoleto
IARC	Possible cancerígeno 2B

Otros sistemas de clasificación
p.e., UE, USEPA

Categoría de peligro

--	--

--	--

3.2 Ulterior información sobre las propiedades del producto químico

3.2.1 Descripción de las propiedades físico-químicas del producto químico

Punto de fusión: 485 °C

Presión de vapor: less than 1 mg/mL at 75° F (NTP, 1992)

K_{owlogP}: 6,89

Constante de Henry: 1,48 X 10⁻¹Pam³mol⁻¹

Densidad: 18,8

Solubilidad en agua: 0.0001 20°C (mg l⁻¹)

Solubilidad en solventes orgánicos: cloroformo: 17000, xileno: 14300

Referencia

Hertfordshire, U. (2020). mirex. Retrieved 11 February 2020, from
<https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1294.htm>

3.2.2 Descripción de las propiedades toxicológicas del producto químico

Toxicidad aguda. DL50/CL50 oral (ratas): 306 mg/kg; inhalación (ratas): nd; dérmico (ratas): >2000 mg/kg; dérmico (conejos): 800 mg/kg. Clasificación: nd (OMS); nd (EPA). Acción tóxica y síntomas: síndrome tóxico por organoclorados. Toxicidad tópica: capacidad irritativa: ocular nd; dérmica positiva; capacidad alergénica: nd.

Toxicidad crónica y a largo plazo: neurotoxicidad: nd; teratogenicidad: positiva; mutagenicidad: nd; carcinogenicidad: 2B. Posible carcinógeno en humanos (IARC); nd (EPA); disrupción endocrina: categoría 1; otros efectos reproductivos: nd; genotoxicidad: nd; Parkinson: nd; otros efectos crónicos: hepatotóxico. Frases de riesgo UE: R22: Nocivo por ingestión. R40: Posibles efectos carcinogénicos. R62: Posible riesgo de perjudicar la fertilidad. R63: Posible riesgo durante el embarazo de efectos adversos para el feto. R64: Puede perjudicar a los niños alimentados con leche materna.

Referencia

declarano. (2020). Retrieved 11 February 2020, from
<http://www.plaguicidasdecentroamerica.una.ac.cr/index.php/base-de-datos-menu/170-declarano>

3.2.3 Descripción de las propiedades ecotoxicológicas del producto químico

Toxicidad aguda: peces: ligera, CL50 (96h) trucha arco iris 100 mg/L; crustáceos: extrema a alta, CE50 (48h) dáfnidos 0,1 mg/L, >1 mg/L; anfibios: nd; aves: ligera; insectos (abejas): nd, (quironómidos): nd; lombrices de tierra: nd; algas: alta, CE50 (72h) Chlorella pyrenoidosa 0,1 mg/L; plantas: helecho acuático: nd.

Observaciones: R50: Muy tóxico para organismos acuáticos. R53: Puede causar efectos adversos a largo plazo en el ambiente acuático. Su metabolito tiene toxicidad aguda alta

para mamíferos, peces y crustáceos y mediana para aves, algas y lombrices de tierra. Como mirex está incluido en la lista del Fondo Mundial para la Naturaleza (WWF) de plaguicidas reportados como disruptores endocrinos y/o con efectos reproductivos.

Solubilidad en agua: baja. Persistencia en el suelo: extrema. Movilidad en el suelo: inmóvil. Persistencia en agua sedimento: más persistente. Volatilidad: alta a ligera. Bioacumulación: alta.

Referencia

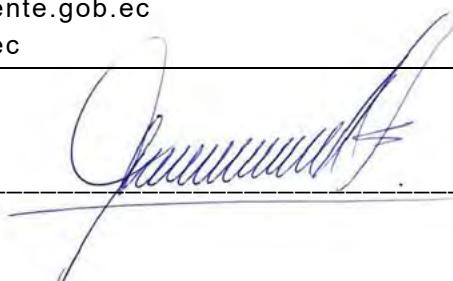
declarano. (2020). Retrieved 11 February 2020, from
<http://www.plaguicidasdecentroamerica.una.ac.cr/index.php/base-de-datos-menu/170-declarano>

