CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the peer review of the pesticide risk assessment of the active substance tebufenpyrad

Reissued on 23 October 2008

SUMMARY

Tebufenpyrad is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on tebufenpyrad in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 12 March 2007. The peer review was initiated on 6 February 2008 by dispatching the DAR for consultation of the Member States and the sole applicant BASF AG. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in June-July 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as acaricide, insecticide as proposed by the notifier, which comprise foliar spraying in pome fruit for the control of mite pests on all developmental stages of mites. Full details of the GAP can be found in the attached list of endpoints.

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

The representative formulated product for the evaluation was "BAS 31806I" ("MASAI"), a wettable powder (WP) containing 200 g/kg tebufenpyrad.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. The specification cannot be finalised as there are outstanding issues. Also a shelf-life study and a new suspensibility study have been identified as data gaps.
Adequate methods are available to monitor tebufenpyrad residues in food/feed of plant origin and environmental matrices.

Mammalian toxicology of tebufenpyrad was assessed in a series of tests. Tebufenpyrad is absorbed extensively but slowly. It is widely distributed and has no potential for accumulation. It is excreted slowly but completely and is rapidly and extensively metabolized. It is of moderate toxicity by the oral and the inhalation route and of low toxicity by the dermal route. Tebufenpyrad is neither irritant to skin nor to the eyes but is a skin sensitizer. Based on the available data on acute toxicity a classification as **Xn; R20 ("Harmful; Harmful by inhalation"), Xn; R22 ("Harmful; Harmful if swallowed")** and **Xi; R43 ("Irritant; May cause sensitization by skin contact")** is proposed.

In short term tests with tebufenpyrad effects on bodyweight and food consumption were observed in all species tested (rat, mouse, dog and rabbit). While in rats and mice the liver was the target of toxicity, in dogs gastrointestinal effects and lesions were prevalent. The lowest no observed adverse effect level (NOAEL) was achieved in the rat (0.7 mg/kg bw/day). In dogs an overall NOAEL of 2 mg/kg bw/day was set. Tebufenpyrad is not genotoxic. A 2-year rat study and an 18-month study with mice were reported. In the rat study a systemic NOAEL of 0.8 mg/kg bw/day was derived based on effects on bodyweight and food consumption, altered erythrocyte parameters, and liver effects. The liver adenomas observed were considered not relevant for human risk assessment. In the mouse study a NOAEL of 3.6 mg/kg bw/day was derived based on increased liver and kidney weights, and reduced bodyweight and food consumption. No tumours were observed. Tebufenpyrad did not cause specific effects on reproduction in a two-generation study. While no effects on development were observed in rabbits, in rats increased incidences of supernumerary ribs were seen at maternally toxic doses.

The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) were set at 0.01 mg/kg bw/day. An acute reference dose (ARfD) of 0.02 mg/kg bw was allocated.

Using the German model operator exposure amounted to 65% (tractor-mounted application) and to 92% (hand-held application) of the AOEL when personal protective equipment (PPE) was used. In the UK POEM exposure exceeded the AOEL in all scenarios. Worker exposure was calculated to be 57% of the AOEL when PPE is used. A refined exposure assessment after the PRAPeR meeting of experts showed a bystander exposure of 93% of the systemic AOEL.

The metabolism of tebufenpyrad in apples was investigated. Application was made at a rate of 2.22 kg a.s./ha which is a 22N rate. Some minor metabolites were identified but given that the study was conducted at such a high rate the only significant residue will be tebufenpyrad. The residue definition for monitoring and risk assessment is therefore tebufenpyrad only. Sufficient residue trials were supplied for the critical GAP in the north and south of Europe. Residues of tebufenpyrad were stable under freezer storage for a period of at least two years. On processing, the nature of the residue will be unchanged, and sufficient data were supplied to derive processing factors for juice and pomace. Metabolism data in goat and hen were provided; the most significant residues were tebufenpyrad, CL 810,720[2] and CL 810,721[3]. In a ruminant feeding study, even at 3N, significant residues of tebufenpyrad as well as these two metabolites were not found. Also at the 10N rate, only very low levels were found. The meeting of experts concluded that there will be no significant residues present in products of animal origin. The residue definition was therefore set as tebufenpyrad for monitoring and risk assessment for ruminant only. The meeting noted however, that this should be considered again if other uses lead to higher intakes. No conclusion was reached on the residue definition for poultry. However, the notified uses would not give rise to significant residues in poultry as there is no dietary exposure. The risk assessment showed that maximum intakes are 28 % of the ADI and 64 % of the ARfD. An MRL for pome fruit was set at 0.2 mg/kg.

In soil under aerobic conditions tebufenpyrad exhibits moderate to medium persistence forming the major soil metabolite CL 810,721 (accounting for up to 23% of applied radioactivity (AR)), which exhibits low to moderate persistence, and the minor non-transient metabolite CL 810,728[4] (accounting for up to 5.1 % AR). Mineralisation of both the benzene- and pyrazole rings to carbon dioxide accounted for 16% AR and 9.2-43.9% AR, respectively, after 120-122 days. The formation of unextractable residues accounted for 3.5 % AR and 2.5-35.5% AR, respectively, after 120-122 days. Photolysis studies with tebufenpyrad on soil revealed CL 810,729[5] to be the major photo-degradation product accounting for up to 12% AR. Tebufenpyrad is immobile to low mobile in soil; CL 810,721 and CL 810,729 exhibit high to very high mobility in soil, and CL 810,728 is very highly mobile. There was no indication that adsorption of tebufenpyrad, CL 810,728 and CL 810,729 were pH-dependent, whilst sorption of CL 810,721 was clearly dependent on pH in soil.
In dark natural sediment water systems tebufenpyrad partitioned rapidly from water to sediment, where the metabolite CL 810,721 was formed at maximum 16.5% of AR in the water phase. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for tebufenpyrad up to step 4, step 3 for metabolite CL 810,728

[2] CL 810,720: 4-chloro-3-ethyl-*N*-[4-(1-hydroxy-2-methylpropan-2-yl)phenyl]-1-methyl-1*H*-pyrazole-5-carboxamide
[3] CL 810,721: 2-(4-{[(4-chloro-3-ethyl-1-methyl-1*H*-pyrazol-5-yl)carbonyl]amino}phenyl)-2-methylpropanoic acid
[4] CL 810,728 = 4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxylic acid
[5] CL 810,729 = 4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxamide

and step 2 for metabolites CL 810,721 and CL 810,729. These values are the basis for the risk assessment discussed in this conclusion.
The potential for groundwater exposure from the applied for intended uses by tebufenpyrad and its metabolites CL 810,721, CL 810,728 and CL 810,729 above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations, that are represented by all 9 FOCUS groundwater scenarios.

The acute and short-term risk to birds and the acute and long-term risk to mammals were assessed as low in a first-tier risk assessment. The long-term (reproductive) endpoint for birds was discussed by the experts. A long-term NOEL of 6.6 mg a.s./kg bw/day was agreed based on effects on reduced number of hatchlings, eggs laid and 14-day old survivors at the higher tested concentrations. The first-tier long-term TER was below the Annex VI trigger of 5. The refined risk assessment based on the agreed PD (proportion of different food types) resulted still in a TER below 5, and a data gap was identified to further refine the long-term risk to insectivorous birds. The risk to earthworm- and fish-eating birds was assessed as low.
Tebufenpyrad was very toxic to fish and to aquatic invertebrates with steep dose-response curves. All FOCUS step 4 scenarios resulted in acute TERs >100 for daphnids, if a no-spray buffer zone of 20m was applied. However, no full FOCUS step 4 scenario resulted in TERs above the Annex VI trigger for fish. The risk assessment for fish was refined by HC5 (hazard concentration of the 5th percentile of the species distribution) calculation based on five species. The experts suggested using the lower limit HC5 (95%tile lower confidence limit) of 6.1 µg a.s./L together with a reduced safety factor of 10. The trigger was exceeded in all FOCUS step 4 scenarios with a no-spray buffer zone of 20m. The long-term risk assessment for invertebrates was based on a population development study with daphnids (NOEC of 4 µg a.s./L). The Annex VI trigger of 10 was exceeded in the full scenarios D3, D4, R1, R4 and the part scenario D5 (pond), but was below the trigger in the full scenarios R2, R3 and the part scenario D5 (stream), if a 20m no-spray buffer zone was applied. The risk from the major metabolites in water and soil was assessed as low. The maximum bioconcentration factor (BCF) for fish, normalised to the lipid content, was 953. Tebufenpyrad was rapidly metabolised and excreted with a clearance time CT_{90} of 1.65 days. It is applied only once per year and it dissipates rapidly from the water phase. Therefore it was concluded, that the risk from bioconcentration and bioaccumulation is low. The risk to sediment-dwelling organisms was assessed as low.
T. pyri was the most sensitive arthropod species tested. A potential for high in-field and off-field risk was indicated in the first-tier risk assessment. In higher tier (extended laboratory) tests it was shown that the off-field risk to *T. pyri* is low. Recolonisation of the in-field area was considered as plausible, since effects were <50% after 14 days of ageing of residues.
The risk to bees, earthworms, other soil macro-organisms, soil micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

Key words: tebufenpyrad, peer review, risk assessment, pesticide, acaricide, insecticide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Tebufenpyrad is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on tebufenpyrad, hereafter referred to as the draft assessment report, received by EFSA on 12 March 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1095/2007 on 6 February 2008 to the Member States and on 8 November 2007 to the main applicant BASF AG as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in June-July 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (revision 1-1 of 23 April 2008)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (revision 2-1 of 25 September 2008).

Given the importance of the draft assessment report including its addendum (compiled version of August 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Tebufenpyrad is the ISO common name for *N*-(4-*tert*-butylbenzyl)-4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide (IUPAC).

Tebufenpyrad belongs to the class of pyrazole insecticides, and acaricides. It is a mitochondrial respiration inhibitor acting by blocking the electron transport in the complex I. Tebufenpyrad has acaricide activity by contact and ingestion, has a broad spectrum of activity on a wide variety of mite pests, with fast knockdown and long residual control. Tebufenpyrad is used as a horticultural acaricide on pome fruit for the control of mite pests on all developmental stages (eggs, larvae, nymphs and adults).
The representative formulated product for the evaluation was "BAS 31806I" ("MASAI"), a wettable powder (WP) containing 200 g/kg tebufenpyrad, registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying to control *Metatetranychus ulmi*, *Panonychus ulmi* and *Tetranychus urticae* in pome fruit, from growth stage of BBCH 68 up to growth stage of BBCH 88, at a single application, at maximum application rate of 100 g a.s./ha.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of tebufenpyrad is 980 g/kg. There is no FAO specification available.

The proposed specifications based on laboratory, pilot plant and full scale production batches were not considered acceptable by the PRAPeR 51 meeting of experts (June 2008) for some impurities, and a new data gap was identified for a revised technical specification. The experts agreed that information concerning the compound listed in row 5 of Table C.1.1.1 of Volume 4 of the DAR in the technical material is needed as the description of the manufacturing process is not sufficient to exclude its presence. Additionally, the following data gaps were identified:

- to clarify what happens with batches which are found outside of specification
- to confirm that the manufacturing process has not been substantially changed since the production of the submitted batch analyses (1991)

Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should be regarded as provisional for the moment.
The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of tebufenpyrad or the respective formulation. However, the following data gaps were identified:

- Shelf life data for the new formulation "BAS 31806I" ("MASAI")
- Data for suspensibility at the highest application rate

The main data regarding the identity of tebufenpyrad and its physical and chemical properties are given in appendix 1.

Adequate analytical methods are available for the determination of tebufenpyrad in the technical material and in the representative formulation (GC-FID, HPLC-UV) as well as for the determination of the respective impurities in the technical material (GC-FID).
Sufficient test methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor tebufenpyrad residues in food/feed of plant origin and environmental matrices.
The multi-residue method DFG S19 (GC-MS) is applicable for the determination of residues of tebufenpyrad in apples, grapes, with LOQ of 0.01 mg/kg, and with LOQ of 0.05 mg/kg for oilseed rape.

Residues of tebufenpyrad in food/feed of animal origin are not required as no MRL is proposed, however GC-MS and HPLC-MS/MS methods exist for the determination of tebufenpyrad residues in food of animal origin.
Residues of tebufenpyrad in soil can be monitored by HPLC-UV with LOQ of 0.01 mg/kg.
Residues of tebufenpyrad in drinking- and surface water can be determined by LC-MS/MS with LOQ of 0.1 µg/l.
Adequate method is available to monitor tebufenpyrad residues in air by GC-MS with an LOQ of 2 µg/m^3.
Analytical methods for the determination of residues in body fluids and tissues are not required as tebufenpyrad is not classified as toxic or highly toxic.

2. Mammalian toxicology

Tebufenpyrad was discussed at the PRAPeR meeting of experts for mammalian toxicology (PRAPeR 54, round 11) in July 2008.

At the meeting the experts agreed that, if the compound listed in row 5 of Table C.1.1.1 of Volume 4 of the DAR is present in the technical specification of tebufenpyrad, it should be considered as a relevant impurity.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Tebufenpyrad is absorbed orally extensively but relatively slowly (C_{max} reached after 8 hours), to an extent of more than 80% based on urinary (16 - 30%) and biliary (48 - 74%) excretion, and, to a lesser extent, on tissue residues. It is widely distributed. The highest residue amounts are found in mesenteric lymph nodes, and (at high dose) in bones. It is slowly (within 168 hours) but virtually completely excreted mainly via the faeces (48 - 74%) and urine (24 - 44%). Biliary excretion is significant (about 60% within 24 hours). Enterohepatic circulation of tebufenpyrad has been demonstrated. Despite the slow elimination of the compound it has no potential for accumulation. Tebufenpyrad is rapidly and completely metabolised. Only less than 0.1% of unchanged tebufenpyrad could be detected in excreta. More than 22 tebufenpyrad metabolites have been identified. The major metabolic pathway proposed is the hydroxylation, oxidation, and carboxylation of the ethyl- and/or tertiary butyl substituents, followed (occasionally) by sulphatation. In addition, two minor pathways are described; firstly, the demethylation at the 1-position of the pyrazole followed by cleavage within the pyrazolcarboxamide, and secondly, the cleavage between the NH-group of the carboxamide moiety and the benzyl substituent.

2.2. ACUTE TOXICITY

Tebufenpyrad is of moderate toxicity by the oral (202 mg/kg bw < LD_{50}> 320 mg/kg bw) and inhalation route (LC_{50} > 2.7 mg/L), and of low toxicity by the dermal route (LD_{50} > 2000 mg/kg bw). It is neither a skin nor and eye irritant, but was positive in a skin sensitisation test (Magnusson & Kligman) with guinea pigs.

Based on the available data on acute toxicity, a classification as **Xn; R20 "Harmful; Harmful by inhalation"**, **Xn; R22 "Harmful; Harmful if swallowed"** and **Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed.

2.3. SHORT TERM TOXICITY

With rats two 28-day and a 90-day feeding study, with mice a 28-day and a 90-day feeding study and with dogs two 90-day and a 1-year capsule study are reported in the DAR. A 21-day dermal study has been carried out with rabbits.

Application of tebufenpyrad caused reduced bodyweight gain and food consumption in all four species. While the liver was the main target of toxicity in rats and mice (increased organ weight, changes in clinical chemistry indicative of liver damage and liver histopathology were observed); in dogs application of tebufenpyrad exerted effects predominately on the gastrointestinal tract (vomiting, diarrhoea, stomach irritation, histological lesions in stomach and intestine). The lowest relevant oral NOAELs were set at 0.7 mg/kg bw/day (90-day rat study), 41 mg/kg bw/day (90-day mouse study), and 2 mg/kg bw/day (overall NOAEL of 90-day and 1-year dog studies). In the dermal study with rabbits a NOAEL of 200 mg/kg bw/day was derived based on effects on bodyweight and on increased liver weights in male animals at the highest dose.

2.4. GENOTOXICITY

Tebufenpyrad showed some weak clastogenic potential *in vitro*. The experts agreed, however, when taking into account the entire database on genotoxicity and in particular the absence of a clastogenic potential *in vivo,* that overall, tebufenpyrad is devoid of genotoxic potency.

2.5. LONG TERM TOXICITY

In this section a 2-year feeding study with rats and an 18-month feeding study with mice were reported.

In the rat study the experts confirmed the NOAEL of 0.8 mg/kg bw/day as proposed in the DAR, which is based on findings of reduced bodyweight gain and food consumption, slightly altered erythrocyte parameters (lowered haematocrit, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin and increased incidences of spherocytes) indicative of anaemia, and increased liver weights and clinical liver parameters indicative of liver damage. In male animals also liver tumours occurred. Considering that these tumours were benign, occurred only in one sex and in

one species (no tumours were observed in mice) and taking into account that tebufenpyrad has been shown to act as peroxisome proliferator (a mechanism for tumour induction in the liver not relevant for humans), the experts agreed to dismiss them as not relevant for humans.
In the mouse study a NOAEL of 3.6 mg/kg bw/day was derived from reduced bodyweight gain and food consumption and increased liver- and kidney weights. No tumours were detected.

2.6. REPRODUCTIVE TOXICITY

A two-generation study, two developmental studies with rats and one with rabbits are presented in the DAR.
In the two-generation study the parental and the offspring NOAEL were set at 8 mg/kg bw/day based on reduced bodyweight gain and food consumption in adults, and on reduced bodyweight gain and delayed vaginal opening in pups. The NOAEL for reproduction was set at the highest dose tested (17 mg/kg bw/day) based on the lack of relevant findings.
Considering the overall evidence of effects in the two developmental rat studies, the experts agreed to set the maternal and the developmental NOAEL for rats at 15 mg/kg bw/day, based on observations of reduced bodyweight gain and food consumption seen in the dams at higher doses in both studies, and on reduced bodyweight gain and increased incidences of 14th pair of ribs in pups in the second study (increased incidences of 14th pair of ribs have not been observed in the first study).
In the rabbit study the maternal NOAEL of 15 mg/kg bw/day was derived from reduced bodyweight gain and food consumption, while the developmental NOAEL was set at 40 mg/kg bw/day, which was the highest dose tested, since no relevant effects were seen.

