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

Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Eleventh meeting
Geneva, 1–12 May 2023
Item 5 (b) of the provisional agenda*

Matters related to the implementation of the Convention: listing of chemicals in Annex III to the Convention

Inclusion of iprodione in Annex III to the Rotterdam Convention

Addendum

Draft decision guidance document

Note by the Secretariat

As is mentioned in document UNEP/FAO/RC/COP.11/10, the Chemical Review Committee, at its eighteenth meeting, in decision CRC-18/1, adopted a draft decision guidance document on iprodione. The draft decision guidance document is set out in the annex to the present note for the consideration of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The annex has not been formally edited.

* UNEP/FAO/RC/COP.11/1.

Annex

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Draft Decision Guidance Document

Iprodione

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

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its […] meeting, held in […] on […], the Conference of the Parties agreed to list [chemical name] in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on […], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical listed in the relevant category(ies) in Annex III to the Convention. Further information on import response can be found on the website of the Rotterdam Convention[3].

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

[1] According to the Convention, the term “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.

[2] According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

[3] http://www.pic.int/Procedures/ImportResponses/tabid/1162/language/en-US/Default.aspx.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

Standard core set of abbreviations[4]

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AAOEL	acute acceptable operator exposure level
b.p.	boiling point
bw	body weight
CN	combined nomenclature
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
cm	centimetre
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria
E_rC_{50}	Concentration of test substance which results in a 50 percent reduction in growth rate relative to the control within 72hrs exposure.
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
ILO	International Labour Organization
IMDG	International Maritime Dangerous Goods
IPAM	International Peoples Agroecology Multiversity
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (× 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre

[4] This core list should serve as the basis for DGDs for industrial chemicals, pesticides and severely hazardous pesticide formulations. It should be augmented by abbreviations used in the individual DGDs relevant to the chemical(s) in question.

Definitions and spelling should, as far as practicable, follow the IUPAC glossary of terms in toxicology and the IUPAC glossary of terms relating to pesticides in their current editions.

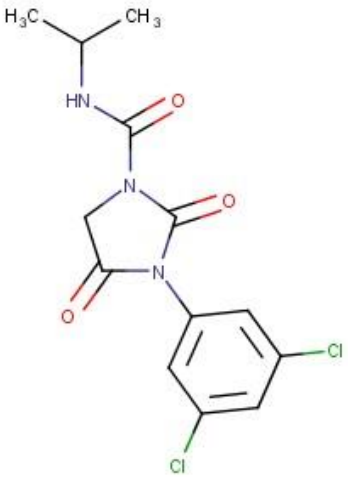
As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations.

STANDARD CORE SET OF ABBREVIATIONS	
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
m	metre
mbyp	meat-by-product
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	Maximum Tolerated Dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
OISAT	Online Information Service for Non-Chemical Pest Management in the Tropics
PEC	predicted environmental concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPDB	Pesticides Properties DataBase
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	reference dose (for chronic oral exposure; comparable to ADI)
SMR	standard(ized) mortality ratio
STEL	short-term exposure limit
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

Iprodione **Published:**

1. Identification and uses (see Annex 1 for further details)

Common name	Iprodione
Chemical name and other names or synonyms	3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine- 1-carboxamide
Molecular formula	$C_{13}H_{13}Cl_2N_3O_3$
Chemical structure	
CAS-No.(s)	36734-19-7
Harmonized System Customs Code	380861 (formulation) 293321 (active ingredient)
Other numbers	EC number 253-178-9 CIPAC: 278 Combined Nomenclature (CN) code of the European Union: 2933 21 00 HS code 380892 (fungicides)
Category	Pesticides
Regulated category	Pesticides
Use(s) in regulated category	In Mozambique iprodione was used as a fungicide in vines, fruit trees and vegetables. In the European Union iprodione was used as a fungicide.
Trade names	lprodione 25,5% SC; Rovral WG (BAS 610 06 F) Iprodine; Glycophene; Chipco 26019; Anfor; RP-26019; Rovral; Amazzones, Botrix, Dirac, Diva, Kidan, Rover, Verisan, Viroval *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Suspension concentrate; water dispersible granules
Uses in other categories	-
Basic manufacturers	Bayer CropScience[5]; BASF[6] *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

[5] https://www.environmentalscience.bayer.co.uk/turf-management/turf-news/turf-press-releases/update-on-the-withdrawal-of-iprodione-based-products.

[6] Final Renewal report for the active substance iprodione finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 6 October 2017 in view of the non-renewal of the approval of XXX as active substance in accordance with Regulation (EC) No 1107/2009; https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=234.

2. Reasons for inclusion in the PIC procedure

Iprodione is included in the PIC procedure as a pesticide. It has been listed on the basis of the final regulatory actions to ban its use, notified by the European Union and Mozambique.

2.1 Final regulatory action (see Annex 2 for further details)

European Union

Iprodione is not included in the list of approved active substances under Regulation (EC) No 1107/2009. It was concluded that no plant protection product containing the active substance iprodione 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) No 546/2011. As a consequence, it is prohibited to place on the market or use plant protection products containing iprodione in the European Union as of 6 March 2018. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing iprodione is prohibited as of 6 June 2018.

Reason: Human Health and Environment

Mozambique

Based on the decision Nr 001/DNSA/2014, iprodione was banned by the National Directorate of Agrarian Services (The Pesticide Register Authority) from further import and use in Mozambique. The ban of all uses and the cancellation of the products containing iprodione in the country 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 and animal health. The decision to cancel the registration of iprodione was taken as the last step of the project for Risk Reduction of Highly Hazardous Pesticides (HHPs), which identified HHPs that are registered in Mozambique. After consultations with different actors (public sector, private sector, civil society and others), cancelation of registrations and consequent non-approval for their use in Mozambique was approved. The regulatory action entered into force on 15 July 2014.

The final regulatory action has been taken for the pesticide category to protect human health.

Reason: Human Health

2.2 Risk evaluation (see Annex 1 for further details)

European Union

According to the evaluation related to human health the following information was identified:

a) Iprodione currently has a harmonized classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council while in the conclusion of the EFSA it is indicated that iprodione should be classified as carcinogen category 1B and as toxic for reproduction category 2;

b) Given the GHS classification and the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin;

c) An acute consumer risk that cannot be excluded based on a preliminary risk assessment.

According to the evaluation related to the environment the following information was identified: the high long-term risk of iprodione to aquatic organisms.

Mozambique

The notification states that the ban of all uses and the cancellation of the products containing iprodione in Mozambique was decided based on the toxic nature and hazardous properties which, combined with the improper use in the country due to the local specific conditions of use, can damage human and animal health.

Iprodione and the products containing iprodione were considered as harmful for human health taking into consideration of the local conditions of use in Mozambique and the requirement for risk mitigation measures. The notification refers to a consultancy report ‘Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides (Come A.M. and van der Valk H., 2014), which identified iprodione as carcinogenic equivalent or similar to GHS Class 1B. The conclusion was based on United States Environment Protection Agency (US EPA) and EFSA assessments where iprodione was classified as likely to be carcinogenic and on the EU classification in category 2 of carcinogenicity classification.

