



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Dinocap
SANCO/4345/2000 – final
5 January 2007

Review report for the active substance **dinocap**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
3 March 2006
in view of the inclusion of dinocap in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of dinocap, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Dinocap is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Rohm & Haas UK (legal successor: Dow AgroSciences) on 22 July 1993 notified to the Commission of its wish to secure the inclusion of the active substance dinocap in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Austria as rapporteur Member State to carry out the assessment of dinocap on the basis of the dossier submitted by the notifier. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for dinocap this deadline was 30 April 1995.

Only Rohm & Haas UK (legal successor: Dow AgroSciences) submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

supported uses. Therefore Rohm & Haas UK (legal successor: Dow AgroSciences) was considered to be the main data submitter. No information has furthermore been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Austria submitted on 18 May 2000 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of dinocap in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on dinocap from Rohm & Haas UK (legal successor: Dow AgroSciences), on 5 January 2001.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 27 June 2000 as well as to Rohm & Haas UK (legal successor: Dow AgroSciences) being the main data submitter, on 25 August 2000.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to September 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 16 November 2001 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the **Standing Committee on the Food Chain and Animal Health**, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from July 2001 to January 2006, and was finalised in the meeting of the **Standing Committee** on 3 March 2006.

The documents and information were also submitted to the Scientific Panel on Plant Health, Plant Protection Products and their Residues of the European Food Safety Authority (“the Scientific Panel”) for a separate independent consultation. As regards dinocap two questions were submitted to the Scientific Panel. The first question concerned the relevance to humans of eye effects that have been observed in dogs and the second related to the appropriate value for dermal absorption that could be derived from the different studies that have been made available by the notifier. On the first question the Scientific Panel considered that there is not sufficient information to conclude that the eye effects in dogs would only be specific to that species and that more research on the mechanisms involved may be necessary. Consequently, it is concluded that these effects in dogs cannot be regarded to be irrelevant to humans. On the second question, the Scientific Panel

considered a value of 10% dermal absorption to be appropriate for the purpose of the assessment. In both cases, the recommendations of the Scientific Panel⁵ have been taken into consideration in formulating this Directive and the relevant review report.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2006/136/EC concerning the inclusion of dinocap in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing dinocap they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the sole notifier for this active substance under Article 4(1) of this Regulation.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing dinocap will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive

⁵ Opinion of the Scientific Committee on Plant Health, Plant Protection Products and their Residues on a request from the Commission related to the evaluation of Dinocap in the context of Council Directive 91/414/EEC (Question N° EFSA-Q-2004-26, Opinion adopted on 30 June 2004)

91/414/EEC, for each dinocap containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 40 % (for wine grapes) of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems. With respect to the acute exposure via diet, NESTI calculations according to the UK-model for adults show 60.7 % of the ARfD for wine grapes (the acute dietary risk assessment for children is not regarded relevant considering wine grapes).

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of dinocap are given in Appendix I.

As given in Appendix I of this report, there is no FAO specification available.

The review has established that for the active substance notified by the main data submitter Rohm & Haas UK (legal successor: Dow AgroSciences), the following manufacturing impurities to be of relevance (of toxicological, environmental and/or other significance): 2,6-dinitro-4-octylphenol (2,6-DNOP) and 2,4-dinitro-6-octylphenol (2,4-DNOP).

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing dinocap

On the basis of the proposed and supported uses (as listed in Appendix IV), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Therefore the Member States must pay particular attention for the protection of:

- aquatic organisms. An appropriate distance must be kept between treated areas and surface water bodies. This distance may depend of the application or not of drift reducing techniques or devices;
- birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species;
- operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment;
- workers, who must wear suitable protective clothing, in particular gloves, if they must enter a treated area before the specific re-entry period has expired. This re-entry period may not be less than 24 hours.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of dinocap in Annex I under the current inclusion conditions.

Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems and require sales data and a survey of use patterns so that a realistic picture of the use conditions and the possible toxicological impact of dinocap can be obtained.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

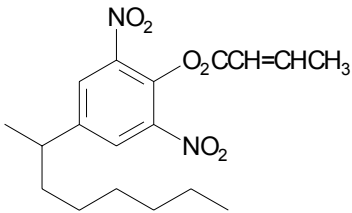
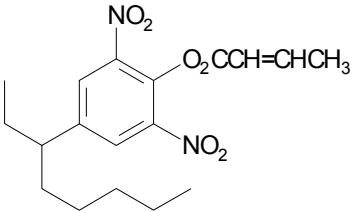
9. Updating of this review report

The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the **Standing Committee on the Food Chain and Animal Health**, in connection with any amendment of the inclusion conditions for dinocap in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

DINOCAP

Common name (ISO)	Dinocap
Chemical name (IUPAC)	2,6-dinitro-4-octylphenyl crotonates and 2,4-dinitro-6-octylphenyl crotonates in which 'octyl' is a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl groups
Chemical name (CA)	2-butenoic acid, 2-isooctyl-2,4-dinitrophenyl ester and 2-butenoic acid, 4-isooctyl-2,6-dinitrophenyl ester
CIPAC No	98
CAS No	39300-45-3 (for isomer mixture)
EEC No	254-408-0
FAO SPECIFICATION	-
Minimum purity	920 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance)	2,6-dinitro-4-octylphenol and 2,4-dinitro-6-octylphenol 25 g/kg
Molecular formula	$C_{18}H_{24}N_2O_6$
Molecular mass	364.18
Structural formula	
2,6-dinitro-4-(1-methyl heptyl)-phenyl crotonate	
	
2,6-dinitro-4-(1-ethyl hexyl)-phenyl crotonate	
	

Melting point	-25°C (freezing point of the isomer mixture) purity 92.4 %
Boiling point	Not relevant
Appearance	Dark red viscous liquid technical material
Relative density	1.135 purity 92.4 %
Vapour pressure	2,4-dinitro-6-octylphenyl crotonate purity 99.3% at 25°C $7.92 \cdot 10^{-6}$ 2,6-dinitro-4-octylphenyl crotonate purity 98.8% at 25°C $< 6.67 \cdot 10^{-6}$
Henry's law constant	2,4-dinitro-6-octylphenyl crotonate $1.16 \cdot 10^{-2}$ Pa m ³ /mole 2,6-dinitro-4-octylphenyl crotonate $2.08 \cdot 10^{-2}$ Pa m ³ /mole
Solubility in water	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate pH = 5 $1.51 \cdot 10^{-4}$ g/l at 20°C 2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate pH = 7 $2.48 \cdot 10^{-4}$ g/l at 20°C 2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate pH = 7 $1.17 \cdot 10^{-4}$ g/l at 20°C
Solubility in organic solvents	Dinocap (mixture of isomers) Solubility at 20°C purity 92.4% Acetone 7 – 95 wt.% Dichloromethane 6 – 93 wt.% Ethyl acetate 6 – 96 wt% Hexane 5 – 96 wt% Methanol 6 – 94 wt% Toluene 5 – 94 wt% 2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate Solubility at 25°C purity 96.9% Acetone > 251 g/l 1,2-Dichlorethane > 251 g/l Ethyl acetate > 250 g/l n-Heptane 8.5 – 10.2 g/l Methanol 20.4 – 25.3 g/l Xylene > 251 g/l

