EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

methoxyfenozide

SANCO/10384/2002 - rev. 4

7 October 2004

COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Review report for the active substance **methoxyfenozide**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 8 October 2004 in view of the inclusion of methoxyfenozide in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance methoxyfenozide, made in the context of the work provided for in Articles 5 and 6 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.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the British authorities received on 21 February 2000 an application from Rohm and Haas France SA (now Dow AgroSciences), hereafter referred to as the applicant, for the inclusion of the active substance methoxyfenozide in Annex I to the Directive. British authorities indicated to the Commission on 13 October 2000 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on methoxyfenozide was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 02 February 2001, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 2001/385/EC [1] of 4 May 2001 that these requirements were satisfied.

[1] OJ No L 137, 19.05.2001, p. 30.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that The United Kingdom would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

The United Kingdom submitted to the Commission on 2 August 2002 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of methoxyfenozide in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Dow AgroSciences being the sole applicant on 7 August 2002.

The Commission organised further an intensive consultation of specialised scientific experts from a representative 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 November 2002 to July 2003.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 14 October 2003.

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, 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 May 2004 to October 2004, and was finalised in the meeting of the Standing Committee on 8 October 2004.

The present review report contains the conclusions of this 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.

The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or the Panel on Plant Health, Plant Protection Products and their Residues of the European Food Safety Authority.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2005/3EC[2] concerning the inclusion of methoxyfenozide in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing methoxyfenozide 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 parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the 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 applicant.

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 possession of 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 methoxyfenozide 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 91/414/EEC, for each methoxyfenozide 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 sole 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.

---

[2] OJ No L 020, 22.01.2005, p. 19-23

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of methoxyfenozide in foodstuffs

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) for a 60 kg adult is 1.2 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994) and acute exposure was estimated to be up to 16 % of the acute reference dose (ARfD). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Ecotoxicology

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 7 of this report.

5. Identity and Physical/chemical properties

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

The active substance shall have a minimum purity of 970 g/kg technical product.

The review has established that for the active substance notified by the applicant (Dow AgroSciences), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. 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 as identified during the evaluation process are listed in Appendix II.

7. 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 methoxyfenozide

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

In this overall assessment, Member States should pay particular attention to the protection of terrestrial and aquatic non-target arthropods.

Risk mitigation measures should be applied where appropriate.

8. List of studies to be generated

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

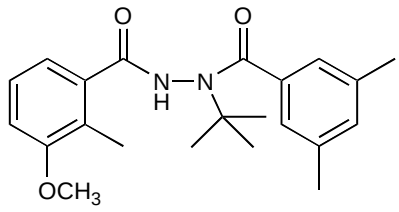
9. Updating of this review report

The technical information in this report may require periodic updating 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 methoxyfenozide in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

Methoxyfenozide

Common name (ISO)	Methoxyfenozide
Development Code (for new actives only)	RH - 2485
Chemical name (IUPAC)	N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide
Chemical name (CA)	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CIPAC No	656
CAS No	161050-58-4
EEC No	Not allocated
FAO SPECIFICATION	Not available
Minimum purity	≥ 970 g/kg
Molecular formula	$C_{22}H_{28}N_2O_3$
Molecular mass	368.47
Structural formula	

Melting point	TGAI: 204-206.6°C PAI: 206.2-208°C
Boiling point	Not possible - decomposition of methoxyfenozide at 262.9-264.8ºC
Appearance	Brown powder (99.8%)
Relative density	TGAI: 0.634 PAI: 0.740
Vapour pressure	<1.33x10-5 Pa at 25, 35 and 45 °C
Henry's law constant	<1.64 x 10-4 $Pa.m^3.mol^{-1}$ @ 20°C
Solubility in water	pH 7 : 3.3 mg/L at 20°C
Solubility in organic solvents	Solvent solubility (g/l, 25 °C) n-heptane 1.87 xylene 3.38 1,2 dichloroethane 36.72 methanol 192.92 2-propanol 50.22 acetone 126.88 butyl acetate 18.76
Partition co-efficient (log P_{ow})	3.72 at 25°C
Hydrolytic stability (DT_{50})	pH 5: stable pH 7: stable pH 9: stable
Dissociation constant	Not applicable
Quantum yield of direct photo-transformation in water at λ >290 nm	1.91 x 10^{-3}
Flammability	Not highly flammable. Does not undergo spontaneous combustion
Explosive properties	Not explosive
UV/VIS absorption (max.)	ε 55313 at 203 nm
Photostability in water (DT_{50})	No significant degradation in either light or dark conditions within 30 days.

