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

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Chemical Review Committee
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Item 5 (c) (iv) of the provisional agenda**

Technical work: review of notifications of final regulatory action: chlorpyrifos

Chlorpyrifos: 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 has received four notifications of final regulatory action for chlorpyrifos that meet the requirements of Annex I to the Convention from Parties in the following two prior informed consent regions:

(a) Asia: Malaysia (pesticide);[1]

(b) Asia: Sri Lanka (pesticide);[2]

(c) Europe: European Union (pesticide);[3]

(d) Europe: Türkiye (pesticide).[4]

2. The notifications from Malaysia, Sri Lanka, the European Union and Türkiye are set out in the annex to the present note. The supporting documentation provided by Malaysia, Sri Lanka, the European Union and Türkiye is set out in documents UNEP/FAO/RC/CRC.19/INF/13, UNEP/FAO/RC/CRC.19/INF/14, UNEP/FAO/RC/CRC.19/INF/15 and UNEP/FAO/RC/CRC.19/INF/16, respectively.

II. Proposed action

3. The Committee may wish:

(a) To review the information provided in the notifications and the supporting documentation from Malaysia, Sri Lanka, the European Union and Türkiye related to chlorpyrifos, in accordance with the criteria set out in Annex II to the Convention;

* Reissued for technical reasons on 2 October 2023.

** UNEP/FAO/RC/CRC.19/1/Rev.1.

[1] See PIC Circular LVII, June 2023.

[2] See PIC Circular XLIX, June 2019.

[3] See PIC Circular LVI, Dec. 2022.

[4] See PIC Circular LIV, Dec. 2021.

(b) If it concludes that at least one notification from each of two different prior informed consent regions meets the criteria meet 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 chlorpyrifos.

Annex

Notifications of final regulatory action for chlorpyrifos

I. Notification of final regulatory action for chlorpyrifos in the pesticide category submitted by Malaysia

II. Notification of final regulatory action for chlorpyrifos in the pesticide category submitted by Sri Lanka

III. Notification of final regulatory action for chlorpyrifos in the pesticide category submitted by the European Union

IV. Notification of final regulatory action for chlorpyrifos in the pesticide category submitted by Türkiye

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: MALAYSIA

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	Common name	Chlorpyrifos
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	O,O-diethyl O-(3,5,6-trichloro-2-pyridinyl) phosphorothioate.
1.3	Trade names and names of preparations	CHEMITOX 75 G-505 STARFOS 505 LORSBAN 40EC NURELLE-D505 EC DURSBAN 75+ ECLIPSE 505 PEST-BAN 100 FIGHTER 505 TRICEL 21.2EC TRICEL 38.7 EC ZA 505

1.4 Code numbers

1.4.1	CAS number	2921-88-2
1.4.2	Harmonized System customs code	2921.5110
1.4.3	Other numbers (specify the numbering system)	EC number: 247-435-0 UN number: 2783 EPA number: 352-10

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

The Pesticides Board of Malaysia issued a Circular Letter dated April 28, 2021, informing the industry of the Board's decision to cancel the registration of all products containing chlorpyrifos for agricultural use effective from May 1, 2023.

This means that effective from May 1, 2023, chlorpyrifos will no longer be authorized as a plant protection product in agriculture. However, the registration of chlorpyrifos products for use in public health and urban pest control will continue.

Effective from the date of the Circular Letter, the Pesticides Board stopped accepting new applications and re-registrations of pesticide products containing chlorpyrifos for the agricultural sector. All new applications that were pending approval or in the process of evaluation were automatically cancelled.

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

1. Circular from the Pesticides Board, dated April 28, 2021.
2. Minutes from the 88th Pesticides Board Meeting, dated April 9, 2021.

2.2.3 Date of entry into force of the final regulatory action

May 1, 2023

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

Prior to the final regulatory action chlorpyrifos had been registered for use in both agriculture and public health sector.

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 ☒ Pesticide

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

All types of chlorpyrifos formulations for use in the agricultural sector are no longer allowed.

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

Chlorpyrifos are still permitted for use in public health to control urban pests, such as cockroaches, termites, mosquitoes, ants, flies, and bugs

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

According to an internal report from the Department of Agriculture's Pesticides Monitoring Program, chlorpyrifos residues consistently exceeded national maximum residue limits (MRLs) in recommended crops, including crops intended for export. From the dietary risk assessment, it is clearly that the use of chlorpyrifos in agriculture possesses risk to the consumers from the exposure to chlorpyrifos residue exceeding legal limits over a long terms exposure. In addition, according to data gathered by the National Poison Centre Malaysia over a 10-year period (2006-2015), 40% of reported cases of insecticide poisoning involved pesticides from the Organophosphate group, with Chlorpyrifos being the most commonly reported pesticide. The data from 2016-2019 recorded that 24%

of insecticide poisoning cases (N=1374) involved Chlorpyrifos (National Poison Centre Malaysia, unpublished report, [22 Jan 2021]).

In a study conducted by Rozita Hod et al. (2011), the presence of chlorpyrifos and the pesticide exposure symptoms of paddy farmers in Sabak Bernam, Malaysia were investigated. The study involved 100 respondents and showed that 7% of the farmers had chlorpyrifos in their blood, with a mean of 7.29 nanogram per millilitre blood (SD 5.84 nanogram per millilitre). The study revealed that 75% of the farmers had experienced at least one pesticide exposure symptom, indicating that many of them were at risk of suffering from the harmful effects of pesticides, including chlorpyrifos (Hod et al., 2011).

Furthermore, studies conducted by other regulatory bodies such as the European Food Safety Authority (EFSA) and the Department of Pesticide Regulation in California (DPR) have shown that chlorpyrifos has the potential to cause genotoxic effects and developmental toxicity in humans.

EFSA found that chlorpyrifos can cause developmental neurotoxicity, which can lead to lifelong cognitive and behavioural problems in children exposed to the substance. The EFSA's findings were later confirmed by the European Commission, and the use of chlorpyrifos was banned in the European Union in 2020.

In the USA, based on its human health risk assessment, DPR has concluded that developmental neurotoxicity is the critical endpoint for chlorpyrifos and has derived a point of departure for chlorpyrifos risk assessment. DPR presented its Toxic Air Contaminant (TAC) findings to California's Scientific Review Panel at a meeting on July 30, 2018, and the Panel subsequently concluded that the DPR assessment of the developmental neurotoxicity of chlorpyrifos was "based on sound scientific knowledge and represents a balanced assessment of our current scientific understanding." As a result of this assessment, the sale of chlorpyrifos was banned effectively from February 6, 2020. The use of chlorpyrifos among farmers was allowed up to the end of 2020 until the stock was finished in California.

Malaysia used both findings from the EU and California to assess the situation locally and determine if the risk is lower, similar, or higher under Malaysian conditions. It is anticipated that the risk to human health under Malaysian conditions is much higher than in the EU and California. The hot and humid conditions in the tropics can make wearing proper protective clothing sometimes

impossible, and if the proper protective equipment (PPE) is available, the cost might be an issue for poor farmers.