	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate Solubility at 25°C purity >95 % Acetone > 252 g/l 1,2-Dichlorethane > 252 g/l Ethyl acetate > 256 g/l n-Heptane > 251 g/l Methanol > 253 g/l Xylene > 256 g/l
Partition co-efficient (log P_{ow})	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate log P _(o/w) = 6,55 ± 0,33 at pH 7, 20.5°C
	2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate log P _(o/w) = 6,45 ± 0,33 at pH 7, 20.5°C
Hydrolytic stability (DT₅₀)	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate DT ₅₀ (at 20°C) DT ₅₀ (at 30°C) pH 4 447 days 91.4 days pH 7 30.4 days 30.5 days pH 9 9.25 days 2.34 days
	2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate DT ₅₀ (at 20°C) DT ₅₀ (at 30°C) pH 4 114 days 55 days pH 7 16.2 days 14.8 days pH 9 3.65 days 1.01 days
Dissociation constant	Not determined due to the low water solubility of the active substance
Quantum yield of direct photo-transformation in water at λ >290 nm	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate Φ 6.65 * 10 ⁻⁴ mole.einstein ⁻¹ 2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate Φ 3.57 * 10 ⁻⁴ mole.einstein ⁻¹
Flammability	Not relevant for liquids
Explosive properties	Not explosive
UV/VIS absorption (max.)	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate under neutral conditions wavelength ε (l . mole ⁻¹ . cm ⁻¹)
	240 nm 16727 310 nm 2155
	2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate neutral conditions (methanol /water = 90/10 v/v) 240 nm 16149 304 nm 2177
	Dinocap (92.4%, mixture of isomers) under neutral conditions 235 nm (max) 17034 300 nm (max) 2511

Photostability in water (DT₅₀)	2,4-dinitro-6-(1-methylheptyl)-phenyl crotonate DT ₅₀ = 0.63 days at pH 4 2,6-dinitro-4-(1-methylheptyl)-phenyl crotonate DT ₅₀ = 0.73 days at pH 4
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APPENDIX II

END POINTS AND RELATED INFORMATION

DINOCAP

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	70 % based on urinary excretion following oral and intravenous administration (rabbit study)
Distribution:	Widely distributed (highest levels found in kidney and liver)
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Urine (rat, mouse): 31 – 58 % within 96 h (most excreted within 24 h) Feces (rat, mouse): 32 – 64 % within 96 h (most excreted within 48 h)
Toxicologically significant compounds:	Parent compound and metabolites (DNOP-isomers)
Metabolism in animals:	Extensively metabolized in rat and mouse (> 96 % of the absorbed dinocap) via hydrolysis of the croton ester and apparently subsequent by α - and β -oxidation of the methylheptyl group

Acute toxicity

Rat LD ₅₀ oral:	1212 mg/kg bw (rat) 150 – 180 mg/kg bw (mouse)
Rat LD ₅₀ dermal:	> 2000 mg/kg bw (rabbit)
Rat LC ₅₀ inhalation:	> 3.0 mg/l (male) 4 h (nose only) 3.0 mg/l (female) 4 h (nose only)
Skin irritation:	Irritant
Eye irritation:	Non irritant
Skin sensitization (test method used and result):	Sensitizer (Buehler test)

Short term toxicity

Target / critical effect:	Indications of liver toxicity (mouse, rat)
Lowest relevant oral NOAEL / NOEL:	Insufficient information
Lowest relevant dermal NOAEL / NOEL:	No data, not required
Lowest relevant inhalation NOAEL / NOEL:	No data, not required

Genotoxicity

Genotoxic in bacteria No genotoxic potential in mammalian cells <i>in vitro</i> and <i>in vivo</i>

Long term toxicity and carcinogenicity

Target / critical effect:	Decreased body weight gain Liver and thyroid hypertrophy (rat) Testicular atrophy (mouse) Retinal atrophy (dog)
Lowest relevant NOAEL:	18-mo mouse: 15 ppm (2.27 mg/kg bw/d) 2-yr dog: 15 ppm (0.4 mg/kg bw/d)
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Increased pup mortality at parental toxic dose
Lowest relevant reproductive NOAEL / NOEL:	200 ppm (12.9 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Developmental toxicity including teratogenicity in at least 3 species (mouse, rabbit, hamster) Malformations (cleft palate, open eyelids, impaired otolith formation) in mice in the absence of maternal toxicity
Lowest relevant developmental NOAEL / NOEL:	4.0 mg/kg bw/d (oral mouse) 10.0 mg/kg bw/d (dermal mouse)

Delayed neurotoxicity

No data, not required

Other toxicological studies

Data indicate that dinitro-octylphenols are more acutely toxic than parent compound in rats Data indicate cataractogenic effects in rabbits
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Medical data

Following dermal contact: WP and EC formulation have produced irritations to the skin and delayed contact hypersensitivity in human subjects.

Summary

	Value	Study	Safety factor
ADI:	0.004 mg/kg bw/d	Two year dog study	100
AOEL systemic:	0.003 mg/kg bw/d	Two year dog study (70 % oral absorption)	100
AOEL inhalation:	Not necessary		
AOEL dermal:	Not necessary		
ARfD (acute reference dose):	0.004 mg/kg bw	Two year dog study	100

Dermal absorption

1 % for the concentrate [Karathane LC] and 10 % for the spray dilution (*in vitro* human skin; stratum corneum included) supported by results from *in vivo* mouse study and comparative *in vitro* mouse and human skin study (performed with another formulation)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

17-36 % AR

Non-extractable residues after 100 days:

38-46 % AR

Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)

2,4-DNOP: max. 22 % AR (30 d), 1-22 % AR (0-120 d)

2,6-DNOP: max. 16 % AR (7 d), 1-16 % (0-120 d)

Supplemental studies

Anaerobic:

not submitted

Soil photolysis:

2,4-DNOPC:

DT₅₀: 14.9 d of natural summer sunlight at latitude 40°N

DT₉₀: 49.6 d of natural summer sunlight at latitude 40°N

Major metabolites: 2,4-DNOP and CO₂

Remarks:

Only a slight influence of light on degradation was shown

Rate of degradation

Laboratory studies

Linear regression: n=4

data in italics: non-linear regression: n=1

DT_{50lab} (20 °C, aerobic):

2,4-DNOPC: DT_{50lab} (20°C, aerobic): 4 – 24 d, 10 d, mean=12 d

2,6-DNOPC: DT_{50lab} (20°C, aerobic): 4.5 d

DT_{90lab} (20 °C, aerobic):

2,4-DNOPC: DT_{90lab} (20°C, aerobic): 14 – 80 d, 113 d, mean=57 d

2,6-DNOPC: DT_{90lab} (20°C, aerobic): 16.4 d

DT_{50lab} (10 °C, aerobic):

