ROTTERDAM CONVENTION

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

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

Country: European Union
(Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom)

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Dichlorvos**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**IUPAC: 2,2-Dichlorovinyl dimethyl phosphate** **CA: Phosphoric acid, 2,2-dichloroethenyl dimethyl ester**
1.3	**Trade names and names of preparations**	**Denkavepon, Vapona, Nuvan, Nogos, DDVP**

1.4 Code numbers

1.4.1	CAS number	62-73-7
1.4.2	Harmonized System customs code	2919 90
1.4.3	Other numbers (specify the numbering system)	CIPAC Number: 11 EINECS Number: 200-547-7 Harmonised EU customs Combined Nomenclature (CN) code: 2919 90 00

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☒ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☐ **banned** **OR** ☒ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

It is prohibited to place on the market or use plant protection products containing dichlorvos. Dichlorvos is not included in the list of authorised active substances in Annex I to Directive 91/414/EEC. Authorisations for plant protection products containing dichlorvos had to be withdrawn by 6 December 2007.

From 7 June 2007 no authorisations for plant protection products containing dichlorvos can be granted or renewed.

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

Commission Decision 2007/387/EC of 6 June 2007 concerning the non-inclusion of dichlorvos in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. Official Journal of the European Union, L 145, 6.6.2007, p. 16.

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_145/l_14520070607en00160017.pdf

2.2.3 Date of entry into force of the final regulatory action

Complete entry into force of all provisions of Commission Decision 2007/387/EC of 6 June 2007 was 6 December 2008 since all uses of plant protection products containing dichlorvos were prohibited as from that date at the latest.

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

Dichlorvos is a plant protection product classified as an organophosphate acaricide and insecticide. Dichlorvos is a contact and respiratory insecticide with a fast knock-down effect on most flying insects and acts as an acetyl cholinesterase inhibitor. It is for example used indoors (with fogging vaporising equipment) to protect flower bulbs against thrips at an application rate of 2.2 g dichlorvos/100 m^3, with maximal 3 applications resulting in a maximum total dose of 6.6 g/100m^3.

Dichlorvos has been used on the following crops: flower bulbs; starting material of strawberries, eggplants, cucumbers, paprika, red peppers, tomatoes and other crops; flowering crops, ornamental plants and trees; cereals in store and silos.

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

Use or uses prohibited by the final regulatory action

Not relevant

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

Not relevant

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

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

All the applications as a plant protection product.

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

Uses as biocidal product in the form of product-type 18 - insecticides, acaricides and products to control other arthropods, which are products used for the control of arthropods (e.g. insects, arachnids and crustaceans), remain allowed for the time being pursuant to Directive 98/8/EC concerning the placing of biocidal products on the market (Official Journal of the European Communities L 123, 24.04.1998, p. 1) since the chemical is currently being reviewed.

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

A risk assessment was carried out on the basis of Directive 91/414/EEC, which provides for the European Commission to issue a programme of work for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Article 8(7) of Regulation (EC) No 451/2000.

This resulted in several documents, including:

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorvos. EFSA Scientific Report 77, p. 1-43.

http://www.efsa.europa.eu/en/scdocs/doc/77r.pdf

European Commission (2006): Review report for the active substance dichlorvos finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 September 2006 (SANCO/10031/2006 final)

http://ec.europa.eu/food/plant/protection/evaluation/existactive/dichlorvos.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

Available information is insufficient to perform a risk assessment regarding the operator, worker and bystanders' exposure. There is moreover a lack of data on the toxicity of breakdown products. Hence, it has not been demonstrated that the risks for operators, workers and bystanders arising from the use of plant protection products containing dichlorvos are acceptable. Moreover, the risk assessment is inconclusive due to uncertainties on the genotoxic and carcinogenic properties of dichlorvos.

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products containing dichlorvos, in particular for operators, workers and bystanders.

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	No information	
imported	No information	
exported	No information	
used	No information	

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

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

2.5.3 Other relevant information that may cover:

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

No information

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

No information

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

The risk assessment for dichlorvos under Directive 91/414/EEC for use as plant protection product was carried out for the specific use as room treatment for protection of flower bulbs against thrips. Therefore, very few data had been submitted for the environmental risk assessment and experts agreed that a comprehensive environmental risk assessment was not needed for the indoor use since e.g. non-target organisms (e.g. terrestrial vertebrates, aquatic organisms, bees and other non-target arthropods, soil macro- and micro-organisms) were not expected to be exposed to dichlorvos.