References:

1. California Department of Pesticide Regulation. (2019). California takes action to protect children from brain-harming pesticide. https://calepa.ca.gov/2019/05/08/california-acts-to-prohibit-chlorpyrifos-pesticide/

2. California Department of Pesticide Regulation. (2020). Cancellation of chlorpyrifos registrations in California. https://www.cdpr.ca.gov/docs/chlorpyrifos/index.htm

3. Human Health Assessment Branch Department of Pesticide Regulation California Environmental Protection Agency (July 2018). Final Toxic Air Contaminant Evaluation of Chlorpyrifos: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders. https://www.cdpr.ca.gov/docs/whs/pdf/chlorpyrifos_final_tac.pdf

4. Department of Agriculture. (unpublished data). Internal report on Pesticides Residues Monitoring Program.

5. Hod, R., Ismail, S. N., & Hamzah, H. (2011). Chlorpyrifos Blood Level and Exposure Symptoms among Paddy Farmers in Sabak Bernam, Malaysia. International Journal of Public Health Research, Vol. 1, No. 1, pp. 1-6.

6. European Union. (2020). Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 prohibiting the use of chlorpyrifos. Official Journal of the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0017&from=EN

7. EFSA Journal 2011;9(1):Conclusion on the peer review of the pesticide risk assessment of the active substance chlorpyrifos https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.1961

8. European Parliament (2014-2019). Sustainable use of pesticides European Parliament resolution of 12 February 2019 on the implementation of Directive 2009/128/EC on the sustainable use of pesticides (2017/2284(INI)) https://www.europarl.europa.eu/doceo/document/TA-8-2019-0082_EN.pdf

9. National Poison Centre. Assessment of carbofuran and chlorpyrifos. (Unpublished report). Retrieved from internal document database, [2021].

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

Summary description of the risk or hazard evaluation

Department Agriculture Malaysia has revealed that food crops, including those intended for export, have consistently exceeded the national maximum limits for chlorpyrifos residues. This presents a potential risk to both workers and consumers who may be exposed to the pesticide.

Agricultural workers in Malaysia who have been exposed to chlorpyrifos have reported symptoms such as headaches, dizziness, and skin irritation. A study conducted in Sabak Bernam, Malaysia found that 7% of paddy farmers had chlorpyrifos in their blood, with a mean concentration of 7.29 nanograms per milliliter blood. Furthermore, 75% of the farmers in the study reported experiencing at least one pesticide exposure symptom.
In addition to its impact on human health, chlorpyrifos has been shown to cause neurotoxic symptoms in animals, including hypoactivity, lacrimation, salivation, foot splay, ataxia, and tremors. The lethal dose (LD50) for mammals (oral) ranges from 80 to 250 mg/kg/d, while the dermal LD50 for male rats is 202 mg/kg. The inhalational lethal dose is calculated to be 78 and 94 mg/kg for female mice and rats, respectively. However, rats have shown tolerance to prolonged and significant acetylcholinesterase (AChE) inhibition after subcutaneous injection.

In terms of genotoxicity, chlorpyrifos has been shown to induce micronuclei in erythroblasts and cause cytogenetic effects in human lymphoid cells. It has also produced significant increases in sister chromatid exchanges (SCEs), X chromosome loss, and sex-linked recessive lethality in Drosophila melanogaster.

Expected effect of the final regulatory action

Significant health risk reduction for farmers and consumers; being a high-volume pesticide, there will be significant reduction of chlorpyrifos exposure in consequent to this decision.

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	NA	
imported	1688.5 1001.9	2020 2021
exported	NA	
used	NA	

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

Malaysia exports a number of agriculture produces to neighbouring countries. With the withdrawal of chlorpyrifos from use in agriculture in Malaysia, the risk of consumers' exposure to chlorpyrifos in crops exported to these countries will be reduced.

2.5.3 Other relevant information that may cover:

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

It is anticipated that the withdrawal of chlorpyrifos usage in agriculture would not cause any adverse impacts in agriculture, as there are many cost-effective alternatives that are safer than chlorpyrifos.

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

Alternative options for certain major crops are as follows: **Vegetables:** cypermethrin, deltamethrin, permethrin, indoxacarb, Bacillus thuringiensis subsp. kurstaki (3A, 3B), fenvalerate, imidacloprid, lufenuron, emamectin benzoate, diafenthiuron + fenoxycarb, diflubenzuron, diazinon + cypermethrin, teflubenzuron, abamectin, azadirachtin, chlorfluazuron, diafenthiuron, spinosad, thiocyclam hydrogen oxalate, alpha-cypermethrin, esfenvalerate, malathion, and diazinon.

Paddy: sulfoxaflor + fipronil, imidacloprid, pymetrozine, triflumezopyrim, cartap hydrochloride, malathion, fenobucarb, dinotefuran, carbaryl, fenitrothion + fenobucarb, etofenprox, buprofezin + cartap hydrochloride, buprofezin + esfenvalerate, buprofezin + tebufenozide, cartap hydrochloride + isoprocarb, and lambda-cyhalothrin, methoxyfenozide, and tebufenozide. **Oil palm**: *Bacillus thuringiensis* subsp. Kurstaki, chlorantraniliprole, and fipronil.

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

NA

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

NA

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	moderately hazardous (Class II)
IARC	Group 2B carcinogen, which means it is possibly carcinogenic to humans

Other classification systems e.g. EU, USEPA	**Hazard class**
USEPA	Restricted Use Pesticide (RUP) due to its high acute toxicity and potential to cause adverse effects to human health and the environment

EU	Substance of very high concern (SVHC) under the REACH Regulation due to its endocrine-disrupting properties

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Chlorpyrifos is an organophosphorus insecticide that has the following physico-chemical properties:

Chemical formula: C9H11Cl3NO3PS
Molecular weight: 350.6 g/mol
Physical state: Colorless to white crystalline solid
Odor: Mild mercaptan
Melting point: 41-43°C
Boiling point: 156-157°C at 0.1 mmHg
Vapor pressure: 2.3 x 10^-6 mmHg at 25°C
Water solubility: 0.0012 g/L at 25°C
Octanol/water partition coefficient: 4.8
Stability: Stable under normal conditions

Reference

National Center for Biotechnology Information. PubChem Compound Summary for CID 2715, Chlorpyrifos. https://pubchem.ncbi.nlm.nih.gov/compound/Chlorpyrifos

3.2.2 Description of toxicological properties of the chemical

Acute toxicity: Chlorpyrifos is highly toxic if ingested, inhaled, or absorbed through the skin. Acute exposure can cause symptoms such as headache, dizziness, nausea, vomiting, abdominal cramps, diarrhea, and in severe cases, convulsions, respiratory depression, and coma.

Chronic toxicity: Chronic exposure to chlorpyrifos can lead to long-term effects such as developmental and reproductive toxicity, neurotoxicity, immunotoxicity, and carcinogenicity. Prenatal exposure to chlorpyrifos has been associated with developmental delays, cognitive deficits, and behavioral disorders in children.