2,4-DNOPC: DT_{50lab} (10°C, aerobic): 31 d

DT_{50lab} (20 °C, anaerobic):

Not submitted, not required

Metabolites:

Pseudo 1st order kinetics (Microsoft Excel), n=3

DT_{50lab} (20 °C, aerobic):

2,4-DNOP: DT_{50lab} (20° C, aerobic): 2.0 - 8.9 d, mean = 4.9

DT_{50lab} (10 °C, aerobic):2,6-DNOP: DT_{50lab} (20° C, aerobic): 18 - 31 d,
mean = 222,4-DNOP: DT_{50lab} (10° C, aerobic): 32 d2,6-DNOP: DT_{50lab} (10° C, aerobic): 32 d**Field studies (country or region)**DT_{50f} from soil dissipation studies:Dinocap formulated as Karathane WD
(containing 2,4- and 2,6-DNOPC and 2,4- and
2,5-DNOP 25.5 % each) at rates equivalent to
1.68 kg ai/ha and 3.36 kg ai/ha. Two US soils
(Newton, Fresno).Half-lives of residues (DNOPC+DNOP)
expressed as DT₅₀ of DNOP: 2,4-Isomer: 4.3-
7.5 d; 2,6-Isomer: 3.8-8.9 dDT_{90f} from soil dissipation studies:

Not calculated

Soil accumulation studies:

not submitted, not required

Soil residue studies:

Not submitted, not required

Remarks:

e.g. effect of soil pH on degradation rate

Degradation of total dinocap residues was not
significantly influenced by application rate.

Adsorption/desorption

K_f / K_{oc}:

K_f^{ads} ($\mu\text{g}^{1-1/n}(\text{cm}^3)^{1/n}\text{g}^{-1}$)
K_{oc} (cm^3g^{-1})

2,4-DNOPC (n=5(6)): K_f = 52-206 (3102),
mean = 136, K_{oc} = 2889-15300 (310200),
mean = 7854 (58245),
1/n = 0.87-1.03 (1.73), mean = 0.910 (1.05)

2,6-DNOPC (n=4(5)): K_f = 199 – 254 (827),
mean = 227 (448), K_{oc} = 7700 – 40222
(207000), mean = 20556 (57844), 1/n = 0.8-0.99
(1.32), mean = 0.91 (0.988)

2,4-DNOP (n=3(4)): K_f = 74.6 – 195 (501),
mean = 143 (232), K_{oc} = 3930 – 10833 (50100),
mean = 6528 (17421), 1/n = 0.85-1.06 (1.13),
mean = 0.96 (1.005)

2,6-DNOP (n=4): K_f = 50 – 185, mean = 133,
K_{oc} = 1515 – 12900, mean = 8381, 1/n = 0.92-
1.09, mean = 1.02

K_f^{des} ($\mu\text{g}^{1-1/n}(\text{cm}^3)^{1/n}\text{g}^{-1}$)

2,4-DNOPC (n=6): 400 – 1610, mean = 904,
1/n = 0.99-1.23, mean = 1.083

2,6-DNOPC (n=5): 163 – 1120, mean = 637,
1/n = 0.79-1.21, mean = 1.004

2,4-DNOP (n=4): 77.1 – 475, mean = 260,
1/n = 0.86 -1.16, mean = 1.008

2,6-DNOP (n=4): 119 – 380, mean = 255,
1/n = 1.00 -1.16, mean = 1.08

K_d:

2,4-DNOPC (n=5 (6)): 52 – 206 (3102),
mean = 136 (630)

2,6-DNOPC (n=5): 205 – 724, mean = 381

2,4-DNOP (n=4): 87-545, mean = 332

2,6-DNOP (n=4): 85-169, mean = 124

pH dependence:

No

Mobility

Laboratory studies:

Column leaching:

3.7 % and 1.4 % AR in leachate, data not sufficient

Aged residue leaching:

Ageing period: 2,4-DNOPC: 6 d
2,6-DNOPC: 5 d

% AR in leachate: 2,4-DNOPC: 0.2, 0.3 %
2,6-DNOPC: 0.4, 0.5 %

Field studies:

Lysimeter/Field leaching studies:

not submitted, not required

Remarks:

2,4- and 2,6-DNOPC and its metabolites show very low leaching potential

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

	2,4-DNOPC: pH 4 (20°C): 447 d pH 4 (30°C): 91.4 d	2,6-DNOPC: pH 4 (20°C): 114 d pH 4 (30°C): 55 d
	pH 7 (20°C): 30.4 d pH 7 (30°C): 30.5 d	pH 7 (20°C): 16.2 d pH 7 (30°C): 14.8 d
	pH 9 (20°C): 9.3 d pH 9 (30°C): 2.3 d	pH 9 (20°C): 3.7 d pH 9 (30°C): 1.0
Major metabolites:	2,4-DNOP: pH 4 (20°C/30°C): stable	2,6-DNOP: pH 4 (20°C/30°C): stable
	pH 7 (20°C/30°C): stable	pH 7 (20°C/30°C): stable
	pH 9 (20°C/30°C): stable	pH 9 (20°C/30°C): stable
Photolytic degradation:	2,4-DNOPC: pH 4 (40°N): 0.63 d ¹⁾ pH 5 (30°N): 0.2 d (initial) and 2.4 d (terminal) ²⁾	2,6-DNOPC: pH 4 (40°N): 0.73 d ¹⁾
	¹⁾ calculated with linear regression assuming a pseudo first order degradation kinetic ²⁾ calculated with non-linear function assuming a bi-phasic degradation	
Major metabolites:	2,4-DNOP: pH 4 (40°N): 8.7 d	2,6-DNOP: pH 4 (40°N): 20.8 d
	Calculated with linear regression assuming a pseudo first order degradation kinetic. The only degradation product of DNOP which could be identified was CO ₂ (max. 57 % after 367 h at pH 5).	

Biological degradation

Readily biodegradable:

Water/sediment study:

DT₅₀ water:

DT₉₀ water:

DT₅₀ whole system:

DT₉₀ whole system:

not readily biodegradable	
2,4-DNOPC: pH 7.7 and 7.8, 20°C 7.3 d and 4.1 d not stated	2,6-DNOPC: pH 7.9 and 7.5, 20°C 0.95 d and 1.77 3.2 d and 5.9 d
= DT ₅₀ water not stated	1.38 d and 15.5 4.6 d and 51.6 d

Distribution in water / sediment systems
(active substance)

2,4-DNOPC declined in waterphase:
System 1: 71.3 % AR (day 0) – 11.0 % AR (day 30)
System 2: 87.5 % AR (day 0) – 0.2 % AR (day 30)
after 61 d no as was detectable
sediment: < 10 % (extractable)
2,6-DNOPC declined in water:
system 1: 95.1 % AR (day 0) – 2.4 % AR (day 4)
system 2: 94.5 % AR (day 0) – 2.8 % AR (day 7)
after 4 d and 7 d no as was detectable