SECTION 3 PROPERTIES

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

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**
IARC	Group 2B, possible human carcinogen
WHO	1b, highly hazardous

Other classification systems **e.g. EU, USEPA**	**Hazard class**
Classification of the EU in accordance with Council Directive 67/548/EEC	T+: Very toxic R26: Very toxic by inhalation T: Toxic R24: Toxic in contact with skin R25: Toxic if swallowed R43: May cause sensitisation by skin contact N: Dangerous for the environment R50: Very toxic to aquatic organisms
Classification of the EU according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council	Acute Tox. 2 * - H330 Acute Tox. 3 * - H311 Acute Tox. 3 * - H301 Skin Sens. 1 - H317 Aquatic Acute 1 - H400
US EPA	B2, probable human carcinogen

3.2 Further information on the properties of the chemical

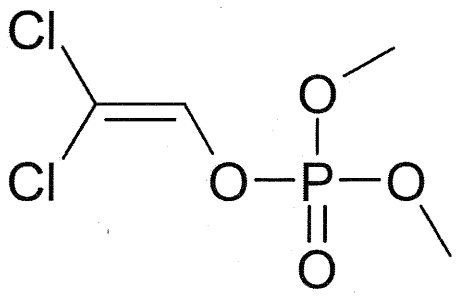
3.2.1 Description of physico-chemical properties of the chemical

Minimum Purity: 950 g/kg (open point)

Molecular formula: $C_4H_7Cl_2O_4P$

Molecular Mass: 221.0

Structural Formula:



Appearance: very pale yellow clear liquid

Melting Point: Not applicable as it is a liquid (freezing point <-80°C)

Boiling Point: Decomposes at >190°C (98% purity)

Vapour Pressure: 2.1 Pa at 25°C (99.8% purity)

Henry's Law Constant: 2.58 $x10^{-2}$ $Pa.m^3/mol$ at 25°C

Solubility in Water: 80 000 mg/l at 25°C (99.8% purity)

Solubility in Organic Solvents: At 25°C, dichlorvos is fully miscible in ethanol, acetone, toluene, *n*-octanol and *n*-hexane. Dichlorvos is soluble in 1,2-dichloroethane and ethyl acetone at a ratio of 1:1

Relative Density: 1.42 kg/l at ca. 20°C (98% purity)

Dissociation Constant (pKa): Does not dissociate or associate between pH range of 5 to 9

Log Kow: 1.9 (±0.11) at 25°C (99.8% purity)

Hydrolysis Stability: -

Photostability in water DT50: Not required. Molar absorption coefficient (ε) <10 $M^{-1}.cm^{-1}$ at wavelengths >290 nm

Reference

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorvos. EFSA Scientific Report 77, p. 1-43.

http://www.efsa.europa.eu/en/scdocs/doc/77r.pdf

3.2.2 Description of toxicological properties of the chemical

Toxicokinetics

Following oral exposure, at least 93% of the test compound is absorbed. Approximately 30% of the dose is retained in the tissues of exposed animals (residual carcass 13-26%, liver 3-5%, other tissues 1-2%). Complete excretion occurs within a few days and no accumulation of dichlorvos occurs following repeated exposure. There are two main pathways for the metabolism of dichlorvos; a metabolic pathway starting with hydrolysis and a pathway starting with demethylation, with the former being more important than the latter in most mammals. Metabolites identified in the urine are dimethyl phosphate, phosphate, dichloroethanol glucuronide, hippuric acid, mercapturic acid, methyl-cysteine and urea. Metabolism to carbon dioxide and excretion via the lungs also occurs.

Acute toxicity

Rat LD50 oral: 57-108 mg/kg bw

Rat LD50 dermal: 120-265 mg/kg bw

Rat LC50 inhalation: 0.083-0.23 mg/l

Skin irritation: not assessed due to high toxicity

Eye irritation: not assessed due to high toxicity

Skin sensitisation: skin sensitiser (Split Adjuvant test)

Short term toxicity

Target/critical effect: nervous system/cholinesterase inhibition

Lowest relevant oral NOEL: 52-week dog study NOEL 0.05 mg/kg bw/day based on significant decreases in plasma, erythrocyte and/or brain (males only) cholinesterase levels.

Lowest relevant dermal NOAEL/NOEL: No good studies available

Lowest relevant inhalation NOAEL/NOEL: No data

Genotoxicity

There were a number of positive *in vitro* tests but methodological deficiencies restrict the evaluation of these results. It is likely that the mechanism of genotoxicity is DNA alkylation but that the rate of methylation is nine-times greater than phosphorylation and so mutagenic activity should only be apparent at doses where there are cholinergic symptoms.

There is limited evidence that it is an *in vivo* contact mutagen. Dichlorvos is not mutagenic in systemic *in vivo* assays. This is consistent with the observation that genotoxicity is more pronounced in the absence of exogenous metabolic activation and that dichlorvos is rapidly metabolised after oral administration, thus limiting systemic exposure. The mutagenic potential of dichlorvos is still not fully resolved.

Long term toxicity and carcinogenicity

Target/critical effect: Cholinesterase inhibition

Lowest relevant NOAEL: In a 2-year dog study, NOAEL of 0.008 mg/kg bw/day (tentative value) was derived.