Reference

Agency for Toxic Substances and Disease Registry (ATSDR). 1997. Toxicological profile for Chlorpyrifos. Atlanta, GA: U.S. Department of Health and Human

Services, Public Health Service. https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=495&tid=88

National Pesticide Information Center. (2021). Chlorpyrifos general fact sheet. Oregon State University. http://npic.orst.edu/factsheets/archive/chlorptech.html

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (2020). Third Revised Human Health Risk Assessment for Registration Review. https://downloads.regulations.gov/EPA-HQ-OPP-2008-0850-0944/content.pdf

3.2.3 Description of ecotoxicological properties of the chemical

Chlorpyrifos has been shown to be highly toxic to various non-target organisms, including birds, bees, earthworms, and aquatic life.

Avian: Chlorpyrifos is toxic to birds, with lethal concentrations varying among species. The acute oral LD50 values for birds range from 2.7 to 110 mg/kg body weight. Chronic exposure to low levels of chlorpyrifos can also cause reproductive toxicity in birds.

Bees: Chlorpyrifos is highly toxic to bees and other pollinators. Even at low doses, chlorpyrifos can impair the cognitive functions of bees, affecting their ability to navigate and forage. The acute oral LD50 values for honeybees range from 0.11 to 1.5 ng/bee.

Earthworms: Chlorpyrifos can be toxic to earthworms, which play an important role in soil health and nutrient cycling. The acute toxicity of chlorpyrifos to earthworms varies depending on the species and soil type. The LC50 values range from 0.06 to 40 mg/kg soil.

Terrestrial life: Chlorpyrifos has been shown to be toxic to various terrestrial organisms, including beneficial insects, earthworms, and soil microorganisms. The toxicity of chlorpyrifos to terrestrial organisms is dependent on the exposure route, dose, and duration.

Fish and aquatic life: Chlorpyrifos is highly toxic to fish and other aquatic organisms, with lethal concentrations varying among species. The acute LC50 values for fish range from 0.03 to 1.7 mg/L. Chlorpyrifos can also cause sublethal effects, such as reduced growth, altered behaviour, and reproductive toxicity, in fish and other aquatic life.

Reference

Agency for Toxic Substances and Disease Registry (ATSDR). 1997. Toxicological profile for Chlorpyrifos. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=495&tid=88

National Pesticide Information Center. (2021). Chlorpyrifos general fact sheet. Oregon State University. http://npic.orst.edu/factsheets/archive/chlorptech.html

United States Environmental Protection Agency. (2021). Chlorpyrifos: Ecological risk assessment for the registration review. EPA 4485-R-20-002. Environmental Protection Agency (2020) Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review. https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0940

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	PESTICIDES AND FERTILIZERS CONTROL DIVISION DEPARTMENT OF AGRICULTURE MINISTRY OF AGRICULTURE AND FOOD INDUSTRY
Address	6TH FLOOR, WISMA TANI JALAN SULTAN SALAHUDDIN 50632 KUALA LUMPUR MALAYSIA
Name of person in charge	MAT IESAK BIN NGATHINEE
Position of person in charge	DIRECTOR
Telephone	+603 20301504
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Date, signature of DNA and official seal: MAT IESAK BIN NGATHINEE
Secretary
Pesticides Board of Malaysia
Department of Agriculture
50632 Kuala Lumpur
20/3/2013

PESTICIDES CONTROL & FERTILIZER DIVISION D.O.A

PLEASE RETURN THE COMPLETED FORM TO:

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ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
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IN INTERNATIONAL TRADE

UNEP

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

Country: Sri Lanka

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Chlorpyrifos**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**O,O-Diethyl 0-3,5,6-trichloropyridin-2-yl phosphorothioate**
1.3	**Trade names and names of preparations**	**More than 21 trade products; e.g. Pyrinex, Vltashield, Pyrimac, Pyriban, Lidorban, Unifos 400, Cyren 40, Mackfos**
1.4	**Code numbers**	
1.4.1	CAS number	292 1 -88-2
1.4.2	Harmonized System customs code	38.08
1.4.3	Other numbers (specify the numbering system)	

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

The Pesticide Technical & Advisory Committee of Sri Lanka during its 28th meeting on 7th May 2004 decided to prohibit the residential indoor use of chlorpyrifos for termite controls in Sri Lanka, while other uses remained allowed. As a result of the above decision, all labels of registered chlorpyrifos products were amended to reflect the above decision.

The Pesticide Technical & Advisory Committee of Sri Lanka during its 65th meeting on 05.04.2013 made a final regulatory action to ban chlorpyrifos in Sri Lanka. As a result of the decision, the registration of all products and formulations containing active ingredient chlorpyrifos was cancelled on 28 December 2016 (REF: *Government Extraordinary Gazette No. 1999/33 dated 28.12.2016 under the Control of Pesticides Act No.33 of 1980*). Effective from that date, the use of chlorpyrifos as a pesticide for agriculture and structural termite controls were prohibited in Sri Lanka. Effective from the same date the production, trade and import of chlorpyrifos had all been prohibited.

[Dealers and farmers were given grace periods to finish off the old stock of chlorpyrifos products at the end of the following dates:

Cancellation of registration:	28 December 2016
Stock Clearance at dealers/shops:	28 December 2018
Use-up old stocks by farmers:	No decision

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

Ban of registration by the *Government Extraordinary Gazette* No. 1999/33 dated 28.12.2016 under the Control of Pesticides Act No.33 of 1980.

2.2.3 Date of entry into force of the final regulatory action

28.12.2016

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

All uses of agricultural pest control (include Rice leaf-folder, Rice case worm , Rice stem borer, Stem borer, legume pod borer, Root-eating ants & Structural termite control in construction sites.

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 ☒ Pesticide

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

All formulations containing chlorpyrifos (active ingredients).

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

None/Not applicable

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

The followings documentations/reports were used and referred during the decision-making processes.

1. USEPA Regulatory Report (Human Health Risk Assessment Chlorpyrifos Phase 4, U.S. Environmental Protection Agency Office of Pesticide Programs Health Effects Division (7509C) Deborah C. Smegal, M.P.H., Risk Assessor, June 8, 2000).

Based on the USEPA Regulatory Report review, the Pesticide Technical & Advisory Committee of Sri Lanka during its 28th meeting on 7th May 2004 made a decision to withdraw the recommendation for indoor termite control of all registered chlorpyrifos products. As a result of that, all labels of chlorpyrifos products in Sri Lanka were amended to reflect the decision.

According to the USEPA report, exposure to chlorpyrifos by children has been mitigated in the USA due to increasing susceptibility occurring at high doses in the developmental neurotoxicity.

2. "Exposure and Risk Assessment for Farmers Occupationally Exposed To Chlorpyrifos" by Aponso et al., (2002) Annals of the Sri Lanka Department of Agriculture, 2002, 4: 233-244

The study showed that farmers using chlorpyrifos on cucurbits (grows on trellises) can be exposed to unnecessary high level of chlorpyrifos via dermal exposure. It was revealed that wearing long pant during spraying did not necessarily reduce the exposure. This indicates the high occupational risk of chlorpyrifos to the farmer under use conditions.

3. " Analysis of water for pesticides in two major agricultural areas of the dry zone" by Aponso et al. (2003) Annals of the Sri Lanka Department of Agriculture, 2003, 5: 7-22

The study showed that the farming community in the study area was reported to have clinical symptoms of exposure by 83%, related to acute toxicity, but 21% of the group had confirmed effects related to pesticide exposure. The main symptoms found were dysuria, myalgia & headache.