SECCIÓN 4

AUTORIDAD NACIONAL DESIGNADA

Institución	Agencia de Regulación y Control Fito y Zoosanitario AGROCALIDAD
Dirección	Avenida Eloy Alfaro y Amazonas Edificio MAG - 9 piso Código postal: 170518/Quito- Ecuador
Nombre de la persona responsable	Ing. Patricio Almeida Granja
Cargo de la persona responsable	Director Ejecutivo
Teléfono	+593 23828860 ext.2121
Fax	
Correo electrónico	direccion@agrocalidad.gob.ec relaciones.internacionales@agrocalidad.gob.ec consultasregistros@agrocalidad.gob.ec internacional@ambiente.gob.ec carlos.velasco@ambiente.gob.ec esperanza.hernandez@ambiente.gob.ec juan.lliquin@ambiente.gob.ec

Fecha, firma de la AND y sello oficial: _07-04-2020_____



SÍRVASE REMITIR EL FORMULARIO RELLENADO A:

Secretaría para el Convenio de Rotterdam
Organización de las Naciones Unidas para
la Agricultura y la Alimentación (FAO)
Viale delle Terme di Caracalla
00153 Roma, Italia
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 3224
Correo electrónico: pic@fao.org

O

Secretaría para el Convenio de Rotterdam
Programa de las Naciones Unidas para el
Medio Ambiente (PNUMA)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Ginebra, Suiza
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
Correo electrónico: pic@pic.int

Definiciones utilizadas en el Convenio de Rotterdam según el artículo 2:

- a) Por 'producto químico' se entiende toda sustancia, sola o en forma de mezcla o preparación, ya sea fabricada u obtenida de la naturaleza, excluidos los organismos vivos. Ello comprende las siguientes categorías: plaguicida (incluidas las formulaciones plaguicidas extremadamente peligrosas) y producto químico industrial;
- b) Por 'producto químico prohibido' se entiende aquél cuyos usos dentro de una o más categorías hayan sido prohibidos en su totalidad, en virtud de una medida reglamentaria firme, con objeto de proteger la salud humana o el medio ambiente. Ello incluye los productos químicos cuya aprobación para primer uso haya sido denegado o que las industrias hayan retirado del mercado nacional o de ulterior consideración en el proceso de aprobación nacional cuando haya pruebas claras de que esa medida se haya adoptado con objeto de proteger la salud humana o el medio ambiente;
- c) Por 'producto químico rigurosamente restringido' se entiende aquél cuyos usos dentro de una o más categorías hayan sido prohibidos casi en su totalidad, en virtud de una medida reglamentaria firme, para proteger la salud humana o el medio ambiente, pero del que se sigan autorizando algunos usos específicos. Ello incluye los productos químicos cuya aprobación para casi cualquier uso haya sido denegada o que las industrias hayan retirado del mercado nacional o de ulterior consideración en el proceso de aprobación nacional, cuando haya pruebas claras de que esa medida se haya adoptado con objeto de proteger la salud humana o el medio ambiente;
- d) Por 'medida reglamentaria firme' se entiende toda medida para prohibir o restringir rigurosamente un producto químico adoptada por un país Parte que no requiera la adopción de ulteriores medidas reglamentarias por esa Parte.



ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE



FORM FOR NOTIFICATION

OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT
A CHEMICAL

Country:

ECUADOR

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	Dodecachloro-pentacyclodecane
1.3	Trade names and names of preparations	Not available, this molecule is banned since 1992
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)	219-196-6 (EC number) 375 (CIPAC number)

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 X 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: _____

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 MINISTRY OF AGRICULTURE

Resolves:

Art. 1 - Registration is prohibited by the National Program of Plant Health, as these pesticides are harmful for the human health; and the manufacture, marketing or use of the following pesticides has been prohibited in several countries: Aldrin, Dieldrin, Endrin, BHC, Camphechlor (Toxaphene), Chlordimeform (Galecron and Fundal), Chlordano, DDT, DBCP, Lindane, EDB, 2,4,5 T, Amitrole, Mercury and Lead Compounds, Carbon Tetrachloride, Leptophos, Heptachloro, Chlorobenzilate.

Art.2 – Registration is also prohibited due to environmental contamination and toxic effects; and for having been cancelled in several other countries the following products: Methyl, Diethyl and Ethyl Parathion, Mirex and Dinoseb.