2.7. NEUROTOXICITY

No specific studies have been carried out, however, tebufenpyrad, a pyrazole carboxamide is not suspected to affect the nervous system in mammals. In addition, in none of the studies reported in other chapters have relevant effects been detected. Therefore, specific studies on acute, subchronic or delayed neurotoxicity are not deemed necessary.

2.8. FURTHER STUDIES

Studies on metabolites

The tebufenpyrad metabolite **CL 810,721**[6] was detected in the rat (3-12% of the applied dose of tebufenpyrad), and also in soil and water. CL 810,721 is of moderate acute oral toxicity in the rat (500 mg/kg bw < LD_{50} > 2000 mg/kg bw), and was negative in an *in vitro* bacterial and mammalian mutagenicity, and in an *in vitro* clastogenicity assay.

[6] CL 810,721: 2-(4-{[(4-chloro-3-ethyl-1-methyl-1*H*-pyrazol-5-yl)carbonyl]amino}phenyl)-2-methylpropanoic acid

Metabolite **CL810,729**[7] is formed by cleavage of tebufenpyrad between the carboxylamide and the benzyl-moiety and was detected in very small amounts in the rat (less than 1% of the applied dose of tebufenpyrad), and in soil photolysis. It is of moderate acute oral toxicity in the rat (300 mg/kg bw < LD_{50} > 2000 mg/kg bw) and was negative in a bacterial mutagenicity assay.

Mechanistic studies

In mechanistic studies it could be shown that short term exposure of (female) rats to tebufenpyrad results in increased activity of palmitoyl-CoA oxidase and in hepatomegaly. Both findings suggest peroxisome-proliferation potency of the compound.

2.9. MEDICAL DATA

No adverse health effects related to tebufenpyrad have been observed in occupational health surveillance programs.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

The experts agreed to set the **ADI and the AOEL at 0.01 mg/kg bw/day** (rounded) on the basis of the NOAELs of 0.8 mg/kg bw/day and 0.7 mg/kg bw/day obtained in the chronic and the 90-day rat study, respectively, applying a safety factor of 100. In the original DAR a value of 0.02 mg/kg bw/day was proposed for both reference values.

An **ARfD of 0.02 mg/kg bw** was set based on the overall NOAEL of 2 mg/kg bw/day obtained in the subchronic dog studies applying a safety factor of 100.

2.11. DERMAL ABSORPTION

No adequate studies have been provided in the DAR. The rapporteur proposed to set the value of 10% (rounded) for the concentrate and the diluted formulation taking into account the physico- chemical properties of the substance together with a comparison of the NOAELs obtained in oral and dermal short term studies. The experts agreed to apply that approach for the concentrate, however, to set a default value of 100% dermal absorption for the diluted product.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product "BAS 31806I" ("MASAI") is formulated as a wettable powder packed in water soluble bags containing 200 g/kg tebufenpyrad. It is used to control mites in pome fruits. It is applied by spraying (air-assisted or hand-held) once a year, at a dose of 100 g a.s./ha (active substance tebufenpyrad), in a minimum volume of 200 L water per ha.

[7] CL 810,729: 4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxamide

As requested at the meeting of experts the rapporteur member State has provided revised exposure calculations for operators, workers and bystanders in addendum 5 to the DAR (1st August, 2008), using the agreed values for dermal absorption.

Operator exposure

Operator exposure has been assessed using the German model and the UK POEM and is given in the tables below in percentages of the systemic AOEL of 0.01 mg/kg bw/day.

German model

Application	No PPE*	PPE[8]	PPE[9]
High crop tractor-mounted (HCTM)	1316%	195%	65%
High crop hand-held (HCHH)	581%	432%	92%

*PPE (personal protective equipment)

In the original DAR only an assessment assuming no use of PPE was provided for both applications (high crop tractor-mounted/hand-held). In the addendum 5 to the DAR (1st August 2008) next to the revised calculations without PPE during application, a refinement of the risk assessment assuming the use of two different types of PPE has been provided (see table above). These calculations have not been peer-reviewed.

UK POEM

Application	No PPE	PPE*
Tractor drawn airblast spray (HCTM) – low volume application (200 L)	6198%	3948%
Tractor drawn airblast spray (HCTM) – high volume application (1500 L)	1347%	950%

*PPE (personal protective equipment): gloves during application

Worker exposure

Exposure of workers to tebufenpyrad was assessed using the German re-entry model[10] and amounts to 57% and 1143% of the AOEL with and without the use of PPE (gloves and coverall), respectively.

[8] PPE: gloves and coverall during application
[9] PPE: gloves, hood and visor and coverall during application
[10] Hoernicke E, Nolting HG, Westphal D (1998) Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflanzenschutzmitteln behandelten Kulturen (worker re-entry) (1998) Nachrichtenblatt des Deutschen Pflanzenschutzdienstes. Vol 50 (10) 1998.

EFSA Note: At the meeting of experts it was noted that for some member states considering the use of gloves for re-entry activities (i.e. harvesting) was not acceptable.

In the addendum 5 to the DAR (1st August, 2008) a refined assessment of exposure of workers to tebufenpyrad was provided by the rapporteur Member State, and the exposures calculated amounted to 514% and 26% of the AOEL without and with PPE (gloves and coverall), respectively. However, this additional assessment was not requested by the PRAPeR meeting of experts and has not been peer reviewed.

Bystander exposure

Bystander exposure was calculated using input parameters from the EU Technical Guidance Document[11] and the draft values proposed for the EUROPOEM II[12]. During the meeting of experts re-calculations were requested to the RMS based on the new AOEL and on the 100% default dermal absorption: the estimated bystander exposure amounted to 515% of the systemic AOEL. In the Addendum 5 to the DAR (1st August 2008) the rapporteur Member State provided also a refined approach for the calculation of the exposure of bystanders to tebufenpyrad.

EFSA note (post PRAPeR meeting): It is noted that the re-assessment applying the input parameters already present in the DAR, and giving a figure of 515% of the AOEL, should be regarded as quite conservative, mainly due to the application of a drift value of 15.44% (typical for early growth stage application, whereas the proposed scenario foresees late growth stage spraying) and due to the use of 100% dermal absorption, extreme worst case, as well as to the use of an uncovered skin area of 2 m2. In the second refinement presented in the DAR the rapporteur Member State applied input parameters adjusted to the actual growth stage of the culture and anticipating a more realistic estimation of uncovered skin of bystanders resulting in a bystander exposure value of 92.9% of the systemic AOEL. Based on further scientific considerations, this assessment should be regarded as more reliable. However, this new approach has not been agreed upon, nor peer reviewed.

[11] Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. European Communities 2003.

[12] EUROPOEM II (2003) *The development, maintenance and dissemination of a European Predictive Operator Exposure Model* (EUROPOEM II) database. A EUROPEAN II Database and Harmonised Model, FAIR-3CT96-1406, TNO-BIBRA International, Carshalton.

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of tebufenpyrad was investigated in apples with application of tebufenpyrad labelled in either the phenyl- or pyrazole ring. The application in total was 2.22 kg a.s./ha, which is 22N. Tebufenpyrad was only slightly metabolised and made up circa 63 % of the radioactivity. Some minor metabolites were identified but they were only present at or below 0.01 mg/kg. Given that this is a 22N study none of the metabolites will be significant residues in apples. Therefore, the residue definition for monitoring and risk assessment is tebufenpyrad only. A full set of residue trials data were available for both the north and south of Europe. A freezer storage stability study conducted at -18 ºC demonstrated that residues will be stable for at least two years. A simulated processing study was conducted to investigate the nature of the residue on processing. This study showed that tebufenpyrad is stable and no breakdown products will be formed on processing. Effects on the magnitude of the residue on processing were investigated. No increase of residue concentrations could be detected after processing into juice (maximum transfer factor: 0.06) and sauce (maximum transfer factor: 0.7). This was confirmed by several residue trials, where residue levels in processed products were at or below the LOQ. Residues in apples nearly completely remain in pomace after different processing methods. A maximum transfer factor of 1.7 is derived from the studies with wet pomace, and is used in the calculation of the maximum dietary burden for cattle.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Not relevant, because apples, pears and other pome fruit are permanent crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism of tebufenpyrad was investigated in lactating goats and laying hens. Animals were dosed with tebufenpyrad at the equivalent of 0.3 - 0.9 mg (hen) and 2 - 9 mg (goat) tebufenpyrad per kg diet. Both animal species efficiently metabolised tebufenpyrad to more polar compounds, which were readily excreted predominantly via faeces (79 - 102 % of the cumulative dose after seven days). The proposed metabolic pathways were the same as those seen in the rat. Metabolites CL 810,720[13], CL 810,721, CL 810,722[14] and CL 810,723[15] were found in edible tissues or in milk from goats or eggs from hens.

[13] CL 810,720: 4-chloro-3-ethyl-*N*-[4-(1-hydroxy-2-methylpropan-2-yl)phenyl]-1-methyl-1*H*-pyrazole-5-carboxamide
[14] CL 810,722: 4-chloro-3-(1-hydroxyethyl)-*N*-[4-(1-hydroxy-2-methylpropan-2-yl)phenyl]-1-methyl-1*H*-pyrazole-5-carboxamide
[15] CL 810,723: 2-[4-({[4-chloro-3-(1-hydroxyethyl)-1-methyl-1*H*-pyrazol-5-yl]carbonyl}amino)phenyl]-2-methylpropanoic acid

Poultry are normally not fed on fruit pomace, which is the only foodstuff with residues of tebufenpyrad that may arise due to the use of tebufenpyrad on pome fruit. Therefore, no residues of tebufenpyrad are to be expected in poultry. Hence, the hen metabolism study was submitted only for reasons of completeness.

Tebufenpyrad was the major residue component in milk, egg and fat. In goat muscle, liver, and kidney, metabolite CL 810,720 showed similar or higher concentrations than tebufenpyrad. Concentrations of metabolite CL 810,721 exceeded those of the active substance in goat liver and kidney. However, the doses administered in the goat metabolism study exaggerated worst-case doses in cattle-feed by factors of 20 to 80.

An animal feeding study was conducted in lactating cows. The animals were dosed for 28 days at dose levels of 0.3 (1N), 0.9 (3N) and 3.0 (10N) mg a.s./kg feed. The study showed that no residues of tebufenpyrad or metabolites CL 810,721 and CL 810,720 above the LOQ (0.01 mg/kg) are to be expected in milk or tissues of dairy cattle that fed worst-case amounts of tebufenpyrad (0.3 mg as/kg feed). Even at 3-times higher residue levels in feed no quantifiable residues are to be expected in milk, while highest residues in tissues will be at the LOQ (0.01 mg/kg). These results of the 3x dose-group are relevant for beef cattle that consume the 3.5-fold dose of tebufenpyrad in pome fruit pomace compared to dairy cattle. Hence, residues of tebufenpyrad and metabolites above 0.01 mg/kg will not be present in edible products from beef cattle.

The meeting of experts considered tebufenpyrad and metabolites CL 810,721 and CL 810,720 for inclusion in the residue definition but concluded that even at the 10N feeding rate only low residues were seen. Therefore the residue definition for risk assessment and monitoring is tebufenpyrad. It was also concluded from these studies that no significant residues will occur in products of animal origin from this use. This residue definition is for ruminant only. The residue definition for poultry was not concluded on. However, the notified uses would not give rise to significant residues in poultry as there is no dietary exposure. The meeting also pointed out, that if other uses are considered in the future that lead to higher animal intakes, the residue definition for risk assessment should be reviewed.

3.3. CONSUMER RISK ASSESSMENT

The chronic dietary exposure assessment has been based on the theoretical maximum daily intake (TMDI) approach and on the EFSA model for calculation, covering the consumption data of the european population. As residue input data, the proposed maximum residue limit (MRL) for pome fruits and the LOQ for other human edible commodities of plant origin were used. Based on these assumptions, the maximum calculated TMDI is 28 % of the ADI (0.01 mg/kg bw).

The acute dietary exposure assessment (NESTI) was based on the highest residue found in supervised trials with pome fruits and on the EFSA model, leading to a maximum contribution of 64 % of the ARfD (0.02 mg/kg bw).

3.4. PROPOSED MRLS

The proposed MRL for pome fruit is 0.2 mg/kg. MRLs for products of animal origin are not proposed as no significant residues will be present from the representative use evaluated.

4. Environmental fate and behaviour

Tebufenpyrad was discussed at the PRAPeR meeting of experts for environmental fate and behaviour (PRAPeR 52) in June-July 2008.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The aerobic soil metabolism of tebufenpyrad was investigated under laboratory conditions (20-25°C at 45 % maximum water holding capacity (MWHC) or 75% of 1/3 bar) using [^{14}C]-labelled tebufenpyrad with radiolabels in the pyrazole position (1 soil) and in the benzene ring (4 soils). The formation of unextracted residues was a sink for the applied benzene ring- and pyrazole position [^{14}C] radiolabels (3.5 % and 2.5-35.5 %, respectively, of the applied radiolabels (AR) after 120-122 days). Mineralisation to carbon dioxide of these radiolabels accounted for 16.3 % AR ([^{14}C]-benzene label) and for 9.2-43.9 % AR ([^{14}C]-pyrazole label) after 120-122 days. As a result of oxidative metabolism of both the benzene- and the pyrazole rings of tebufenpyrad, the metabolites CL 810,719[16]; CL 810,721 and CL 810,723 were formed, all of them characterised by the otherwise intact molecule structure. The additional metabolite CL 810,728[17], which was detected only in the pyrazole-labelled samples, resulted from cleavage of the amide bond. The major (>10 % AR) extractable breakdown product present was **CL 810,721** (max. 23.4 % AR at 45d). The minor (<10 % AR) but non-transient extractable breakdown product (that accounted for > 5 % AR at two consecutive sampling times), CL 810,728 accounted for max 5.1% AR after 21 and 29 days. One of the soils tested with tebufenpyrad, radiolabelled in the pyrazole ring, was also incubated at 10°C. The amount of non-extractable residue remained less than 1% AR from day 0 to 31 and then increased from 1.0% AR at 45d to 9.8% AR at 120d. There were no volatile organic residues detected in the ethylene glycol traps throughout the study.

[16] CL 810,719 = N-(4-t-butylbenzyl)-3-acetyl-4-chloro-1-methyl-5-pyrazolecarboxamide
[17] CL 810,728 = 4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxylic acid

Data on anaerobic degradation in soil in the laboratory were provided, which indicated that the degradation of tebufenpyrad was almost immediately stopped and the pattern of degradates remained identical to that under aerobic conditions. The amounts of volatiles, metabolites and non-extractable residues did not change significantly compared to the preceding aerobic period.

The photolysis of tebufenpyrad in soil was investigated under laboratory conditions using [^{14}C]-labelled tebufenpyrad with radiolabels in two parts of the molecule (benzene ring and pyrazole position). There were no photo-products formed with the benzene label, which individually accounted for greater than 10% AR. Only one photo-product was formed from the pyrazole label, **CL 810,729**, accounting for a maximum of 12.2% AR after 26 days. The control samples showed less than 2% degradation throughout the course of the study.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The rate of degradation of tebufenpyrad was estimated from the results of one of the studies described in 4.1.1 above with [3-^{14}C-pyrazole]-tebufenpyrad. DT_{50} were: 26.7-74.4 days (single first order (SFO) non linear regression, 20-25°C and 45 % MWHC or 75% of 1/3 bar, four different soils). After normalisation to FOCUS reference conditions[18] (20°C and -10kPa soil moisture content) this range of single first order DT_{50} was 17.7-76.5 days (the geometric mean that is appropriate for use in FOCUS modelling is 33.9 days). At lower temperature (10°C) the rate of degradation was slower by a factor of 3. The degradation rate of the major soil metabolite CL 810,721 was derived from the laboratory study conducted on the parent compound tebufenpyrad in three different soils. DT_{50} values of 7, 22 and 54 days were calculated by applying first order regression kinetics. After normalisation to FOCUS reference conditions this range of single first order DT_{50} was 4.5-45.3 days (geometric mean: 14.2 days).
For the soil photolysis metabolite CL 810,729 no subsequent derivation of a degradation rate from the parent photolysis study was possible. Therefore, a separate aerobic laboratory soil degradation study in three biologically active soils was performed in the dark (20°C and 50 % MWHC). The results showed that this metabolite is very low persistent in soil, with SFO DT_{50} varying between 0.4 and 1.1 days and corresponding DT_{90} values between 1.5 and 3.7 days. From the latter experiments with CL 810,729, the degradation rates of CL 810,728 were also derived. Metabolite CL 810,728 exhibits low to moderate persistence in soil with SFO DT_{50} values in the range of 3-13 days.

Three field soil dissipation studies (bare soil) were performed to investigate the degradation and dissipation of tebufenpyrad in soil. In total, seven trials were conducted: two trials in the UK, two trials in Germany, one trial in France and two trials in Spain. A range of soils with organic carbon content from 0.2% to 2.4% and with a pH range from 4.8 to 8.1 was covered. Details on climatic

[18] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

conditions of the trial sites were provided in addendum 4 (June 2008). Using the residue levels of the parent tebufenpyrad from the soil layers where it was detected (0-5cm at two trial sites or 0-10cm at five sites), first order DT_{50} were 0.05-22.4 days. The dissipation rate was re-calculated based on non-linear pseudo-first order regression kinetics, where no such rate was provided in the original report. DT_{90} was reached clearly within less than 100 days except for the French trial where an estimated DT_{90} value of 482 days was reported. However, since there were no detectable residues on day 360 (<0.005 mg a.s./kg) and the fitting was done only using data until day 180, the DT_{90} is considered to be less than 360 days. As the degradation/dissipation data were not used for modelling purposes, no normalisation of the field DT_{50} values was performed. Low levels of the metabolites CL 810,721 and CL 810,729 were determined only in the 0-10 cm horizon of the Spanish and French trials.