APPENDIX II

END POINTS AND RELATED INFORMATION

METHOXYFENOZIDE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	About 60-70% within 72h in the rat (biliary excretion taken into account) following a single gavage dose of 10 mg/kg bw
Distribution:	Widely distributed. Highest absorbed levels after 15 min – 2 h in the liver . Highest levels after 5 days also chiefly in liver.
Potential for accumulation:	Data indicate low potential
Rate and extent of excretion:	86-96% of a single dose in faeces after 5 days (with significant biliary excretion)
Toxicologically significant compounds:	Parent compound and metabolites. Impurities 1 and 6
Metabolism in animals:	Extensive (no parent found in urine or bile). M14 (desmethylated parent) and M24 (hydroxy methyl derivative) were main metabolites in urine and faeces. Very few metabolites formed by cleavage of parent.

Acute toxicity

Rat LD_{50} oral:	> 5000 mg/kg bw
Rat LD_{50} dermal:	5000 mg/kg bw
Rat LC_{50} inhalation:	>4.3 mg/l (4h, nose only, maximum achievable concentration)
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Non-sensitiser in submitted study (M &K)

Short term toxicity

Target / critical effect:	Liver (hypertrophy), red blood cells (MetHb and haemolysis)
Lowest relevant oral NOAEL / NOEL:	500 ppm (18 mg/kg bw/day) 2 week and 1 year dog
Lowest relevant dermal NOAEL / NOEL:	>1000 mg/kg bw/day 28-day rat
Lowest relevant inhalation NOAEL / NOEL:	Studies not required – methoxyfenozide in non-volatile and acute study showed low toxicity

Genotoxicity

Sufficient evidence to conclude that the proposed technical specification of methoxyfenozide for which authorisation is sought is not genotoxic.

Long term toxicity and carcinogenicity

Target / critical effect:	RBC (reduced parameters), liver (hypertrophy), thyroid (hypertrophy)
Lowest relevant NOAEL:	200 ppm (10 mg/kg bw/day) 80-90 week rat
Carcinogenicity:	No evidence of a substance-related carcinogenic response

Reproductive toxicity

Target / critical effect - Reproduction:	No substance-related adverse effects at parental toxic dose level
Lowest relevant reproductive NOAEL / NOEL:	>20,000 ppm (>1333 mg/kg bw/day)
Target / critical effect - Developmental toxicity:	No evidence of substance-related adverse effects up to limit dose
Lowest relevant developmental NOAEL / NOEL:	> 1000 mg/kg bw/day (rat and rabbit)

Delayed neurotoxicity

NOAEL (acute neurotoxicity rat) > 2000 mg/kg bw
NOAEL (90-day neurotoxicity rat) >20,000 ppm (1318 mg/kg bw/day)

Other toxicological studies

Major initial rat metabolite (M14)
Mouse oral LD50 > 5000 mg/kg bw
Ames test: not mutagenic

Medical data

No adverse effects reported but data limited (new compound). Further information requested.

Summary

	Value	Study	Safety factor
ADI:	0.1 mg/kg bw/day	Chronic rat	100
AOEL systemic:	0.1 mg/kg bw/day	2-week and 1-year dog	100 (60% oral absorption)
AOEL inhalation:	Not required		
AOEL dermal:	Not required		
ARfD (acute reference dose):	0.2 mg/ kg bw/ day	2-week dog	100

Dermal absorption

8% based on in vivo rat, with skin residue included (for concentrate and in-use dilution of RH 2485 240 SC)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	At 25ºC, after 120 days, 0.9-3.6%AR, 2.6%AR and 2.7%AR for A-ring label, B-ring label and t-label, respectively (4 soils).
Non-extractable residues after 100 days:	At 25ºC, after 120 days, 12-27%AR, 26%AR and 24%AR for A-ring label, B-ring label and t-label respectively (4 soils).
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	No metabolites found at >10%AR in the lab soil studies. No metabolites analysed in field studies.

