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

Chemical Review Committee
Eighteenth meeting
Rome, 19–23 September 2022
Item 5 (c) (x) of the provisional agenda*

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

Thiodicarb: notifications of final regulatory action

Note by the Secretariat

I. Introduction

1. At its seventeenth meeting, the Chemical Review Committee considered notifications of final regulatory action for thiodicarb submitted by Mozambique and the European Union,[1] as set out in document UNEP/FAO/RC/CRC.17/9, along with supporting information set out in documents UNEP/FAO/RC/CRC.17/INF/20 and UNEP/FAO/RC/CRC.17/INF/21. The Committee agreed that the notification from the European Union met all the criteria of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and adopted a rationale for its conclusion, as set out in the annex to decision CRC-17/3.[2] With regard to the notification from Mozambique, the Committee was unable to reach consensus on whether it met the criteria of Annex II, specifically the criterion of paragraph (b) (iii), and agreed to continue its consideration at the eighteenth meeting of the Committee. The text of a draft rationale for the conclusion by the Chemical Review Committee on the notification of final regulatory action submitted by Mozambique in respect of thiodicarb in the pesticide category, which was under consideration by the contact group on thiodicarb established at the seventeenth meeting of the Committee, is set out in document UNEP/FAO/RC/CRC.17/INF/35, as the draft rationale stood when the contact group adjourned its work, for further consideration by the Committee at its eighteenth meeting.

2. The Secretariat has since received an additional notification of final regulatory action for thiodicarb that meets the requirements of Annex I to the Convention, from a Party in the Europe prior informed consent region: Türkiye (pesticide).[3]

3. The notifications from Mozambique and Türkiye are set out in the annex to the present note. The supporting documentation provided by Türkiye is set out in document UNEP/FAO/RC/CRC.18/INF/30.

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

[1] In accordance with the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community (*Official Journal of the European Union*, C 306, 17 Dec. 2007), the term "Community" is replaced by "Union", with the European Union taking the place of the Community and being its legal successor.

[2] UNEP/FAO/RC/CRC.17/10, annex I.

[3] See PIC Circular LIII, June 2021.

II. Proposed action

4. The Committee may wish:

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

(b) If it concludes that the notification from Mozambique 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 thiodicarb.

Annex

Notifications of final regulatory action for thiodicarb

A. Notification of final regulatory action for thiodicarb in the pesticide category submitted by Mozambique

B. Notification of final regulatory action for thiodicarb 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

UNEP

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

Country: Mozambique

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Thiodicarb
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	3,7,9,13-tetramethyl-5,11-dioxa-2,8,14-trithia-4,7,9,12-tetra-azapentadeca3,12-diene-6,10-dione
1.3	**Trade names and names of preparations**	Larvin 37,5% SC
1.4	**Code numbers**	
1.4.1	CAS number	59669-26-0
1.4.2	Harmonized System customs code	380891
1.4.3	Other numbers (specify the numbering system)	261-848-7 (EC)

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 the decision Nr 001/DNSA/2014 thiodicarb was banned by the National Directorate of Agrarian Services from further import and use in Mozambique. The ban of all uses and the cancellation of the products containing thiodicarb was decided due to the toxic nature and hazardous properties of this active substance which combined with the improper use in the country due to the local specific conditions of use can damage human health. The decision to ban the registration of thiodicarb was taken as the last step of the project for risk reduction of highly hazardous pesticides which identified highly hazardous pesticides that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others) cancelation of registrations and consequent ban and non-approval for their use in Mozambique was approved.

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

Deliberacao Nr. 001/DNSA/2014 by the National Directorate of Agriculture and Agrarian Services (The Pesticide Register Authority).

2.2.3 Date of entry into force of the final regulatory action

15/07/2014

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

Thiodicarb has been registered as insecticide with trade names of Larvin 37, 5% SC to be used on cotton.

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

Use or uses prohibited by the final regulatory action

N/A

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

N/A

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

Ban all formulations and for all uses.