4. Seasonal Exposure of Fish to Neurotoxic Pesticides in An Intensive Agricultural Catchment, Uma-Oya, Sri Lanka: Linking Contamination and Acetylcholinesterase Inhibition, Sumith et.al (2012). Environmental Toxicology and Chemistry, 31(7), 1501–1510, 2012.

The above study showed that chlorpyrifos, diazinon and carbosulfan had the greatest amount of agricultural application in the agricultural catchment, and they were the dominant pollutants found. Chlorpyrifos and diazinon were detected in both various local fish species studied and sediments, at various concentrations. This study revealed dynamic impact of agricultural pollutants (including chlorpyrifos) on indigenous fish communities & their existence.

5. Menike et al. (2012) showed agricultural catchment scale concern of chlorpyrifos residues. Marasinghe et al. (2014) have shown high exposure risk of farmers after spraying of chlorpyrifos under the conditions of use in Sri Lanka.

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

The following study "Exposure and risk assessment for farmers occupationally exposed to chlorpyrifos" by Aponso et al., (2002) Annals of the Sri Lanka Department of Agriculture, 2002, 4: 233-244 showed that farmers using chlorpyrifos on cucurbits (grows on trellises) can expose to unnecessary residue levels as measured by major metabolite, 3,5,6-trichloro-2-pyridinol (TCP): results indicated that dermal exposure under normal use ranged from 4.8-19.6 microgram/cm2 on exposed skin; the elimination half-life of the urinary TCP metabolite was 31 .2 hr; the calculated hazard quotient of cholinesterase inhibition ranged from 0.8-2.7, and margin of safety ranged from 3.6-14.3 for the farmer. This indicates the high occupational risk of chlorpyrifos to the farmer under use conditions. It was further revealed that the use of long-sleeved shirts had decrease the internal dose of chlorpyrifos (measured as TCP) than wearing short-sleeved shirts; the contrasting difference was that wearing long pants had increase the internal dose (may be due to prolonged exposure).
The following study " Analysis of water for pesticides in two major agricultural areas of the dry zone" by Aponso et al. (2003) Annals of the Sri Lanka Department of Agriculture, 2003, 5: 7-22 showed that the farming community in

the study area was reported to have clinical symptoms of exposure by 83%, related to acute toxicity, but 21% of the group had confirmed effects related to pesticide exposure. The main symptoms found were dysuria, myalgia & headache.

The first review which was done by Pesticide Technical & Advisory Committee (PeTAC) at its 28th meeting held on 07.05.2004; based on the regulatory overview of the USEPA. (Human Health Risk Assessment Chlorpyrifos Phase 4, U.S. Environmental Protection Agency Office of Pesticide Programs Health Effects Division (7509C) Deborah C. Smegal, M.P.H., Risk Assessor, June 8, 2000). According to the report available exposure of chlorpyrifos by children has been mitigated as follows; the use on tomatoes, all indoor residential uses, all outdoor residential uses (except limited public health uses), all indoor non-residential uses were eliminated.
Accordingly, as a preliminary step, the PeTAC at its 29th meeting held on 12.07.2004 decided to prohibit indoor residential uses on termite control in Sri Lanka. All labelling was amended to reflect the above decision by 2004. During the progressive review of use, the PeTAC at its 30th meeting held on 07.09.2004 decided to ban post-construction use as a termiticide while taking further attention to assess the risks associated for possible phase out from agriculture under the conditions of use by farmers.

Expected effect of the final regulatory action

Significant health risk reduction for farmers; being a high-volume pesticide, there will be significant reduction of chemicals & environmental load in consequent to this decision.

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

The following study by Sumith et al. (2012) showed that chlorpyrifos, diazinon and carbosulfan had the greatest amount of agricultural application in the agricultural catchment, and chlorpyrifos, diazinon, and carbofuran were the dominant pollutants found. Chlorpyrifos and diazinon were detected in sediments at concentrations of 16.36 mg/kg (dry wt.). The study showed that 73% inhibition in muscle AChE activity in *Garra ceylonensis* was associated with intense pesticide exposure months. The AChE inhibition more than 70% in *G. ceylonensis* eyes in both Yala (76%) and Maha (72.5%) seasons indicates particular sensitivity of eye tissue to inhibitors. The less dramatic AChE inhibition in the eye tissues in *Devario malabaricus* and *Rasbora daniconius* in

both seasons indicates exemplary protective capacity of muscle AChE in fish. The highest inhibition of AChE (up to 60% in brain and up to 56% in muscle AChE activity in *R. daniconius* and up to 47.8% in brain and up to 64.6% in muscle AChE activity in *D. malabaricus*) occurred during the intense pesticide exposure months. This study revealed dynamic impact of agricultural pollutants (including chlorpyrifos) on indigenous fish communities & their existence. Ref. Sumith et al. (2012). SEASONAL EXPOSURE OF FISH TO NEUROTOXIC PESTICIDES IN AN INTENSIVE AGRICULTURAL CATCHMENT, UMA-OYA, SRI LANKA: LINKING CONTAMINATION AND ACETYLCHOLINE-STERASE INHIBITION. Environmental Toxicology and Chemistry, 31 (7), 1 501-1 51 0, 2012. (risk assessment 2)

Expected effect of the final regulatory action

Less chemical burden to the environmental.

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	None	
imported	341	2011
	251	2012
	97	2013
exported	None	
used		

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

Similar human health and environmental risk associated with the use of chlorpyrifos are anticipated in other states and regions, in particular under the similar cultural and agro-climatic conditions of developing countries.

2.5.3 Other relevant information that may cover:

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

Manuweera et al (2008) showed in their review "Do targeted bans of insecticides to prevent deaths from self-poisoning result in reduced agricultural output? Environ Health Perspect. 2008; 1 16:492—495" that during the period of 1 980-2005, they found no good evidence that a pesticide ban necessarily results in reduced output or increased costs to the farmer. Overall, they found no significant change in food production during the 1990s, and no change in the rate of increase in production costs or yield that could be attributed to the pesticide restrictions. During the focussed study period, several highly hazardous pesticides of WHO Class I Organophosphates (Parathion, Monocrotophos, Methamidophos) & Endosulfan (Organochorine) were banned in Sri Lanka.

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

The following chemical alternatives were considered sufficient for all uses of chlorpyrifos:

Rice leaf-folder, Rice case worm - Chlorfluazuron 5%, Methoxyfenozide 24%, Flubendiamide 24%, Novaluron 1 0%, Chromafenozide 5%

Rice stem borer - Thiocyclam 4%, Chlorantraniliprole 20%, Thiamethoxam 20%

Stem borer, legume pod borer - Novaluron 10%, Chlorfluazuron 5%, Etofenprox 10%

Root-eating ants - Diazinon 5%

Integrated Pest Management (IPM) concept & its practices have been practised as the government policy over the years.

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

Some studies (Eddleston et al. 2005) showed that chlorpyrifos formulations were intensively misused for suicides e.g. 17.78% of all cases (which was the highest), and corresponding case fatality rate (CFR) at 7.73% between 20022005 (medium rate compared to some of the other organophosphates, like dimethoate

& fenthion).