Supplemental studies

Anaerobic:	No data supplied. None required – due to proposed use pattern.
Soil photolysis:	DT50 = 173 days (1st order) for irradiated, compared with 332 days for dark controls, 30 days study (DT50 values extrapolated beyond end of study), irradiation comparable to natural sunlight 40ºN June-August, minor degradates only (max 2%).
Remarks:	None

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	DT_{50lab} (25°C, aerobic): At 25ºC, DT50 (1st order) = 336-1100 days, considered as not representative of field conditions, as microbial viability upto 1 year declined, with results extrapolated well beyond study duration, (4 soils, all 3 label positions, r^2 = 0.72-0.91). Calculated DT50 at 20°C: 487 – 1596 days, mean 1008 days.
DT_{90}lab (20 °C, aerobic):	DT_{90lab} (25°C, aerobic): At 25ºC, DT90 (1st order) = 1120-3666 days. Calculated DT90 at 20°C: 1618 – 5302 days, mean 3350 days.

DT_{50}lab (10 °C, aerobic):	DT_{50lab} (10°C, aerobic): No data, none required. Calculated values 1071 – 3511 days, mean 2218 days.
DT_{50}lab (20 °C, anaerobic):	DT_{50lab} (20°C, anaerobic): No data, none required.

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50f}: 6 sites (4 N EU at 144 g a.s./ha and 2 S EU at 192 g a.s./ha), single applications, parent only analysed. DT50field (not 1st order) = 39-133 days, r^2 = 0.91-0.98. Longest DT50 of 133 days (2nd order) used for PECsoil. For FOCUS gw modelling – DT50field, 1st order kinetics used, range = 121-231 days, r^2 = 0.85-0.94, geometric mean (1st order values only) = 181 days. Arithmetic means – temp. 11.01°C, moisture content 41.5 %FC.
DT_{90f} from soil dissipation studies:	DT_{90f}: DT90field = 434->1000 days, r^2 = 0.91-0.98, results extrapolated beyond study duration (713-736 days).
Soil accumulation studies:	Two long term field studies (Germany and Spain), total annual dose = 216 g a.s./ha to bare soil, considered worst case as normal use would be to high canopy interceptions. Modelling of results from 6 years used to predict plateau concns. – achieved after 6 years in N EU and 5 years in S EU, with accumulation factors of 1.34 and 1.66 respectively, compared to the first year concn.
Soil residue studies:	Not required

Remarks: e.g. effect of soil pH on degradation rate	None

Adsorption/desorption

K_f / K_{oc}:	Koc = 200-922 ml/g (mean 402 ml/g), 9 soils, pH 5.8-8.1, %oc 0.12-2.85. Freundlich coeff. (1/n) = 0.93-1.06 (mean 0.98).
K_d:	
pH dependence:	No

Mobility

Laboratory studies:

Column leaching:	Not required
Aged residue leaching:	Not required

Field studies:

Lysimeter/Field leaching studies:	Not required

Remarks:	Not required

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH_5: At 25ºC, with 30 days incubation, no significant degradation of a.s. detected. pH_7: At 25ºC, with 30 days incubation, no significant degradation of a.s. detected. pH_9: At 25ºC, with 30 days incubation, no significant degradation of a.s. detected.
Major metabolites:	None
Photolytic degradation:	Standard sterile aqueous photolysis study produced no significant degradation. In a study with pond water, DT50 (1^{st} order) of a.s. = 77 days, r^2 = 0.75, minor degradates only.
Major metabolites:	None