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

None

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

Project document EP/MOZ/101/UEP – Reducing risk of Highly Hazardous pesticides in Mozambique

- Come A.M. & van der Valk H., 2014. Step 1 – Shortlisting highly hazardous pesticides Consultancy report undertaken under the Project EP/MOZ/101/UEP – Reducing Risks of Highly Hazardous Pesticides in Mozambique.
- Come A.M.; Dona L.L.; Mancini F. & van der Valk H., 2014. Step 2 – Survey of pesticide use practices in selected cropping systems
- FAO/WHO (2008) Report of the 2nd Joint Meeting on Pesticide Management and the 4th Session of the FAO Panel of Experts on Pesticide Management. 6-8 October 2008, Geneva. Food and Agriculture Organization of the United Nations, Rome & World Health Organization, Geneva.

http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Report.pdf

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

A project entitled Reducing Risks of Highly Hazardous Pesticides (HHPs) in Mozambique was initiated by the Government of Mozambique with the objective to reduce the greatest risks associated with pesticide use in the country. The ultimate goal was to develop and implement an "HHP Risk Reduction Action Plan" for the most dangerous pesticides and use situations, resulting over time in the implementation of a variety of risk reduction measures based on a review of use conditions.

In the first step of the project, a review of all the pesticides registered in Mozambique was carried out and a shortlist of highly hazardous pesticides was established. This shortlist was based on an assessment of the hazards of the pesticides, based on criteria established by the FAO/WHO Joint Meeting on Pesticide Management (JMPM) (FAO/WHO, 2008).

During the second step of the project, a use survey was carried out in selected regions and cropping systems in Mozambique. The main goal of the survey was to identify the conditions under which pesticides are being used in the country and their contribution to potential risks for human health and the environment.

The third step of the project consisted of a stakeholder consultation to further discuss the use and risks of highly hazardous pesticides in Mozambique and fine-tune the shortlist based on the survey results and the expertise and experience of stakeholders.

As result, a short list of HHPs, including "coming close" to HHPs, which were used in the country, was established.
Thiodicarb 375 g/l (37,5%) SC pesticide formulation was on the short list as a pesticide "coming close" to HHPs based on the below indicated criteria:

- For liquid formulations: pesticide products with an acute oral LD50< 200 mg/kg or an acute dermal LD50< 400 mg/kg (note that these are the Class Ib limits in the previous version of the WHO Classification (WHO, 2005).

All pesticide formulations registered in Mozambique were classified using the oral and dermal LD50 value of the formulation, as provided in the registration dossier. LD50 values for the formulation were available or could be estimated for all registered pesticide products except for three microbial pesticides and one citronella oil (i.e. > 99% of the total).

Thiodicarb 375 g/l (37,5%) SC pesticide formulation, which was registered in Mozambique, was Class II of WHO Classification, but very close to Class Ib (Come A.M. & van der Valk H., 2014).

The a.i. was registered in US, but was banned in the European Union for human health and environment reasons.

During the second phase of the project field surveys on the pesticide use and exposure were carried out.

The surveys (325 subsistence farmers interviewed) revealed that most of the farmers applied pesticides (95%), and that the conditions of use were likely to result in undue (excessive) exposure. Half of the farmers interviewed never received any training on pesticides use, and even the other half that did, often lacked understanding of the risks involved.

Farmers were spraying vegetable crops at least 14 times per growing season. One out of three applications was involving one of the HHP containing formulation (Farmers using HHPs includes almost 30% of the interviewed farmers).

Also almost none of the farmers (93%) owned or wore adequate PPE having only one or no protective items at all. Only 2% of those applying HHPs wore adequate full body protection PPE. About half of the farmers had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayer (36%), followed by electric sprayer (with batteries); 33% and followed by inappropriate equipment such as watering can (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed to receive pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use by farmers noticing symptoms were headaches, skin rashes, burning eyes, vomiting, burning nose, blurred vision, dizziness and excessive sweating. Almost half of the farmers declared they did not read pesticide labels, including use instructions such as proper dosage and protective measures, the main reason being illiteracy. One out of four farmers poorly understood the hazard colour band on pesticide labels that indicates acute toxicity.

The survey results showed that the use of pesticides in general, and of HHPs in particular, was likely to result in excessive exposure of farmers in Mozambique. Therefore enforcing risk mitigation measures depending solely on wearing the appropriate PPE under the local conditions of use to be difficult and unlikely to give results.

Thiodicarb and the products containing this a.i. were considered as harmful for the human health taking into consideration of the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban the a.i. thiodicarb from future use in the country and to cancel the registration of all the products containing it.