Ref. Eddleston et al. Differences between organophosphorus insecticides in human self-poisoning: a prospective cohort study. Lancet, 2005, 366: 1452-9

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

Traditional chlorpyrifos manufacturing in developing world impact highest risk of contaminants such as sulfotepp as claimed by original manufacturers like M/S Dow Agro Sciences. The typical manufacturing process by generics has shown that following typical impurity specifications: e.g.

Chlorpyrifos content 94% (w/w) min.

Water content 0.04% (w/w) max.

O,O,O,O-diethyl phosphoro chloro thioate 1 .0% (w/w) max.

O,O,O,O-tetraethyl dithio phosphate (sulfotepp) 0.3% (w/w) max.

Solvent (xylene) 5.0% (w/w) max.

phosalone 0.1 % (w/w) max.

Chlorpyrifos technical manufacturing can be done by 2 processes:

1. SYMTET Route

2. TCAC Route

The differences in two processes have implicated a contrasting impurity profiles because SYM TET route produces >97% (high pure) & low level of sulfotepp.

Whereas, TCAC route gives low purity (90%) & high sulfotepp content i.e. >0.3% The TCAC manufacturers follow solvent crystallization to make 90% technical products to make them at or above 94-97% pure & resulting follow up residue (mother liquor or reject bottom) may end up with a solution of Chlorpyrifos 51 % with a load of impurities. Generic manufacturers may re-formulate bottom reject to 20% EC formulations with lots of impurity hazards & high risks of consumers/farmers.

Sulfotepp itself is an insecticide belongs to WHO toxicity Class I and presence of impurities may enhance toxicity of final formulations to a considerable degree.

The major reasons for regulatory concerns over chlorpyrifos include;

- The risk of certain impurities with hazardous profiles (some of which are potentially genotoxic) result from the use of chlorpyrifos, which leads to concerns about the exposure of consumers and the possible risk of environmental contamination.
- Impurities, of which at least one is extremely hazardous (sulfotepp), have been implicated in the active substance as sold on the market (technical material) at levels raising concerns (as evidenced by original

manufacturers).

- Residue intake by sensitive groups such as children might exceed the acceptable daily intake and that consumption of a number of crops might pose an acute risk to children and adults.
- The risk evaluation raised concerns regarding a possible risk to groundwater due to potential contamination by the parent substance and a number of relevant metabolites (e.g. TCP).
- Concerns remained regarding the risk for aquatic organisms, bees and earthworms.
- Banning is expected to lead to a significant decrease in the quantity of the chemical used, resulting in a significant reduction of risk to human health and the environment.
- Non-compliance with recommended measures for the safe use of chlorpyrifos by users.
- The low rate of utilization of protective equipment by growers/applicators.
- The existence of alternatives to the use of chlorpyrifos.

(risk assessment 3)

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	II

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

Physical Properties:

Specific gravity: 1.398 at 43 degrees C

H_2O solubility: low; 2 ppm at 35 degrees C; 2 ppm water at 2 degrees C

Solubility in other solvents: In benzene 790, acetone 650, chloroform 630, carbon disulfide 590, diethyl ether 510, xylene 645, methylene chloride 714, isooctane 79, methanol 45 (all in g/100 g at 25 degrees C)

Melting Point:41 .5 to 44 degrees C (106 to 108 degrees F)

Flash point: greater than 200 degrees F

Vapor pressure: 1 .87 x 10 to the minus 5 power mm Hg at 25 degrees C

Kow: 66,000 at 23 degrees C log Kow = 4.7

Koc: 6070 g/ml, • mug pc = 128,000 (20); 13,490

Chemical Class/Use: Organophosphate insecticide

Reference

EXTOXNET 9/93

3.2.2 Description of toxicological properties of the chemical

The oral LD_{50} for chlorpyrifos in rats is 82 to 270 milligrams per kilogram (mg/kg). This indicates that it takes 82 to 270 mg of chlorpyrifos for each kg of body weight to kill 50 percent of the experimental animals tested. The LD_{50} for chlorpyrifos in mice is 60 mg/kg, 1000 mg/kg in rabbits, 32 mg/kg in chickens, 500 to 504 mg/kg in guinea pigs, and 800 mg/kg in sheep. The dermal LD_{50} in rats is greater than 2000 mg/kg, and 1000 to 2000 mg/kg in rabbits.

The lethal concentration fifty, or LC_{50}, is that concentration of a chemical in air or water that kills half of the experimental animals exposed to it for a set time period

Reference

EXTOXNET 9/93

3.2.3 Description of ecotoxicological properties of the chemical

Effects on Birds;

Chlorpyrifos is moderately to very highly toxic to birds. Its oral LD_{50} in pheasants is 8.41 mg/kg, 112 mg/kg in mallard ducks, 21.0 mg/kg in house sparrows, and 32 mg/kg in chickens. The LD_{50} for a granular product (15G) in bobwhite quail is 108

mg/kg.

Two one-generation reproductive studies resulted in NOELs of 125 ppm (the highest dose tested) for bobwhite quail and 25 ppm for mallard ducks. At 125 ppm, mallards laid significantly fewer eggs.

There was no evidence of changes in weight gain, or in the number, weight and quality of eggs produced by hens fed dietary levels of 50 parts per million (ppm), or about 5.12 mg/kg, of chlorpyrifos. Bird deaths have not been observed in repeated mosquito control efforts.

Effects on Aquatic Organisms;

Chlorpyrifos is very highly toxic to freshwater fish, aquatic invertebrates and estuarine and marine organisms. Cholinesterase inhibition was observed in acute toxicity tests of fish exposed to very low concentrations of this insecticide. Precautions and restrictions are being imposed by EPA to decrease potential hazards. Application of concentrations as low as 0.01 pounds of active ingredient per acre may cause fish and aquatic invertebrate deaths.

Chlorpyrifos accumulates in the tissues of aquatic organisms. Studies involving continuous exposure of fish during the embryonic through fry stages have shown BCF values of 58 to 5100.

Chlorpyrifos toxicity to fish may be related to water temperature. Its 96-hour LC_{50} varied in rainbow trout from 7.1 micrograms per liter (µg/l) to 51 µg/l at three different temperatures. The 24-hour LC_{50} for chlorpyrifos in goldfish is 180 µg/l, and less than 1,000 µg/l in mosquito fish. The 96-hour LC_{50} for chlorpyrifos in mature rainbow trout is 9 µg/l, 98 µg/l in lake trout, 806 µg/l in goldfish, 10 µg/l in bluegill, and 331.7 µg/l in fathead minnow.

Due to its high acute toxicity and its persistence in sediments, chlorpyrifos may represent a hazard to sea bottom dwellers. Smaller organisms appear to be more sensitive than larger ones.

When fathead minnows were exposed to Dursban for a 200-day period during which they reproduced, the first generation of offspring had decreased survival and growth, as well as a significant number of deformities. This occurred at approximately 2.68 microgram per liter (µg/l) exposure for a 30 day-period.

