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

chloridazon

finalised: 27 July 2007

(version of 31 July 2007 with a minor editorial correction)

SUMMARY

Chloridazon is one of the 79 substances of the third stage, part A, of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise 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 one year a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on chloridazon in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 3 January 2005. Following a quality check on the DAR, the peer review was initiated on 3 June 2005 by dispatching the DAR for consultation of the Member States and the sole applicant BASF. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed during a written procedure in February – March 2006. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in September 2006.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 26 June 2007 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 herbicide as proposed by the applicant which comprises spraying applications between pre seeding respective pre-emergence up to crop growth stage BBCH 19 to control important annual broad-leaved weeds in beta beet, onion, shallot, garlic, flowers and nursery in Northern Europe and beta beet in Southern Europe, at application rates max. 2.6 kg chloridazon per hectare. Full details of the application rates and timings can be found in the attached end points.
The representative formulated product for the evaluation was "Pyramin WG", a water dispersible granule (WG), registered under different trade names in Europe. The formulation contains 650 g/kg pure chloridazon.

[1] OJ No L 224, 21.08.2002, p. 25

Methods are available to monitor all compounds given in the respective residue definitions for food of plant origin, water, soil and air, however additional data gap was identified.
Analytical methodology is available for the determination of the active substance and the impurities in the technical material as manufactured and for the active substance in the formulation. Additional validation data were submitted but not peer reviewed.

Chloridazon is of low acute oral, dermal and inhalation toxicity, is not irritant to eyes or skin and has no skin sensitising properties. The main findings in short-term oral toxicity studies were dose-dependent effects on body weight and liver in rats, mice and dogs and kidney toxicity and effects on the gastric mucosa in dogs at very high dose levels. Chloridazon has neither mutagenic nor genotoxic properties. No evidence of an oncogenic potential was found in rat or mouse. Chloridazon is not teratogenic, has no effects on fertility and is not neurotoxic. The estimated operator exposure does not exceed the AOEL according to the German model even when no personal protective equipment is worn.

In root crops chloridazon is metabolised through cleavage of the phenyl ring, leading to metabolite B (5-amino-4-chloropyridazin-3(2H)-one). This metabolite is generally present in mature commodities at higher levels than those of the parent compound. The proposed residue definition for monitoring is the sum of both compounds. Their conjugates need to be considered for risk assessment. MRLs ranging from 0.2 to 3 mg chloridazon/kg are proposed for crops selected as representative uses.
Following uptake from the soil by rotational crops, residues of the parent compound and its metabolite B may be present at quantifiable levels in foliar plant parts. Only cereals, root or tuber crops are possible to be grown as rotational crops with residues below the limit of quantification in their parts used for human consumption. Residue trials under field conditions would be necessary to set MRLs on other potential rotational crops.
A transfer of residues of metabolite B to animal commodities is possible up to 0.1 mg/kg in the case of ruminants fed with feed items produced from treated sugar beets or (rotational) cereal fodder or straw.
The risk assessment based on the representative uses did not show any concern for the consumer, even considering the possible use as drinking water of groundwater containing residues of metabolites B and B1.

Chloridazon is low to high persistent in soil under dark aerobic conditions, with degradation characterized by a rapid mineralization to CO_2 of the phenyl moiety and a slow to moderate mineralization of the pyridazon moiety. Chloridazon was primarily degraded to its main metabolite B, which contains the pyridazinon ring part of the molecule. A part from insignificant metabolism/degradation, the further fate of metabolite B consisted predominantly in the formation of high amounts of bound residues, whereas only a moderate amounts are converted to metabolite B-1. Ultimate aerobic degradation of both metabolites B and metabolite B-1 was negligible. Both metabolites were shown to be of medium to high persistence in soil.

Photolysis may contribute to the environmental degradation of chloridazon in soil and in water.
Batch equilibrium adsorption/desorption studies indicated that chloridazon is medium to high mobile in soil, metabolite B is high to very high mobile and metabolite B-1 is medium to very high mobile. Results from the lysimeter studies confirmed that metabolites B and B-1 have a high leaching potential.
Chloridazon was stable to sterile aqueous hydrolysis at environmentally relevant pH values.
In water-sediment systems chloridazon dissipated slowly from the water phase. Metabolite B was the only major metabolite in the water phase and is considered stable. Ultimate biodegradation was negligible with moderate transformation to bound residues.
Predicted environmental concentrations of chloridazon in surface water (PEC_{sw}) and sediment (PEC_{sed}) resulting from pre-emergence spray application on sugar beet and bulb vegetables were recalculated for chloridazon and its metabolite B using the agreed FOCUS scenarios approach.
New PEC_{gw} were provided after the DAR was finalised. Results for metabolites B and B-1 showed that unacceptable leaching to groundwater is very likely to occur. PECgw after application every third year exceeded 10 µg/L in 5 out of 9 scenarios for metabolite B, and exceeded 0.75 µg/L in all 9 scenarios for metabolite B-1.
Long range transport in air and deposition of chloridazon may be considered negligible.

The acute and short-term risk to birds was assessed as low for the representative uses in a first-tier risk assessment. However the long-term TERs for insectivorous and herbivorous birds and for herbivorous mammals were below the Annex VI trigger of 5. The refined risk assessment based on focal species, PT and PD refinement was discussed in the expert meeting and data gaps were identified to justify the suggested refinements (e.g. focal species lapwing and grey partridge and PT values). On the basis of the available information a high long-term risk to birds cannot be excluded. The refined long-term risk assessment for mammals based on measured residues and hare as a focal species was accepted by the expert meeting. The risk to aquatic organisms was assessed as low except for algae where some of the run-off scenarios (R3 use in beet, R3 and R4 use in bulb vegetables) resulted in FOCUS step3 PECsw leading to TERs below the trigger of 10. Member States in which run-off is an important route of entry into surface water need to consider the risk to aquatic organisms further. The risk from the metabolites B and B1 to aquatic organisms was assessed as low. The risk to bees, other non-target arthropods, earthworms, soil non-target micro-organisms and biological methods of sewage treatment were assessed as low for the representative uses evaluated.

Key words: chloridazon, peer review, risk assessment, pesticide, herbicide

TABLE OF CONTENTS

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, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Chloridazon is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Sweden as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Germany submitted the report of its initial evaluation of the dossier on chloridazon, hereafter referred to as the draft assessment report, to the EFSA on 3 January 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 3 June 2005 to the Member States and the main applicant BASF 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, representatives from Member States identified and agreed during a written procedure in February – March 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised by EFSA in September 2006. 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 with representatives from Member States on 26 June 2007 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 Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11(4) 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 (rev. 1-1 of 4 April 2006)

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 (rev. 2-1 of 29 June 2007).

Given the importance of the draft assessment report including its addendum (compiled version of May 2007 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

Chloridazon is the ISO common name for 5-amino-4-chloro-2-phenylpyridazin-3(2*H*)-one

The pyridazinone compound chloridazon belongs to the group of photosynthesis inhibitor herbicides, it acts as a systemic soil and leaf herbicide.

The representative formulated product for the evaluation was "Pyramin WG", a water dispersible granule (WG), registered under different trade names in Europe. The formulation contains 650 g/kg pure chloridazon.

The evaluated representative uses as pre-seeding, pre-emergence and post emergence herbicide comprise broadcast spraying to control important annual broad-leaved weeds in beta beet (sugar and fodder beets, red beets and chard), onion, shallot, garlic, flowers and nursery in Northern Europe and beta beet in Southern Europe, at application rates maximum 2.6 kg chloridazon per hectare. The intended method of application is spraying by means of each type of spraying equipment which is normally used in practical agricultural production.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of chloridazon is 920 g/kg which is higher than the minimum purity given in the FAO specification (910 g/kg) (111/TC/S/F (1997)). The higher value relates to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity.

A new specification was provided and presented in addendum 3 to vol. 4. Impurities #9 and #10 were no longer specified, and the new specification was considered equivalent to the originally submitted specification. Another new specification was provided in addendum 6 to vol. 4, removing some of the impurities (impurities #4, #7 and #8) below 1 g/kg, however two impurities found below 1 g/kg were still specified. A data gap was identified: to provide quality control data to support the new technical specification for impurities that are included in the specification, but not found above 1 g/kg in the batch analysis. This new specification was not peer reviewed. Data to confirm the identity of the impurities revealed by chemical analysis and the validation data were provided and reported in addendum 4 to vol. 4, but this assessment was not peer reviewed.
Beside the specification, 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 chloridazon or the respective formulation. The technical material contains the 4-amino-5-chloro-isomer, which is regarded in the FAO specification as relevant impurity. Because of lack of data the experts of mammalian toxicology (PRAPeR04) and ecotoxicology (PRAPeR03) could not make a decision on the relevance of this impurity and pending on provision of further information agreed to consider it as relevant with a limit of 60g/kg, as it is in the FAO specification.

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

Sufficient test methods and data relating to physical, chemical and technical properties are available.
A CIPAC method is available for the determination of chloridazon in technical material and formulations, based on RP HPLC and UV detection. Adequate analytical methods are available for the determination of the impurities in the technical material as manufactured, based on RP HPLC and UV/DAD detection, however the assessment of the validation data for the specificity and repeatability presented in addendum 4 to vol. 4 was not peer reviewed.

Several methods are available to determine chloridazon, its metabolite B and metabolite A in different matrices of plant origin, using HPLC-MS/MS. In the method for the parent compound a second confirmatory transition is not presented, in the case of metabolite B a second, confirmatory transition was proposed. Methods are available for the determination of chloridazon metabolite B in sample materials of animal origin, based on HPLC-MS/MS with two transitions. An HPLC/DAD method is available for the determination of chloridazon and its metabolites B and B-1 residues in tap water and surface water.
Adequate analytical methods are available to monitor all compounds given in the respective residue definitions for food of plant origin, water, soil and air, however the following data gap was identified:

- The method A9202 used for determination of residues in plants and product of plant origin as described in the DAR has to omit the hydrolysis step to determine parent chloridazon only.

2. Mammalian toxicology

Chloridazon was discussed at the PRAPeR experts' meeting for mammalian toxicology in September 2006 (PRAPeR 04, Round 1).

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

The absorption of chloridazon from the gastro-intestinal tract is rapid (>80% is excreted in urine within 24h) and the peak plasma level was reached within 1 hour. The highest amounts were found in the heart, adrenal glands and in the gastro-intestinal tract, but no potential for bioaccumulation was shown. The excretion is mainly via urine (85-90%) and faeces (7-26%, virtually all related to biliary excretion) with a half-life of 16 to 49h. The metabolism of chloridazon consists of oxidative mechanisms (hydroxylation and conjugation) giving at least 9 metabolites in urine, and some of them also in faeces and bile. Only minor amounts of parent compound were detected in urine and faeces.

2.2. Acute toxicity

Chloridazon is characterized by a low acute oral, dermal and inhalation toxicity in rats (oral LD_{50} 2140 mg/kg bw, dermal LD_{50} >2000 mg/kg bw, LC_{50} >5.4 mg/L over 4h). It is not a skin or an eye irritant, nor a skin sensitizer in the Guinea Pig Maximization Test.

The isomer reduced chloridazon was tested for all the relevant endpoints of the acute toxicity. When data on isomer rich chloridazon were available (considered as supplementary by the RMS) they indicated comparable results, with the exception of an acute oral toxicity study in Sprague-Dawley rats (and not Wistar as with the isomer reduced) in which the isomer rich material was somewhat more toxic ($1000<LD_{50}<1470$ mg/kg bw).

2.3. Short term toxicity

Short term toxicological studies were performed in rats (4-week, 90-day), mice (90-day) and dogs (4-week, 90-day, 12-month). To determine whether there are toxicological differences between the isomer rich (original lower purity) and the isomer reduced (current higher purity) chloridazon, both were tested comparatively in two 4-week feeding studies in rats. There were no major differences, the same NOAEL was proposed for both purities (i.e. 40 mg/kg bw/d).

The target organs were the liver (all species) and the kidneys (dogs, rats). At high dose levels liver function was impaired resulting in clinical chemical changes, whereas at lower dose levels only liver weight increases were seen. Kidney toxicity and effects on the gastric mucosa were observed in dogs at very high dose levels.

The validity of the 90-day rat study was discussed by the experts with regard to the unknown purity of the test material. Nevertheless the relevant short term NOAEL of 21 mg/kg bw/day based on this study was confirmed, because the value is supported by the 2-year and the multi-generation rat studies.

The relevance of the body weight effects in the 1-year dog study was discussed by the experts, based on a reevaluation of the results in an addendum (Add. 2, August 2006). They agreed that the changes

were incidental and not substance-related, and that the NOAEL was 99 mg/kg bw/d (instead of 11 mg/kg bw/day).

In a 21-day dermal study in rabbits neither systemic toxicity nor signs of local irritation were observed at 1000 mg/kg bw/day indicating the very low toxic potential of the test substance after dermal exposure.

2.4. GENOTOXICITY

Chloridazon was evaluated for possible mutagenic/genotoxic effects *in vitro* and *in vivo*. The experts agreed that the present isomer reduced active ingredient is negative in the Ames test including Salmonella and E. coli test strains. No mutagenic effect was observed in point mutation test with Chinese hamster ovary cells or chromosome aberration test with human lymphocytes. Additional *in vitro* results with bovine peripheral lymphocytes (see addendum 2, August 2006) were considered as non relevant. DNA damage and repair was investigated *in vitro* in bacterial cells and in the UDS test in primary rat hepatocytes, all results were negative. The micronucleus test *in vivo* with the isomer reduced chloridazon and the dominant lethal assay in mice with the isomer rich chloridazon gave both negative results. It was concluded that chloridazon had no mutagenic or genotoxic potential.

2.5. LONG TERM TOXICITY

Chronic effects of chloridazon were studied in rats and mice. In the rat study with the isomer reduced compound, the agreed NOAEL is 13 mg/kg bw/day, based on reduced body weight. In the mice study with the isomer reduced compound, the effects were limited to reduced body weight and increased relative liver weight. The agreed NOAEL is 134 mg/kg bw/day. Supportive results in rats and mice were provided in the DAR from studies with the isomer rich compound which gave similar results.

From these results, it was concluded that chloridazon is not carcinogenic in rats and in mice.

2.6. REPRODUCTIVE TOXICITY

The potential toxicity of chloridazon for the reproductive parameters was investigated in one multigeneration study in rats performed with the isomer reduced compound. Effects on parental animals (body weight, body weight gain, increased triglycerides and liver weights, hepatocyte swelling and lipid deposits) were noted at the high dose. The only finding in pups was a reduced body weight and body weight development at this dose level. The NOAEL for systemic toxicity in parental animals and offspring was 37 mg/kg bw/day, and the NOAEL for the reproductive performance and fertility was 148 mg/kg bw/day. Another multigeneration study was described in the DAR for the isomer rich compound, but considered of limited validity and not used for the derivation of the NOAELs (no effects on parental animals and pups, on reproduction and fertility parameters).

A developmental toxicity study with the isomer rich chloridazon was performed with rats, but considered as supplementary information. Effects were only observed during the peri/postnatal phase at the high dose (slightly decreased pup viability index, increased liver weight in dams and pups). No anomalies, variations or malformations were noted in pups. In the rat and the rabbit study with the isomer reduced chloridazon, the maternal effects were reduced food consumption and body weight, but no indications of embryo-/foetotoxicity or malformations at any dose level. The agreed maternal

NOAELs were 50 mg/kg bw/day for the rat, and 55 mg/kg bw/day for the rabbit. The agreed NOAELs for development/teratogenic effect were 250 mg/kg bw/day for the rat, and 495 mg/kg bw/day for the rabbit.

2.7. NEUROTOXICITY

Chloridazon showed no clinical signs of neurotoxicity and no histopathological changes of the central of peripheral nervous system in any of the acute, short-term, long-term or reproductive/developmental toxicity studies. Furthermore, the structure of chloridazon is not similar to that of compounds known to be able of inducing delayed neurotoxicity.