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

Ministerial Agreement No. 0112.- published in the Official Registry No. 64, November 12, 1992. Art. 1

2.2.3 Date of entry into force of the final regulatory action

12 November 1992

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

Insecticide

2.3.2 Final regulatory action has been taken for the category Industrial

Use or uses prohibited by the final regulatory action

-

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

-

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

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

Use of Mirex is totally banned

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

X 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

-

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 health? X Yes

No

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

Possible carcinogenic effects, may harm breastfed children.
Harmful if in contact with the skin and if swallowed.

Expected effect of the final regulatory action

The intended effect of the regulatory action is the elimination of the exposure to this pesticide and consequent health risks

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? X Yes

No

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

environment

Bioaccumulative, persistent, persistent organic pollutant (POP).

H400. Very toxic for aquatic organisms. Acute aquatic (CAt. 1): Dangerous to the aquatic environment.

H410: Very toxic to aquatic life with long lasting toxic effects. Chronic Aquatic (Cat: 1): Dangerous to the aquatic environment.

Expected effect of the final regulatory action

The intended effect of the regulatory action is the elimination of the exposure to this pesticide and the consequent health risks

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	-	-
imported	-	-
exported	-	-
used	-	-

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

Ecuador was not exporter of the chemical, therefore, it would not affect other countries.

2.5.3 Other relevant information that may cover:

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

No socioeconomic effects have been reported.

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

The proposed alternative is the application of IPM (integrated pest management), which implies the use of preventive, mechanical and biological controls, and the adoption of a chemical control; the latter based on pesticides approved in the country. Since the regulation prohibiting the use of this molecule dates from 1992, there is no information on the approved uses, therefore, there is no information on chemical alternatives

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

Because harmful to health, and manufacture, marketing or use has been banned in several countries

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

WHO	O obsolete
IARC	2B possible carcinogenic

Other classification systems
e.g. EU, USEPA

Hazard class

--	--

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Melting point: 485 °C

Vapor pressure: less than 1 mg/mL at 75° F (NTP, 1992)
6.89^[L]_{SEP}

Kow^[L]_{SEP} logP:

Henry's constant: 1.48 X 10⁻¹ Pam³mol⁻¹

Density: 18.8

Solubility in water: 0.0001 20°C (mg l⁻¹)^[L]_{SEP}

Solubility in organic solvents: chloroform: 17000, xylene: 14300

Reference

Hertfordshire, U. (2019). Carbon tetrachloride. Retrieved from
<http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1350.htm>

3.2.2 Description of toxicological properties of the chemical

Acute toxicity. LD50/LC50 oral (rats): 306 mg/kg; inhalation (rats): n.a; dermal (rats): >2000 mg/kg; dermal (rabbits): 800 mg/kg.

Classification: n.a. (WHO); n.a. (EPA).

Toxicity and symptoms:

organochlorine toxic syndrome. Topical toxicity: irritative capacity: ocular n.a; positive dermal; allergenicity: n.a.

Chronic and long-term toxicity: neurotoxicity: n.a; teratogenicity: positive; mutagenicity: n.a; carcinogenicity: 2B. Possible human carcinogenic (IARC); n.a (EPA); endocrine disruption: Category 1; other reproductive effects: n.a; genotoxicity: n.a; Parkinson's: n.a; Other chronic effects: hepatotoxic. EU Risk: R22: Harmful if swallowed. R40: Possible carcinogenic effects. R62: Possible risk of impairing fertility. R63: Possible risk during pregnancy of adverse effects for the fetus. R64: May be harmful for breastfed children.

Reference

Dechlorane. (2020). Retrieved 11 February 2020, from
<http://www.plaguicidasdecentroamerica.una.ac.cr/index.php/base-de-datos-menu/170-declorano>

3.2.3 Description of ecotoxicological properties of the chemical

Acute toxicity: fish: light, LC50 (96h) rainbow trout 100 mg/L; crustaceans: extreme to high, EC50 (48h) daphnids 0.1 mg/L,> 1 mg/L; amphibians: n.a; birds: light; insects (bees): n.a, (chironomids): n.a; earthworms: n.a; algae: high, EC50 (72h) Chlorella pyrenoidosa 0.1 mg/L; plants: water fern: n.a.