Expected effect of the final regulatory action

Reducing the risk posed by the use of HHPs in Mozambique specially thiodicarb in the context of human health.

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

N/A

Expected effect of the final regulatory action

N/A

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	1000 L 2500 L	2003 2004
exported	N/A	N/A
used		

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

Countries with similar conditions as well as where the farmers use pesticides without protective equipment could make similar decision in order to protect their population human health.

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

The Ministry engaged with the producer association to assess alternative Insecticide options and facilitate registration of lower-risk products. In parallel the Ministry of Agriculture and Food Security is also promoting

the use of biological pest control measures.

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

N/A

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

None

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	Class II (Moderately hazardous)
GHS Hazard Statements	Category 2 ➢ H301 (100%): Toxic if swallowed [Danger Acute toxicity, oral] ➢ H330 (97.3%): Fatal if inhaled [Danger Acute toxicity, inhalation] ➢ H400 (95.95%): Very toxic to aquatic life [Warning Hazardous to the aquatic environment, acute hazard]

Other classification systems **e.g. EU, USEPA**	**Hazard class**
USEPA	Probable Human Carcinogen (Class B2)

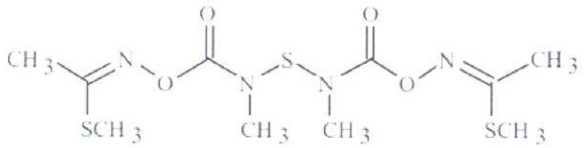
3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Molecular formula: C10H18N4O4S3

Molecular mass: 354.5

Structural formula:



Melting point (state purity) ‡	172.6 °C purity 99.9%
Boiling point (state purity) ‡	No boiling point observed
Temperature of decomposition	184.7 °C purity 99.9%
Appearance (state purity) ‡	White powder purity 99..9% Off-white powder purity 94.1%
Relative density (state purity) ‡	1.47 g/ml at 20 °C purity 99.9% 1.48 g/ml at 20 °C purity 94.1% Density reported not relative density
Surface tension	71.97 mN.m-1 purity 94.1%. The test concentration was circa 20 mg/L.
Vapour pressure (in Pa, state temperature) ‡	2.7 x 10-3 @ 25 °C purity 99.9%
Henry's law constant (Pa m3 mol -1) ‡	4.31x10-2 Pa m3 mol-1 @ 25 °C
Solubility in water ‡ (g/L or mg/L, state temperature	22.19 mg/L deionised water at 25 °C purity 99.9% 24.47 mg/L pH 7 at 25 °C 26.88 mg/L pH 3 at 25 °C 29.83 mg/L pH 5 at 25 °C
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	Ethanol 0.97 g/L n-hexane 0.32 g/L Toluene 0.92 g/L Dichloromethane 200-300 g/L Acetone 5.33 g/L Ethylacetate 1.79 g/L All carried out at 20 °C purity 99.9%
Partition co-efficient (log POW) ‡ (state pH and temperature)	1.62 in unbuffered water purity 99.9 %
Hydrolytic stability (DT50) ‡ (state pH and temperature)	69 days at pH 5 31 days at pH 7

	0.26 days at pH 9 All tests were carried at 25 °C purity > 99%.
Dissociation constant ‡	Thiodicarb does not dissociate
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	232-234 nm ε ~ 18000 L.mol -1.cm-1 purity 99.9% ε < 10 at ≥ 290 nm
Photostability (DT50) ‡ (aqueous, sunlight, state pH)	7.6 days at pH 6
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	ε < 10 l.mol-1.cm-1
Flammability ‡	Not flammable
Explosive properties ‡	Not explosive