Reference

EXTOXNET 9/93

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Office of the Registrar of Pesticides
Address	1056, Gatambe, Peradeniya 20400, Sri Lanka
Name of person in charge	Dr. J.A. Sumith
Position of person in charge	Registrar of Pesticides
Telephone	+94 81 2388076
Telefax	+94 81 2388135
E-mail address	mail2me.sumith@yahoo.com

Date, signature of DNA and official seal: 27.09.2009

DR. J.A. SUMITH
Registrar of Pesticides
Department of Agriculture
P.O. Box. 49, Getambe
Peradeniya

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

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:

European Union Member States are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Chlorpyrifos
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	*O*,*O*-diethyl *O*-3,5,6-trichloro-2-pyridyl phosphorothioate
1.3	**Trade names and names of preparations**	Pyrinex 250 CS, Pyrinex, EF-1551 EC, RIMI 101 RB, Chlorpyrifos-ethyl 5G GR, SAP250 CS, Dursban, OMS 0971, Lorsban, Brodan, Killmaster, Suscon, Coroban, Terial, Danusban, Durmet, Eradex

1.4 Code numbers

1.4.1	CAS number	2921-88-2
1.4.2	Harmonized System customs code	2933.39
1.4.3	Other numbers (specify the numbering system)	CIPAC: 221 EC: 220-864-4 Combined Nomenclature (CN) code of the European Union: 2933 39 99

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

It is prohibited to place on the market or use plant protection products containing chlorpyrifos because chlorpyrifos is not approved as an active substance under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

EU Member States had to withdraw all authorisations for plant protection products containing chlorpyrifos as active substance by 16 February 2020 at the latest. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos is prohibited as of 16 April 2020.

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

Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Official Journal of the European Union L 7, 13.1.2020, p. 14)

http://data.europa.eu/eli/reg_impl/2020/18/oj

2.2.3 Date of entry into force of the final regulatory action

Complete entry into force of all provisions of Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos was on 16 January 2020.

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

Acaricide, insecticide

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

Use or uses prohibited by the final regulatory action

Not relevant

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

Not relevant

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

All applications as a plant protection product

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

Not relevant

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

The evaluation of the active substance chlorpyrifos, following the submission of an application to renew its approval for the use in plant protection products, was made in the context of the work provided for in Articles 7 to 13 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

A Member State was designated to undertake a hazard and risk assessment based on the information submitted by the applicant and to establish a draft assessment report, which was subject to European Union peer review during which the European Food Safety Authority (EFSA) undertook consultations with experts from Member States as well as with the applicant.

The risk evaluation was done inter alia by means of simulation models (e.g. FOCUS groundwater and surface water models) that have been developed for the EU risk evaluation and/or with data generated in the EU in order to represent the conditions that prevail in the EU. Detailed information on the risk evaluation can also be found in the respective guidance produced by EFSA.

In April 2019, EFSA convened an expert meeting to discuss certain elements related to mammalian toxicology and human health. The results of the expert discussions led the European Commission to send, on 1 July 2019, a mandate to EFSA asking for a statement on the main findings of the assessment related to human health, and to indicate whether chlorpyrifos can be expected to meet the approval criteria that are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.

On 31 July 2019, EFSA sent to the European Commission a statement on the outcomes of the risk assessment for human health for chlorpyrifos, in which it took the view that the active substance cannot be expected to meet the approval criteria.

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report to the Standing Committee on Plants, Animals, Food and Feed, for examination on 22 October 2019. The draft renewal report was finalised in the meeting of the Standing Committee on 6 December 2019.

The PAFF Committee concluded that no plant protection product containing the active substance chlorpyrifos is expected to satisfy in general the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) 546/2011. Therefore, chlorpyrifos should not be approved in accordance with Regulation (EC) No 1107/2009.

Final Renewal report for the active substance chlorpyrifos finalised by the Standing Committee on Plants, Animals, Food and Feed on 6 December 2019 in view of the non-renewal of the approval of chlorpyrifos as an active substance in accordance with Regulation (EC) No 1107/20091 (SANTE/11938/2019 Rev 1).

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=548

EFSA, 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos. EFSA Journal 2019;17(5):5809.

https://doi.org/10.2903/j. efsa.2019.5809

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

The overall conclusion of the assessment of chlorpyrifos in relation to impacts on human health, based on the information available and the proposed conditions of use, is that the approval criteria as set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 are not satisfied as concerns were identified with regards to:

- The genotoxic potential of chlorpyrifos, which cannot be ruled out based on the information available - positive findings were found in an in vitro chromosome aberration study and two in vitro unscheduled DNA synthesis assays; in vivo positive findings were found in open literature on chromosome aberration and on DNA damage

caused through oxidative stress or by topoisomerase II inhibition which is considered a molecular initiating event for infant leukaemia. Consequently, health-based reference values cannot be established for chlorpyrifos and the dietary and non-dietary risk assessments cannot be conducted.

- Developmental neurotoxicity (DNT) - effects were observed in the available study on developmental neurotoxicity in rats (adverse effects were seen at the lowest dose tested in rats and a no observed adverse effects level 'NOAEL' could not be established) and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children.
- Based on the evidence for DNT, experts during the peer review suggested that a classification of chlorpyrifos as toxic for reproduction, category 1B, H360D 'May damage the unborn child', in accordance with the criteria set out in Commission Regulation (EC) No 1272/2008 would be appropriate.

Expected effect of the final regulatory action

Reduction of risk for human health from the use of plant protection products containing chlorpyrifos

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

As regards the environmental risk assessment it should be noted that, based on the human health risk assessment, it has not been established, with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The environmental risk assessment, although not finalised, cannot alter this conclusion since the approval criteria related to the effects on human health are not satisfied and should therefore not delay further the decision- making on the renewal of the approval of the active substance.

Expected effect of the final regulatory action

Not relevant

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	no information	
imported	no information	
exported	Exports to 22 countries were notified in 2022	2022
used	no information	

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

Similar human health problems are likely to be encountered in other regions where the substance is used, particularly in developing countries.

2.5.3 Other relevant information that may cover:

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

Not relevant

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

Not relevant

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

Not relevant

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

Not relevant

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**

Other classification systems e.g. EU, USEPA	Hazard class
Classification of the EU according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council.	Acute Tox. 3 * - H301 - Toxic if swallowed Aquatic Acute 1 - H400 - Very toxic to aquatic life (M=10000) Aquatic Chronic 1 - H410 - Very toxic to aquatic life with long lasting effects * The manufacturers or importers must apply at least the minimum classification, but must classify in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for the classification in the more severe category (see Annex VI, Section 1.2.1 of the CLP Regulation.)

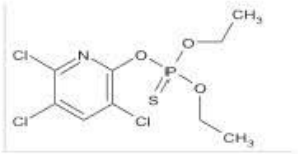
3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Molecular formula: $C_9H_{11}Cl_3NO_3PS$

Molecular weight: 350.6 g/mol

Structural formula:



Minimum purity of the active substance as manufactured: 970 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured:

O,O,O',O'-tetraethyl dithiopyrophosphate < 3.0 g/kg (Sulfotep)

Acetone insolubles < 5.0 g/kg

Melting point: 41-42 °C (purity 97-99 %)

Boiling point: Decomposes before boiling. Thermal decomposition 170-180 °C.

