FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

OXAMYL

N,*N*-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio)acetamide

FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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DISCLAIMER[1]

FAO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

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[1] This disclaimer applies to all specifications published by FAO.

INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of plant protection products with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

From 2002, the development of WHO specifications follows the **New Procedure**, described in the 1st edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2002) and amended with the supplement of this manual (2006), which is available only on the internet through the FAO and WHO web sites. This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts, namely the specifications and the evaluation report(s):

Part One: The Specification of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the "Manual on development and use of FAO and WHO specifications for pesticides".

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications developed under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

* NOTE: PUBLICATIONS ARE AVAILABLE ON INTERNET UNDER
http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/en/

PART ONE

SPECIFICATIONS

OXAMYL

OXAMYL

INFORMATION

ISO common name:

Oxamyl

Synonyms:

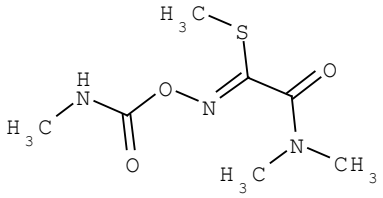
DPX-D1410, IN-D1410, Vydate®

Chemical names:

IUPAC *N*,*N*-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio)acetamide

CA methyl 2-(dimethylamino)-*N*-[[(methylamino)carbonyl]oxy]-2-oxoethanimidothioate

Structural formula:



Empirical formula:

$C_7H_{13}N_3O_3S$

Relative molecular mass:

219.3

CAS Registry number:

23135-22-0

CIPAC Number:

342

EEC Number:

245-445-3

Identity tests:

Reversed-phase HPLC-UV assay method; IR and UV spectra.

OXAMYL TECHNICAL CONCENTRATE

FAO specification 342/TK (April 2008*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (*342/2007*). It should be applicable to TK produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for TK produced by other manufacturers. The evaluation report (*342/2007*), as PART TWO, forms an integral part of this publication.*

1 Description

The material shall consist of technical oxamyl together with related manufacturing impurities in the form of a colourless to yellow transparent liquid, free from visible extraneous matter and added modifying agents, except for the diluent.

2 Active ingredient

2.1 Identity tests (Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Oxamyl content (Note 1)

The oxamyl content shall be declared (g/kg or g/l at 20 ± 2ºC) (Note 2), and when determined, the average measured content shall not differ from that declared by more than the following tolerances.

Declared content, g/kg or g/l at 20ºC	Tolerance
above 100 up to 250 above 250 up to 500 Note. the upper limit is included in each range	± 6% of the declared content ± 5% of the declared content

3 Relevant impurities (Note 3)

Note 1 Methods for the identification and determination of oxamyl content were adopted by CIPAC in 2006 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org.

Note 2 If the buyer requires both g/kg and g/l at 20ºC then, in case of dispute, the analytical results shall be calculated as g/kg.

Note 3 There are no relevant impurities to be controlled in oxamyl products of the manufacturer identified in evaluation report 342/2007. However, *N*-nitrosamines could occur as a result of certain manufacturing processes. If *N*-nitrosamines occur at ≥0.1 mg/kg (of oxamyl) in the products of other manufacturers, they may be designated as relevant impurities and require a clause to limit the concentration.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/en/

OXAMYL GRANULES

FAO specification 342/GR (April 2008*)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (*342/2007*). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (*342/2007*), as PART TWO, forms an integral part of this publication.*

1 Description

The material shall consist of granules containing technical oxamyl complying with the requirements of FAO specification 342/TK (April 2008), together with suitable carriers and any other necessary formulants. It shall be dry, free from visible extraneous matter and hard lumps, free-flowing, essentially non-dusty and intended for application by machine.

2 Active ingredient

2.1 **Identity tests** (Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Oxamyl content** (Note 1)

The oxamyl content shall be declared (g/kg) and, when determined, the averaged measured content shall not differ from that declared by more than the following tolerance:

Declared content, g/kg	Tolerance
above 25 up to 100 Note. the upper limit is included in the range	± 10% of the declared content

3 Relevant impurities (Note 2)

4 Physical properties

4.1 **Tap bulk density** (MT 186, CIPAC Handbook K, p. 151, 2003)

Tap bulk density: 0.74 to 0.84 g/ml.