Biological degradation

Readily biodegradable:	No data submitted, but it is assumed that a.s. is not readily biodegradable.
Water/sediment study: DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system: Distribution in water / sediment systems (active substance) Distribution in water / sediment systems (metabolites)	1. Aerobic lab sediment/water at 25°C, Texas (TX) and California (CA) rice-growing systems (not to SETAC EU guideline) - DT50 = 150 days (CA total system), DT25 = 50 days (TX total system). M14 was the only major metabolite – upto max 16%AR in CA whole system (3% water, 13% sediment) - DT50 (1st order) 120 days, r^2 = 0.95 for M14 in CA whole system and sediment. CO_2 was less than 6%AR for both systems. Unext. r/a – max 9.6%AR (TX), 44%AR (CA). 2. *Chironomid* larvae study, 20°C, illuminated; mean water phase DT50 a.s. = 48 days. 3. Rice residues field study, 8 – 33°C, mean water phaseDT50 a.s. = 26 days, with DT90 = 89 days. 4. 20°C SETAC guideline study, 2 systems. DT50 water = 5.9-7.9 days (multi compartment model) DT90 water = 72-330- days R^2 = 0.99 DT50 whole system = 159-274 days (first order) DT90 whole system = 527 – 910 days R^2 = 0.98 M14 was the only major metabolite – upto max 13.5%AR in whole system (1.6% water, 11.9% sediment), CO_2 was less than 2.9%AR for both systems.Unext. r/a – max 67%AR. 5. Microcosm study, mean temperature 19.5°C, mean 1st order water phase DT50 a.s. = 50 days – selected to calculate PECsurface water.
Accumulation in water and/or sediment:	EXAMS modelling of sediment accumulation – concns. from use in consecutive years may be 50% higher than peak from 1 season's use.

Degradation in the saturated zone

Not required

Remarks:

None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	<1.33x10-5 Pa at 25, 35 and 45 °C
Henry's law constant:	<1.64 x 10-4 $Pa.m^3.mol^{-1}$ @ 20°C

Photolytic degradation

Direct photolysis in air:	Not applicable.
Photochemical oxidative degradation in air DT_{50}:	DT50 = 3.3 hours (Atkinson calculation).
Volatilisation:	from plant surfaces: Non-volatile. from soil: Non-volatile.

Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50: >5000 mg a.s./kg bw (rat)
Acute toxicity to birds:	LD50: >2250 mg a.s./kg bw (*Colinus virginianus*)
Dietary toxicity to birds:	LC50: >5620 ppm (*Colinus virginianus*)
Reproductive toxicity to birds:	NOEC 1000 ppm (*Anus platyrhynchos* and *Colinus virginianus*)
Short term oral toxicity to mammals:	NOAEL 1552 mg a.s./kg bw (rat)

Aquatic Organisms

	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:				
Oncorhynchus mykiss	active substance	96 hr	LC50	>4.2
Lepomis macrochirus	active substance	96 hr	LC50	>4.3
Cyprinodon variegatus	active substance	96 hr	LC50	>2.8
Pimephales promelas	active substance	96 hr	LC50	>3.8
Oncorhynchus mykiss	RH-112485 2F [1]	96 hr	LC50	>130 product
Lepomis macrochirus	RH-112485 2F	96 hr	LC50	>130 product
Long term toxicity fish:				
Pimephales promelas	active substance	33 day ELS	NOEC	2.4
Cyprinodon variegatus	active substance	32 day ELS	NOEC	2.6
Pimephales promelas	active substance	262 day FLS	NOEC	0.53
Bioaccumulation fish:	active substance	28 days	bioconc factor	max 11.0 whole fish
Acute toxicity invertebrate:				
Daphnia magna	active substance	48 hr	EC50	3.7
Daphnia magna	RH-2485 240- SC	48 hr	EC50	420 product
Chronic toxicity invertebrate:				
Daphnia magna	active substance	21 day	NOEC	0.39
Acute toxicity algae:				
Selenastrum capricornutum	active substance	120 hr	EbC50/ErC50	>3.4
Selenastrum capricornutum	RH-112485 2F	96 hr	EbC50/ErC50	107 product
Chronic toxicity sediment dwelling organism:				
Chironomus riparius	active substance	28 day	NOEC	0.018

Honeybees

Acute oral toxicity:	Active substance: >100 µg a.s./bee RH-2485 240 SC: >289 µg a.s./bee
Acute contact toxicity:	Active substance: >100 µg a.s./bee RH-2485 240 SC: >200 µg a.s./bee