2.8. FURTHER STUDIES

Supplementary mechanistic studies were described in the DAR showing that the effect of chloridazon on the vegetative nervous system *in vitro* is predominantly parasympathicomimetic, no effect was observed on the intravasal and cardiovascular systems, no pathological changes were induced in the EEG of the rat.

Studies from the open literature (in ruminants, in rats, in pheasants, interaction with cell membranes or with activity of sheep leucocytes in vitro) were presented in the addendum (August 2006). However these studies were not considered reliable by the RMS since only limited information was available.

Metabolites

In groundwater (see 4.2.2), the metabolite B exceeds 10 µg/L in some scenarios, and the metabolite B1 exceeds 0.75 µg/L for all the scenarios. Metabolite B is also the major plant metabolite (see point 3.1.1).

The **metabolite B**[2] was not toxic after acute oral administration (rat $LD_{50} \geq 5000$ mg/kg bw). It was not mutagenic or genotoxic in three *in vitro* tests covering the end points of gene mutation and chromosome aberration. In short term studies (one 4-week and two 3-month studies in rats), the target organs were the liver and the kidney, with an overall short term NOAEL of 15 mg/kg bw/day. In a prenatal toxicity study in rats, the maternal NOAEL was 60 mg/kg bw/day and the developmental NOAEL 120 mg/kg bw/day. The experts agreed that, since this metabolite is of comparable or lower toxicity than chloridazon, the same ADI could be applied, i.e. 0.1 mg/kg bw/day.

The **metabolite B-1**[3] was moderately toxic after acute oral administration (rat LD_{50} 1200 mg/kg bw), not mutagenic in the Ames test or gene mutation assay in mammalian cells (CHO) *in vitro*, negative in the UDS assay with rat hepatocytes, and not clastogenic *in vivo* in the bone marrow cells of rats. Based on a 3-month rat study, the short term NOAEL is 50 mg/kg bw/day. In a developmental study in rats, signs of foetotoxicity were observed at a maternally toxic dose level (reduced mean fetal weight, delayed ossification, rudimentary cervical ribs), but no indications for teratogenicity. The maternal and developmental NOAEL is 10 mg/kg bw/day.

[2] Metabolite B: 5-amino-4-chloro-3(2H)-pyridazinone
[3] Metabolite B-1: 5-amino-4-chloro-2-methyl-3(2H)-pyridazinone

Long term and multigeneration studies are missing for both metabolites. However the experts concluded that the two metabolites are not of toxicological relevance based on the available information and on the fact that the parent compound does not show any carcinogenic or mutagenic potential.

Relevance of impurities and technical specification

Taking into account the final technical specification (addendum 3, Vol 4, August 2006), the impurities 1, 4, 9 and 10 were discussed by the experts (see also addendum 4, Vol 4, April 2007). They could not conclude on the toxicological relevance of the 4-amino-5-chloro-isomer impurity (**impurity #1**) in the absence of information on its toxicological properties. However the proposed limit of 60 g/kg in the technical specification was considered acceptable based on the available information obtained with different toxicological batches and the toxicological profile of the parent compound.

Toxicological studies performed with the **impurity #4** were presented in the addendum 2 (August 2006). It was not acutely toxic by oral administration, slightly irritating to the skin, it induced severe damage to the eye and was a skin sensitiser. In a 28-day rat study, the forestomach was the target organ and the NOAEL was 94 mg/kg bw/day. This impurity was not mutagenic in the Ames test, showed a clastogenic potential *in vitro* in the chromosome aberration test in mammalian cells, but did not reveal any clastogenic effect or numerical aberrations in the *in vivo* micronucleus test in mice. In addition to these results, the impurity #4 was also present in three main batches used in the toxicological testing of chloridazon (which was not mutagenic in vivo nor carcinogenic or toxic to reproduction). The experts concluded that the proposed maximum level of 2 g/kg was acceptable for this impurity. EFSA notes that in the final technical specification (addendum 6 to Vol 4, May 2007), this impurity is no longer specified (below 1 g/kg).

As the **impurities #9 and #10** are not part of the final technical specification, the assessment of their toxicological relevance is not needed any more.

2.9. MEDICAL DATA

The personnel handling chloridazon in manufacturing, research and formulation is observed regularly by medical examinations. No adverse effects on health have been observed which could be related to an exposure to chloridazon. No poisoning incidents were reported in the published literature.

A few cases of irritation of skin and eyes were reported in the published literature. One case of sensitisation with allergic contact dermatitis and a positive patch-test was observed. There was no positive patch-test reaction in 149 tested persons (40 of them worked as farmers). This lead in the initial DAR to the proposal R43 May cause skin sensitization by skin contact. After revision of the available human and animal data (see 2.2), the experts decided to withdraw this proposal.

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

The **agreed ADI** is 0.1 mg/kg bw/day, with the use of a safety factor 100, based on the long-term study in rats.

The **agreed AOEL** is 0.2 mg/kg bw/day, with the use of a safety factor 100, based on the 90-day rat study supported by the 2-year and the multi-generation rat studies.
Chloridazon is of low acute oral, dermal and inhalation toxicity. No acute effects have been observed after single exposure in repeat-dose studies. The establishment of an **acute reference dose** was not considered necessary.

2.11. DERMAL ABSORPTION

The dermal absorption was studied *in vivo* in rats with the formulation BAS 119 50 H, considered as comparable to the representative formulation BAS 119 33 H. The maximum relative absorption was approximately 0.42% for the undiluted formulation (10h exposure, 72h sacrifice) and 0.67% or less for the aqueous dilutions 1:6 and 1:33 (10h exposure, 24h sacrifice). As the experiment was stopped before serial non-detects were observed in excreta, the amount located in the skin was considered as being absorbed and included into the calculation. The dermal absorption was found to be approximately 4 % (10 h exposure; including skin residues) both for the diluted and undiluted product.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Pyramin WG (or BAS 119 33 H) is formulated as water-dispersible granules containing 650 g chloridazon/kg for use on beta beet, onion, shallot, garlic, flowers and nursery.
Operator exposure
The estimations are based on the standard tractor-mounted spraying application as pre- or post-emergence herbicide. This is supposed to represent a worst case when compared to band spraying application in combination with sowing, due to reduced application rates, lower daily work rate and lower spray drift during this second type of application. The maximum application rate is 2.6 kg a.s./ha in 200-400 L water.
Calculations with the German model and the first version of the UK POEM model were provided in the addendum. Values for the revised UK POEM were provided in a comment in the reporting table, and were below the AOEL only when gloves and respiratory protective equipment are worn during mixing/loading, and gloves used during application (giving an estimated exposure of 63% or the AOEL). Numerical results are given in the following table.

Estimated exposure presented as % of AOEL (0.2 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model. The treated area is 20 ha/day for the German model and 50 ha/day for the UK POEM.

Model	No PPE	With PPE*	With PPE**	With PPE***
German	63	34	28	not determined
UK POEM (old)	1053	195	35	not determined
UK POEM (new)	696	451	299	63

PPE*: (personal protective equipment): gloves during mixing/loading

PPE**: gloves during mixing/loading and application

PPE***: gloves during mixing/loading and application, respiratory protective equipment when mixing

EFSA note: an exposure assessment for hand-held use has been performed by UK and the estimates were 51.5% of the AOEL without PPE according to the German model, and 97% of the AOEL with gloves during mixing/loading/application and impermeable coveralls during application according to the UK POEM model.

Worker exposure

Worker exposure was estimated in the DAR for a worst-case scenario, where a worker is walking into the field to elucidate plant growth or health status after the spray solution has dried. A German re-entry model[4] was used for the calculations, and resulted in an estimated exposure of 5.9% of the AOEL (without the use of PPE).

Bystander exposure

For the estimation of bystander exposure, RMS used assumptions from EU Technical Guidance Documents for chemicals and draft values proposed for the EUROPOEM II model. The resulting value is 0.76% of the agreed AOEL when bystanders are exposed to spray drift.

3. Residues

Chloridazon was discussed at the PRAPeR experts' meeting for residues in September 2006 (PRAPeR 05, Round 1).

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of chloridazon has been investigated in sugar beets under conditions relevant for the representative uses supported by the applicant, with application of the product in pre or post emergence at 4-6 leaf growth stage. The parent compound, the soil metabolite B, resulting from the loss of the phenyl ring, and conjugates of both substances were identified as main constituents of the Total Radioactive Residues (TRR). The ratio of these compounds varies widely according to the stage of application of the product and the crop part (root or leaves). Minor parts of the TRR were incorporated in starch, cellulose, lignin and protein.

As chard is included under the supported representative uses, it was agreed by the expert meeting to consider that use of chloridazon on leafy crops was covered by the confined rotational crop on chard, which shows a similar metabolic pattern as in sugar beets.

Based on the metabolic pattern and given that metabolite B is considered to be of comparable toxicity to the parent compound as indicated under point 2.8, the residue definition for risk assessment should include the parent compound, its metabolite B and their conjugates, the sum being expressed as

[4] Hoenicke *et al.*, 1998. Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflantzenschutzmitteln behandelten Kulturen. Nachrichtenbl. Deut. Pflantzenschutzd. 50 (10), p 267.

chloridazon. It was discussed during the expert meeting whether conjugates of metabolite B, for which no field data are available, could be excluded from this residue definition. This was considered not appropriate as the metabolism data in sugar beet roots after post-emergence application at the relevant growth stage indicated a high contribution of conjugates of metabolite B to the total toxicological burden (about 40 % of the TRR, representing about half of the extractable material). In addition, supervised residue trials indicate that residues of metabolite B are clearly higher in practice than residues of choridazon and its glycoside conjugate, what suggests a further potentially significant contribution of conjugates of metabolite B.

The proposed residue definition for monitoring can be restricted to the sum of chloridazon and its metabolite B, expressed as chloridazon as this sum is sufficiently indicative of the residual level of contamination.

A conversion factor between residue definitions for monitoring and risk assessment is not possible to determine as metabolism studies are not fully conclusive and field trials with analysis of all conjugates are not available.

A sufficient number of supervised residue trials have been submitted covering the supported uses. In the vast majority of cases, chloridazon, including its glycoside conjugate and metabolite B were separately determined. As mentioned above, conjugates of metabolite B were not analysed.

In sugar beets 24 trials were carried out covering European Northern and Southern regions. Residues of chloridazon and its glycoside conjugate were in most cases below the Limit Of Quantification (LOQ) of 0.05 mg/kg and the highest values found were 0.06 and 0.08 mg chloridazon equivalent /kg in root and top samples respectively. Residues of metabolite B were present at higher levels with highest values found at 0.15 and 0.79 mg chloridazon equivalent/kg in root and top samples respectively.

Six trials were performed in Northern Europe on red beets. The residue levels of chloridazon and its glycoside metabolite amounted up to 0.35 mg chloridazon equivalent /kg in leaves and were consistently below the LOQ of 0.05 mg/kg in roots while metabolite B levels reached the highest values of 1.14 and 0.14 mg chloridazon equivalent/kg in leaves and roots respectively.

Eight trials on onions conducted in Northern Europe are available. Residues of chloridazon and its glycoside metabolite as well as of metabolite B were below the respective LOQs, with the exception of one sample containing measurable metabolite B residues (0.09 mg chloridazon equivalent/kg).

All these results can be considered as reliable based on storage stability studies demonstrating that residues of chloridazon, its glycoside metabolite and metabolite B are stable under deep-freeze condition over storage periods up to 24 months.

The effects of processing on the nature of residues were investigated through hydrolysis studies simulating sterilisation, boiling and pasteurisation. Chloridazon and its metabolite B were stable under these processing conditions. A processing study in order to investigate the transfer of chloridazon and its metabolite B to white sugar included sugar beet samples from 4 locations in Germany. Residues of both compounds in white sugar were below the LOQ (0.05 mg/kg), but no valid transfer factor could be calculated given the low residual content. The study suggests a transfer of the residues to molasses.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A confined rotational crop study using sorghum, wheat, oats, radish, sugar beets and chard planted in soil treated with chloridazon indicated a clear potential for residues in succeeding crops, in all scenarios (emergency replant, post harvest or annual replant) resulting from soil uptake of the active substance and its degradation products. As in primary crops, the major constituents of the residue were the parent compound and the soil metabolite B. In most cases metabolite B was present at clearly higher level than chloridazon and was mainly present as free form. In addition, another major metabolite was tentatively identified as an analogue of metabolite B. Lesser amounts of 2 other metabolites (p-OH-chloridazon[5] and 1 unidentified metabolite) were also present. Due to the similarity of metabolite patterns, the residue definitions proposed for primary crops are also valid for rotational crops.

Field trials were performed in USA (6 trials) and Germany (4 trials), with pre-planting intervals of 1 year and 30 days respectively. The overall conclusion drawn by the expert meeting from the obtained results in rotational crop studies is that foliar crop parts present a high probability of residues (mainly metabolite B) being present at measurable level, whatever the delay observed for the sowing or planting of the succeeding crop, while residues in root and tuber vegetables as well as in cereal grains are normally below the LOQ.

Management options can consist in fixing MRLs in certain categories of succeeding and rotational crops and/or in setting label restrictions for crop rotation. Based on the available information a MRL of 0.3 mg/kg would be needed for spinach as rotational crop, but MRL proposals for other commodities would require further appropriate field data. If the label restriction option is considered more appropriate, cereals or root/tuber crops can be grown as rotational crops with residues below the LOQ in their parts used for human consumption.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolisms of chloridazon and of its metabolite B have been separately investigated in goats and laying hens.

Two main metabolic pathways were observed for chloridazon and consisted in dechlorination of the parent compound and in hydroxylation of the phenyl ring, followed by sulphate conjugation. The ratio between the parent compound and its main metabolites (*4*-OH-chloridazon, its sulphate conjugate and deschloro-chloridazon) is varying from tissue to tissue. Metabolite B is not formed from chloridazon in livestock metabolism.

Metabolite B is not metabolised by livestock and is found unchanged in all tissue, representing more than 95 % of the respective TRR.

No sign of accumulation was found in any species for any compound.

Based on these findings the expert meeting agreed on establishing the residue definition for risk assessment as the sum of chloridazon and its metabolite B expressed as chloridazon. The inclusion of major metabolites of chloridazon is not needed from the point of view of the consumer safety as their toxicity is not expected to be higher than that of the parent and the exposure of livestock to

[5] 5-amino-4-chloro-2-(4-hydroxyphenyl)-3(2H)-pyridazinone

chloridazon through primary or rotational crops is estimated to be one order of magnitude lower than the exposure to metabolite B.

For monitoring, the residue definition consists in metabolite B of chloridazon only.

Livestock is mainly exposed to residues through the consumption of feed items produced from sugar beets as well as from the consumption of fodder or straw when cereals are sowed in crop rotation after sugar beets. In these 2 feed items, as mentioned in points 3.1.1 and 3.1.2, residues consist essentially in metabolite B. The animal exposure to chloridazon and its metabolite B is in a ratio 1:6 (1:10 when metabolite B is expressed as chloridazon equivalent). The critical exposure of dairy and beef cattle is about 0.3 mg chloridazon equivalent/kg bw, considering nutrition practices as recommended by the current guidelines, and considering under a worst case scenario that 100 % of the animal diet consists of cereal green fodder, sowed 30 days after application of chloridazon (simulating emergency replant) and containing the HR found in rotational field studies. This was considered by the expert meeting as an extreme scenario, mainly regarding the very infrequent use of cereals at early growth stage as feed item, but was considered valid as in accordance with the current draft OECD guidelines.

Considering this potential exposure, feeding studies as well as information from metabolism studies conducted on lactating goats and dairy cows, suggest that low, but measurable levels of metabolite B (up to 0.1 mg/kg) may be present in milk and ruminant products.

The critical exposure of pigs consuming feed items produced from sugar beet is about 0.1 mg chloridazon equivalent/kg bw, which is about 3 times lower than the ruminant exposure. No specific feeding study is available.

The poultry exposure is minimal and it can be expected from metabolism studies that no residues will be present in eggs and poultry meat.

3.3. CONSUMER RISK ASSESSMENT

The chronic dietary exposure assessment has been based on the Theoretical Maximum Daily Intake (TMDI) calculation model of WHO using the WHO typical European diet for adult consumers and the German national diet for the 4-6 year old girl. Residues in beetroots (red beets), onions, shallots, garlic, chard and animal products were considered to be at the level of respective MRLs. As a processing factor from sugar beet to sugar could not be establish given analytical difficulties at low residue levels, sugar was estimated to contain in a worst case a residue level of 0.1 mg/kg. Based on these assumptions, the TMDI resulting from the representative uses was below 5 % of the ADI for both considered diets. A valid estimation of the potential contribution of residues in rotational crops in the absence of any label restriction is not possible.

It must be noted that these TMDI calculations do not take into account plant conjugates of metabolite B, which are included in the residue definition for risk assessment, as these conjugates were not analysed in field trials. Nevertheless, given the level of ADI exhaustion as determined without considering them, and given indicative information available from metabolism studies in primary and succeeding crop, it is not expected that the contribution of conjugates to the toxicological burden would be so that the ADI would be exceeded.

In groundwater the level of 0.1 µg /L is expected to be exceeded by the metabolites B and B1. As indicated under point 2.8, the ADI of chloridazon should apply to these metabolites. Therefore, an additional exposure assessment through consumption of drinking water was performed. This assessment is based on the default assumptions for water consumption laid down in the WHO Guidelines of drinking water quality and on the highest predicted values from FOCUS modelling (36 µg chloridazon equivalent/l for the sum of both metabolites under Hamburg scenario) for the use of chloridazon on sugar beet at the intended application rate of 2.6 kg/ha, every third year, in order to reflect the worst case.

For the considered model consumers, 5-kg bottle-fed infant (consuming 0.75 l/day), 10-kg child (consuming 1 l/day) and 60-kg adult (consuming 2 l/day) the estimated intakes of metabolites B and B1 together, expressed as chloridazon, from drinking water are 0.0054 mg/kg bw/day, 0.0036 mg/kg bw/day and 0.0012 mg/kg bw/day, respectively corresponding to *ca* 5%, 4% and 1% of the ADI of chloridazon, respectively. Therefore, it can be considered that the exposure to chloridazon degradation products through consumption of drinking water, calculated according to the above mentioned worst case assumption, represents a toxicological burden of the same order of magnitude as that resulting from the consumption of plant commodities.

As it was considered that an ARfD was not necessary for chloridazon, an acute intake assessment was not performed.

3.4. PROPOSED MRLS

Plant products

In plants, the results of residue trials include the glycoside conjugate of chloridazon, which is not included in the residue definition for monitoring, but it can be considered that this has only a minor influence on the MRL setting as generally residues of metabolite B were clearly higher and have the most determining effect on the MRL proposals. Therefore, based on these results and their analysis according to the analytical methods recommended by the current European guidelines, the proposed MRLs are:

Sum of chloridazon and its metabolite B, expressed as chloridazon (mg/kg)

Sugar and fodder beet	0.3
Beetroot (red beet)	0.5
Onion, garlic and shallots	0.2
Chard	3

The MRL proposed for chard relies on extrapolation of residue data in red beet leaves.

Animal products

Metabolism and feeding studies in ruminants indicated that residues of metabolite B may be present above the LOQ of validated method for milk (0.01 mg/kg) and all other ruminant tissues (0.05

mg/kg). For poultry products, no measurable residues are anticipated given the expected lower exposure. Therefore the proposed MRLs are:

Metabolite B (mg/kg)	
Milk, meat, fat, liver and kidneys of ruminants	0.1
Poultry products	0.05*

* Indicates that the MRL is set at the LOQ.

A risk management decision has to be taken whether an extrapolation from ruminant for MRL setting in pig products is appropriate, even if the dietary exposure is lower.

4. Environmental fate and behaviour

Chloridazon was discussed at the PRAPeR experts' meeting for environmental fate and behaviour (PRAPeR 02) in September 2006.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The route of degradation under laboratory conditions was investigated with chloridazon ^{14}C-radiolabelled in the pyridazinone ring under dark conditions (25 ºC and 75% 1/3 bar moisture) with two different soils (pH: 5.9-7.7; clay content: 14.0-24.0% and organic matter content: 0.5-2.2%).
In aerobic conditions chloridazon is primarily degraded to its main metabolite **B** which contains the pyridazinone ring part of the molecule. This metabolite accounts for a maximum of 55.9% AR at the end of the study (373 days) and is considered stable.
The fate of the phenyl moiety of chloridazon in soil was described in an amendment to the study. While the phenyl ring part of chloridazon is microbially attacked, opened and mineralised to CO_2 (up to 76% AR after 30 days in 4 soils), the pyridazinone ring persists with a very low mineralization rate (5.6% AR after 120 days and 18.6% AR after 373 days). In the pyridazinone-labelled chloridazon study non-extractable residues evolved to 9.3%AR and 13.3%AR after 120 and 124 days respectively, and reached maximum levels of 13% AR and 19% AR at the end of the corresponding studies.

The degradation of the major soil metabolite B was investigated in a laboratory study under aerobic conditions in four soils at 25 ºC and 40% maximum water holding capacity. The soils cover a pH range ($CaCl_2$) from 5.8 to 7.3, clay content from 6.3% to 9.5% and organic carbon content from 1.0% to 1.9%. By the end of the study (121 days) unchanged metabolite B accounted for up to 51% AR. Degradation of metabolite B produced metabolite **B-1** (1.0-14.1% AR after 120 days) and bound residues up to 42% AR (after 92 days). The degradation of metabolite B-1 was also investigated in detail showing that the reaction sequence between methylation and demethylation at the pyridazinone nitrogen N-2 is reversible. In fact, a partial conversion from metabolite B-1 back to metabolite B was

observed (max. 10.5% AR after 120 days) in an additional laboratory study with ^{14}C-radiolabelled metabolite B-1. Mineralization was extremely low for both metabolite B and metabolite B-1, with max CO_2 amounts of approximately 5% AR released from each molecule after 120 and 121 days of testing respectively.

No reliable soil metabolism studies at lower temperatures (10ºC) were available.

Under anaerobic conditions in soil, chloridazon is not metabolised to a significant extent (< 4% AR in two soils). After 90 days apart from a mean of approx. 86% AR unchanged chloridazon, only metabolite B (< 9% AR) was found. The main route of metabolism of chloridazon in soil under anaerobic conditions is the same as under aerobic conditions.

A soil photolysis study is available. Results showed that under the influence of light at soil surfaces chloridazon can be partly degraded to CO_2 with a maximum of 14% AR after 15 days, whereas the dark samples showed only low mineralisation of about 1% AR. Therefore, under the influence of light at soil surfaces chloridazon can be substantially degraded (pseudo first order kinetics half-life calculated by linear regression was estimated to be 37.8 days, employing a 12 h light/12 h dark cycle). A number of polar and non polar products where found but none of them exceeding 5% AR.

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

Degradation rate of chloridazon was investigated in the same studies used to establish the route of degradation in soil. After a re-evaluation[6] of the validity of the laboratory degradation study with non-radiolabelled chloridazon in four additional soils, available single first order for chloridazon ranged from 8.6 days (20 ºC) to 187.6 days (25 ºC) and thus cover a wide spectrum. The corresponding half-lives for chloridazon normalised to reference conditions (20 ºC and pF2) are in a similar order of magnitude, ranging from 8.6 to 173.9 days, with a geometric mean of 43.1 days (n= 6). The Member State experts agreed with this assessment, confirming that chloridazon can be classified as low to high persistent in soil.
Under anaerobic conditions, much longer half-lives for chloridazon between 370 and 607 days were determined in laboratory studies.
For the metabolites B and B-1, half-lives were derived using ModelMaker software on the basis of a best fit estimation and determined graphically. Both the major metabolites are medium to high persistent in soil under aerobic conditions with $DT_{50\ 20\ ºC}$ ranging from 80 to 132 days for metabolite B, and from 118 to 170 days for metabolite B-1.

A total of ten field dissipation trials were carried out. Chloridazon was applied onto bare soil (eight European trials) and to sugar beet (two US trials) considering a range of different soils and climatic conditions. The trials were situated in different regions of Europe (5 in German, 1 in Sweden, 1 in

[6] See addendum 5 to the DAR (24 April 2007), p. 268.

Italy and 1 in Spain) and America (2 in California). In the DAR the calculation of the degradation rates were performed according to the existing knowledge and accepted methods, including also Timme and Frehse (best fit). The resulting fieldDT_{50} ranged from 3 to 78.5 days. As these values were not used in the exposure assessment, a normalisation to standardised conditions according to FOCUS was not necessary. However, before the experts' meeting, the applicant provided a re-evaluation of the field data (see addendum 2), where the half-lives were calculated on the basis of the normalised degradation rate constants of chloridazon in the field to a reference temperature of 20ºC and reference soil moisture at pF2. For three of the field dissipation studies, a reliable estimation of standardised half-life could not be established because of low coefficients of determination or because the number of available data points fall below the minimum number of required data points according to FOCUS kinetics. The remaining suitable values ranged from 5.7 to 55.4 days, resulting in a geometric mean of 19.1 days. Following the demand of the experts, further details on the standardisation procedure of field half-lives were provided and summarised in addendum 5, which is not peer review. However, EFSA considers the approach in accordance with the recommendations of FOCUS and therefore appropriate. Before the experts meeting, the RMS has also provided field DT_{50} (not normalised) according to single first order kinetic using Model Maker software for those trials that were not analysed in this way in the DAR (Germany, USA). After recalculations, field DT_{50} ranged from 16 to 94 days. These values were not further discussed during the peer review. As these values were not used in the exposure assessment, the EU risk assessment for chloridazon can be concluded nevertheless.

Predicted environmental concentrations (PEC) in soil were calculated for the parent chloridazon and its major soil metabolites B and B-1 with an application rate of 2.6 kg a.s./ha to beta beets. For chloridazon the degradation was assumed to follow first order kinetics with worst case field half-life of 78.5 days observed in the Swedish field trial. For the degradation of metabolite B the uncorrected worst case laboratory half-life was chosen (132 days), and worst case rate constants describing the kinetic equilibrium between the metabolite B and B-1 (see section 4.1.1) was considered. The potential accumulation of metabolite B following successive applications of chloridazon in realistic crop rotations was calculated by RMS and presented in addendum 2. Although the longest soil DT_{50} (132 days) should have been used in place of the geometric mean (108 days), the experts of the PRAPeR fate meeting agreed that the available assessment can be considered valid. Concerns raised also on the value (= 55.9%) used in the calculations for the formation fraction of metabolite B in soil, which is not the maximum observed in the laboratory studies. Taking into consideration the low toxicity of metabolite B to earthworms, EFSA considers that re-calculations of the plateau concentration of metabolite B are not necessary.

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

Adsorption and desorption of chloridazon, metabolite B and metabolite B-1 have been investigated in three studies using batch equilibrium procedures (5 soils for the parent, 4 soils for metabolite B and 6 soils for metabolite B-1). According these studies chloridazon is medium to high mobile in soil ($K_{f\ oc}$

= 89 – 340 mL/g), metabolite B is high to very high mobile ($K_{f\,oc}$ = 29 – 74 mL/g) and metabolite B-1 is medium to very high mobile ($K_{f\,oc}$ = 27 – 216 mL/g). There is no indication of a pH dependence of the adsorption.

A soil column leaching study with 3 German soils is available. The amount of chloridazon found in the water leachate amounted to 25.2%, < 0.8% and 16.16% of the applied radioactivity. No degradates were detected.

An aged residue (dark aerobic conditions at 22ºC and 40% MWHC for 30 d) column leaching experiment was performed with one soil. 99.6% of radioactivity were retained in the soil segments. Extractable residues showed by a very high extent unchanged chloridazon on TLC: minor amounts were metabolite B. Only 0.4% of radioactivity percolated through the column and was collected in the eluate fractions. These residues were composed of chloridazon and metabolite B.

The leaching behaviour of chloridazon and its metabolites B and B-1 was investigated in two outdoor lysimeters using ^{14}C-chloridazon for two consecutive years. Only one measurable detection of chloridazon and yearly concentrations < 0.05 µg/L were determined in the lysimeter leachates. The metabolites B and B-1 proved to be more mobile with maximum annual average leachate concentrations of 2 and 41 µg/L (metabolite B) and 0.1 and 2 µg/L (metabolite B-1). Concerns raised on remarkable concentration (11.3 µg/L) of non-identified radioactivity (NIR) found in one lysimeter leachate. The Member State experts considered the explanation given in addendum 2 not satisfactory, and therefore further details on the nature of NIR were required to the RMS. EFSA considers the information provided by the RMS in addendum 5 adequate and agrees that, after an exhaustive examination of the chromatograms, it is highly unlikely that individual polar compounds in the percolate will exceed the limit of 0.1 µg/L. Chloridazon was found in moderate concentrations in the soil segments with max. 0.099 µg/g in the silty loam soil in a depth of 10-20 cm and with max. 0.065 µg/g in the loamy sand soil in a depth of 20-30 cm.

Another lysimeter study performed with non-radiolabelled chloridazon confirmed the potential of metabolite B leaching at concentrations > 0.1 µg/L (maximum annual average concentrations in the leachate 4.1 / 12.2 µg/L).

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Chloridazon was stable to sterile aqueous hydrolysis at environmentally relevant pH values.

Photolysis of chloridazon was investigated in pH 7 aqueous solution at 25 ºC. Chloridazon can be degraded by direct photolysis. The photolytical half-life in aqueous solutions decreased from 76 to 22 days from March to June. Both metabolites B and B-1 degrade faster than the parent compound under the influence of light. The half-life of metabolite B in the direct photolysis was determined to be 10 days under continuous irradiation and even faster in natural water (6 days). Degradation of metabolite B-1 in natural water was more rapid with a half-life of 1.2 days under continuous irradiation.

Chloridazon is not readily biodegradable in water.

The distribution and degradation of chloridazon was studied in two natural systems of water and sediment. Primary degradation of chloridazon in the water phase is slow with first-order half-lives of 58 days and 105 days. Disappearance time for the active substance in the total system was calculated to be 182 days (1st order, calculated according to ModelMaker model). The main pathways were a partitioning to the sediment (up to 34% AR after 60 days) and the transformation to metabolite B (up to 43% AR in water and 7% AR in sediment after 100 days) and bound residues in the sediment (21% AR after 100 days). No further individual metabolites were observed in significant (> 10% AR) amounts. Ultimate biodegradation was negligible with maximum degrees of mineralisation up to 3-8% AR.

In the DAR predicted environmental concentrations of chloridazon in surface water (PECsw) and sediment (PECsed) resulting from pre-emergence spray application on sugar beets were calculated by RMS using the FOCUS STEP 1 – 3 approach with FOCUS scenarios D3, D4, R1 and R3. For the simulations the geometric mean (= 43.2 days) of the laboratory DT_{50} values in soil after standardisation to reference conditions was used for chloridazon. New PECsw and PECsed calculations for chloridazon and its metabolite B for sugar beet and bulb vegetables were provided by the applicant and summarised by RMS in addendum 2. The experts of the meeting on fate and behaviour discussed and agreed the input parameters of the modelling (both FOCUS surface water and groundwater), including the geometric mean DT_{50} in soil of 19.1 days derived from field dissipation studies (normalised to reference conditions). It was concluded that although the kinetics used to derive the soil DT_{50} for metabolite B is not consistent with the first order kinetics used by the FOCUS models, the modelling is considered acceptable due to the non relevance of metabolite B. Concerns raised also on the value for the maximum formation fractions of metabolite B in soil and details were provided in addendum 5, which is not peer reviewed. However, since the value used for calculations represents a worst case (64.8%), the experts considered the available PECsw acceptable.
At Step 3, the worst case global maximum concentrations for chloridazon in the water phase are 125.95 µg/L for sugar beets (scenario R3, stream) and 82.06 µg/L for bulb vegetables (scenario R4, stream). For metabolite B, the worst case global maximum concentrations in the water phase are 35.23 µg/L for sugar beets (scenario R3, stream) and 22.96 µg/L for bulb vegetables (scenario R4, stream). Results for PECsed of the simulation of Step 3 indicated that the worst case global maximum concentrations in the sediment are 37.87 µg/kg (scenario D6, ditch, in 2nd season) after application to bulb vegetables for chloridazon, and 45.18 µg/kg (scenario R3, stream) after application to sugar beets for metabolite B.

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

In the DAR predicted environmental concentrations in groundwater for chloridazon and its metabolites B and B-1 were re-calculated by RMS based on standardised DT_{50} values from the laboratory studies (soil DT_{50} for chloridazon = 57.3 days). The applicant submitted new PECgw calculations with DT_{50} (= 19.1 d) obtained from field trials, together with further details on the transformation scheme and the respective formation half-lives used in FOCUS-PELMO calculations

(addendum 2). The experts from Member States at the PRAPeR meeting considered acceptable the input parameters for modelling (see section 4.2.1), even if further clarifications on the standardisation of the field DT_{50} were required and, subsequently, evaluated by RMS in addendum 5 (see section 4.1.2).

The simulated concentrations in groundwater after annual, biennial and application every third year of the active substance to sugar beets showed that the 80th percentile annual leachate concentrations of chloridazon at 1 m depth do not exceed 0.001 µg/L in all the 9 FOCUS scenarios. Simulations for metabolite B and metabolite B-1 indicated that leaching to groundwater is very likely to occur. PECgw after application once every three years exceeded 10 µg/L in 5 out of 9 scenarios for metabolite B, (max. 14.35 µg/L in Hamburg scenario) and exceeded 0.75 µg/L in all 9 scenarios for metabolite B-1 (max. 8.13 µg/L in Jokioinen scenario). In the list of endpoints the 80th percentile annual leachate concentrations after 20 year simulation period are also included. Toxicological data are available to conclude that these metabolites are not of toxicological relevance (see section 2.8).

4.3. FATE AND BEHAVIOUR IN AIR

Laboratory study on the volatilisation of chloridazon after application on soil and plant surfaces indicated that volatilisation of the active substance under field conditions is considered to be negligible. A half-life of less than 7 hours for the photochemical transformation of chloridazon in air has been estimated with the Atkinson method. Long range transport and deposition may be considered negligible.

5. Ecotoxicology

Chloridazon was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 03) in September 2006. The ecotoxicological relevance of impurities #4, #9 and #10 were discussed. It was noted that impurities #9 and #10 are not present in relevant concentrations according to phys-chem criteria and were not considered further. The suggested increase of impurity #4 in the new technical specification would not lead to an increase in toxicity of more than 5times indicating equivalence of the new technical specification (assuming a 10times higher toxicity for the most sensitive organisms and that all the toxicity rests with the impurity for all other groups of aquatic organisms).

5.1. RISK TO TERRESTRIAL VERTEBRATES

The representative uses evaluated are the uses as an herbicide in beta beet in Northern and Southern Europe. Onion, shallot, garlic, flowers and nursery were also suggested as representative uses in Northern Europe.

The acute and short-term risk to birds was assessed as low for the representative uses in a first-tier risk assessment. However the long-term TERs for insectivorous and herbivorous birds and for herbivorous mammals were below the Annex VI trigger of 5. Lapwing (*Vanellus vanellus*) and grey partridge (*Perdix perdix*) were chosen as focal species to refine the long-term risk assessment. The choice of focal species was questioned during the peer review process. Since lapwing feeds

predominantly on earthworms it was unclear if the risk to small insectivorous birds would be covered by the risk assessment presented. Some member state experts suggested skylark (*Alauda arvensis*) and yellow wagtail (*Motacilla flava*) as focal species because they are smaller and their diet consists to a greater extend of arthropods compared to lapwing. The meeting concluded that more information is required to justify the choice of lapwing as a focal species. A data gap was identified by the meeting to submit information on the abundance of insects in the treated area in the context of the feeding behaviour of insectivorous birds. If the abundance of insects is below a certain threshold, then the treated area would not be an attractive feeding habitat for small insectivorous birds and the choice of lapwing as a focal species would be supported. The refined long-term risk assessment for lapwings was based on the assumption that 40% of the prey was taken in the off-field areas. This was rejected by the meeting since no information was provided to quantify this assumption and a data gap was identified by the meeting. The refinement based on measured residues was accepted by the meeting. The PT value of 0.25 used to refine the long-term risk for grey partridge was questioned during the peer-review. The information provided suggests that grey partridge avoids beet fields if other structures/fields are available which gave rise to concerns with regard to the appropriateness of grey partridge as a focal species. The RMS considered the PT of 0.25 as a realistic estimate based on the assumption that partridges spend half of the time in off-crop areas and that the crop area consists to 50% of sugar beet fields. However the data do not allow a robust estimate of PT for individual birds and include assumptions on a certain structure/composition of the agricultural landscape. Hence the risk to individual birds may be underestimated for individual birds and also if the agricultural landscape consists of larger beet fields with lower proportion of attractive alternative habitats.
No risk assessment was conducted for uptake of contaminated drinking water and no argumentation was provided if exposure of birds and mammals via this route can be excluded. A first-tier risk assessment based on the guidance document SANCO 4145/2000 would result in acute TERs below the trigger of 10 and hence needs to be addressed further. (data gap).

The risk from secondary poisoning and bioaccumulation is considered to be low since the log Pow of chloridazon is < 3.

The acute and long-term TERs for herbivorous mammals were below the Annex VI trigger values. The refinement based on measured residues and the choice of hare as a focal species was agreed by the meeting.

Overall it is concluded that a high long-term risk to birds cannot be excluded for the representative uses evaluated.

5.2. RISK TO AQUATIC ORGANISMS

Algae were the most sensitive group of aquatic organisms tested. The EbC_{50} for algae of 0.6 mg chloridazon/L was driving the risk assessment. The original risk assessment in the DAR was questioned during the peer-review process. The new aquatic risk assessment presented in the addendum 2 of August 2006 was discussed and accepted by the meeting of experts. Studies with

chloridazon formulated as BAS 119 33H suggest that the toxicity to aquatic organisms was not increased in the formulation. The TERs based on FOCUS step2 PECsw for all aquatic organisms were above the Annex VI triggers except for algae. In 4 out of 5 FOCUS step 3 scenarios the calculated PECsw resulted in TERs above the trigger of 10 for the use in beet and in 5 out of 7 FOCUS step 3 scenarios for the use in bulb vegetables (onion, shallot, garlic). The trigger of 10 was breached in some of the run-off scenarios (R3 for the use in beet, R3 and R4 for the use in bulb vegetables). Therefore the risk to aquatic organisms needs to be addressed further in Member States where run-off is a relevant route of entry into surface water.

The metabolites B (major metabolite in water) and B1 (metabolite in groundwater) were of low toxicity to aquatic invertebrates and more than 2 orders of magnitude less toxic to algae compared to chloridazon. The TERs were above the trigger for metabolite B based on FOCUS step 1 PECsw indicating a low risk to aquatic organisms. The groundwater metabolite B1 can reach surface water via inflow of groundwater. If the endpoint of 18.6 mg B1/L is compared to the maximum concentration in groundwater of 25.9 µg/L then the resulting TER is 718 suggesting a low risk to algae.

Information was required regarding the evaluation of the validity criterion biomass increase for the studies with the metabolites B and B-1 and algae. New information was submitted prior to the experts meeting. The data requirement was considered fulfilled for metabolite B but the data requirement remained open for metabolite B-1. Further explanations were submitted after the expert meeting. The RMS considered the explanations as sufficient and a summary of the evaluation was included in addendum 5 (not peer reviewed).

5.3. RISK TO BEES

Technical chloridazon and formulated as BAS 11933 H is of low toxicity to bees (acute oral and contact LD_{50} > 200 µg/bee. The HQ values were calculated as 13 for oral and contact exposure. Overall it is concluded that the risk to bees is low for the representative uses evaluated.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Chloridazon is of low toxicity to non-target arthropods. The LR_{50} values for the indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* were 4000 g BAS 11933 H/ha and >4000 g BAS 11933 H/ha, respectively. The in-field and off-field HQ values were below the trigger of 2 indicating a low risk to non-target arthropods from the representative uses evaluated. Exteneded Laboratory studies with *Chrysoperla carnea*, *Aleochara bilineata* and *Pardosa spp*. were submitted in addition to the standard laboratory tests. The extended lab tests confirmed that the risk to non-target arthropods is low.

5.5. RISK TO EARTHWORMS

The acute toxicity of technical and formulated chloridazon, metabolite B and B1 to earthworms is low. A long-term (reproduction) study was conducted with the soil metabolite B. The acute and long-term TERs based on initial peak soil concentrations resulted in TERs above the trigger of 10 and 5

respectively. It was discussed during the expert meeting whether a long-term study with chloridazon or the lead-formulation is required. The experts concluded that no long-term study is required given the low acute risk of chloridazon, the low long-term risk of metabolite B and that the DT_{90} of chloridazon is less than 1 year. Overall the risk to earthworms was considered to be low for the representative uses evaluated.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

Since the DT_{90} is <365 days and the risk to non-target arthropods and earthworms was assessed as low no further studies with chloridazon and other soil non-target organisms are required.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25% on soil respiration and nitrification were observed in studies with chloridazon and the metabolites B and B1 at concentrations of up to 40 mg BAS 11933 H /kg (equivalent to an application rates of 30 kg BAS119 33 H/ha) and 8.53 mg metabolite B/kg and 1.75 mg metabolite B-1/kg (equivalent to application rates of 6.4 and 1.3 kg/ha). Therefore it is concluded that the risk to soil micro-organisms is low for the representative uses evaluated.

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

The ER_{50} (plant weight) values for spray applications of BAS 119 33 H were >3924 g chloridazon/ha for pea, sunflower, flax, onion and oat. The ER_{50} was 3127 g chloridazon/ha except for oilseed rape. Tests where the formulation was incorporated into soil resulted in lower endpoints. However incorporation into soil is not a relevant exposure route for non-target plants in the off-field area and therefore the test results form these studies were not considered in the risk assessment. The TERs for exposure at 1m distance (43.5 g chloridazon/ha) from the sprayed field were above the trigger of 5 indicating a low risk to non-target plants. The metabolites B and B1 showed no herbicidal acitivity in tests with 7 dicotyl and 1 monocotyl plant species.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No inhibitory effects were observed on oxygen consumption of activated sludge at a concentration of 500 mg chloridazon/L. It is not expected that chloridazon would enter sewage treatment plants at higher concentrations than 500 mg/L if applied according to the GAP. Therefore the risk to biological methods of sewage treatment is considered to be low for the representative uses evaluated.

6. Residue definitions

Soil

Definitions for risk assessment: chloridazon, metabolite B[7], metabolite B-1[8]

Definitions for monitoring: chloridazon

[7] B: 5-amino-4-chloro-3(2H)-pyridazinone

[8] B-1: 5-amino-4-chloro-2-methyl-3(2H)-pyridazinone

Water

Ground water

Definitions for exposure assessment: chloridazon, metabolite B, metabolite B-1

Definitions for monitoring: chloridazon. Member States who wish to monitor groundwater concentrations of metabolites against a 10 µg/L level[9] should include metabolite B.

Surface water

Definitions for risk assessment: chloridazon, metabolite B

Definitions for monitoring: chloridazon

Sediment

Definitions for risk assessment: chloridazon

Definitions for monitoring: chloridazon

Air

Definitions for risk assessment: chloridazon

Definitions for monitoring: chloridazon

Food of plant origin

Definitions for risk assessment: sum of chloridazon, 5-amino-4-chloropyridazin-3(2H)-one and their conjugates, expressed as chloridazon

Definitions for monitoring: sum of chloridazon and 5-amino-4-chloropyridazin-3(2H)-one, expressed as chloridazon

Food of animal origin

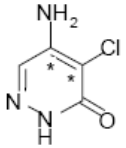
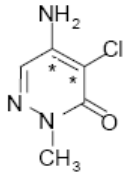
Definitions for risk assessment: sum of chloridazon and 5-amino-4-chloropyridazin-3(2H)-one, expressed as chloridazon

Definitions for monitoring: 5-amino-4-chloropyridazin-3(2H)-one, expressed as chloridazon

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (Sanco/221/2000 – rev. 10- final).

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
chloridazon	low to high persistence (first order $DT_{50\ lab}$ = 8.6-173.9 d, 20°C and pF2 soil moisture); (first order $DT_{50\ field}$ in Europe and US = 6-55 d, 20°C and pF2 soil moisture)	The risk to earthworms and soil micro-organisms were assessed as low.
metabolite B 	medium to high persistence (best fit $DT_{50\ lab}$ = 92.9-128.7 d, 20°C and pF2 soil moisture)	The acute and long-term risk to earthworms and the risk to soil micro-organisms were assessed as low
metabolite B-1 	high persistence (best fit $DT_{50\ lab}$ = 131-176.8 d, 20°C and pF2 soil moisture)	The acute risk to earthworms and the risk to soil micro-organisms were assessed as low.

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
chloridazon	medium to high mobile (K_{foc} = 89-340 mL/g)	FOCUS-PELMO 3.3.2: no Lysimeter: no	Yes	Yes	Yes
metabolite B	high to very high mobile (K_{foc} = 29-74 mL/g)	FOCUS-PELMO 3.3.2: yes, all 9 pertinent FOCUS groundwater scenarios (concentrations 0.38-14.35 µg/L after application every third year) Lysimeter: yes (max annual average concentrations: 2.13-40.6 µg/L)	No	No	Less toxic to aquatic organisms compared to chloridazon.
metabolite B-1	medium to very high mobile (K_{foc} = 27-216 mL/g)	FOCUS-PELMO 3.3.2: yes, all 9 pertinent FOCUS groundwater scenarios (concentrations 2.5-8.13 µg/L after application every third year) Lysimeter: yes (max annual average concentrations: 0.1-2.1 µg/L)	No	No	Less toxic to aquatic organisms compared to chloridazon

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
chloridazon (water and sediment)	See 5.2.
metabolite B (only water)	Less toxic to aquatic organisms compared to chloridazon, low risk to aquatic organisms
metabolite B-1 (when groundwater becomes surface water)	Less toxic to aquatic organisms compared to chloridazon, low risk to aquatic organisms

Air

Compound (name and/or code)	Toxicology
chloridazon	Not acutely toxic by inhalation in rats (LC_{50} >5.4 mg/L)

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

- Further justification e.g. quality control data to support the specification for impurities that are included in the specification but were not found above 1 g/kg in the batch analysis (relevant for all uses evaluated; data gap identified by PRAPeR 01 (September 2006); date of submission unknown)
- Field residue studies in rotational crops (other than cereals, root and tuber crops) for appropriate MRL setting and withdrawal of the label restriction (relevant for all representative uses evaluated; data gap identified by the expert meeting; no submission date proposed; refer to point 3.2)
- Information on the abundance of insects in the treated area in the context of the feeding behaviour of insectivorous birds is required to support choosing lapwing (*Vanellus vanellus*) as a focal species instead of a small insectivorous bird. (relevant for all representative uses; data gap identified by PRAPeR 03 (September 2006); no submission date proposed; refer to point 5.1.)
- The assumption that 40% of the prey of lapwings was taken in the off-field areas needs to be supported by data. (relevant for all representative uses evaluated; data gap identified by PRAPeR 03 (September 2006); no submission date proposed; refer to point 5.1.)
- A risk assessment for uptake of contaminated drinking water (relevant for all representative uses evaluated; data gap identified by EFSA after the expert meeting PRAPeR 03 (September 2006); no submission date proposed; refer to point 5.1.)
- Information on the evaluation of the validity criterion biomass increase for the study with the metabolite B1 from Reuschenbach P. 1999 (relevant for all representative uses evaluated; Data requirement identified by the RMS and confirmed by PRAPeR 03 (September 2006); information submitted and included in addendum 5; RMS considered the information as sufficient; not peer reviewed; refer to point 5.2.)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprises spraying applications between pre seeding respective pre-emergence up to crop growth stage BBCH 19 to control important annual broad-leaved weeds in beta beet, onion, shallot, garlic, flowers and nursery in Nothern Europe and beta beet in Southern Europe, at application rates max. 2.6 kg chloridazon per hectare.

The representative formulated product for the evaluation was "Pyramin WG", a water dispersible granule (WG), registered under different trade names in Europe. The formulation contains 650 g/kg pure chloridazon.

Adequate methods are available to monitor all compounds given in the respective residue definition.

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.

Chloridazon is of low acute oral, dermal and inhalation toxicity, is not a skin or eye irritant, and is not a skin sensitizer. In addition with a dose-related effect on body weight, the target organs in the short term studies were the liver in rats, mice and dogs, the kidney and the gastric mucosa in dogs at very high dose levels. Chloridazon has no genotoxic properties, and is not oncogenic in rats or mice. No teratogenic properties or effects on fertility parameters were observed. The agreed ADI is 0.1 mg/kg bw/day based on the rat long term study, the agreed AOEL is 0.2 mg/kg bw/day based on the 90-day rat study supported by the long term and the multigeneration rat studies. An ARfD was not considered necessary. The dermal absorption value is 4% both for the diluted and undiluted product.
The estimated operator exposure is below the AOEL (63%) according to the German model without the use of PPE. Estimates with the UK POEM model are below the AOEL only when gloves and RPE are worn during mixing/loading, and gloves used during application.

In root crops chloridazon is metabolised through cleavage of the phenyl ring, leading to metabolite B (5-amino-4-chloropyridazin-3(2H)-one). This metabolite is generally present in mature commodities at higher levels than those of the parent compound. The proposed residue definition for monitoring is the sum of both compounds. Their conjugates need to be considered for risk assessment. MRLs ranging from 0.2 to 3 mg chloridazon/kg are proposed for crops selected as representative uses.
Following uptake from the soil by rotational crops, residues of the parent compound and its metabolite B may be present at quantifiable levels in foliar plant parts. Only cereals, root or tuber crops are possible to be grown as rotational crops with residues below the limit of quantification in their parts used for human consumption. Residue trials under field conditions would be necessary to set MRLs on other potential rotational crops.
A transfer of residues of metabolite B to animal commodities is possible up to 0.1 mg/kg in the case of ruminants fed with feed items produced from treated sugar beets or (rotational) cereal fodder or straw.
The risk assessment based on the representative uses did not show any concern for the consumer, even considering the possible use as drinking water of groundwater containing residues of metabolites B and B1.

Sufficient data are available to assess the route and rate of degradation of chloridazon in soil, surface water and associated sediment and air. For the representative uses parent chloridazon would not be expected to leach to groundwater above 0.1 µg/L. Whilst the identified metabolites B and B-1 would be expected to exceed 0.75 µg/L in vulnerable groundwater situations (max. 17 µg/L in Hamburg FOCUS scenario for metabolite B, and max. 8.13 µg/L in Jokioinen FOCUS scenario for metabolite B-1), data are available to conclude that they are not of toxicological relevance.

The acute and short-term risk to birds was assessed as low for the representative uses in a first-tier risk assessment. However the long-term TERs for insectivorous and herbivorous birds and for herbivorous mammals were below the Annex VI trigger of 5. The refined risk assessment based on focal species, PT and PD refinement was discussed in the expert meeting and data gaps were identified to justify the suggested refinements (e.g. focal species lapwing and grey partridge and PT values). On the basis of the available information a high long-term risk to birds cannot be excluded. The refined long-term risk assessment for mammals based on measured residues and hare as a focal species was accepted by the expert meeting. The risk to aquatic organisms was assessed as low except for algae where some of the run-off scenarios (R3 use in beet, R3 and R4 use in bulb vegetables) resulted in FOCUS step3 PECsw leading to TERs below the trigger of 10. Member States in which run-off is an important route of entry into surface water need to consider the risk to aquatic organisms further. The risk from the metabolites B and B1 to aquatic organisms was assessed as low. The risk to bees, other non-target arthropods, earthworms, soil non-target micro-organisms and biological methods of sewage treatment were assessed as low for the representative uses evaluated.

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

- None

Critical areas of concern

- Non relevant metabolite B showed the potential to leach to groundwater above a level of 10 µg/L under European geoclimatic conditions represented by 5 out of 9 FOCUS groundwater scenarios (see appendix 1 for details).

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

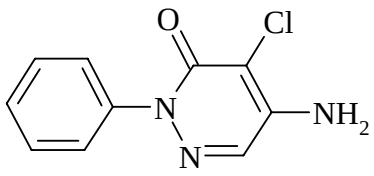
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Chloridazon
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	Germany
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	5-amino-4-chloro-2-phenylpyridazin-3(2H)-one
Chemical name (CA) ‡	5-amino-4-chloro-2-phenyl-3(2*H*)-pyridazinone
CIPAC No ‡	111
CAS No ‡	1698-60-8
EC No (EINECS or ELINCS) ‡	216-920-2
FAO Specification (including year of publication) ‡	910 g/kg (minimum purity) (AGP:CP/346, 1997) max 60 g/kg 4-amino-5-chloro-isomer max 20 g/kg water
Minimum purity of the active substance as manufactured ‡	920 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	4-amino-5-chloro-isomer max. 60 g/kg
Molecular formula ‡	$C_{10}H_8ClN_3O$
Molecular mass ‡	221.6 g/mol
Structural formula ‡	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	205.9 – 206.8 °C (99.9 %)
Boiling point (state purity) ‡	No boiling point < 360 °C
Temperature of decomposition (state purity)	> 360 °C (99.9 %)
Appearance (state purity) ‡	Crystalline, colourless solid (99.9 %) light yellow-brown solid (93.0 %)
Vapour pressure (state temperature, state purity) ‡	$1 \cdot 10^{-9}$ Pa at 20 °C (based on calculation)
Henry's law constant ‡	$5.3 \cdot 10^{-10}$ Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	0.410 g/L at 20 °C (pH 4) (99.9 %) 0.422 g/L at 20 °C (pH 7) (99.9 %) 0.422 g/L at 20 °C (deionised water) (99.9 %))
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (99.8 %) Methanol 15.1 Acetone 12.4 Acetonitrile 8.4 Isopropanol 5.4 Ethylacetate 3.7 Octanol 3.1 Dichloromethane 1.9 Toluene 0.1
Surface tension ‡ (state concentration and temperature, state purity)	71.7 mN/m at 20 °C (0.5 % w/w) (99.9 %) 72.1 mN/m at 20 °C (1.0 % w/w) (99.9 %)
Partition co-efficient ‡ (state temperature, pH and purity)	1.2 at 25 °C (high purity solvent grade water) (98.8 % radio purity
Dissociation constant (state purity) ‡	No dissociation takes place in water.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	10.89 mg/L methanol solution λ_{max} (nm) ε ($L.mol^{-1}.cm^{-1}$) 210 18577 229 25043 286 10088
Flammability ‡ (state purity)	None
Explosive properties ‡ (state purity)	None
Oxidising properties ‡ (state purity)	None

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of representative uses evaluated (Chloridazon)*

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)	kg a.s./hL min - max (l)	water L/ha min - max	kg a.s./ha min - max (l)		
Beta beet, onion, shallot, garlic, flowers and nursery	Northern Europe	Pyramin WG	F	Weeds (general) up to BBCH 14-16	WG	650	Hydraulic sprayer overall	Pre-seeding Pre-emergence Post emer-gence up to BBCH 19	1 1 3 (split appli-cation)	Not fixed, because the interval is chosen according to local infestation levels	1.3 0.975 0.325	200-400	max. 2.6 1.95 0.650	1) 1) 1)	supported under the provision: max. of 2.6 kg/ha only every third year on the same field
Beta beet	Southern Europe	Pyramin WG	F	Weeds (general) up to BBCH 14-16	WG	650	Hydraulic sprayer overall	Pre-seeding Pre-emergence Post emer-gence up to BBCH 19	1	-	1.3	200-300	max. 2.6	1)	supported under the provision: max. of 2.6 kg/ha only every third year on the same field

* 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 / [1]) PHI covered by conditions of use

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV
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		Chloridazon and metabolite B, expressed as chloridazon equivalents (chloridazon = 5-amino-4-chloro-2-phenylpyridazin-3(2H)-one metabolite B = 4-amino-5-chloropyridazone)
Food of animal origin		Metabolite B, expressed as chloridazon
Soil		Chloridazon
Water	surface	Chloridazon
	drinking/ground	Chloridazon
Air		Chloridazon

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS; 0.1 mg/kg (all kinds of crops)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS; 0.01 mg/kg (bovine milk) HPLC-MS/MS; 0.05 mg/kg (bovine muscle, liver, kidney, fat, hen egg)
Soil (analytical technique and LOQ)	HPLC-DAD; 0.01 mg/kg
Water (analytical technique and LOQ)	Surface water: HPLC-DAD; 0.05µg/L Drinking/ground water: HPLC-DAD; 0.05µg/L
Air (analytical technique and LOQ)	HPLC-UV; 3 µg/m³
Body fluids and tissues (analytical technique and LOQ)	Not relevant

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

	RMS/peer review proposal
Active substance	None

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid and nearly complete (> 90 %) oral absorption in rats
Distribution ‡	Initially widely, highest concentrations after 72 h in heart and adrenals
Potential for accumulation ‡	Low
Rate and extent of excretion ‡	85-90 % via urine, 7-26 % via faeces within 72 h (biliary excretion 37 % in males, 12 % in females)
Metabolism in animals ‡	Rapid, extensive, primarily by oxidation, hydroxylation and conjugation to glucoronide and sulfate, 3 major metabolites in urine (of at least 9 metabolites)
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound, soil and plant metabolites B and B-1
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	2140 mg/kg bw (females)[10]	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.4 mg/L air (4 h, nose only)	
Skin irritation ‡	Not irritant	
Eye irritation ‡	Not irritant	
Skin sensitisation ‡	Not sensitising (M&K test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Body weight gain↓ (all species), liver in rodents (increased organ weight, histological findings, changes in clinical chemistry parameters)	
Relevant oral NOAEL ‡	21 mg/kg bw/day (90-day rat) 99 mg/kg bw/day (12-month dog)	
Relevant dermal NOAEL ‡	1000 mg/kg bw/day (21-day rabbit)	
Relevant inhalation NOAEL ‡	Not submitted, not necessary	

[10] Isomer reduced compound produced since about 1985

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Genotoxicity ‡ (Annex IIA, point 5.4)

…….	Overall, no genotoxic potential	

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

Target/critical effect ‡	Reduced body weight and changes in haematological and clinical chemistry parameters in rats and mice; skeletal muscle atrophy in rats; liver (organ weight↑)	
Relevant NOAEL ‡	13 mg/kg bw/day (25/30-month rat) 134 mg/kg bw/day (24-month mouse)	
Carcinogenicity ‡	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Impaired bw gain in pups at parentally toxic doses (rat 2-generation)	
Relevant parental NOAEL ‡	37 mg/kg bw/day	
Relevant reproductive NOAEL ‡	148 mg/kg bw/day	
Relevant offspring NOAEL ‡	37 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	No foetotoxic or teratogenic potential	
Relevant maternal NOAEL ‡	50 mg/kg bw/day (rat) 55 mg/kg bw/day (rabbit)	
Relevant developmental NOAEL ‡	250 mg/kg bw/day (rat) 495 mg/kg bw/day (rabbit)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No studies provided and required as other toxicological studies demonstrated no evidence of neurotoxic potential.	
Repeated neurotoxicity ‡	No studies provided and required as other toxicological studies demonstrated no evidence of neurotoxic potential.	
Delayed neurotoxicity ‡	Chloridazon does not belong to chemical classes which are known to induce this effect.	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Not required
Studies performed on metabolites or impurities ‡	**Metabolites are toxicologically not relevant.** **Metabolite B:** Acute tox., rat: LD_{50} > 5000 mg/kg bw 90 days, rat: NOAEL 15 mg/kg bw/d (200 ppm) No evidence of mutagenicity *in vitro* (Ames test, V79/HPRT test, cytogenetics) Developmental tox. in rats: maternal NOAEL 60 mg/kg bw/d, developmental NOAEL 120 mg/kg bw/d **Metabolite B-1:** Acute tox., rat: LD_{50} 1200 mg/kg bw 90 days, rat: NOAEL > 50 mg/kg bw/d No evidence of mutagenicity *in vitro* (Ames test, CHO/HPRT, cytogenetics) and *in vivo* (bone marrow cytogenetics) Developmental tox. in rats: maternal and developmental NOAEL 10 mg/kg bw **Impurity #4:** Acute tox., rat: LD_{50} > 5000 mg/kg bw Severe damage to eye, sensitising 28 days, rat: NOAEL: 94 mg/kg bw/d (1000 ppm) Some *in vitro* positive (cytogenetics) and negative (Ames test) results, but *in vivo* (bone marrow cytogenetics) negative; overall no evidence for genotoxic potential.

Medical data ‡ (Annex IIA, point 5.9)

……..	Skin/eye irritation (few cases) and sensitisation (one confirmed case) reported

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.1 mg/kg bw	2-yr rat	100
AOEL ‡	0.2 mg/kg bw/day	90 days rat, supported by 2-yr rat and multigen. rat	100
ARfD ‡	Not allocated (low acute toxicity and no other relevant acute effects identified from repeat dose studies)		

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (BAS 119 50 H)	4 % (rat *in vivo*, 10 h exposure; including skin residues) for the concentrate and the dilution

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**German model**, tractor mounted equipment (exposure estimates in % of AOEL)		
	No PPE	Gloves m/l*	
	63	34	
	UK model (exposure estimates in % of AOEL)		
	No PPE	Gloves m/l+appl	Gloves m/l+appl., RPE m/l
	696	299	63
Workers	Variable assumptions: ~ 5.9 % of the AOEL; no PPE		
Bystanders	Variable assumptions: ~ 0.76 % of the AOEL		

*) m/l: mixing/loading

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

	RMS/peer review proposal
Substance classified (chloridazon)	None

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4: Residues

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

Plant groups covered	Root vegetables (sugar beets) and leafy vegetables (considering data on chard from metabolism in rotational crops)
Rotational crops	Chard, sugar beet, oat, wheat and sorghum
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Pressed pulp, pressed water, raw juice, thin juice, mud, thick juice, raw sugar, molasses, affination syrup, white sugar
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring	Sum of chloridazon and metabolite B (5-amino-4-chloropyridazin-3(2H)-one), expressed as chloridazon equivalents
Plant residue definition for risk assessment	Sum of chloridazon, metabolite B (5-amino-4-chloropyridazin-3(2H)-one) and their conjugates, expressed as chloridazon
Conversion factor (monitoring to risk assessment)	Not possible to determine

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

Animals covered	Lactating goat, laying hen
Time needed to reach a plateau concentration in milk and eggs	1 week
Animal residue definition for monitoring	Metabolite B (5-amino-4-chloropyridazin-3(2H)-one), expressed as chloridazon
Animal residue definition for risk assessment	Sum of chloridazon and metabolite B (5-amino-4-chloropyridazin-3(2H)-one), expressed as chloridazon equivalents
Conversion factor (monitoring to risk assessment)	1
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

……..…….….	Field rotational crops studies show residues of chloridazon and/or metabolite B present above the LOQ (0.05 mg/kg) in spinach, carrot tops, cauliflower (whole plant) and wheat straw and below the LOQ in potatoes, carrot roots, cauliflower head and cereal grains under practical conditions.

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

……..…….	Sugar beet root, sugar beet top, refined sugar, molasses, dried pulp <24 months

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)	0.75 mg/kg chloridazon 4.4 mg/kg met B	0.12 mg/kg chloridazon 0.16 mg/kg met B	0.36 mg/kg chloridazon 1.2 mg/kg met B
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	No	Yes
	Feeding studies (1.5/3.5 mg/kg chloridazon/metabolite B) Residue levels in matrices :		
	chloridazon/ metabolite B (mg/kg)	Not necessary	Not submitted
Muscle	< 0.3/< 0.1	-	-
Liver	< 0.3/< 0.1	-	-
Kidney	< 0.3/< 0.1	-	-
Fat	< 0.3/< 0.1	-	-
Milk	<0.1/0.06-0.08		
Eggs		-	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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)
Sugar beet, fodder beet	North	Roots: <0.13(7), 0.13(3), 0.14, 0.16, 0.18, 0.2 mg/kg chloridazon/metabolite A + metabolite B, calculated as chloridazon leaves and tops: 0.16, 0.24, 0.24, 0.38, 0.39, 0.4, 0.51, 0.51, 0.52, 0.6, 0.63, 0.69, 0.78, 0.78 mg/kg chloridazon/metabolite A + metabolite B, calculated as chloridazon		0.3 mg/kg	0.2 mg/kg	0.13 mg/kg
	South	Roots: <0.13(6), 0.13(4) mg/kg chloridazon/metabolite A + metabolite B, calculated as chloridazon leaves and tops: <0.13, <0.13, 0.16, 0.21, 0.21, 0.31, 0.32, 0.64, 0.65, 0.84 mg/kg chloridazon/metabolite A + metabolite B, calculated as chloridazon				

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1 – list of end points

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)
Beetroot, beta beet	North	Roots: <0.13, 0.14, 0.16(3), 0.19 mg/kg chloridazon + metabolite A + metabolite B, expressed as chloridazon		0.5 mg/kg	0.19 mg/kg	0.16 mg/kg
		Leaves: 0.62, 0.76, 0.86, 1.2, 1.4, 1.5 mg/kg chloridazon/metabolite A + metabolite B, calculated as chloridazon	Data used for chard	3 mg/kg	1.5 mg/kg	1.03 mg/kg
Onion, shallot, garlic	North	<0.13(4) mg/kg chloridazon/metabolite A + metabolite B, calculated as chloridazon <0.13(3), 0.14 mg/kg chloridazon + metabolite B, calculated as chloridazon		0.2 mg/kg	0.14 mg/kg	0.13 mg/kg

[1]: chloridazon/metabolite A + metabolite B, calculated as chloridazon
[2]: Sum of chloridazon, metabolite A and metabolite B, all expressed as chloridazon
(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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

ADI	0.1 mg/kg bw
TMDI (% ADI) according to WHO European diet	< 5 %
TMDI (% ADI) according to German VELS diet	< 5 %

Notes:

1) TMDI calculations need to be considered as under estimations as the contribution of metabolite B conjugates was not accounted for. Nevertheless, given information available from metabolism studies, their amount are not expected to be sufficient to increase TMDI values above the ADI.

2) No contribution from rotational crops are included in TMDI calculations.

3) The contribution of metabolites B and B1 to ADI exhaustion, due to their presence in groundwater, calculated under the worst case scenario, and according to the WHO guidelines related to drinking water quality, does not exceed 5 %.

IEDI (WHO European Diet) (% ADI)	Not necessary.
NEDI (specify diet) (% ADI)	Not necessary.
Factors included in IEDI and NEDI	Not necessary
ARfD	Not necessary
IESTI (% ARfD)	Not necessary
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not necessary
Factors included in IESTI and NESTI	-

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Thick juice, molasses	1	>1	Not relevant	Not available

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Sugar and fodder beet	0.3 mg/kg
Beetroot (red beet)	0.5 mg/kg
Onion, shallot and garlic	0.2 mg/kg
Chard	3 mg/kg
Poultry muscle, poultry fat, poultry liver, eggs	0.05* mg/kg
Beef and pork meat, ruminant and pork fat, ruminant and pork liver, ruminant and pork kidney, milk	0.1 mg/kg

* LOQ

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5: Fate and bahaviour in the Environment

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

Mineralisation after 100 days ‡	Pyridazinone-^{14}C-labelled chloridazon Sandy loam: 5.6 % AR after 120 days 18.6 % AR after 373 d (study end) Sandy clay loam: 2.2 % AR after 124 days 3.9 % AR after 367 days (study end)
Non-extractable residues after 100 days ‡	Pyridazinone-^{14}C-labelled chloridazon Sandy loam: 9.3 % AR after 120 days 12.7 % AR after 373 days (study end) Sandy clay loam: 13.3 % AR after 124 days 19.0 % AR after 367 days (study end)
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	Metabolite B (5-amino-4-chloro-pyridazine-3-one): increasing during the study 13.8 - 16.9 % AR after 120 days max. 55.9 % AR after 373 days (study end) (^{14}C-chloridazon, 25 °C, 75 % field capacity, soil: % sand/silt/clay 54/32/14 and 67/9/24) Metabolite B-1 (5-amino-4-chloro-2-methylpyridazine-3-one) was not analysed in metabolism studies, but detected in rate study with metabolite B and in lysimeter leachate.

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

Anaerobic degradation ‡

Mineralisation after 100 days	Chloridazon (tested: 14C-chloridazon):	
	Sandy clay loam	Sandy loam
Unchanged as:	81.5 % after 91 d	89.6 % after 90 d
Mineralisation:	1.2 % after 91 d	3.5 % after 90 d
Non-extractable residues after 100 days	Chloridazon (tested: 14C-chloridazon):	
	Sandy clay loam	Sandy loam
Bound residues:	9.7 % after 91 d	6.2 % after 90 d
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Chloridazon (tested: 14C-chloridazon):	
	Sandy clay loam	Sandy loam
Metabolite B:	8.8 % after 91 d	4.8 % after 90 d

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Soil photolysis ‡

…….	Soil: loamy sand, OM 1.9 %, 80 % sand, 13 % silt, 6.7 % clay After 15 d (% TAR 14C-chloridazon): 57 %- 61 % chloridazon remained; Mineralisation 13 % - 14 %; bound residues 6 %; no metabolites > 5 % TAR

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

Laboratory studies ‡

Parent Chloridazon	Aerobic conditions						
Soil type	X[11]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy clay loam	-	7.7	25 °C / 75 %	187.6 / -	173.9	0,98	DT_{50}: Model maker Version 4.0
Sandy loam	-	5.9	25 °C / 75 %	154.9 / -	157.1	0,96	DT_{50}: Model maker Version 4.0
Loam	-	7.2	20 °C / 40 %	10.7 / 50	9.0	0.98	DT_{50}: Model maker Version 4.0 DT_{90}: Timme and Frese best fit
Loamy sand	-	6.7	20 °C / 40 %	8.6 / 54	8.6	0.96	DT_{50}: Model maker Version 4.0 DT_{90}: Timme and Frese best fit
Clay	-	7.4	20 °C / 40 %	82.1 / > 100	40.6	0.97	DT_{50}: Model maker Version 4.0 DT_{90}: Timme and Frese best fit
Loamy sand	-	5.6	20 °C / 40 %	43 / 140	75.1	0.95	DT_{50}: Model maker Version 4.0 DT_{90}: Timme and Frese best fit
Geometric mean/median					43.1 / 57.9		
	-	-	10 °C	-	18.9 – 382.6-	-	Calculated by RMS with Q10 (2.2) from above-quoted pF2 normalised 20 °C DT_{50} values

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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Met B	Aerobic conditions							
Soil type	X1	pH	t. oC / % MWHC	DT_{50}/ DT_{90} (d)	f. f. kdp /kf	DT_{50} (d) 20 °C pF2/10kPa	St. (r2)	Method of calculation
Sandy loam Limburgerhof	-	-	20 °C/40 %	80/>120*	-	92.9	0.97	ModelMaker 3.0.4, best fit
Loamy sand Limburgerhof	-	-	20 °C/40 %	93/>120*	-	97.3	0.94	ModelMaker 3.0.4, best fit
Sandy loam LUFA 2.3	-	-	20 °C/40 %	132/>120*	-	116.9	0.79	ModelMaker 3.0.4, best fit
Loamy sand LUFA 2.2	-	-	20 °C/40 %	120/>120*	-	128.7	0.95	ModelMaker 3.0.4, best fit
Geometric mean/median						108.0 / 107.1		
Met B 1	Aerobic conditions							
Soil type	X1	pH	t. oC / % MWHC	DT_{50}/ DT_{90} (d)	f. f. kdp /kf	DT_{50} (d) 20 °C pF2/10kPa	St. (r2)	Method of calculation
Sandy loam Limburgerhof	-	-	20 °C/40 %	135/>120*	-	139.5	0.97	ModelMaker 3.0.4, best fit
Loamy sand Limburgerhof	-	-	20 °C/40 %	118/>120*	-	131	0.95	ModelMaker 3.0.4, best fit
Sandy loam LUFA 2.3	-	-	20 °C/40 %	152/>120*	-	135.4	0.84	ModelMaker 3.0.4, best fit
Loamy sand LUFA 2.2	-	-	20 °C/40 %	170/>120*	-	176.8	0.94	ModelMaker 3.0.4, best fit
Geometric mean/median				-		144.6 / 137.5		

* DT_{90} values greater than 2 times study duration and therefore considered to be beyond the period of reliable extrapolation.

Field studies ‡

Parent Chloridazon	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X^1	pH	Depth (cm)	DT_{50} (d) actual[4]	DT_{90}(d) actual	St. (r^2)	DT_{50}/ DT_{90} (d) Norm.[3]	Method of calculation
Silty sand (bare soil)	Sweden		6	-	79	214	0.85	16 / 54	Model Maker 3.0.4, 1st order kinetic

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Field studies ‡

Parent Chloridazon	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual[4]	DT_{90}(d) actual	St. (r^2)	DT_{50}/ DT_{90} (d) Norm.[3]	Method of calculation
Sandy loam (bare soil)	Germany		6.5	-	16	54	0.94	6 / 19	Model Maker 3.0.4, 1st order kinetic
Clayey sand (bare soil)	Germany		4.6	-	69	230	0.96	55 / 184	Model Maker 3.0.4, 1st order kinetic
Heavy loam sand (bare soil)	Germany		5.1	-	13	44	0.86	10 / 32.4	Model Maker 3.0.4, 1st order kinetic
Loam (bare soil)	Germany		7.1	-	17	57	0.90	16 / 53[1]	Model Maker 3.0.4, 1st order kinetic
Loam (bare soil)	Germany		6.8	-	14	47	0.89	3 / 9[1]	Model Maker 3.0.4, 1st order kinetic
Clay (pre-emergence, sugar beet)	USA		7.3	-	94	313	0.77	105 / 349[1]	Model Maker 3.0.4, 1st order kinetic
Sandy loam (pre-emergence, sugar beet)	USA		6.6	-	59	195	0.83	42 / 138	Model Maker 3.0.4, 1st order kinetic
Sandy loam (bare soil)	Italy		6.5	-	17	56	0.89	20 / 67	Model Maker 3.0.4, 1st order kinetic
Clay silt loam (bare soil)	Spain		8.1	-	30	100	0.89	22 / 73	Model Maker 3.0.4, 1st order kinetic
Geometric mean								19 / 63[2]	

[1)] no reliable results (below minimum data points or low coefficient of determination)
[2)] data for DT_{50} values, n = 7, values marked with [1] were not included
[3)] Half-lives were calculated on the basis of the normalised degradation rate constants.
[4)] 1st order kinetic, Model Maker 3.0.4 (Sweden, Italy, Spain) or 4.0 (others); calculated by RMS

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Based on degradation studies, no accumulation expected

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Laboratory studies ‡

Parent Chloridazon	Anaerobic conditions						
Soil type	X[12]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy clay		-	25 °C	370	-	-	Regression analysis
Sandy loam		-	25 °C	607	-	-	Regression analysis
Geometric mean/median							

Met 1	Anaerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median								

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent chloridazon							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sandy loam	-	-	-	-	0.2	89	0.568
Sandy loam	-	-	-	-	0.69	128	0.914
Sand	-	-	-	-	0.25	220	1.030
Silty loam	-	-	-	-	1.0	220	0.836
Clay	-	-	-	-	3.6	340	0.877
Arithmetic mean/median					-	199	0.845
pH dependence, Yes or No			no pH dependency				

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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolite B ‡							
Soil Type (% particels < 0.02 mm)	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
- (10.7)	0.7	7.0	-	-	0.34	49	0.804
- (23.2)	0.9	7.3	-	-	0.42	46	0.819
- (40.0)	0.6	7.3	-	-	0.43	74	0.844
- (14.9)	2.4	6.0	-	-	0.71	29	0.868
Arithmetic mean/median						50	0.834
pH dependence (yes or no)			no pH dependency				
Metabolite B 1 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	-	-	-	-	0.40	100	0.794
Loamy sand	-	-	-	-	0.43	39	0.861
Sandy loam					0.50	33	0.851
Loam	-	-	-	-	0.68	136	0.915
Sand/loamy sand	-	-	-	-	0.68	27	0.907
Sandy clay loam	-	-	-	-	7.34	216	0.871
Arithmetic mean/median						92	0.867
pH dependence (yes or no)			no pH dependency				

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

Column leaching ‡	Eluation (mm): 200 mm irrigation Time period (d): 2 d
	Guideline: BBA Merkblatt No 37 German standard soils LUFA 2.1, 2.2, 2.3 Applied amount 2.6 kg a.s./ha, 200 mm irrigation Conc. in leachate: LUFA soil 2.1 2.2 2.3 Chloridazon 25.2 % < 0.8 % 16.2 % Metabolites not detected
Aged residues leaching ‡	Aged for (d): 30 d Time period (d): 2 d Eluation (mm): 200 mm
	14.7 % TRR (total) retained in top soil segment 1

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	Guideline: BBA IV 4-2 German standard soil LUFA 2.1 (sandy soil); soil conc. 3 mg a.s./ha, 200 mm irrigation, 30 d aerobic preincubation (22 °C, 40 % WHC) Conc. in leachate: 0.3 % of total residue radioactivity as chloridazon and metabolite B.
Lysimeter/ field leaching studies ‡	**1)** Location: Germany, Northrhine-Westfalia Study type: lysimeters, 1x silty loam (LY-TP, 0.1-6.4 % sand, 73-78 % silt, 15-27 % clay); 2 x loamy sand (LY -SPB, 50-94 % sand, 4.6-37 % silt, 1.7-13.8 % clay) Test substance: (4,5-^{14}C)chloridazon Number of applications: 1 application equiv. to 2.6 kg a.s./ha on sugar beet, pre-emergence LY-TP / LY-SPB - Average annual rainfall 1. year 773 mm 785 mm 2. year 820 mm 808 mm - Annual leachate volume (1989-1991): 1. year 113 L/m² 130 L/m² 2. year 127 L/m² 200 L/m² - % radioactivity in leachate (overall balance): % TAR 0.32 7.05 - Maximum annual average concentrations (µg/L): Chloridazon as: 0.009 µg/L <0.05 µg/L Metabolite B: 2.13 µg/L 40.6 µg/L Metabolite B-1: 0.1 µg/L 2.1 µg/L **2)** Location: Germany, Northrhine-Westfalia Study type: lysimeters, loamy sand (LY-SPB, 71-91 % sand, 5.9-25 % silt, 2.9-5.2 % clay Test substance: non-radiolabelled chloridazon Number of applications: 1 application correspond. to 1.82 kg a.s./ha on sugar beet, pre-emergence Average annual rainfall: 1st year 839.8 mm/year; 2nd year 780.3 mm/year Average annual leachate volume (1990-1992): 59.5 L 1st year, 261.2 L 2nd year Maximum annual average concentrations: Chloridazon as: <0.05 µg/L Metabolite B: 4.1 / 12.2 µg/L

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT_{50} (d): 78.5 days Chloridazon
Method of calculation	Kinetics: Compartment model, ModelMaker 4.0, all fluxes were parameterised with first order rate constants. Field or Lab: representative worst case from field studies.
Application data	Crop: Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Interval (d): - Application rate(s): 2600 g a.s./ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		3.467			
Short term	24 h	3.436	3.451	--	--
	2 d	3.406	3.435		
	4 d	3.346	3.406		
Long term	7 d	3.259	3.362	--	--
	28 d	2.707	3.071		
	50 d	2.392	2.897		
	100 d	1.434	2.303		
Plateau concentration		Not available, not required			

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolites	
Method of calculation	Compartment model, ModelMaker 4.0, covering the as and its metabolites B and B-1. Worst case first order transformation rate constants based on worst case laboratory (uncorrected) half-life of metabolite B (132 d) and worst case rate constants describing the kinetic equilibrium between the metabolite B and B-1. All fluxes were parameterised with first order rate. The molar formation fraction of metabolite B from as was 64.8 % obtained in a laboratory metabolism study. No corrections of transformation rates for temperature or soil moisture. Results include corrections for molar weight differences of the compounds. Worst case kinetic equilibrium between Metab. B and Metabolite B-1: k_{12}=0.00329 Metabolite B-1: k_{21}=0.0105
Application data	2.6 kg a.s./ha, one annual application per-emergence, 0 % crop interception, soil bulk density 1.5 kg/L, 5 cm soil layer

PEC$_{(s)}$ (mg/kg)		Metabolite B Single application Actual	Metabolite B Single application Time weighted average	Metabolite B 1 Single application Actual	Metabolite B 1 Single application Time weighted average
Initial		0.600			
Short term	24 h	0.600	0.600	0.172	0.172
	2 d	0.600	0.600	0.172	0.172
	4 d	0.600	0.600	0.172	0.172
Long term	7 d	0.600	0.600	0.172	0.172
	28 d	0.591	0.599	0.171	0.172
	50 d	0.582	0.598	0.169	0.172
	100 d	0.521	0.589	0.156	0.170
Plateau concentration Metabolite B		1.27 mg/kg after *1*yr*			

* calculated with formation fraction of metabolite B 55.9 %, DT_{50} Metabolite B: 108 d (= geometric mean of lab values; the appropriate value should be the longest lab DT_{50} value of 128.7 d), application rate 2600 g a.s./ha, soil depth 5 cm, bulk density 1.5 g/cm³

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5 25 °C: no hydrolysis occurred, chloridazon is stable over 30 days
	pH 7 25 °C: no hydrolysis occurred, chloridazon is stable over 30 days
	pH 9 25 °C: no hydrolysis occurred, chloridazon is stable over 30 days
Photolytic degradation of active substance and metabolites above 10 % ‡	Direct photolysis Chloridazon: Theoretical DT_{50} March, April, May, June: 75.6, 36.8, 25.9, 21.6 days (calculation on algorithms by Frank and Klöpper, information on quantum yield, absorption spectrum used) Metabolite B: Theoretical DT_{50} April, May, June, July, August: 8.72, 6.96, 6.25, 6.95, 7.0 days (calculation on algorithms by Frank and Klöpper, information on quantum yield, absorption spectrum used) Photolysis in natural water pH 8, TOC 12-13 mg/L, nitrate < 0.5-2 mg/L, Suntest, 15 days continuous irradiation, 22 °C:

DT_{50}	continuous irradiation	12/12 h day/night
Chloridazon:	23.3 d	46.6 d
Metabolite B:	5.9 d	11.8 d
Metabolite B-1	1.2 d	2.4 d

Quantum yield of direct phototransformation in water at Σ > 290 nm	$z \cdot 10^{-y}$ mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	No data submitted, none required

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Degradation in water / sediment

Parent Chloridazon	Distribution (details in box below)									
Water / sediment system	pH water phase	pH sed.	t. °C	DT_{50} - DT_{90} whole sys.	St. (r^2)	DT_{50} - DT_{90} water	St. (r^2)	DT_{50} / DT_{90} sed.	St. (r^2)	Method of calculation
System A "Krempe", lay loam (USDA), OC 3.6 %	8.5	6.7		-/-		57.6 / -		-/-		Model Maker 3.0.4, 1st order
				182 / > 200		76 / -		-/-		Timme and Frehse, 1st order
(water, only degradation)						108.2				Model Maker 4.0
System B "Ohlau", sand, OC 0.19 %	8.0	6.7				104.5 / -				Model Maker 3.0.4, 1st order
(water, only degradation)						145.6				Model Maker 4.0
Geometric mean/median						125.5*				Model Maker 4.0

* geom.-mean value of DT_{50} calculated by Model Maker 4.0

Distribution in water / sediment systems (active substance) ‡	Maximum values: Sediment: 34.0 % applied radioactivity (AR) in sediment after 60 days (system A) 16.5/15.8 % AR in sediment after 30/60 days(system B) % total applied radioactivity (14C chloridazon)

DAT	(A)	**water** (B)	(A)	**sediment** (B))
0	93.6	89.3	0.6	2.8
0.25	89.6	87.0	5.3	5.5
1	80.6	80.0	10.8	10.0
2	77.2	78.5	13.2	8.9
7	66.8	74.2	22.3	13.3
14	59.9	72.0	25.9	12.6
30	47.9	64.6	29.7	16.5
60	38.5	59.1	34.0	15.8
100	37.1	0.3	27.1	2.2

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Distribution in water / sediment systems (metabolites) ‡	**Metabolite B**: maximum values Water 1.4 % AR after 100 days (system A) 42.6 % AR after 100 days (system B) sediment: 0.6 % AR after 30 days (system A) 7.3 %AR after 100 days (system B) % total applied radioactivity (14C chloridazon) DAT (A) **water** (B) (A) **sediment** (B) 0 <0.1 <0.1 <0.1 <0.1 0.25 <0.1 <0.1 <0.1 <0.1 1 <0.1 <0.1 <0.1 <0.1 2 <0.1 <0.1 <0.1 <0.1 7 <0.1 <0.1 <0.1 0.2 14 <0.1 <0.1 <0.1 0.1 30 1.0 0.5 0.6 0.2 60 0.8 2.3 0.3 0.5 100 1.4 42.6 0.3 7.3 **Metabolite B-1**: maximum values Water < 0.1 % AR in sediment after 100 days (system A, B) sediment: < 0.1 % AR in sediment after 100 days (system A, B)

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

Parent **chloridazon**	FOCUS surface water STEP 3. FOCUS SWAH 1.1 tool
Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight (g/mol): 221.65, vapour pressure 10^{-9} Pa, water solubility (mg/L): 422 mg/L (pH 4.4, 20 °C); K_{OM} (L/kg): 115.4 L/kg (arithm mean); 1/n 0.845 (arithm mean); DT_{50} soil (d): 19.1 d field studies, (geom. mean standardised to 20 °C and pF2, n = 7) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} whole system 182 days (system A "Krempe") DT_{50} water: 125.5 days (geom mean) DT_{50} sediment: 1000 days (default since no degradation); Crop interception (%): 0 % pre-emergence
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	See above
Application rate	Crop: sugar beets and bulb vegetables

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop interception: 0% Number of applications: 1 Interval (d): - Application rate(s): 2600 g a.s./ha Application window: March – April (sugar beets), February – May (bulb vegetables), October (2nd season, Scenario D6)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Sugar beets and bulb vegetables	0 h	775.01		866.77	
	24 h	768.89	771.95	887.30	877.03
	2 d	765.96	769.69	883.92	881.32
	4 d	760.15	766.37	877.22	880.94
	7 d	751.52	761.85	867.25	877.21
	14 d	731.75	751.72	844.44	866.50
	21 d	712.50	741.84	822.22	855.42
	28 d	693.75	732.15	800.60	844.41
	42 d	657.73	713.29	759.02	822.81
	50 d	637.99	702.82	736.24	810.77
	100 d	527.37	641.87	608.59	740.58

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	151.16		173.24	
sugar beets and bulb vegetables	24 h	149.40	150.28	172.40	172.82
	2 d	148.67	149.66	171.56	172.40
	4 d	147.23	148.81	169.90	171.57
	7 d	145.09	147.67	167.43	170.32
	14 d	140.22	145.16	161.81	167.46
	21 d	135.52	142.72	156.38	164.67
	28 d	130.97	140.35	151.13	161.93
	42 d	122.32	135.76	141.15	156.65
	50 d	117.64	133.24	135.75	153.74
	100 d	92.18	118.82	106.37	137.10
Southern EU	0 h	281.09		323.07	
sugar beets and bulb vegetables	24 h	278.61	279.85	321.50	322.28
	2 d	277.25	278.89	319.93	321.50
	4 d	274.56	277.40	316.83	319.94
	7 d	270.57	275.32	312.23	317.62
	14 d	261.49	270.67	301.75	312.29
	21 d	252.71	266.14	291.62	307.08
	28 d	244.23	261.71	281.83	301.98
	42 d	228.11	253.17	263.22	292.13
	50 d	219.38	248.46	253.15	286.69
	100 d	171.90	221.57	198.36	255.67

FOCUS STEP 3 Scenario **sugar beets**	Water body	Chloridazon Global max. concentration	
		PECsw, ini (µg/L)	PECsed, ini (µg/kg)
D3	ditch	13.624	4.34
D4	pond	0.579	1.93
D4	stream	11.305	0.63
R1	pond	1.143	3.92
R1	stream	15.527	4.56
R3	stream	125.945	26.59

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS STEP 3 Scenario **bulb vegetables**	Water body	Chloridazon Global max. concentration	
		PECsw,ini (µg/L)	PECsed, ini (µg/kg)
D3	ditch	16.460	5.1
D4	pond	1.298	5.09
D4	stream	12.819	3.48
D6	ditch (1st season)	16.476	4.54
D6	ditch (2nd season)	54.098	37.87
R1	pond	1.178	4.05
R2	stream	26.562	6.57
R3	stream	66.921	15.05
R4	stream	82.061	25.16

Metabolite B	
Parameters used in $FOCUS_{sw}$ step 1 and 2	FOCUS Surface water STEP 3 FOCUS SWASH 1.1 tool Molecular weight: 145.55; vapour pressure 10^{-9} Pa,; water solubility (mg/L): 422 mg/L (pH 4.4, 20 °C) Soil or water metabolite: K_{om} (L/kg): 29 L/kg (arithm mean); 1/n 0.834 (arithm mean) DT_{50} soil (d): 108 d (laboratory studies, geom. mean standardised) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d)and DT_{50} sediment (d): no degradation in water and sediment phase (worst case) Crop interception (%): 0 % pre-emergence Maximum occurrence observed (% molar basis with respect to the parent) PECsw initial calculated based on maximum percentage observed, max. in water 42.6 %, in soil 64.8 %. % (n=4, no radiolabelled study).
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	See above
Application rate	Crop: sugar beets and bulb vegetables Number of applications: 1 Interval (d): - Application rate(s): 2600 g a.s./ha Application window: : March-April (sugar beets), February-May (bulb vegetables), October (2nd season, Scenario D6)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Main routes of entry	Spray drift and run-off

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
sugar beets and bulb vegetables	0 h	360.92		102.73	
	24 h	360.43	360.67	104.52	103.63
	2 d	360.18	360.49	104.45	104.06
	4 d	359.68	360.21	104.31	104.22
	7 d	358.93	359.82	104.09	104.21
	14 d	357.19	358.94	103.59	104.02
	21 d	355.46	358.07	103.08	103.79
	28 d	353.74	357.20	102.59	103.55
	42 d	350.33	355.48	101.60	103.07
	50 d	348.39	354.50	101.03	102.79
	100 d	336.52	348.46	97.59	101.04

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	75.54		21.87	
sugar beets and bulb vegetables	24 h	75.41	75.48	21.85	21.86
	2 d	75.36	75.43	21.84	21.85
	4 d	75.25	75.37	21.81	21.84
	7 d	75.10	75.29	21.76	21.82
	14 d	74.73	75.10	21.66	21.76
	21 d	74.37	74.92	21.55	21.71
	28 d	74.01	74.74	21.45	21.66
	42 d	73.30	74.38	21.24	21.55
	50 d	72.89	74.17	21.12	21.49
	100 d	70.41	72.91	20.40	21.13

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	144.60		41.88	
sugar beets and bulb vegetables	24 h	144.42	144.51	41.85	41.87
	2 d	144.32	144.44	41.82	41.85
	4 d	144.12	144.33	41.77	41.82
	7 d	143.82	144.17	41.68	41.78
	14 d	143.12	143.82	41.48	41.68
	21 d	142.43	143.47	41.28	41.58
	28 d	141.74	143.12	41.08	41.48
	42 d	140.37	142.43	40.68	41.28
	50 d	139.59	142.04	40.45	41.16
	100 d	134.84	139.62	39.08	40.46

FOCUS STEP 3 Scenario **sugar beets**	Water body	metabolite B Global max. concentration	
		PECsw,ini (µg/L)	PECsed, ini (µg/kg)
D3	ditch	3.811	4.89
D4	pond	0.162	0.69
D4	stream	3.162	4.06
R1	pond	0.320	1.37
R1	stream	4.344	5.57
R3	stream	35.232	45.18

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS STEP 3 Scenario **bulb vegetables**	Water body	metabolite B Global max. concentration	
		PECsw, ini (µg/L)	PECsed, ini (µg/kg)
D3	ditch	4.605	5.90
D4	pond	0.363	1.55
D4	stream	3.586	4.60
D6	ditch (1st season)	4.609	5.91
D6	ditch (2nd season)	15.133	19.41
R1	pond	0.330	1.41
R1	stream	9.156	11.74
R2	stream	7.430	9.53
R3	stream	18.720	24.01
R4	stream	22.956	29.44

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS PELMO 3.3.2 with all 9 standard scenarios. Formation fraction: metabolite B: 56 % (from parent), Formation half-lives in soil: metabolite B 34.1 d, metabolite B-1 771.4 d. Formation fraction of metabolite B-1 from metabolite B: 14 %. No equilibrium between the metabolites. DT_{50} soil: chloridazon 19.1 d (geometric mean of normalised DT_{50} values from field studies , n=7, 20 °C, pF2) metabolite B 108 d (geom. mean of standardised laboratory values, n=4) metabolite B-1 144.6 d (geom. mean of standardised laboratory values, n=4). K_{oc} values 199 (arithm mean), 50 (arithm mean), 27 (min) for parent, metabolite B and B-1.
Application rate	2600 g a.s./ha, pre-emergence, no interception. - annually and - triannually (agricultural practice)
Maximum concentration	Not required
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	80^{th} percentile annual leachate concentrations at 1 m depth out of a 20 year simulation period were reported. (see detailed results in table below)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Metabolite B	Metabolite B 1	--
FOCUS-PELMO 3.3.2 / pre-emergence (sugar beets) after annual application	Chateaudun	< 0.001	44.404	16.878	
	Hamburg	< 0.001	56.253	22.181	
	Jokioinen	< 0.001	36.171	25.900	
	Kremsmünster	< 0.001	41.632	18.359	
	Okehampton	< 0.001	42.177	16.347	
	Piacenza	< 0.001	44.735	11.722	
	Porto	< 0.001	3.095	7.847	
	Sevilla	< 0.001	2.983	9.005	
	Thiva	< 0.001	17.886	14.342	

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Metabolite B	Metabolite B 1	--
FOCUS-PELMO 3.3.2 / pre-emergence (sugar beets) after application every third year	Chateaudun	< 0.001	14.346	5.784	
	Hamburg	< 0.001	17.001	7.073	
	Jokioinen	< 0.001	8.631	8.126	
	Kremsmünster	< 0.001	11.360	6.252	
	Okehampton	< 0.001	13.059	5.291	
	Piacenza	< 0.001	14.153	3.703	
	Porto	< 0.001	0.506	2.498	
	Sevilla	< 0.001	0.379	2.677	
	Thiva	< 0.001	1.404	4.866	

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

Not provided, not required

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	2.0×10^{-4} mol/Einstein
Photochemical oxidative degradation in air ‡	Tropospheric DT_{50} of chloridazon: < 7.0 h (derived by Atkinson (1987) method of calculation)
Volatilisation ‡	From plant surfaces: ‡ ≤ 1 % (BBA IV 6-1 guideline)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	from soil: ‡ ≤ 4 % (BBA IV 6-1 guideline)
Metabolites	None

PEC (air)

Method of calculation	Volatilisation highly unlikely, therefore no calculation performed

$PEC_{(a)}$

Maximum concentration	Not applicable

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: active substance, metabolite B and metabolite B-1 Water: active substance and metabolite B Sediment active substance Groundwater: active substance, metabolite B and metabolite B-1 Air: active substance

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)	**Netherlands, Scheldt estuary**: Literature study: Monitoring study with systematic sampling from river end to ocean end considering the flush time of the estuary, 3 sampling times in June/July 1998, concentrations of chloridazon at river end: 0.09, 0.15, 0.08 µg/L decreasing towards the sea end of the estuary to 0.01 µg/L (LOQ 0.007 µg/L). **Portugal**: Literature study: Large scale, systematic surface water monitoring program of organic pollutants in portuguese rivers (14 months, 46 sampling points, monthly sampling); no detects of chloridazon in any sample (LOQ not given). Remark to both studies: There is no information on the agricultural area in use treated with chloridazon in the catchment area of the investigated waterbody.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Ground water (indicate location and type of study)	Germany, groundwater monitoring programme

	number				
	total	<LOQ	≤0.1	>0.1-1.0	>1.0 µg/L
1999	1446	1433	8	4	1
2000	1482	1470	7	2	1
2001	1425	1419	3	2	1
2002	1701	1682	14	4	0
total	6054	6004	32	12	3

Air (indicate location and type of study)	Not available

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

R53	May cause long-term adverse effects in the aquatic environment

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6: 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/day)	Endpoint (mg/kg feed)
Birds ‡				
Colinus virginianus	a.s.	Acute	LD_{50} = > 2000 mg a.s./kg bw	
Anas platyrhynchos	a.s.	Short-term	LC_{50} = 1112 mg a.s./kg bw	LC_{50} = 4260 mg a.s./kg feed
Colinus virginianus	a.s.s	Long-term	NOAEL =21.8 mg/kg b w	NOAEL =300 mg a.s./kg feed
Mammals ‡				
Female rat	a.s.	Acute	LD_{50} = 2140 mg a.s./kg bw	
	Preparation	Acute	LD_{50} = 825mg /kg bw (LD_{50} = 536 mg as /kg bw)	
Rat, 2-generation study	a.s.	Long-term	NOAEL = 37 mg a.s./kg bw	
Additional higher tier studies ‡ -				

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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (**Birds**)				
Beets/herbivorous bird	Acute	172	12	10
Beets/herbivorous bird	Short-term	79	14	10
Beets/herbivorous bird	Long-term	42	0.5	5
Beets/insectivorous bird	Acute	141	14	10
Beets/insectivorous bird	Short-term	78.4	14	10
Beets/insectivorous bird	Long-term	78.4	0.3	5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (**Mammals**)				
Beets/medium herbivorous mammal	Acute	63.3	8.5	10
Beets/medium herbivorous mammal	Long-term	15.4	2.4	5
Higher tier refinement (Mammals) medium herb. mammal: hare, RUD 51.8 (acute), 16.5 (long-term), ftwa 0.34				
Hare (medium herbivorous mammal)	Acute	37.7	14	10
Hare (medium herbivorous mammal)	Long-term	4.1	9	5

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 (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	a.s.	96 h	LC_{50} mortality	41.3
Oncorhynchus mykiss	a.s.	28 d	NOEC juvenile growth	3.16
Oncorhynchus mykiss	product BAS 119 33H	96 h	LC_{50} mortality	50.0 (32.8 as)
Oncorhynchus mykiss	metabolite B	96 h	LC_{50} mortality	> 100
Oncorhynchus mykiss	metabolite B-1	96 h	LC_{50} mortality	> 100
Aquatic invertebrate				
Daphnia magna	a.s.	48 h	EC_{50} immobilisation	132
Daphnia magna	a.s.	21 d	NOEC reproduction	10
Daphnia magna	product BAS 119 33H	48 h	EC_{50} immobilisation	79.5 (52.0 as)
Daphnia magna	metabolite B	48 h	EC_{50} immobilisation	> 100
Daphnia magna	metabolite B-1	48 h	EC_{50} immobilisation	> 100
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h	EC_{50} biomass EC_{50} growth rate EC_{10} [3)] biomass EC_{10} [3)] growth rate	0.6 > 3.0 (3.7[1)]) 0.1 0.42

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity (mg/L)
Pseudokirchneriella subcapitata	Product BAS 119 33H	72 h	EC_{50} biomass EC_{50} growth rate NOEC biomass (EC_{10})[3)] NOEC growth rate (EC_{10})[3)]	0.99 (0.65 as) 4.01 (2.62 as) 0.24 (0.16 as) 0.73 (0.48 as)
Pseudokirchneriella subcapitata	metabolite B	72 h	EC_{50} biomass EC_{50} growth rate EC_{10}[3)] biomass EC_{10}[3)] growth rate	> 100 > 100 34.8 > 100
Scenedesmus subspicatus	metabolite B-1	72 h	EC_{50} biomass EC_{50} growth rate NOEC biomass (EC_{10})[3)] NOEC growth rate (EC_{10})[3)]	18.6 37.1 9.9 12.5
Higher plant				
Lemna gibba	a.s.	7 d	EC_{50} frond no. EC_{50} growth rate NOEC frond no. NOEC growth	3.03 > 3.16 0.1 0.1
Microcosm or mesocosm tests study was not performed, not required				

[1)] extrapolated
[2)] data are requested for the evaluation of the validity criterion biomass increase.
[3)] Since there were still effects at the lowest tested concentration a value for EC10 instead for NOEC is given.

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

FOCUS Step1

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
a.s.	Not performed, not relevant. Expected that trigger will be failed						
Metabolite B	Fish	> 100	Acute	361		> 277	100
Metabolite B	Aquatic invertebrates	> 100	Acute	361		> 277	100
Metabolite B	Algae	> 100	Chronic	361		> 277	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
product BAS 119 33H	Not performed, not relevant. Expected that trigger will be failed						

FOCUS Step 2

sugar beets and bulb vegetables, 2600 g as/ha, pre-emergence, Southern Europe = worst case

Test substance	N/S	Organism	Toxicity endpoint (mg/L)	Time scale	PECmax	TER	Annex VI Trigger
a.s.	S	Fish	41.3	Acute	281	147	100
a.s.	S	Fish	3.16	Chronic	281	11	10
a.s.	S	Aquatic invertebrates	132	Acute	281	470	100
a.s.	S	Aquatic invertebrates	10	Chronic	281	36	10
a.s.	S	Algae	0.6	Chronic	281	**2**	10
a.s.	S	Higher plants	3.03	Chronic	281	11	10
product BAS 119 33H	S	Fish	32.8 (as)	Acute	281 (as)	117	100
product BAS 119 33H	S	Aquatic invertebrates	52 (as)	Acute	281 (as)	185	100
product BAS 119 33H	S	Algae	0.65 (as)	Chronic	281 (as)	**2**	10

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Sugar beets, 2600 g a.s./ha, pre-emergence

Test substance	Scenario	Water body type	Test organism most sensitive	Time scale	Toxicity endpoint (mg/L)	PECsw, max	TER	Annex VI trigger
a.s.	D3	ditch	Algae	chronic	0.6 (E_bC_{50})	13.624	44	10
	D4	pond				0.579	1036	
	D4	stream				11.305	53	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Test substance	Scenario	Water body type	Test organism most sensitive	Time scale	Toxicity endpoint (mg/L)	PECsw, max	TER	Annex VI trigger
	R1	pond				1.143	525	
	R1	stream				15.527	39	
	R3	stream				125.945	**5**	
product BAS 119 33H	D3	ditch	Algae	chronic	0.65 (as) (E_bC_{50})	13.624[6]	48	10
	D4	pond				0.579[6]	1123	
	D4	stream				11.305[6]	58	
	R1	pond				1.143[6]	567	
	R1	stream				15.527[6]	42	
	R3	stream				125.945[6]	**5**	

bulb vegetables, 2600 g a.s./ha, pre-emergence

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity endpoint (mg/L)	PECsw, max[4]	TER	Annex VI trigger[5]
a.s.	D3	ditch	Algae	chronic	0.6 (E_bC_{50})	16.460	37	10
	D4	pond				1.298	462	
	D4	stream				12.819	47	
	D6	ditch (1st season)				16.476	36	
	D6	ditch (2nd season)				54.098	11	
	R1	pond				1.178	509	
	R1	stream				32.730	18	
	R2	stream				26.562	23	
	R3	stream				66.921	**9**	
	R4	stream				82.061	**7**	
product BAS 119 33H	D3	ditch	Algae	chronic	0.65 (as) (E_bC_{50})	16.460[6]	40	10
	D4	pond				1.298[6]	501	
	D4	stream				12.819[6]	51	
	D6	ditch (1st season)				16.476[6]	39	
	D6	ditch (2nd season)				54.098[6]	12	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity endpoint (mg/L)	PECsw, max[4]	TER	Annex VI trigger[5]
	R1	pond				1.178[6]	552	
	R1	stream				32.730[6]	20	
	R2	stream				26.562[6]	25	
	R3	stream				66.921[6]	10	
	R4	stream				82.061[6]	**8**	

[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.
[6] active substance values

FOCUS Step 4

Not performed, not relevant.

Bioconcentration				
not relevant, log Pow < 3 (no bioaccumulation potential)	Active substance	Metabolite B1	Metabolite 2	Metabolite 3
log $P_{O/W}$	1.2	0.33		
Bioconcentration factor (BCF)[1] ‡	not relevant	not relevant.		
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})	not relevant	not relevant		
(CT_{90})	not relevant	not relevant		
Level and nature of residues (%) in organisms after the 14 day depuration phase	not relevant	not relevant		

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

Effects on honeybees (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)

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	> 200	> 200
Preparation	> 159 µg BAS 199 33 H/bee	> 200 BAS 199 33 H/bee
Metabolite	-	-
Field or semi-field tests In one cage test no negative effects on the test colonies could be observed regarding mortality, development of the colonies and brood development.		

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

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	contact	13	50
a.s.	oral	13	50
Preparation	contact	20	50
Preparation	oral	25	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/ha1)
Typhlodromus pyri ‡	product BAS 119 33 H	Mortality/Reproduction	4000
Aphidius rhopalosiphi ‡	product BAS 119 33 H	Mortality/Reproduction	> 4000

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
product BAS 119 33 H	*Typhlodromus pyri*	4000	1.0	0.056	2
product BAS 119 33 H	*Aphidius rhopalosiphi*	> 4000	< 1.0	< 0.056	2

[1] 1 m distance assumed, drift rate 2.77 %

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Further laboratory and extended laboratory studies ‡

Species	Stage	Test Substance and duration	Dose (g a.s./ha)	Endpoint	Adverse Effect (%)[1)]	Annex VI Trigger
Laboratory tests: Standard tests on inert substrates						
Chrysoperla carnea	larvae	product BAS 119 33 H glass plate, 9 weeks	3924	mortality/ reproduction	7.1 / -27.5	50
Pardosa spec.	adult	product BAS 119 33 H quartz sand, 14 days	3924	mortality/ feeding capacity	0 / 0	50
Aleochara bilineata	adult	product BAS 119 33 H quartz sand, 28 days	3924	reproduction	4	50

[1] negative values indicate an increase compared to the control

Field or semi-field tests
No field test performed; data 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	Endpoint1
Earthworms			
	as ‡	Acute 14 days	LC_{50} > 1000 mg a.s./kg dw soil
	as ‡	Chronic	not relevant
	product BAS 119 33 H	Acute	LC_{50} > 1000 mg /kg dw soil (>650 mg a.s./kg dw soil)
	product BAS 119 33 H	Chronic	not relevant
	Metabolite B	Acute	LC_{50} > 1132 mg/kg dw soil
	Metabolite B	Chronic	NOEC 15 mg/kg dw soil
	Metabolite B1	Acute	LC_{50} > 1000 mg/kg dw soil
Other soil macro-organisms			
Soil mite	as ‡		not relevant

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Test organism	Test substance	Time scale	Endpoint1
	Preparation		not relevant
	Metabolite B1		not relevant
Collembola	as ‡		not relevant
	Preparation		not relevant
	Metabolite 1		not relevant
Soil micro-organisms			
Nitrogen mineralisation	as ‡	28 days	12 % effect at 40 mg BAS 119 33 H/ kg dw soil (26 mg a.s./kg dw soil) corresponding to 30 kg BAS 119 33 H/ha
	Metabolite B	28 days	8.2 % effect at 8.53 mg metabolite B/kg dw soil corresponding to 6.40 kg metabolite B/ha
Carbon mineralisation	as ‡	28 days	5.3 % effect at 40 mg BAS 119 33 H/ kg dw soil (26 mg a.s./kg dw soil) corresponding to 30 kg BAS 119 33 H/ha
	Metabolite B	28 days	2.9 % effect at 8.53 mg metabolite B/kg dw soil corresponding to 6.40 kg metabolite B/ha
	Metabolite B1	28 days	6.4 % effect at 1.75 mg metabolite B-1/kg dw soil corresponding to 1.3 kg metabolite B-1/ha
Field studies[2] no field test performed; data not required			

[1] indicate where end point has been corrected due to log Pow >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

Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	as ‡	Acute	3.5 (PEC_{ini})	> 288	10
	as ‡	Chronic		not relevant	
	product BAS 119 33 H	Acute	3.5 (PEC_{ini})	> 188	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
	product BAS 119 33 H	Chronic		not relevant	
	Metabolite B	Acute	0.6 (PEC_{ini})	> 1887	10
	Metabolite B	Chronic	0.6 (PEC_{ini})	> 25	5
	Metabolite B1	Acute	0.17 (PEC_{ini})	> 5814	10
Other soil macro-organisms					
Soil mite	as ‡			not relevant	
	Preparation			not relevant	
	Metabolite 1			not relevant	
Collembola	as ‡			not relevant	
	Preparation			not relevant	
	Metabolite 1			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

Not required for herbicides as ER_{50} tests should be provided

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 (1m distance)	Trigger
Brassica napus	product BAS119 33 H	4781 (3130 as)	> 6000 (> 3924 as)	111	53	5

[1] based on Ganzelmeier drift data (1m: 2.77 %)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

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

Pesticidial activity of the metabolite B and B-1: Greenhouse screening test at pre-emergence application to maize, nightshade (black), henbit, speedwell, sugarbeet, fat-hen, redshank, mustard (white), application rate 0.25, 0.5, 1.0 and 2.0 kg a.s./ha. Results: Metabolite B and B-1 showed no herbicidal activity (no damage above 20 %). Chloridazon showed effects (75 % at 0.25 g a.s./ha for speedwell).

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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

Test type/organism	Endpoint
Activated sludge	NOEC of oxygen consumption: 500 mg a.s./L 1000 mg a.s./L (nominal) highest test conc.: 29 % inhibition of respiration.

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

Compartment	
soil	Parent (chloridazon)
water	Parent (chloridazon)
sediment	Parent (chloridazon)
groundwater	Parent (chloridazon)

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, Harmful R50/53 Very toxic to the aquatic environment, may cause long-term adverse effects to the aquatic environment according to the 26. ATP for the Directive 67/548/7EEC

	RMS/peer review proposal
Preparation BAS119 33 H	R 51/53 Toxic to the aquatic environment, may cause long-term adverse effects to the aquatic environment

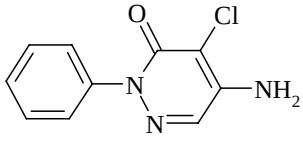
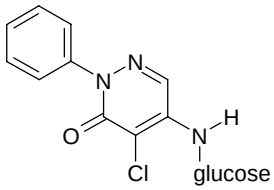
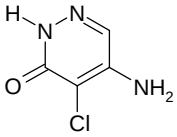
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

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
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
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
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)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
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
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
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Chloridazon	5-amino-4-chloro-2-phenyl-pyridazinone	
Metabolite A	5-(1-amino-1-desoxyglucopyranosyl)-4-chloropyridazin-3(2H)-one	
Metabolite B	5-amino-4-chloro-3(2H)-pyridazinone	
Metabolite B-1	5-amino-4-chloro-2-methyl-3(2H)-pyridazinone