Carcinogenicity: Inconclusive. Positive results were observed in 2 out of 11 studies, with evidence of pancreatic adenomas and leukaemia

Reproductive toxicity

Target/critical effect – Reproduction:

2-generation rat study, parental and pup cholinesterase inhibition, decreased bodyweight, reduced pup survival

Lowest relevant reproductive NOAEL:

maternal NOAEL = 0.5 mg/kg bw/day
reproductive/offspring NOAEL = 2 mg/kg bw/day

Target/critical effect – Developmental toxicity

Lowest relevant developmental NOAEL:

rabbit oral developmental study NOAEL 5 mg/kg bw/day (highest dose tested)

Lowest relevant developmental NOAEL:

rabbit and rat inhalation developmental study NOAEL >6.25 µg/l (ca. 1.7 mg/kg bw/day) (highest dose tested)

Neurotoxicity/delayed neurotoxicity: no potential for delayed neuropathy (rat)

Other studies: Alterations of liver enzyme activities at doses higher than those causing cholinesterase inhibition.

Chloral (trichloroacetaldehyde) is a toxicologically relevant impurity.

Medical data

A number of case studies have shown dichlorvos to cause irritation and dermatitis upon dermal contact. However, most studies examine the effects on plasma cholinesterase and/or erythrocyte acetyl cholinesterase activity.

ADI: Insufficient information for the setting of reference values

AOEL: Insufficient information for the setting of reference values

ARfD (acute reference dose): Insufficient information for the setting of reference values

Dermal absorption: 30% for concentrated and diluted dichlorvos (*in vivo* rat studies).

Reference

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorvos. EFSA Scientific Report 77, p. 1-43.

http://www.efsa.europa.eu/en/scdocs/doc/77r.pdf

3.2.3 Description of ecotoxicological properties of the chemical

Fate and Behaviour

Soil

Dichlorvos dissipates rapidly from soil, with a half-life of less than 1 day. The main degradation process is mineralisation to carbon dioxide, with several studies indicating 67-77% conversion to carbon dioxide within 35 days, and one study indicating 60% conversion after 2 days. Degradation of dichlorvos is much lower in sterile soils, and negligible mineralisation occurs. The formation of soil bound residues reaches a maximum of 12-26% after 1-14 days, and subsequently declines, indicating that soil bound residues are also mineralised. Residues relevant to the environment are desmethyl dichlorvos and 2,2-dichloroacetaldyde.

Water

Hydrolytic degradation (DT_{50})

pH1 30°C = 71 hours
pH7 20°C = 31 hours
pH13 20°C = 0.013 hours

Using the Arrhenius relation, a half-life of 6.2 days was extrapolated for dichlorvos in seawater at 20°C.

At 37°C and pH 2, 2,2-dichloroacetaldehyde was identified as a conversion product (26% in 30 days).

Photolysis

The phototransformation of dichlorvos in water is negligible.

Biodegradation

Dichlorvos is considered not readily biodegradable in water by Member State experts.

Dichlorvos is rapidly degraded in static water/sediment systems; the main conversion product from mineralisation is carbon dioxide (69-76%). 2,2-dichloroethanol was identified as a minor metabolite.

Air

The estimated half-life in the atmosphere by hydroxyl radical oxidation is 13-20 hours, assuming a hydroxyl concentration of 1.5 $x10^{-6}$ OH-radicals/cm^3 and 12 hour day.

Ecotoxicity

As the use of dichlorvos was on flower bulbs in storage, no environmental concentration was foreseen. Therefore, toxicity/exposure ratios (TERs) could not be calculated.

Birds

Dietary toxicity: Japanese Quail LD50 251 mg/kg.

Aquatic organisms

Fish

Acute toxicity:

Rainbow trout (*Oncorhychus mykiss*) 96-hour LC50 = 0.55 mg/l

Fathead minnow (*Pimephales promelas*) 96-hour LC50 = 3.72 mg/l

Long-term toxicity:

No studies were considered to be acceptable by the Member State experts.

Invertebrates

Acute toxicity:

No studies were considered to be acceptable by the Member State experts.

Chronic toxicity

No studies were considered to be acceptable by Member State experts.

Honey bees

No studies were considered to be acceptable by the Member State experts.

Earthworms

No studies were considered to be acceptable by the Member State experts.

Soil micro-organisms

Nitrogen and carbon mineralisation: No effect at concentrations of up to 13.4 mg/kg.

Reference

EFSA (2006): Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorvos. EFSA Scientific Report 77, p. 1-43.

http://www.efsa.europa.eu/en/scdocs/doc/77r.pdf

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	European Commission
Address	B-1049 Brussels Belgium
Name of person in charge	Juergen Helbig
Position of person in charge	Policy Officer
Telephone	+32 2 298 8521
Telefax	+32 2 296 7617
E-mail address	Juergen.Helbig@ec.europa.eu

EUROPEAN COMMISSION
DG ENVIRONMENT

Date, signature of DNA and official seal: 26.9.2011

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Food and Agriculture Organization
of the United Nations (FAO)
Viale delle Terme di Caracalla
00100 Rome, Italy
Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

OR

Secretariat for the Rotterdam Convention
United Nations Environment
Programme (UNEP)
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland
Tel: (+41 22) 917 8177
Fax: (+41 22) 917 8082
E-mail: pic@pic.int

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

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

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

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

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