2,6-DNOPC sediment:
system 1: from max. 16.8 % (day 1) to 2.4 (day 59)
system 2: from max 42.2 % (day 4) to 16.4 (day 30)
after 59 and 30 d no as was detectable

Distribution in water / sediment systems
(metabolites)

2,4-DNOP declined in waterphase:
System 1: 23.7 % AR (day 0) – 5.3 % AR (day 30)
System 2: 19.1 % AR (day 0) – 0.2 % AR (day 30)
after 61 d no 2,4-DNOP was detectable
sediment: < 10 % (extractable)
Residues became bound (non-extractable) to the sediment

2,6-DNOP in water:
system 1: from max. 4.1 % AR (day 1) to 1.5 % AR (day 4)
system 2: from max 5.8 % AR (day 2) to 0.2 % AR (day 14)
after 4 d and 14 d no 2,6-DNOP was detectable

2,6-DNOP sediment:
system 1: from max. 8.5 % AR (day 2) to 0.4 % AR (day 59)
system 2: from max 9.8 % AR (day 4) to 1.9 % AR (day 30)
after 59 d no 2,6-DNOP was detectable

3'-(4-hydroxy-3,5-dinitrophenyl)butyric acid in water:
system 1: from max. 19.9% AR (day 2) to 1.1% AR (day 14)
system 2: from max 22.3% AR (day 4) to 0.7% AR (day 30)
after 30 d no metabolite was detectable

Accumulation in water and/or sediment:

3'-(4-hydroxy-3,5-dinitrophenyl)butyric acid in sediment: not detectable

no

Degradation in the saturated zone

not required

Remarks:

Due to the very low leaching potential it is very unlikely that dinocap or its metabolites will reach deeper soil layers
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2.3 Fate and behaviour in air

Volatility

Vapour pressure:

2,4-dinitro-6-octylphenyl crotonate purity 99.3% at 25°C $7.92 * 10^{-6}$ 2,6-dinitro-4-octylphenyl crotonate purity 98.8% at 25°C $< 6.67 * 10^{-6}$
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Henry's law constant:

2,4-dinitro-6-octylphenyl crotonate $1.16 * 10^{-2} \text{ Pa m}^3 / \text{mole}$ 2,6-dinitro-4-octylphenyl crotonate $2.08 * 10^{-2} \text{ Pa m}^3 / \text{mole}$
--

Photolytic degradation

Direct photolysis in air:

not submitted

Photochemical oxidative degradation in air

2,4-DNOPC: 1.89 – 1.9 h 2,6-DNOPC: 1.9 h

DT₅₀:

Volatilisation:

from plant surfaces: not submitted from soil: not submitted
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Remarks:

Due to its rapid photochemical oxidative degradation in air no significant residues of dinocap in the atmosphere are expected.
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3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD ₅₀ = 150 mg ai/kg bw (Mouse) LD ₅₀ = 1212 mg ai/kg bw (Rat)
Acute toxicity to birds:	LD ₅₀ > 2150 mg ai/kg bw (Bobwhite quail)
Dietary toxicity to birds:	LC ₅₀ = 2298 mg ai/kg feed (Bobwhite quail) LC ₅₀ = 2024 mg ai/kg feed (Mallard duck)
Reproductive toxicity to birds:	NOEC = 250 mg/kg feed \cong NOEL = 27.5 mg/kg bw (bobwhite quail)
Short term oral toxicity to mammals:	NOEC = 250 mg/kg feed (rat)

Aquatic Organisms

	Group / Organism	Test substance	Time-scale	Endpoint	Toxicity ($\mu\text{g ai/l}$)
Acute toxicity fish:	Bluegill sunfish	Dinocap technical	96 h	LC ₅₀	5.3
	Rainbow trout	2,4-DNOP	96 h	LC ₅₀	67
	Rainbow trout	LC-Formulation	96 h	LC ₅₀	16.5
	Fathead minnow	Dinocap techn.	96 h	LC ₅₀	20
	Common carp	Dinocap techn.	96 h	LC ₅₀	14
	Onchorynchus mykiss	LC-Formulation	96 h	LC ₅₀	44.3 ^a
	Lepomis machrochius	LC-Formulation	96 h	LC ₅₀	10.9 ^b
Long term toxicity fish:	Fathead minnow	Dinocap technical	33 d	NOEC	1.79
	Onchorynchus mykiss	LC-Formulation	28 d	NOEC	> 37.5 ^a
Bioaccumulation fish:	Lepomis machrochius	Dinocap technical	28 d exposure	BCF _{kin} ^d	992
			14 d depuration	CT ₅₀	0.8 d

Acute toxicity invertebrate:

Daphnia	Dinocap technical	48 h	EC ₅₀	4.2	
Daphnia	2,4-DNOP	48 h	EC ₅₀	26	
Daphnia	2,6-DNOP	48 h	EC ₅₀	126	
Daphnia	LC-Formulation	48 h	EC ₅₀	5.3	
Ceriodaphnia dubia	Dinocap techn.	48 h	EC ₅₀	4.2	
Gammarus pseudolim.	Dinocap techn.	96 h	LC ₅₀	7.4	
Daphnia magna	LC-Formulation	48 h	EC ₅₀	5.3 ^a / 9.5 ^b	
Chronic toxicity invertebrate:	Daphnia	Dinocap technical	21 d	NOEC	0.94
	Daphnia magna	Dinocap techn.	41 d	NOEC (population)	11 ^c
	Daphnia magna	LC-Formulation	21 d	NOEC	3.75 ^a
Acute toxicity algae:	Green algae	Dinocap technical	72 h	E _b C ₅₀ and E _r C ₅₀	320
	Green algae	2,4-DNOP	72 h	E _b C ₅₀ / E _r C ₅₀	91 / 187
	Green algae	LC-Formulation	72 h	E _b C ₅₀ / E _r C ₅₀	2500 / > 3600
Chronic toxicity sediment dwelling organism:	Chironomus riparius	Dinocap techn.	28 d	NOEC (emergence)	240 a

^a exposure in water/sediment system with artificial sediment

^b exposure in water/sediment system with natural sediment

^c exposure in indoor microcosm (water/sediment system with natural sediment)

^d BCF determination based on the total radiolabelled residues (parent compound and its possible metabolites)

Honeybees

Acute oral toxicity:

LD50: 6.4 µg ai/bee (Karathane LC)

Acute contact toxicity:

LD50: 29.3 µg ai/bee (Karathane LC)