Reference

https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2006.55r

3.2.2 Description of toxicological properties of the chemical

- Oral LD 50 Rat (mg/kg): 66; WHO, 2009
- 2.2 ACUTE TOXICITY The acute toxicity is high, (oral LD50 59 mg/kg bw) as well as during inhalatory exposure (LC50 0.81 mg/L air). Acute dermal LD50 is greater than 2000 mg/kg bw. It is not a skin or an eye irritant but is a skin sensitizer (Magnusson and Kligman test). Classification for acute toxicity is needed and the proposed risk phrases are: T; R23/R25 (Toxic by inhalation and if swallowed) and R43 (May cause sensitization by skin contact). 2.3 SHORT TERM TOXICITY Repeated exposures to thiodicarb resulted in decreased body weight and food consumption, alterations in haematological parameters, haemolytic anemia, haemosiderosis and extramedullary haematopoiesis, as well as signs of cholinergic effects. The relevant oral NOAEL is 5 mg/kg bw/day from the 6-month and the 1-year study in dog. A MS proposed to classify thiodicarb as R48, due to the haemolytic anemia seen both in short and long term studies. The experts agreed that R48 is not justified, since effects are present only at dose levels at which significant cholinesterase inhibition occurs and no severe dysfunctions are registered. The final decision is up to ECB (European Chemical Bureau, Ispra). All the repeated dose dermal studies submitted failed in determining a NOAEL. However, the whole picture indicates that thiodicarb should be less toxic via dermal route. A repeated inhalation study produced cholinergic signs at 0.005 mg/L

and above, (corresponding to a systemic dose of approximately 1.5 mg/kg bw/day), indicating a high toxicity via inhalation. Thus, a classification for toxicity during repeated inhalation exposure might be warranted. Final decision is up to ECB. 2.4 GENOTOXICITY In the DAR the genotoxic properties of thiodicarb were studied in a battery of tests consisting of nine in vitro studies and three in vivo studies. The gene mutation assay with mouse lymphoma cells gave positive results, as well as the mitotic gene conversion assay in some concentrations. The three in vivo studies showed negative results. The experts agreed that the data package on genotoxicity with the technical material was complete. Differences among purities of technical materials in different tests were noticed (minimum purity of the technical material: 94%): the UDS was performed with technical material 95.4% pure, while the micronucleus and the dominant lethal test were conducted with a >99% pure thiodicarb. The 3 in vitro studies were performed with a technical material with 91.5% purity. Even with an additional Ames test using the correct minimum purity material, a positive result would not affect the overall picture, since the UDS test is negative. Thus, the experts concluded that there is no genotoxic potential for thiodicarb and no new studies are required. 2.5 LONG TERM TOXICITY The long term toxicity and carcinogenic potential of thiodicarb were assessed in 2 long term studies in rats and 2 in mice. Signs of cholinergic toxicity were not seen consistently in any of the chronic toxicity studies performed with thiodicarb. Inhibition of plasma and erythrocyte activities varied pending on the animal fasting/non fasting conditions. Brain cholinesterase was not inhibited in a statistically significant way throughout the studies. Effects other than cholinesterase inhibition consisted in reduction of body weight and food consumption, macrocytic/haemolytic anemia and splenic lesions. The NOAELs in rats is 3 mg/kg bw/day and in mice 5 mg/kg bw/day. A MS proposed to classify thiodicarb as R48, due to the haemolytic anemia seen both in short and long term studies but it was not agreed on by the experts (see 2.3). In mice, a statistically significant increase in adenoma and carcinoma of the liver was recorded. The occurrence of these tumours was considered to be of no relevance to human risk assessment because the dose at which the tumours occurred greatly exceeded the maximum tolerated dose. In a rat study, the overall incidence of benign and malignant tumours was lower than controls in the top dose group. Incidence of thyroid carcinomas in females was slightly above the historical control range,

even of no statistical significance. Top dose males showed also interstitial cell adenoma with testicular atrophy. Nevertheless, a clear threshold for tumours is 12 mg/kg bw/day. Thus, the overall conclusion is that thiodicarb does not show carcinogenic potential. 2.6 REPRODUCTIVE TOXICITY One multigeneration study in the rat in order to determine the reproductive effects of thiodicarb is presented in the DAR. The parental NOAEL was 7 mg/kg bw/day based on significantly reduced body weights in adults and pups at 15 mg/kg bw/day. The relevant NOAEL for reproduction is 7 mg/kg bw/day as well, based on significantly reduced pup viability at 15 mg/kg bw/day. In this study, pups were found with no milk in the stomach. Therefore, some MS proposed the classification R64. Neither thiodicarb nor its metabolites were identified in the milk. No correlation was found between dead pups and the number of pups with no milk in the stomach. However, due to the increased mortality of pups at dose levels which are not associated with marked maternal toxicity (the effects in offspring are apparently related to maternal exposure). Therefore, a classification as Cat. 2 and R61 was proposed instead by the experts. A statement was forwarded to ECB (European Chemical Bureau, Ispra). The NOAEL for maternal effects in the rat is 1 mg/kg bw/day, based on reduced body weight and clinical signs. The relevant developmental NOAEL is from the rat which is 30 mg/kg bw/day (highest tested dose). Classification for reproductive effects is needed and the proposed risk phrase is Cat. 2, R61 "May cause harm to the unborn child". 2.7 NEUROTOXICITY In a single neurotoxicity study in rats, no NOAEL was established, due to the occurrence of clinical signs even at the lowest dose tested (5 mg/kg bw). In a 90-day study in rats, the NOAEL is 6 mg/kg bw/day, based on the inhibition of brain acetylcholinesterase at 23 mg/kg bw/day and above. (EFSA, 2006)