In the original DAR, initial, short and long-term, actual- and time-weighted average predicted concentrations in soil ($PEC_{soil, act}$ and $PEC_{soil, twa}$) of tebufenpyrad and its soil metabolites CL 810,721 and CL 810,729, as well as CL 810,728 were calculated using the geometric mean half-lives from aerobic degradation studies, which did not constitute the required "realistic worst case". However, since only one application per season is intended and the risk assessment for soil organisms is based on initial PECsoil values, it was agreed that the selection of the DT_{50} values for PECsoil calculations is irrelevant in this case.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The adsorption/desorption of tebufenpyrad was investigated in nine soils in satisfactory batch adsorption experiments. Calculated adsorption $K_f$oc values varied from 1894 mL/g to 8552 mL/g (excluding the value of 8552 mL/g due to the low organic carbon content of 0.29%, the mean is 4204 mL/g) (1/n 0.817 – 0.9725, mean: 0.92). There was no evidence of a correlation of adsorption with pH.

The adsorption/desorption behaviour of metabolites CL 810,721 and CL 810,729 was investigated in five soils in satisfactory batch adsorption experiments. Calculated adsorption $K_f$oc values for CL 810,721 varied from 15.0 to 139.1 mL/g (mean: 61.2 mL/g) (1/n 0.92 – 0.95, mean: 0.94), indicating that this metabolite exhibits high to very high mobility in soil. The sorption of CL 810,721 was clearly dependent on pH in soil (r^2= -0.995). Therefore, soil-horizon specific $K_f$oc values were used in PEC_{gw} calculations, depending on the pH of the respective horizons in each FOCUS scenario.

For the adsorption isotherms of CL 810,729, $K_f$oc values ranged from 12.2 to 53.6 mL/g (mean: 29.6 mL/g) for experiments, where 1/n ranged between 0.72 and 1.44 (mean: 0.964). There was no evidence of a correlation of adsorption with pH.

The adsorption/desorption behaviour of metabolite CL 810,728 was investigated in three european soils. Calculated adsorption $K_f$oc values ranged from 2 to 5 mL/g (mean: 3.7 mL/g) (1/n 0.76 – 0.85, mean: 0.81), indicating that this metabolite is very highly mobile in soil. As CL 810,728 is a carboxylic acid derivative, a pH dependence of soil adsorption might be expected for this metabolite.

However, based on the available data, this hypothesis could be neither confirmed nor rejected with sufficient certainty. It was agreed by the experts that the approach of using only the $K_f$oc values from soils with pH ≥ 7 to reflect the worst case was appropriate.

The leaching characteristics of tebufenpyrad were studied in a column leaching study with three different German standard soils. Following the elution of about 395 mL of water over a period of 2 days, no quantifiable amounts of tebufenpyrad were found in the leachates, i.e. the total amount was below 0.2 µg per leachate or below 2% of the applied amount for all soils.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Tebufenpyrad is stable to hydrolysis in water under dark sterile conditions in the range of pH 4 to pH 9. This is also valid for temperatures up to 120°C, which may be used during processing of raw commodities like fruits (apples and pears).
Tebufenpyrad is stable to direct and indirect aqueous photolysis under sterile conditions.

A ready biodegradability test (OECD 301F) indicated that tebufenpyrad is 'not readily biodegradable' using the criteria defined by the test.
The metabolism of tebufenpyrad in aquatic systems was investigated using [^{14}C]-labelled tebufenpyrad, uniformly labelled in the benzene ring or in the pyrazole ring (two systems studied at 20°C in the laboratory). Tebufenpyrad partitioned rapidly from the water to the sediment (maximum in sediment: 80.4% AR after 0h). Two metabolites were identified: CL 810,721 (maximum in water 16.5% AR after 100 days, maximum in sediment 7% AR after 110 days) and CL 810,723 (< 5% AR in both water and sediment). The degradation rates of tebufenpyrad were re-calculated using Model-Maker (see addendum 1 for details). The calculated SFO total-system DT_{50} values for the benzene- and pyrazole labelled test substance were 89 and 59 days in the pond system, and 98 and 125 days in the brook system. It was concluded that the total-system DT_{50} value of 89 days should not be considered reliable due to the poor fitting of the kinetics. Reliable SFO $DT_{50\ water}$ and $DT_{50\ sed}$ values for tebufenpyrad were 4-58 days and 60-151 days, respectively. The experts agreed that the $DT_{50\ water}$ and $DT_{50\ sed}$ values derived from the two systems with the benzene labelled tebufenpyrad should not be used in the risk assessment as they were calculated using root 1.5 or second order kinetics. The degradation rates for the major metabolite CL 810,721 could not be calculated due to the limited set of data available.

FOCUS surface water modelling was evaluated up to step 4 for tebufenpyrad, step 3 for metabolite CL 810,728 and step 2 for the metabolites CL 810,721 and CL 810,729. The member state experts discussed the suitability of the degradation rates used in step 3 and step 4 for tebufenpyrad. In the original DAR a conservative default $DT_{50\ water}$ value of 300 days and $DT_{50\ sed}$ value of 90 days (= total

system half-life) were used. It was considered that this combination of parameters ensure highest possible residues remaining in the water phase, and thus, constitute a worst case as compared to using the available DT_{50} data in reverse assignment (i.e. the system value for the fastest degrading compartment (=water) and a conservative value for the other). The applicant provided further information on the nature of PECglobal, maximum values in FOCUS step 3 and step 4 calculations, indicating that in all FOCUS scenarios these values are caused by initial spray drift entries (see addendum 5 for more details). Therefore, it was concluded that minor changes to model input parameters for tebufenpyrad would have no material effect on the predicted concentrations. The peer review agreed that the available PEC surface water and sediment values were appropriate for use in risk assessment.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Predicted environmental concentrations in groundwater (PEC_{gw}) for the active substance tebufenpyrad and its metabolites CL 810,721, CL 810,728 and CL 810,729 were re-calculated by the rapporteur Member State in agreement with the general recommendations of the FOCUS groundwater scenarios working group. In particular, the K_f/K_{fOC} and 1/n values of those soils with pH>7 were used in that PEC groundwater calculation for metabolite CL 810,728. For metabolite CL 810,721, K_{fOC} values were calculated for each soil horizon in the FOCUS scenarios with their corresponding pH, using a linear regression function $K_f = f(pH)$ as obtained from the experimental adsorption values for five soils (refer to section 4.1.3).

Parent tebufenpyrad and metabolites CL 810,721 and CL 810,729 were calculated to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations of <0.001µg/L at all 9 FOCUS groundwater scenarios, except for one scenario for CL 810,721 with 0.056 µg/L. For metabolite CL 810,728, this range for the 9 FOCUS groundwater scenarios was <0.001-0.006µg/L, i.e. below the 0.1µg/L parametric drinking water limit.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of tebufenpyrad (<1.6×10^{-6} Pa at 20°C) indicates that it is very slightly volatile, therefore significant losses due to volatilisation would not be expected. Calculations using the method of Atkinson for indirect photo-oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 7.3 hours (assuming an atmospheric hydroxyl radical concentration of 5×10^5 radicals cm^{-3}) indicating that the small proportion of applied tebufenpyrad that will volatilise would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Tebufenpyrad was discussed at the PRAPeR meeting of experts for ecotoxicology (PRAPeR 53) in July 2008 on the basis of the draft assessment report (DAR), addendum 1 of April 2008 and addendum 4 of June 2008. The representative use evaluated is the use as an acaricide in pome fruit. The risk assessment was conducted according to the following guidance documents: *Risk Assessment for Birds and Mammals*, SANCO/4145/2000 September 2002; *Aquatic Ecotoxicology*, SANCO/3268/2001 rev.4 final, October 2002; *Terrestrial Ecotoxicology*, SANCO/10329/2002 rev.2 final, October 2002; *Risk Assessment for non-target arthropods*, ESCORT 2, March 2000, SETAC.

Following a statement in chapter 1 (identity, physical/chemical/technical properties and methods of analysis), if the compound listed in row 5 of Table C.1.1.1 of Volume 4 of the DAR is present in the technical specification of tebufenpyrad, an ecotoxicological risk assessment should be carried out.

In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, new studies could not be considered in the peer review.

5.1. Risk to terrestrial vertebrates

The LD_{50} values for birds were >2000 mg/kg bw (acute) and >439 and >75 mg/kg bw/day (short-term). The acute and short-term TERs in the first-tier risk assessment were above the Annex VI trigger of 10. The long-term endpoint was statistically not verified, and the long-term risk assessment was not considered finalized in the DAR. During the peer-review a statistical evaluation of the study was provided by the applicant and a NOEC of 130mg a.s./kg diet was suggested. The experts disagreed to this proposal. It was noted that the number of hatchlings per hen were statistically significantly reduced at the highest tested concentration. Although not statistically significant, there were also effects on the number of hatchlings, eggs laid and 14-day old survivors at the next lower concentration of 130 mg a.s./kg diet. The observed effects followed a dose-response relationship, and the experts suggested a NOEC of 65 mg a.s./kg diet with a corresponding NOEL of 6.6 mg a.s./kg bw/day. The risk assessment was updated by the rapporteur Member State in addendum 5 of August 2008 (not peer-reviewed). The experts agreed to *blue tit* as a focal species and the PD refinement of 70% small and 30% large insects in the diet. The refined long-term TER for insectivorous birds was 2.9 including the agreed refinement of PD. A data gap was identified in the meeting to further refine the long-term risk assessment for insectivorous birds.
The acute toxicity of technical tebufenpyrad to mammals was 320 mg a.s./kg bw. The toxicity of tebufenpyrad was not significantly increased, if formulated as "BAS 318 00I" (LD_{50} = 291.6 mg/kg bw). The long-term endpoint of 8 mg a.s./kg bw/day (NOEL) was based on adverse effects on bodyweight. The first-tier acute TERs for technical and formulated tebufenpyrad were calculated as

27 and 25, respectively. The long-term TER was 7.4 taking into account an interception of 80% since the product is applied after flowering and full development of leaves.
The metabolites identified in fruits (apples) also appear in the metabolism studies conducted with rats, goats and hens and thus, would be covered by the endpoints observed for the parent tebufenpyrad. Some uncertainty remains with regard to potentially formed metabolites in green plant material, but it may be that also unknown metabolites are covered by the rat metabolism considering the high number of compounds identified. It was concluded by the experts that the risk from plant metabolites to herbivorous mammals was low.
The TERs for earthworm- and fish-eating birds were above the Annex VI trigger of 5 indicating a low risk of secondary poisoning.

The risk to birds and mammals was assessed as low for the representative use evaluated except the long-term risk to insectivorous birds, which needs further refinement of the risk assessment.

5.2. RISK TO AQUATIC ORGANISMS

Tebufenpyrad is very toxic to fish and to aquatic invertebrates with steep dose-response curves. The lowest endpoints were observed in the studies with rainbow trout (*Oncorhynchus mykiss*) 96h LC_{50} = 19 µg a.s./L, *Mysidopsis bahia* 96h EC_{50} = 22 µg a.s./L and daphnids EC_{50} = 46 µg a.s./L. The toxicity of tebufenpyrad to fish (but not to daphnids) was slightly increased in the tested formulations "BAS 318 00 I" and "BAS 318 06 I". The TERs for algae were above the trigger of 10 for all FOCUS step 3 scenarios, but the acute and chronic TERs for fish and invertebrates were below the Annex VI trigger based on FOCUS step 3 PECsw values. All scenarios resulted in acute TERs >100 for daphnids, if a no-spray buffer zone of 20 m was included in the FOCUS step 4 calculations. However, no full FOCUS step 4 scenario resulted in TERs above the trigger for fish and *Mysidopsis bahia*. A flow-through test design was used in the study with *Mysidopsis bahia* that may have led to an overestimation of the risk since tebufenpyrad is applied only once per year and dissipates rapidly from the water phase. Furthermore, the 48 hours EC_{50} value for *Mysidopsis bahia* of 42.5 µg a.s./L is similar to the 48 hours EC_{50} for daphnids and hence, the risk may be considered to be covered by the risk assessment for daphnids.
The risk assessment for fish was refined by HC5 calculation based on five species. The rapporteur Member State proposed using the mean HC5 (20.9 µg a.s./L) of the LC_{50} values together with a safety factor of 30. This approach was questioned in the peer-review. The experts in the meeting agreed to use the species sensitivity distribution in the risk assessment. The experts suggested using the lower limit HC5 (95%tile lower confidence limit) of 6.1 µg a.s./L to account for the distribution of the data. A reduced safety factor of 10 was suggested by the experts. The rapporteur Member State updated the acute risk assessment for fish in the not peer reviewed addendum 5 according to the recommendations of the member state experts, and included also a risk assessment based on the mean HC5 with a safety factor of 35 (the reduced safety factor of 10 was multiplied by the quotient of the mean HC5 and the

lower limit HC5). The outcome of both approaches is identical. The Annex VI triggers were exceeded in all FOCUS step 4 scenarios with a no-spray buffer zone of 20m and in one full scenario (D4) out of seven scenarios, if a no-spray buffer zone of 10m is applied.

A population development study with daphnids and the presence of sediment was considered as not valid by the rapporteur Member State, but was re-assessed in addendum 4. The re-assessment of the study was discussed and agreed by the experts. The NOEC of 4 µg a.s./L was confirmed. The experts suggested that the endpoint should be compared to initial PECsw values since dissipation of tebufenpyrad was already taken into account in the test system. The trigger of 10 was exceeded in the full scenarios D3, D4, R1, R4 and the part scenario D5 (pond), but was below the trigger in the full scenarios R2, R3 and the part scenario D5 (stream).
The TER for *Chironomus riparius* was calculated as 13 based on FOCUS step 2 PECsed of 50.5 µg a.s./kg suggesting a low risk to sediment-dwelling organisms.

The toxicity of the major metabolite in water CL 810,721 was low (LC/EC_{50} for fish, daphnia and algae >100 mg/L). The TERs were well above the trigger of 100 with FOCUS step1 PECsw values. No studies were available with aquatic organisms and the major soil metabolites CL 810,729 and CL 810,728. In the risk assessment it was assumed that the metabolites are 10-times more toxic than the parent compund. The TERs were above the triggers with FOCUS step 2 PECsw values for metabolite CL810,729. For metabolite CL810,728, all TERs calculated on the basis of FOCUS step 3 PECsw values were above or very close to the Annex VI triggers. The risk from metabolites to the aquatic environment was considered as low.
The log P_{ow} of tebufenpyrad is 4.93 triggering the assessment of bioconcentration. The bioconcentration factors (BCF) observed in studies with rainbow trout and bluegill sunfish were in the range of 406 – 510 (not normalised to lipid content). The maximum BCF normalised to the lipid content was 953. An early life stage study (ELS) with fish is available and the endpoint (NOEC = 2.45 µg a.s./L) was considered in the long-term risk assessment covering potential toxic effects due to bioconcentration. Tebufenpyrad was rapidly metabolised and excreted with a clearance time CT_{90} of 1.65 days. It is applied only once per year and it dissipates rapidly from the water phase. Therefore it was concluded that the risk from bioconcentration and bioaccumulation is low.

5.3. RISK TO BEES

Acute oral and contact toxicity studies were conducted with technical and formulated tebufenpyrad. The LD_{50} values were in the range of 6.7 to 75.9 µg /bee. The HQ values ranging from 1.7 to 15.6 were below the Annex VI trigger of 50 indicating a low risk to bees.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory tests were conducted with formulated tebufenpyrad and the indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. LR_{50} values of 0.69 and 7.3 g a.s./ha were observed. The in-field HQ values were calculated as 145 and 13.7. The off-field HQs were 22.8 and 2.2 indicating a potential high risk. Extended laboratory and aged residue tests with *A. rhopalosiphi* and *T. pyri* were conducted with natural substrate (excised leaves = 2 dimensional, and whole plants treated = 3 dimensional structure). In addition, studies with *Chrysoperla carnea*, *Aleochara bilineata* and *Pardosa sp*. were submitted. *T. pyri* was the most sensitive species tested.

The effects were <50%, if the arthropods were exposed to residues after 14 days of ageing. This observation suggested that recolonisation of the in-field area would be possible within one year, provided that the off-field risk to non-target arthropods is low. The off-field rate at a standard distance of 3m was 7.9 g a.s./ha. The LR_{50} values derived from exposure to fresh residues in extended laboratory studies with the most sensitive species (*T. pyri*) exceeded the rate of 7.9 g a.s./ha. Therefore, it was concluded that the off-field risk was low, and that the risk to non-target arthropods was low for the representative use of tebufenpyrad.

5.5. RISK TO EARTHWORMS

The acute toxicity to earthworms was tested with technical and formulated tebufenpyrad. The observed acute 14-day LC_{50} values were 20.5 and 21.1 mg a.s./kg soil (corrected by a factor of 2). The chronic NOEC for the formulation was 0.17 mg a.s./kg soil (corrected by a factor of 2). The acute and chronic TERs were calculated with a PECsoil of 0.027 mg a.s./kg resulting in acute TERs far above the trigger of 10, and in a chronic TER of 6.3 above the trigger of 5.

The acute toxicity of the metabolites is low. The corrected acute 14-day LC_{50} were > 1000 mg/kg for the metabolites CL 810,721 and CL 810,728, and an LC_{50} of 392 mg/kg soil was observed for metabolite CL 810,729. The TERs were several orders of magnitude above the trigger of 10 based on initial PECsoil of 0.0068mg CL 810,721/kg, 0.0015mg CL 810,728/kg and 0.0018mg CL 810,729/kg. The metabolites degrade rapidly in soil and therefore no long-term studies with earthworms were required.

Overall, it was concluded that the risk to earthworms is low for the representative uses evaluated.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Studies with tebufenpyrad formulated as "BAS 318 00 I" with collembola (*Folsomia candida*) and predaceous mites (*Hypoaspis aculeifer*) were submitted. The observed NOECs of 6.25 and 200 mg a.s./kg soil were compared to the initial PECsoil of 0.027 mg a.s./kg. The resulting TERs were more than 2 orders of magnitude greater than the Annex VI trigger of 5, indicating a low risk.