Remarks: R50: Very toxic to aquatic organisms. R53: May cause long-term adverse effects in the aquatic environment. Its metabolite has high acute toxicity for mammals, fish and crustaceans and medium for birds, algae and earthworms. As Mirex is included in the list of the World Wide Fund for Nature (WWF) of pesticides reported as endocrine disruptors and/or with reproductive effects. Solubility in water: low. Ground persistence: extreme. Ground mobility: immobile. Persistence in sediment water: more persistent. Volatility: high to light. Bioaccumulation: high.

Reference

Dechlorane. (2020). Retrieved 11 February 2020, from
<http://www.plaguicidasdecentroamerica.una.ac.cr/index.php/base-de-datos-menu/170-declorano>

SECTION 4

DESIGNATED NATIONAL AUTHORITY

Institution	Agency for Agricultural Quality- AGROCALIDAD
Address	Avenida Eloy Alfaro y Amazonas Edificio MAG - 9 piso 170516
Name of person in charge	Ing. Patricio Almeida Granja
Position of person in charge	Executive Director
Telephone	+593 23828860 ext. 1092-2121
Telefax	
E-mail address	direccion@agrocalidad.gob.ec relaciones.internacionales@agrocalidad.gob.ec consultasregistros@agrocalidad.gob.ec internacional@ambiente.gob.ec carlos.velasco@ambiente.gob.ec esperanza.hernandez@ambiente.gob.ec juan.lliquin@ambiente.gob.ec

Date, signature of DNA and official seal: _____

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 3224
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

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.



ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE



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

Country: Republic of Indonesia

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	1,1a,2,2,3,3a,4,5,5,5a,5b,6-dodecachlorooctahydro-1 <i>H</i> - 1,3,4-(methanetriyl)cyclobuta[cd]pentalene
1.3	Trade names and names of preparations	C6-1283; ENT 25719; Dechlorane; Hexachloropentadienedimer
1.4	Code numbers	
1.4.1	CAS number	2385-85-5
1.4.2	Harmonized System customs code	2903.83
1.4.3	Other numbers (specify the numbering system)	EC NUMBER: 219-196-6

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: _____

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

Based on Government Regulation No. 74 Year 2001 on Hazardous Substances Management, the use of Mirex has been banned for manufacture, import, export, and use as both industrial and agricultural purposes. No remaining uses are allowed.

Ministerial Decree of Agriculture No. 43 year 2019 concerning Pesticide Registration regulates the field of use, pesticide classification, type of permit issued and its requirements, sampling and testing, packaging and labeling, importation, limited use of pesticides, pesticide commissions, sanctions, attachments of active ingredients and ingredients extras are prohibited. Based on that regulation, The Indonesia pesticides committee prohibit the use of all the formulations containing Mirex.

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

Government Regulation Number 74 Year 2001 concerning Hazardous Substances Management

(<http://jdih.menlh.go.id/pdf/ind/IND-PUU-3-2001-PP%2074%20thn%202001.pdf>)

(<http://sib3pop.menlhk.go.id/uploads/Regulasi/PP742001a.pdf>)

Minister of Agriculture Regulation No. 43 Year 2019 on Pesticide Registration

(<http://ditlin.tanamanpangan.pertanian.go.id/index.php/regulasi/40>)

Minister of Trade Regulation Number 12/2020 on Prohibited Goods to be Import
(<http://jdih.kemendag.go.id/pdf/Regulasi/2020/Permendag%20No.%2012%20Th.%202020.pdf>)

2.2.3 Date of entry into force of the final regulatory action

26 May 2002 (for the GR 74/2001) and 14 February 2007 (for the MAR)

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

Mirex used as flame retardant in plastics, rubbers, paints, etc and used as insecticide in agricultural.

2.3.2 Final regulatory action has been taken for the category

Industrial

Use or uses prohibited by the final regulatory action

Mirex is prohibited/banned for all uses.

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

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

Mirex is prohibited/banned for all use of the pesticide formulation.

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

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 health? Yes

No

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

Expected effect of the final regulatory action

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

Expected effect of the final regulatory action

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	0	2020
imported	0	2020
exported	0	2020
used	0	2020

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

N/A

2.5.3 Other relevant information that may cover:

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

N/A

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

N/A

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

- Toxicological properties on Environmental Health Criteria 44 (Mirex)
- National concern to the toxicological properties of the initial POPs presented during the INC process of the Stockholm Convention. Thus, Govt of Indonesia committed to regulate POPs as covered by the Convention in order to support the global act to reduce and eliminate the impact of POPs to the environment

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

N/A

SECTION 3 PROPERTIES

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

International classification systems **Hazard class**
e.g. WHO, IARC, etc.