Acute toxicity (Annex IIA, point 5.2)	
Rat LD50 oral ‡	50 mg/kg bw R23
Rat LD50 dermal ‡	>2000 mg/kg bw
Rat LC50 inhalation ‡	0.66 mg/L R25
Skin irritation ‡	Not irritant
Eye irritation ‡	Mild, transient irritant (no classi proposed)
Skin sensitization ‡ (test method used and result)	Positive (M&K); negative in human pa R43
Short term toxicity (Annex IIA, point 5.3)	
Target / critical effect ‡	Cholinesterase inhibition, clinical

	(including tremors) red cell effects (mild macrocytic anaemia) & associated splenic findings,
Lowest relevant oral NOAEL / NOEL ‡	5 mg/kg bw/d (6-month and 1-year dog studies)
Lowest relevant dermal NOAEL / NOEL ‡	No NOAEL possible to be determined due to poor quality of the studies
Lowest relevant inhalation NOAEL / NOEL ‡	LOAEL 0.005 mg/L, lowest dose tested
Long term toxicity and carcinogenicity (Annex IIA, point 5.5)	
Target/critical effect ‡	Macrocytic anaemia, splenic effects (haemosiderin deposition, extramedullary haematopoiesis); liver hyperplasia in mice
Lowest relevant NOAEL / NOEL ‡	3 mg/kg bw/d
Carcinogenicity ‡	Liver tumours in mice at toxic doses. Clear NOAEL identified (12 mg/kg bw/day). Unlikely to pose a risk to humans
Reproductive toxicity (Annex IIA, point 5.6)	
Reproduction target / critical effect ‡	Reduced pup viability and weight
Lowest relevant reproductive NOAEL / NOEL ‡	Maternal and reproductive: 7 mg/kg bw/d
Developmental target / critical effect ‡	Not teratogenic; no specific embryo- / foetotoxicity (rats & rabbits)
Lowest relevant developmental NOAEL / NOEL ‡	Maternal: 1 mg/kg bw/day Developmental: >30 mg/kg bw/d (rats)
Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)	
Acute (gavage)	<5 mg/kg bw; cholinesterase inhibition, no neuropathy
90 day (diet)	6 mg/kg bw/d; no neuropathy

Reference

The WHO recommended classification of pesticides by hazard and guidelines to classification: 2009. (World Health Organization, 2010)
https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2006.55r

3.2.3 Description of ecotoxicological properties of the chemical

Property	Value	Source
Bio-concentration factor BCF (l kg^{-1})	6.3	A5 Whole fish
Birds - Acute LD50 (mg kg-1)	2023	B5 Colinus virginianus
Birds - Short term dietary (LC50/LD50)	> 5620 mg kg feed-	A5 Anas platyrhynchos
Fish - Acute 96 hour LC50 (mg l-1)	1.4	A5 Lepomis macrochirus
Aquatic invertebrates - Acute 48 hour EC50 (mg l-1)	0.027	A5 Daphnia magna
Aquatic invertebrates - Chronic 21 day NOEC (mg l-1)	0.0016	A5 Daphnia magna

Aquatic crustaceans - Acute 96 hour LC50 (mg l-1)		0.014	F3 Americamysis bahia
Algae - Acute 72 hour EC50, growth (mg l-1)		8.3	F4 Pseudokirchneriella subcapitata
Algae - Chronic 96 hour NOEC, growth (mg l^{-1})		3.2	Q2 Unknown species
Honeybees (*Apis* spp.)	Contact acute LD_{50} (worst case from 24 , 48 and 72 hour values - µg bee^{-1})	3.1	A5
	Oral acute LD50 (worst case from 24 , 48 and 72 hour values - µg bee-1)	0.153	A5