Litter bag study was not provided, but it is not necessary since tebufenpyrad did not fail the persistence trigger (field DT90 <395 days), and a single application per year was proposed.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25 % on soil respiration and nitrification were observed in tests with formulated tebufenpyrad and with the metabolites CL 810,721 and CL 810,729 up to concentrations of 3.33 mg a.s./kg soil, 0.363 mg CL 810,721/kg and 0.112 mg CL 810,729/kg. The initial PEC soils are several orders of magnitude lower than the tested concentrations suggesting a low risk to soil micro-organisms for the representative uses evaluated.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Herbicidal effects of the formulation "BAS 318 00 I" on vegetative vigour and emergence were investigated in tests with four dicotyl plant species and with two monocotyl plant species. The ER_{50} values were >1 kg (equivalent to 200 g a.s./ha). The NOEC was determined as 0.5 kg formulation/ha. Since the effects were less than 50% at the recommended application rate, the risk to non-target plants in the off-crop area was considered to be low for the representative use evaluated.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The EC_{50} for inhibition of respiration of activated sewage sludge was >6 mg a.s./L. It was not expected that tebufenpyrad would reach concentrations in biological sewage treatment plants high enough to cause adverse effects, if applied according to the GAP. Therefore, the risk to biological methods of sewage treatment was considered to be low.

6. Residue definitions

Soil

Definition for risk assessment:	tebufenpyrad; CL 810,721; CL 810,729 (soil photolysis metabolite)
Definition for monitoring:	tebufenpyrad

Water

Ground water

Definition for exposure assessment:	tebufenpyrad; CL 810,721; CL 810,728; CL 810,729 (soil photolysis metabolite)
Definition for monitoring:	tebufenpyrad

Surface water

Definition for risk assessment:	tebufenpyrad; CL 810,721; from soil runoff and drainage: CL 810,729 (soil photolysis metabolite)
Definition for monitoring:	tebufenpyrad

Air

Definition for risk assessment:	tebufenpyrad
Definitions for monitoring:	tebufenpyrad

Food of plant origin

Definition for risk assessment:	tebufenpyrad
Definition for monitoring:	tebufenpyrad

Food of animal origin

Definition for risk assessment:	tebufenpyrad (based on ruminant study only)
Definition for monitoring:	tebufenpyrad (based on ruminant study only)

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
tebufenpyrad	moderate to medium persistence Single first order DT_{50} 17.7-76.5 days (20°C, PF2 soil moisture)	The acute toxicity to earthworms soil non-target arthropods and soil micro-organisms is low. The risk to earthworms, soil non-target arthropods and soil micro-organisms was assessed as low.
CL 810,721	low to moderate persistence Single first order DT_{50} 4.5-45.3 days (20°C, PF2 soil moisture)	The acute toxicity and the risk to earthworms and soil micro-organisms was low.
CL 810,729 (soil photolysis)	very low persistence Single first order DT_{50} 0.39-0.87 days (20°C, PF2 soil moisture)	The acute toxicity and the risk to earthworms and soil micro-organisms was low.
CL 810,728*	low persistence Single first order DT_{50} 2.68-10.4 days (20°C, PF2 soil moisture)	The acute toxicity and the risk to earthworms and soil micro-organisms was low.

**minor, non-transient metabolite (max. 5.1% AR)*

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
tebufenpyrad	immobile to low mobile K_{foc} 1894-8552 mL/g	no	Yes	Yes	Yes
CL 810,721	highly to very highly mobile K_{foc} 15-139 mL/g	no	No data submitted. No assessment required.	No assessment required.	No
CL 810,729 (soil photolysis)	highly to very highly mobile K_{foc} 12-54 mL/g	no	No data submitted. No assessment required.	No assessment required.	No
CL 810,728	very highly mobile K_{foc} 2-5 mL/g	no	No data submitted. No assessment required.	No assessment required.	No

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
tebufenpyrad	Very toxic to fish and aquatic invertebrates. Risk mitigation is necessary to achieve TERs above the Annex VI trigger.
CL 810,721 (only water)	Low toxicity and low risk to aquatic organisms.
CL 810,729 (soil photolysis)	No information on the toxicity to aquatic organisms was made available. The risk to aquatic organisms was assessed as low assuming a 10 times higher toxicity compared to tebufenpyrad.
CL 810,728 (from soil via runoff/drainage)	No information on the toxicity to aquatic organisms was made available. The risk to aquatic organisms was assessed as low assuming a 10 times higher toxicity compared to tebufenpyrad.

Air

Compound (name and/or code)	Toxicology
tebufenpyrad	Tebufenpyrad is of moderate acute toxicity by inhalation (LC_{50} > 2.7 mg/L). A classification as Xn; R20 “Harmful; Harmful by inhalation” is proposed.

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- A revised specification for the technical material was identified as a data gap (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting of experts (June 2008), date of submission unknown; refer to chapter 1)
- Information concerning the content of the compound listed in row 5 of Table C.1.1.1 of Volume 4 of the DAR in the technical material is required (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting of experts (June 2008), date of submission unknown; refer to chapter 1)
- To clarify what happens with batches which are found outside of specification (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting of experts (June 2008), date of submission unknown; refer to chapter 1)
- To confirm that the manufacturing process has not been substantially changed since the production of the submitted batch analyses (1991) (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting of experts (June 2008), date of submission unknown; refer to chapter 1).
- Shelf life data for the new formulation "BAS 31806I" was identified as a data gap (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting of experts (June 2008), date of submission unknown; refer to chapter 1)
- Data for suspensibility at the highest application rate was identified as a data gap (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting of experts (June 2008), date of submission unknown; refer to chapter 1)
- A refined long-term risk assessment for insectivorous birds was identified as a data gap (relevant for all representative uses evaluated; no submission date proposed by the notifier; data gap identified at the PRAPeR 53 meeting of experts (July 2008); refer to point 5.1.)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as an acaricide and insecticide as proposed by the notifier, which comprise foliar spraying in pome fruit for the control of mite pests on all developmental stages of mites. Full details of the GAP can be found in the attached end points.

The representative formulated product for the evaluation was "BAS 31806I" ("MASAI"), a wettable powder (WP) containing 200 g/kg tebufenpyrad.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. The specification cannot be finalized as there are outstanding issues. Also a shelf-life study and a new suspensibility study have been identified as data gaps.
Adequate methods are available to monitor tebufenpyrad residues in food/feed of plant origin and environmental matrices.

Tebufenpyrad is absorbed extensively but slowly. It is widely distributed and has no potential for accumulation. It is excreted slowly but completely and is rapidly and extensively metabolized. It is of moderate toxicity by the oral and the inhalation route and of low toxicity by the dermal route. Tebufenpyrad is neither irritant to skin nor to the eyes, but is a skin sensitizer. Based on the available data on acute toxicity a classification as **Xn; R20 "Harmful; Harmful by inhalation", Xn; R22 "Harmful; Harmful if swallowed"** and **Xi; R43 "Irritant; May cause sensitization by skin contact"** is proposed. In short term tests with tebufenpyrad effects on bodyweight and food consumption were observed in all species tested (rat, mouse, dog, and rabbit). While in rats and mice the liver was the target of toxicity, in dogs gastrointestinal effects and lesions were prevalent. The lowest NOAEL was achieved in the rat study (0.7 mg/kg bw/day). In dogs an overall NOAEL of 2 mg/kg bw/day was set. Tebufenpyrad is not genotoxic. A 2-year rat study and an 18-month study with mice were reported. In the rat study a systemic NOAEL of 0.8 mg/kg bw/day was derived based on effects on bodyweight and food consumption, altered erythrocyte parameters and liver effects. The liver adenomas observed were considered not relevant for human risk assessment. In the mouse study a NOAEL of 3.6 mg/kg bw/day was derived based on increased liver and kidney weights, and reduced bodyweight and food consumption. No tumours were observed. Tebufenpyrad did not cause specific effects on reproduction in a two-generation study. While no effects on development were observed in rabbits, in rats increased incidences of supernumerary ribs were seen at maternally toxic doses. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) were set at 0.01 mg/kg bw/day. An acute reference dose (ARfD) of 0.02 mg/kg bw was allocated. Using the German model operator exposure amounted to 65% (tractor-mounted application) and to 92% (hand-held application) of the AOEL when personal protective equipment (PPE) was used. In the UK POEM exposure exceeded the AOEL in all scenarios. Worker exposure was calculated to be 57% of the AOEL when PPE is used. A refined exposure assessment after the PRAPeR meeting of experts showed a bystander exposure of 93% of the systemic AOEL.

The metabolism of tebufenpyrad in apples was investigated. Application was made at a rate of 2.22 kg a.s./ha, which is a 22N rate. Some minor metabolites were identified but given that the study was conducted at such a high rate the only significant residue will be tebufenpyrad. The residue definition for monitoring and risk assessment is therefore tebufenpyrad only. Sufficient residue trials were supplied for the critical GAP in the north and south of Europe. Residues of tebufenpyrad were stable

under freezer storage for a period of at least two years. On processing, the nature of the residue will be unchanged, and sufficient data were supplied to derive processing factors for juice and pomace. Metabolism data in goat and hen were provided; the most significant residues were tebufenpyrad, CL 810,720 and CL 810,721. In a ruminant feeding study, even at 3N, significant residues of tebufenpyrad and these two metabolites were not found. Also at the 10N rate, only very low levels were found. The meeting of experts concluded that there will be no significant residues present in products of animal origin. The residue definition was therefore set as tebufenpyrad for monitoring and risk assessment for ruminant only. The meeting noted however, that this should be considered again, if other uses lead to higher intakes. No conclusion was reached on the residue definition for poultry. However, the notified uses would not give rise to significant residues in poultry as there is no dietary exposure. The risk assessment showed that maximum intakes are 28 % of the ADI and 64 % of the ARfD. An MRL for pome fruit was set at 0.2 mg/kg.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at EU level. For the applied for intended uses, the potential for groundwater exposure by tebufenpyrad and its metabolites CL 810,721, CL 810,728 and CL 810,729 above the parametric drinking water limit of 0.1 µg/L, is low.

The risk to birds and mammals was assessed as low for the representative use evaluated, except the long-term risk to insectivorous birds, which needs further refinement (data gap).
Tebufenpyrad is very toxic to fish and to aquatic invertebrates with steep dose-response curves. All FOCUS step 4 scenarios resulted in acute TERs >100 for daphnids, if a no-spray buffer zone of 20m was included. However, no full FOCUS step 4 scenario resulted in acute TERs above the Annex VI trigger for fish. The experts suggested using the lower limit HC5 (95%tile lower confidence limit) of 6.1 µg a.s./L together with a reduced safety factor of 10. The trigger was exceeded in all FOCUS step 4 scenarios with a no-spray buffer zone of 20 m. The long-term risk assessment for invertebrates was based on a population development study with daphnids (NOEC of 4 µg a.s./L). The Annex VI trigger of 10 was exceeded in the full scenarios D3, D4, R1, R4 and the part scenario D5 (pond), but was below the trigger in the full scenarios R2, R3 and the part scenario D5 (stream), if a 20m no-spray buffer zone is applied. The risk of bioaccumulation as well as the risk from the major metabolites in water and soil were assessed as low. *T. pyri* was the most sensitive arthropod species tested. A potential high in-field and off-field risk was indicated in the first-tier risk assessment. In higher tier (extended laboratory) tests it was shown that the off-field risk to *T. pyri* is low. Recolonisation of the in-field area was considered as plausible since effects were <50% after 14 days of ageing of residues.
The risk to bees, earthworms, other soil macro-organisms, soil micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- For operators and workers personal protective equipment is needed.
- A no-spray buffer zone of 20 m is required to achieve acute TERs above the Annex VI trigger for fish in all FOCUS step 4 scenarios and in the majority of the scenarios for the long-term TERs for invertebrates. The trigger was exceeded in the scenarios D3, D4, R1, R4 and the part scenario D5 (pond), but was below the trigger in the full scenarios R2, R3 and the part scenario D5 (stream).

Critical areas of concern

- Calculated exposure for bystanders (using very conservative agreed input parameters) exceeds the AOEL. However, in a more reliable refined assessment (not peer reviewed) an exposure of 93% of the AOEL was calculated.
- The long-term risk to insectivorous birds needs to be further refined.

Appendix 1 – list of endpoints

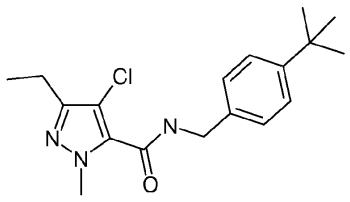
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Chapter 1 (identity, physical and chemical properties, details of uses, further information, classification and labelling)

Active substance (ISO Common Name) ‡	Tebufenpyrad
Function (e.g. fungicide)	Acaricide/insecticide
Rapporteur Member State	Federal Republic of Germany

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-(4-*tert*-butylbenzyl)-4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide
Chemical name (CA) ‡	4-chloro-N-[[4-(1,1-dimethylethyl)phenyl]-methyl]-3-ethyl-1-methyl-1H-pyrazole-5-carboxamide
CIPAC No ‡	725
CAS No ‡	119168-77-3
EEC No (EINECS or ELINCS) ‡	none
FAO Specification (including year of publication)‡	none
Minimum purity of the active substance as manufactured‡	980 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured	open
Molecular formula ‡	$C_{18}H_{24}ClN_3O$
Molecular mass ‡	333.8 g mol^{-1}
Structural formula ‡	

Appendix 1 – list of endpoints

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	64 – 66 °C (99.0 %)
Boiling point (state purity) ‡	no boiling before decomposition starts
Temperature of decomposition (state purity)	starting at 250 °C (98.8 %)
Appearance (state purity) ‡	white, crystalline solid (> 99 %, tech.)
Vapour pressure (state temperature, state purity) ‡	< 1.6 x 10^{-6} Pa (20 °C, extrapolated) < 9.7 x 10^{-6} Pa (25 °C) (LOD) 3.6 x 10^{-5} Pa (46 °C) (all 98.8 %)
Henry's law constant ‡	< 1.1 x 10^{-3} Pa m³ mol^{-1}
Solubility in water (state temperature, state purity and pH)‡	2.6 mg/L (deionised water, 25 °C) 3.2 mg/L (pH 4 buffer, 25 °C) 2.4 mg/L (pH 7 buffer, 25 °C) 2.3 mg/L (pH 10 buffer, 25 °C)(all 98.8 %, tech.)
Solubility in organic solvents (state temperature, state purity) ‡	hexane: 255 toluene: 772 acetonitrile: 785 methanol: 818 acetone: 819 dichloromethane: 1044 (all in g per L solution at 25 °C) (all 98.8 %, tech.)
Surface tension ‡ (state concentration and temperature, state purity)	67.4 mN/m at 20.3 °C (99.6 %) for a 90 % saturated solution
Partition co-efficient (state temperature, pH and purity)‡	log $P_{O/W}$ = 4.93 (25 °C, 96.1 %) effect of pH not investigated
Dissociation constant (state purity)‡	no dissociation in pH range 4 – 10 (calculation)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	ε [L mol-1 cm-1] λ [nm] 16882 223 82 295 (> 99 %)
Flammability ‡ (state purity)	not "highly flammable" (98.8 %, tech.)
Explosive properties ‡ (state purity)	not explosive (statement)
Oxidising properties ‡ (state purity)	not oxidising (statement)

Appendix 1 – list of endpoints

Summary of representative uses evaluated (tebufenpyrad)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min - max (l)	water L/ha min - max	g as/ha min - max (l)		
Pome fruit	Northern and Southern Europe	BAS 318 06 I	F	*Metatetranychus ulmi, Panonychus ulmi, Tetranychus urticae*	WP	200 g/kg	Spraying (Air-assisted spraying, hand-held spraying)	BBCH 68 - 88	1	n.a.	6.7 - 50	200 - 1500	100	7	[1] [2] [3]

[1]Bystander exposure exceeds the AOEL. However, in a refined assessment (not peer reviewed) the AOEL was not exceeded.
[2] Technical specification not finalised.
[3] The long-term risk to birds needs further refinement.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse 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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Appendix 1 – list of endpoints

Chapter 2 (methods of analysis)

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	GC/FID
Impurities in technical as (analytical technique)	GC/FID
Plant protection product (analytical technique)	HPLC/UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		tebufenpyrad
Food of animal origin		tebufenpyrad, based on ruminant study only.
Soil		tebufenpyrad
Water	surface	tebufenpyrad
	drinking/ground	tebufenpyrad
Air		tebufenpyrad

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S19 (GC-MS) 0.01 mg/kg (apples, grapes) 0.05 mg/kg (oil-seed rape)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	not relevant, no MRL proposed
Soil (analytical technique and LOQ)	HPLC-UV 0.01 mg/kg
Water (analytical technique and LOQ)	LC-MS/MS 0.1 µg/L (drinking and surface water)
Air (analytical technique and LOQ)	GC-MS 2 µg/m³
Body fluids and tissues (analytical technique and LOQ)	not relevant, not classified as toxic or very toxic

Appendix 1 – list of endpoints

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

Appendix 1 – list of endpoints

Chapter 3 (impact on human and animal health)

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Extensive (> 80 % based on 16-30 % urinary and biliary 48-74 % excretion and tissue residues in bile cannulated rats), but relatively slow (C_{max} reached after 8 h) after application of the low dose of 10 mg/kg bw to rats
Distribution ‡	Initially widely distributed, after 168 h highest residues in mesenteric lymph nodes and (at 50 mg/kg bw only) in bone
Potential for accumulation ‡	No potential of accumulation in any organ in spite of delayed elimination
Rate and extent of excretion ‡	Relatively slow but virtually complete after 168 hours post dosing, mainly via faeces (48 - 74 %) with urinary elimination (24 - 44 %) less important; significant biliary excretion (about 60 % in 24 hr) and enterohepatic circulation
Metabolism in animals ‡	Extensive with at least 22 identified metabolites; main pathways hydroxylation, oxidation, sulfate conjugation
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	202-320 mg/kg bw	**R 22**
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	2.7 mg/L air (4-hr nose-only exposure)	**R 20**
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Sensitiser (M&K)	**R 43**

Appendix 1 – list of endpoints

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Bw gain/food consumption↓ (all species); liver (organ weight↑, clinical chemistry, histopathology) in rats and mice; GIT (clinical signs and histological lesions) in dogs	
Relevant oral NOAEL ‡	Dog, 90 d and 1 yr (overall NOAEL): 2 mg/kg bw/d Rat, 90 d: 0.7 mg/kg bw/d Mouse, 90-day: 41 mg/kg bw/d	
Relevant dermal NOAEL ‡	Rabbit, 21 d: 200 mg/kg bw/d	
Relevant inhalation NOAEL ‡	No data, not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Weak clastogenic activity *in vitro*, negative *in vivo*.Overall no genotoxic potential.	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Bw gain, food consumption↓, liver (organ weight↑, clinical chemistry, hepatocyte hypertrophy), minor haematological changes (anaemia)	
Relevant NOAEL ‡	Rat, 2 yr: 0.8 mg/kg bw/d Mouse, 18 mo: 3.6 mg/kg bw/d	
Carcinogenicity ‡	Liver adenoma in male rats (possibly peroxisome proliferation) at 6.5 mg/kg bw/d and above; no relevance for humans.	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: reduced bw and food consumption Reproduction: no evidence for impairment of fertility and reproduction Offspring: Reduced bw development in pups at parentally toxic doses; delayed vaginal opening	
Relevant parental NOAEL ‡	8 mg/kg bw/d	
Relevant reproductive NOAEL ‡	≥ 17 mg/kg bw/d	

Appendix 1 – list of endpoints

Relevant offspring NOAEL ‡	8 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: Rat and rabbit: reduced bw and food consumption Developmental: Rat: Skeletal variations (additional ribs) at maternally toxic doses in rats Rabbit: none	
Relevant maternal NOAEL ‡	Rat: 15 mg/kg bw/d Rabbit: 15 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat: 15 mg/kg bw/d Rabbit: ≥ 40 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data, not required	
Repeated neurotoxicity ‡	No data, not required	
Delayed neurotoxicity ‡	No data, not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Increased activity of palmitoyl-CoA oxidase suggesting peroxisome proliferating properties of tebufenpyrad; no tumour promoting activity after initiation with a known carcinogen
Studies performed on metabolites or impurities ‡	Studies on two soil/groundwater metabolites that also occur in rats available: **CL 810,721 (M-CA)** Acute oral toxicity test, LD_{50}: 500-2000 mg/kg bw Ames test, *in vitro* mouse lymphoma test, *in vitro* chromosome aberration test: negative **CL 810,729 (PAM)** Acute oral toxicity, LD_{50}: 300-2000 mg/kg bw ~~and~~ Ames tests: negative

Medical data ‡ (Annex IIA, point 5.9)

No adverse health effects reported

Appendix 1 – list of endpoints

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.01 mg/kg bw/day	2yr and 90-day rat (overall assessment, rounded)	100
AOEL ‡	0.01 mg/kg bw/day	2 yr and 90-day rat (overall assessment, rounded)	100
ARfD ‡	0.02 mg/kg bw	Acute clinical signs in dog studies (overall assessment)	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

No specific studies provided, default: 10 % for the concentrate (based on physico-chemical properties and a comparison of NOAELs in oral and dermal short-term studies in rabbits), 100 % for the dilution

Appendix 1 – list of endpoints

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Tebufenpyrad 20 WP (enclosed in water soluble bags) - acceptable for high crop applications using PPE according to the German model German model - HCTM (pome fruits: 0.1 kg as/ha): - exposure = 1,316 % of AOEL, syst. (no PPE) - exposure = 65 % of AOEL, syst. (gloves, hood and visor and coverall during application) German model - HCHH (pome fruits: 0.1 kg as/ha): - exposure = 581 % of AOEL, syst. (no PPE) - exposure = 92 % of AOEL, syst. (gloves, coverall, hood and visor during application) UK-POEM – HCTM, low volume appl. (pome fruits: 0.1 kg as/ha): - exposure = 6,198 % of AOEL, syst. (no PPE) - exposure = 3,948 % of AOEL, syst. (gloves during application) UK-POEM – HCTM, high volume appl. (pome fruits 0.1 kg as/ha): - exposure = 1,347 % of AOEL, syst. (no PPE) - exposure = 950 % of AOEL, syst. (gloves during application)
Workers	Acceptable (pome fruits: 0.1 kg as/ha) (Model: Hoernicke et al., 1998) exposure = 1143 % of AOEL, syst. (no PPE) exposure = 57 % of AOEL, syst. (with PPE) Refined exposure assessment (not peer reviewed): - exposure = 514 % of AOEL, syst. (no PPE) - exposure = 26 % of AOEL, syst. (with PPE)
Bystanders	Refined exposure assessment (considering input parameters more reliable than the ones applied as first tier leading to 515% of the AOEL, not peer reviewed): - exposure = 93 % of AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS proposal
Tebufenpyrad	Xn, R 20-22-43

Appendix 1 – list of endpoints

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Pome fruit (apples, pears etc.)
Rotational crops	not applicable
Metabolism in rotational crops similar to metabolism in primary crops?	not applicable
Processed commodities	juice, sauce, (pomace)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	yes
Plant residue definition for monitoring	tebufenpyrad
Plant residue definition for risk assessment	tebufenpyrad
Conversion factor (monitoring to risk assessment)	1

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	lactating goats
Time needed to reach a plateau concentration in milk and eggs	Not applicable, since no significant residues in milk even at exaggerated residue intakes
Animal residue definition for monitoring	Tebufenpyrad
Animal residue definition for risk assessment	Tebufenpyrad
Conversion factor (monitoring to risk assessment)	1
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	Yes

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

not relevant

Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stable in crops with high water content for at least 24 months under freezer storage conditions (-18 °C)

Appendix 1 – list of endpoints

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	yes (0.288 mg/kg dry weight)	no	no
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	no	no	no
	Feeding studies Relevant feeding rates: 0.3 and 0.9 mg/kg feed, i.e. 1x and 3x the maximum residue level expected in pome fruit pomace Residue levels in matrices: Mean (max) mg/kg		
Muscle	< 0.01 mg/kg	Feeding studies with poultry or pigs are not required since none of the crops (pome fruit) are used as feeding stuff for poultry or pigs.	
Liver	< 0.01 mg/kg		
Kidney	< 0.01 mg/kg		
Fat	< 0.01 mg/kg		
Milk	< 0.01 mg/kg		
Eggs	not applicable		

Appendix 1 – list of endpoints

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Pome fruit (apples, pears etc.)	Northern	0.05, 4 x 0.07, 2 x 0.08, 0.09 mg/kg	Residue behaviour shown to be very similar in N-EU and S-EU. Therefore, the calculation of the MRL is based on summarised residue data from N-EU and S-EU.	0.2	0.09 mg/kg	0.07 mg/kg
	Mediterranean	0.02, 0.04, < 0.05, 0.07, 0.09, 0.11, 0.12, 2 x 0.13 mg/kg			0,13 mg/kg	0.09 mg/kg
Pome fruit (apples, pears etc.)	Northern and Mediterranean	0.02, 0.04, < 0.05, 0.05, 5 x 0.07, 2 x 0.08, 2 x 0.09, 0.11, 0.12, 2 x 0.13 mg/kg	see above	0.2	0.13 mg/kg	0.07 mg/kg

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Appendix 1 – list of endpoints

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.01 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	3.4 % (EFSA PRIMo)
TMDI (% ADI) according to national (to be specified) diets	27.8 % (VELS PRIMo)
IEDI (WHO European Diet) (% ADI)	not required
NEDI (specify diet) (% ADI)	not required
Factors included in IEDI and NEDI	not applicable
ARfD	0.02 mg/kg bw
IESTI (% ARfD)	63.7 % (EFSA model, apples, UK infant)
NESTI (% ARfD)	59.2 % (VELS model, pears, German child)
Factors included in IESTI and NESTI	not applicable

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/process/processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Highest transfer factor	Yield factor	
Apple/washed apple	3	0.92	--	--
Apple/juice	11	0.06	--	--
Apple/sauce	11	0.70	--	--
Apple/wet pomace	11	1.70	--	--

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Plant matrices (tebufenpyrad)	0.2 mg/kg for pome fruit
Animal matrices (tebufenpyrad)	No MRLs have been proposed for animal products due to negligible transfer of residues into animal products.

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure. Indicates LOQ on the basis of the newer analytical methods.

Appendix 1 – list of endpoints

Chapter 5 (fate and behaviour in the environment)

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡	16.3 % AR after 122 d, [^{14}C-benzene]-label (n = 1) 9.2 - 43.9 % after 120 - 122 d, [^{14}C-pyrazole]-label (n = 4)
Non-extractable residues after 100 days ‡	3.5 % AR after 122 d, [^{14}C-benzene]-label (n = 1) 2.5 - 35.5 % AR after 120 - 122 d, [^{14}C-pyrazole]-label (n = 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	CL 810,721: 0.6 - 6.6 % AR at 3 - 29 d, [^{14}C-benzene]-label (n=1) 1.6 - 23.4 % AR at 7 - 120 d, [^{14}C-pyrazole]-label (n=4) max 23,4 % AR after 45 d CL 810,728: 0.3 - 5.1 % AR at 3 - 29 d, [^{14}C-pyrazole]-label (n = 7) max. 5.1 % AR after 21 d and 29 d, i.e. at 2 sequential measurements

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡ 30 d aerobic / 56 d anaerobic

no significant degradation was observed under anaerobic conditions

Mineralisation after 100 days	7.3 % AR after 30+56 days, [^{14}C-benzene]-label (n = 1) 1.2 % AR after 30+56 days, [^{14}C-pyrazole]-label (n = 1)
Non-extractable residues after 100 days	3.8 % AR after 30+56 days, [^{14}C-benzene]-label (n = 1) 4.3 % AR after 30+56 days, [^{14}C-pyrazole]-label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	CL 810,728 max. during anaerobic phase: 6.9 % AR [^{14}C-pyrazole]-label (n = 1) (> 5 % AR at 2 sequential measurements) (metabolite has already been present in the 30-d aerobic phase)

Appendix 1 – list of endpoints

Soil photolysis ‡	
Mineralisation after 30 d	Not measured
non-extractable residues after 30 d	0.8 % - 3.4 % after 26 days
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	CL 810,729: 12.2 % at day 26, [^{14}C-pyrazole]-label

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type (site)	X[19]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Model, Kinetics; Method of calculation
Princeton, sandy loam		5.8	25 °C / 75 % of 1/3 bar (field capacity)	74.4 / 247*	76.5	0.952	SFO
Bearden, clay loam,		8.4	20 °C / 45 % MWHC	32.7 / 108.7	20.5	0,964	SFO
Otisville, loamy sand		7.2	10 °C / 45 % MWHC	173 / 575	-	0,991	SFO
Otisville, loamy sand		7.2	20 °C / 45 % MWHC	56 / 186.1	47.7	0,995	SFO
Painesville, loam		7.5	20 °C / 45 % MWHC	26.7 / 88.6	17.7	0,969	SFO
Geometric mean/median (DT_{50})					**33.9 / 34.1**		

* DT_{90} values estimated by the RMS

[19] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Appendix 1 – list of endpoints

CL 810,721	Aerobic conditions						
Soil type (site)	X	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20 °C pF2/10 kPa	St. (r^2)	Model, Kinetics; Method of calculation
Bearden, clay loam,		8.4	20 °C / 45 % MWHC	22.1 / 73.3	13.9	0.964	SFO
Otisville, loamy sand		7.2	20 °C / 45 % MWHC	54.3 / 180.5	45.3	0.991	SFO
Painesville, loam		7.5	20 °C / 45 % MWHC	6.8 / 22.5	4.5	0.969	SFO
Geometric mean/median (DT_{50})					**14.2 / 13.9**		

CL 810,729*	Aerobic conditions						
Soil type (site)	X	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Model, Kinetics; Method of calculation
LUFA 5M Mechtersheim, sandy loam		8.1	20 °C / 50 % MWHC	0.54 / 1.78	0.43	0.967	SFO
LUFA 2.2 Hanhofen, loamy sand		6.3	20 °C / 50 % MWHC	0.44 / 1.46	0.39	0.938	SFO
Bruch West Limburgerhof, sandy loam		8.0	20 °C / 50 % MWHC	1.11 / 3.7	0.87	0.904	SFO
Geometric mean/median (DT_{50})					**0.5 / 0.4**		

* calculated from a degradation study with CL 810,729 as active substance using 3-compartment-model (Modelmaker 4.0)

Appendix 1 – list of endpoints

CL 810,728*	Aerobic conditions						
Soil type (site)	X	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Model, Kinetics; Method of calculation
LUFA 5M Mechtersheim, sandy loam		8.1	20 °C / 50 % MWHC	8.22 / 27.3	6.47	0.967	SFO
LUFA 2.2 Hanhofen, loamy sand		6.3	20 °C / 50 % MWHC	2.99 / 9,92	2.68	0.938	SFO
Bruch West Limburgerhof, sandy loam		8.0	20 °C / 50 % MWHC	13.2 / 43.7	10.4	0.907	SFO
Geometric mean/median (DT_{50})					**5.6 / 6.5**		

* calculated from a degradation study with CL 810,729 as active substance using 3-compartment-model (Modelmaker 4.0)

Appendix 1 – list of endpoints

Field studies ‡

Parent	Aerobic conditions								
Soil type (all bare soils).	Location	X	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
sandy clay loam	Wilson, Derbyshire, UK		8.1	0-10	19.3	64.1	0.9741	not calculated	SFO
sandy clay loam	Ulcombe, Kent, UK		7.2	0-10	22.4	74.3	0.9147	not calculated	SFO
sandy loam	Cunnersdorf , Germany		4.8	0-05	12.8	42.3	0.9249	not calculated	SFO
loamy sand	Trossin Germany		5.6	0-05	5.9	19.5	0.8774	not calculated	SFO
sand	Utrera, Spain		7.0	0-10	0.05	3.0	0.98	not calculated	FOMC
sandy clay loam	Manzanilla, Spain		7.8	0-10	2.1	30.6	0.98	not calculated	FOMC
sandy clay loam	St. Paul les Romaines, France		6.4	0-10	10.9	(482)*	0.93	not calculated	FOMC
Geometric mean/median (DT50, n = 7)					**4.5 / 10.9**	-		-	

* Estimated since the value was extrapolated beyond the study duration. Fitting was done using a FOMC model and input data until day 180. Since there were no detectable residues on day 360 (< 0.005 mg as/kg), the DT_{90} is considered to be less than 360 days.

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	With regard to the rapid dissipation of tebufenpyrad in soil, no soil accumulation studies are triggered.

Appendix 1 – list of endpoints

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Arkansas, loamy sand	0.29	6.5	18	(6207)*	24.8	(8552)*#	(1.122)*
New Jersey, sandy loam	0.58	6.9	54	9310	36.8	6345#	0.892
Wisconsin,loam	1.39	7.1	92	6619	45.0	3237#	0.817
Indiana, silt	1.80	5.2	95	5278	62.7	3483#	0.895
Engelstadt, silty loam	2.27	7.4	49	2159#	43	1894	0.9638
Ingelheim, loam	1.33	7.6	41	3083#	37	2782	0.9605
Inveresk, sandy loam	4.7	5.8	561	11936#	388	8255	0.9296
Bedfordshire, loamy sand	0.73	6.1	35	4795#	26	3562	0.9102
Birmingham, sandy loam	3.19	6.1	145	4545#	130	4075	0.9725
Arithmetic mean/median					**88.1**	**4204/3522**	**0.92/0.93**
pH dependence, Yes or No			No				

* not used when calculating the mean value due to the low organic carbon content of 0.29 %
# not given by the applicant, calculated by RMS

Appendix 1 – list of endpoints

CL 810,721 ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sora, loam	1.7	6.5	n.calc.#	n.calc.#	0.817	48.1	0.9159
Birnbaum, sandy loam	1.4	5.4	n.calc.#	n.calc.#	1.947	139.1	0.9538
Stetten, loam	1.0	7.5	n.calc.#	n.calc #	0.169	16.9	0.9508
LUFA 2.2, loamy sand	2.26	5.3	n.calc.#	n.calc #	1.962	86.8	0.9432
LUFA 3A, loam	3.1	7.1	n.calc.#	n.calc #	0.465	15.0	0.9174
Arithmetic mean/median					**1.072**	**61.2**	**0.94**
pH dependence (yes or no)			Yes r^2 = - 0.995				
K_f Input in FOCUSPELMO			K_f values should be calculated for each scenario as a function of the regression straight line K_f = -0.84297 pH + 6.43329 of experimental adsorption values of five soils and entered directly in the modelling results see PEC_{GW}-calculation Vol.3				

#: not relevant

CL 810,729 ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sora, loam	1.7	6.5	n.calc.#	n.calc.#	0.208	12.2	1.4439
Birnbaum, sandy loam	1.4	5.4	n.calc.#	n.calc.#	0.365	26.1	1.0019
Stetten, loam	1.0	7.5	n.calc.#	n.calc #	0.536	53.6	0.7198
LUFA 2.2, loamy sand	2.26	5.3	n.calc.#	n.calc #	0,541	23.9	0.9200
LUFA 3A, loam	3.1	7.1	n.calc.#	n.calc #	0.991	32.0	0.7337
Arithmetic mean/median					**0.525**	**29.6**	**0.964**
pH dependence (yes or no)			No				

#: not relevant

Appendix 1 – list of endpoints

CL 810,728 ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Speyer 2.2, loamy sand	2.3	5.6	n.calc.#	n.calc.#	0.107	5	0.85
Mechtildshausen, loam	1.3	7.4	n.calc.#	n.calc.#	0.054	4	0.82
Mussig, clay loam	4.7	7.5	n.calc #	n.calc #	0.086	2	0.76
Arithmetic mean/median					**0.08**	**3.7**	**0.81**
pH dependence (yes or no)			No				

#: not relevant

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Elution (mm): 395 mm Time period (d): 2 d
	no quantifiable amounts in the leachate (LOQ = 2 µg as/L) metabolites were not studied total residues/radioactivity retained in the soil column: not analysed
Aged residues leaching ‡	Short half-lives and moderate to high adsorption coefficients were determined for tebufenpyrad and its major metabolites in laboratory studies. Model calculation of PEC_{gw} using PELMO and European standard scenarios show that there is a low risk for any of these compounds to be transported into the groundwater. Therefore, no aged residue column leaching study is deemed necessary.
Lysimeter/ field leaching studies ‡	no studies performed

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): not considered (single application) Kinetics: -

Appendix 1 – list of endpoints

Application data	Crop: apples and pears (BBCH 68 - 88) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 80 Number of applications: 1 Interval (d): - Application rate(s): g as/ha

PEC(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.02667		n.a.	
Plateau concentration	no plateau reached			

Metabolite CL 810,721 Method of calculation	Molecular weight relative to the parent: 1.08 DT_{50} (d): not considered (single application) Kinetics: -
Application data	Application rate assumed: 100 g as/ha, assumed Met CL 810,721 is formed at a maximum of 23 % of the applied dose or formation fraction (if sequential modelling is employed)

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0068		n.a.	
Plateau concentration	no plateau reached			

Appendix 1 – list of endpoints

Metabolite CL 810,729*		Molecular weight relative to the parent: 0.562		
Method of calculation		DT_{50} (d): not considered (single application) Kinetics:-		
Application data		Application rate assumed: 100 g as/ha, assumed Met CL 810,729 is formed at a maximum of 12 % of the applied dose or formation fraction (if sequential modelling is employed)		
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0018		n.a.	
Plateau concentration	no plateau reached			

Metabolite CL 810,728		Molecular weight relative to the parent: 0.565		
Method of calculation		DT_{50} (d): not considered (single application) Kinetics: -		
Application data		Application rate assumed: 100 g as/ha, assumed Met CL 810,728 is formed at a maximum of 5.1 % of the applied dose or formation fraction (if sequential modelling is employed)		
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0015		n.a.	
Plateau concentration	no plateau reached			

Appendix 1 – list of endpoints

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: stable (up to 120 °C)
	pH 7: stable (up to 120 °C)
	pH 9: stable (up to 120 °C)
Photolytic degradation of active substance and metabolites above 10 % ‡	study 1: DT_{50} : stable during the study natural light, 40°N; DT_{50} stable study 2: residue 90.3 % after 28 d natural light, 40°N; DT_{50}: 187 d
Quantum yield of direct phototransformation in water at λ > 290 nm	not determined, no photolytic degradation
Readily biodegradable ‡ (yes/no)	no

Degradation in water / sediment

Parent	max. in water: 33 % after 0 h, max. in sediment: 80.4 % after 0 h									
Water / sediment system	pH water phase	pH sed.	t. °C	DT_{50} - DT_{90} whole sys. (d)	St. (r^2)	DT_{50} - DT_{90} water (d)	St. (r^2)	DT_{50} - DT_{90} sed. (d)	St. (r^2)	Method of calculation
Mühlenteich benzene label	9.3	7.2	20	89* / -	0.477					SFO
Mühlenteich pyrazole label	9.3	7.2	20	59 / 197	0.87	4 / -**	0.90	60 /200	0.87	1st order
Wennebrook benzene label	7.4	7.7	20	98* / -	0.887					SFO
Wennebrook pyrazole label	7.4	7.7	20	125 / -	0.90	58 / 193	0.90	151 / -	0.81	1st order
Geometric mean DT_{50}				**90** [a]						

* recalculated DT_{50} by Gurney (2004)

Appendix 1 – list of endpoints

** root 2nd order
[a] Mühlenteich benzene label was not considered

CL 810,721*	max in water: 16.5 % AR after 100 d (pyrazole label), max in sediment: 7 % after 110 d (benzene label) > 5 % AR in sediment at two sequential measurements

* Calculation of the degradation kinetics for the main metabolite CL 810,721 was not performed due to the limited set of data available.

Mineralisation and non extractable residues				
Water / sediment system	pH water phase	pH sed.	Mineralisation x % after n d (end of the study)	Non-extractable residues in sed. max x % after n d
Mühlenteich study 1 [C-14-benzene]-label	9.3	7.2	1 % volatiles after 110 d	29 % after 110 d
Wennebrook study 1 [C-14-benzene]-label	7.4	7.7	2 % volatiles after 110 d	19 % after 110 d
Mühlenteich study 2 [C-14-pyrazole]-label	9.3	7.2	0.3 % CO_2 after 100 d 0.5 % org. volatiles after 100 d	32.5 % after 100 d
Wennebrook study 2 [C-14-pyrazole]-label	7.4	7.7	0.2 % CO_2 after 100 d 1.0 % org. volatiles after 100 d	13.5 % after 100 d

Appendix 1 – list of endpoints

PEC surface water and PEC sediment (Annex IIIA, point 9.2.3)

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Version control no. of FOCUS calculator: 1.1. Molecular weight (g/mol): 333.8 Water solubility (mg/L): 2.39 K_{fOC} (L/kg): 4677[*1] (Median) DT_{50} soil (d): 33.9 days (Lab, in accordance with FOCUS SFO) DT_{50} water (d): 300 d (conservative default) DT_{50} sediment (d): 90 d (total system half life)[*2] Crop interception (%): 80 % Main entry route (Step 2) 15.725 % drift (3 m), 2 % - 3 % runoff/drainage
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Version control no.'s of FOCUS software: 1.1.1 Vapour pressure: : 1.6×10^{-6} Pa (20 °C) K_{fOC} (L/kg): 4677[*1] (Median) 1/n: 0.92
Application rate	Crop: apples and pears Crop interception: calculated by PRZM/MACRO Number of applications: 1 Interval (d): - Application rate(s): 100 g as/ha Application window: June to September
Main routes of entry	Main entry route (Step 1) 15.725 % drift (3 m), 10 % runoff/drainage Main entry route (Step 2) 15.725 % drift (3 m), 2 % - 3 % runoff/drainage

*1: ar. mean = 4204 L/kg, but median is acceptable
*2: geom. mean = 83.5 d, but applicant's selection acceptable

Appendix 1 – list of endpoints

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	9.85		215	
	24 h	5.29	7.57	247	231
	2 d	5.25	6.42	246	239
	4 d	5.17	5.81	242	241
	7 d	5.05	5.51	236	240
	14 d	4.79	5.22	224	235
	21 d	4.53	5.03	212	229
	28 d	4.3	4.88	201	224
	42 d	3.86	4.61	180	213

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.24		44.6	
	24 h	2.23	3.73	44.3	44.5
	2 d	1.36	2.76	44	44.3
	4 d	1.28	1.99	43.4	44
	7 d	0.95	1.57	42.5	43.5
	14 d	0.9	1.25	40.5	42.5
	21 d	0.86	1.12	38.6	41.5
	28 d	0.82	1.05	36.7	40.5
	42 d	0.74	0.96	33.3	38.7

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	5.24		50.5	
	24 h	2.23	3.73	50.2	50.3
	2 d	1.36	2.76	49.8	50.2
	4 d	1.41	2	49.1	49.8
	7 d	1.07	1.63	48.1	49.3
	14 d	1.02	1.34	45.8	48.1
	21 d	0.97	1.22	43.7	47
	28 d	0.93	1.16	41.6	45.9
	42 d	0.84	1.06	37.7	43.8

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	3.653		3.436	
		24 h	2.5	3.099	3.312	3.419
		2 d	0.863	2.379	3.107	3.374
		4 d	0.062	1.339	2.729	3.237
		7 d	0.023	0.78	2.296	3.009
		14 d	0.011	0.398	1.661	2.559
		21d	0.007	0.268	1.306	2.231
		28 d	0.005	0.203	1.082	1.987
		42 d	0.003	0.136	0.809	1.651
D5	pond	0 h	0.164		1.337	
		24 h	0.158	0.161	1.337	1.337
		2 d	0.153	0.158	1.336	1.337
		4 d	0.144	0.153	1.336	1.337
		7 d	0.134	0.147	1.333	1.336
		14 d	0.117	0.136	1.324	1.335
		21 d	0.105	0.128	1.311	1.334
		28 d	0.096	0.121	1.297	1.332
		42 d	0.082	0.11	1.26	1.326

Appendix 1 – list of endpoints

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1	pond	0 h	0.163		1.247	
		24 h	0.157	0.16	1.247	1.247
		2 d	0.152	0.157	1.246	1.247
		4 d	0.142	0.152	1.245	1.247
		7 d	0.13	0.145	1.241	1.246
		14 d	0.111	0.132	1.227	1.245
		21 d	0.099	0.123	1.209	1.242
		28 d	0.088	0.116	1.187	1.238
		42 d	0.075	0.104	1.135	1.228
R3	stream	0 h	3.956		1.089	
		24 h	0.016	1.476	1.051	1.081
		2 d	0.002	0.74	1.007	1.061
		4 d	0.002	0.371	0.93	1.022
		7 d	0.101	0.217	0.837	0.97
		14 d	0.001	0.115	0.688	0.928
		21 d	< 0.001	0.077	0.59	0.873
		28 d	< 0.001	0.057	0.51	0.815
		42 d	< 0.001	0.038	0.397	0.716

FOCUS STEP 4 20 m buffer Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 20 m buffer	ditch	0 h	0.34		0.327	
		24 h	0.232	0.288	0.316	0.325
		2 d	0.08	0.221	0.299	0.322
		4 d	0.005	0.124	0.268	0.31
		7 d	0.002	0.072	0.23	0.291
		14 d	0.001	0.037	0.17	0.252
		21d	0.001	0.025	0.135	0.222
		28 d	< 0.001	0.019	0.112	0.199
		42 d	< 0.001	0.013	0.084	0.166

Appendix 1 – list of endpoints

FOCUS STEP 4 20 m buffer Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5	pond	0 h	0.047		0.397	
		24 h	0.046	0.046	0.397	0.397
		2 d	0.044	0.046	0.397	0.397
		4 d	0.042	0.044	0.397	0.397
		7 d	0.038	0.042	0.396	0.397
		14 d	0.033	0.039	0.393	0.397
		21 d	0.03	0.037	0.389	0.396
		28 d	0.027	0.035	0.385	0.396
		42 d	0.023	0.031	0.374	0.394
R1	pond	0 h	0.047		0.406	
		24 h	0.045	0.046	0.406	0.406
		2 d	0.044	0.045	0.406	0.406
		4 d	0.041	0.044	0.405	0.406
		7 d	0.037	0.042	0.404	0.406
		14 d	0.032	0.038	0.4	0.405
		21 d	0.029	0.036	0.394	0.404
		28 d	0.026	0.033	0.386	0.403
		42 d	0.025	0.03	0.37	0.4
R3	stream	0 h	0.425		0.497	
		24 h	0.002	0.159	0.485	0.494
		2 d	< 0.001	0.08	0.472	0.489
		4 d	< 0.001	0.04	0.449	0.478
		7 d	0.101	0.027	0.42	0.461
		14 d	< 0.001	0.019	0.369	0.43
		21 d	< 0.001	0.013	0.332	0.404
		28 d	< 0.001	0.01	0.297	0.383
		42 d	< 0.001	0.007	0.243	0.346

Appendix 1 – list of endpoints

All global maximum concentration in surface water and sediment for tebufenpyrad at step 4

Scenario	Water body	PECsw/ µg/L					PECsed /µg/ kg				
		Step 3	5m	10m	15m	20m	Step 3	5m	10m	15m	20m
D3	Ditch	3.653	2.465	1.101	0.556	0.340	3.436	2.328	1.048	0.532	0.327
D4	Pond	0.164	0.187	0.104	0.066	0.047	1.308	n.c.	0.839	0.542	0.389
	Stream	3.538	2.761	0.380	0.622	0.380	0.328	0.256	0.035	0.058	0.035
D5	Pond	0.164	0.187	0.104	0.066	0.047	1.337	n.c	0.857	0.553	0.397
	Stream	3.958	3.089	1.380	0.696	0.426	1.107	0.865	0.387	0.196	0.120
R1	Pond	0.163	0.187	0.104	0.066	0.047	1.247	n.c.	0.817	0.545	0.406
	Stream	2.806	2.190	0.978	0.494	0.302	0.511	0.489	0.445	0.428	0.420
R2	Stream	3.762	2.936	1.311	0.662	0.404	0.309	0.241	0.109	0.101	0.101
R3	Stream	3.956	3.087	1.379	0.580	0.425	1.089	0.946	0.660	0.524	0.497
R4	Stream	2.806	2.189	0.978	0.411	0.302	0.444	0.347	0.256	0.236	0.232

Metabolite CL 810,721

Parameters used in $FOCUS_{sw}$ step 1 and 2

Molecular weight: 363.8 g/mol
Water solubility (mg/L): 1000
Soil or water metabolite: soil and water
K_{oc} (L/kg): (if necessary, soil metabolites): 61.2[*1]
DT_{50} soil (d): 14.2 days (Lab)
DT_{50} water (d): 300 d (worst case default)
DT_{50} sediment (d): 300 d (worst case default)
Crop interception (%): 80
Maximum occurrence observed (% molar basis with respect to the parent):
Water/sediment: 19
Soil: 23

Appendix 1 – list of endpoints

Application rate	Crop: apples and pears Number of applications: 1 Interval (d): - Application rate(s): 100 g as/ha Depth of water body: 30 cm Application window: June to September
Main routes of entry	Main entry route (Step 1) 10 % runoff/drainage Main entry route (Step 2) 15.725 % drift (3 m), 2 % - 3 % runoff/drainage related to metabolite's formation

*1: consideration of K_f instead of K_{OC} would have been the better choice (sorption is pH-dependent), but application's selection is nevertheless accepted

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CL 810,721	0 h	8.81		4.73	
	24 h	8.71	8.76	5.33	5.03
	2 d	8.69	8.73	5.31	5.18
	4 d	8.65	8.7	5.29	5.24
	7 d	8.59	8.66	5.26	5.26
	14 d	8.45	8.59	5.17	5.23
	21 d	8.32	8.52	5.09	5.2
	28 d	8.18	8.45	5.01	5.16
	42 d	7.92	8.32	4.85	5.08

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Metabolite CL 810,721	0 h	1.4		0.84	
	24 h	1.37	1.39	0.84	0.84
	2 d	1.37	1.38	0.84	0.84
	4 d	1.36	1.37	0.83	0.84
	7 d	1.35	1.37	0.83	0.83
	14 d	1.33	1.35	0.81	0.83
	21 d	1.31	1.34	0.8	0.82
	28 d	1.29	1.33	0.79	0.81
	42 d	1.25	1.31	0.76	0.8
Southern EU	0 h	1.59		0.96	
	24 h	1.56	1.58	0.95	0.96
	2 d	1.56	1.57	0.95	0.95
	4 d	1.55	1.56	0.95	0.95
	7 d	1.54	1.56	0.94	0.95
	14 d	1.52	1.54	0.93	0.94
	21 d	1.49	1.53	0.91	0.93
	28 d	1.47	1.52	0.9	0.93
	42 d	1.42	1.49	0.87	0.91

Metabolite CL 810,729
Parameters used in $FOCUS_{sw}$ step 1 and 2

Molecular weight: 187.6 g/mol
Water solubility (mg/L): 1000
Soil or water metabolite: soil
K_{oc} (L/kg): (if necessary, soil metabolites): 33.9
DT_{50} soil (d): 0.5 days (Lab)
DT_{50} water (d): 300 d (worst case default)
DT_{50} sediment (d): 300 d (worst case default)
Crop interception (%): 80
Maximum occurrence observed (% molar basis with respect to the parent):
Water/sediment: -
Soil: 12

Appendix 1 – list of endpoints

Application rate	Crop: apples and pears Number of applications: 1 Interval (d): - Application rate(s): 100 g as/ha Depth of water body: 30 cm Application window: June to September
Main routes of entry	Main entry route (Step 1) 10 % runoff/drainage Main entry route (Step 2) 2 % - 3 % runoff/drainage related to metabolite's formation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CL 810,729	0 h	2.15		0.73	
	24 h	2.15	2.15	0.73	0.73
	2 d	2.14	2.15	0.73	0.73
	4 d	2.13	2.14	0.72	0.73
	7 d	2.12	2.13	0.72	0.72
	14 d	2.08	2.12	0.71	0.72
	21 d	2.05	2.1	0.69	0.71
	28 d	2.02	2.08	0.68	0.71
	42 d	1.95	2.05	0.66	0.69

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Metabolite CL 810,729	0 h	<0.01		<0.01	
	24 h	<0.01	<0.01	<0.01	<0.01
	2 d	<0.01	<0.01	<0.01	<0.01
	4 d	<0.01	<0.01	<0.01	<0.01
	7 d	<0.01	<0.01	<0.01	<0.01
	14 d	<0.01	<0.01	<0.01	<0.01
	21 d	<0.01	<0.01	<0.01	<0.01
	28 d	<0.01	<0.01	<0.01	<0.01
	42 d	<0.01	<0.01	<0.01	<0.01
Southern EU	0 h	<0.01		<0.01	
	24 h	<0.01	<0.01	<0.01	<0.01
	2 d	<0.01	<0.01	<0.01	<0.01
	4 d	<0.01	<0.01	<0.01	<0.01
	7 d	<0.01	<0.01	<0.01	<0.01
	14 d	<0.01	<0.01	<0.01	<0.01
	21 d	<0.01	<0.01	<0.01	<0.01
	28 d	<0.01	<0.01	<0.01	<0.01
	42 d	<0.01	<0.01	<0.01	<0.01

Metabolite CL 810,728

Parameters used in $FOCUS_{sw}$ step 1 and 2

Molecular weight: 188.6 g/mol
Water solubility (mg/L): 1000
Soil or water metabolite: soil
K_{oc} (L/kg): (if necessary, soil metabolites): 4
DT_{50} soil (d): 5.6 days (Lab)
DT_{50} water (d): 300 d (worst case default)
DT_{50} sediment (d): 300 d (worst case default)
Crop interception (%): 80
Maximum occurrence observed (% molar basis with respect to the parent):
Water/sediment: -
Soil: 10

Appendix 1 – list of endpoints

Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Vapour pressure: - K_{om}/K_{oc}: 4 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively): 0.81 Metabolite kinetically generated in simulation (yes/no): yes Formation fraction in soil (k_{dp}/k_f): (if formation degradation of metabolite is kinetically simulated by PRZM): 10
Application rate	Crop: apples and pears Number of applications: 1 Interval (d): - Application rate(s): 100 g as/ha Depth of water body: 30 cm Application window: June to September
Main routes of entry	Main entry route (Step 1) 10 % runoff/drainage Main entry route (Step 2) 2 % - 3 % runoff/drainage related to metabolite's formation

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Metabolite CL 810,728	0 h	1.87		0.07	
	24 h	1.87	1.87	0.07	0.07
	2 d	1.86	1.87	0.07	0.07
	4 d	1.86	1.86	0.07	0.07
	7 d	1.84	1.86	0.07	0.07
	14 d	1.81	1.84	0.07	0.07
	21 d	1.78	1.83	0.07	0.07
	28 d	1.76	1.81	0.07	0.07
	42 d	1.7	1.79	0.07	0.07

Appendix 1 – list of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Metabolite CL 810,728	0 h	0.07		<0.01	
	24 h	0.07	0.07	<0.01	<0.01
	2 d	0.07	0.07	<0.01	<0.01
	4 d	0.07	0.07	<0.01	<0.01
	7 d	0.07	0.07	<0.01	<0.01
	14 d	0.07	0.07	<0.01	<0.01
	21 d	0.07	0.07	<0.01	<0.01
	28 d	0.06	0.07	<0.01	<0.01
	42 d	0.06	0.07	<0.01	<0.01
Southern EU	0 h	0.1		<0.01	
	24 h	0.1	0.1	<0.01	<0.01
	2 d	0.1	0.1	<0.01	<0.01
	4 d	0.1	0.1	<0.01	<0.01
	7 d	0.1	0.1	<0.01	<0.01
	14 d	0.1	0.1	<0.01	<0.01
	21 d	0.1	0.1	<0.01	<0.01
	28 d	0.1	0.1	<0.01	<0.01
	42 d	0.09	0.1	<0.01	<0.01

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4	stream	0 h	0.006		0.002	
		24 h	0.004	0.005	0.002	0.002
		2 d	0.004	0.005	0.002	0.002
		4 d	0.004	0.005	0.002	0.002
		7 d	0.002	0.004	0.002	0.002
		14 d	0.002	0.003	0.002	0.002
		21d	0.001	0.003	0.001	0.002
		28 d	<0.001	0.002	0.001	0.002
		42 d	<0.001	0.002	0.002	0.002

Appendix 1 – list of endpoints

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4	pond	0 h	0.004		0.006	
		24 h	0.004	0.004	0.006	0.006
		2 d	0.004	0.004	0.006	0.006
		4 d	0.004	0.004	0.006	0.006
		7 d	0.004	0.004	0.006	0.006
		14 d	0.004	0.004	0.006	0.006
		21 d	0.004	0.004	0.006	0.006
		28 d	0.004	0.004	0.006	0.006
		42 d	0.004	0.004	0.005	0.006
R1	pond	0 h	0.001		0.001	
		24 h	0.001	0.001	0.001	0.001
		2 d	0.001	0.001	0.001	0.001
		4 d	0.001	0.001	0.001	0.001
		7 d	<0.001	0.001	0.001	0.001
		14 d	<0.001	<0.001	0.001	0.001
		21 d	<0.001	<0.001	0.001	0.001
		28 d	<0.001	<0.001	0.001	0.001
		42 d	<0.001	<0.001	0.001	0.001
R4	stream	0 h	0.024		0.004	
		24 h	<0.001	0.018	0.003	0.004
		2 d	<0.001	0.009	0.002	0.003
		4 d	<0.001	0.005	0.002	0.003
		7 d	<0.001	0.005	0.004	0.002
		14 d	<0.001	0.004	0.002	0.002
		21 d	<0.001	0.003	0.002	0.002
		28 d	0.014	0.002	0.003	0.002
		42 d	<0.001	0.002	0.001	0.002

Appendix 1 – list of endpoints

PEC ground water (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Model(s) used: (with version control no.(s)) FOCUS PELMO 3.3.2 Scenarios (list of names): C - Châteaudun H - Hamburg J - Jokioinen K - Kremsmünster N - Okehampton P - Piacenza O - Porto S - Sevilla T - Thiva Crop: apples (crop interception: 80 %) Geometric mean parent DT_{50lab}: 33.9 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2) K_{OC}: parent, arithmetic mean 4204 L/kg[*1], $^1/_n$ = 0.92. Geometric mean CL 810,721 DT_{50lab}: 14.2 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2) K_f: CL 810,721 calculated pH- and horizon-dependent for each scenario with regression straight line K_f = -0.84297 pH + 6.43329 [*2] $^1/_n$ = 0.936 arithmetic mean Geometric mean CL 810,729 DT_{50lab}: 0.5 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2) K_{OC}: CL 810,729, arithmetic mean 29.6 L/kg[*3], $^1/_n$ = 0.964[*3] Geometric mean CL 810,728 DT_{50lab}: 5.6 d (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2) K_{OC}: CL 810,728, conservative value 3 L/kg[*4], $^1/_n$ = 0.81.
Application rate	Application rate: 100 g/ha. No. of applications: 1 Time of application (month or season): 30 Sept

*1: applicant's selection (4677 L/kg) not reasonable
*2: applicant's selection (K_{foc} = 61.2 L/kg) was not acceptable, as sorption depends on pH

Appendix 1 – list of endpoints

*3: applicant's selection (K_{foc} = 33.9 L/kg and 1/n 0.936) is not reasonable, calculation was performed with K_{foc} = 29.6 L/kg and 1/n=0.964
*4: applicant's selection not acceptable. The conservative value of K_{foc} in alkaline soils was used instead.

PEC_{gw} - FOCUS modelling results (80th percentile annual average concentration at 1 m)

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			CL 810,721	CL 810,729	CL 810,728
FOCUS PELMO 3.3.2 / apples	Châteaudun	<0.001	0.056	<0.001	<0.001
	Hamburg	<0.001	< 0.001	<0.001	0.004
	Jokioinen	<0.001	< 0.001	<0.001	0.002
	Kremsmünster	<0.001	< 0.001	<0.001	0.001
	Okehampton	<0.001	< 0.001	<0.001	0.003
	Piacenza	<0.001	< 0.001	<0.001	0.006
	Porto	<0.001	< 0.001	<0.001	<0.001
	Sevilla	<0.001	< 0.001	<0.001	0.001
	Thiva	<0.001	< 0.001	<0.001	0.002

The groundwater simulation was performed by the RMS considering modified sorption constants.

$PEC_{(gw)}$ From lysimeter / field studies

Compound	1st year	2nd year	3rd year
Annual average (µg/L)	no studies performed	no studies performed	no studies performed

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not relevant, tebufenpyrad is stable
Quantum yield of direct phototransformation	not studied
Photochemical oxidative degradation in air ‡	DT_{50} of 7.3 hours derived by the Atkinson model (version v1.91). OH (24 h) concentration assumed = 5 x 10^5 cm^{-3}
Volatilisation ‡	from plant surfaces (BBA guideline): not studied
	from soil surfaces (BBA guideline): negligible (1 %) after 24 hours
Metabolites	None

Appendix 1 – list of endpoints

PEC_{air}

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil

$PEC_{(air)}$

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology)	Soil: tebufenpyrad; CL 810,721; (CL 810,729 soil photolysis study) Surface Water: tebufenpyrad; CL 810,721; (CL 810,729 via run-off/drainage, soil photolysis study) Sediment: tebufenpyrad Ground water: tebufenpyrad; CL 810,728; CL 810,721; (CL 810,729 soil photolysis study) Air: tebufenpyrad

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	not available

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

candidate for R 53 (tebufenpyrad should be classified as ”not readily biodegradable”)

Appendix 1 – list of endpoints

Chapter 6 (effects on non-target species)

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds ‡				
Anas platyrhynchus Colinus virginianus	Tebufenpyrad	Acute	LD_{50} > 2000	Not relevant
	Preparation	Acute	No data submitted – justification accepted	
	Metabolites	Acute		
Colinus virginianus	Tebufenpyrad	Short-term	LD_{50} > 439	LC_{50} > 5000
Anas platyrhynchus	Tebufenpyrad	Short-term	LD_{50} > 75	LC_{50} > 5000
Anas platyrhynchus	Tebufenpyrad	Long-term	NOEL 6.6	
Mammals ‡				
Rat	Tebufenpyrad	Acute	LD_{50} approx. 320(Fisher 344 rats, sexes combined)	Not relevant
Rat	Preparation MASAI 20WP (BAS 318 00 I)	Acute	LD_{50} 1458 product LD_{50} 291.6 as	Not relevant
Rat	Metabolites	Acute		Not relevant
Rat	Tebufenpyrad	Long-term, 2-generation repro study reduced offspring bw: reproduction:	NOEL 8.4 NOAEL 15.3	NOEC 100 NOAEC 200
Rat	Metabolites	Long-term	Not relevant	

Appendix 1 – list of endpoints

Additional higher tier studies ‡ No data submitted – justification accepted. Not relevant.

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Pome fruits, 0.1 kg as/ha

Indicator species/Category[2]	Time scale	ETE (mg/kg bw/d)	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Anas platyrhynchus *Colinus virginianus*	Acute	5.4	> 370	10
Anas platyrhynchus	Short-term	3.0	> 25	10
Anas platyrhynchus	Long-term	3.0	2.2	5
Earthworm-eating bird	Long-term	0.4	18	5
Fish-eating bird	Long-term	0.5	12.3	5
Higher tier refinement (Birds)				
Not required	Acute			10
Not required	Short-term			10
Small insectivore RUD = 21.9 for mixed diet of 70/30 (by weight) small/large arthropods	Long-term	2.3	2.9	5
Tier 1 (Mammals)				
Rat	Acute	11.8	25	10
Rat	Long-term	3.4	2.5	5
Earthworm-eating mammal	Long-term	0.5	18	5
Fish-eating mammal	Long-term	0.3	25	5
Higher tier refinement (Mammals)				
Not required	Acute			10
Small herbivore RUD = 22.8 for 70 % interception. Product is sprayed after flowering	Long-term	1.7	5.0	5

Appendix 1 – list of endpoints

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (µg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Tebufenpyrad	96 hr (static)	Mortality, LC_{50}	30 $_{mm}$
Oncorhynchus mykiss	Tebufenpyrad	96 hr (static)	Mortality, LC_{50}	23.2 $_{mm}$ (geom. mean of 3 values, including preparation tests)
Oncorhynchus mykiss	Tebufenpyrad	Chronic 94 d (flow-through) ELS	NOEC	2.45 $_{mm}$
Oncorhynchus mykiss	Preparation	96 hr (flow through)	Mortality, LC_{50}	19 as $_{mm}$ 97 product 21.8 $_{mm}$ 109 product
SSD	Tebufenpyrad and preparation	96 hr	HC5 over LC_{50} LL-HC5 *O. mykiss* *D. rerio* *L. macrochirus* *P. promelas* *O. latipes*	20.9 6.1 (23.2 46 54 78 82)
Oncorhynchus mykiss	Metabolite M10 (CL 810,721)	96 hr (static)	Mortality, EC_{50}	> 100 000_{nom}

Appendix 1 – list of endpoints

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (µg/L)
Aquatic invertebrate				
Daphnia magna	Tebufenpyrad	48 hr (static)	Mortality, EC_{50}	46.0 $_{nom}$
Mysidopsis bahia [2)]	Tebufenpyrad	48 hr 96 hr (flow-through) [2)]	Mortality, EC_{50}	42.5 $_{nom}$ 22.0 $_{nom}$
Daphnia magna	Tebufenpyrad	21 d (flow-through)	Reproduction, NOEC	2.4 $_{mm}$
Daphnia magna	Tebufenpyrad	28 d (static, with sediment)	Abundance, NOEC	4.0 $_{mm}$
Daphnia magna	Preparation MASAI 20WP (BAS 318 00 I)	48 hr (static)	Mortality, EC_{50}	58 as $_{mm}$ 285 product
Daphnia magna	Preparation Tebufenpyrad 20 % WP (BAS 318 06 I)	48 hr (static)	Mortality, EC_{50}	55.4 as $_{nom}$ 277 product
Daphnia magna	Metabolite M10 (CL 810,271)	48 hr (static)	Mortality, EC_{50}	> 100 000 $_{mm}$
Sediment dwelling organisms				
Chironomus riparius	Tebufenpyrad	28 d (static)	NOEC	190 $_{nom\ initial}$ 110 $_{mm}$ 640 µg/kg sed $_{mm}$
Algae				
Pseudokirchneriella subcapitata (= Selenastrum capricornutum)	Preparation MASAI 20WP (BAS 318 00 I)	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	52 as $_{mm}$ 256 product > 68 as $_{mm}$ > 340 product
Pseudokirchneriella subcapitata (= Selenastrum capricornutum)	Metabolite M10 (CL 810,721)	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>100000 $_{nom}$ >100000 $_{nom}$
Scenedesmus subspicatus	Preparation Tebufenpyrad 20 % WP (BAS 318 06 I)	72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	480 as $_{mm}$ 2400 product 1320 as $_{nom}$ 6600 product

Appendix 1 – list of endpoints

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (µg/L)
Higher plant				
Lemna gibba	Not performed, not relevant			
Microcosm or mesocosm tests				
Not performed, not relevant				

[1] Indicate whether based on nominal ($_{nom}$ = analytically confirmed) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column "Test substance".
[2] Additional data, studies were submitted within the framework of national authorisation, not included in dossier.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Pome fruits, 0.1 kg as/ha

Test substance	Organism	Toxicity endpoint (mg as/L)	Time scale	PEC_{sw}i µg/L	PEC_{tw} a	TER	Annex VI Trigger[1]
Product BAS 318 00 I	Fish	0.019	Acute	9.85 (as)	-	1.9	100
as	Fish	0.00245	Long-term	9.85		0.25	10
as	Fish	0.023	Acute	9.85	-	2.3	100
as	Aquatic invertebrates	0.046	Acute	9.85		4.7	100
as	Aquatic invertebrates	0.022[1]	Acute	9.85		2.2	100
as	Aquatic invertebrates	0.0024	Long-term	9.85	-	0.24	10
Product BAS 318 00 I	Algae	0.052	Long-term	9.85 (as)	-	5.3	10
as	Sediment dwellers	0.11 mg/L 0.64 mg/kg sed.	Long-term	9.85 PEC_{sed} i: 215 µg/kg	-	19 3	10

Appendix 1 – list of endpoints

Test substance	Organism	Toxicity endpoint (mg as/L)	Time scale	PEC_{sw}i µg/L	PEC_{tw} a	TER	Annex VI Trigger[1]
Metabolite CL 810,721	Fish	> 100	Acute	8.81	-	1135 1	100
Metabolite CL 810,728	Fish, calculated: 1/10 of as	0.0023	Acute	1.87	-	1.2	100
Metabolite CL 810,728	Aquatic invertebrates, calculated: 1/10 of as	0.0046	Acute	1.87	-	2.5	100
Metabolite CL 810,729	Fish, calculated: 1/10 of as	0.0023	Acute	2.15	-	1.1	100
Metabolite CL 810,729	Aquatic invertebrates, calculated: 1/10 of as	0.0046	Acute	2.15	-	2.1	100

0 saltwater organism *Mysidopsis bahia*

FOCUS Step 2

Pome fruits, 0.1 kg as/ha

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg as/L)	Time scale	PEC_{max}[3] µg as/L	TER	Annex VI Trigger
Product BAS 318 00 I	N, S	Fish	0.019	Acute	5.24	3.6	100
as	N, S	Fish	0.00245	Long-term	5.24	0.5	10
as	N, S	Aquatic invertebrates	0.046	Acute	5.24	8.8	100
as	N, S	Aquatic invertebrates	0.0024	Long-term	5.24	0.5	10
Product BAS 318 00 I	N, S	Algae	0.052	Long-term	5.24	9.9	10
as	N, S	Sediment dwellers	0.64 mg/kg sediment	Long-term	PEC_{sed} i: 50.5 µg/kg sed	13	10

Appendix 1 – list of endpoints

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg as/L)	Time scale	PEC $_{max}$[3] µg as/L	TER	Annex VI Trigger
Metabolite CL 810,728	N, S	Fish, calculated: 1/10 of as	0.0023	Acute	0.1	23	100
Metabolite CL 810,728	N, S	Aquatic invertebrates, calculated: 1/10 of as	0.0046	Acute	0.1	46	100
Metabolite CL 810,729	N, S	Fish, calculated: 1/10 of as	0.0023	Acute	< 0.01	>230	100
Metabolite CL 810,729	N, S	Aquatic invertebrates, calculated: 1/10 of as	0.0046	Acute	< 0.01	>460	100

1 Indicate whether Northern or Southern.
2 Include critical groups which fail at Step 1.
3 Indicate whether maximum or twa values have been used.