Other arthropod species

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests (contact exposure only)						
Aphidius rhopalosiphi	adults	RH-2485 240 SC	0.192*	Mortality Repro	<30% # <30%	>30%
Aphidius rhopalosiphi	pupae	RH-2485 240 SC	0.192*	Mortality Repro	<30% <30%	>30%
Aphidius rhopalosiphi	adults	RH-2485 240 SC	0.192**	Mortality Repro	<30% # <30%	>30%
Trichogramma cacoeciae	adults	RH-2485 240 SC	0.192 (x2)	Mortality Repro	<30% # <30%	>30%
Trichogramma cacoeciae	pre-imaginal	RH-2485 240 SC	0.038	Mortality Repro	<30% <30%	>30%
Typhlodromus pyri	adults	RH-2485 240 SC	0.192	Mortality Repro	>30% (i.e. 40%) # <30%	>30%
Typhlodromus pyri	adults	RH-2485 240 SC	0.096 (x4)	Mortality Repro	<30% # <30%	>30%
Pardosa sp. (Lycosid spider)	adults	RH-2485 240 SC	0.192	Mortality Feeding	<30% # <30%	>30%
Chrysoperla carnea	larvae	RH-2485 240 SC	0.096 (x3)	Mortality Repro	<30% <30%	>30%
Orius laevigatus	larvae	RH-2485 240 SC	0.096 (x3)	Mortality Repro	<30% <30%	>30%
Extended laboratory tests (contact and oral exposure)						
Chrysoperla carnea	larvae	RH-2485 240 SC	Up to 0.157	Mortality Repro	<30% <30%	>30%
Field or semi-field tests (contact and oral exposure possible) *T. pyri* - In three field / semi-field studies (3 studies)on grapevines using RH-2485 240 SC (4 sprays at 0.092-0.096 kg a.s./ha with 10-15 day intervals), no adverse effects on mites or eggs were seen.						

Note: Given the mode of action of methoxyfenozide (a growth regulator insecticide which adversely affects moulting) effects on mortality from adult exposure would not be expected, therefore these test results are considered of very limited relevance.

*Aphidius exposed to dried methoxyfenozide formulation residue on glass plate substrate

** Aphidius exposed to dried methoxyfenozide formulation residue on natural substrate (wheat foliage)

Earthworms

Acute toxicity:	LC50 14-day >607 mg a.s./kg soil # LC50 14-day >148 mg a.s./kg soil (RH-2485 240 SC) #
Reproductive toxicity:	NOEC 56-day 8.86 mg a.s./kg soil #

Includes a reduction of the test LC50/NOEC value by a factor of two, to allow for the relatively high organic matter content of the artificial test soil (as per EPPO guidance).

Soil micro-organisms

Nitrogen mineralization:	<25% after 28 days at 1.96 kg a.s./ha
Carbon mineralization:	<25% after 28 days at 1.96 kg a.s./ha

APPENDIX III

METHOXYFENOZIDE

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**
IIIA 2.7	Zimmermann	2000	Title : storage stability of RH2485 SC 240 - final report Owner Company : Rohm & Haas (UK) Ltd Report No.: AB 0189890 Date : 15/08/2000 GLP status : no, unpublished
IIA, 4.2.1 /09 IIA, 4.2.5 /01	Chen, J. et al.	1998	Tolerance enforcement method for residues due to RH-2485 in bovine commodities. Rohm & Haas Company, Report no. TR 34-98-106,ER ref 25.2 Date: 7.7.1998 non GLP, unpublished
IIA, 4.2.1 /10 IIA, 4.2.5 /02	Wickremesinhe, E.	1998	Independent laboratory method validation trials of the tolerance enforcement method for residues due to RH-2485 in bovine commodities (TR 34-98-106) Rohm & Haas Company Report no. TR 34-98-139, ER ref 31.7 Date: 28.8.1998 GLP, unpublished
IIA 2.1	SCHWAKE J	2003	Title : Determination of the Boiling Point/Decomposition Temperature of Methoxyfenozide Owner Company : Dow AgroSciences S.A.S. Report No.: FAPC033134 Date : 24/07/2003 GLP status : yes

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
IIA 5.4.1	MECCHI MS	2003	Title : Escherichia coli/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with Methoxyfenozide - Final Report Owner Company : Dow AgroSciences S.A.S. Report No.: 031058 Date : 21/10/2003 GLP status : yes