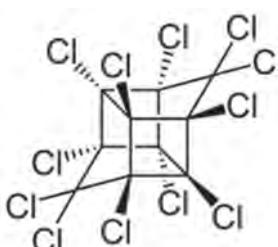
WHO	II (Moderately hazardous)
IARC	Group 2B (Possibly carcinogenic to humans)

Other classification systems **Hazard class**
e.g. EU, USEPA

EU	Xn (Harmful), N (Dangerous for the environment), F (Highly Flammable), Xi (Irritant)
----	--

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Structural Formula	
Molecular Formula	C ₁₀ Cl ₁₂
Molecular Weight	545.5 g/mol
Description	White crystalline, odourless solid

Boiling-point	485 °C
Melting-point	485 °C
Solubility	Soluble in several organic solvents including tetrahydrofuran (30%), carbon disulfide (18%), chloroform (17%), and benzene (12%), but is practically insoluble in water
Vapour pressure	at 25 °C of 3 x 10 ⁻⁷ mm

Reference

1. Environmental Health Criteria (EHC) 44, 1984
2. Nuclear Regulatory Commission (US NRC) 1978
3. International Agency for Research on Cancer (IARC) 1979

3.2.2 Description of toxicological properties of the chemical

Mirex is moderately toxic in single-dose animal studies (oral LD₅₀ values range from 365-3000 mg/kg body weight). It can enter the body via inhalation, ingestion, and via the skin. It is one of the most stable pesticides in use today. It accumulates in adipose tissue and biomagnifies in food chains. Excretion is slow and elimination half-lives can extend over many months. The most sensitive effects of repeated exposure in experimental animals are principally associated with the liver, and these have been observed with doses as low as 1.0 mg/kg diet (0.05 mg/kg body weight per day), the lowest dose tested. At higher dose levels, it is fetotoxic (25 mg/kg in diet) and teratogenic (6.0 mg/kg per day). Mirex was not generally active in short-term tests for genetic activity. There is sufficient evidence of its carcinogenicity in mice and rats. No data on effects on human beings were available.

No data on human health effects are available in connection with occupational exposure to mirex. Based on the findings in mice and rats, this chemical should be considered, for practical purposes, as being potentially carcinogenic for human beings.

Reference

- | |
|--|
| Environmental Health Criteria (EHC) 44, 1984 |
|--|

3.2.3 Description of ecotoxicological properties of the chemical

Information on the toxicity of mirex is available for a wide range of aquatic organisms. Results of disc assay tests of estuarine bacterial growth inhibition were inconsistent from batch to batch of technical grade mirex, with some batches producing little or no growth inhibition in the bacterial isolates while others showed marked inhibition (Brown et al., 1975). Although purified mirex was not toxic, UV irradiated mirex was bacteriologically toxic. The only appreciable microbial activity affected by mirex at concentrations below 100 mg/litre was the inhibition of primary production. This is unlikely to be a significant effect in the field, since most phytoplankton are in the aqueous phase, whereas mirex tends to become associated with the sediments. Mirex

degradation products with substitution at the 5 and/or 10 positions were highly toxic for bacterial cultures and, as these compounds are more polar than mirex, they may be more soluble in water and therefore pose a greater environmental threat for aquatic bacteria (EHC 1984).