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

Pome fruits, 0.1 kg as/ha

Test substance	Scenario [1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg as/L)	PEC$_{sw\ i}$ [4] µg as/L Max.	TER	Annex VI trigger [5]
Product BAS 318 00 I	7 scenarios (D3, D4, D5, R1, R2, R3, R4)	ditch, stream, pond	Fish	Acute	0.019	0.164-3.958	4.8 – 116 no scenario with safe use	100
as			Fish	Long-term	0.00245	0.164-3.958	0.60 – 15 (no scenario with safe use)	10
as			Aquatic invertebrates	Acute	0.046	0.164-3.958	12 - 282 safe use in 3 out of 10 subscenarios	100

Appendix 1 – list of endpoints

Test substance	Scenario [1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg as/L)	$PEC_{sw\ i}$ [4] µg as/L Max.	TER	Annex VI trigger [5]
as			Aquatic invertebrates	Long-term	0.0024	0.164-3.958	0.6 - 15 no scenario with safe use	10
Product BAS 318 00			Algae	Long-term	0.052	0.164-3.958	13 - 319	10
Metabolite CL 810,728	R4 (max. PEC)	Stream	Fish, calculated: 1/10 of as	Acute	0.0023	0.024	96	100
Metabolite CL 810,728	R2 (2^{nd}-highest PEC)	Stream	Fish, calculated: 1/10 of as	Acute	0.0023	0.018	128	100
Metabolite CL 810,728	R4 (max. PEC)	Stream	Aquatic invertebrates, calculated: 1/10 of as	Acute	0.0046	0.024	192	100

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] Include critical groups which fail at Step 2.
[4] Indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used.
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Appendix 1 – list of endpoints

FOCUS Step 4 – calculation with buffer zones for spray drift reduction

Pome fruits, 0.1 kg as/ha

Scenario [1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg as/L)	Buffer zone distance	PEC_{SW}[4] (µg as/L)	TER	Annex VI trigger[5]
						$PEC_{max\ i}$		
D3	Ditch					1.101	19	
D4	Pond					0.104	201	
D4	Stream	Fish, SSD with 5 species				0.380	55	
D5	Pond	*O. mykiss*		LC_{50} 0.0209		0.104	201	
D5	Stream	*L. macrochirus*	Acute	HC5	10 m	1.380	15	35
R1	Pond	*P. promelas*				0.104	201	
R1	Stream	*O. latipes*				0.978	21	
R2	Stream	*D. rerio*				1.311	16	
R3	Stream					1.379	15	
R4	Stream					0.978	21	
						$PEC_{max\ i}$		
D3	Ditch					1.101	6	
D4	Pond					0.104	59	
D4	Stream	Fish, SSD with 5 species				0.380	16	
D5	Pond	*O. mykiss*		LC_{50} 0.0061		0.104	59	
D5	Stream	*L. macrochirus*	Acute	LL-HC5	10 m	1.380	4	10
R1	Pond	*P. promelas*				0.104	44	
R1	Stream	*O. latipes*				0.978	6	
R2	Stream	*D. rerio*				1.311	5	
R3	Stream					1.379	4	
R4	Stream					0.978	6	
D5	Stream	Fish, SSD with 5 species	Acute	LC_{50} 0.0209 HC5	20 m	$PEC_{max\ i}$ 0.43	49	35
D5	Stream	Fish, SSD with 5 species	Acute	LC_{50} 0.0061 LL-HC5	20 m	$PEC_{max\ i}$ 0.43	14	10
D3	Ditch	Fish, 94-d ELS	Long-term	NOEC-growth 0.00245	20 m	$PEC_{twa\ 2\ d}$ 0.221	11	10

Appendix 1 – list of endpoints

Scenario [1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg as/L)	Buffer zone distance	PEC_{SW}[4] (µg as/L)	TER	Annex VI trigger[5]
D3	Ditch	Fish, 94-d ELS	Long-term	NOEC-hatch 0.00489	20 m	$PEC_{max\ i}$ 0.43	12	10
D5	Stream	Aquatic invertebrates	Acute	EC_{50} 0.046	20 m	$PEC_{max\ i}$ 0.43	108	100
D3 D4 D4 D5 D5 R1 R1 R2 R3 R4	Ditch Pond Stream Pond Stream Pond Stream Stream Stream Stream	Aquatic invertebrates	Long-term	NOEC 0.0024 (flow-through exposure)	20 m	$PEC_{max\ i}$ 0.340 0.047 0.380 0.047 0.426 0.047 0.302 0.404 0.425 0.302	7.1 51 6.3 51 5.6 51 7.9 5.9 5.7 7.9	10
D3 D4 D4 D5 D5 R1 R1 R2 R3 R4	Ditch Pond Stream Pond Stream Pond Stream Stream Stream Stream	Aquatic invertebrates	Long-term	NOEC 0.004 (peak exposure, with sediment)	20 m	PECmax i 0.340 0.047 0.380 0.047 0.426 0.047 0.302 0.404 0.425 0.302	11.7 85.1 10.5 85.1 9.4 85.1 13.2 9.9 9.4 13.2	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] Include critical groups which fail at Step 3.
[4] Indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used.
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a

Appendix 1 – list of endpoints

Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

TER values calculated on the basis of FOCUS Step 3 PECs reduced by overall 95 % spray drift are reported in the addendum 4. However, these PECs are not in line with standard approach recommended by FOCUS SW. The exclusion of this data does not affect the outcome of the aquatic risk assessment.

Bioconcentration				
	Active substance	Metabolite CL 810,721	Metabolite CL 810,720	Metabolite 3
logPow	4.93			
Bioconcentration factor (BCF)[1] ‡ (k1/k2) normalised to 6 % lipid, TAR Not normalised to lipid, TAR Related to active substance (not normalised)	 max. 953 406-510 33			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	< 1 d (TAR)			
(CT_{90})	1.65 d			
Level and nature of residues (%) in organisms after the 14 day depuration phase	0.9 ng as/g 1 % of TAR	38 - 45 % of TAR in edible	2 - 20 % of TAR in edible	

[1] only required if log Pow >3.
* based on total [^{14}C] or on specific compounds

Effects on honey bees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
as ‡	60.3	6.7
Preparation (µg product/bee)	32	71
Preparation (µg product/bee)	40	75.9
Metabolite 1	-	-
Field or semi-field tests		
Tests are not required as the test substance is of low toxicity for Honey bees.		

Appendix 1 – list of endpoints

Hazard quotients for honey bees (Annex IIIA, point 10.4)

pome fruit

Test substance	Route	Hazard quotient	Annex VI Trigger
as (100 g /ha)	Contact	14.9	50
as (100 g /ha)	oral	1.7	50
Preparation (500 g /ha)	Contact	7.0	50
Preparation (500 g /ha)	oral	15.6	50
Preparation (500 g /ha)	Contact	6.6	50
Preparation (500 g /ha)	oral	12.5	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Preparation (BAS 31800 I; 200 g as/L)	Mortality	0.69 g as/ha
Typhlodromus pyri ‡	Preparation (BAS 31806 I; 200 g as/L)	Mortality	> 1.0 g as/ha
Aphidius rhopalosiphi ‡	Preparation (BAS 31800 I; 200 g as/L)	Mortality	7.3 g as/ha

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

Crop and application rate: pome fruit and 100 g as/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
preparation	*Typhlodromus pyri*	0.69 g as/ha	145	22.8	< 2
preparation	*Aphidius rhopalosiphi*	7.3 g as/ha	13.7	2.2	< 2

[1] indicate distance assumed to calculate the drift rate

Appendix 1 – list of endpoints

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g as/ha)[1,2]	Endpoint	% adverse effect[3]	Trigger value
Further laboratory tests - inert substrate, further test organisms						
C. carnea	larvae	BAS 318 00 I; inert glass plates; 38 d	30 100	Mortality / reproduction	24.6 / no effect 56.0 / no effect	50 %
A. bilineata	adult	BAS 318 00 I; inert quartz sand; 66 d	30 100 300	Reproduction	-10.0 -8.0 -4.0	50 %
Pardosa spp.	adult	BAS 318 00 I; inert quartz sand; 21 d	30.0 100.0 100.0* (*spiders not over-sprayed)	Mortality (21 d) / prey consumption (18 d)	11.5 / -1.6 11.5 / 3.1 19.3 / -0.9	50 %
Extended laboratory tests - natural substrate						
Typhlodromus pyri	Proto-nymphs	BAS 318 00 I; natural bean leaves; 14 d	1.28 3.2 8.0 20.0 50.0 1.28 3.2 8.0 20.0 50.0	Mortality Reproduction	21.0 9.0 19.0 88.0 90.0 -6.0 -27.0 15.0 -- --	50 %
A. rhopalosiphi	Adults	BAS 318 00 I; natural barley	21.9 43.76 87.5 175.0 350	Mortality / reproduction	-3.0 / 13.0 10.0 / 16.0 31.0 / 6.0 62.0 / -- 83.0 / --	50 %
C. carnea	larvae	BAS 318 00 I; natural bean leaves; 23 d	50 8.1 132 215 350	Mortality / reproduction	-5.0 / -- -2.0 / -- 18.0 / no effect 16.0 / no effect 21.0 / no effect	50 %
Extended laboratory tests - aged residues						

Appendix 1 – list of endpoints

Species	Life stage	Test substance, substrate and duration	Dose (g as/ha)[1,2]	Endpoint	% adverse effect[3]	Trigger value
Typhlodromus pyri	Proto-nymphs	BAS 318 00 I; natural aged residues on bean plants; 21 d	30.0 100.0 150.0 30.0 100.0 150.0 30.0 100.0 150.0 150.0	Mortality / reproduction	**0 DAT** 65.9 / - 87.8 / - 70.7 / - **7 DAT** 24.1 / +61 95.2 / - 75.9 / **14 DAT** 7.1 / +12 29.8 / -18 77.4 / **21 DAT** 27.7 / -8	50 %
A. rhopalosiphi	Adults	BAS 318 00 I; natural aged residues on barley plants; 15 d	100.0 100.0	Mortality (48 h) / reproduction (13 d)	**0 DAT** 25.0 / 15.1 **7 DAT** 0.0 / 25.7	50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of as or preparation
[3] indicate when the effect is not adverse

Field or semi-field tests
Field or semi-field tests were not required.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA, points 8.4 and 8.5, Annex IIIA, points 10.6 and 10.7)

Test organism	Test substance	Time scale	Endpoint[1]
Earthworms			
	as ‡	Acute 14 days	LC_{50corr} = 20.5 mg as/kg d.w. soil (15.375 kg as/ha)
	as ‡	Chronic 8 weeks	See preparation
	Preparation MASAI 20 WP BAS 318 00 I	Acute	LC_{50corr} = 21.1 mg as/kg d.w. soil (15.83 kg as/ha)

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Endpoint[1]
	Preparation MASAI 20 WP BAS 318 00 I	Chronic	$NOEC_{corr}$ = 0.17 mg as/kg d.w. soil (125 g as/ha)
	Preparation TEBUFENPYRAD 20 WP BAS 318 06 I	Chronic	$NOEC_{corr}$ = 0.33 mg as/kg d.w. soil (250 g as/ha)
	Metabolite CL 810,721	Acute	LC_{50} > 1000 mg as/kg d.w. soil (> 750 kg as/ha)
	Metabolite CL 810,721	Chronic	Not relevant
	Metabolite CL 810,728	Acute	LC_{50}-> 1000 mg as/kg d.w. soil (> 750 kg as/ha)
	Metabolite CL 810,728	Chronic	Not relevant
	Metabolite CL 810,729	Acute	LC_{50} = 392 mg as/kg d.w. soil (294 kg as/ha)
	Metabolite CL 810,729	Chronic	Not relevant
Other soil macro-organisms			
Soil mite	as ‡	Chronic	See preparation
	Preparation MASAI 20 WP BAS 318 00 I	Chronic 4 weeks	NOEC = >200 mg as/kg d.w. soil (> 150.00 kg as/ha)
	Metabolite		Not relevant
Collembola			
	as ‡	Chronic	See preparation
	Preparation MASAI 20 WP BAS 318 00 I	Chronic 4 weeks	$NOAEC_{corr}$ = 6.25 mg as/kg d.w. soil (4.69 kg as/ha)
	Metabolite		Not relevant

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Endpoint[1]
Soil micro-organisms			
Nitrogen mineralisation	Preparation MASAI 20 WP BAS 318 00 I	28 days	0 % effect at day 28 at 0.67 mg as/kg d.w. soil (500 mg as/ha)
	Metabolite CL 810,721	28 days	18.2 % effect at day 28 at 0.36 mg/kg d.w. soil (270 mg/ha)
	Metabolite CL 810,728	28 days	Not relevant
	Metabolite CL 810,721	28 days	11.8 % effect at day 28 at 0.11 mg/kg d.w. soil (84 mg/ha)
Carbon mineralisation	Preparation MASAI 20 WP BAS 318 00 I	28 days	3.6 % effect at day 28 at 0.67 mg as/kg d.w. soil (500 mg as/ha)
	Metabolite CL 810,721	28 days	0 % effect at day 28 at 0.36 mg as/kg d.w. soil (270 mg as/ha)
	Metabolite CL 810,728	28 days	Not relevant
	Metabolite CL 810,721	28 days	3.3 % effect at day 28 at 0.11 mg/kg d.w. soil (84 mg/ha)
Field studies[2]			
Indicate if not required	not required		

[1] indicate where endpoint has been corrected due to log $P_{o/w} > 2.0$ (e.g. LC_{50corr})

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

Appendix 1 – list of endpoints

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	as ‡	Acute	PEC_i 0.02667 mg/kg	767	10
	as ‡	Chronic	PEC_i 0.02667 mg/kg	See preparation	5
	Preparation MASAI 20 WP BAS 318 00 I	Acute	PEC_i 0.02667 mg/kg	791	10
	Preparation MASAI 20 WP BAS 318 00 I	Chronic	PEC_i 0.02667 mg/kg	6.3	5
	Preparation TEBUFENPYRAD 20 WP BAS 318 06 I	Chronic	PEC_i 0.02667 mg/kg	12.5	5
	Metabolite CL 810,721	Acute	PEC_i 0.0068 mg/kg	> 147058	10
	Metabolite	Chronic	Not relevant	Not relevant	5
	Metabolite CL 810,728	Acute	PEC_i 0.0015 mg/kg	> 666667	10
	Metabolite	Chronic	Not relevant	Not relevant	5
	Metabolite CL 810,729	Acute	PEC_i 0.0018 mg/kg	217778	10
	Metabolite	Chronic	Not relevant	Not relevant	5

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Other soil macro-organisms					
Soil mite	as ‡		See preparation	See preparation	
	Preparation MASAI 20 WP BAS 318 00 I	Chronic	PEC_i 0.02667 mg/kg	7500	5
	Metabolite		Not relevant	Not relevant	
Collembola	as ‡		See preparation	See preparation	
	Preparation MASAI 20 WP BAS 318 00 I	Chronic	PEC_i 0.02667 mg/kg	234	5
	Metabolite		Not relevant	Not relevant	

[1] to be completed where first Tier triggers are breached

[2] indicate which PEC soil was used (e.g. plateau PEC)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

The highest nominal application rate of the preparation BAS 318 00 I (500 g preparation/ha) caused no effect on six plant species (2 monocotyledonous, 4 dicotyledonous) in a vegetative vigour test. Since no hints for any negative effect on plants occur, no further tests are required.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
	as ‡ and preparation	Not relevant	Not relevant			

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

[2] for preparations indicate whether dose is expressed in units of as or preparation

Appendix 1 – list of endpoints

Additional studies (e.g. semi-field or field studies)

Not relevant

Effects on biological methods for sewage treatment (Annex IIA, point 8.7)

Test type/organism	endpoint
Activated sludge	EC_{50} = >6 mg as/L (i.e. > 2 times water solubility) The value is considered plausible, although the test failed to pass all relevant validity criteria. However, considering also the toxicity control in a ready biodegradability study, which indicates no inhibition of biodegradation up to 130 mg/L, no further information is necessary.
Pseudomonas sp.	Not relevant

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	active substance tebufenpyrad
water	active substance tebufenpyrad
sediment	active substance tebufenpyrad
air	active substance tebufenpyrad
groundwater	active substance tebufenpyrad

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N, R 50 / R 53 dangerous for the environment very toxic to aquatic organisms, may cause long-term effects

Appendix 2 – abbreviations used in the list of endpoints

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
BCF	bioconcentration factor
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry

Appendix 2 – abbreviations used in the list of endpoints

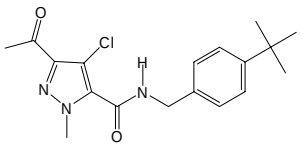
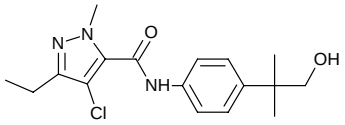
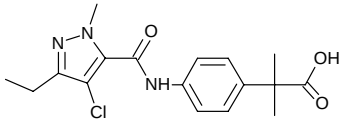
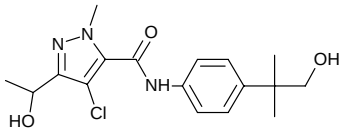
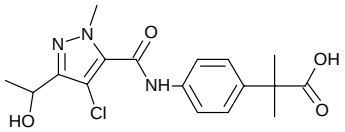
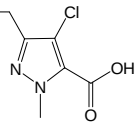
HQ	hazard quotient
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
LR_{50}	lethal rate
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
MWHC	maximum water holding capacity
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
SFO	single first order

Appendix 2 – abbreviations used in the list of endpoints

STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
TWA	time-weighted average
UV	ultraviolet
WHO	World Health Organisation
WP	Wettable powder
yr	year

Appendix 3 – used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
CL 810,719	*N*-(4-t-butylbenzyl)-3-acetyl-4-chloro-1-methyl-5-pyrazolecarboxamide	
CL 810,720	4-chloro-3-ethyl-*N*-[4-(1-hydroxy-2-methylpropan-2-yl)phenyl]-1-methyl-1*H*-pyrazole-5-carboxamide	
CL 810,721	2-(4-{[(4-chloro-3-ethyl-1-methyl-1*H*-pyrazol-5-yl)carbonyl]amino}phenyl)-2-methylpropanoic acid	
CL 821,722	4-chloro-3-(1-hydroxyethyl)-*N*-[4-(1-hydroxy-2-methylpropan-2-yl)phenyl]-1-methyl-1*H*-pyrazole-5-carboxamide	
CL821,723	2-[4-({[4-chloro-3-(1-hydroxyethyl)-1-methyl-1*H*-pyrazol-5-yl]carbonyl}amino)phenyl]-2-methylpropanoic acid	
CL 810,728	4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxylic acid	
CL 810,729	4-chloro-3-ethyl-1-methyl-5-pyrazolecarboxamide