Other arthropod species

<i>Test species</i>	Stage	Test Substance	Dose (g ai/ha)	Endpoint	% Effect
Laboratory tests					
<i>Aphidius colemani</i>	Adults	Karathane LC	490	Mortality	100
<i>Typhlodromus pyri</i>	Protonymphs	Karathane LC	490	Mortality	100
<i>Typhlodromus pyri</i>	Protonymphs	Karathane LC	2.24 3.92 6.86 12 21	Mortality / reproduction	7.5 / 8.9 3.8 / 9.5 37.5 / 9.5 62.5 / n.a. 90 / n.a.
<i>Poecilus cupreus</i>	Adults	Karathane LC	490	Mortality, feeding behaviour	0
<i>Orius insidiosus</i>	Nymphs	Karathane LC	490	Reduction of beneficial capacity	80
Semi-field tests					
<i>Chrysoperla carnea</i>	Larvae, adults	Karathane LC	1 x 210	Reduction of beneficial capacity	2.2
			2 x 210		34.4
			2 x 210 + 1 x 315		13.2
<i>Trichogramma cacoeciae</i>	Adults	Karathane LC	210	Reduction of parasitization	89.5/-52.5
			210 + 263		78.9/33.2
			210 + 263 + 315		60.7 / 47.3
<i>Aphidius rhopalosiphi</i>	Adults	Karathane LC	8 x 210	Reproductive capacity	71.1 (0DAA) 22.5 (7DAA) 38.4 (14DAA)
Field tests					
<i>Typhlodromus pyri</i>	Motile stages	Karathane LC	8 – 9 x 490	Mortality	6 x not significant 8 x significant
<i>Amblyseius aberrans</i>	No details given	Karathane LC	3 x 78	Mortality	Significant
		Karathane FN	2 x 210		
<i>Amblyseius aberrans</i>	No details given	Dinosip LC	4 x 360	Mortality	3 x significant
			4 x 540	Egg production	2 x significant

Phytoseiidae (mainly <i>Typhlodromus pyri</i>)	Nymphs and adults	Karathane LC	2 x 210 5 x 210 8 x 210	Mortality (maximal reduction in the season of treatment)	13.5 - 50.5 18.9 - 63.7 14 - 67.8 recovery proved until end of season
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Earthworms

Acute toxicity:

LC ₅₀ = (120) 60*

Reproductive toxicity:

LC ₅₀ = (>8.11) 4.06* mg ai/kg

NOEC (reproduction, body weight): (>8.11) 4.06 * mg ai/kg
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Soil micro-organisms

Nitrogen mineralization:

< 25 % at 2.1 kg ai/ha (2.8 mg ai/kg soil) after 28 d

Carbon mineralization:

< 25 % at 2.1 kg ai/ha (2.8 mg ai/kg soil) after 28 d

APPENDIX IIIA

DINOCAP

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.



B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
IIA 1.8	Thompson, W.R.	1964	Process Information for the Manufacture of Technical Karathane in Mozzanica, Italy Company file no: ER Ref. 40.9 non-GLP study	
IIA 1.8, 1.9, 1.10, 1.11	Berrier, J.V.	1987	Karathane Technical -Product Identity and Composition, -Analysis and Certification of Product Ingredients Company file no: ER Ref. 28.3 Company file no: US Ref No: RWN 87-150 GLP study not published	
IIA 1.11	Rothman, A.M,	1984	Karathane Accountability Company file no: ER Ref. 40.8 non-GLP study not published	
IIA 1.11	Rothman, A.M., Platek, W.A.	1985	Karathane Accountability Study Company file no: ER Ref. 17.1 non-GLP study not published	