Although specific information related to actual or measured exposure of agricultural workers to iprodione in Mozambique was not included as part of the risk evaluation, the notification and supporting documentation provide an assessment of the prevailing conditions of use of pesticides in Mozambique. Iprodione was imported into Mozambique in 2013 and registrations of the formulation remained in place; future use could not therefore be precluded (UNEP/FAO/RC/CRC.17/INF/11, p. 35). The registered uses for iprodione formulations were for vines, fruit trees and vegetables. Vegetable cropping systems were included in the survey of users conducted, and vegetables were the predominant crops in two of the regions of Mozambique surveyed (UNEP/FAO/RC/CRC.17/INF/11, pp. 52–77). The notification and supporting documentation indicate that the use of pesticides in general was likely to result in excessive exposure of farmers given the availability, knowledge and use of PPE among farmers, and was evidenced by a high level of reporting of adverse health effects. The final regulatory action was taken as a result of Mozambique's national objective of reducing the greatest risks associated with pesticide use.

According to the survey, similar pesticide uses and application techniques to those in the United States (use on field, fruit and vegetable crops) were used in Mozambique. The Mozambican authorities considered that the risk mitigation measures required in the United States could not be achieved in Mozambique.

Therefore, taking into consideration the national objective of Mozambique of reducing risks of the most dangerous pesticides, including HHPs, the results of the survey of pesticide use practices in selected cropping systems in Mozambique (some of which are representative of registered iprodione uses), which included the identification of inadequate availability and use of PPE and iprodione's likely carcinogenicity, and noting the bridging information to the PPE requirements in the United States, it is concluded that the final regulatory action was based on a risk evaluation involving the prevailing conditions within the Party taking the action.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

European Union

Iprodione was not included in the list of approved active substances under Regulation (EC) No 1107/2009.

Mozambique

National Directorate of Agrarian Services banning further import and use of iprodione in Mozambique by the decision Nr 001/DNSA/2014.

3.2 Other measures to reduce exposure

European Union

None reported.

Mozambique

None reported.

General

While iprodione was registered in the USA, all residential uses were cancelled (see supporting documentation). Also, back pack sprayers and mixers should wear double layer Personal Protective Equipment (PPE), masks and gloves.

3.3 Alternatives

European Union

The uses evaluated in the European Union risk assessment (EFSA, 2016) were foliar spray field applications for the control of fungal diseases in carrots and lettuce and greenhouse application in lettuce. No information on alternatives was made available.

Mozambique

Iprodione was used in Mozambique as a fungicide in vines, fruit trees and vegetables. No information on alternatives was made available.

General

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Where necessary, priority should be given to the introduction of integrated pest management or integrated vector management that makes optimal use of agro-ecological approaches and reduces reliance on pesticides. This approach is explicitly supported by a broad range of international policy documents, including those of FAO, WHO, World Bank and the OECD Development Assistance Committee.

SAICM's Fourth International Conference on Chemicals Management recommended that awareness should be raised to identify and share information about viable alternatives to HHPs, including cultural and environmental management measures, biological controls, biopesticides or less hazardous pesticides.

Where necessary, priority should be given to the introduction of integrated pest management or integrated vector management, agroecology and organics that make optimal use of agro-ecological approaches and reduces reliance on pesticides. This approach is explicitly supported by a broad range of international policy documents, including those of FAO, UNEP, WHO, World Bank and the OECD Development Assistance Committee.

Information on such practices can be found at the following websites:

a) FAO Agroecology hub: http://www.fao.org/agroecology/en/

b) IPAM (International Peoples Agroecology Multiversity): http://ipam-global.org/

c) OISAT (Online Information Service for Non-Chemical Pest Management in the Tropics): http://www.oisat.org/

Replacing Chemicals with Biology: Phasing out Highly Hazardous Pesticides with Agroecology: https://saicmknowledge.org/library/replacing-chemicals-biology-phasing-out-highly-hazardous-pesticides-agroecology

3.4 Socio-economic effects

European Union

No assessment of socio-economic effects is foreseen in the legal text for authorisation of plant protection products (Regulation (EC) No 1107/2009).

Mozambique

No assessment of socio-economic effects was reported.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification	
WHO / IPCS	Not available
IARC	Not available
European Union	According to the harmonised classification and labelling (CLP) approved by the European Union, this substance is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and is suspected of causing cancer. (https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.048.328) Care 2, H351 - Suspected of causing cancer. Aquatic acute 1, H400 - Very toxic to aquatic life (Acute M = 100). Aquatic chronic 1, H410 - Very toxic to aquatic life with long lasting effects (Chronic M = 100).
US EPA	Cancer Classification: Likely to be Carcinogenic to Humans https://pubchem.ncbi.nlm.nih.gov/source/hsdb/6855#section=Human-Health-Effects
Australia	Carcinogenicity - category 2 Hazardous to the aquatic environment (acute) - category 1 Hazardous to the aquatic environment (chronic) - category 1 URL: http://hcis.safeworkaustralia.gov.au/HazardousChemical/Details?chemicalID=2629

4.2 Exposure limits

European Union

ADI (Iprodione) 0.02 mg/kg bw/day [European Commission, 2017]

ADI (metabolite 3,5-dichloroaniline: 0.0005 mg/kg bw/day [EFSA, 2016]

ARfD 0.06 mg/kg bw [European Commission, 2017]

AOEL 0.04 mg/kg bw/day [European Commission, 2017]

AAOEL 0.04 mg/kg [European Commission, 2017]

Drinking water values

USA: Florida 280 µg/l

USEPA/Office of Water; Federal-State Toxicology and Risk Analysis Committee (FSTRAC). Summary of State and Federal Drinking Water Standards and Guidelines (11/93) To Present

https://pubchem.ncbi.nlm.nih.gov/source/hsdb/6855#section=State-Drinking-Water-Guidelines-(Complete)

Groundwater

EU: 0.1 µg/L. To be noted: this official value is not based on toxicological information, but on (previous) detection limits.

MRL values

European Union

Pursuant to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Official Journal of the European Union L 70, 16.3.2005, p. 1), the maximum residue limit is 0.01 mg/kg, except 0.02 mg/kg for herbs and edible flowers, 0.05 mg/kg for teas, coffee beans, herbal infusions, cocoa beans and carobs, hops, spices, honey and other apiculture products. The limit values are specified in Commission Regulation (EU) 2019/38 (OJ L 9, 11.1.2019, p. 94).

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest_res_ids=135&product_ids=&v=1&e=search.pr

USA

The Code of Federal Regulations contains the most recent US tolerances for iprodione in a number of commodities.

https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.399.

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	Class 9 Subsidiary Risk Packing Group III
International Maritime Dangerous Goods (IMDG) Code	UN-Number 3082 Class 9 Packaging group III Marine pollutant Description of the goods ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (IPRODIONE SOLUTION)
Transport Emergency Card	F-TEC-5

Further specific guidance on appropriate symbols and label statements applicable for iprodione products may be available in the FAO/WHO *Guidelines on Good Labelling Practice for Pesticides* (FAO, 2015).

4.4 First aid

No internationally peer-reviewed chemical safety information for iprodione is available.

The following information can be found in the Rovral WG manufacturer material safety data sheet (MSDS) (https://www.agricentre.basf.co.uk/Documents/product_files_uk_files/safety_data_sheets_files/Rovral_WG_MSDS.pdf):

Description of first aid measures

Show container, label and/or safety data sheet to physician.

Remove contaminated clothing.

If inhaled: Keep patient calm, remove to fresh air, seek medical attention.

On skin contact: Wash thoroughly with soap and water.

On contact with eyes: Wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

On ingestion: Immediately rinse mouth and then drink 200-300 ml of water, seek medical attention.

Most important symptoms and effects, both acute and delayed:

Symptoms: The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11. Further important symptoms and effects are so far not known.