Reference

https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/637.htm

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	MINISTRY OF AGRICULTURE AND FOOD SECURITY
Address	Rua da Resistência Nº 1742 Maputo - Mozambique
Name of person in charge	Khalid Cassam
Position of person in charge	Technician
Telephone	+258 823071000 / +258 84468208
Telefax	+258 21 415103
E-mail address	khalidcassam@yahoo.com.br

Date, signature of DNA and official seal: 8/4/2020

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: TURKEY

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Thiodicarb
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	methyl (1E)-N-[methyl-[methyl-[(E)-1-methylsulfanylethylideneamino]oxycarbonylamino]sulfanyl carbamoyl]oxyethanimidothioate
1.3	**Trade names and names of preparations**	N/A

1.4 Code numbers

1.4.1	CAS number	59669-26-0
1.4.2	Harmonized System customs code	2930 90 90
1.4.3	Other numbers (specify the numbering system)	EC No. 261-848-7

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

Thiodicarb is not registered as plant protection product in the country. By the Ministry of Agriculture, production and import of Thiodicarb were banned in 2012 and its use was banned in 2013.

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

31/08/2012

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 (100%): Toxic if swallowed [Danger Acute toxicity, oral] H330 (98.48%): Fatal if inhaled [Danger Acute toxicity, inhalation] H400 (97.73%): Very toxic to aquatic life [Warning Hazardous to the aquatic environment, acute hazard]
WHO	II =Moderately hazardous

Other classification systems e.g. EU, USEPA	Hazard class
USEPA	Group B2 Probable Human Carcinogen

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Physical State: White powder
Formula: $C_{10}H_{18}N_4O_4S_3$
Molecular mass: 354.47
Solubility - In water at 20 °C (mg l^{-1}): 22.2
Melting point (°C): 172.6
Boiling point: Decomposes before boiling
Degradation point (°C): 184.7
Flashpoint (°C): Not expected to self ignite; Not highly flammable
Octanol/water partition coefficient as log Pow: 1.62

Reference

https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/637.htm

3.2.2 Description of toxicological properties of the chemical

Mammals - Acute oral LD_{50} (mg kg^{-1}): 50 (rat)

Mammals - Dermal LD_{50} (mg kg^{-1} body weight): 2000 (rat)

Mammals - Inhalation LC_{50} (mg l^{-1}): 0.66 (rat)

Acute percutaneous (LD50, mg/kg) rabbits >2000

Skin irritation Not an irritant (rabbits)

Eye irritation Mild irritant (rabbits)

Skin sensitisation Sensitiser (guinea pigs)

NOEL (2 y) for rats 3.75 mg/kg daily, for mice 5.0 mg/kg daily.

ADI-RfD (EFSA) ADI 0.01, aRfD 0.01, AOEL 0.014 mg/kg b.w. [2006]; (JMPR) ADI 0.03, aRfD 0.04 mg/kg b.w. [2000]; (EPA) cRfD 0.03 mg/kg b.w. [1998].

Reference

https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/637.htm

BCPC Pesticide Manual Online, 2021

3.2.3 Description of ecotoxicological properties of the chemical

Mammals - Acute oral LD_{50} (mg kg^{-1}): 50 (rat)

Birds - Acute LD_{50} (mg kg^{-1}): 2023 (Colinus virginianus)

Fish - Acute 96 hour LC_{50} (mg l^{-1}): 1.4 (Lepomis macrochirus)

Aquatic invertebrates - Acute 48 hour EC_{50} (mg l^{-1}): 0.027 (Daphnia magna)

Aquatic crustaceans - Acute 96 hour LC_{50} (mg l^{-1}): 0.014 (Americamysis bahia)

Algae - Acute 72 hour EC_{50}, growth (mg l^{-1}): 8.3 (Pseudokirchneriella subcapitata)

Worms LC50 for earthworms 38.5 mg/kg soil.

Bees (LD50, µg/bee) 3.1 (contact) (48 h), 0.153 (oral) (48 h)

Reference

https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/637.htm

BCPC Pesticide Manual Online, 2021

SECTION 4 DESIGNATED NATIONAL AUTHORITY

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Date, signature of DNA and official seal: 29 Nisan 2021