4.2 **Nominal size range** (MT 58, CIPAC Handbook F, p. 173, 1995)

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/en/

Not less than 950 g/kg of the formulation shall be within the size range 250 to 850 µm.

4.3 **Dustiness** (MT 171, CIPAC Handbook F, p. 425, 1995)

Essentially non-dusty, with a maximum 18 mg dust measured by the gravimetric method (Notes 3 and 4).

4.4 **Attrition resistance** (MT 178, CIPAC Handbook H, p. 304, 1998)

Minimum: 99% attrition resistance.

5 Storage stability

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p. 128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average of the active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for:

- nominal size range (4.2),
- dustiness (4.3),
- attrition resistance (4.4).

Note 1 Methods for the identification and determination of oxamyl content were adopted by CIPAC in 2006 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org.

Note 2 There are no relevant impurities to be controlled in oxamyl products of the manufacturer identified in evaluation report 342/2007. However, *N*-nitrosamines could occur as a result of certain manufacturing processes. If *N*-nitrosamines occur at ≥0.1 mg/kg (of oxamyl) in the products of other manufacturers, they may be designated as relevant impurities and require a clause to limit the concentration.

Note 3 The higher end of the CIPAC standard range for the upper limit on dust content, 12-30 mg, corresponding to the classification “essentially non-dusty” in the gravimetric method MT 171.1, is not acceptable for oxamyl GR. The more restricted range, up to 18 mg dust, must be applied.

Note 4 The optical method, MT 171.2, usually shows good correlation with the gravimetric method (MT 171.1) and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 5 Samples of the formulation taken before and after the storage stability test should be analyzed together after the test in order to reduce analytical error.

OXAMYL SOLUBLE CONCENTRATE

FAO Specification 342/SL (April 2008)

*This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (*342/2007*). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated sources. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (*342/2007*), as PART TWO, forms an integral part of this publication.*

1 Description

The material shall consist of a solution of technical oxamyl complying with the requirements of FAO specification 342/TK (April 2008), together with any necessary formulants. It shall be in the form of a clear liquid, free from visible suspended matter and sediment, to be applied as a true solution of the active ingredient in water. The formulation shall contain an embittering agent (Note 1) and a green or blue dye.

2 Active Ingredient

2.1 Identity tests (Note 2)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Oxamyl content (Note 2)

The oxamyl content shall be declared (g/kg or g/l at 20 ± 2°C) (Note 3) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances

Declared content g/kg or g/l at 20ºC	Tolerance
above 25 up to 100	±10% of the declared content
above 100 up to 250	±6% of the declared content
above 250 up to 500	±5% of the declared content
Note: the upper limit is included in each range	

3 Relevant impurities (Note 4)

4 Physical properties

4.1 pH range (MT 75, CIPAC Handbook F, p. 205, 1995)

pH range: 3.0 to 6.0.

4.2 Solution stability (MT 41, CIPAC Handbook F, p. 131, 1995)

The formulation, after the stability test at 54°C (see 5.2) and following dilution (Note 5) with CIPAC standard water D and standing at 30 ± 2°C for 18 hours,

shall give a clear or opalescent solution, free from more than a trace of sediment and visible solid particles. Any visible sediment or particles produced shall pass through a 45 μm test sieve.

4.3 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 6)

Maximum: 20 ml after 1 minute.

5 Storage stability

5.1 **Stability at 0°C** (MT 39.3, CIPAC Handbook J, p. 126, 2000)

After storage at 0 ± 2°C for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

5.2 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p. 128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 7) and the formulation shall continue to comply with the clause for:

- pH range (4.1).

Note 1 A qualitative CG-MS method for determination of the embittering agent, sucrose octaacetate (SOA), is available from the Pesticide Management Group of the FAO Plant Protection Service or can be downloaded here.

Note 2 Methods for the identification and determination of oxamyl content were adopted by CIPAC in 2006 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org.

Note 3 If the buyer requires both g/kg and g/l at 20ºC then, in case of dispute, the analytical results shall be calculated as g/kg.

Note 4 There are no relevant impurities to be controlled in oxamyl products of the manufacturer identified in evaluation report 342/2007. However, *N*-nitrosamines could occur as a result of certain manufacturing processes. If *N*-nitrosamines occur at ≥0.1 mg/kg (of oxamyl) in the products of other manufacturers, they may be designated as relevant impurities and require a clause to limit the concentration.