Indication of any immediate medical attention and special treatment needed:

Treatment: Treat according to symptoms (decontamination, vital functions), no known specific

antidote.

Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media: dry powder, foam, water spray

Unsuitable extinguishing media for safety reasons: carbon dioxide

Special hazards arising from the substance or mixture

Carbon monoxide, Hydrogen chloride, Carbon dioxide, nitrogen oxides, organochlorine compounds. The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters

Special protective equipment: Wear self-contained breathing apparatus and chemical-protective clothing. Further information: In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Use personal protective clothing. Avoid contact with the skin, eyes and clothing. Avoid dust formation.

Environmental precautions

Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater. Do not allow contamination of public drains or surface or ground waters. Inform local water plc [public limited company] if spillage enters drains and the Environment Agency (England & Wales), the Scottish Environmental Protection Agency (Scotland), or the Environment and Heritage Service (Northern Ireland) if it enters surface or ground waters. Keep people and animals away.

Methods and material for containment and cleaning up

For small amounts: Contain with dust binding material and dispose of.

For large amounts: Sweep/shovel up. Avoid raising dust. Dispose of absorbed material in accordance with regulations. Collect waste in suitable containers, which can be labeled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations.

Other distributor MSDS can also be found online:

Canada https://fingal.ca/wp-content/uploads/userfiles/msds/Rovral.pdf

South Africa https://www.villacrop.co.za/wp-content/uploads/2021/07/Iprodione-500-SC_Aug2020_UCP_SDS.pdf

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticides the following guidelines are available: FAO *Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (FAO, 1995), The Pesticide Storage and Stock Control Manual (FAO, 1996a) and Guidelines for the management of small quantities of unwanted and obsolete pesticides (FAO, 1999).*

In all cases waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines thereunder, and any other relevant regional agreements.

It should be noted that the disposal/destruction methods recommended in the literature are often not available in, or suitable for, all countries; e.g., high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in *Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (FAO, 1996b).*

Iprodione must be disposed of or incinerated in accordance with local regulations.

The UK Environmental Protection (Duty of Care) Regulations (EP) and amendments should be noted (United Kingdom). This product and any uncleaned containers must be disposed of as hazardous waste in accordance with the 2005 Hazardous Waste Regulations and amendments (United Kingdom). Contaminated packaging should be emptied as far as possible and disposed of in the same manner as the substance/product (www.agricentre.basf.co.uk/Documents/product_files_uk_files/safety_data_sheets_files/Rovral_WG_MSDS.pdf).

A manufacturer of iprodione products, Bayer, recommend responsible disposal of unused iprodione products in a biobed or local hazardous waste company. Bayer has developed a blueprint document to help greenkeepers build their own waste chemical disposal unit, known as the Phytobac. The system is similar to a bio-bed and can be filled with soil and barley straw to harbour bacteria, which feed on the pesticides to dispose of them naturally, without harming the external environment. The blueprint to build a Phytobac can be downloaded for free from the Bayer website. However, if this isn't an option, it's recommended that a local hazardous waste company is contacted to

take away any unwanted chemicals. (https://www.environmentalscience.bayer.co.uk/turf-management/turf-news/turf-press-releases/reminder---dispose-of-iprodione-safely)

The most recent FAO tools and resources on pesticide related waste management are available from the Pesticide Related Waste Management section of the International Code of Conduct on Pesticide Management website (https://www.fao.org/pest-and-pesticide-management/pesticide-risk-reduction/code-conduct/waste-management/en/) and via the FAO's Pesticide disposal series webpage at https://www.fao.org/publications/search/en/?serialtitle=RkFPIFBlc3RpY2lkZSBEaXNwb3NhbCBTZXJpZXM

Annexes

Annex 1 **Further information on the substance**

Annex 2 **Details on Final regulatory action**

Annex 3 **Address of designated national authorities**

Annex 4 **References**

Annex 1 Further information on iprodione

The information presented in this Annex reflects the conclusions of the notifying parties: European Union and Mozambique. The notification of the European Union was published in PIC Circular L of December 2019. The notification from Mozambique was published in PIC Circular LI of June 2020.

Where possible, information on hazards provided by the notifying parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the documents referenced in the notifications in support of the final regulatory actions to ban iprodione.

1.	**Physico-Chemical properties**[7]	
1.1	**Identity**	ISO: iprodione IUPAC: 3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine- 1-carboxamide
1.2	**Formula**	$C_{13}H_{13}C_{l2}N_3O_3$
1.3	**Colour and Texture**	White crystalline powder (99.9%)
1.4	**Decomposition temperature**	164.5°C (99.7%)
1.5	**Melting point**	134 °C (purity 99.9%)
1.6	**Density (g/cm^3)**	Open
1.7	**Vapour pressure**	5×10^{-7} Pa at 25°C (99.7%)
1.8	**Henry's law constant**	0.7×10^{-5} Pa m^3 mol^{-1} (20°C)
1.9	**Solubility in water**	8.9 mg/Lat 20°C (pH 5) (99.8%) 6.8 mg/Lat 20°C (pH 7) (99.8%) 9.0 mg/Lat 30°C (pure water, pH 6.1) (99.8%)
1.10	**Solubility in organic solvents**	Hexane 590 mg/L (96.1%) Acetonitrile 168 g/L (96.1%) Dichloromethane 450 g/L (96.1%) Ethylacetate 22.5 g/L (96.1%) Acetone 342 g/L (96.1%) Toluene 147 g/L (96.1%) 1-octanol 10 g/L (96.1%) (temperature not provided)
1.11	**Partition co-efficient n-octanol/water (log Pow)**	log Pow= 2.99 at 25°C (pH 3) (99.7%) log Pow= 3.00 at 25°C (pH 5) (99.7%)
1.12	**Resistance to alkalis**	No information available.
1.13	**Tensile strength (10^3 kg/cm^2)**	No information available.

2	**Toxicological properties**	
2.1	**General**	
2.1.1	**Mode of Action**	**<u>Mozambique</u>** Contact action with protectant and some eradicant activity. Signal transduction inhibitor.
2.1.2	**Symptoms of poisoning**	**<u>USEPA</u>** Dizziness and skin rashes
2.1.3	**Absorption, distribution, excretion and**	**<u>European Union (EFSA (2016)</u>** In the toxicokinetics studies, iprodione was extensively and rapidly absorbed. Oral absorption was estimated to be greater than 60%. There was no evidence for

[7] Peer review of the pesticide risk assessment of the active substance iprodione. European Food Safety Authority. EFSA Journal 2016;14(11):4609. (See Appendix A for substance properties).