B.7 Residues 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
IIA 6.1	Comezoglu SN	1996	Title : RH-2485: NATURE OF RESIDUE IN COTTON Owner Company : Rohm & Haas (UK) Ltd Report No.: TR34-95-207 Date : 09/04/1996 GLP status : yes
IIA 6.1	Carpenter DH	1999	Title : RH-112485: NATURE OF RESIDUES IN RICE Owner Company : Rohm & Haas (UK) Ltd Report No.: TR34-98-156 Date : 09/02/1999 GLP status : yes
IIA 6.2	Wu D	1998	Title : METABOLISM OF 14C RH-112,485 IN LAYING HENS Owner Company : Rohm & Haas (UK) Ltd Report No.: TR34-97-48 Date : 24/04/1998 GLP status : yes
XXX	Sharma AK	1998	Title : Intrepid (RH-2485) Residue Decline on Targeted Orchard Foliage and Non-Target Environmental Constituents (Turf and Soil) by Air Blast Application Procedures Owner Company : Dow AgroSciences Ltd Report No.: 34-98-79 Date : 26/06/1998 GLP status : yes

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
IIIA, 9.1.3	Schafer H	2002	Long term Predicted Environmental Concentrations of RH2485 in Soil after Repeated Use Bayer CropScience AG Report no. MR-508/02 Date: 10/12/2002 non GLP, unpublished
IIA 7.2.1	Sneikus J	2002	Aerobic degradation and metabolism of RH2485 in the water/sediment system Bayer CropScience AG Report no. MR-338/02 Date: 27/11/2002 GLP, unpublished
IIA 7.1.1	Sommer H	2002	Soil accumulation study with RH2485 (240 SC) in Germany and Spain under Field Conditions Bayer CropScience AG Report no. RA-2164/97 Date: 26/11/2002 GLP, unpublished
IIIA 9.2.1, 9.2.3	Gorlitz G	2003	Methoxyfenozide - Rough estimate for the effect of runoff and erosion on the PEC sw and PEC sediment Dow AgroSciences Date: Not GLP, unpublished

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
IIA 8.3.2, IIIA 10.5	Schnorbach HJ Barber I Miles M	XXX	Title : METHOXYFENOZIDE (RH 2485) : ECOTOXICOLOGICAL RISK ASSESSMENT FOR LEPIDOPTERA Owner Company : Dow AgroSciences S.A.S. Report No.: RH2485 Date : GLP status : no

APPENDIX IV

List of uses supported by available data

Methoxyfenozide

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/hl min max	water l/ha min max	kg as/ha min max		
Apple and Pear	N/S	RH-2485 240 SC	F	*Carpocapsa pomonella*	SC	240 g/l	Overall spray application	1st app BBCH 55 other applications depending on number of generation or at infestation	1-3	14 days	0.0144-0.096	1000-1500	0.144	14	14 day spray interval .
Grape (wine)	N/S	RH-2485 240 SC	F	*Polychrosis botrana* *Clysia ambiguella* *Sparaganot his pilleriana*	SC	240 g/l	Overall spray application	1st app BBCH 53-57 2nd- 3rd depending on number of generation	3	14 days	0.0096-0.006	1000-1600	0.096	14	14 day spray interval .

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/hl min max	water l/ha min max	kg as/ha min max		
Grape (table)	S	RH-2485 240 SC	F	*Polychrosis botrana*	SC	240 g/l	Overall spray application	1st app BBCH 53-57 2nd- 4th depending on number of generation	4	14 days	0.0096-0.006	1000-1600	0.096	7	14 day spray interval .
Orange and mandarin	S	RH-2485 240 SC	F	*Phyllocnistis citrella*	SC	240 g/l	Overall spray application	1st – 2nd app: start at begin of infestation	2	10 days	0.0096	max 2000	0.192	14	10 day spray interval .
Peach and nectarine	S	RH-2485 240 SC	F	*Laspeyresia molesta* *Anarsia lineatella*	SC	240 g/l	Overall spray application	1st app BBCH 71 2nd app: at infestation	2	14 days	0.0180-0.0120	1000-1500	0.180	7	14 day spray interval .
Tomato	N/S	RH-2485 240 SC	G	*Laphygma exigua* *Chrysodeixes chalcites*	SC	240 g/l	Overall spray application	1st – 3rd app: start at begin of infestation	3	7 days	0.0096	max 2000	0.192	1	7 day spray interval .
Pepper	N/S	RH-2485 240 SC	G	*Laphygma exigua*	SC	240 g/l	Overall spray application	1st – 3rd app: start at begin of infestation	3	7 days	0.0096	max 2000	0.192	1	7 day spray interval .

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