⁶ Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
IIA 1.11	Mayeros, W.E.	1997	Analysis of KARATHANE Technical Lots 2692 and RS4914-1 for Weight % 2,4-DNOPC and 2,6-DNOPC Company file no: ER Ref .8 Company file no: APR-97-173 GLP study not published	
IIA 2.	Graves, D.	2000	Comparison of the similarities and differences between dinocap isomers ER 48.4 not published	
IIA, 2.1.1 IIA, 2.2 IIA, 2.4.1 IIA, 2.5 IIA, 2.7	Ardern, D.	1997 (a)	RH-65,601: Physical and Chemical Properties Generated by: Huntingdon Life Sciences Ltd. Company file no: ER Ref. 43.2 Company file no: US Ref. No. APR-97-221 GLP study not published	
IIA, 2.1.1 IIA, 2.2 IIA, 2.4.1 IIA, 2.5 IIA, 2.7	Ardern, D.	1997 (b)	RH-23,163: Physical and Chemical Properties Generated by: Huntingdon Life Sciences LTD. Company file no: ER Ref. 43.3 Company file no: US Ref. No. APR-97-223 GLP study not published	
IIA, 2.3.1	Betteley, J.	2001 (a)	Karathane ® Fungicide: Vapour Pressure Generated by: Huntingdon Life Sciences Submitted by: Rohm and Haas Report No. APR-01-049 Company file No ER 48.12 GLP study not published	
IIA, 2.3.2	Bettely, J.	2001 (b)	Karathane ® Fungicide: Henry's Constant Generated by: Huntingdon Life Sciences Submitted by: Rohm and Haas Report No. APR-01-050 Company file No. ER 48.11 GLP study not published	
IIA 2.5	Ardern, D.	1997 (d)	RH-22,992: Spectral Data Generated by: Huntingdon Life Sciences Ltd. Company file no: ER Ref. 43.1 Company file no: US Ref.No. APR-97-222 GLP study not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports⁶ on previous use in granting national authorizations
IIA 2.5.2	Arderm, D.	1997 (c)	RH-148,697: Spectral Data Generated by: Huntingdon Life Sciences Ltd. Company file no: ER Ref. 43.4 Company file no: US Ref.No. APR-97-224 GLP study not published	
IIA 2.6	Betteley, J.M.T.	1997 (b)	1-Methylheptyl Isomers of the Crotonates and Phenols of Dinocap: Water Solubility Generated by Huntingdon Life Sciences Ltd. Company file no: ER Ref. 42.7 Company file no: TR34-97-105 GLP study not published	
IIA 2.8	Betteley, J.M.T.	1997 (a)	1-Methylheptyl Isomers of the Crotonates and Phenols of Dinocap: Partition Coefficient Generated by Huntingdon Life Sciences Ltd. Company file no: ER Ref. 42.5 Company file no: TR34-97-104 GLP study not published	
IIA, 2.10	Betteley, J.	1999	Dinocap – Stability in air: Estimation of gas phase and aerosol photochemical oxidative degradation Rohm and Haas Report No. TR34-99-21 (ER 45.5) GLP study not published	
IIA, 2.10	Betteley, J.	2001 (c)	DNOP: Stability in air Generated by: Huntingdon Life Sciences Submitted by: Rohm and Haas Report No. APR-01-044 Company file No. ER Ref. 48.10 GLP not published	
IIA 4	Howie, D., Lees, M.J.	1996	Validation of the Method of Analysis for the Determination of Residual Concentrations of Dinocap on Field Operator Protective Clothing and Spray Tank Mixes Company file no: ER 41.7 Company file no: TR34-96-170 GLP study not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ⁶ on previous use in granting national authorizations
IIA 4.2.1	Brackett, C.K.	1991	Analytical Method for the Determination of Dinocap Residues on Apples Company file no: ER Ref No. 26.2 Company file no: US Ref No. TR 34-91-19 non-GLP study not published	
IIA 4.2.1	Howie, D.	1997	Dinocap: Validation of the confirmatory method of analysis for the determination of residues in apples company file no: ER 42.9 company file no: TR34-97-121 GLP study not published	
IIA 4.2.1	Lees, M.J.	1998 (a)	Validation of the Method of Analysis for the Determination of Residues in Grapes, Wine, Grape Juice, Cucumbers, Peppers, Apple Puree, Apple Juice, Strawberry Jam, and Strawberry Preserves Company file no: ER Ref. 42.4 Company file no: TR34-97-112 GLP study not published	
IIA 4.2.1	Lees, M.J.	1998 (b)	Validation of the Method of Analysis for the Determination of Residues in Tomatoes, Tomato Juice, Puree, Ketchup, Canned Tomatoes, Peaches Peach Juice, Preserves, Melons and Apple pomace Company file no: ER Ref. 43.9 Company file no: TR34-97-154 GLP study not published	
IIA 4.2.2	Burton, J.	1995 (a)	Karathane- Method Validation in Soil Company file no: ER Ref No. 39.6 Company file no: US Ref. No. TR34-95-08 GLP study not published	
IIA 4.2.3	Burton, J.	1995 (b)	Karathane- Method Validation in Water Company file no: ER Ref No. 39.5 Company file no: US Ref No. TR34-95-07 GLP study not published	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.1	Potter, D.W.	1996	Identification of 2,4-dinitro-6-(1-methyl-heptyl)phenyl-crotonate metabolites in rat and mouse urine. Rohm and Haas Company, Report No. 95R-064; ER Ref. No. 41.5 GLP, Not published	
IIA 5.2.3	Ferguson, J.S.	1997	Karathane technical: acute inhalation toxicity study in rats. Rohm and Haas Company, Report No. 96R-126; ER Ref. No. 41.11 GLP, Not published	
IIA 5.5	Ferguson, J.S., Morrison, R.D., and Bernacki, H.J. Jr.	1999	Karathane technical fungicide-miticide: one-year dietary toxicity study in rats. Rohm and Haas Company, Report No. 95R-169 ER Ref. No. GLP, Not published	
IIA 5.6.2	Foss, J.A.	1995	Dermal dose-range developmental toxicity study of Karathane LC [®] XF in mice. Argus Research Laboratories, Inc. USA Rohm and Haas Company, Report No. 95P-024; ER Ref. No. 39.13 GLP, Not published	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6	Howie, D.	1995	Dinocap Determination of stability of residues in grapes and apples ER Ref No. 68.1, 68.2 US Ref No. TR34-94-164 GLP not published	
IIA 6.1	Dohmeier, D.M.	1993	Nature of the residues in plants: Metabolism of ¹⁴ C dinocap in apples ER Ref No. 30.2 US Ref No. TR34-93-21 GLP not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.1	Dohmeier, D.M.	1994	Nature of the residues in plants: Metabolism of ¹⁴ C dinocap in apples Supplement to Rohm and Haas Technical Report 34-93-21 ER Ref No. 32.1 US Ref No. TR34-94-14 GLP not published	
IIA 6.1	Howie, D.	1994	Dinocap: The comparison of the rates of decline of isomers in apples and strawberries ER Ref No. 31.7 US Ref No. TR34-94-107 not published	
IIA 6.1	Graves, D.	2000	Comparison of the similarities and differences between dinocap isomers ER 48.4 not published	
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Conraux, M.T.	1994 (a)	Residue at harvest of dinocap in grapes, must and wine after treatment with Karathane LC (350 g/l dinocap EC formulation) in the south-part of France 1992 ER Ref No. 66.19 residue analysis : GLP compliant not published	
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (b)	Degradation curve of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in Portugal 1992 ER Ref No. 63.2 residue analysis : GLP compliant not published	
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (c)	Degradation curve of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in Portugal 1992 ER Ref No. 63.3 residue analysis : GLP compliant not published	
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (d)	Residue at harvest of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in France 1992 ER Ref No. 63.14 not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (e)	Determination of the residues of dinocap (Karathane LC - 350 g/l dinocap EC formulation) in grapes 1991. (Reanalysed samples from trials are R 64.10.) ER Ref No. 61.17, 61.18, 61.23, 61.24, 61.38/ ER 64.10 residue analysis : GLP compliant not published	
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Feilden, A.D.	1999	To determine the magnitude of residues of dinocap during the twenty eight days following the final application in the raw agricultural and processed commodity of wine grapes resulting from sequential directed application of Karathane LC or Karathane FN57 in Germany and Northern France ER Ref No. 72.1 (LC) and 72.2 (FN57) GLP not published	
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Lees, M.J.	1998 (c)	To determine the magnitude of residues of dinocap during the twenty eight days following the final application in the raw and processed agricultural commodity of grapes resulting from sequential directed application of Karathane LC in Germany ER Ref No. 68.6 GLP not published	
IIA 6.3, IIIA 8.1	Lees, M.J.	1998 (d)	To determine the magnitude of residues of dinocap during the twenty one days following the final application in the raw agricultural commodity of wine grapes resulting from sequential directed application of Karathane LC in Europe ER Ref No. 69.1 GLP not published	
II A 6	Lees, M.J.	1998 (j)	Dinocap Determination of the storage stability of residue levels of dinocap in cucumbers, tomatoes, peaches, apples and strawberries ER Ref No. 74.3 US Ref No. TR34-98-37 GLP not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1993 (e)	Dinocap grape residue studies 1992 40492-62 and 40492-63 with Karathane LC (350 g/l dinocap formulation) ER Ref No. 64.12 residue analysis : GLP compliant not published	
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1993 (f)	Dinocap grape residue studies 1992 40491-40, 40491-41, 40491-42, 40491-49, 40491-50 and 40491-51 with Karathane LC (350 g/l dinocap formulation) ER Ref No. 62.6 not published	
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1994 (b)	Dinocap grapes (must & wine) residue studies - 1993; trials 4839301 and 4839302 with Karathane FN (18.25 % dinocap WP formulation) and Karathane LC (350 g/l dinocap LC formulation) residue analysis : GLP compliant ER Ref No. 67.9 and 67.10 not published	
IIA 6.3, IIIA 8.1	Sutcliffe, S.J.	1998 (c)	To determine the magnitude of residues of dinocap during the twenty one days following the final application in the raw agricultural commodity of wine grapes resulting from sequential directed application of Karathane LC or Karathane FN57 in Italy and Greece ER Ref No. 70.2 (LC) and 70.3 (FN57) residue analysis : GLP compliant not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA 6	Howie, D.	1995	Dinocap Determination of stability of residues in grapes and apples ER Ref No. 68.1, 68.2 US Ref No. TR34-94-164 GLP not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA 6.1	Dohmeier, D.M.	1993	Nature of the residues in plants: Metabolism of ¹⁴ C dinocap in apples ER Ref No. 30.2 US Ref No. TR34-93-21 GLP not published
IIA 6.1	Dohmeier, D.M.	1994	Nature of the residues in plants: Metabolism of ¹⁴ C dinocap in apples Supplement to Rohm and Haas Technical Report 34-93-21 ER Ref No. 32.1 US Ref No. TR34-94-14 GLP not published
IIA 6.1	Howie, D.	1994	Dinocap: The comparison of the rates of decline of isomers in apples and strawberries ER Ref No. 31.7 US Ref No. TR34-94-107 not published
IIA 6.1	Graves, D.	2000	Comparison of the similarities and differences between dinocap isomers ER 48.4 not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Conraux, M.T.	1994 (a)	Residue at harvest of dinocap in grapes, must and wine after treatment with Karathane LC (350 g/l dinocap EC formulation) in the south-part of France 1992 ER Ref No. 66.19 residue analysis : GLP compliant not published
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (b)	Degradation curve of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in Portugal 1992 ER Ref No. 63.2 residue analysis : GLP compliant not published
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (c)	Degradation curve of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in Portugal 1992 ER Ref No. 63.3 residue analysis : GLP compliant not published
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (d)	Residue at harvest of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in France 1992 ER Ref No. 63.14 not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (e)	Determination of the residues of dinocap (Karathane LC - 350 g/l dinocap EC formulation) in grapes 1991. (Reanalysed samples from trials are R 64.10.) ER Ref No. 61.17, 61.18, 61.23, 61.24, 61.38/ ER 64.10 residue analysis : GLP compliant not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Feilden, A.D.	1999	To determine the magnitude of residues of dinocap during the twenty eight days following the final application in the raw agricultural and processed commodity of wine grapes resulting from sequential directed application of Karathane LC or Karathane FN57 in Germany and Northern France ER Ref No. 72.1 (LC) and 72.2 (FN57) GLP not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Lees, M.J.	1998 (c)	To determine the magnitude of residues of dinocap during the twenty eight days following the final application in the raw and processed agricultural commodity of grapes resulting from sequential directed application of Karathane LC in Germany ER Ref No. 68.6 GLP not published
IIA 6.3, IIIA 8.1	Lees, M.J.	1998 (d)	To determine the magnitude of residues of dinocap during the twenty one days following the final application in the raw agricultural commodity of wine grapes resulting from sequential directed application of Karathane LC in Europe ER Ref No. 69.1 GLP not published
II A 6	Lees, M.J.	1998 (j)	Dinocap Determination of the storage stability of residue levels of dinocap in cucumbers, tomatoes, peaches, apples and strawberries ER Ref No. 74.3 US Ref No. TR34-98-37 GLP not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1993 (e)	Dinocap grape residue studies 1992 40492-62 and 40492-63 with Karathane LC (350 g/l dinocap formulation) ER Ref No. 64.12 residue analysis : GLP compliant not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1993 (f)	Dinocap grape residue studies 1992 40491-40, 40491-41, 40491-42, 40491-49, 40491-50 and 40491-51 with Karathane LC (350 g/l dinocap formulation) ER Ref No. 62.6 not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1994 (b)	Dinocap grapes (must & wine) residue studies - 1993; trials 4839301 and 4839302 with Karathane FN (18.25 % dinocap WP formulation) and Karathane LC (350 g/l dinocap LC formulation) residue analysis : GLP compliant ER Ref No. 67.9 and 67.10 not published
IIA 6.3, IIIA 8.1	Sutcliffe, S.J.	1998 (c)	To determine the magnitude of residues of dinocap during the twenty one days following the final application in the raw agricultural commodity of wine grapes resulting from sequential directed application of Karathane LC or Karathane FN57 in Italy and Greece ER Ref No. 70.2 (LC) and 70.3 (FN57) residue analysis : GLP compliant not published