	metabolism in mammals	accumulation. Excretion of the active substance was predominantly through the urine but with appreciable amounts excreted in the faeces. The main metabolic pathway identified was hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain and rearrangement followed by cleavage of the hydantoin moiety. Metabolic patterns in rats and humans were similar. No unique human metabolite is expected.
2.2	**Toxicology studies**	
2.2.1	**Acute toxicity**	**European Union (EFSA, 2016)**No reported adverse effects in workers or poisoning incidents.
2.2.2	**Short term toxicity**	**European Union (EFSA, 2016)** **Target organ/critical effect:** Rat: decreased body weight and food consumption, adrenals, ovary, uterus Mouse: liver, adrenals Dog: liver, adrenals, haematology, prostate, kidney Relevant oral NOAEL: 1-year, dog: 17.5 mg/kg bw per day (400 ppm) 90-day, rat: 30.8 mg/kg bw per day (500 ppm) 90-day, mouse: 260 mg/kg bw per day. Relevant dermal NOAEL: 28-day, rabbit: 1000 mg/kg bw per day
2.2.3	**Genotoxicity (including mutagenicity)**	**European Union (EFSA, 2016)** Based on available genotoxicity studies, the substance is unlikely to be genotoxic, but the metabolite RP 30228 (found as a residue and impurity in the technical material) has genotoxic potential. However, data gaps were identified for a new in vitro gene mutation and an Ames test including strain TA102 performed with the representative technical specification.
2.2.4	**Long term toxicity and carcinogenicity**	**European Union (EFSA, 2016)** **Target organ / critical effect:** Rat: liver, adrenals, testes, epididymis, seminal vesicles, prostate, spleen Mouse: liver, testes, non-glandular stomach, uterus, ovaries, spleen, kidney, adrenals LOAEL = 6.1 mg/kg bw per day (2-year rat) NOAEL = 23 mg/kg bw per day (18-month mouse) **Carcinogenicity:** Classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008. Rat: interstitial Leydig cell tumours Mouse: ovary luteomas, benign and malignant liver cell tumours LOAEL (carcinogenicity) = 6.1 mg/kg bw per day (2-year rat) NOAEL = 115 mg/kg bw per day (18-month mouse) **USEPA (1998)** Classified as a Group B2, or "likely" human carcinogen, based on evidence of tumors in both sexes of mouse (liver) and in the male rat (Leydig cell) and, in addition an increased incidence of ovarian luteomas in female mice. A Q* of 4.39×10^{-2} was used for estimating carcinogenic risk (Leydig cell). **Mozambique** In a study of carcinogenicity in mice, iprodione was administered over 99 weeks at dietary concentrations at 0, 160, 800, or 4000 ppm. At 800 ppm, non-neoplastic lesions were seen that included hepatocellular enlargement and hypertrophy of interstitial cells in the testis. At 4000 ppm, reduced body-weight gain, increased liver weights and increased levels of alanine and aspartate transaminases were observed. An increased incidence of liver tumours in animals of each sex and an increased incidence of luteomas of the ovaries were observed at 4000 ppm. The NOAEL was 160 ppm, equal to 23 mg/kg bw per day. In a 104-week study of carcinogenicity in rats, the dietary concentrations were 0, 150, 300, or 1600 ppm of

iprodione. At 300 ppm, increased liver weights, changes in the male reproductive system including an increased incidence of interstitial-cell hyperplasia in the testis, and hypertrophic changes in the adrenals of male rats were observed. At 1600 ppm, reduced body-weight gain and an increased incidence of interstitial-cell tumours of the testis were noted. The NOAEL was 150 ppm, equal to 6 mg/kg bw per day. (FAO/WHO, 1995)

2.2.5 Effects on reproduction

European Union (EFSA, 2016)

Reproduction toxicity

In 2-generation study:

Parental toxicity: effects on adrenals. Highest dose level: decreased body weight gain and food consumption Reproductive toxicity: sperm abnormalities

Offspring's toxicity: sperm abnormalities F1 and marginal delay in preputial separation. Highest dose levels:

persistence of areolas/nipples F1/F2, decreased bodyweight gain, decreased male anogenital distances F1/F2 in an older 2-generation study:

Parental toxicity: decreased body weight gain and food consumption Reproductive toxicity: decreased mean number of pups per litter

Offspring's toxicity: clinical signs, decreased number of live/dead pups delivered, decreased pup survival and pup bodyweight during lactation

parental NOAEL = 26.9 mg/kg bw per day

reproductive LOAEL = 26.9 mg/kg bw per day offspring LOAEL = 26.9 mg/kg bw per day

The assessment suggests a classification as Repr 2 (H361f).

Developmental toxicity

Rat:

Maternal toxicity: effects on adrenals, decreased bodyweight gain

Developmental toxicity: slight effect on male anogenital distance, delayed fetal development (bodyweight and increased space between the body wall and organs)

Rabbit:

Maternal toxicity: slight decreased maternal bodyweight gain. Highest dose level: bodyweight losses, abortions, postimplantation losses

Developmental toxicity: umbilical hernia

maternal NOAEL = 20 mg/kg bw per day (rat, rabbit) developmental LOAEL = 20 mg/kg bw per day (rat) developmental LOAEL > 20 mg/kg bw per day (rabbit)

The assessment suggests a classification as Repr 2 (H361f).

2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available

European Union (EFSA, 2016)

No potential for neurotoxicity was observed in the standard toxicity studies.

2.2.7 Summary of mammalian toxicity and overall evaluation

European Union (EFSA, 2016)

In the acute toxicity studies, the substance has low acute toxicity when administered orally, dermally or by inhalation to rats. It is not a skin or eye irritant or a skin sensitiser.

In short-term oral toxicity studies with rats, mice and dogs, the toxicity targets were the adrenals (rats, mice, dogs), liver (mice), haematology (dogs), kidney (dogs), prostate (dogs), uterus and ovary (rats). Non-specific critical effects as reduced body weight gain and food consumption were also observed in rats. Although the dog was considered the most sensitive species during expert consultation some effects were observed in rats at similar dose range than in dogs.

In long-term toxicity and carcinogenicity studies with rats and mice, the toxicity targets were the liver, adrenals, testes, epididymis, seminal vesicles, prostate and spleen in rats and the liver, testes, non-glandular stomach, uterus, ovaries, spleen,

kidney and adrenals in mice. The rat was the most sensitive species. The carcinogenic potential was also discussed during the experts' meeting: the majority of the experts considered that tumours observed in several organs and in different species (interstitial Leydig cell tumours in rats and ovary luteomas, benign and malignant liver cell tumours in mice), as well as progression to malignancy in liver tumours (and possibly pituitary adenocarcinoma); and a plausible endocrine-mediated (antiandrogenic) mode of action would suggest that classification as 'Carc. Cat. 1B (H350)' would be more appropriate for iprodione than current harmonized classification as 'Carc. Cat. 2 (H351)'3 leading to a critical area of concern.

In reproductive toxicity studies, fertility and overall reproductive performance was not impaired; however, increased abnormal sperm was observed in F1. Iprodione has been shown to induce developmental toxicity, i.e. delayed onset of male puberty and persistence of areolas in the two-generation study and umbilical hernia in the rabbit developmental toxicity study. Mechanistic studies indicated that iprodione is an antiandrogenic compound. On the basis of the reassessment of reproductive toxicity studies, new mechanistic data and taking into account guidance on the application of the CLP Criteria (ECHA, 2015) the adverse effects observed in the reproductive toxicity studies and adverse effects in reproductive organs in other toxicity studies, as well as the results of the mechanistic studies, suggest that classification regarding reproductive toxicity would be required for iprodione as 'toxic for reproduction category 2 (H361df)'3. No potential for neurotoxicity was observed in the standard toxicity studies.

Endocrine disrupting properties:

lprodione showed endocrine disrupting properties, particularly anti-androgenic effects. lprodione may interfere with steroidogenesis at the level of cholesterol transport but another mode of action, implying its metabolites, cannot be totally excluded.