Exposure of phytoplankton to mirex at 1 mg/litre for 4 h reduced productivity by 28 - 46% (Butler, 1963). The ciliate protozoan *Tetrahymena pyriformis* exhibited reduced growth rate when exposed to 0.9 µg mirex/litre during the exponential growth phase (Cooley et al., 1972). Exposure of pure cultures of the green marine algae *Chlamydomonas* sp. to 1 mg mirex/litre for 168 h reduced net photosynthesis by 55% and respiration by 28.4% (de la Cruz & Naqvi, 1973). Population growth and oxygen evolution in marine unicellular algae were not affected by exposure to 0.2 µg mirex/litre (highest concentration of mirex obtainable in seawater) when tested under various conditions of salinity and nutrient concentration (Hollister et al., 1975). Exposure to 10.2 µg/litre (maximum concentration of mirex obtainable in synthetic seawater) did not adversely affect photosynthesis and the chemical composition of green and red marine algae (Sikka et al., 1976). Mirex at a concentration of 100 µg/litre in a culture medium of a freshwater algae, *Chlorella pyrenoidosa*, depressed population growth by 8% in 92 h and 19% in 164 h (Kritchler et al., 1975). Mirex is highly toxic for crustacea. Delayed mortality appears to be characteristic of mirex poisoning in crustacea. Freshwater crayfish, particularly third instars, were extremely sensitive to mirex, through direct and indirect exposure under laboratory conditions (Ludke et al., 1971).

Although general environmental levels are low, it is widespread in the biotic and abiotic environment. Mirex is both accumulated and biomagnified. Mirex is strongly adsorbed on sediments and has a low water solubility. The delayed onset of toxic effects and mortality is typical of mirex poisoning. The long-term toxicity of mirex is uniformly high. Mirex is toxic for a range of aquatic organisms, with crustacea being particularly sensitive. Mirex induces pervasive long-term physiological and biological disorders in vertebrates. Although no field data are available, the adverse effects of long-term exposure to low levels of mirex combined with its persistence suggest that the use of mirex presents a long-term environmental risk (EHC, 1984).

Reference

1. Environmental Health Criteria (EHC) 44, 1984
2. Brown, L.R., Alley, E.G., and Cook, D.W. 1975. The effect of mirex and carbofuran on estuarine microorganisms, Cornwallis, Oregon, US Environmental Protection Agency, Office of Research & Development, Natural Environmental Research Center, 47 pp (US EPA 660/3-75-024)
3. Butler, P.A. 1963. A review of fish and wildlife service investigations during 1961 and 1962. In: George, J.L., ed. Commercial fisheries investigations, pesticide – wildlife series, Washington DC, US Department of the Interior, Fish and Wildlife Services, pp. 11-25 (Circular No. 167)

4. Cooley, N.R., Keltner, J.M., and Forrester, J. 1972. Mirex and aroclor 1254: effect on an accumulation by Tetrahymena pyriformis strain W. J. Protozool., 19: 636-638
5. De La Cruz, A.A., and Naqvi, S.M. 1973. Mirex incorporation in the environment: uptake in aquatic organisms and effects on the rates of photosynthesis and respiration. Arch. environ. Contam. Toxicol., 1: 255-264
6. Hollister, T.A., Walsh, G.E., and Forester, J. 1975. Mirex and marine unicellular algae: accumulation, population growth and oxygen evolution. Bull. Environ. Contam. Toxicol., 14: 753-759
7. Sikka, H.C., Butler, G.L., and Rice, C.P. 1976. Effects, uptake and metabolism of methoxychlor, mirex and 2,4-D in seaweeds, Gulf Breeze, Florida, US Environmental Protection Agency Research Laboratory, NTIS, 48 pp (EPA 600/3-76-048)
8. Kritcher, Y.C., Urey, J.C., and Hawes, M.L. 1975. The effects of mirex and methoxychlor on the growth and productivity of Chlorella pyrenoidosa. Bull. Environ. Contam. Toxicol., 14: 617-620
9. Ludke, J.L., Finley, M.T., and Lusk, C. 1971. Toxicity of mirex to crayfish, Procambarus blandus. Bull. Environ. Contam. Toxicol., 6: 89-95

SECTION 4**DESIGNATED NATIONAL AUTHORITY**

Institution	Ministry of Environment and Forestry
Address	Jl. D.I. Panjaitan Kav. 24 Kebon Nanas 13410 Jakarta Indonesia
Name of person in charge	Rosa Vivien Ratnawati
Position of person in charge	Director General of Solid Waste, Hazardous Waste and Hazardous Substances Management
Telephone	+62 21 85905637
Telefax	+62 21 85905637
E-mail address	rosavivien@gmail.com geneva@mission-Indonesia.org

Date, signature of DNA and official seal:



15 April 2021

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: (+39 06) 5705 2188
Fax: (+39 06) 5705 3224
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8296
Fax: (+41 22) 917 8082
E-mail: pic@pic.int