Note 5 The concentration used for the test should not be higher than the highest concentration recommended in the instructions for use.

Note 6 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 7 Samples of the formulation taken before and after the storage stability test should be analyzed together after the test in order to reduce analytical error.

PART TWO

EVALUATION REPORTS

OXAMYL

OXAMYL

FAO/WHO EVALUATION REPORT 342/2007

Recommendation

The Meeting recommended that the specifications for oxamyl TK, GR and SL, proposed by DuPont Crop Protection (USA), should be adopted by FAO.

Appraisal

The Meeting considered data on oxamyl, provided by DuPont Crop Protection (USA), in support of proposed new specifications for TK, GR and SL. The data submitted were in accordance with the requirements of the FAO/WHO Manual.

Oxamyl was evaluated by the FAO/WHO JMPR in 2002. The WHO hazard classification for oxamyl is Class Ib, highly hazardous. Oxamyl was reviewed by the US EPA in 2000 and by the EC in 2006 (Directives 2006/16/EC and 2006/59/EC).

Oxamyl is a solid which is soluble in water and, although stable under mildly acidic conditions, is subject to slow hydrolysis at pH 7 and rapid hydrolysis at pH 9. Photolysis is very slow and thermal decomposition occurs above 165ºC. It has essentially no acidic or basic characteristics.

The Meeting was provided with confidential information on the manufacturing process for oxamyl technical concentrate (TK). The manufacturing process compared exactly to that described in a submission to the US EPA (MRID 44977503).

The Meeting noted that oxamyl is not isolated as a technical material (TC), rather its manufacture involves dilution of the product from synthesis with a solvent, to nominal concentrations of 42% and 24% (w/w) oxamyl in the TK.

The TK is registered in the USA. The GR formulation is the representative product for evaluation in the EU and is registered in the Netherlands and the United Kingdom.

The results of five-batch analyses on product from the LaPorte (USA) manufacturing site were provided, with a lower reporting limit of 0.1% (w/w). No unknowns were reported and mass balances were 98.7–100.3% These data were identical to those reported to the US EPA (MRID 46443502). The manufacturing QC limit (technical specification) provided to the Meeting differed in that it included several impurities (all at or below 0.1 g/kg) not in the US Confidential Statement of Formula and no maximum limits were given for several additional impurities included in the US Confidential Statement of Formula. The values presented to the Meeting were consistent with the five batch analysis data. The apparently inconsistent data related only to impurities at <1 g/kg, the cut-off below which the JMPS does not normally require data unless the impurities are exceptionally hazardous (FAO/WHO 2006).

The Meeting concluded that none of the impurities occurring at ≥1 g/kg should be considered relevant.

The manufacturer presented information on the precautions taken to avoid the possibility of forming non-polar *N*-nitrosamines during the manufacturing process.

No non-polar *N*-nitrosamines were detected in 5 batches of an oxamyl formulation, analyzed by GC/TEA (thermal energy analyzer) with a measurement limit of 0.1 mg/kg. The Meeting agreed that clauses and limits for *N*-nitrosamines are not required for oxamyl TK and formulations produced by DuPont but that the standard cautionary footnote should be inserted into the specifications, alerting buyers to the possibility of their occurrence, and potential relevance, in the products of other manufacturers.

The Meeting considered other aspects of the proposed specifications.

GR. The Meeting noted that the standard clause for dustiness (FAO/WHO 2006) requires GR formulations to be "essentially non-dusty", although the more stringent "nearly dust-free" is adopted where practicable. Using CIPAC method MT 171, the classification "essentially non-dusty" encompasses the range 12 to 30 mg dust obtained from a 30 g sample. In view of the acute hazard presented by the active ingredient, the Meeting was concerned to minimize the risks presented by oxamyl GR dust. The manufacturer proposed that the "essentially non-dusty" range should have an upper limit of 18 mg dust in this case. The Meeting agreed that dust should be restricted to the lowest level practicable and that the dustiness clause should be amended accordingly.

SL. The manufacturer proposed that the description clause should be modified to include suitable dyes and an embittering agent, to minimize the possibility of accidental or deliberate ingestion of the formulation. In view of the acute hazard presented by the active ingredient, the Meeting agreed. The identity and concentration of these safeners is not particularly critical, so peer-validated test methods are not required. The manufacturer provided details of a qualitative GC-MS method to determine the presence of the embittering agent (sucrose octaacetate, SOA) added to the SL.

A reversed-phase HPLC for the determination of oxamyl in TC, SL, and GR formulations was adopted as a full CIPAC method in 2007. The method may used with internal or external standardization.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 342/2006

Uses

Oxamyl is a broad-spectrum carbamate insecticide/nematicide with systemic properties, active against many species of insects, mites and nematodes. It is an acetylcholinesterase inhibitor which can be can be applied as a foliar spray, by soil incorporation, or by watering onto soil in field, fruit and vegetable crops.

Identity

ISO common name:

Oxamyl

Synonyms:

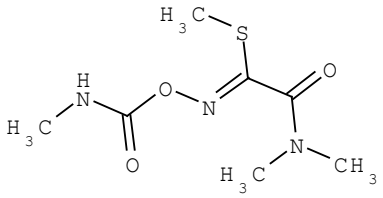
DPX-D1410, IN-D1410, Vydate®

Chemical names:

IUPAC *N*,*N*-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio)acetamide

CA methyl 2-(dimethylamino)-*N*-[[(methylamino)carbonyl]oxy]-2-oxoethanimidothioate

Structural formula:



Empirical formula:

$C_7H_{13}N_3O_3S$

Relative molecular mass:

219.3

CAS Registry number:

23135-22-0

CIPAC Number:

342

EEC Number:

245-445-3

Identity tests:

Reversed-phase HPLC-UV assay method; IR and UV spectra.

Physico-chemical properties of oxamyl

Table 1. Physico-chemical properties of pure oxamyl

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	5.12×10^{-5} Pa at 25°C (3.84×10^{-7} mm Hg $\pm 2.26 \times 10^{-7}$)(n = 9)	99.2	Gas saturation (W. J. Sonnenfeld, W. H. Zoller, and W. E. May, *Anal. Chem., 1983, 55*, 275-280), U.S. EPA Pesticide Assessment Guidelines Subdivision D, Series 63-9	AMR-1267-88
Melting point	99.2°C	98.0	OECD 102 (DSC and capillary)	DuPont-14983
Boiling point	Decomposes before boiling	98.0	OECD 102 (DSC and capillary)	DuPont-14983
Decomposition temperature	Above 165°C	98.0	OECD 102 (DSC and capillary)	DuPont-14983
Relative Density	1.313 ± 0.001 g/cm^3 at 23.6 ± 0.1°C (n = 15)	100	EEC A.3, OECD 109, pycnometer, EPA 830.7300	DuPont-2165
Solubility in water	28.2 ± 1.09 g/100 g at 25°C (n = 9)	95.7	U.S. EPA Pesticide Assessment Guidelines Subdivision D, Series 63-8, CG1500	D1410.E
Octanol/water partition coefficient	Log K_{OW} = 0.36 ± 0.021 at 25°C at pH 5 (n = 8)	98.0	U.S. EPA Pesticide Assessment Guidelines Subdivision D, Series 63-11	AMR 980-87
Hydrolysis characteristics	Half-life at 25°C pH 5, >31 days pH 7, ~8 days pH 9, ~3 hours	98.2 radio-chemical	U.S. EPA Pesticide Assessment Guidelines Subdivision D, Series 161-1	AMR 961-87
Photolysis characteristics	Simulated sunlight: Half-life ~7.0 days at pH 5, 25°C in sterile buffer solution	98.2 radio-chemical	U.S. EPA Pesticide Assessment Guidelines Subdivision N, Series 161-2	AMR 960-87
Dissociation characteristics	pKa = -2.11 (calculated)	-	-	DuPont-7158

Table 2. Physico-chemical properties of oxamyl technical grade (TK)

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 98.7–100.3%.
Declared minimum oxamyl content	407 g/kg*
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them:	None
Stabilizers or other additives and maximum limits for them:	None
Melting or boiling temperature range	Not applicable (TK is a solution)

* The minimum value declared to USEPA, based on the TK nominally containing 42% oxamyl. It does not refer to the declared minimum content given in the FAO specification for oxamyl TK, with or without the corresponding tolerance.