3 Human exposure/Risk evaluation

3.1 Food

PubChem [internet]

Iprodione was one of many pesticides that has been detected in U.S. foods by the US Food and Drug Administration's regulatory monitoring of domestic foods for fiscal years 1983–1986 and 1978–1982; frequencies of occurrence and concentrations were not reported. In a US monitoring survey of 6970 produce samples (fruits and vegetables) collected between 1989 and 1991, iprodione was detected (detection limit of 2.0 ppm) in only two samples; the concentration in the samples (one grape and one lettuce sample) was not reported. During a 5 yr study conducted during 1981–1986, the Los Angeles District Office of the FDA analyzed 19,851 samples of domestic and imported food for pesticide residues; iprodione was detected in 111 samples at concentrations ranging from 0.05 to >2.0 ppm; most detections were in the range from 0.5–2.0 ppm. In 1989 monitoring conducted by the California Department of Food and Agriculture, iprodione was not detected (detection limit of 2.0 ppm) in 40 almond or 29 lettuce samples; however, it was detected in 2 peach and one prune samples.

During the 27 month period between January 1st 1992, and March 31st 1994, Agriculture and Agri-Food Canada analyzed 21,982 samples of fruit and vegetable commodities for pesticide residues. Iprodione was detected in cherries (0.5 ppm), grapes (0.1 ppm), nectarines (< 0.05 ppm), peaches (< 0.05 ppm), and raspberries (< 0.05 ppm). Eight adult foods consumed in relatively large quantities by infants/children were selected from the domestic and import monitoring for 1985-1991 in the United States. These foods included apple juice, apples, bananas, grape juice, milk, orange juice, oranges, and pears. Of the 10,000 samples analyzed, only two imported foods, these being pears, had detectable quantities of iprodione at a maximum concentration of 0.22 ppm. From 1992-1993, the U.S. Food and Drug Administration(FDA) conducted a statistically based study of pesticide residues in domestic and imported pears and tomatoes. Iprodione was detected in one pear sample (concentration not reported). The concentration of various pesticides was determined on fruits, vegetables, and milk products in New York State. Iprodione detected in two peaches ranging from 0.003–0.006 ppm (total number of samples

not indicated). In 1995, fruits and vegetable samples (397) were collected from eight local markets in Egypt and examined for 52 pesticides. Iprodione was detected three times in tomatoes maintain concentration from 0.05–0.22 ppm (0.11 ppm mean).

3.2 Air

PubChem [internet]

Thirty-nine kinds of pesticides were monitored in Kitakyushu city, Japan using a high-volume air sampler(1). After sampling about 700 cu m of air during summer and spring months, iprodione was not detected at a detection limit of 0.2 ng/cu m.

3.3 Water

PubChem [internet]

GROUNDWATER: From April to October 1996, pesticide monitoring in 40 wells along the Oregon coastal region was conducted. Eighty-nine samples were collected, up to four samples at some wells, over the period of the study. All samples were reported as below the level of quantification; 0.1 ppb. No correlation with use areas was established, although samples were collected from areas with known grape production. In another study along the Central Snake River Basin in Oregon, 27 wells were sampled for a total of 30 samples. Iprodione was detected in all samples, but were reported as below the level of quantification (0.1 ppb). The study was conducted during a 3 day period in August 1996. A study conducted in the Lake Superior Western Basin in Wisconsin during July 1995 at 2 wells reported all samples as below the level of quantification of 0.55 ppb. Iprodione was monitored in 4 surface water features in the central coastal region of California near Santa Cruz in 1994. It is known that iprodione was applied in the watershed of the monitored sites. All four samples exceeded the minimum protection limits (0.1 ppb) on the day of sampling; the date of pesticide application was not ascertained prior to sampling. Concentrations ranged from 1.07 ppb at Hawkins Slough to 3.53 ppb in a drainage ditch from a nearby field. The mean concentration of the four samples was 2.7 ppb. The Pesticides in Ground Water Database (PGWDB) was created to provide a more complete picture of groundwater monitoring for pesticides in United States. It was a collection of ground-water monitoring studies conducted by federal, state and local governments, the pesticide industry and private institutions from 1971-1991. Of 15 groundwater studies which monitored for iprodione during this time period, it was never detected.

SURFACE WATER: Water samples were collected using solid-phase extraction at the mouth of the Shinano River in Niigata Prefecture, Japan from May to September 1996 and analyzed for iprodione. Iprodione was not detected (limit of detection = 0.02 ug/ml) in any of the samples.

3.4 Occupational exposure

Mozambique

Field surveys on general pesticide use and exposure in Mozambique (325 subsistence farmers interviewed) revealed that 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 (50.2%) had not received any training on the use of pesticides. The majority of pesticide applicators used manual sprayers (36%), followed by electric sprayers with batteries (33%), and followed by inappropriate equipment such as watering cans (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed receiving pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use noticed by farmers 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.

European Union (EFSA, 2016)

The intended use with ‘BAS 610 06 F’ is as a fungicide in lettuce and carrots for open field and lettuce for greenhouse (protected permanent structure). Non-dietary exposure estimates are below the AOEL for the operator (wearing personal protective equipment (PPE)), the bystander, the resident and the worker (wearing PPE) for the intended uses of ‘BAS 610 06 F’. However, operator exposure in

greenhouse was estimated according to the European Crop Protection Association (ECPA) greenhouse model that it is not an agreed EU model. The applicant was requested to provide non-dietary exposure estimates according to the Dutch model. Nevertheless, the applicant only submitted worker exposure calculation according to the European Predictive Operator Exposure Model (EUROPOEM) II/Dutch model leading to a data gap and issue that could not be finalised for operator exposure estimates for indoor lettuce use.

3.5 Medical data contributing to regulatory decision

European Union (EFSA, 2016) No reported adverse effects in workers or poisoning incidents.

3.6 Public exposure

PubChem [internet]

The general population may be exposed to iprodione through fungicide use on fruit and vegetable gardens, ornamentals, turfgrass, professional use at residential sites, and other sites where non-occupational exposure may occur (e.g. golf courses, parks, and recreational areas).

Based upon results of the FDA's pesticide residue monitoring program for fiscal year 1988, the average daily intake of iprodione for various age groups were as follows: 6–11 months old: 0.0017 ug/kg body wt/day; 14–16 years old males: 0.0013 ug/kg body wt/day; 60–65 years old females: 0.0014 ug/kg body wt/day. In September of 1998, the EPA estimated that the exposure of iprodione through the consumption of red meat was 0.002668 ug/kg/day, for poultry was 0.001999 ug/kg/day, and for total dairy was 0.004552 ug/kg/day. The estimated exposure for the consumption of grapes, wine and sherry, was 0.0000114 ug/kg/day. From June 1984 to April 1986, a U.S. National Total Diet Study was performed that determined the average daily intake of iprodione for infants aged 6–11 months and 2 years was 0.1 and 2.6 ng/kg body weight/day, respectively. For males aged 14–16, 25–30 and 60–65 years of age the average daily intake was 2.1, 1.8, and 1.3 ng/kg body weight/day, respectively, while for women aged 14–16, 25-30, and 60–65 years of age, the average daily intake was 0.4,0.4, and 0.3 ng/kg body weight/day, respectively. From July 1986 to April 1991, a U.S. National Total Diet Study was performed that determined the average daily intake of iprodione for infants aged 6–11 months and 2 years was 2.7 and 3.3 ng/kg body weight/day, respectively. For males aged 14–16, 25–30 and 60–65 years of age the average daily intake was 1.1, 0.9, and 1.4 ng/kg body weight/day, respectively, while for women aged 14–16, 25–30, and 60–65 years of age, the average daily intake was 0.7, 1.4, and 1.7 ng/kg body weight/day, respectively.

3.7 Summary-overall risk evaluation

European Union

According to the evaluation by the European Union related to human health the following concerns were identified:

a) The genotoxic potential of metabolite RP 30228 (found as a residue and impurity in the technical material). It is noted that metabolite RP 30228 is predicted to occur in groundwater above 0.1 µg/L in one FOCUS GW scenario according to the representative uses;
b) lprodione currently has a harmonised classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council;
c) For the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin;
d) An acute consumer risk that cannot be excluded based on a preliminary risk assessment.

Mozambique

Iprodione and the products containing iprodione were considered as harmful for human health taking into consideration of the local conditions of use in Mozambique requiring risk mitigation measures. The notification refers to a consultancy report Shortlisting highly hazardous pesticides (Come A.M. and van der Valk H., 2014), which identified iprodione as carcinogenic equivalent or similar to

GHS Class 1B. The conclusion was based on United States Environment Protection Agency (US EPA) and EFSA assessments where iprodione was classified as likely to be carcinogenic or in category 2 of carcinogenicity classification.

The final conclusion for the highly hazardous pesticides assessment in Mozambique identified iprodione as carcinogenic equivalent or similar to GHS Class 1B, and therefore considered as "coming close" to highly hazardous pesticides. (Come A.M. & van der Valk H., 2014).

4	**Environmental fate and effects**	
4.1	**Fate**	
4.1.1	**Soil**	**PubChem [internet]**
		If released to soil, iprodione is expected to have moderate mobility based upon a Koc of 700. Volatilization from moist soil surfaces is not expected to be an important fate process based upon a Henry's Law constant of 3.12×10^{-9} atm-cu m/mole. Iprodione is not expected to volatilize from dry soil surfaces based upon its vapor pressure. The US Department of Agriculture's Pesticide Properties Database lists a soil half-life of 14 days for iprodione however, in acclimated soil, the half-life can be as low as 2 days; in non-acclimated soil, the half-life can be >35 days.
4.1.2	**Water**	**PubChem [internet]**
		If released into water, iprodione is expected to adsorb to suspended solids and sediment based upon the Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's Henry's Law constant. An estimated BCF of 41 suggests the potential for bioconcentration in aquatic organisms is moderate. The high rate of hydrolysis, however, should be considered especially when determining BCF. Under basic conditions, iprodione will rapidly hydrolyze decreasing the potential for bioconcentration. Based upon experimental measurements at 60°C and conversion to pseudo first-order rate constants at 25°C, the aqueous hydrolysis half-lives of iprodione at respective pHs of 3, 5, 7, and 9 are 545.2, 37.4, 1.1, and 0.015 days.
4.1.3	**Air**	**PubChem [internet]**
		If released to air, a vapor pressure of 3.75×10^{-9} mm Hg at 25°C indicates iprodione will exist solely in the particulate phase in the ambient atmosphere. Particulate-phase iprodione will be removed from the atmosphere by wet and dry deposition.
4.1.4	**Bioconcentration**	**European Union (EFSA, 2016)**
		A steady state bioconcentration factor (BCF) of 46.8 was measured (whole fish; (total wet weight/normalised to 5% lipid content and based on total 14C or on specific compounds). Note that this value is of the same order of magnitude as the BCF value reported in section 4.1.2.
4.1.5	**Persistence**	**European Union (EFSA, 2016)**
		In reliable field soil dissipation studies, iprodione exhibited low to medium persistence. Iprodione is not significantly photodegraded on the soil surface.
4.2	**Effects on non-target organisms**	**European Union (EFSA, 2016)**
		Low in-field and off-field risk to non-target arthropods other than bees could be concluded. Furthermore, the risk to soil micro- and macro-organisms, non-target terrestrial plants and to organisms involved in biological methods for sewage treatment could be concluded as low for all the representative uses.
4.2.1	**Terrestrial vertebrates**	**Mozambique**
		Birds - Acute LC_{50} (mg/kg) > 2000 (*Colinus virginianus)*
		Birds – Short-term dietary (LC_{50}/LD_{50}) > 5620 mg/kg feed (*Colinus virginianus*)
		European Union (EFSA, 2016)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Colinus virginianus	Iprodione	Acute	LD_{50}	> 2000*
Colinus virginianus	Iprodione	Short-term	LD_{50}	> 3988.4
Anas platyrhynchos	Iprodione	Short-term	LD_{50}	> 1301
Colinus virginianus	Iprodione	Long-term	NOEL	**22.3**
Anas platyrhynchos	Iprodione	Long-term	NOEL	26
Mammals				
Rat	Iprodione	Acute	LD_{50}	**> 2000**
Rat	BAS 610 06 F	Acute	LD_{50}	> 2000
Rat	Iprodione	Long-term [*for screening step*]	NOAEL [developmental study]	20
Rabbit	Iprodione	Long-term [*for screening step*]	NOAEL [developmental study]	**< 20**
Rat	Iprodione	Long-term [*for first tier risk assessment*]	LOAEL [2-generation study]	**26.9**

4.2.2 Aquatic species

European Union

Classification of the EU according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

Aquatic acute 1, H400 - Very toxic to aquatic life (Acute M = 100).

Aquatic chronic 1, H410 - Very toxic to aquatic life

with long-lasting effects (Chronic M = 100)

Fish

LC_{50} (mortality) = 3.1 mg/L *(Ictalurus punctatus,* acute 96h flow-through)

LC_{50} (mortality)= 0.550 mg/L *(Lepomis macrochirus,* acute 96h flow-through, test substance RP 30228)

LC_{50} (ELS, 28d) = 1.3 mg/L *(Dania rerio,* chronic, semi-static, test substance RP 32596) NOEC (Partial LC, 56 d) = 0.0731 mg/L *(Pimephales promelas,* chronic flow-through)

Aquatic invertebrates

EC_{50} (mortality) = 0.660 mg/L (*Daphnia magna*, 48 h static)

EC_{50} (mortality) > 0.500 mg/L (*Daphnia magna*, 48 h static, test substance RP 30228)

EC_{50} (mortality) = 0.364 mg/L (*Daphnia magna*, 48 h static, test substance RP 36221)

EC_{50} (mortality) = 56.28 mg/L (*Daphnia magna*, 48 h static, test substance RP 25040)

EC_{50} (mortality) = 1.26 mg/L (*Daphnia magna*, 48 h static, test substance RP 32596)

NOEC (reproduction) = 0.0075 mg/L (*Americamysis bahia*, 28d flowthrough)

NOEC = 0.057 mg/L (*Chironomus riparius*, 28d static, test substance RP 30228, spiked water)

NOEC = 95.3 mg/L (*Chironomus riparius*, 28d static, test substance RP 30228, spiked sediment)

Algae

E_rC_{50} (growth rate) > 1.5 mg/L (*Pseudokirchneriella supcapitata*, 72h static)

E_rC_{50} (growth rate) > 0.352 mg/L (*Scenedesmus subspicatus*, 72h static, test substance RP 30228)

E_rC_{50} (growth rate) = 0.567 mg/L (*Pseudokirchneriella supcapitata*, 72h static, test substance RP 36221)

E_rC_{50} (growth rate) = 86.9 mg/L (*Pseudokirchneriella supcapitata*, 72h static, test substance RP 25040)

		E_rC_{50} (growth rate) = 7.76 mg/L (*Pseudokirchneriella supcapitata*, 72h static, test substance RP 32596)
4.2.3	**Honeybees and other arthropods**	**European Union (EFSA, 2016)** Honeybees (*Apis mellifera*) Contact acute LD_{50} (48-hour value in µg a.s./bee) >100 Oral acute LD_{50} (48-hour value in µg a.s. /bee) >100 The EFSA (2016) report also includes a number of (semi)field studies with bees and data on solitary bees.
4.2.4	**Earthworms**	**European Union (EFSA, 2016)** Mortality/reproduction tests with earthworm Eisenia foetida showed a NOEC of 1000 mg a.s./kg d.w.soil (NOECcorr = 500 mg a.s./kg d.w.soil).
4.2.5	**Soil microorganisms**	**European Union (EFSA, 2016)** In a nitrogen transformation test iprodione caused < 25 % effect at day 28 at concentration of 8 mg a.s./kg d.w.soil (equivalent to 6.0 kg a.s./ha)
4.2.6	**Terrestrial plants**	**European Union (EFSA, 2016)** Laboratory dose response tests with iprodione and its metabolites on a number of non-target higher terrestrial plants showed no herbicidal activity. Effective rates (ER50 in g/ha) on vegetative vigour were found to be > 2500.
5	**Environmental Exposure/Risk Evaluation**	
5.1	**Terrestrial vertebrates**	**European Union (EFSA, 2016)** The long-term risk assessment for wild mammals could not be finalised due to the lack of a reliable endpoint.
5.2	**Aquatic species**	**European Union (EFSA, 2016)** According to the evaluation by the European Union related to the environment the there was a high long-term risk of iprodione to aquatic organisms.
5.3	**Honey bees**	**European Union (EFSA, 2016)**Low risks to bees (larvae and adults) as long as mitigation measures are implemented No assessment was available for sublethal effects (i.e., hypopharyngeal glands (HPG)) on honeybees (data gap) or for accumulative effects. Data were not available to perform a risk assessment for bumble bees.
5.4	**Earthworms**	**European Union (EFSA, 2016)** The risk to soil micro- and macroorganisms (including earthworms), non-target terrestrial plants and to organisms involved in biological methods for sewage treatment could be concluded as low for all the representative uses.
5.5	**Soil microorganisms**	**European Union (EFSA, 2016)** The risk to soil micro- and macro-organisms, non-target terrestrial plants and to organisms involved in biological methods for sewage treatment could be concluded as low for all the representative uses.
5.6	**Summary – overall risk evaluation**	**European Union** According to the evaluation by the European Union related to the environment the following concerns were identified: a) The predicted concentrations in groundwater that exceed 0.1 µg/L for relevant metabolites RP 35606 and RP 30181. Metabolite RP 35606 also exceeds 0.75 µg/L, in acidic soils, and metabolite RP 30181 exceeds 0.75 µg/L in both acidic and slightly acidic to alkaline soils for both intended uses (carrots and lettuce); b) The high long-term risk of iprodione to aquatic organisms. Furthermore, in respect of one metabolite, found as a residue in plants and as an impurity in the technical material, the pesticide authority concluded that the

genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover, based on the available information, the dietary risk assessment could not be finalised as it is not possible to establish residue definitions for risk assessment; nevertheless, an acute consumer risk could not be excluded. Finally, the long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalised, based on the information submitted in the dossier.

Annex 2 – Details on final regulatory actions reported

Country Name: European Union

1	**Effective date(s) of entry into force of actions**	6 March 2018
	Reference to the regulatory document	Commission Implementing Regulation (EU) 2017/2091 of 14 November 2017
2	**Succinct details of the final regulatory action(s)**	It was concluded that no plant protection product containing the active substance iprodione 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) No 546/2011. As a consequence, it is prohibited to place on the market or use plant protection products containing iprodione in the European Union as of 6 March 2018. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing iprodione is prohibited as of 6 June 2018.
3	**Reasons for action**	Reduction of risk from the use of plant protection products containing iprodione to human health and the environment.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in the EU.
4.1	**Risk evaluation**	According to the evaluation by the European Union related to human health the following concerns were identified: a) The genotoxic potential of metabolite RP 30228 (found as a residue and impurity in the technical material). It is noted that metabolite RP 30228 is predicted to occur in groundwater above 0.1 µg/L in one FOCUS GW scenario according to the representative uses; b) lprodione currently has a harmonised classification (GHS) as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council with the view of the pesticide authority that a classification carcinogenic category might be more appropriate; c) For the representative uses considered, residue levels exceed the default value for maximum residue levels of pesticides in or on food and feed of plant and animal origin; d) An acute consumer risk that cannot be excluded based on a preliminary risk assessment. According to the evaluation by the European Union related to the environment the following concerns were identified: a) The predicted concentrations in groundwater that exceed 0.1 µg/L for relevant metabolites RP 35606 and RP 30181. Metabolite RP 35606 also exceeds 0.75 µg/L, in acidic soils, and metabolite RP 30181 exceeds 0.75 µg/L in both acidic and slightly acidic to alkaline soils for both intended uses (carrots and lettuce); b) The high long-term risk of iprodione to aquatic organisms. Furthermore, in respect of one metabolite, found as a residue in plants and as an impurity in the technical material, the pesticide authority concluded that the genotoxic potential cannot be excluded and therefore the setting of reference values for that metabolite cannot be confirmed based on the information available. Moreover, based on the available information, the dietary risk assessment could not be finalised as it is not possible to establish residue definitions for risk assessment; nevertheless, an acute consumer risk could not be excluded. Finally, the long-term risk assessment for wild mammals for all the relevant routes of exposure could not be finalised, based on the information submitted in the dossier.[8]

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R2091&qid=1619436102485&from=EN#ntr6-L_2017297EN.01002501-E0006.

4.2	**Criteria used**	Risks to human health and the environment
	Relevance to other States and Region	Similar concerns to those identified are likely to be encountered in other countries where the substance is used,
5	**Alternatives**	Information not available
6	**Waste management**	The notifying Party did not provide information on waste management of iprodione. See Section 4.5
7	**Other**	None reported

Country Name: Mozambique		
1	**Effective date(s) of entry into force of actions**	15 July 2014
	Reference to the regulatory document	National Directorate of Agrarian Services decision Nr 001/DNSA/2014
2	**Succinct details of the final regulatory action(s)**	The ban of all uses and the cancellation of the products containing iprodione in the country 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 and animal health. The decision to ban the registration of the iprodione 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.
3	**Reasons for action**	Reduction of risk from using plat protection products containing iprodione to human health
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health. Taking into consideration Mozambique's national objective of reducing risks of the most dangerous pesticides including HHPs, the results of the survey of pesticide use practices in selected cropping systems in Mozambique, (some of which are representative of registered iprodione uses), which included the identification of inadequate availability and use of PPE and iprodione's likely carcinogenicity, and noting the bridging information to the PPE requirements in the USA, it is concluded that the final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.
4.1	**Risk evaluation**	The notification states that the final regulatory action was based on a risk or hazard evaluation involving prevailing conditions within the Party in order to protect human health (UNEP/FAO/RC/CRC.17/5, section 2.4 of the Mozambique notification). With the goal of reducing the greatest risks associated with pesticide use in Mozambique, the Reducing Risks of Highly Hazardous Pesticides in Mozambique project was initiated by the Government of Mozambique, with the technical support of FAO's Pesticides Management Unit, and funded by SAICM Quick Start Programme Trust Fund. Its ultimate goal was to develop and implement an "HHP Risk Reduction Action Plan" in Mozambique 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. These could include the cancellation of specific registrations of HHPs, implementation of risk mitigation measures, appropriate use restrictions, development of alternative pest management strategies, promotion of good agricultural practices, and possible phase-out of specific pesticides (UNEP/FAO/RC/CRC.17/INF/11). The project was separated into three steps, the first of which involved the review of all the pesticides registered in Mozambique and the establishment of a shortlist of HHPs. 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), and additional criteria for pesticides with characteristic coming close to JMPM criteria. The iprodione formulation registered at the time in Mozambique was Iprodione 25.5% SC (UNEP/FAO/RC/CRC.17/5, section 1.3 of the Mozambique notification and UNEP/FAO/RC/CRC.17/INF/11, p. 49). This formulation was assessed against the FAO/WHO JMPM criteria for identification of HHPs and the following additional criterion used by Mozambique for identifying pesticides with characteristics which 'come close' to the HHP criteria: pesticides for which carcinogenicity evaluations by different registration/assessment authorities did not lead to consistent classification as GHS Category 1A or 1B, but which were, based on the evidence of one of these authorities, considered of particular concern for use in Mozambique. As a result, iprodione was on the short list as a pesticide 'coming close' to HHPs.

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 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 sprayers (36%), followed by electric sprayer (with batteries) (33%), and followed by inappropriate equipment such as watering cans (13.5%) or other (unknown) means (12.5%). Approximately about half of the farmers surveyed reported that they noticed receiving pesticide on their clothes, bare skin or eyes when using pesticides. The main health symptoms associated with pesticide use noticed by farmers 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 would be difficult and unlikely to protect the human health.

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.

Iprodione and the products containing this active ingredient were considered as harmful to human health taking into consideration the local conditions of use in Mozambique requiring risk mitigation measures. Therefore, the authorities decided to ban the active ingredient iprodione from future use in the country and to cancel the registration of all the products containing it (Section 2.4.2.1 of notification - UNEP/FAO/RC/CRC.17/5, with a focus on iprodione specific information as included in the supporting documentation).

4.2 Criteria used

Risk to human health

Relevance to other States and Region

The final regulatory action was based on information on use of and exposure to pesticides during application (UNEP/FAO/RC/CRC.17/5, section 2.4.2.1 of the Mozambique notification) as well as international information on hazard. As no specific exposure values for iprodione in Mozambique were derived, the considerations are not geographically limited).

The survey on pesticide use in Mozambique revealed poor use of protective equipment (UNEP/FAO/RC/CRC.17/5, section 2.4.2.1 of the Mozambique notification). The notification notes that 93% of the farmers did not own or wear adequate personal protective equipment, having only one or no protective items at all. Approximately half of the farmers surveyed reported that they noticed getting pesticides on their clothes, bare skin or eyes when using pesticides. 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. This information was not related to iprodione specifically, but pesticide use in general. Similar conditions could be found elsewhere as well.

5	**Alternatives**	Information not available.
6	**Waste management**	The notifying Party did not provide information on waste management of iprodione. See Section 4.5
7	**Other**	None reported

Annex 3 – Addresses of designated national authorities

EUROPEAN UNION

Rotterdam Convention Designated national authority for industrial chemicals and pesticides (DNA CP), Rotterdam Convention Official contact point (OCP) Name: Mr. Juergen Helbig Job title: International Chemicals Policy Coordinator Department: DG Environment, Unit ENV.B2 - Sustainable Chemicals Institution: European Commission	Postal address: 1049 Brussels Belgium Phone: +32 2 298 8521 Fax: +32 2 298 8874 Email: juergen.helbig@ec.europa.eu

MOZAMBIQUE

Rotterdam Convention Designated national authority for pesticides (DNA P) Name: Mr. Khalid Cassam Department: Plant Protection Department Institution: Ministry of Agriculture and Rural Development	Postal address: c/o INIA P.O. Box 3658 Maputo Mozambique Phone: +258 1 46 05 91 Fax: +258 1 46 01 95 Email: khalidcassam@yahoo.com.br

C Industrial chemicals
CP Pesticides and industrial chemicals
P Pesticides

Annex 4 – References

Regulatory actions

European Union

Commission Implementing Regulation (EU) No 2017/2091 of 14 November 2017 concerning the non-renewal of approval of the active substance iprodione, 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 Commission Implementing Regulation (EU) No 540/2011. Official Journal of the European Union L 297, 15.11.2017, p. 25.

Commission Regulation (EU) 2019/38 of 10 January 2019 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for iprodione in or on certain products. Official Journal of the European Union L 9, 11.1.2019, p. 94.

Mozambique

National Directorate of Agrarian Services decision Nr 001/DNSA/2014 (see UNEP/FAO/RC/CRC.17/INF/11)

Other Documents

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1996. Available at: www.basel.int

Come A.M. & van der Valk H. 2014. Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 1 – Shortlisting highly hazardous pesticides, Consultancy report undertaken under the Project EP/MOZ/101/UEP.

Come A.M.; Dona L.L.; Mancini F. & van der Valk H. 2014. Reducing Risks of Highly Hazardous Pesticides in Mozambique: Step 2 – Survey of pesticide use practices in selected cropping systems.

EFSA (European Food Safety Authority) 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance iprodione. EFSA Journal 2016;14(11):4609, 31 pp.doi:10.2903/j.efsa.2016.4609.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1996. Available at: www.basel.int

European Commission 2017. Final Renewal report for the active substance iprodione finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 6 October 2017 in view of the non-renewal of the approval of XXX as active substance in accordance with Regulation (EC) No 1107/2009. SANTE/10627/2017 rev 2, 6 October 2017

FAO 1995. Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks. FAO, Rome. Available at: http://www.fao.org/3/a-v7460e.pdf

FAO 1996a. The Pesticide Storage and Stock Control Manual, Rome. Available at: http://www.fao.org/agriculture/crops/obsolete-pesticides/resources0/en/

FAO 1996b. Technical guidelines on disposal of bulk quantities of obsolete pesticides in developing countries. Available at: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/

FAO 1999. Guidelines for the management of small quantities of unwanted and obsolete pesticides, Rome. Available at: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/

FAO/WHO 1995. Pesticide residues in food 1995. Joint FAO/WHO Meeting on Pesticide Residues. FAO

Plant Production and Protection Paper 133. https://www.fao.org/3/cb2732en/cb2732en.pdf

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 (p. 14–18).

FAO/WHO 2015. Guidelines on Good Labelling Practice for Pesticides. https://www.who.int/publications/i/item/9789241509688

PPDB [Internet] Pesticide Properties Database Iprodione (Ref: ROP 500F), [cited 2022 Feb 7 for this document]. Available from: http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/403.htm#0

PubChem [Internet]. Bethesda (MD): National Library of Medicine (US), National Center for Biotechnology Information; 2004-. PubChem Compound Summary for CID 37517, Iprodione; [cited 2022 Feb 7]. Available from: https://pubchem.ncbi.nlm.nih.gov/compound/Iprodione

UNEP/FAO/RC/CRC.17/5: Notifications of final regulatory action for iprodione in the pesticide category submitted by Mozambique and the European Union

UNEP/FAO/RC/CRC.17/INF/11: Supporting documentation provided by Mozambique (unedited advance)

UNEP/FAO/RC/CRC.17/INF/12: Supporting documentation provided by the European Union (unedited advance)

USEPA 2008. Iprodione. R.E.D. Facts. EPA-738-F-98-017
https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-109801_1-Nov-98.pdf

Relevant guidelines and reference documents

Rovral WG manufacturer material safety data sheet (MSDS)
(https://www.agricentre.basf.co.uk/Documents/product_files_uk_files/safety_data_sheets_files/Rovral_WG_MSDS.pdf)