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA, 7.1.1/04	Lewis C.J.	1995	(¹⁴ C)-Dinocap: Soil Metabolism And Degradation Rohm and Haas Company Report No. TR34-94-172 In accordance with GLP, not published
IIA, 7.2.1	Randazzo, D.J.	1994	Quantum yield calculations for the aqueous photolysis of Dinocap. Rohm and Haas Company, Spring House, PA, USA Report No. TR34-94-136 not published
IIA, 7.1.1/05	Whittle, E.B.	1998	Dinocap Aerobic Soil Metabolism: Aerobic Soil Metabolism Under Laboratory Conditions Of 1-Methylheptyl Isomers Of The Crotonates Rohm and Haas Company Report No. TR-34-98-101 In accordance with GLP, not published
IIA, 7.2.1	Winwick, T.	1998	Dinocap photolysis: Determination of the photolytic degradation of the 1-methylheptyl isomers of the crotonates and phenols. Huntingdon Life Sciences Ltd Report Nr. TR34-98-35 GLP-compliance not published
IIA, 7.2.1	Winwick, T.	1998	Dinocap: Determination of the hydrolysis under laboratory conditions of the 1-methylheptyl isomers of the crotonates and phenols at 20° and 30°C. Huntingdon Life Sciences Ltd. Report Nr. TR34-98-65 GLP-compliance not published

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA, 8.3.3	Candolfi, M.P.	1994f	Karathane LC: Laboratory Contact LD50 Test with the Honeybee, <i>Apis mellifera</i> , following EPPO Guideline 170 (1992) Rohm & Haas Report No. 94RC-0083A In accordance with GLP, not published
IIA, 8.3.3	Candolfi, M.P.	1994 a	Karathane LC: Laboratory Oral LD50 Test with the Honeybee, <i>Apis mellifera</i> , following EPPO Guideline 170 (1992) Rohm & Haas Report No. 34.7 In accordance with GLP, not published
IIA, 8.2.3	Corden, M.T.	1998	Dinocap: determination of the bioconcentration in bluegill sunfish of the 1-methylheptyl isomer of the 2,4-dinitrophenyl crotonate. Huntington Life Sciences Ltd. Report NO. TR34-98-114 GLP-compliance not published
IIA, 8.4	Downing, J., Leak, T.	1994	Karathane ^R Technical: Toxicity to the Earthworm, <i>Eisenia foetida</i> ABC Lab. Inc. Report No. 41620 Rohm & Haas Report No. 94RC-0085 In accordance with GLP, not published
IIA, 8.2.5	Forbis, A.D	1994	Chronic toxicity of Karathane [®] to <i>Daphnia magna</i> under flow-through test conditions. ABC Laboratories Inc. Report No. 41619 GLP-compliance not published
IIA, 8.2.6	Hicks, S.L. & T. Leak	1997	Acute toxicity of Karathane [®] technical to <i>Selenastrum capricornutum</i> Printz. ABC Laboratory Report No. 43815 GLP-compliance not published
IIA, 8.6	Musco, V.A.	1994	Greenhouse Screening Test with Karathane LC Rohm & Haas Report No.36.3 Not in accordance with GLP, not published
IIA, 8.2.2.2	Rhodes, J.E. & T. Leak	1995	Early life-stage toxicity of Karathane [®] to the Fathead minnow (<i>Pimephales promelas</i>) under flow-through conditions. ABC Laboratories Inc. Report No. 41618 GLP-compliance not published