Physical state: Tan, crystalline solid. Munsell colour notation 2.5Y 7/4 (purity 94 %). Mild mercaptan odour (purity 99.6%)

Relative density: 1.51 (purity 98.1 %)

Vapour pressure: $3.35 \cdot 10^{-3}$ Pa at 25° C (purity 99.8 %); $1.43 \cdot 10^{-3}$ Pa at 20°C (purity 99.8%)

Henry's law constant: 0.478 $Pa \cdot m^3 \cdot mol^{-1}$

Solubility in water: 1.05 mg/l at 20° C in unbuffered solution. No pH dependency reported

Solubility in organic solvents (purity 99.9 %; 20° C):

Hexane 77.4 g/l

Toluene: > 4000 g/l
Dichloromethane: >4000 g/l
Methanol: 290 g/l
Acetone: > 4000 g/l
Ethyl acetate: > 4000 g/l

Partition co-efficient n-octanol/water (log Pow): 4.7 (20° C, neutral pH)

UV/VIS absorption (max.):

No absorption maximum above 290 nm but there is significant absorption (ε > 10).

λ_{max} = 202.7 nm, 230 nm and 283.4 nm

Reference

European Commission (2005): Review report for the active substance chlorpyrifos. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 June 2005 in view of the inclusion of chlorpyrifos in Annex I of Directive 91/414/EEC (SANCO/3059/99 - rev. 1.5)

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=548

3.2.2 Description of toxicological properties of the chemical

Acute toxicity:

Rat LD_{50} oral: 66–223 mg/kg bw
Rat LD_{50} dermal: 1,250–2,000 mg/kg bw

Short term toxicity

Relevant oral NOAEC:
90-day, rat: 0.1 mg/kg bw per day (Nervous system/RBC AChE inhibition)
90-day, mouse: 1 mg/kg bw per day (RBC and brain AChE inhibition)
90-day & 2-year, dog: 0.1 mg/kg bw per day (RBC AChE inhibition)

Genotoxicity

In vitro studies:

Bacterial gene mutation tests: 6 negative
Mammalian gene mutation tests: 3 negative

Chromosome aberration tests: 2 negative (cultured rat lymphocytes and Chinese hamster ovary cells) – with some reservations; 1 positive (mouse spleen cells) – with some reservations; 1 negative (human peripheral blood lymphocytes) – acceptable

Unscheduled DNA synthesis (UDS):

Primary culture of rat hepatocytes: negative – with some reservations
Rec-assay with *Bacillus subtilis*: negative – supportive

Microtitration SOS chromotest: negative – supportive

Sister chromatid exchange assay: negative – supportive with some reservations

Cytokinetic and cytogenetic effect on human lymphoid cells: positive – supportive with some reservations

ICR mouse hepatocytes: dose-related increase in DNA damage (in the form of strand breaks) was seen in the comet assay, but UDS was not affected. DNA hypomethylation was seen at all concentrations – with some reservations

In vivo studies:

Micronucleus tests: 3 negative (supportive with reservations), 1 negative (supportive), 1 negative (acceptable)

DNA damage (mainly clastogenicity) reported in the public literature:
– for chromosomal aberrations
– for DNA damage in in vivo Comet assays

Potential for genotoxicity:

Chlorpyrifos did not induce gene mutation nor clastogenic effects in regulatory studies.

Regarding DNA damage, positive results in Comet assay were observed *in vitro* and *in vivo* and (well-documented publications)

DNA damaging potential cannot be ruled out for chlorpyrifos

Reproductive toxicity

Developmental toxicity

Relevant maternal NOAEL:
Rat: 0.1 mg/kg bw per day (RBC AChE inhibition)
Rabbit: 81 mg/kg bw per day (Increased post-implantation loss at maternal toxic doses)
Mouse: 1 mg/kg bw per day (RBC AChE inhibition)

Relevant developmental NOAEL:
Rat: 2.5 mg/kg bw per day (Increased post-implantation loss at maternal toxic doses)
Rabbit: 81 mg/kg bw per day (decreased foetal size and increased post-implantation loss)
Mouse: 1 mg/kg bw per day (reduced AChE activity)

Neurotoxicity

Developmental neurotoxicity
Maternal LOAEL= 0.3 mg/kg bw per day (RBC AChE inhibition in rat)

Developmental neurotoxicity LOAEL= 0.3 mg/kg bw per day, based on reduction in cerebellum height – that could not be explained by the maternal AChE inhibition

Epidemiological evidence showed an association between chlorpyrifos exposure during development and neurodevelopmental outcomes. DNT potential of chlorpyrifos cannot be dismissed on the basis of the evaluation of the DNT studies provided in the RAR, the epidemiological evidence and analysis of the overall literature (in vivo, in vitro and human data)

Summary

Acceptable Daily Intake (ADI): open

Acceptable Operator Exposure Level (AOEL): open

Acute acceptable operator exposure level (AAOEL): open

Acute Reference Dose (ARfD): open

Reference values could not be derived since a genotoxic potential could not be excluded for chlorpyrifos.

Reference

EFSA, 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos. EFSA Journal 2019;17(5):5809.

https://doi.org/10.2903/j. efsa.2019.5809

3.2.3 Description of ecotoxicological properties of the chemical

Toxicity to birds:
Coturnix coturnix
LD_{50} (Acute) = 13.3 mg/kg a.s. bw

Colinus virginianus
LD_{50} (Acute) = 39.24 mg/kg a.s. bw

Toxicity data for aquatic species
Fish
Onchorhynchus mykiss
LC_{50} (96 h flow through): 8.0 µg a.s./L

Aquatic invertebrate
Daphnia magna
LC_{50} (48 h flow through): 0.1 µg a.s./L

Toxicity to bees *(Apis mellifera)*
Acute oral toxicity LD_{50}: 0.15 µg/bee
Acute contact toxicity LD_{50}: 0.068 µg a.s./bee
Acute larval oral toxicity NOED: 0.018 µg a.s./larva

Toxicity to other non-target arthropod species
Aphidius colemani (Hymenoptera: Braconidae)
Tier 1 dose-response; glass plates
LR_{50}< 1 ppm (< 0.2 g a.s./ha)

Typhlodromus pyri (Acari: Phytoseiidae) proto-nymphs
Tier 2 dose-response. Initial residues on bean leaf disc.
ER_{50}: 134.7 g a.s./ha

Reference

European Commission (2017): Draft Renewal Assessment Report (RAR) on the active substance chlorpyrifos prepared by the rapporteur Member State Spain in the framework of Commission Implementing Regulation (EU) No 844/2012.

https://www.efsa.europa.eu/en/consultations/call/171018-0

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	European Commission
Address	B-1049 Brussels Belgium
Name of person in charge	Juergen Helbig
Position of person in charge	Team Leader International Chemicals Policy
Telephone	+322 298 8521
Telefax	+322 296 7617
E-mail address	Juergen.Helbig@ec.europa.eu

Date, signature of DNA and official seal: __19.10.2022___ ___

EUROPEAN COMMISSION
DG ENVIRONMENT

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

UNEP

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

Country: TURKEY

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Chlorpyrifos-ethyl
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	diethoxy-sulfanylidene-(3,5,6-trichloropyridin-2-yl)oxy-λ5-phosphane
1.3	**Trade names and names of preparations**	N/A
1.4	**Code numbers**	
1.4.1	CAS number	2921-88-2
1.4.2	Harmonized System customs code	29333990
1.4.3	Other numbers (specify the numbering system)	EC No. 220-864-4

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

Chlorpyrifos-ethyl is not registered as plant protection product in the country. By the Ministry of Agriculture, production import and use of Chlorpyrifos-ethyl were banned in 2016.

The general framework for the prohibition and restriction of plant protection products, including pesticides, for the purpose of protecting human health and the environment is determined by the Veterinary Services, Plant Health, Food and Feed Law.

According to the By-law on Licensing and Placing on the Market of Plant Protection Products enforced in accordance with above-mentioned Law, it is forbidden to manufacture, use and placing on the market of unlicensed plant protection products within the borders of the country.

In this context, in order to protect human health and the environment the Ministry of Agriculture and Forestry prohibits hazardous active substances used in plant protection products. The prohibition process is done by not granting a license to hazardous active substances for manufacture, use and placing on the market or canceling the existing license.

Once the Ministry of Agriculture and Forestry prohibits a hazardous active

substance, all Provincial Directorates of the Ministry, importers and manufacturers are informed by Ministerial Circulars.

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

By-law on Licensing and Placing on the Market of Plant Protection Products (Official Gazette no. 30235 dated 09.11.2017)

The By-law and the list of prohibited hazardous active substances can be found in the links below;

- Consolidated version in Turkish:
  https://kms.kaysis.gov.tr/Home/Goster/137422
- The list of prohibited hazardous active substances in Turkish:
  https://www.tarimorman.gov.tr/GKGM/Belgeler/DB_Bitki_Koruma_Urunleri/yasakli_aktifler.xls

2.2.3 Date of entry into force of the final regulatory action

08/04/2016

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

Data on uses of the chemical prior the FRA in the country is not available.

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 ☒ Pesticide

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

All uses, formulations and applications as a plant protection product have been prohibited.

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	N/A	N/A
imported	N/A	N/A
exported	N/A	N/A
used	N/A	N/A

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

The purpose (art. 1) of the Veterinary Services, Plant Health, Food and Feed Law is to protect and ensure food and feed safety, public health, plant and animal health, animal breeding and welfare, taking into account consumer interests and the protection of the environment. Furthermore, Turkey follows the international chemicals management agreements/legislations and also since Turkey is still a candidate country to EU, Turkey also follows the EU approach on chemicals for restriction, prohibition decisions and regulatory actions which are relevant to protection of human health and 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 **e.g. WHO, IARC, etc.**	**Hazard class**
GHS Hazard Statements	H301: Toxic if swallowed [Danger Acute toxicity, oral] H400: Very toxic to aquatic life [Warning Hazardous to the aquatic environment, acute hazard] H410: Very toxic to aquatic life with long lasting effects [Warning Hazardous to the aquatic environment, long-term hazard]
WHO (a.i.)	II

Other classification systems e.g. EU, USEPA	Hazard class
USEPA	Group E Evidence of Non-carcinogenicity for Humans

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Physical State: COLOURLESS-TO-WHITE CRYSTALS WITH CHARACTERISTIC ODOUR

Formula: $C_9H_{11}Cl_3NO_3PS$

Molecular mass: 350.6

Boiling point: No boiling point at normal pressure; decomposes at 160°C

Melting point: 41-42°C

Density: 1.4 g/cm³

Solubility in water, mg/l at 25°C: 1.4 (very poor)

Vapour pressure, Pa at 25°C: 0.0024

Octanol/water partition coefficient as log Pow: 4.96

Reference

http://www.inchem.org/documents/icsc/icsc/eics0851.htm

3.2.2 Description of toxicological properties of the chemical

LD50 oral rat: 82 mg/kg

LD50 dermal rabbit: 2000 mg/kg

LC50 inhalation rat: > 0,2 mg/l/4 h

Acute oral (LD_{50}, mg/kg)Acute oral toxicity as LD_{50} in mg of active ingredient per kg of animal body weightrats 135 (female), rats 163 (male), mice 300, guinea pigs 504, rabbits 1000–2000

Acute inhalation (LC_{50}, mg/L)Acute inhalation toxicity as LC_{50} per litre of active ingredient per kg of animal body weightrats >0.2 (4 h)

Acute percutaneous (LD_{50}, mg/kg)Acute percutaneous toxicity as LD_{50} in mg of active ingredient per kg of animal body weightrats >2000, rabbits >5000 (tech.)

Skin irritation Slight irritant (rabbits)

Eye irritation Slight irritant (rabbits)

Skin sensitisation Not a sensitiser (guinea pigs)

NOEL No observed effect level: the highest dose in an animal toxicology study at which no biologically significant increase in frequency or severity of an effect is observed (see Background Information: Guide)(2 y) for rats 0.1 mg/kg b.w.daily; (18 mo) for mice 0.7 mg/kg b.w.daily; (2 y) for dogs 0.1 mg/kg b.w. daily. Acute oral NOEL for humans 1.0 mg/kg b.w. daily; acute dermal NOEL for humans 5.0 mg/kg b.w. daily.

ADI-RfD Acceptable daily intake and reference dose. Values are ADIs unless otherwise indicated (see Background Information: Guide)(JMPR) ADI 0.01, aRfD 0.1 mg/kg b.w. [2006]; (EFSA) ADI 0.001, aRfD 0.005, AOEL 0.001 mg/kg b.w. [2014]; (EPA) aRfD 0.005 mg/kg b.w., cRfD 0.0003 mg/kg b.w. [2001].

Reference

https://gestis-database.dguv.de/data?name=510119 BCPC Pesticide Manual Online, 2021

3.2.3 Description of ecotoxicological properties of the chemical

LC50; Species: Coturnix (Japanese quail) oral 293 ppm for 5 days (95% confidence limit 112-767 ppm) /Technical material, 97% active ingredient/ LD50; Species: Coturnix coturnix (Japanese quail) 2.5 month old males; oral 15.9 mg/kg (95% confidence limit: 10.5-24.0 mg/kg) /purity 94.5%/ LD50; Species: Coturnix coturnix (Japanese quail) 2-month old males; oral 17.8 mg/kg (95% confidence limit: 15.0-21.2 mg/kg) /purity 94.5%/ LD50; Species: Anas platyrhynchos (Mallard duck) female; oral 75.6 mg/kg (95% confidence limit: 35.4-161 mg/kg) /purity 99%/ LD50; Species: Anas platyrhynchos (Mallard) ducklings, 15-19 days old, male and female; oral 167 mg/kg (95% confidence limit 11.5-1089 mg/kg) /purity 99%/

Reference

https://pubchem.ncbi.nlm.nih.gov/compound/2730#section=Ecotoxicity-Values

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Ministry of Environment and Urbanization
Address	Mustafa Kemal Mahallesi Eskisehir Devlet Yolu (Dumlupinar Bulvari) 9, Km. No: 278 Cankaya, Ankara 06530 Turkey
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Date, signature of DNA and official seal: _____