Hazard Summary

Oxamyl has been evaluated by the FAO/WHO JMPR (JMPR 2002). The JMPR established the ADI as 0–0.009 mg/kg bw and the ARfD as 0.009 mg/kg bw. Oxamyl has the WHO hazard classification 1b, highly hazardous.

The US EPA has re-evaluated oxamyl (USEPA 2000) and determined that a chronic endpoint (ADI equivalent) is unnecessary due to rapid reversibility of cholinesterase inhibition (2–3 hours). An acute reference dose (population adjusted) was set at 0.001 mg/kg. In regard to occupational concerns, EPA concluded that oxamyl is highly toxic via the oral, dermal, and inhalation routes (toxicity categories I, IV and II, respectively).

For consumer risk assessment, the EC established an ADI of 0.001 mg/kg bw/day and an ARfD of 0.001 mg/kg bw. Oxamyl was designated R26/28, very toxic by inhalation and if swallowed (EFSA 2005; EC 2006).

Formulations and co-formulated active ingredients

The main types of oxamyl formulation available are soluble concentrate (SL) and granules (GR). These formulations are registered and sold in many countries throughout the world.

Methods of analysis and testing

The analytical method for determination of oxamyl (including identity tests) is based on reversed-phase HPLC with UV detection at 240 nm and internal standardization with acetanilide. The method was adopted by CIPAC, with provisional status in 2006 and full CIPAC method status in 2007. The manufacturer and CIPAC have noted that the method can be used with external standardization.

The method for determination of impurities is based on reversed-phase HPLC with UV detection at 205 nm and external standardization.

Test methods for determination of physico-chemical properties of the pure and technical active ingredient were OECD, EEC, EPA and ASTM while those for the formulations were CIPAC.

Containers and packaging

There are no special requirements for containers or packaging.

Expression of the active ingredient

The active ingredient is expressed as oxamyl.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: the proposer provided written confirmation that the toxicological data included in the following summary were derived from oxamyl having impurity profiles similar to those referred to in Table 2, above.

Table A. Toxicology profile of oxamyl (isolated from TK unless otherwise stated), based on acute toxicity, irritation and sensitization

Species	Test	Duration and conditions	Result	Reference
Rat (m,f)	Oral	14 d; Directive 92/69/EEC method B.1. Oxamyl 97.1% purity	LD_{50} = 3.1 mg/kg bw (m) 2.5 mg/kg bw (f)	HLR 775-80
Rabbit, New Zealand white (m,f)	Dermal	14 d; Directive 92/69/EEC method B.3; USEPA Subdivision F, 81-2. Oxamyl 97.1% purity	LD_{50} = 5027 mg/kg bw (m) 5000 mg/kg bw (f)	HLR 114-88
Rat (m,f)	Inhalation	14 d; Directive 92/69/EEC method B.2; USEPA 870.1300; 59 NohSan No. 4200; OECD 403. Oxamyl 98.1% purity	LC_{50} = 56 mg/m^3 (0.056 mg/l) (m,f)	DuPont-6331
Rabbit, New Zealand white (m,f)	Skin irritation	72 h; Directive 92/69/EEC method B.4; USEPA 870.2500; 59 NohSan No. 4200; OECD 404. Oxamyl 98.1% purity	Non-irritant	DuPont-7060
Rabbit, New Zealand white (m,f)	Eye irritation	72 h; Directive 92/69/EEC method B.5; USEPA 870.2400, OECD 405; 59 NohSan No. 2400. Oxamyl 98.2% purity	Non-irritant	DuPont-7059
Guinea pig, Dunkin-Hartley	Skin sensitization	3 weeks; 48 h challenge; Buehler method; Directive 92/69/EEC method B.6; USEPA Subdivision F, 81-6. Oxamyl TK 42.0% purity	Not a sensitizer	HLR 179-88

Table B. Toxicology profile of oxamyl (isolated from TK), based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions	Result	Reference
Rabbit, New Zealand white (m,f)	Dermal	21 d, doses 0, 20, 40, 50, 75 mg/kg/d USEPA 82-2, 59; Nohsan No. 4200; OECD 410; Directive 92/69/EEC Method B.9. Oxamyl 96.9% purity	NOAEL = 50 mg/kg bw/d	DuPont-1599
Rat	Sub-acute, gavage	14 d, dose 2.4 mg/kg/d, study conducted prior to guidelines. Oxamyl 0.05% solution, Oxamyl 100% purity	No evidence of cumulative toxicity	HLR 150-68
Rat, Cr1:CD (m,f)	Feeding	90 d, doses 0, 50, 100 and 500 ppm Meets requirements of Directive 87/302/EEC Part B, 90-Day oral rodent. Oxamyl ~100% purity	NOAEL = 50 ppm (3.9 and 4.3 mg/kg bw/d, m and f, respectively)	HLR 308-69
Dog, beagle (m,f)	Feeding	1 year, doses 0, 12.5, 20, 35, 50, 150 and 250 ppm; USEPA Subdivision F, 83-1; Directive 87/302/EEC Part B, chronic toxicity test non-rodent. Oxamyl 97.1% purity	NOAEL = 50 ppm (1.36 and 1.46 mg/kg bw/d, m and f, respectively)	HLR 381-90, HLO 555-90
Rat (m,f)	Feeding	2 years, doses 0, 25, 50, 100 and 150 ppm; USEPA 83-5, 59; Nohsan No. 4200; OECD 410, Directive 87/302/EEC Part B chronic toxicity test rodent. Oxamyl 97.1% purity	NOAEL = 50 ppm (1.97 and 2.69 mg/kg bw/day, m and f, respectively) Not carcinogenic	HLR 278-91

Table B. Toxicology profile of oxamyl (isolated from TK), based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions	Result	Reference
Mouse (m,f)	Feeding	2 years, doses 0, 25, 50 and 75 ppm Directive 87/302/EEC part B chronic toxicity test rodent. Oxamyl 97.1% purity	NOAEL = 25 ppm (4.2 and 5.2 mg/kg bw/d, M and f, respectively) Not carcinogenic	HLO 252-81
Rat (m,f)	Acute neurotoxicity, gavage	Doses (m) 0, 0.1, 1.0, 2.0 mg/kg; (f) 0, 0.1, 0.75, 1.5 mg/kg USEPA Subdivision F, 81-8. Oxamyl 98.3% purity	NOAEL = 0.1 mg/kg bw/day	HLR 1118-96
Rat	Sub-chronic neurotoxicity, gavage	Doses 0, 10, 30 and 250 ppm USEPA Subdivision F, 81-8. Oxamyl 98.3% purity	NOAEL = 1.69 mg/kg bw/day	HL-1998-00708
Rat	Teratology, gavage	USEPA Subdivision F, 83-3; Directive 87/302/EEC Part B, teratogenicity test rodent. Oxamyl 97.2% purity	Maternal NOAEL = 0.5 mg/kg bw/d Foetal NOAEL = 0.5 mg/kg bw/d Developmental NOAEL >1.5 mg/kg bw/d*	HLR 473-88
Rabbit	Teratology, gavage	Directive 87/302/EEC Part B, teratogenicity test non-rodent. Oxamyl 97.1% purity	Maternal NOAEL = 1.0 mg/kg bw/d Foetal NOAEL = 2.0 mg/kg bw/d Developmental NOAEL >4 mg/kg bw/d*	HLO-801-80
Rat	Reproduction, feeding	USEPA Subdivision F, 83-4; Directive 87/302/ EEC Part B, 2-generation reproduction test. Oxamyl 97.1% purity	Parental NOAEL = 50 ppm (1.43 mg/kg bw/d) Offspring NOAEL = 1.43 mg/kg bw/d Reproductive NOAEL >12.2 mg/kg bw/d*	HLR 423-90

* Highest doses tested.

Table C. Mutagenicity profile of oxamyl (isolated from TK), based on *in vitro* and *in vivo* tests

Species	Test	Duration and conditions	Result	Reference
Salmonella typhimurium, E. coli	Bacterial gene mutation	Directive 92/69/EEC methods B.13 & B.14; 59 NohSan No. 4200. Oxamyl 96.9% purity	Negative ± activation	DuPont-3084
Chinese hamster ovary cells (HGPRT)	Mammalian cell gene mutation	Directive 87/302/EEC part B *in vitro* mammalian cell mutation test; USEPA 870.5300. Oxamyl 96.9% purity	Negative ± activation	DuPont-2937

Table C. Mutagenicity profile of oxamyl (isolated from TK), based on *in vitro* and *in vivo* tests

Species	Test	Duration and conditions	Result	Reference
Rat hepatocytes	*In vitro* unscheduled DNA synthesis (UDS)	U.S. EPA Pesticide Assessment Guidelines, 84-2; Directive 87/302/EEC Part B - DNA damage repair - unscheduled DNA synthesis. Oxamyl 97.1% purity	Negative	HLR 719-82
Human lymphocytes	*In vitro* mammalian cell cytogenetics	U.S. EPA 870.5375; 59 NohSan No. 4200; Directive 92/69/EEC method B.10. Oxamyl 96.9% purity	Negative ± activation	DuPont-2936
Mouse bone marrow	*In vivo* micronucleus	Directive 2000/32/EEC; Annex 4C-B.12; 59 NohSan No. 4200; OPPTS 870.5395; OECD 474. Oxamyl 98.2% purity	Negative	DuPont-10618

Table D. Ecotoxicology profile of oxamyl (isolated from TK)

Species	Test	Duration and conditions	Result	Reference
Lepomis macrochirus (bluegill sunfish)	Acute	96 h, static renewal (unaerated) U.S. EPA Pesticide Assessment Guidelines, Subdivision E, 72-1; OECD 203; EEC Method C.1. Oxamyl 96.9% purity	LC_{50} = 6.12 mg/l	HLO 69-69
Oncorhynchus mykiss (rainbow trout)	Acute	96 h, static renewal (unaerated) U.S. EPA Pesticide Assessment Guidelines, Subdivision E, 72-1; OECD 203; EEC Method C.1. Oxamyl 96.9% purity	LC_{50} = 3.13 mg/l	DuPont-2907
Daphnia magna (water flea)	Acute toxicity	48 h, static. U.S. EPA Pesticide Assessment Guidelines, Subdivision E, 72-2, OECD 202, EEC Method C.2. Oxamyl 96.9% purity	EC_{50} = 0.319 mg/l	DuPont-2553
Daphnia magna (water flea)	Chronic toxicity	21 d, static renewal (unaerated). OECD Guideline 202; U.S. EPA Pesticide Assessment Guidelines, Subdivision E, 72-4. Oxamyl 96.9% purity	NOEC = 0.0268 mg/ LOEC = 0.0502 mg/l MATC = 0.0367 mg/ 21 day EC_{50} = 0.119 mg/l (adult immobilization)	DuPont-2554
Oncorhynchus mykiss (rainbow trout)	Chronic toxicity, early life stage	21 d, flow-through. OECD Guideline 210; U.S. EPA Pesticide Assessment Guidelines, Subdivision E, 72-1. Oxamyl 97.2% purity	NOEC = 0.77 mg./l LOEC = 1.5 mg/l (% hatch and larval swim-up) MATC between 0.77 and 1.5 mg/l	AMR 468-88

Table D. Ecotoxicology profile of oxamyl (isolated from TK)

Species	Test	Duration and conditions	Result	Reference
(fathead minnow)	Chronic toxicity, early life stage	28 d, flow-through. Standard practice for toxicity tests on early life stages of fishes, ASTM Committee E-47. Oxamyl 97.1% purity	NOEC = 0.5 mg/l LOEC = 1.0 mg/l (larval survival) (MATC between 0.5 and 1.0 mg/l)	HLR 877-81
Lemna minor (duckweed)	Growth and reproduction	14 d. U.S EPA Pesticide Assessment Guidelines, Growth and reproduction of aquatic plants - Tier 1 and 2, Subdivision J, 122-2, 123-2. Oxamyl 100.0% purity	EC_{50} = 30.0 mg/l (No. normal fronds) 32.3 mg/l (biomass) NOEC = 10.2 mg/l (No. normal fronds) 20.4 mg/l (biomass)	DuPont-5612
Selenastrum capricornutum (green alga)	Growth and reproduction	120 h. OECD 201; FIFRA, Subdivision J, 123-2. Oxamyl 96.9% purity	Area under growth curve: EC_{50} = 1.37 mg/l NOEC <0.517 mg/l Growth rate EC_{50} = 4.16 gm/l NOEC = 1.01 mg/l	DuPont-2909
Anabaena flos-aquae (Blue/green alga)	Growth and reproduction	120 h. U.S. EPA Pesticide Assessment Guidelines, Growth and reproduction of aquatic plants - Tier 2, Subdivision J, 123-2. Oxamyl 100.0% purity	Cell density: EC_{50} = 0.398 mg/l NOEC = 0.137 mg/l Area under growth curve: EC_{50} = 0.299 mg/l NOEC <0.137 mg/l Growth rate: EC_{50} >2.10 mg/l NOEC = 0.137 mg/l	DuPont-5610
Eisenia foetida andrei (Earthworm)	Acute toxicity	14 d. OECD 207; EEC Guideline C(L1)4, Directive 79/831. Oxamyl 96.4% purity	LC_{50} = 112 mg/kg soil dw	AMR 3068-94
Apis mellifera (honey bee)	Acute contact toxicity	48 h. FIFRA Subdivision L, Series 141-1, hazard evaluation, nontarget insects, EPP0170. Oxamyl 96.9% purity	LD_{50} = 0.47 μg/bee	HLO 267-89
Apis mellifera (honey bee)	Acute oral toxicity	48 h. FIFRA Subdivision L, Series 141-1, hazard evaluation: nontarget insects, EPP0170. Oxamyl 96.9% purity	LD_{50} = 0.38 μg/bee	DuPont-2740
Colinus virginianus (Bobwhite quail)	Acute oral toxicity	14 d. USEPA 850.2100. Oxamyl 96.9% purity	LD_{50} = 9.5 mg/kg bw LOEL = 1.3 mg/kg bw	DuPont-2954
Anas platyrhynchos (Mallard duck)	Acute oral toxicity	14 d. Pesticide assessment guidelines, FIFRA subdivision E, 71-1; hazard evaluation: wildlife and aquatic organisms. Oxamyl 97.1% purity	LD_{50} = 3.16mg/kg bw LOEL = 1.0 mg/kg bw NOEL <1.0 mg/kg	HLO 89-81

Table D. Ecotoxicology profile of oxamyl (isolated from TK)

Species	Test	Duration and conditions	Result	Reference
Colinus virginianus (Bobwhite quail)	Dietary toxicity	5 d. Pesticide assessment guidelines, FIFRA subdivision E, 71-2; hazard evaluation: wildlife and aquatic organisms, USEPA 71-2. Oxamyl 97.1% purity	LC_{50} = 340.0 mg/kg diet NOEC = 39.0 mg/kg diet	HLO 47-88
Anas platyrhynchos (Mallard duck)	Dietary toxicity	5 d. Pesticide assessment guidelines, FIFRA subdivision E, 71-2; hazard evaluation: wildlife and aquatic organisms. Oxamyl (97.1% purity)	LC_{50} = 766 mg/kg diet NOEC <78 mg/kg diet	HLO 48-88

ANNEX 2. REFERENCES

DuPont document number or other reference	Year and title of report or publication details
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AMR 3068-94	1995. DPX-D1410: Determination of toxicity in earthworms.
AMR 468-88	1988. Early life-stage toxicity of IN-D1410-196 (oxamyl) to Rainbow Trout, *Oncorhynchus.*
AMR 960-87	1988. Photodegradation of [1^{14}C]DPX-D1410 in buffer solution pH 5 (conducted in simulated sunlight).
AMR 961-87	1988. Hydrolysis of [1^{14}C]DPX-D1410 in buffer solutions of pH 5, 7 and 9
AMR 980-87	1988. n-Octanol/water partition coefficient determination of DPX-D1410 at pH 5 and pH 7.
D1410.E	1988. Solubility of oxamyl (DPX-D1410) in water.
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DuPont-14983	2004. DPX-D1410: Laboratory Study of Melting Point and Decomposition Point.
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DuPont-2554	2000. Chronic toxicity of DPX-D1410 to *Daphnia magna.*
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DuPont-7060	2001. Primary dermal irritation study with DPX-D1410-196 in rabbits.
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HLO 252-81	1981. Oncogenicity study with oxamyl technical two year feeding study in mice.
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HLO 48-88	1988. A dietary LC_{50} study with the mallard. HLO 48-88.
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HLR 150-68	1968. Ten Dose Subacute Oral Test of IN D1410 in Rats HLR 150-68.
HLR 179-88	1988. Maximization sensitization study (Buehler method) with DPX-D1410-304 in Guinea pigs.
HLR 278-91	1991. Combined chronic toxicity/oncogenicity study with IN-D1410-196 two-year feeding study in rats.
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