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
IIA, 8.2.1	Sword, M.C. & T. Leak	1994a	Acute flow-through toxicity of Karathane [®] technical to bluegill (<i>Lepomis macrochirus</i>). ABC Laboratory Report No. 41621 GLP-compliance not published
IIA, 8.2.4	Sword, M.C. & T. Leak	1994b	Acute flow-through toxicity of Karathane [®] technical to <i>Daphnia magna</i> . ABC Laboratory Report No. 41484 GLP-compliance not published
IIA, 8.1.2	Williams, B. A.	1994 a	Karathane Technical: 8-Day Acute Dietary LC ₅₀ Study in Bobwhite Quail Ecological Planning Toxicology, Inc., Report No 94RC-0058 GLP-compliance not published
IIA, 8.1.2	Williams, B. A.	1994 b	Karathane Technical: 8-Day Acute Dietary LC ₅₀ Study in Mallard Ducklings Ecological Planning Toxicology, Report No 94RC-0060 GLP-compliance not published

APPENDIX IIIB

DINOCAP

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant), Published or not
IIA, 2.	Graves, D.	2000	Comparison of the Similarities and Differences Between Dinocap Isomers Rohm and Haas Technical Report No. 34-00-92 (ER Ref. No. 48.4) not GLP not published
IIA, 2.3.1	Betteley, J.	2001 (a)	Karathane ® Fungicide: Vapour Pressure Generated by: Huntingdon Life Sciences Submitted by: Rohm and Haas Report No. APR-01-049 Company file No ER 48.12 GLP study not published
IIA, 2.3.2	Bettely, J.	2001 (b)	Karathane ® Fungicide: Henry's Constant Generated by: Huntingdon Life Sciences Submitted by: Rohm and Haas Report No. APR-01-050 Company file No. ER 48.11 GLP study not published
IIIA, 2.3	Licata-Messana, L.	2000 (b)	Karathane LC XF- Self ignition temperature of liquids Report o. 00-918015-053 (ER 48.3) GLP study

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not
			not published
IIA, 2.10	Betteley, J.	1999	Dinocap – Stability in air: Estimation of gas phase and aerosol photochemical oxidative degradation Rohm and Haas Report No. TR34-99-21 (ER 45.5) GLP study not published
IIA, 2.10	Betteley, J.	2001 (c)	DNOP: Stability in air Generated by: Huntingdon Life Sciences Submitted by: Rohm and Haas Report No. APR-01-044 Company file No. ER Ref. 48.10 GLP not published
IIA 4.2.4 IIIA 5.2.4	Anonymous	Not speci- fied	Rohm Haas Company Corporate Industrial Hygiene Laboratory- Karathane Method I.H.717 Company file no. ER 47.8 non GLP study

IIIA, 2.1	Grandcolas, D.	2000	Karathane LC- Determination of odor Ref.No. 47.12 GLP study not published
IIIA, 2.2.1	Licata-Messana, L.	2000 (a)	Karathane LC XF- Explosive properties (liquid) Report o. 00-918015-052 (ER 48.2) GLP study not published

B.6 Toxicology and metabolism

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
II A 6	Lees, M.J.	1998 (j)	Dinocap Determination of the storage stability of residue levels of dinocap in cucumbers, tomatoes, peaches, apples and strawberries ER Ref No. 74.3 US Ref No. TR34-98-37 GLP not published
IIA 6	Howie, D.	1999	Dinocap

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
			Determination of stability of residues in cucumbers, tomatoes, peaches, apples and strawberries ER Ref No. 76.1 GLP not published
IIA 6.1	Dohmeier, D.M.	1993	Nature of the residues in plants: Metabolism of ¹⁴ C dinocap in apples ER Ref No. 30.2 US Ref No. TR34-93-21 GLP not published
IIA 6.1	Dohmeier, D.M.	1994	Nature of the residues in plants: Metabolism of ¹⁴ C dinocap in apples Supplement to Rohm and Haas Technical Report 34-93-21 ER Ref No. 32.1 US Ref No. TR34-94-14 GLP not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Conraux, M.T.	1994 (a)	Residue at harvest of dinocap in grapes, must and wine after treatment with Karathane LC (350 g/l dinocap EC formulation) in the south-part of France 1992 ER Ref No. 66.19 residue analysis : GLP compliant not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Feilden, A.D.	1999	To determine the magnitude of residues of dinocap during the twenty eight days following the final application in the raw agricultural and processed commodity of wine grapes resulting from sequential directed application of Karathane LC or Karathane FN57 in Germany and Northern France ER Ref No. 72.1 (LC) and 72.2 (FN57) GLP not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Lees, M.J.	1998 (c)	To determine the magnitude of residues of dinocap during the twenty eight days following the final application in the raw and processed agricultural commodity of grapes resulting from sequential directed application of Karathane LC in Germany ER Ref No. 68.6 GLP not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1993 (e)	Dinocap grape residue studies 1992 40492-62 and 40492-63 with Karathane LC (350 g/l dinocap formulation) ER Ref No. 64.12 residue analysis : GLP compliant not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1993 (f)	Dinocap grape residue studies 1992 40491-40, 40491-41, 40491-42, 40491-49, 40491-50 and 40491-51 with Karathane LC (350 g/l dinocap formulation) ER Ref No. 62.6

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
			not published
IIA 6.3, IIA 6.5, IIIA 8.1, IIIA 8.3	Pessina, F.	1994 (b)	Dinocap grapes (must & wine) residue studies - 1993; trials 4839301 and 4839302 with Karathane FN (18.25 % dinocap WP formulation) and Karathane LC (350 g/l dinocap LC formulation) residue analysis : GLP compliant ER Ref No. 67.9 and 67.10 not published
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (b)	Degradation curve of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in Portugal 1992 ER Ref No. 63.2 residue analysis : GLP compliant not published
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (c)	Degradation curve of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in Portugal 1992 ER Ref No. 63.3 residue analysis : GLP compliant not published
IIA 6.3, IIIA 8.1	Conraux, M.T.	1993 (d)	Residue at harvest of dinocap in grapes after treatment with Karathane LC (350 g/l dinocap EC formulation) in France 1992 ER Ref No. 63.14 not published
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IIA 6.3, IIIA 8.1	Sutcliffe, S.J.	1998 (c)	To determine the magnitude of residues of dinocap during the twenty one days following the final application in the raw agricultural commodity of wine grapes resulting from sequential directed application of Karathane LC or Karathane FN57 in Italy and Greece ER Ref No. 70.2 (LC) and 70.3 (FN57) residue analysis : GLP compliant not published

B.8 Environmental fate and behaviour

B.9 Ecotoxicology

APPENDIX IV

List of uses supported by available data

DINOCAP

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Berries and small fruits															
Grapes: Wine grapes	NE	Karathane LC	F	Powdery Mildew	EC	350 g/l	air-blast sprayer	ripening of fruits summer	8	10	0.021	1000	0.21	21	
Grapes: Wine grapes	SE	Karathane LC	F	Powdery Mildew	EC	350 g/l	air-blast sprayer	ripening of fruits summer	8	10	0.021	1000	0.21	21	

DINOCAP

APPENDIX IV
List of uses supported by available data
05 October 2005

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions