Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report

Triflumuron

Product-type 18
(Insecticide)

February2015

Italy

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance Triflumuron as product-type 18 (Insecticide), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Triflumuron (CAS no. 64628-44-0) was notified as an existing active substance, by Bayer Environmental Science AG, hereafter referred to as the applicant, in product-type **18**.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Italy was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Triflumuron as an active substance in Product Type 18 was from 1 November 2005 until 30 April 2006, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 30th April 2006, the Italian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 1st November 2006.

On 30th September 2008, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency. Revisions agreed upon were presented at the Biocidal Products Committee and Biocides Technical Meetings (TMIII2011; TMII2012) and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the non-approval of Triflumuron for product-type **18**. For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

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[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

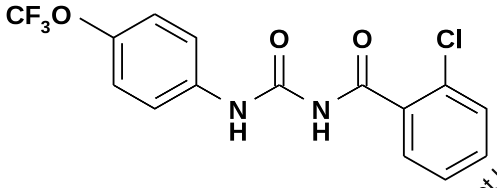
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identification of the active substance

CAS-No.	64628-44-0
EINECS-No.	264-980-3
Other No.	CIPAC number: 548 WHO number: OMS-2015
IUPAC Name	1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea
CAS Name	Benzamide, 2-chloro-*N*-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]-
Molecular formula	$C_{15}H_{10}ClF_3N_2O_3$
Structural formula	
Molecular weight	358.7 g/mol
Purity (%w/w)	≥ 990 g/kg

The impurities of the active substance are considered as confidential information and, hence, are given in the confidential annex, where the method of manufacture is also described.

Identification of the product

Trade name	Baycidal 25 WP
Manufacture's development code number(s)	SIR8514 25WP UVP No. 04007425 AB No. 0087761
Active substance	Triflumuron
Content of the a.s. [g/kg]	250 (declared content of the pure a.s.; tolerance range ±6%)
Function of preparation	Insecticide
Physical state of preparation	Solid
Nature of preparation	Wettable Powder

Detailed qualitative and quantitative composition of Baycidal 25 WP product, including identity, content and function of non-active ingredients, is reported in the confidential annex of the dossier.

Physico-Chemical Properties

Triflumuron is a white odourless powder melting at 195°C, with relative density $D_4^{20} = 1.551$ (purity: >99.8%). The boiling point could not be determined, due to molecule decomposition after melting (decomposition temperature: > 200°C). The vapour pressure at 20°C and 25°C, extrapolated from experimental values, was found to be 2×10^{-7} Pa and 4×10^{-7} Pa, respectively. The volatilization of the substance from water is expected to be slow, as indicated by the Henry's Law constant, which was calculated to be 1.79×10^{-3} Pa m^3 mol^{-1} at 20°C.

UV/VIS, IR, NMR (proton, ^{13}C, ^{19}F) spectra and MS spectrum were found consistent with the molecular structure. Absorption spectra (UV/VIS, IR, NMR) and mass spectra have been submitted also for five impurities, though none is of (eco) toxicological relevance.

Triflumuron proved to have a low solubility in water. The effects of temperature and pH on solubility were not tested in the relevant study. Solubility turned out to increase with temperature, as showed by an additional non-GLP study, where solubility is reported to be ca. 0.014 mg/l and 0.200 mg/l at 10°C and 60°C, respectively. Solubility is not expected to be pH-dependent, since Triflumuron has not acidic/basic properties. Hence, no additional data on the effect of pH were requested.

No dissociation constant could be determined, since the active substance does not dissociate. Triflumuron is readily soluble in dimethyl-sulfoxide, but slightly soluble in acetone, acetonitrile, ethylacetate, and polyethylene glycol. Low solubility was observed in xylene, 1-octanol, 2-propanol and n-heptane. The effect of temperature on solubility has not been tested. Anyway, solubility in organic solvents is expected to increase with temperature, as confirmed by a non-GLP study in propylene glycol successively submitted by the Applicant. According to a study submitted after TMIII2011, Log P_{OW} (3.5 at 20°C) turned out to be not significantly temperature dependent.

Triflumuron is not highly flammable, not explosive nor oxidizing. As a result, it is not classified under Directive 67/548/EEC for physico-chemical hazards. Triflumuron does not react with container materials such as stainless steel #316, aluminium, brass, copper, HDPE, teflon, nylon, Viton, and polypropylene, but reactivity was observed with plain steel. Its stability allows storage under practical and commercial conditions.

Baycidal® 25 WP is a yellow powder with a slight characteristic odour. Pour density and tap density proved to be 0.40 and 0.49 g/ml, respectively. The pH of the 1% suspension of the product was found to be 7.3 at room temperature.
After two accelerated storage regimes, no significant changes were observed in the product. Baycidal® 25 WP does not form agglomerates in water, but readily wets and suspends, forming an acceptable amount of foam during dilution. These technical properties suggest that the product will perform acceptably under normal use.
Baycidal® 25 WP is neither explosive, nor flammable nor oxidising. It does not self ignite or self heat, either. Its particle size distribution seems to be typical of this type of formulation; anyway, the study submitted has been deemed inadequate and hence further data are required for the product authorization phase at national level.
In conclusion, Baycidal® 25 WP is not classified for physico-chemical hazards.

Analytical methods

An analytical procedure based on RP-HPLC/UV is presented for the determination of Triflumuron and its impurities in the technical material. The full validation of the method is described. A CIPAC method for the determination of the active substance in the technical material by RP-HPLC/UV using UV detection at 250 nm and external standardization is also available.

The analytical method used for the determination of the Triflumuron content in formulations is based on normal phase chromatography using isocratic elution. After UV detection, the quantitative determination is carried out by comparing the peak areas with those of reference substances, using an external standard. Method was fully validated in a separate report.

An analytical method which enables the analysis of Triflumuron in soil down to a level of 0.01 mg/kg is described. Soil samples are extracted in a microwave extractor with water and acetonitrile (1:1, v/v). After extraction, samples are centrifuged to remove fine particles of soil prior to analysis by HPLC/MS-MS. The method is unsatisfactorily summarized, but is fully validated as regards one mass transition. The method has been deemed acceptable by the RMS. Nevertheless, additional validation on a second mass transition is necessary in order to consider the method as highly specific, as required by the Additional guidance on analytical methods for detection and identification. The requested data should preferably be submitted to the evaluating Competent Authority (Italy) at the latest 6 months before the date of approval.
Further analytical methods based on HPLC/UV, GC/ECD, GC/NFID and GC/ND are also available, but cannot be accepted due to remarkable deficiencies affecting the validation work.

A method for the determination of Triflumuron residue in air is presented. Air is sucked through tenax or XAD-2 adsorption tubes. The adsorbed active ingredient is extracted with acetonitrile and determined by RP-HPLC/DAD. The method succeeds in the determination of Triflumuron residue down to a level of 0.002 mg/m^3 (≤ C = 0.0042 mg/m^3 calculated according to SANCO/825/00, chapter 5.3, using an AEL of 0.014 mg/kg bw/d), but is not adequately validated. Moreover, the original study report lacks in the description of the preparation of the blank samples, stock solutions and spiked samples used to obtain the validation data already available. In conclusion, the method needs to be validated and reported in compliance with SANCO/825/00. A RP-HPLC/DAD method using different chromatographic conditions is also available for confirmation. The method cannot be accepted, due to remarkable deficiencies affecting the validation work. Hence, full validation as described in SANCO/825/00 is required.
In Sept 2011, a HPLC/DAD method validated at 0.0012 mg/m^3 on Tenax sampling tubes has been provided. Apart from some reporting inconsistencies affecting the summary of the original study report, results are acceptable, but validation at 10x0.0012 mg/m^3 is also necessary, as required by guidelines. It shall be noted that up to date no study summary has been made available by the Applicant. The requested data should preferably be submitted to the evaluating Competent Authority (Italy) at the latest 6 months before the date of approval.

An analytical method which enables the analysis of Triflumuron residue in surface water down to a level of 0.03 μg/l is presented. After addition of 20% acetonitrile and 0.1% acetic acid, analysis by HPLC/MS-MS is performed. The method is unsatisfactorily summarized, but is fully validated as regards one mass transition. The method has been deemed acceptable by the RMS. Nevertheless, additional validation on a second mass transition is necessary in order to regard the method as highly specific, as required by the Additional guidance on analytical methods for detection and identification. The requested data should preferably be submitted to the evaluating Competent Authority (Italy) at the latest 6 months before the date of approval.
At TM III 2011, the RMS accepted the Applicant conclusion, supported also by UK, that validation data generated on surface water can be extrapolated to support a monitoring method for drinking water and ground water, since surface water is a more complex matrix and the LOQ validated (0.03 μg/l < EU drinking water limit) is also applicable to drinking water and ground water.
Further analytical methods based on HPLC/UV and GC/ECD are also available, but cannot be accepted due to remarkable deficiencies affecting the validation work.

Triflumuron is not classified as toxic or highly toxic. Therefore, methods for the determination of residues in animal and human body fluids and tissues are not required.

With regard to food and feeding stuffs of plant origin, no submission of data is deemed necessary, as stated by TNsG for active substances used as product types 18. The product is used

for the control of flies in animal houses. Based on the use pattern, there will be no contact with crops or stored animal feeds. Exposure via manure applications is not possible.
As for food and feeding stuffs of animal origin, RMS acknowledges that livestock exposure must be considered and addressed by an exposure assessment to be carried out in compliance with the Guidance on Estimating Livestock Exposure to Biocidal Active Substances. Depending on results, analytical methods for the determination of residues in food/feed of animal origin might be necessary. At any rate, no definite conclusions can be drawn at the moment, since at TM III 2011 RMS has accepted to carry on Tier I assessment only.

2.1.2. Intended Uses and Efficacy

Triflumuron is an insecticide, for the control of the house fly (*Musca domestica*) and litter beetle (*Alphitobius diaperinus*) indoors, in livestock and poultry houses. It is applied to locations where insects breed such as litter, the surface of manure, cesspools and bedding materials. Efficacy studies have been conducted with Baycidal® 25 WP (containing 250 g/kg Triflumuron): these tests have been evaluated under Doc. III B, from 5.10.2/01 to 13. Laboratory tests with Triflumuron demonstrated high activity against *Alphitobius diaperinus* and *Musca domestica*, particularly against developing larvae and pupae. Activity in the laboratory was confirmed in field studies; field tests focused on *A. diaperinus* showed that the level of litter beetle larvae control achieved was excellent even in sheds where no adulticide was previously applied. The effectiveness of Triflumuron as an insecticide is well established and efficacy data presented in the dossier is adequate to show that Triflumuron is effective against the target species.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data, provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

In addition to the reported points some considerations around cases of resistance may be done. A laboratory assay carried on in Australia on wild population of the sheep louse *Bovicola ovis* (Schrank) (*Phthiraptera: Trichodectidae*) confirmed the development of resistance to Triflumuron and Diflubenzuron in at least two instances (James et al., 2008).

In a study on *Aedes aegypti* in Brazil a positive correlation between pupal mortality rates and the temephos resistance ratios was noted, suggesting a potential Triflumuron tolerance in populations resistant to this organophosphate (Belinato et al. 2013).

In Turkey, the results of a larval feeding assay with technical Diflubenzuron, Methoprene, Novaluron, Pyripoxyfen, and Triflumuron indicate that low levels of resistance to the IGRs exist in the house fly populations from Antalya province (Cetin et al, 2009). It appears important to monitor for signs of resistance or of reduced efficacy as an alarm for an alternative active substance from a different chemical class should to be used. Management strategies are based on various measures as the use of the recommended rates and the recommended application intervals; rotating of the active substance, using different active substances with different modes of action in control programs.

Studies on triflumuron resistance in *Musca domestica* (Kristensen and Jaspersen, 2003) confirmed that by acknowledging and applying the recommendations of resistance risk assessments the development of resistance in not completely avoided, but it could not rise to a biological or economic importance level.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. *Classification and Labelling*

Triflumuron is currently not classified according to Annex I of Council Directive 67/548/EEC (with amendments). Based on the results from studies presented in the dossier, classification of Triflumuron was proposed according to the criteria set out in Directive 67/548/EEC (with amendments), 99/45/EC (with successive adaptations) and 2006/8/EC.

Proposal for the classification and labelling of the active substance

On the basis of review of the submitted data, specific concentration limits have been agreed for the environmental classification, and the substance is not readily biodegradable.

The risk phrase R 48/22 is not proposed on the basis of the document “Proposal for criteria to be used in the classification of R 48 for haemolytic anaemia in repeated dose toxicity studies” (ECBI/07/03 Add.1, final report of August 2004). Considering also that the extent of haemolytic anaemia after the administration of Triflumuron was not representing a severe functional disorder, the classification with R48/22 was not justified. The decision is in accordance with the EFSA Document (EFSA Journal 2011; 9(1):1941).

Proposed classification and labelling of the active substance based on Directive 67/548/EEC with amendments

Hazard symbol	N Dangerous to the environment	
Risk phrases	R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in aquatic environments
Safety phrases	S 22 S 60 S 61	Do not breathe dust This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/safety data sheets
Specific concentration limits for the environmental effects	$C_n \geq 0.25\%$ N; R50/53 $0.025\% \leq C_n < 0.25\%$ N; R51/53 $0.0025\% \leq C_n < 0.025\%$ R52/53	

Proposed classification and labelling of the active substance based on Regulation EC 1272/2008 with amendments

Classification:	
Hazard Class and Category	Aquatic Acute 1 Aquatic Chronic 1
Hazard Statement Codes	H400 H 410
Labelling:	
GHS Pictogram	GHS09
Signal Word	Warning
Hazard Statement	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects
M factors	M factor=100
As precautionary statements are not included in Annex VI of Regulation EC 1272/2008, no proposal is made.	

Proposal for the classification and labelling of the representative product Baycidal® 25 WP

Hazard symbols	N Dangerous for the environment	
Risk phrases	R 51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases	S 22 S 26 S 29/35 S 57 S 61	Do not breathe dust In case of contact with eyes, rinse immediately with plenty of water and seek medical advice Do not empty into drains; dispose of this material and its container in a safe way Use appropriate container to avoid environmental contamination Avoid release to the environment. Refer to special instructions / safety data sheets

Classification and labelling for the mixture according to Regulation EC 1272/2008 is required from June 2015.

2.2. Summary of the Risk Assessment

Triflumuron is a broad spectrum insect growth regulator (IGR) that inhibits the production of chitin and acts on insect larvae.

The human health effects, toxicity, toxicokinetics and metabolism of Triflumuron, the active substance in Baycidal® 25 WP, have been investigated in studies summarised under Sections IIIA 6.1.1 to IIIA 6.13.

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Toxicokinetics and metabolism

Based on data obtained in bile cannulation experiments in rats, low Triflumuron oral doses were found to be absorbed nearly completely within the testing period (up to 96% of the administered dose for the [chlorophenyl-UL-^{14}C] label and > 78% for the [trifluoromethoxyaniline-UL-^{14}C] label, respectively). The amount of absorption (≥ 80%) accounted for urinary and biliary excretion as well as residues in tissues and carcass.

The absorption process started immediately after administration but was relatively slow (t_{max} in plasma ≅ 48 h). The absorption process was saturable: high dose level administration resulted in 91% of the administered dose excreted in the faeces as unchanged parent compound, very likely mainly unabsorbed material.

The radioactivity was distributed within the body of the treated animals at generally low concentration levels. The highest concentrations were detected in liver, kidney, spleen, lungs and in all fatty tissues. The blood levels indicate a possible binding of metabolites - which still contain the trifluoromethoxy-phenyl moiety - to blood components. However, the levels in blood plasma dropped to <0.1 mg/kg within 24 hours after dosing. The low amount of residues at 168 hours after treatment, the similarity of kinetics after single and repeated doses and the rapid excretion (almost completed in 72-96 hours) led to conclusion that no bioaccumulation occurred in the rat.

Independently on the label position, in rats excretion via urine and faeces was essentially completed 96 hours after dosing by oral administration. After a single low dose, excretion via urine and faeces was at approximately equal amounts; after multiple low dose administration, urinary excretion almost doubled the faecal elimination. In the high dose faecal excretion was highly preferred (92% of the administered dose). Females excreted slightly less of the radioactivity in urine over a longer period than males. Biliary excretion was approximately 50% of the dose within 48 hours. The main part of biliary excreted radioactivity was subject to enterohepatic circulation.

The metabolism of Triflumuron was extensive and rapid: no unmetabolized parent compound was detected in urine, and only about 20% in faeces at low dose administration. Metabolites were formed mainly through hydrolysis followed by oxidation and subsequent conjugation (with sulphate and glucuronic acid) to allow for ready excretion. The most abundant metabolites were Triflumuron 2-hydroxyaniline, Triflumuron 3-hydroxyaniline and their corresponding sulphate conjugates. Two plant metabolites, which are considered as toxicologically relevant, i.e. 4-trifluoro-methoxyaniline (M07) and 4-trifluoro-methoxyphenyl urea (M08), were proposed in the early steps of the rat metabolites (M08 being a precursor of M07), but only found in trace in faeces or up to 3% in bile (M08).

Based on results from human and rat *in vitro* studies and from a rat *in vivo* study on Baycidal 25 WP formulated as a suspension concentrate containing 480 g Triflumuron/l, the extent of dermal absorption was: 1% during mixing/loading (undiluted product:480 mg a.s./ml) and 5% during application (in use spray dilutions: 0.362 mg a.s./ml).

Acute toxicity, skin and eye irritation and skin sensitization

Triflumuron exhibits very low acute oral toxicity to rats. The animals displayed transient non-specific symptoms (disturbances in general condition e.g. fatigue) following oral administration. Oral studies with other mammals (mouse, sheep and dogs) also indicated very low acute oral toxicity with no adverse treatment related clinical signs observed. Very low acute toxicity was also observed following intraperitoneal and subcutaneous administration to rats and mice; the symptoms corresponded to those following oral administration but no mortality at a dose level of 5000 mg/kg bw.

The acute dermal toxicity to the rat is very low: there were no signs or mortality up to the highest tested dose (5000 mg/kg bw). Also inhalation toxicity was low: after inhalation of the highest technically feasible concentration only transient disturbances in the general condition and nasal discharge occurred in rats. The LC_{50} did exceed the guideline limit dose level. The results of the sub-acute inhalation study supported the single dose study results indicating a very low order of acute inhalation toxicity.

Triflumuron exhibited no dermal irritant properties to rabbit skin and only slight transient ocular reactions, none of which exceeded the threshold for EC classification as an eye irritant. In addition, no skin sensitization was observed in the maximization tests on guinea pigs.

2.2.1.2. Effects assessment

Erythrocyte damage represents the main toxic effect following repeated administration of Triflumuron, independently on the animal species. Compensation or regeneration processes (highly active bone marrow, extramedullary haematopoiesis in the spleen and frequent appearance of immature erythrocytes in the peripheral blood) were observed as a result of the erythrocyte damage. The elevated metabolic activity of the spleen and the haemosiderosis in spleen, liver and kidneys represent secondary effects. The elevated leukocyte and thrombocyte counts in the peripheral blood sometimes observed simultaneously are viewed in the sense of an entrainment effect of the increased haematopoiesis. The increased haematopoiesis indicates that the primary attack by the substance takes place on the peripheral blood. No impairment in the sense of a haematogenic organ depression or general cytotoxic effect was observed in any study.

The effects were generally consistent irrespective of route or duration of administration and were similar among species. In 4-week and 13-week oral studies in rats, splenic changes and reduced erythrocyte counts were indicative of haemolytic anaemia and compensatory changes in reticulocytes and thrombocytes figures were evident (the NOAEL of the 90-day rat study is 3.6 mg/kg bw/day). In the dog, subchronic exposure resulted in haemolytic anaemia, increased methaemoglobin production and compensatory erythropoiesis and similar effects were noted following 3 months exposure (NOAEL values equivalent to 2.68 mg/kg bw/day) and 1 year exposure. At the mid dose in the 1-year dog study the presence of haematological effects was equivocal (although accompanied by some histopathological findings, as marker of increased erythropoiesis), and the NOAEL value for dog was set equivalent to 1.42 mg/kg bw/day applying a conservative approach.

Dermal exposure of rabbits at intact or abraded sites resulted in no dermal irritation but there were increases in spleen weight and reductions in erythrocytes, haemoglobin levels and heamatocrit values and splenic haemosiderosis. Based on this effects the NOAEL in rabbits was 100 mg/kg bw/day.

Repeated exposure of rats via the inhalation route resulted in elevated reticulocyte and thrombocyte counts and lowered haemoglobin and haematocrit values, and increased weight and discoloration of spleens. Based on this effects the NOAEC in rabbits was 0.0045 mg/l.

No evidence for genotoxic potential could be found in any of the *in-vitro* and *in vivo* assays.

Chronic non neoplastic effects were the same evidenced after subchronic toxicity studies: the erythropoietic system was disrupted, and enlarged spleens were also evident with pronounced haemosiderosis and extramedullary erythropoiesis indicating compensatory mechanisms counteracting the induced anaemia. at the highest dose, with increased spleen weight and pigment deposit. The haematological changes at mid dose (LOAEL) were very slight, although consistent with the effects seen at the highest dose. This resulted in a NOAEL of 0.82 and 1.1 mg/kg bw/day in M and F (i.e. the lowest dose tested), by applying a conservative approach, being the LOAEL 10 fold higher. In addition elevated liver and kidney weights were observed in rat treated at the highest dose, which were considered secondary effects of Triflumuron-induced anaemia.

A much higher NOAEL (5.19 mg/kg bw/day) was derived from the long term toxicity study in mice. Although elevated fluoride levels were determined in the bones and teeth of rats and mice in chronic studies, no macroscopic or microscopic alterations of the bones or teeth were observed. The quantities of fluoride incorporated from Triflumuron were thus insufficient to produce fluorosis even at the highest doses used in the rat chronic studies.

Triflumuron was tested for oncogenic potential in two long-term studies without indications of such potential being discovered. In the rat study there were no tumours in the target organ (spleen) and other tumours were within normal background incidence.

Triflumuron is not a developmental toxicant in the rat or the rabbit at dose levels devoid of maternal toxicity. Embryotoxic effects were only observed at high doses (1000 mg/kg bw) that resulted in maternal toxicity (at high doses the splenic changes with associated erythropoiesis, commonly seen in other studies, were also noted for the rat and rabbit dams). The incidence and type of malformation observed in foetuses was not affected by maternal treatment

No significant and/or dose-related effects on fertility, reproductive parameters or pup development or viability were evident in a multi-generation study in the rat.

There were no indications of acute neurotoxicity in rats or mice by a variety of routes including oral gavage, percutaneous application, subcutaneous and intraperitoneal injection. None of these studies highlighted any clinical observations indicative of selective neurotoxicity, despite the very high doses employed. A range of short-term toxicity studies as well as long term studies were completed in different species and none of them gave any indications of delayed effects attributable to systemic or delayed neurotoxicity.

Medical Data

No significant effects caused by Triflumuron in personnel with occupational exposure have been observed.

2.2.1.3. Exposure assessment

Primary exposure for professional users

Total systemic exposure to Triflumuron of professional operators applying Baycidal® 25 WP inside animal houses with a sprayer is estimated at 9.82 x 10^{-3} mg/kg bw/day (wearing a face mask and PPEs) and at 0.60 mg/kg bw/day (without a face mask and PPEs). On the other hand, the total exposure for professionals applying Baycidal® 25 WP by using watering can is estimated at 1.42 x 10^{-3} mg/kg bw/day (wearing a face mask and PPEs) and at 0.25 mg/kg bw/day (without a face mask and PPEs) (see doc IIB).

Primary exposure for non-professional users

Baycidal® 25 WP is not used by non-professional users.

Secondary exposure

Adults or children are not permitted to be present during applications of Baycidal® 25 WP or immediately after application when surfaces inside animal houses may be wet. Additionally, Baycidal® 25 WP is only sprayed on breeding areas such as around the edges of boxes, around piles, under slatted floors, under feed troughs and on crusts in lagoons/tanks, where the access to treated surface by children is unlikely. Children or adult workers may enter animal houses where Baycidal® 25 WP has been applied but dermal exposure to dried residues of Triflumuron after application can be considered negligible. Moreover, due to the very low vapour pressure of Triflumuron (2 x 10^{-7} Pa at 20ºC) inhalation exposure of children and adults to dried residues of Triflumuron is expected to be negligible.

Dietary exposure assessment

The Technical Meeting on biocides (TMIII2011, October 2011) agreed that an estimate should be also carried out for dietary exposure of biocidal active substance following the application in animal houses. Currently, the only available guideline dealing with the external exposure assessment of the livestock animals ("Guidance on Estimating Livestock Exposure to Biocidal Active Substances") has not been endorsed yet. However, acknowledging that a potential risk can arise from the exposure of livestock animals with the Baycidal® 25 WP, the Rapporteur Member State has performed a preliminary exposure estimate according to the criteria set in the draft version of the guideline at Tier 1 level, only. This Tier 1 assessment showed that the trigger value of 0.004 mg/kg bw/d is exceeded in several scenarios. Subsequently, a refined assessment (also considering the further steps prescribed in the draft guidance) is required. It is proposed to postpone this to product authorization level, once (endorsed) guidance is available.

2.2.1.4. Risk characterisation

The lowest oral NOAELs for subchronic exposure were from the 90 day-dog study (2.68 mg/kg bw/day) and from the 90 day-rat study (3.6 mg/kg bw/day). The lowest oral NOAELs for chronic exposure were 1.42 mg/kg bw/day in the 1-yr dog study and 0.82-1.11 mg/kg bw/day derived from the 2-yr rat study in males and females, respectively.

The NOAEL from the developmental toxicity in rabbit is regarded as appropriate for establishment of the systemic acute AEL. Since oral absorption was ≥ 80% it is not necessary to adjust the systemic AEL to account for oral absorption. With an assessment factor of 100 an **$\text{AEL}_{\text{acute}}$ of 3 mg/kg bw /day** is derived for systemic effects.

The NOAELs from the subchronic toxicity studies in rat and dog are regarded as equally appropriate for establishment of the systemic medium term AEL, resulting in very similar values (2.7 and 3.6 mg/kg bw/d). During the TMIII 2011, it was agreed to use the value coming from rat study, to be consistent with the EFSA evaluation by for the registration of Triflumuron as a plant protection product (EFSA Journal 2011; 9(1):1941). Since oral absorption was ≥ 80% it is not necessary to adjust the systemic AEL to account for oral absorption. With an assessment factor of 100 an **$\text{AEL}_{\text{medium term}}$ of 0.036 mg/kg bw /day** is derived for systemic effects.

The NOAEL from the 1-yr toxicity in dog, 1.42 mg/kg bw/d, based on the slight effects observed at the LOAEL (2-fold higher dose). is used for the derivation of an $\text{AEL}_{\text{long term}}$. This NOAEL value was supported by the results from the chronic study in rat, for which the NOAEL was 0.82 and 1.11 in males and females, respectively. The NOAEL value derivation in the rat study was based on slight effects seen at the LOAEL, which was a 10-fold higher dose: since the NOAEL could be higher due, to the dose spacing, the NOAEL coming from the dog study was regarded as more appropriate for the establishment of the systemic chronic AEL. This is in agreement with the evaluation made by EFSA for the registration of Triflumuron as a plant protection product (EFSA Journal 2011;9(1):1941). Since oral absorption was ≥ 80% it is not necessary to adjust the systemic AEL to account for oral absorption. With an assessment factor of 100 an **$\text{AEL}_{\text{chronic}}$ of 0.014 mg/kg bw/day** is derived for systemic effects.

The results of the calculations (see doc IIC) show that no risk is expected for both the intended uses (inside animal houses with a sprayer and watering can applications) of Baycidal® 25 WP. The estimated primary exposure is always well below the acceptable exposure (AEL) accounting for a maximum of 70.1% of the AEL for spray application and 10.1% of the AEL for watering can application when Respiratory Protective Equipment and Personal Protective Equipment are worn. In addition to Respiratory Protective Equipment (*i.e.*, protection factor of 90%), for both the intended uses specific PPEs should be prescribed. In particular, during spray application impermeable coveralls ensuring a high degree of protection against heavy contamination (*i.e.*, protection factor of 95%) should be prescribed as mandatory. On the other hand, during watering can application the professional users can be allowed to wear coated coveralls which can guarantee an appropriate degree of protection (protection factor of 80%).

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Biodegradation

The active substance, Triflumuron, is not readily biodegradable under environmentally relevant conditions or during sewage treatment processes.

Abiotic Degradation

Hydrolysis of the active substance is not expected to be a significant process in the environment. Similarly, aqueous photolysis of the active substance is slow (quantum yield 0.0095).

Triflumuron was stable at pH 5 and pH 7 with minor amounts of degradation products. At pH 9, a DT_{50} of 57 days at 25°C (DT_{50} of 161 days at 12°C) was calculated according to first order kinetic (r^2=0.99). The major metabolite is 2-chlorobenzoic acid (M02), with a peak concentration of 28.9% of the applied radioactivity after 30 days. At pH 5 and pH 7, degradation products, i.e. 2-chlorobenzamide (M0l) and 2-chlorobenzoic acid (M02) occurred at minor amounts only (5.2% for each metabolite at one sampling point).

Biotic Degradation

In aquatic systems Triflumuron is rapidly degraded with an overall DT_{50} value in the range 4.1 to 7.1 days. The DT_{50} values normalised to 12°C, according to TGD, are in the range 7.8 to 13.5 days. Degradation of Triflumuron in aquatic systems led to the formation of two major metabolites, M02 (2-chlorobenzoic acid) and M08 (trifluoromethoxyphenyl urea, TMPU) which were observed at maximum levels of 63.5 and 62.0% of the applied radioactivity at 14 days and were subsequently degraded with worst-case DT_{50} values of 62.9 and 11.7 days. The DT_{50} values normalised to 12°C, according to TGD, are 119.3 days (M02) and 25.6 days (M08).

Triflumuron is quickly degraded in soil under aerobic conditions with a DT_{50} value of 4.6 to 40.8 days (4 soils, mean 16.3 days), normalised to a temperature of 20°C and pF 2 moisture content. Degradation of Triflumuron did not appear to be dependent on soil type or soil pH. Degradation of Triflumuron under aerobic conditions led to the formation of two significant metabolites M02 (maximum formation 5.9% and 3.9% after 3 and 7 days, subsequent degradation to < 1% AR after 30 to 56 days) and M08, maximum formation 13.5% and 12.3% after 3 and 7 days, 0.3% and 2.8% at day 120. The DT_{50} values of the metabolites M02 and M08 were determined to be 0.4 to 3.3 (5 soils, mean 1.9 days) and 1.3 to 20.5 (4 soils, mean 7.0 days) days, respectively. Triflumuron degrades faster in soil when anaerobic conditions succeed aerobic conditions

The release of $^{14}CO_2$ by mineralisation was dependent on the label position of the a.s. used in the experiment. At termination of the test, the $^{14}CO_2$ recoveries were 35.7% (Hoenniger) and 25.4% (Von Diergardt) of the applied amount for the chlorophenyl-label, but only 2.4% (both systems) for the trifluoromethoxyphenyl-label. The chlorophenyl-labelled part of the molecule is much better to mineralise. In the test systems dosed with chlorophenyl-label each less than 0.05% of the applied radioactivity could be found in the PU traps during the entire incubation period. However, in the test systems dosed with trifluoromethoxyphenyl-labelled Triflumuron, at maximum 1 .3% (Hoenniger, at interval 62 days) and 4.2% (Von Diergardt, at interval 100 d) of the applied radioactivity was determined in the polyurethane foam (PU). The main ingredient of PU extracts was 4-trifluoromethoxyaniline (M07). This portion of 4-trifluoromethoxyaniline (M07) was more or less the total amount of 4-trifluoromethoxyaniline found in the total water/sediment-systems (highest value: 2.6%).

The degradation pathway of Triflumuron observed under anaerobic conditions was essentially the same as that observed under aerobic conditions. However, under anaerobic conditions Triflumuron was degraded in sediment more slowly (worst-case DT_{50} value 150 days). Two metabolites M01 (maximum of *ca* 52% AR after 240 days) and M08 (maximum of *ca* 44% AR after 240 days) were observed in significant quantities (i.e. > 10% of AR). Under anaerobic conditions the metabolite M02 was only observed in minor quantities (i.e. < 10% of AR) and comprised approximately 2 to 3% of AR throughout from 14 to 365 days.

Triflumuron is not photo-degraded on soil surfaces.

Distribution

Adsorption of Triflumuron to soil gave a good correlation to the Freundlich equation and is not dependant on soil pH. Triflumuron is quickly and strongly adsorbed to soil and the Koc, in all soil types with a Freundlich soil adsorption coefficient, normalised for organic carbon content, is in the range of 1629 to 30006 ml/g (5 soils, geomean 7332 ml/g).

The metabolites M08 and M02 K_{OC} values are 113 to 280 ml/g (mean 176 ml/g) and 3.97 to 8.82 ml/g (mean 6.7 ml/g), respectively. The Koc values indicate a moderate and weak adsorption to soil respectively.

Degradation of the active substance Triflumuron is addressed under IIA 4.1.1. Triflumuron is degraded in the environment and is characterised by a worst-case DT_{50} value of 40.8 days (temperature 20°C and moisture pF 2), consequently, due to the restricted usage patterns, Triflumuron is not expected to accumulate in the environment.

Mobility

Triflumuron and its metabolites are strongly adsorbed to soil, moderately adsorbed and weakly adsorbed, respectively. The GUS index (Groundwater Ubiquitary Score), a simple method for assessing pesticide leachability. The index is based on graphical examination of a plot formed by two widely available pesticide properties: half-life in soil (t½soil) and partition coefficient between soil organic carbon and water (Koc):

$GUS = \log(DT_{50})*(4-\log Koc)$

If GUS > 2.8 leacher

If GUS 1.8- 2.8 Transitional or intermediate leacher

If GUS < 1.8 Non-leacher

GUS Triflumuron = 0.2

GUS M02 = 0.9

GUS M08 = 1.5

On the basis of the GUS index values Triflumuron and its metabolites are not expected to contaminate groundwater.

Atmosphere

The vapour pressure of Triflumuron at ambient temperature as determined by OECD guideline no. 104 is 2×10^{-7} Pa and Henry's law constant is 1.79×10^{-3} Pa m^3 mol^{-1} (based on a water solubility of < 4.8 mg/l). Therefore Triflumuron is not considered volatile and is not expected to volatilise to air in significant quantities. This was confirmed experimentally where the amount of Triflumuron volatilised from a soil surface was shown to be < 2% AR after 24 hrs following a spray application. Furthermore, the photochemical oxidative degradation half-life of Triflumuron in air was estimated using the Atmospheric Oxidation Program v1.90 (AOPWIN), which is based on the structural activity relationship (QSAR's) methods developed by Atkinson, R (1985 to 1996). A calculated overall OH reaction rate of 38.1498 E-12 cm^3/molecule-sec is obtained by addition reactions to aromatic rings. Based on this OH rate constant and using a 24-hrs day with 0.5 E^6 OH radicals/cm^3, a half-life of Triflumuron in air of 0.421 days, corresponding to a chemical lifetime of 0.61 days was assessed. Employing a conservative approach, using only half of the estimated overall OH reaction rate (19 E-12 cm^3/molecules-sec), a maximum chemical lifetime of Triflumuron in air of 1.2 days is to be expected. Therefore, even if present, Triflumuron is not expected to persist in air.

Bioaccumulation

Triflumuron has a log Kow of 3.5, which indicates a potential for bioaccumulation. Based on a laboratory study, in which bluegill sunfish were exposed to Triflumuron under flow through test conditions for 28 days, followed by a 14 day depuration phase, Triflumuron was accumulated and excreted rapidly by bluegill sunfish with a mean bioconcentration factor of 612 for whole fish.

In soil, metabolites M02 and M08 undergo to faster degradation than the parent, while in water/sediment system degradation is slower both in case of M02 (DT_{50} = 62.9d) and M08 (DT_{50} = 11.7d) than Triflumuron (DT_{50} = 7.1d). Metabolites are not expected to accumulate in the environment.

2.2.2.2. Effects assessment

Triflumuron is a broad spectrum insect growth regulator (IGR) that inhibits the production of chitin and acts on insect larvae. Larvae are unable to moult and therefore die as they try to split the old cuticle and free themselves. Other larvae may form pupae that have larval characteristics (‘larviform’) or are elongated, shortened or ‘C-shaped’ (*Musca domestica*) or ‘J-shaped’ (*Alphitobius diaperinus)*. Triflumuron also has ovicidal activity interfering with egg hatching by direct exposure of adults or after uptake by adults. The embryo in the insect egg also forms chitin and synthesis of chitin is disturbed by Triflumuron. Due to the lack of chitin the embryo either fails to hatch or does not develop properly once hatched. Triflumuron acts mainly as a stomach poison but also has some contact action.

Aquatic compartment including sediments

As far as concerns acute toxicity, Triflumuron was tested on one cold-water (*Oncorhynchus mykiss)* and one warm water species *(Lepomis macrochirus)* fish species at concentrations of 24.2 and 20.8 µg a.s./l (the practical limit of solubility under the test conditions) under flow-through conditions. Neither sublethal effects nor mortality were observed in the fish exposed to the treated test solutions. The 96-hour LC_{50} > 24.2 µg/l and LC_{50} > 20.8 µg/l (mean measured concentrations) were set for rainbow trout and bluegill, respectively.

There were no adverse effects on the growth or biomass of the green alga *Scenedesmus subspicatus* at the highest tested concentration of 25 µg a.s./l, corresponding to the nominal water solubility limit under the test conditions. Therefore the following endpoint were retrieved: 72-h NOEC ≥ 25 µg a.i./l, 72-hour E_rC_{50} > 25 µg a.i./l, and 72-h E_bC_{50} > 25 µg a.i./l (nominal concentrations, analytically confirmed).

The acute toxicity of Triflumuron to *Daphnia magna* was investigated in a 48h semistatic test where animals were exposed to a series of concentrations up to 25 µg a.i./l (corresponding to the nominal water solubility limit under the test conditions). Neither immobility or other symptoms have been observed at concentrations up to 0.22 µg a.i./l after 24 and 48 hours (NOEC). Highest observed immobility was 83 % after 48 hours at 25 µg a.i./l. The 48-hour EC_{50} was calculated equal to 1.6 µg/l (based on mean measured concentrations).

The aquatic invertebrate *D. magna* resulted the aquatic organism most sensitive to Triflumuron.

As described in section 2.2.2.1 (Fate and distribution in the environment), the degradation of Triflumuron in water/sediment systems is rapid (DT_{50} max = 7.1 days) and leads to the formation of three metabolites: 2-chlorobenzoic acid (M01), 2-chlorobenzamide and 4-trifluoromethoxyphenyl urea. The acute toxicity of the three metabolites were tested against the most sensitive aquatic organism, *D. magna*, exposed for 48h under static conditions. The 48h EC_{50} was determined to be > 100 mg 2-chlorobenzamide/l (M01, the minor metabolite), 48h EC_{50} > 100 mg p.m./l. for 2-chlorobenzoic acid (M02, major metabolite) and 48h EC_{50} = 3.4 mg pm/l for 4-trifluoromethoxyphenyl urea (M08, major metabolite).The results indicate that the metabolites are significantly less toxic to *D. magna* than the parent Triflumuron.

The toxicity of Triflumuron technical towards aquatic microbial activity was investigated using activated sludge exposed for 3 hours up to a nominal concentration of 10 000 mg a.i./l. No effects were recorded up to 1 800 mg a.i./l. Since nominal concentrations were much higher than the water solubility (WS=0.04 mg/l), the NOEC is set greater than the water solubility (NOEC > 40 µg/l).

The long-term toxicity of Triflumuron technical has been assessed in fish and sediment dwelling invertebrates while the long-term effects to *D. magna* were measured using the product Alsystin.

Triflumuron showed no effects to the early life-stages of the warm water fish species *Pimephales promelas* exposed for 36 days at the concentration of 22.8 µg a.s./l (measured concentration), corresponding to the practical water solubility limit of Triflumuron under test conditions. Therefore the NOEC for all tested parameters (egg hatchability, larval development, behaviour, growth, and survival) is 22.8 µg a.i./l.

The chronic study with *D. magna* was carried out with the formulation Alsystin WP 25/l. Under static renewal regime, the growth and reproduction were the most sensitive parameters with statistically significant effects at concentrations ≥ 0.13 µg formulation/l. Therefore the 21d NOEC= 0.018 µg Triflumuron/l.

The results of a 28d study (water-spiking) with sediment dwelling invertebrates are available. When tested in a water-sediment system under static conditions, overlying concentrations of Triflumuron at concentrations higher than 1.8 µg/l prevented the emergence of adult *Chironomus riparius*. Based on the data of emerged midges, the EC_{10} was calculated to be 0.25 µg a.i./l (initial concentrations). This endpoint has been converted into sediment concentration using the equilibrium partitioning formula (eq. 70 of TGD) into EC_{10} = 40 µg a.i./kg ww. It should be noted that, due to the fresh food feeding, this endpoint might underestimate the toxicity to sediment organisms.

Triflumuron metabolites were tested in a 28d chronic study in a water-sediment system where the water was spiked with the test substance.

As with effects on sediment dwelling invertebrates of the Triflumuron metabolites, exposure to 2-chlorobenzoic acid (M02) and 2-chlorobenzamide (M01), *via* the water column had no adverse impact on the life-cycle of *C. riparius* at limit concentrations of 100 000 µg a.s./l (NOEC). The metabolite 4-trifluoromethoxyphenyl urea (M08) showed limited toxicity, relative to the parent Triflumuron, with a EC_{10} (emergence) of 12 800 µg a.s./l. The endpoints of the major metabolites were converted into sediment concentration (eq. 70 of TGD), giving:

2-chlorobenzoic acid (M02): $NOEC_{\text{spiked sediment}}$ = 95 700 µg/kg

4-trifluoromethoxyphenyl urea (M08): $EC_{10\text{spiked sediment}}$ = 59 000 µg/kg

It should be noted that, due to the fresh food feeding, the endpoints might underestimate the toxicity to sediment organisms. Despite this uncertainty, it can be concluded that both the minor metabolite (2-chlorobenzamide) and the major ones (2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea) are several orders of magnitude less toxic to sediment dwelling organisms than the parent substance Triflumuron.

In addition to laboratory studies, a field microcosm study was submitted, which was conducted according to the proposed practice for the use of the plant protection product (2 spray applications made with an aqueous dilution of Alsystin (Triflumuron) 480 SC at a 42 day interval). The test concentrations of 0.1, 0.32, 1.0, 3.2 and 10 µg a.i./l were checked analytically. The test system was judged representative of aquatic biocenosis including groups potentially sensitive, with a focus on arthropods and macro invertebrates. The communities were assessed for 4 months after treatment. Although the study was conducted according to the application pattern of Triflumuron as pesticide rather than its proposed use as biocide, the study was considered to adequately cover the anticipated exposure to pelagic organisms from the proposed biocidal use, based on considerations of test substance, exposure (analysed by FOCUS modelling) and bioavailability.

At the lowest tested concentration (0.1 µg/l), clear short-term effects lasting <8 weeks (class 3a effects) were observed in zooplankton population of daphnidae and copepods, hence a NOEC population/community was set at < 0.1 µg/l. The nature and characteristics of these effects (short-term, recovery within 8 weeks), permits to set a NOEAEC = 0.1 µg/l.

At 0.1 µg/l, insects were affected only slightly (class 2 effects), and represented the NOEC for this group. The endpoints are based on peak concentrations recorded during the test, which were found in most cases within 2 days after application and corresponded to the nominal application (*via* spray).

DERIVATION OF PNECs

PNEC $_{aquatic}$

As agreed at TMIII2011, in the first instance, the PNEC is derived from the lowest NOEC value (daphnia 21d NOEC = 0.018 µg/l) among the three laboratory chronic toxicity endpoints for fish, *Daphnia magna* and algae, with an application of an assessment factor of 10.

PNEC$_{\text{aquatic organisms}}$ = 0.0018 µg/l

The results from the microcosm study cannot be directly used for PNEC derivation because the NOEC is below the lowest test concentration (< 0.1 µg/l) and the NOEAEC (0.1 µg/l) was not considered appropriate for biocide risk assessment (conclusion of TMII2012). Nevertheless, during the TMII2012 it has been agreed that this higher tier study can be used to refine the AF to be applied to the laboratory endpoint in case relevance and appropriateness of this mesocosm study can be demonstrated.

Based on the considerations made above about the relevance of the microcosm, and in particular taking into account that

- in the mesocosm a diverse enough edge of the field water body bio-community was tested (which included several insects groups) and *Daphniidae* was the most sensitive family (covering also the copepods), as also demonstrated in the acute and chronic laboratory tests;

and

- the laboratory endpoint is based on continuous exposure (static renewal) which is clearly worst case in regard to the actual peak exposure scenario occurring in reality;

the uncertainty in the toxicity endpoint is reduced.

The RMS proposes that the AF can be safely reduced to 5. Hence:

PNEC$_{\text{aquatic organisms}}$ = 0.0036 µg/l (refined PNEC)

Metabolites

No PNEC can be derived for the one minor (M01) and two major (M02 and M08) metabolites of Triflumuron, expected to be formed in surface water, as only the acute toxicity *of D. magna* is tested. However, the acute toxicity of the three metabolites to the most sensitive aquatic organism, *D. magna* was significantly lower than Triflumuron. It is concluded that the PNEC of the active substance accounts for the toxicity of Triflumuron metabolites.

PNEC$_{\text{micro-organisms}}$

On the basis of a nominal 3h EC50 > 10,000,000 µg/l (activated sludge respiration inhibition), the PNEC is derived with a safety factor of 100. Therefore, PNEC$_{\text{micro-organisms}}$ = 100,000 µg/l.

Since the nominal concentration of Triflumuron is very far beyond its solubility limit (40 µg/l), a more realistic PNEC is calculated based on the NOEC set greater than its water solubility (NOEC > 40 µg/l). Since effects were not observed at nominal concentration much higher than the water solubility it is considered that adverse effects to micro-organisms in STP are not expected and the PNEC can be set disregarding the application of the AF=10 to the NOEC. Hence:

PNEC$_{\text{micro-organisms}}$ = > 40 µg/l

PNEC$_{\text{sediment}}$

On the basis of one long term EC$_{10}$ (0.25 µg/l, converted to 40 µg/kg ww) determined in a chronic toxicity study with *C. riparius*, the PNEC is calculated with an assessment factor of 100, according to TGD. Therefore,

PNEC$_{\text{sediment}}$ = 0.40 µg/kg ww

Since the RMS highlighted that, due to the fresh food feeding the EC$_{10}$ might underestimate the toxicity to sediment organisms and an assessment factor of 100 might not be sufficient to cover uncertainty, the PNEC$_{\text{sediment}}$ was also calculated based on the equilibrium partitioning method, using the PNEC$_{\text{aquatic organisms}}$ = 0.0036 µg/l, as it was proposed at TMIII2011:

PNEC$_{\text{sediment}}$ (EPM)= 0.58 µg/kg ww

In the risk assessment the lowest figure will be used: PNEC$_{\text{sediment}}$ = 0.40 µg/kg ww.

Metabolites

The PNEC$_{\text{sediment}}$ of the major metabolites M02 M08 is calculated on the basis of the NOEC/EC$_{10}$ values available, with an assessment factor of 100. Therefore,

2-chlorobenzoic acid (M02):
PNEC$_{\text{sediment}}$ = NOEC$_{\text{spiked sediment}}$ /100 = 957 µg a.i./kg

4-trifluoromethoxyphenyl urea (M08):
$PNEC_{sediment}$ = $EC10_{spiked\ sediment}$ /100 = 590 µg a.i./kg

For 2-chlorobenzamide (M01), the NOEC = 100 mg/l has not been converted into sediment concentration because Ksusp cannot be calculated

Terrestrial compartment

Effects of Triflumuron were investigated on micro-organisms activity (soil respiration and nitrogen mineralisation), on earthworms, terrestrial plants and birds. For the two major metabolites of Triflumuron, expected to be formed in soil, i.e. 2-chlorobenzoic acid (M02) and 4-trifluoromethoxyphenyl urea (M08), data on soil microorganisms nitrogen turnover and on two soil dwelling invertebrates species are available.

Since Triflumuron degrades in soil with a mean DT_{50} in soil of 16.3d, the test results based on the nominal concentration have been recalculated based on the TWA concentration, according to the approach recommended in the Document "Environmental effects assessments for biocidal active substances that rapidly degrade in environmental compartments of concern", endorsed at the 32nd meeting of Member States Competent Authority (February 2009).

The acute toxic effects of Triflumuron to soil dwelling invertebrates were tested with *Eisenia foetida* exposed for 14d in artificial soil to a limit nominal concentration of 1000 mg a.i./kg dwt. Since no lethal or sublethal effect were observed, the 14-day LC_{50} > 754 mg a.i./kg dwt soil and NOEC ≥ 754 mg a.i./kg dwt soil are estimated based on twa concentration.

The toxicity of the metabolites M02 and M08 formed in soil was investigated in acute tests with the worm *Eisenia andrei* and in chronic test with the collembola *Folsomia candida*, using artificial soil. No effects were recorded in worms exposed to a limit concentration of M02, therefore a 14d LC_{50} > 1 000 mg 2-chlorobenzoic acid /kg dwt soil and 14d NOEC ≥ 1 000 mg 2-chlorobenzoic acid/kg dwt soil were retrieved based on initial nominal concentration. Worms exposed to a concentration series of M08 died after 7d at 1 000 mg 4-(trifluormethoxy)-phenylurea/kg. Based on initial nominal concentration, the LC_{50} was 562.1 mg 4-(trifluormethoxy)-phenylurea/kg dwt.soil, the NOEC was 100 mg 4-(trifluormethoxy)-phenylurea/kg d.wt. (weight endpoint) and < 10 mg 4-(trifluormethoxy)-phenylurea/kg dry wt.soil [cocoon formation]. The metabolite M08 resulted more toxic also upon chronic exposure in artificial soil. The survival and reproduction of *Folsomia candida* were not affected up to the highest testeds concentration of M02, hence the 28-day $NOEC_{mortality\ and\ reproduction}$ ≥ 100 mg 2-chlorobenzoic acid/kg dry wt.soil, expressed as initial nominal concentration. At this concentration, the metabolite M08 produced significant reduction in the number of juveniles and the 28-day $NOEC_{reproduction}$ was set equal to 31.6 mg 4-(trifluormethoxy)phenylurea/kg d.wt., expressed as initial nominal concentration.

The inhibition to microbial activity of Triflumuron was tested in 28d studies with the active substance and with a SC formulation, originally designed to meet the requirements of Dir. 91/414/CE for agrochemicals (only 2 concentrations tested). Therefore, the results of the tests have been re-evaluated according to the approach agreed at TMII09, following the E-consultation "Effects on soil microorganisms".

The effects of the active substance on microbial mineralization of carbon and on the nitrogen transformation activity of microorganisms were tested for 28d in two soils treated nominal concentrations of 0.33 and 3.33 mg Triflumuron/kg d.wt.s. The $NOEC_{carbon\ mineralization}$ was 3.3 mg/kg dry wt. soil, based on initial nominal concentrations, recalculated as $NOEC_{carbon}$

$_{\text{mineralization}}$= 1.93 mg/kg dry wt. soil, based on the twa concentration. The nitrogen transformation resulted a more sensitive endpoint. Taking into account the results from the soil amended with ammonium sulphate, at the low concentration effects were not significant and equal to 0.6%. Therefore, a NOEC = 0.33 mg/kg dwt soil can be set, based on initial nominal concentrations, recalculated NOEC$_{\text{nitrogen transformation}}$= 0.19 mg/kg dry wt. soil, based on the twa concentration.

The tests with the product Alsystin® 480 SC confirmed the higher sensitivity of the nitrogen transformation endpoint. In the soil respiration test, no statistically significant differences (and <15%) were detected on the tumover of organic material in both soils and both concentrations. Therefore, NOEC = 5.33 mg a.i./kg dry weight soil (highest tested concentration), based on initial nominal concentrations, recalculated as NOEC$_{\text{carbon mineralization}}$= 3.11 mg/kg dry wt. soil, based on the twa concentration. In the nitrogen transformation test, only at the low concentration (0.53 mg a.i./kg d.wt.s., nominal) no significant difference was detected respect to the control. Since the effect was <15%, this concentration was set as the NOEC, corresponding to NOEC$_{\text{nitrogen mineralization}}$= 0.31 mg/kg dry wt. soil, recalculated based on the twa concentration.

Effects of the metabolites 2-chlorobenzoic acid and 4-trifluormethoxyphenyl urea on the soil microflora were tested only with respect to nitrogen transformation, as this test have been shown to be more sensitive than the carbon transformation test. A loamy sand soil was exposed for 28 d to only one nominal concentration, i.e. 0.53 mg M02/kg d.wt.soil and 0.75 mg M08/kg d.wt.s. No statistically significant effects on the amount of nitrate formation was recorded (effects 0% and 2.8% for M02 and M08, respectively), therefore the NOEC$_{\text{nitrogen transformation}}$ ≥ 0.53 mg M02/kg dwt soil, and NOEC$_{\text{nitrogen transformation}}$ ≥ 0.75 mg M08/kg dwt.soil, expressed as initial nominal concentrations.

With regard to terrestrial plants, a 21d herbicidal screening study conducted with Triflumuron SC 480 was submitted which was considered acceptable by TMIII 2011. The test aimed at evaluating the effects of several rates of the test item applied as spray on pre-emergence and post-emergence in 6 dicotyledonae and 4 monocotyledonae plants. In both tests, all plants showed no phytotoxic effects up to the highest application rate of 1080 g a.s./ha, corresponding to a NOEC > 1.27 mg Triflumuron/kg wet soil if a soil mixing depth of 5 cm is assumed. Since this endpoint is based on initial nominal concentrations, the endpoints have been recalculated based on twa concentration.

Correction of endpoints for the organic matter and moisture content of experimental soils

To account for difference in bioavailability of Triflumuron and its metabolites attributable to difference in organic matter content present in experimental soils, the results of the toxicity tests with terrestrial organisms have been corrected for the organic matter fraction. Further, the terrestrial endpoints have been converted into wet weight for their use in the risk assessment.

The final endpoints used for PNEC derivation are listed in the Table below:

Triflumuron					
Species	**Endpoint**	**Exposure duration**	**Re-calculated result for organic matter content**	**Moisture (%, mean)**	**Re-calculated result for organic matter content and moisture**
Soil micro-organisms	Carbon respiration	28 days	NOEC = 4.53 mg/kg dry wt. soil		NOEC = 0.40 mg/kg wwt. soil (N mineralization covering also C respiration)
Soil micro-organisms	Nitrogen mineralisation	28 days	NOEC=0.45 mg/kg dry wt. soil (N mineralization)	**10.3**	
2-chlorobenzoic acid (M02)					
Species	**Endpoint**	**Exposure duration**	**Re-calculated result for organic matter content**	**Moisture (%, mean)**	**Re-calculated result for organic matter content and moisture**
Soil micro-organisms	Nitrogen mineralisation	28 days	NOEC = 2.07 mg metabolite/kg dry wt. soil	40-45% WHC $^{1)}$	NOEC =1.83 mg metabolite/kg wwt. soil
4-trifluoromethoxyphenyl urea (M08)					
Species	**Endpoint**	**Exposure duration**	**Re-calculated result for organic matter content**	**Moisture (%, mean)**	**Re-calculated result for organic matter content and moisture**
Soil micro-organisms	Nitrogen mineralisation	28 days	NOEC =2.9 mg metabolite/kg dry wt. soil	40% WHC$^{1)}$	NOEC= 2.57 mg metabolite/kg wwt. soil
Triflumuron					
Species	**Endpoint**	**Exposure duration**	**Re-calculated result for organic matter content**	**Moisture (%, mean)**	**Re-calculated result for organic matter content and moisture**
Eisenia foetida	Lethality	14 days	LC_{50} > 256 mg/kg dry wt. soil	35	LC_{50} > 166 mg/kg wwt. soil

2-chlorobenzoic acid (M02)

Species	Endpoint	Exposure duration	Re-calculated result for organic matter content	Moisture (%, mean)	Re-calculated result for organic matter content and moisture
Eisenia andrei	Lethality	14 days	LC_{50} > 340 mg metabolite/kg dry wt. soil	39	**LC_{50} > 207 mg** metabolite/kg wwt. soil
Folsomia candida	Lethality and reproduction	28 days	LC_{50} > 34 mg metabolite/kg dry wt. soil NOEC = 34 mg metabolite/kg dry wt. soil	32	LC_{50} > 23.1 mg metabolite/kg wwt. soil **NOEC = 23.1 mg** metabolite/kg wwt. soil

4-trifluoromethoxyphenyl urea (M08)

Species	Endpoint	Exposure duration	Re-calculated result for organic matter content	Moisture (%, mean)	Re-calculated result for organic matter content and moisture
Eisenia andrei	Lethality	14 days	14-day LC_{50} = 191 mg metabolite/kg dry wt.soil	38	**14-day LC_{50} = 118 mg** metabolite/kg wwt. soil
Folsomia candida	Lethality and reproduction	28 days	EC_{50} = 47.8 mg metabolite/kg dry wt. soil NOEC = 10.7 mg metabolite/kg dry wt. soil	41	EC_{50} = 28.2 mg metabolite/kg wwt. soil **NOEC = 6.3 mg** metabolite/kg wwt. soil

Triflumuron

Species	Endpoint	Exposure duration	Re-calculated result for organic matter content	Moisture (%, mean)	Re-calculated result for organic matter content and moisture
Plants	Emergence and growth	21d	21d **EC_{50}** > 0.95 mg/kg **wet** soil (twa concentration)	Watered as needed	21d **EC_{50}** > 0.95 mg/kg **wet** soil (twa concentration)

1)Actual moisture data are not available. The conversion dw to wwt has been carried out dividing the dw value by the conv soil factor 1.13 using the formula $CONV_{soil} = \frac{RHO_{soil}}{Fsolid_{soil} \cdot RHOsolid}$.

Bees

No risk is foreseen for bees following application of Triflumuron in animal houses and exposure to bees via application of contaminated manure on grassland and arable land. Triflumuron is a non-systemic compound; therefore contamination of flowers can only occur via direct spray.

According to normal agricultural practice application of manure on arable land and grassland is performed before or at the beginning of the growing season. On arable land treatment takes place on bare soil, before sowing. Grassland is treated directly after mowing. In both scenarios no flowering weeds or crops are present.

Even for flowering weeds at the edge of the treated field which might be contaminated with Triflumuron via (manure) spray drift no risk to bees is seen. On one hand, drift exposure due to manure spray application is expected to be very low and – due to droplet size – limited to very short distances from the field edge. On the other hand, the contamination with manure, with which the contamination with Triflumuron coincides, obviously prevents attractiveness of these crops for bees.

Other arthropods

Exposure of soil dwelling arthropods to Triflumuron, following the administration of contaminated manure and litter to agricultural soil (pastures, grassland and arable land) cannot be excluded. In addition, due to the mode of action of Triflumuron (Insect Growth Regulator), effects on arthropods are likely. In this respect, data on non target ground dwelling arthropods would be required in order to permit a sound assessment for terrestrial organisms.

DERIVATION OF PNECs

In the available data set, acute toxicity data are available for a producer (plants: 21 d EC$_{50}$ > 0.95 mg/kg wwt soil) and a consumer (earthworms: 14 d LC$_{50}$ > 166 mg/kg wwt soil). Long-term toxicity data are available for a decomposer (micro-organisms: 28 d NOEC= 0.40 mg/kg wwt soil). In consideration of the mode of action of Triflumuron (Insect Growth Regulator) and the likely exposure of soil organisms after application of treated manure to soil, the lack of data on non target ground dwelling arthropods implies a potential high uncertainty. Arthropods were the most sensitive group also in the microcosm study.

To cope with this data gap, TMII 2012 concluded that the PNEC should be derived using the AF approach based on the lowest endpoint in the available data set, and also with the Equilibrium Partitioning Method.

Triflumuron

Based on the long-term test on microorganisms, an AF = 100 is applied to the 28 d NOEC= 0.40 mg/kg wwt soil:

PNEC$_{soil}$ = 0.0040 mg/kg wwt soil = 4.0 µg /kg wwt soil

Based on the equilibrium partitioning method, using the PNEC$_{aquatic\ organisms}$ = 0.0036 µg/l:

PNEC$_{soil}$ (EPM)= 0.47 µg/kg ww.

The lowest PNEC$_{soil}$ will be used in the risk assessment.

Metabolites (M02 and M08)

For both the major metabolites M02 and M08, two NOECs are available from chronic tests with microorganisms (nitrogen mineralisation) and soil invertebrates (the collembolan *Folsomia candida).* By applying an assesment factor of 50 to the lowest chronic endpoints (nitrogen mineralization) expressed as initial nominal concentration, the PNECs for M02 and M08 would result as follows:

2-chlorobenzoic acid (M02):

NOEC = 1.83 mg /kg wwt. soil

PNEC$_{soil}$ = 1.83 /50= 0.0366 mg /kg ww soil

4-trifluoromethoxyphenyl urea (M08):

NOEC= 2.57 mg /kg wwt. soil

$PNEC_{soil}$= 2.57 /50 = 0.0514 mg a.i./kg ww soil

Since the NOEC are based on initial nominal test concentrations, for risk characterization the above PNEC have to be compared to initial PEC values.

Non compartment specific effects relevant to the food chain (secondary poisoning)

No specific studies were carried out to determine whether Triflumuron residues have an impact on secondary poisoning. Triflumuron has a log Kow of 3.5 and the results of a fish bioaccumulation study (see 2.2.2.1 above) provide a BCF_{fish}= 612. Data on the available mammalian toxicity rule out the possibility of accumulation of relevant concentration in mammals and, in addition, Triflumuron is not subject to classification (see Human Health effects assessment).

The toxicity of the major soil and aquatic metabolites of Triflumuron (2-chlorobenzoic acid (M02) and 4 trifluoromethoxy-phenylurea (M08)) is covered by the toxicity of the parent substance in mammals testing. These metabolites have log Pow values < 3, hence no risk due to bioaccumulation of these metabolites is to be expected for earthworm- or fish-eating mammals.

Therefore, in accordance with TGD (2003), the calculation of the $PNEC_{mammals}$ for the secondary poisoning risk assessment is considered not necessary for both Triflumuron and its metabolites.

$PNEC$oral, $_{mammals}$ = calculation not required

No metabolic data are available for birds to evaluate the potential for accumulation. Therefore, a $PNEC_{birds}$ is calculated on the basis of the ecotoxicological data available.

Triflumuron resulted in a low acute (LD_{50} = 561 mg/kg bw), dietary (LC_{50} > 5 626 mg/kg diet) and reproductive (80 mg/kg diet) toxicity to birds. According to TGD, an AF of 30 is applied to the NOEC of 80 mg/kg food (Mallard duck and Bobwhite quail) leading to:

$PNEC_{oral-birds}$ = 80/30 = 2.66 mg/kg food

No data are available on toxicity of Triflumuron metabolites to birds. Anyhow the major soil and aquatic metabolites M02 and M08 have log Pow values < 3. Therefore no risk due to bioaccumulation of these metabolites is to be expected for earthworm- or fish-eating birds.

2.2.2.3. PBT and POP assessment

PBT assessment

Triflumuron is assessed to not fulfil the criteria for PBT substances.

P criterion: Half life > 120 d in freshwater sediment

From data of hydrolysis:
Triflumuron is hydrolytically stable over an environmentally relevant pH range of 5-9.

From data of photolysis in water:
Triflumuron was found to be photolytically stable in the absence of a photosensitiser.

Studies of the distribution in the water sediment system suggest that Triflumuron is rapidly degraded with an overall DT$_{50}$ value in the range 4.1 to 7.1 days at 20°C, in the range 7.8 to 13.5 days at 12°C.

Triflumuron is quickly degraded in soil under aerobic conditions with a DT$_{50}$ of 40.8 days (maximum value), taking into account the new trigger values for the P criteria of the REACH legislation of DT$_{50}$ in soil > 120 d. According to “Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment” 2012, due to the fact that the test methodology for the screening tests on ready biodegradability is stringent, a negative result does not necessarily mean that the chemical will not be degraded under environmental conditions. If sufficient degradation is shown in such a test, i.e. the pass level is reached, the substance can be considered as “not P”.

Therefore, the P criterion is not fulfilled.

B criterion: BCF>2000

Triflumuron has a log Kow 3.5 at 20°C (3.6 at 10°C), indicating a potential to accumulate in organisms. The results of a bioaccumulation study with bluegill sunfish provided a BCF$_{fish}$= 612, therefore. the experimental evidence permits to conclude that the B criterion is not fulfilled.

T criterion: Chronic NOEC or EC10 < 0.01 mg/l for marine or freshwater organism

The substance is classified as N; R 50/53. The substance does not meet the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B) or toxic for reproduction (category 1A, 1B or 2), according to regulation EC 1272/2008 and there is no other evidence of chronic toxicity.

Chronic toxicity endpoints are available for fish (*Pimephales promelas*, NOEC ≥ 22.8 µg a.i./l), algae (*Scenedesmus subspicatus,* 72-h E_bC_{50} > 25 µg a.i./l) and invertebrates (*Daphnia magna*, NOEC = 0.018 µg a.s./l). *Daphnia magna* is clearly the most sensitive organism, providing the lowest endpoint. Based on the latter, it can be concluded that the T criterion is fulfilled.

Conclusion: Triflumuron is neither PBT- nor vPvB-candidate since the P and B criteria are not fulfilled.

POP assessment

The analysis of POPs criteria was not required when the dossier was evaluated and therefore not considered when Triflumuron was discussed at technical meeting level (TMIII2011).

Triflumuron *does* pose adverse effects to human health and to the environment and is not readily biodegradable (please, refer to the classification proposal under chapter 2.1.3 of this document). Nonetheless:

- Triflumuron was concluded to be not persistent. Studies of the distribution in the water-sediment system show that Triflumuron is rapidly degraded with an overall DT$_{50}$ value in the ranges 4.1 to 7.1 days and 7.8 to 13.5 days at 20°C and 12°C, respectively. Triflumuron is also quickly degraded in soil under aerobic conditions with a DT$_{50}$ of 40.8 days as maximum value;
- Triflumuron has a log Kow =3.5 at 20°C and a measured BCF$_{fish}$ = 612.

and

- no potential for long-range environmental transport is expected (the estimated half-life of Triflumuron in air via hydroxyl reactions is not expected to exceed 1.2 days at most;

Triflumuron is quickly and strongly adsorbed to soil with Koc values of 1 629 to 30 006 ml/g (5 soils, geometric mean of 7 332 ml/g and median value of 7 675 ml/g).

Conclusion: There is no evidence indicating that Triflumuron has the POPs-like characteristics (outlined in Annex D 'Information Requirements & Screening Requirements' of the Convention Stockholm Convention on Persistent Organic Pollutants 2001) such that global control is necessary.

2.2.2.4. Exposure assessment

Aquatic compartment (incl. sed.)

- *Spraying application*

Using the exposure scenario (as recommended in the ESD) as an approximation of a worst-case situation (from veal calves, manure application to grassland), overall the worst-case of the active substance in surface water is estimated to be 0.051 µg/l.

Using the exposure scenario (as recommended in the ESD), the maximum potential concentration of the active substance in sediment is 0.0030 mg/kg (wet weight), resulting from run-off from grassland after manure application.

In the following table has been reported the summary of the PECsw and PECsed following manure application to land for all animal categories and subcategories.

Summary of the PECsw and PECsed following manure application to land for all animal categories and subcategories

Index i1	Category	Sub category	PECsw (µg/l)		PECsed* (mg/kg)	
			Arable	Grass	Arable	Grass
1	Cattle	Dairy cattle (housed during grazing season).	0.008	0.022	0.0013	0.0034
		Dairy cattle (outdoors during grazing season).	0,018	0.050	0.0029	0.0080
2	-	Beef cattle (housed during grazing season).	0.002	0.006	0.0003	0.0010
		Beef cattle (outdoors during grazing season).	0.005	0.014	0.0008	0.0023
3	-	Veal calves.	0.019	0.051	0.0030	0.0082
4	Pigs	Sows.	0.014	0.037	0.0022	0.0059
5	-	Sows in groups.	0.017	0.047	0.0028	0.0075
6	-	Fattening pigs.	0.011	0.030	0.0018	0.0049
7	Poultry	Laying hens in battery cages without treatment.	0.004	0.011	0.0007	0.0017
8	-	Laying hens in battery cages with aeration (belt drying).	0.005	0.012	0.0008	0.0019
9	-	Laying hens in battery cages with forced drying (deep pit, high rise)[1].	0.007	0.019	0.0012	0.0031
10	-	Laying hens in compact battery cages.	0.005	0.012	0.0008	0.0019
11	-	Laying hens in free range with litter floor (partly litter floor, partly slatted)[2].	0.019	0.051	0.0030	0.0082

12	-	Broilers in free range with litter floor[2].	0.008	0.022	0.0013	0.0034
13	-	Laying hens in free range with grating floor (aviary system).	0.008	0.023	0.0013	0.0037
14	-	Parent broilers in free range with grating floor.	0.004	0.012	0.0007	0.0019
15	-	Parent broilers in rearing with grating floor.	0.009	0.025	0.0015	0.0040
16	-	Turkeys in free range with litter floor[2].	0.016	0.042	0.0025	0.0067
17	-	Ducks in free range with litter floor[2].	0.017	0.045	0.0027	0.0071
18	-	Geese in free range with litter floor[2].	0.012	0.032	0.0019	0.0051

[1] Manure waste stream.
[2] Manure and liquid waste stream

The potential maximum surface water concentrations of the metabolites M02 and M08 are now considered. According to laboratory studies described under IIA 4.1, degradation of the active substance in water/sediment systems leads to the formation of 2 significant metabolites, M02 (molecular weight 156.6 g/mol) and M08 (molecular weight 220.2 g/mol). In studies the maximum amount of the metabolites M02 and M08 observed were 60.4 and 47.8% of initial levels, respectively.

Therefore the maximum concentrations of the metabolites M02 and M08 in surface water are 0.007 and 0.008 µg/l, respectively for arable land and 0.013 and 0.015 µg/l, respectively for grassland. The maximum concentrations of the metabolites M02 and M08 in sediment are ≤ 1.9 µg/kg.

- *Watering can application*

According to the opinion of BPC-6, a new risk assessment has been performed, based on the new exposure assessment based on watering can application of 0.5 g/m^2.

According to the applicant information, the watering can application is a marginal use which is effectively used only in very small farms. In the exposure assessment, the scenario with the smallest stable surface provided in the ESD for PT 18 was used, which is veal calves using a surface area of 160 m^2. Therefore only for this scenario the exposure assessment has been performed

The predicted environmental concentration (PEC) of the active substance in surface water has been determined using the Tier I procedure as provided in the ESD. The potential concentration of the active substance in surface water is given by the equation reported below.

The concentration of the active substance in surface water, resulting from run-off following land applications of stored manure is estimated to be 0.0038 µg/l to grassland (i.e., covered soil) and 0.0046 µg/l to arable land. This is considered a worst-case situation, as run-off from covered soil or grassland could be expected to be curtailed.

The PEC values for sediment are 0.61 µg/kg and 0.74 µg/kg for grassland and arable land, respectively.

For arable land the maximum concentrations of the metabolites M02 and M08 in surface water are 0.0001 and 0.0005 µg/l, respectively. For grassland the maximum concentrations of the metabolites M02 and M08 in surface water are 0.0004 and 0.0005 µg/l, respectively. The maximum concentrations of the metabolites M02 and M08 in sediment are ≤ 0.09 µg/kg.

- *Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting*

The Applicant revised the composting scenario presented in BPC-6. this time taking into account poultry manure (which is composted): laying hens in battery cages with aeration (belt drying) and spray application. The eCA and ECHA commented on this scenario revising the DT50 used for the degradation in manure (worst case DT50 was used instead of the geometric mean as was done for DFB). The revised scenario was brought to BPC 7 for discussion but the BPC members decided that the BPC is not the appropriate forum to discuss this scenario and therefore required the Environmental WG to review it.

For entry of the substance into the surface water compartment, as a first tier, the ESD recommends considering entry of porewater into the receiving water compartment with a dilution factor of 10.

Predicted concentrations of metabolites M02 and M08 in surface water were calculated from the concentrations of the parent compound, by adjusting for the molecular mass of the metabolite compared to the parent compound, and for the maximum amount of the metabolite observed in water (M02: 60.4%; M08: 47.8%).

Predicted maximum surface water concentrations of Triflumuron, metabolite M02 and metabolite M08

Variable/parameter	**Symbol**	**Unit**	***Napp-bio***$_{max}$	**Value**		
				Triflumuron	**M02**	**M08**
Predicted environmental concentration in surface water (from arable land runoff)	*PIECars-water-N*	[mg.L^{-1}]	1	5.93×10^{-7}	1.56×10^{-7}	1.74×10^{-7}
			4	2.37×10^{-6}	6.25×10^{-6}	6.95×10^{-6}
			5	5.92×10^{-6}	1.56×10^{-6}	1.74×10^{-6}

Predicted concentrations of Triflumuron, M02 and M08 in aquatic sediment were calculated according to the guidelines presented in the Technical Guidance Document:

Predicted maximum sediment concentrations of Triflumuron, metabolite M02 and metabolite M08

Variable/parameter	**Symbol**	**Unit**	***Napp-bio***$_{max}$	**Value**		
				Triflumuron	**M02**	**M08**
Predicted environmental concentration in sediment following land application to arable land	*PIECars-sed-N*	[mg.kg^{-1}]	1	9.50×10^{-5}	6.84×10^{-6}	2.44×10^{-5}
			4	3.80×10^{-4}	2.74×10^{-5}	9.75×10^{-5}
			5	9.50×10^{-4}	6.84×10^{-4}	2.44×10^{-4}

Refined PEC in surface water

Refined predicted environmental concentrations (Koch, B., 2008, MEF-08/199) in surface water (PEC_{sw}) and Sediment (PEC_{sed}) of the insecticidal active substance Triflumuron (SIR8514) were calculated, using realistic worst case scenarios as described in Table 3.3.2-4 and parameter selection according to FOCUS (2001).

The aquatic PEC values were calculated using the FOCUS STEP 3 scenarios (FOCUS, 2001), taking drainage and runoff entry path into account. In the Step 4 calculation mitigation measures (buffer zones) were considered. A summary of key input data is given in Table 3.3.3.2-6

Summary of key input data for the aquatic PEC calculations

Substance data	Triflumuron	
Adsorption Coefficient (K_{OM})	4989[2]	l/kg
Freundlich Exponent	1.07	-
DT50 soil (mean at 20°C and 100% field capacity)	10.9	days
DT50 water / sediment	2.9 / 23.9	days

Application	
Crop, application rate	Grass / alfalfa, groundspray, 0 gha^{-1} + 110.9 gha^{-1} + 27.7 gha^{-1} + 0 gha^{-1}

The PEC_{sw} values resulting from the Step 3 calculations are <0.001 µg l^{-1} for all drainage scenarios. The runoff scenarios result in PEC_{sw} = 0.038 µg l^{-1} (R2, Porto) and PEC_{sw} = 0.010 µg l^{-1} (R3, Bologna). These PEC_{sw} values are reduced by runoff mitigation (Step 4 calculation) to PEC_{sw} = 0.017 µg l^{-1} (R2, Porto) and PEC_{sw} = 0.005 µg l^{-1} (R3, Bologna).

Maximum PECsw values [µg/l] and PECsed values [µg/kg] of Triflumuron (FOCUS STEP 3 and FOCUS STEP 4) after use in rural hygiene and application of the accruing manure to agricultural surfaces

Scenario	Water Body	**PECsw [µg/l]**	
		No Runoff mitigation	60% / 85 % Runoff Mitigation
D1, Lanna	ditch	<0.001	
	stream	<0.001	
D2, Brimstone	ditch	<0.001	
	stream	<0.001	
D3, Vredepeel	ditch	<0.001	
D4, Skousbo	pond	<0.001	
	stream	<0.001	
D5, La Jailliere	pond	<0.001	
	stream	<0.001	
R2, Porto	stream	0.038	0.017

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[2] Corresponding to a Koc of 8601 ml/g

R3, Bologna	stream	0.010	0.005

Sewage Treatment Plant (STP)

- *Spraying application*

For use in animal houses, where waste water from treated areas can be emitted to the sewerage system i.e. poultry batteries with aeration or forced drying (deep pit, high rise stables) the potential concentrations emitted to STP are considered:

PEC$_{STP}$ = 0.0136 mg/l

The predicted environmental concentration (PEC) of the active substance in STP, surface water and sediment has been determined using the general procedures for exposure to STP described in the Technical Guidance Document (TGD) on risk assessment[3]. This level of assessment is deemed adequate for the purposes of this exposure assessment and further refinements are not considered necessary.

The PEC calculations are based on the environmental emissions determined above. The local emissions are assumed to be discharged to a STP facility and the concentration of the active substance entering the STP is 0.016 mg/l calculated using the following equations assuming no degradation between release and entry into the STP as a worst-case situation.

Within the STP the distribution of the active substance between water and sewage sludge and the degree of removal can be estimated using the Simple Treat Model shown in TGD Appendix II. The active substance is not readily biodegradable. Therefore from the model (using the values for Log H[4] = -3) and Log Kow = 3.5, 85% of the active substance will be partitioned to the water phase and 15% will be partitioned to sewage sludge.

STP inflow concentration, Clocalinf = 0.032 x 10^6 / 2000000 = 0.016 mg/l

Water and soil compartment can be contaminated via waste water to STP, using the SimpleTreat model, as indicated above, the effluent concentration (Clocaleff) can be calculated as follows:

STP outflow concentration, Clocaleff = 0.016 x 0.85 = 0.0136 mg/l

Therefore PECsw is 1.2 x 10^{-3} mg/l and PECsed is 0.19 mg/kg after STP release. According to TGD PECsoil after sludge application is 0.06 mg/kg.

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

[4] $H = 1.79 \times 10^{-3}$ Pa.m^3.mol^{-1}

- *Watering can application*

New exposure assessment for STP based on watering can application of 0.5 g/m^2. The Clocalwater calculated is 3.0 x 10^{-4} mg/l. Therefore PECsw is 3.0 x 10^{-4} mg/l and PECsed is 0.05 mg/kg after STP release. According to TGD PECsoil after sludge application is 0.015 mg/kg.

Terrestrial compartment

- *Spraying application*

Following the use of Baycidal® 25 WP indoors in animal houses the realistic worst-case initial PEC in soil is 0.024 and 0.067 mg/kg (wet weight soil) for arable land and grassland, respectively. This realistic worst-case PEC corresponds to the veal calves animal sub-category.

In the following table has been reported the summary of the PECsoil following manure application to land for all animal categories and subcategories.

Summary of the PEC in soil following manure application to land for all animal categories and subcategories

Index i1	Category	Sub category	Initial soil concentration (mg/kg)			
			Arable		Grassland	
			*N	**P	*N	**P
1	Cattle	Dairy cattle (housed during grazing season).	0.010	0.011	0.025	0.031
		Dairy cattle (outdoors during grazing season).	0.024	0.029	0.058	0.080
2	-	Beef cattle (housed during grazing season).	0.003	0.004	0.007	0.012
		Beef cattle (outdoors during grazing season).	0.007	0.010	0.016	0.029
3	-	Veal calves.	0.024	0.014	0.067	0.039
4	Pigs	Sows	0.018	0.007	0.043	0.021
5	-	Sows in groups.	0.022	0.010	0.054	0.027
6	-	Fattening pigs.	0.014	0.007	0.035	0.021
7	Poultry	Laying hens in battery cages without treatment.	0.005	0.003	0.012	0.009
8	-	Laying hens in battery cages with aeration (belt drying).	0.006	0.003	0.014	0.009
9	-	Laying hens in battery cages with forced drying (deep pit, high rise)[1].	0.010	0.005	0.022	0.014
10	-	Laying hens in compact battery cages.	0.006	0.003	0.014	0.009
11		Laying hens in free range with litter floor (partly litter floor, partly slatted)[2].	0.024	0.013	0.067	0.036
12	-	Broilers in free range with litter floor[2].	0.010	0.008	0.025	0.023
13	-	Laying hens in free range with grating floor (aviary system).	0.011	0,005	0.027	0.016
14	-	Parent broilers in free range with grating floor.	0.005	0.003	0.013	0.009
15	-	Parent broilers in rearing with grating floor.	0.012	0.007	0.029	0.020
16	-	Turkeys in free range with litter floor[2].	0.020	0.014	0.049	0.040
17	-	Ducks in free range with litter floor[2].	0.022	0.012	0.052	0.034
18	-	Geese in free range with litter floor[2].	0.015	0.011	0.037	0.030

*N: Nitrogen content
**P: Phosphorus content
All calculation are based on the fraction of the active substance released to the slurry waste stream unless otherwise specified.

[1] Manure waste stream.
[2] Manure and liquid waste stream

The potential maximum soil concentrations of the metabolites M02 and M08 are now considered. According to the laboratory studies described under IIA 4.1, degradation of the active substance in soil leads to the formation of the two significant metabolites, M02 (molecular weight 156.6 g/mol) and M08 (molecular weight 220.2 g/mol). In studies conducted at relevant dose rates, the metabolites M02 and M08 were observed at maximum levels of 5.9 and 19.1% of initial levels after 3 to 7 and 3 to 84 days, respectively. Therefore the maximum concentrations of the metabolites M02 and M08 are 0.0006 and 0.0028 mg/kg (wet weight), respectively for arable land and 0.0017 and 0.008 mg/kg (wet weight), respectively for grassland.

- *Watering can application*

According to the opinion of BPC-6, it was agreed to resume the discussion of this substance at BPC-7 after further consideration of the watering can use scenario with respect to the environmental risk assessment.

According to the applicant information, the watering can application is a marginal use which is effectively used only in very small farms. In the exposure assessment, the scenario with the smallest stable surface provided in the ESD for PT 18 was used, which is veal calves (which is at the same time the worst case scenario for emissions to grassland) using a surface area of 160 m².

Therefore only for veal calves the exposure assessment has been performed.

Following the use of Baycidal® 25 WP indoors in animal houses, considering a Watering Can application of 0.5 g/m^2,the worst-case initial PECs in soil are:

PIECars – N = 0.006 mg/kg

PIECgrs – N = 0.005 mg/kg

PIECars – P2O5 = 0.0037 mg/kg

PIECgrs – P2O5 = 0.004 mg/kg

The potential maximum soil concentrations of the metabolites M02 and M08 are now considered. According to the laboratory studies described under IIA 4.1, degradation of the active substance in soil leads to the formation of the two significant metabolites, M02 (molecular weight 156.6 g/mol) and M08 (molecular weight 220.2 g/mol). In studies conducted at relevant dose rates, the metabolites M02 and M08 were observed at maximum levels of 5.9 and 19.1% of initial levels after 3 to 7 and 3 to 84 days, respectively. Therefore the maximum potential concentrations of the metabolites in soil (wet weight) are:

- for arable land

$$Concentration\ of\ metabolite\ M02\ in\ soil = 0.006 \times \frac{5.9}{100} \times \frac{156.6}{358.7} = 0.00015\ mg/kg$$

$$Concentration\ of\ metabolite\ M08\ in\ soil = 0.005 \times \frac{19.1}{100} \times \frac{220.2}{358.7} = 0.00058\ mg/kg$$

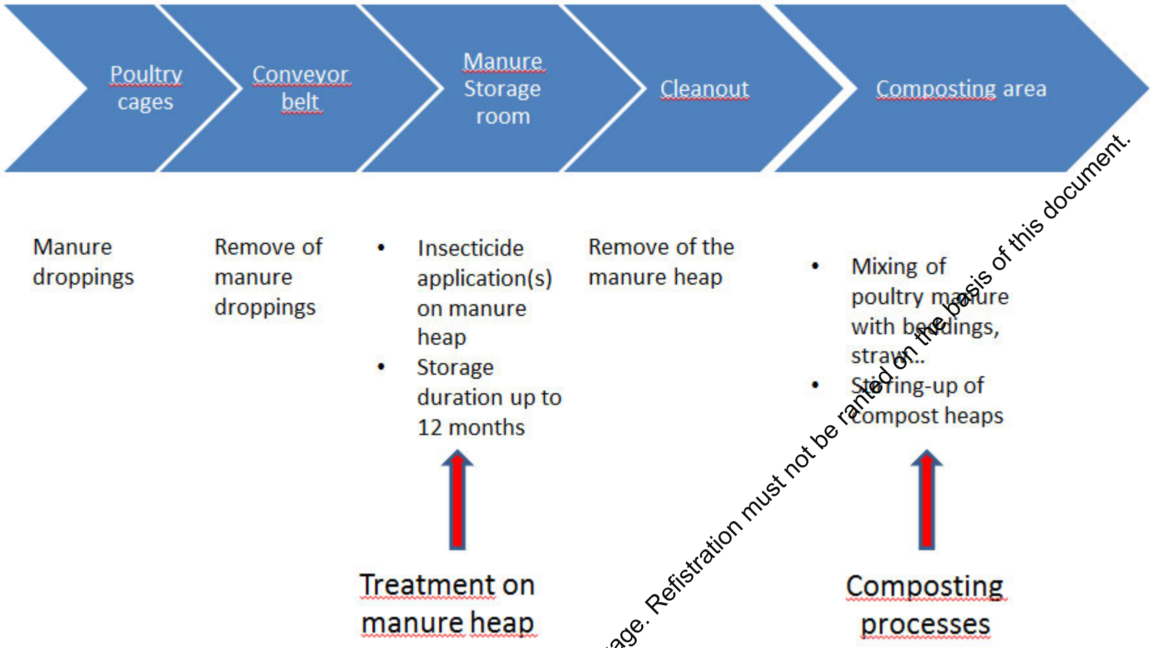
- for grassland:

$$Concentration\ of\ metabolite\ M02\ in\ soil = 0.0037 \times \frac{5.9}{100} \times \frac{156.6}{358.7} = 0.000095\ mg/kg$$

$$Concentration\ of\ metabolite\ M08\ in\ soil = 0.004 \times \frac{19.1}{100} \times \frac{220.2}{358.7} = 0.00047\ mg/kg$$

- *Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting*

Flow chart illustrating the use of triflumuron in poultry house (conveyor belt), the subsequent manure storage and the composting processes



For this risk assessment, predicted concentrations of Triflumuron in soil are calculated based on the nitrogen immission standard, assuming that 100% of the manure spread at a site location is sourced from facilities treated with Triflumuron. The quantity of active substance applied to arable land is therefore assumed to be directly correlated with the quantity of nitrogen in the corresponding amount of manure. In order to determine the quantity of nitrogen produced in a poultry farm (livestock category 8) within the manure storage period.

For application to arable land, the full amount of active ingredient emitted to manure will be spread to land in a single application. The maximum concentration of Triflumuron in soil is therefore represented by the initial concentration in soil (PIEC).

The following initial concentrations of Triflumuron in soil were calculated:

Predicted initial concentrations of Triflumuron in soil (no composting)

Variable/parameter	Symbol	Unit	*Napp-bio$_{max}$*	Value
Initial concentration of the active substance in soil following manure application to arable land, considering the immission standard for nitrogen	*PIECars-N*	[mg kg $_{wwt}$ $^{-1}$]	1	7.68 x 10^{-4}
			4	3.07 x 10^{-3}
			5	7.67 x 10^{-3}

Predicted maximum concentrations of metabolites M02 and M08 in soil (PECsoil$_{arable}$) were calculated by adjusting the initial concentrations of the parent compound to account for the difference in molecular mass between parent and metabolite (molecular weight of 156.6 g/mol and 220.2 g/mol for M02 and M08 respectively), and for the observed formation fractions of each metabolite in soil (at maximum levels of 5.9 and 19.1% of initial levels after 3 to 7 and 3 to 84 days, for M02 and M08 respectively). Calculated maximum concentrations of the metabolites are given below.

Predicted maximum concentrations of metabolite M02 and M08 in soil (no composting)

Variable/parameter	Symbol	Unit	*Napp-bio$_{max}$*	Value	
				Metabolite M02	**Metabolite M08**
Maximum concentration of substance in soil following manure application to arable land, considering the immission standard for nitrogen	*PIECars-N*	[mg.kg$_{wwt}$ $^{-1}$]	1	1.98×10^{-5}	9.00×10^{-5}
			4	7.91×10^{-5}	3.60×10^{-4}
			5	1.98×10^{-4}	8.99×10^{-4}

Time weighted average concentrations of Triflumuron in soil (no composting)

According to the TGD, for risk assessment purposes it is recommended to consider a 30-day time weighted average (TWA) value for the assessment of exposure to soil resulting from sludge application to land. Additionally, soil concentrations over a 180-day time period are considered appropriate for the assessment of bioaccumulation, and as a first tier approach for the assessment of groundwater exposure through the porewater calculation method.

Time Weighted Average concentrations of Triflumuron metabolites M02 and M08 in soil over 30 days (no composting)

Variable/parameter	Symbol	Unit	*Napp-bio$_{max}$*	Value
Time-Weighted Average concentration in soil following manure application to arable land	*PECsoil$_{arable}$ (TWA)*	[mg.kg$_{wwt}$ $^{-1}$]	1	5.78×10^{-4}
			4	2.31×10^{-3}
			5	5.78×10^{-3}

Variable/parameter	Symbol	Unit	*Napp-bio$_{max}$*	Value	
				Metabolite M02	**Metabolite M08**
Time-Weighted Average concentration in soil following manure application to arable land	*PECsoil$_{arable}$ (TWA)*	[mg.kg$_{wwt}$ $^{-1}$]	1	1.49×10^{-5}	6.78×10^{-5}
			4	5.95×10^{-5}	2.71×10^{-5}
			5	1.49×10^{-4}	6.78×10^{-4}

Concentrations of Triflumuron in soil have additionally been calculated by considering the effect of composting. Two composting scenarios were proposed in the Assessment Report prepared by Italy (May 2014). Accordingly, concentrations of Triflumuron in soil for arable land were calculated considering a reduction of nitrogen in soil to 68% of its original value (N_{left}), and a reduction of Triflumuron residues to either 9.05% or 19% of their original values (TFL_{res}) for Scenario 1 and Scenario 2, respectively (corresponding to with or without a “hot phase”).

In the Assessment Report prepared by Italy (May 2014) the mean value was used for DT_{50} instead of the slowest degradation rate of 4 soil tests was used (DT_{50}: 40.8 d, 20˚C) as made for Diflubenzuron. On this base the Remaining Triflumuron residues after composting (TFL_{res}) are 38.4% (Composting scenario 1; including “hot phase”) and 51.55% (Composting scenario 2; without “hot phase”).

Both initial and TWA concentrations in soil (considering composting) are presented below.

Predicted initial and TWA concentrations of Triflumuron in soil (with composting)

Variable/parameter	Symbol	Unit	*Napp-bio$_{max}$*	Value	
				Scenario 1	Scenario 2
Initial concentration in soil following manure application to arable land, considering composting	*PIECars-N$_{comp}$*	[mg.kg $_{wwt}^{-1}$]	1	4.3×10^{-4}	5.8×10^{-4}
			4	1.7×10^{-3}	2.3×10^{-3}
			5	4.3×10^{-3}	5.8×10^{-3}
Time-Weighted Average concentration in soil following manure application to arable land, considering composting	*PECsoil$_{arable,comp}$ (TWA)*	[mg.kg $_{wwt}^{-1}$]	1	3.3×10^{-4}	4.4×10^{-4}
			4	1.3×10^{-3}	1.8×10^{-3}
			5	3.3×10^{-3}	4.4×10^{-3}

Concentrations in porewater

The equation for deriving the concentration (in mg/L) of an active substance in groundwater / porewater for arable land is:

$$PIECars - gw - N = \frac{PIECars - N \times RHOsoil_{wet}}{K_{soil\text{-}water} \times 1000}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Soil-water partitioning coefficient	*Ksoil-water*	[mg.L^{-1}]	220.2	Calculated*
Bulk density of wet soil	*RHOsoil*	[kg.m^{-3}]	1700	Default*
Predicted environmental concentration in arable soil porewater	*PIECars-gw-N*	[mg.L^{-1}]	-	Output

* In accordance with the Technical Guidance Document (European Commission, 2003)

Calculations were performed using initial soil concentrations calculated without considering composting. Predicted concentrations of Triflumuron in soil porewater are presented below. These porewater concentrations are used in the following section to calculate predicted concentrations in surface water, and the risk assessment for groundwater is discussed further below.

Predicted maximum porewater concentrations of Triflumuron

Variable/parameter	Symbol	Unit	*Napp-bio$_{max}$*	Value
Predicted environmental concentration in arable soil porewater	*PIECars-gw-N*	[mg.L^{-1}]	1	5.93×10^{-6}
			4	2.37×10^{-5}
			5	5.92×10^{-5}

The risk assessment for groundwater is covered by the Predicted environmental concentrations of triflumuron in groundwater following use of Baycidal WP 25 in the EU using the FOCUS groundwater scenarios that was submitted in April 2006.

The use of insecticidal formulations in animal houses and manure storage systems and their subsequent impact on the environment is outlined in an Emission Scenario Document (ESD) prepared by the OECD Task Force on Biocides. These emission scenarios have been used to estimate the worst-case potential loadings of the active substance to soil which is determined to be equivalent to a single application of 123.8 g a.s./ha for arable land in the autumn and equivalent to 4 equal applications of 110 g a.s./ha applied between February and September at regular intervals of 53 days. The worst-case potential loadings were estimated considering the maximum 5 insecticides applications sprayed to the floor area (worst case of the spraying application).

Using these treatment patterns and the properties of the active substance triflumuron, simulations were conducted at each of the nine standard FOCUS EU scenario locations using repeated applications each year over a period of 20 years.

The resulting predicted 80th percentile annual average concentrations in groundwater of the active substance and any potential metabolites did not exceed 0.1 µg/L at any of the scenario locations.

It is concluded that Baycidal WP 25 can be used safely in animal houses and manure storage systems as specified throughout the EU without an unacceptable risk to groundwater.

Atmosphere

Due to its low vapour pressure at ambient temperature (2 x 10^{-7} Pa) Triflumuron is not considered volatile and is not expected to volatilise to air in significant quantities.

Non compartment specific exposure relevant to the food chain (secondary poisoning)

The exposure to earthworm eating predators is calculated according to TGD as $PEC_{oral,\ predator}$ = $C_{earthworm.}$. Assuming the worst case Csoil of 0.067 mg Triflumuron/kgwwt soil, following 4 applications of contaminated manure to grassland, Cearthworm results of 0.025 mg/kg.

The exposure to earthworm eating predators is calculated according to TGD as $PEC_{oral,\ predator}$ = $C_{earthworm}$ based on watering can. Assuming the worst case C_{soil} of 0.006 mg Triflumuron/kg_{wwt} soil, following 4 applications of contaminated manure to grassland, $C_{earthworm}$ results of 1.0 x 10^{-6} mg/kg.

The exposure to fish eating predators is calculated according to TGD as PECoral, predator = PECwater * BCFfish * BMF. Assuming the worst case PECwater of 5.1 x 10-5 mg/l, and based on the experimental BCFfish of 612, the PECoral, predator results of 0.031 mg/kg wet fish.

The exposure to fish eating predators is calculated according to TGD as $PEC_{oral,\ predator}$ = PEC_{water} * BCF_{fish} * BMF based on watering can. Assuming the worst case PEC_{water} of 4.6 x 10^{-6} mg/l, and based on the experimental BCF_{fish} of 612, the $PEC_{oral,\ predator}$ results of **0.0028 mg/kg wet fish.**

2.2.2.5. Risk characterisation

2.2.2.5.1 Aquatic compartment

- *Spraying application*

PEC/PNEC ratios (worst case) for Triflumuron following use of Baycidal® 25 WP in animal houses are following reported for surface water and sediment.

Index i1	**Category**	**Sub category**	**PEC/PNECsw**		**PEC/PNECsed**	
			Arable	**Grass**	**Arable**	**Grass**
1	Cattle	Dairy cattle (housed during grazing season).	**2.2**	**6.0**	**3.2**	**8.6**
		Dairy cattle (outdoors during grazing season).	**5.1**	**13.9**	**7.4**	**20**
2	-	Beef cattle (housed during grazing season).	0.6	**1.8**	0.8	**2.5**
		Beef cattle (outdoors during grazing season).	**1.5**	**3.9**	**2.1**	**5.7**
3	-	Veal calves.	**5.3**	**14.3**	**7.6**	**21**
4	Pigs	Sows.	**3.8**	**10.2**	**5.5**	**15**
5	-	Sows in groups.	**4.8**	**13.0**	**6.9**	**19**
6	-	Fattening pigs.	**3.1**	**8.5**	**4.4**	**12**
7	Poultry	Laying hens in battery cages without treatment.	**1.2**	**2.9**	**1.7**	**4.2**
8	-	Laying hens in battery cages with aeration (belt drying).	**1.3**	**3.4**	**1.9**	**4.8**
9	-	Laying hens in battery cages with forced drying (deep pit, high rise)[1].	**2.0**	**5.4**	**2.9**	**7.8**
10	-	Laying hens in compact battery cages.	**1.3**	**3.4**	**1.9**	**4.8**
11		Laying hens in free range with litter floor (partly litter floor, partly slatted)[2].	**5.3**	**14.3**	**7.6**	**21**
12	-	Broilers in free range with litter floor[2].	**2.2**	**6.0**	**3.2**	**8.6**
13	-	Laying hens in free range with grating floor (aviary system).	**2.3**	**6.4**	**3.4**	**9.3**
14	-	Parent broilers in free range with grating floor.	**1.2**	**3.2**	**1.7**	**4.6**
15	-	Parent broilers in rearing with grating floor.	**2.6**	**6.9**	**3.8**	**9.9**
16	-	Turkeys in free range with litter floor[2].	**4.4**	**11.7**	**6.3**	**17**
17	-	Ducks in free range with litter floor[2].	**4.7**	**12.4**	**6.7**	**18**
18	-	Geese in free range with litter floor[2].	**3.2**	**8.9**	**46**	**13**

The PEC/PNEC ratio for surface water after STP releases is 333, and the PEC/PNEC ratio for sediment after STP releases is 475.

Comparing for each scenario the PNEC values calculated for aquatic organisms (0.0036 µg a.s./l) with the above reported PEC_{SW} values, a risk is identified following manure application to arable and grass land in the scenarios, and after STP release except for beef cattle scenario (housed during grazing season for arable land).

Comparing for each scenario the PNEC values calculated for sediment with the above reported PEC_{SED} values risk is identified for all the scenarios, following manure application to arable and grass land and after STP release except for beef cattle scenario (housed during grazing season for arable land).

Refined predicted environmental concentrations (Koch, B., 2008, MEF-08/199) in surface water (PEC_{sw}) of the insecticidal active substance Triflumuron (SIR8514) were calculated, using realistic worst case FOCUS scenarios as described in Doc. IIB according to TMIII2011.The PEC/PNEC ratios for Triflumuron and its metabolite M02 and M08.

The PEC/PNEC ratios for Triflumuron only for Porto and Bologna scenarios are higher than 1. Therefore, for these scenarios there is a concern with regard to the aquatic compartment.
However it should be considered that the Porto and Bologna scenarios are characterized by a slope of more than 5% (20 and 10% respectively); furthermore Good farming practices recommend not to spread manure or slurry on sloppy fields.

Scenario	Water Body	**PEC/PNECsw**	
		No Runoff mitigation	60% / 85 % Runoff *
D1, Lanna	ditch	<0.3	
	stream	<0.3	
D2, Brimstone	ditch	<0.3	
	stream	<0.3	
D3, Vredepeel	ditch	<0.3	
D4, Skousbo	pond	<0.3	
	stream	<0.3	
D5, La Jailliere	pond	<0.3	
	stream	<0.3	
R2, Porto	stream	**10.6**	**4.7**
R3, Bologna	stream	**2.8**	**1.4**

*FOCUS model: The aquatic PEC values were calculated using the FOCUS STEP 3 scenarios (FOCUS, 2001), taking drainage and runoff entry path into account.

The PEC/PNEC ratios for metabolites M02 and M08 are higher than 1 for surface water compartment and therefore, for this compartment an unacceptable risk can occur.

M02

Compartment	**PEC (µg/l)**	**PNEC (µg/l)**	**PEC/PNEC**	**Acceptable PEC/PNEC**
Surface Water (µg/l)	0.005 (arable) 0.013 (grass)	0.0036	**1.4** **3.6**	**Risk**
Sediment (µg/l)	0.2 (arable) 0.7(grass)	957	0.00023 0.0007	<1.0

M08

Compartment	PEC (µg/l)	PNEC (µg /l)	PEC/PNEC	Acceptable PEC/PNEC
Surface Water	0.0056 (arable) 0.015 (grass)	0.0036	**1.6** **4.2**	**Risk**
Sediment	1.2 (arable) 3.1 (grass)	590	0.001 0.00	No risk

Only for Porto and Bologna scenarios (worst case) the risks to the surface water compartment following the use of Baycidal® 25 WP are not acceptable. However it should be considered that the Porto and Bologna scenarios are characterized by a slope of more than 5% (20 and 10% respectively); furthermore good farming practices recommend not to spread manure or slurry on sloppy fields. No risks are predicted for metabolites in sediment while a risk is identified in surface water.

- *Watering can application*

According to the opinion of BPC-6 a new risk assessment has been performed, based on the new exposure assessment for veal calves based on watering can application of 0.5 g/m^2.
The PNEC values calculated for aquatic organisms and sediment are 0.0036 µg a.s./l and 0.40 µg a.s./kg, respectively. Comparing these PNECs with the PECsw and PECsed values (as reported above) unacceptable risks have been identified for both the surface water and sediment compartments.

For surface water and sediment, the PEC/PNEC ratios are as follows:

PEC/PNECsw = 1.3 arable land

PEC/PNECsw = 1.1 grassland

PEC/PNECsed = 1.9 arable land

PEC/PNECsed = 1.5 grassland

For the risk characterisation due to the watering can application, only the major metabolites M02 and M08 have been taken into account.
The PEC/PNEC ratios for these metabolites M02 and M08 are lower than 1 for both surface water compartment and sediment compartments. Therefore, no an unacceptable risk can occur.

M02

Compartment	PEC	PNEC	PEC/PNEC	Acceptable PEC/PNEC
Surface Water (µg/l)	0.0001 (arable land) 0.0004 (grassland)	0.0036	0.03 0.1	No risk
Sediment (µg/kg)	<0.09	957	<<1	No risk

M08

Compartment	PEC	PNEC Triflumuron	PEC/PNEC	Acceptable PEC/PNEC
Surface Water (µg/l)	0.0005 (arable land) 0.0005 (grassland)	0.0036	0.1 0.1	No risk
Sediment (µg/kg)	<0.09	590	<<1	No risk

The risks to the surface water and sediment compartments, following the use of Baycidal® 25 WP during the Watering can application, are not acceptable. No risks are predicted for metabolites.

- *Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting*

The following RCR values were derived for Triflumuron in the soil, surface water and sediment compartments, considering the PNEC values in **Erreur ! Source du renvoi introuvable.** taking into account the revised PEC values.

Compartment	***Napp-bio$_{max}$***	**RCR value for Triflumuron**
Surface water	1	0.16
	4	0.65
	5	**1.64**
Sediment	1	0.23
	4	0.95
	5	**2.37**

2.2.2.5.2 Terrestrial compartment including Groundwater

- *Spraying application*

The PEC/PNEC ratios for Triflumuron have been calculated considering a PNECsoil of 0.47 µg/kg.

Index i1	**Category**	**Sub category**	**PEC/PNEC**			
			Arable		**Grassland**	
			***N**	****P**	***N**	****P**
1	Cattle	Dairy cattle (housed during grazing season).	22	21	59	66
		Dairy cattle (outdoors during grazing season).	51	56	137	171
2	-	Beef cattle (housed during grazing season).	6	8	17	25
		Beef cattle (outdoors during grazing season).	14	19	39	61
3	-	Veal calves.	52	27	142	84
4	Pigs	Sows.	38	14	101	45
5	-	Sows in groups.	48	18	129	57
6	-	Fattening pigs.	30	14	84	44
7	Poultry	Laying hens in battery cages without treatment.	12	5	29	18
8	-	Laying hens in battery cages with aeration (belt drying).	13	6	33	19
9	-	Laying hens in battery cages with forced drying (deep pit. high rise)[1].	20	10	54	30
10	-	Laying hens in compact battery cages.	13	6	33	19
11		Laying hens in free range with litter floor (partly litter floor. partly slatted)[2].	52	25	142	76
12	-	Broilers in free range with litter floor[2].	22	16	59	49
13	-	Laying hens in free range with grating floor (aviary system).	23	10	64	34
14	-	Parent broilers in free range with grating floor.	12	5	32	18
15	-	Parent broilers in rearing with grating floor.	26	14	68	43
16	-	Turkeys in free range with litter floor[2].	43	27	116	85
17	-	Ducks in free range with litter floor[2].	46	23	123	72
18	-	Geese in free range with litter floor[2].	32	21	88	65

*N: Nitrogen content

**P: Phosphorus content

[1] Manure waste stream.

[2] Manure and liquid waste stream

The PEC/PNEC ratios for the major metabolites have been calculated as follows:

Use	**PEC soil (mg metabolite/kg wwt)**	**PNEC (mg metabolite/kg wwt)**	**PEC/PNEC**	**Acceptable PEC/PNEC**
M02				
Indoor spray in animal houses:				
Arable land	0.0006	0.0366	0.02	No Risk
Grassland	0.0017	0.0366	0.05	No Risk
M08				
Indoor spray in animal houses				
Arable land	0.0028	0.0514	0.08	No Risk
Grassland	0.008	0.0514	0.2	No Risk

The risks to the soil compartment following the use of Baycidal® 25 WP are not acceptable considering the worst case scenarios due to the low PNEC value. The risk is possibly over conservative because is based on EPM method. No risks are predicted for metabolites.

Unacceptable risks for the soil compartment were identified following use of Triflumuron in animal houses, the active substance is collected along with the manure and stored as per normal farming practices. Subsequent land application of the manure after storage potentially releases the active substance to soil.

The PECs groundwater for the use of Baycidal® 25 WP in animal houses, estimated with FOCUS PELMO, have been compared to the limit value of 10^{-4} mg/l fixed as maximum permissible concentration of the active substance or of any other substance of concern in groundwater (directive 98/93/EC). The PEC/limit value ratios are lower than 1 for all scenarios, this indicate no risk for groundwater.

Terrestrial compartment after STP releases

In the terrestrial compartment, the risk ratio has been estimated considering the PECsoil of 0.06 mg/kg and the PNECsoil of 0.47µg/kg. Therefore, the PEC/PNECsoil ratio after sludge application results to be of 120 and an unacceptable risk can occur.

- *Watering can application*

For Triflumuron the PEC/PNEC ratios, following Watering Can application and considering the PNECsoil value of 0.00047 µg/kg, are as follows:

PEC/PNECars-N = 12.76

PEC/PNECgrs-N = 10.64

PEC/PNECars-P2O5 = 7.8

PEC/PNECgrs-P2O5 = 8.51

The PEC/PNEC ratios for the major metabolites M02 and M08 have been calculated as follows:

Use	PEC soil (mg metabolite/kg wwt)	PNEC (mg metabolite/kg wwt)	PEC/PNEC	Acceptable PEC/PNEC
M02				
Watering can in animal houses				
Arable land	0.00015	0.0366	0.004	No Risk
Grassland	0.000095	0.0366	0.003	No Risk
M08				
Watering can in animal houses				
Arable land	0.00058	0.0514	0.011	No Risk
Grassland	0.00047	0.0514	0.009	No Risk

The risks to the soil compartment following the use of Baycidal® 25 WP (during the watering can application) are not acceptable considering the worst case scenarios. No risks are predicted for metabolites.

Terrestrial compartment after STP releases

In the terrestrial compartment, the risk ratio has been estimated considering a PECsoil of 0.015mg/kg and the PNECsoil of 0.47µg/kg. Therefore, the PEC/PNECsoil ratio after sludge application results to be of 31.9 and an unacceptable risk can occur.

- *Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting*

The following RCR values were derived for Triflumuron in the soil compartment considering the PNECsoil of 0.47µg/kg.

Compartment	***Napp-bio*** $_{max}$	**RCR value for Triflumuron**
Soil compartment (initial concentration)		
Soil (initial concentration; no composting)	1	**1.63**
	4	**6.53**
	5	**16.3**
Soil (initial concentration; composting scenario 1)	1	0.91
	4	**3.6**
	5	**9.1**
Soil (initial concentration; composting scenario 2)	1	**1.2**
	4	**4.9**
	5	**12.3**
Soil compartment (TWA concentration)		
Soil (30 d TWA concentration; no composting)	1	**1.63**
	4	**6.53**
	5	**16.3**
Soil (30 d TWA concentration; composting scenario 1)	1	0.70
	4	**2.77**
	5	**7.02**
Soil (30 d TWA concentration; composting scenario 2)	1	0.93
	4	**3.83**
	5	**9.36**

A safe use has been identified for the soil compartment only when Triflumuron is applied once per year, with RCR very close to 1, more applications per year lead to an unacceptable risk. Because the active substance degrades in manure re-colonisation is possible when the concentrations drop below efficacious levels. Re-application with the same substance or a substance with a similar mode of action is therefore required considering that flies rapidly develop from egg to adult (the default value used in similar evaluations according to the "Emission Scenario Document for Insecticides for stables and manure Storage System" is 4). Therefore one application per year is therefore not realistic.

The risk is acceptable only if a hot phase is assumed in the composting process and when the TWA approach has to be considered. It cannot be guaranteed that this will occur in practice. The composting process is complex and it could be distinguished essentially between two phases: an initial, 'hot' phase with elevated temperatures created by the heat during the aerobic, microbial decomposition of organic matter, followed by a secondary, 'curing' phase at ambient temperatures. For other active substances no risks were identified without including the hot phase. The TWA (30-day time weighted average) approach would be only relevant to limited extend for grassland applications in case of not rapidly degrading substances; in case of several manure applications, the TWA could calculated in order to consider degradation between the different manure applications steps. The TWA approach, as proposed by the Applicant, is used for arable land considering only one manure application to agricultural soil.

Moreover the risk is acceptable only if the resulting manure is applied to arable land, where it cannot be guaranteed that in practice the resulting manure will also be applied to grassland.
The current safe use, based on composting of manure heaps in poultry farms is very limited.

Regarding metabolites, no risk has been identified in all compartments with or without composting including or not a hot phase. An unacceptable risk in soil has been identified for M08, after 5 applications, without composting.

Secondary poisoning
Triflumuron does not present a risk of secondary poisoning in the environment for all application types.

2.2.3. Assessment of endocrine disruptor properties

With regard to its toxicological properties in mammalian species, Triflumuron has a low acute toxicity. The main adverse effect after repeated administration is haemolytic anaemia with compensative responses and secondary effects in the liver, spleen, bone marrow and the kidneys. No mutagenic potential has been demonstrated. Triflumuron neither induced tumors in endocrine active organs nor in other tissues/organs. In the reproductive toxicity studies, no specific effects on the fertility parameters, on the growth of the offspring or on the foetal development were observed in the absence of maternal toxicity.

With regard to its ecotoxicological properties, due to the intended mode of action as a chitin synthesis inhibitor Triflumuron has a high acute and chronic ecotoxicity towards aquatic arthropods in the mg/l range. In a chronic fish study (ELS) no effects on hatch, survival, growth or behaviour were observed at a mean measured test concentration of 22.8 µg a.s./l at the practical limit of water solubility. Thus, based on the evidence of the toxicological and ecotoxicological database, Triflumuron is considered to have no endocrine disruptive potential.

2.3. Overall conclusions

[Enter here:] The outcome of the assessment for Triflumuron in product-type 18 is specified in the BPC opinion following discussions at the sixth and seventh meetings of the Biocidal Products Committee (BPC).

2.4. List of endpoints

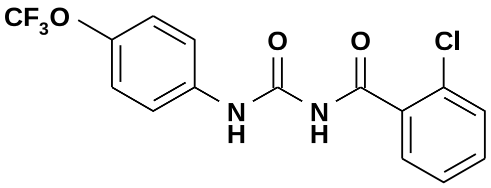
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Triflumuron 2-chloro-N-[[[4-(trifluoromethoxy)phenyl]amino] carbonyl]benzamide (EINECS)
Product-type	PT 18

Identity

Chemical name (IUPAC)	1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl) urea
Chemical name (CA)	Benzamide, 2-chloro-N-[[[4-(trifluoromethoxy) phenyl]amino]carbonyl]-
CAS No	64628-44-0
EC No	264-980-3
Other substance No.	CIPAC No. 548 WHO No. OMS-2015
Minimum purity of the active substance as manufactured (g/kg or g/l)	990 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{15}H_{10}ClF_3N_2O_3$
Molecular mass	358.7 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	195°C (> 99.1%)
Boiling point (state purity)	Not determinable due to molecule decomposition after melting (99.8% w/w)
Temperature of decomposition	> 200°C (99.8%)
Appearance (state purity)	White odourless powder (99.8%)
Relative density (state purity)	D_4^{20} = 1.551 (99.8%)
Surface tension	Not determined, due to the low solubility of the active substance in water
Vapour pressure (in Pa, state temperature)	2×10^{-7} Pa at 20 °C; 4×10^{-7} Pa at 25 °C (obtained by extrapolation of the experimental values)
Henry's law constant (Pa m^3 mol $^{-1}$)	1.79×10^{-3} Pa m^3/mol at 20 °C
Solubility in water (g/l or mg/l, state temperature)	0.04 mg/l at 20 °C (pure water) Effect of pH: not required, since the active substance has not acidic/basic properties in aqueous systems Effect of temperature: solubility turned out to increase with temperature, as showed by an additional non-GLP study (0.014 to 0.200 mg/l from 10 to 60 °C)
Solubility in organic solvents (in g/l or mg/l, state temperature)	acetone: 26.6 g/l acetonitrile: 4.5 g/l dichloro-methane: 11.7 g/l dimethyl-sulfoxide: 127.4 g/l ethylacetate: 23.3 g/l n-heptane: < 0.1 g/l 1-octanol: 1.2 g/l polyethyene-glycol: 9.6 g/l 2-propanol: 1.3 g/l xylene: 1.7 g/l (all results obtained at 20 °C) Effect of temperature: not investigated for individual solvents. Solubility in organic solvents is expected to increase with temperature, as confirmed by an additional non-GLP study for solubility in propylene glycol
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable since the active substance as manufactured does not include any organic solvent and is not formulated in organic solution
Partition coefficient (log P_{OW}) (state temperature)	3.5 (20°C)
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5: stable DT_{50} > 1 year pH 7: stable DT_{50} > 1 year

	pH 9: Chlorophenyl label Triflumuron, DT_{50} (25°C) 57 days (1st order, $r^2 = 0.99$) Major degradation product: M02 (max 28.9% at 30 days) Trifluoromethoxyphenyl label Triflumuron, DT_{50} (25°C) 28.6 days (1st order, $r^2 = 0.991$) Major degradation product: M08 (max 48.8% at 30 days)
Dissociation constant	Not determinable, since the active substance does not dissociate
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λ_{max1}=201 nm (pH 4), 204 nm (pH 7), 206 nm (pH 9) λ_{max2}=252 nm (pH 4), 249 nm (pH 7), 252 nm (pH 9)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Triflumuron: DT_{50} = 32.8 days ($r^2 = 0.965$, SFO) M0: An environmental direct photolysis half-life between 96 days and > 1 year was calculated, indicating that direct photodegradation in water does not significantly contribute to the elimination of 2-chlorobenzamide (M01) in the environment
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.0095
Flammability	Not highly flammable
Explosive properties	Not explosive

Classification and proposed labelling based on Directive 67/548/EEC with amendments

with regard to physical/chemical data	None
with regard to toxicological data	None
with regard to fate and behaviour data	R53
with regard to ecotoxicological data	N; R50 S22-60-61
Specific concentration limits for the environmental classification	$C_n \geq 0.25\%$ N; R50/53 $0.025\% \leq C_n < 0.25\%$ N; R51/53 $0.0025\% \leq C_n < 0.025\%$ R52/53

Classification and proposed labelling based on Regulation EC 1272/2008 with amendments

GHS Pictogram	GHS09
Signal Word	Warning
Hazard Statement	H400; H410
Specific concentration limits for the environmental classification	M=100

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Dissolution in acetonitrile. Determination by RP-HPLC/DAD Dissolution in water-tetrahydrofuran-acetonitrile 10 + 45 + 45 (v/v). Determination by RP-HPLC/UV (CIPAC method
Impurities in technical active substance (principle of method)	Dissolution in acetonitrile. Determination by RP-HPLC/UV

Analytical methods for residues

Soil (principle of method and LOQ)	4.2.1/01 Sample extraction with water/acetonitrile. After centrifugation, HPLC/MS-MS analysis [multiple reaction monitoring mode, selected ions: 357 (parent), 154 (daughter)]. LOQ = 0.01 mg/kg *Validation on a second mass transition is required. Data should preferably be submitted to the evaluating Competent Authority (IT) at the latest six before the date of approval*
Air (principle of method and LOQ)	Sample extraction from Tenax tubes with acetonitrile/water. After filtration and centrifugation, HPLC-DAD analysis. LOQ = 0.0012 mg/m^3 *Validation at 10xLOQ is required. Data should preferably be submitted to the evaluating Competent Authority (IT) at the latest six before the date of approval* No study summary has been made available
Water (principle of method and LOQ)	4.2.3/05 (Surface water) Addition of 20% acetonitrile and 0.1% acetic acid. Determination by HPLC with electro-spray MS-MS detection [selected ions: 357 (parent), 154 (daughter)]. LOQ = 0.03 μg/l *Validation on a second mass transition is required. Data should preferably be submitted to the evaluating Competent Authority (IT) at the latest six before the date of approval* Validation data on surface water also cover drinking/ground water
Body fluids and tissues (principle of method and LOQ)	Not required, since Triflumuron is not classified as toxic or highly toxic
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	*Not required for active substances used as product type 18.* *The product is used for the control of flies in animal houses. Based on the use pattern, there will be no contact with crops or stored animal feeds.* Exposure

	via manure applications is not possible
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Livestock exposure must be considered and be addressed by an exposure assessment to be carried out in compliance with the Guidance on Estimating Livestock Exposure to Biocidal Active Substances. Depending on results, analytical methods for the determination of residues in food/feed of animal origin might be necessary. Anyway, no definite conclusions can be drawn at the moment, since *at* TM III 2011 RMS has accepted to carry on Tier I assessment only

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	In rats, Triflumuron was orally absorbed nearly completely (≥ 80% based on data on urinary and biliary excretion, plus residues in tissues and carcass)
Rate and extent of dermal absorption for the active substance:	1% during mixing/loading (undiluted product: 480 mg a.s./ml) (based on human/rat in vitro studies and rat in vivo study on Baycidal 25 WP-formulated as a suspension concentrate containing 480 g Triflumuron/l)
Rate and extent of dermal absorption for the representative product(s):	5% during application (in use spray dilutions: 0.362 mg a.s./ml) (based on human/rats in vitro studies and rat in vivo study on Baycidal 25 WP-formulated as a suspension concentrate containing 480 g Triflumuron/l)
Distribution:	Widely distributed. Highest level in liver, kidney, spleen, lung, in blood and fatty tissues. Possible binding of parent compound and/or metabolites to blood components
Potential for accumulation:	None (based on low amount of residues and the rapid excretion - completed in 72-96 hours)
Rate and extent of excretion:	In rats, excretion via urine and faeces was essentially completed 96 hours after dosing by oral administration Single low dose: equal excretion via urine and faeces; repeated low dose: urinary excretion almost doubled the faecal elimination; high dose: faecal excretion (92% of the dose). Biliary excretion was approximately 50% of the dose within 48 hours
Toxicologically significant metabolite(s)	The metabolism of Triflumuron was extensive and rapid. Major pathways: hydrolysis followed by oxidation and subsequent conjugation (with sulphate and glucuronic acid). The most abundant metabolites were Triflumuron 2-hydroxyaniline, Triflumuron 3-hydroxyaniline and their corresponding sulphate conjugates. Two plant metabolites, which are considered as toxicologically relevant, i.e. 4-trifluoro-methoxyaniline (M07) and 4-trifluoro-methoxyphenylurea (M08), were proposed in the early steps of the rat metabolism (M08 being a precursor of M07), but only found in trace in faeces or up to 3% in bile (M08)

Acute toxicity

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 5000 mg/kg bw

Rat LC_{50} inhalation	> 5030 mg/m^3
Skin irritation	Non-irritant
Eye irritation	Non irritant
Skin sensitization (test method used and result)	Non-sensitizer (Magnusson & Kligman Test)

Repeated dose toxicity

Species/ target / critical effect	No species-differences / Effects on haematopoietic system
Lowest relevant oral NOAEL / LOAEL	2.7-3.6 mg/kg bw/d (90-day study, dog and rat, respectively) 1.42 mg/kg bw/day (dog, 1-year oral toxicity)
Lowest relevant dermal NOAEL / LOAEL	100 mg/kg bw/day (rabbit, 3-week dermal toxicity)
Lowest relevant inhalation NOAEL / LOAEL	4.5 mg a.s./m^3 (rat, 3-week inhalation toxicity)

Genotoxicity	No genotoxic properties

Carcinogenicity

Species/type of tumour	The number, type, location and distribution of the neoplasms found in the study groups did not provide any indications of carcinogenic actions for the test substance.
lowest dose with tumours	-
Lowest relevant oral NOAEL / LOAEL (chronic)	0.82-1.11 mg/kg bw/day (rat M-F, 2 year oral toxicity) Relevant chronic non neoplastic target: haematopoietic system

Reproductive toxicity

Species/ Reproduction target / critical effect	Rat No effects (including the highest concentration tested –142.5 mg/kg bw/day)
Lowest relevant reproductive NOAEL / LOAEL	NOAEL 142.5 mg/kg bw/day
Species/Developmental target / critical effect	Rats: maternal toxicity: increased spleen weight and haemolytic anemia Developmental toxicity: increased delayed ossification Rabbits: maternal toxicity: increased spleen weight and haemolytic anemia Developmental toxicity: increased post implantation loss

Developmental toxicity

Lowest relevant developmental NOAEL / LOAEL	Maternal toxicity: 300/1000 mg/kg bw/day (rat, rabbit) Developmental toxicity: 300/1000 mg/kg bw/day (rat, rabbit)

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Not applicable
Lowest relevant developmental NOAEL / LOAEL.	Not applicable

Other toxicological studies

Data for metabolites	4-trifluoromethoxyaniline oral LD_{50} (rat) : 63 mg/kg bw dermal LD_{50} (rat) : < 50 µl/kg bw inhalation LC_{50} (rat): 860-950 mg/m^3 skin irritation (rabbit) non-irritant eye irritation (rabbit) non irritant other effects (cat): methemoglobin formation and destruction of hemoglobin (at doses ≥ 1mg/kg) salmonella/microsome test no effects POL A1 test on E. coli no effects on DNA mouse – micronucleus test not mutagenic 6-day single dose toxicity in rat NOAEL = 0.5 mg/kg bw

Medical data

....	No specific effects have been noted

	Value	Study	Safety factor
Summary			
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	0.014 mg/kg bw/day	1-yr dog supported by 2-yr rat	100
ARfD (acute reference dose)			
Parent	Not necessary		
Metabolite M07	0.005	6 days single dose toxicity (rat)	100
Professional user			
AEL-S (Operator Exposure)	Long term: 0.014 mg/kg bw/day	1 yr dog	100
	Medium term: 0.036-mg/kg bw/day	90-day dog and rat	100
	Acute: 3 mg/kg bw	Dev. rabbit	100
Reference value for inhalation (proposed OEL)	-	-	-
Reference value for dermal absorption concerning the active substance:	1%	Human/rat in vitro studies and rat in vivo study	
Reference value for dermal absorption concerning the representative product(s)[4]:	5%	Human/rat in vitro studies and rat in vivo study	

Acceptable exposure scenarios (including method of calculation)

Professional users	Spraying surfaces in animal houses -Spraying Model 1; TNsG on Human Exposure 2002, Part 2 Watering can application - Sub-soil treatment Model 2; TNsG on Human Exposure 2002, Part2
Production of active substance:	Not relevant
Formulation of biocidal product	Not relevant
Intended uses	Spray and watering can applications
Secondary exposure	Negligible
Non-professional users	Not applicable
Indirect exposure as a result of use	Livestock exposure assessment Tier I was performed. As the trigger value is exceeded, and as the guidance was not yet endorsed when the assessment was performed, in this particular case, an exposure refinement step 2 should be postponed at Product Authorization level.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5: Stable, DT_{50} > 1 year. No major metabolites
	pH 7: Stable, DT_{50} > 1 year (extrapolated 465 days). No major metabolites
	pH 9: Chlorophenyl label Triflumuron, DT_{50} (25°C) 57 days (1st order, r^2= 0.99) Major degradation product: M02 (max 28.9% at 30 days) Trifluoromethoxyphenyl label Triflumuron, DT_{50} (25°C) 28.6 days (1st order, r^2= 0.991) Major degradation product: M08 (max 48.8% at 30 days)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Triflumuron DT_{50} (mean of two tests using both labels): 32.8 days (r2=0.965, SFO); corresponding predicted environmental half-lives under solar summer conditions (June) are 119.2 days at Phoenix, US, and 184.8 days Athens, Greece. Major metabolite: 2-chlorobenzamide (M01), max 19.4% day 10 M01 The environmental half-life was assessed by means of two different arithmetic models (GC-SOLAR and Frank & Klöpffer). An environmental direct photolysis half-life between 96 days and > 1 year was calculated, indicating that direct photodegradation in water does not significantly contribute to the elimination of 2-chlorobenzamide (M01) in the environment
Readily biodegradable (yes/no)	No (A study on the ready biodegradability of Triflumuron was not performed. This requirement is covered by the water/sediment study)
Biodegradation in seawater	Not applicable
Degradation in water/sediment (2 systems) - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	1.6 to 3.0 days 17.5 and 17.6 days 4.1 to 7.1 days (20°C) 7.8 to 13.5 days (normalised to 12°C) 36.5 to 65.8 days
Non-extractable residues	

<table>
<tr><td></td><td>System Hönniger Trifluoromethoxyphenyl/ chlorophenyl-label</td><td></td></tr>
<tr><td>Distribution in water / sediment systems (active substance)</td><td>Water layer:</td><td>Sediment:</td></tr>
<tr><td></td><td>day 0: 69.7 / 50.4</td><td>day 0: 24.3 / 43.8</td></tr>
<tr><td></td><td>day 1: 45.2 / 36.5</td><td>day 1: 53.0 / 53.9</td></tr>
<tr><td></td><td>day 3: 32.9 / 42.1</td><td>day 3: 66.1 / 58.1</td></tr>
<tr><td></td><td>day 7: 26.6 / 44.9</td><td>day 7: 67.7 / 49.5</td></tr>
<tr><td></td><td>day 14: 30.5 / 49.9</td><td>day 14: 63.0 / 42.1</td></tr>
<tr><td></td><td>day 30: 21.0 / 50.4</td><td>day 30: 72.6 / 30.4</td></tr>
<tr><td></td><td>day 62: 16.8 / 21.0</td><td>day 62: 70.4 / 39.6</td></tr>
<tr><td></td><td>day 100: 9.2 / 9.4</td><td>day 100: 81.1 / 46.0</td></tr>
<tr><td></td><td>System Von Diergardt Trifluoromethoxyphenyl/ chlorophenyl-label</td><td></td></tr>
<tr><td></td><td>Water layer:</td><td>Sediment:</td></tr>
<tr><td></td><td>day 0: 57.9 / 51.4</td><td>day 0: 36.2 / 42.2</td></tr>
<tr><td></td><td>day 1: 56.2 / 49.0</td><td>day 1: 35.0 / 49.8</td></tr>
<tr><td></td><td>day 3: 53.4 / 51.2</td><td>day 3: 45.2 / 43.3</td></tr>
<tr><td></td><td>day 7: 54.2 / 67.0</td><td>day 7: 41.8 / 27.5</td></tr>
<tr><td></td><td>day 14: 52.3 / 63.1</td><td>day 14: 40.1 / 27.0</td></tr>
<tr><td></td><td>day 30: 26.8 / 58.1</td><td>day 30: 61.2 / 24.4</td></tr>
<tr><td></td><td>day 62: 18.6 / 66.8</td><td>day 62: 65.0 / 16.6</td></tr>
<tr><td></td><td>day 100: 12.7 / 43.6</td><td>day 100: 72.0 / 23.7</td></tr>
<tr><td>Distribution in water / sediment systems (metabolites)</td><td colspan="2">Three metabolites were found in water/sediment systems. M08 and M02 were detected in quantitatively relevant amounts in the water layer. In the sediment extracts M08 occurred as the only major metabolite. M08 could only be detected after the application of trifluoromethoxyphenyl-labelled Triflumuron, whereas M02 was solely formed when applying the chlorophenyl-labelled active substance. The distribution of these two metabolites in water/sediment systems (water layer and sediment) is summarised in this end point list.
M02 DT_{50}: 62.9 days (20°C)
119.3 days (normalised to 12°C)
M08 DT_{50}: 11.7 days (20°C)
25.6 days (normalised to 12°C)
M01 was found in amounts below 10 % of the applied radioactivity in the water layer and sediment extracts. The corresponding distribution values are summarised in IIIA Section 7.1.2.2.2.</td></tr>
<tr><td>4-trifluoromethoxyphenyl urea *(M08)*</td><td>System Hönniger Trifluoromethoxyphenyl-label</td><td></td></tr>
<tr><td></td><td>Water layer:</td><td>Sediment:</td></tr>
<tr><td></td><td>day 0: n.d.</td><td>day 0: 0.00</td></tr>
<tr><td></td><td>day 1: 6.10</td><td>day 1: 2.29</td></tr>
<tr><td></td><td>day 3: 16.30</td><td>day 3: 8.76</td></tr>
<tr><td></td><td>day 7: 17.60</td><td>day 7: 20.36</td></tr>
<tr><td></td><td>day 14: 24.60</td><td>day 14: 20.22</td></tr>
</table>

	day 30: 10.20 day 62: 5.40 day 100: 2.30 System Von Diergardt Trifluoromethoxyphenyl-label Water layer: day 0: n.d. day 1: 7.30 day 3: 22.30 day 7: 43.50 day 14: 47.80 day 30: n.d. day 62: 0.90 day 100: 1.30	day 30: 12.38 day 62: 8.90 day 100: 4.79 Sediment: day 0: 0.00 day 1: 1.33 day 3: 5.10 day 7: 12.03 day 14: 14.10 day 30: 6.16 day 62: 4.95 day 100: 4.87
2-chlorobenzoic acid *(M02)*	System Hönniger Chlorophenyl-label Water layer: day 0: n.d. day 1: 7.50 day 3: 14.50 day 7: 30.40 day 14: 44.80 day 30: 35.60 day 62: 12.20 day 100: 1.40 System Von Diergardt Chlorophenyl-label Water layer: day 0: n.d. day 1: 10.30 day 3: 19.70 day 7: 46.40 day 14: 60.40 day 30: 50.20 day 62: 54.10 day 100: 30.10	Sediment: day 0: 0.00 day 1: 1.23 day 3: 4.03 day 7: 7.86 day 14: 7.94 day 30: 5.97 day 62: 1.87 day 100: 1.19 Sediment: day 0: 0.00 day 1: 0.91 day 3: 1.86 day 7: 4.05 day 14: 3.10 day 30: 2.73 day 62: 3.02 day 100: 2.32

Route and rate of degradation in soil

Mineralization (aerobic)	Trifluoromethoxyphenyl-label 12.8 – 18.1 % at day 120 (n=2) *8.0% at day 112 d (23°C, n=1) Chlorophenyl-label 64.6 – 65.9% at day 120 (n=2) *52.5% at day 112 (23°C, n=1)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, pF 2, aerobic): 4.6 to 40.8 days, mean 16.3 days (n=4)
	DT_{90lab} (20°C, pF 2, aerobic): 15.3 to 136 days

	DT_{50lab} (20°C, pF 2, anaerobic): 143 to 150 days (n=2)
Field studies (state location, range or median with number of measurements)	Not triggered (Field studies on the dissipation of a pesticide in soils have to be conducted, if the DT_{50lab}-value is greater than 60 days (20°C). For Triflumuron, DT_{50}-values from laboratory studies are in the range of 4.6 to 48.4 days with a geometric mean of 19.1 days. Therefore, field dissipation studies are not required
	DT_{90f}: not available
Anaerobic degradation	Triflumuron is slowly degraded under anaerobic conditions (worst-case DT_{50} value 150 days) Degradation of Triflumuron led to the formation of the metabolites M01 and M08 in amounts exceeding 10% AR, minor components including M02 and soil non extracted residues. Insignificant levels of evolved volatile components were formed
Soil photolysis	Triflumuron is photochemically stable on surface soil
Non-extractable residues	In aerobic soil (after 100 days at 20°C) Trifluoromethoxyphenyl –label 68.7 – 70.9% at day 120 (n=2) 54.0%* at day 112 (23°C, n=1) Chlorophenyl-label 24.0 – 30.0% at day 120 (n=2) 18.9%* at day 112 (23°C, n=1)
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	**M08** 4-trifluoromethoxyphenyl urea, (only formed after the application of the trifluoromethoxyphenyl label) max: 13.5% and 12.3% after 3 and 7 days; 0.3% and 2.8% day 120 (n=2) *max: 23.1% after 84 days; 15.6% at day 112 (23°C, n=1) **M02** 2-chlorobenzoic acid, (only formed after the application of the chlorophenyl label max: 5.9% and 3.9% after 3 and 7 days; n.d at 120 days (n=2) *max: 23.5% after 7 days; 0.3% after 112 (23°C, n=1) (The results are expressed as percentage of applied radioactivity except those mark "*" which are expressed as % of recovered radioactivity)
Soil accumulation and plateau concentration	Not applicable: (Soil accumulation testing is not required since DT_{50}-values from laboratory studies are in the range of 4.6 to 48.4 days with a geometric mean of 19.1 days)

Adsorption/desorption

a) Active substance

K_{oc}	K_{oc}: Adsorption: 1629 – 30006 ml/g (n=5) Desorption: 711 – 30641 ml/g (n=5) K_{oc} = 7332 ml/g (geomean value)
K_{oc}	K_{oc}: Adsorption: 2295 – 3510 ml/g (3 soils, 2 – 3 test concentrations per soil)
K_d	K_F: Adsorption: 9.8 – 161.9 ml/g (n=5) Desorption: 4.3 – 287.8 ml/g (n=5)
K	K_d: Adsorption: 21.8 – 68.8 (3 soils, 2 – 3 test concentrations per soil)
pH dependence (yes / no) (if yes type of dependence)	No

b) Relevant metabolites

1) 4-trifluoromethoxyphenyl urea (M08)

K_{oc}	K_{oc}: Adsorption: 113 – 280 ml/g (n=4) mean 176 ml/g Desorption: 261 – 579 ml/g (n=4, first desorption isotherm)
K_d	K_F: Adsorption: 1.19 - 2.86 ml/g (n=4) Desorption: 3.59 – 5.91 ml/g (n=4, first desorption isotherm)
pH dependence (yes / no) (if yes type of dependence)	No

2) 2-chlorobenzoic acid (M02)

K_{oc}	K_{oc}: Adsorption: 8.82 ml/g (n=1) Desorption: 67.9 ml/g (n=1)
K_{oc}	K_{oc}: Adsorption: 3.97 – 7.61 ml/g (n=3) K_{oc} mean: 6.7 ml/g
pH dependence (yes / no) (if yes type of dependence)	No

Fate and behaviour in air

Direct photolysis in air	Not studied
Quantum yield of direct photolysis	0.0095
Photo-oxidative degradation in air	Half-life: 0.421 days based on this OH rate constant and using a 24-hrs day with 0.5 E6 OH radicals/cm^3 Chemical lifetime: 0.61 days A more conservative assessment of the overall OH radical constant could be made by using only the half of estimated rates. This would result in a maximum chemical lifetime for Triflumuron in air of 1.2 days
Volatilization	A field trial on the volatilisation from bare soil and plant surfaces came to the result of 15% volatilisation of Triflumuron and/or its metabolites (mean value for the whole ecosystem) within 12 hours following the application

Monitoring data, if available

Soil (indicate location and type of study)	Not applicable
Surface water (indicate location and type of study)	Not applicable
Ground water (indicate location and type of study)	Not applicable
Air (indicate location and type of study)	Not applicable

Chapter 5: Effects on Non- target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
L. macrochirus	96h	mortality	LC$_{50}$ > 20.8 µg a.i./l
Pimephales promelas	36 days (ELS test)	egg hatchability, larval development, behaviour, growth, and survival	NOEC ≥ 22.8 µg a.i./l
Invertebrates			
D. magna	48h	immobilisation	EC$_{50}$ = 1.6 µg a.i./l Metabolite M01: EC$_{50}$ = 100 000 µg/l Metabolite M02: EC$_{50}$ = 100 000 µg/l Metabolite M08: EC$_{50}$ = 3 400 µg/l
D. magna	21 d	Survival, reproduction	NOEC = 0.018 µg a.s./l
C. riparius	28d	life cycle/emergence	EC$_{10}$ = 0.25 µg/l (converted to 40 µg a.i./kg) Metabolite M02: NOEC = 95 700 µg a.i./kg Metabolite M08: EC$_{10}$ = 59 000 µg a.i./kg
Algae			
S. subspicatus	72h	growth inhibition	NOEC ≥ 25 µg a.i./l E$_r$C$_{50}$ > 25 µg a.i./l, E$_b$C$_{50}$ > 25 µg a.i./l (nominal concentrations, analytically confirmed)
Microorganisms			
Activated sludge	3h	respiration inhibition	EC$_{50}$ > 40 µg/l (corresponding to water solubility) NOEC > 40 µg/l (corresponding to water solubility)
Multispecies microcosm			
Arthropod community	4 months post-treatment	population decline/recovery	NOEC < 0.1 µg/l NOEAEC = 0.1 µg/l (based on peak concentration)

Effects on earthworms or other soil non-target organisms

Acute toxicity to *earthworms*	14d LC_{50} > 256 mg a.i./kg dwt soil (14d LC_{50} > 166 mg/kg wwt. soil), corrected for Fom, based on TWA concentration, *E. foetida* Metabolite M02: 14d LC_{50} > 340 mg M02/kg dwt soil (14d LC_{50} > 207 mg M02/kg wwt. soil), corrected for Fom, nominal concentration, E*isenia andrei* Metabolite M08: 14-day LC_{50} = 191 mg M08/kg dwt soil (14day LC_{50} = 118 mg M08/kg wwt. soil), corrected for Fom, nominal concentration, *Eisenia andrei*
Reproductive toxicity to *Folsomia candida*	Metabolite M02: NOEC = 34 mg M02/kg dwt soil (NOEC = 23.1 mg M02/kg wwt. soil), corrected for Fom, nominal concentration Metabolite M08: NOEC = 10.7 mg M08/kg dwt soil (NOEC = 6.3 mg M08/kg wwt. soil), corrected for Fom, nominal concentration

Effects on soil micro-organisms

Nitrogen mineralization	NOEC=0.45 mg/kg dry wt. soil (NOEC = 0.40 mg/kg wwt. soil), corrected for Fom, based on TWA concentration Metabolite M02: NOEC = 2.07 mg metabolite/kg dry wt. soil (NOEC = 1.83 mg M02/kg wwt. soil), corrected for Fom, nominal concentration Metabolite M08: NOEC = 2.9 mg metabolite/kg dry wt. Soil (NOEC = 2.57 mg M08/kg wwt. soil), corrected for Fom, nominal concentration
Carbon mineralization	NOEC = 4.53 mg/kg dry wt. soil corrected for Fom, based on TWA concentration

Effects on plants

Acute toxicity	21d EC_{50} > 0.95 mg/kg wwt soil (corrected for Fom, based on TWA concentration)

Effects on terrestrial vertebrates

Acute toxicity to mammals	
Acute toxicity to birds	LD_{50} = 561 mg/kg bw (*C. virginianus*)
Dietary toxicity to birds	LC_{50} > 5 626 mg/kg diet (*C. virginianus*)
Reproductive toxicity to birds	NOEC 80 mg/kg diet (*C. virginianus, A. platyrhynchos*)

Effects on honeybees

Acute oral toxicity	Not relevant
Acute contact toxicity	Not relevant

Effects on other beneficial arthropods

Acute oral toxicity	Not available
Acute contact toxicity	Not available
Acute toxicity to …………………………………..	Not available

Bioconcentration

Bioconcentration factor (BCF)	612 (fish whole body)
Depuration time (DT_{50})	1.36
(DT_{90})	Not available
Level of metabolites (%) in organisms accounting for > 10 % of residues	Metabolites not identified or quantified

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Object and/or situation	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
			Type	Conc. of a.s.	method kind	number min max	interval between applications (min)	g a.s./l min max	water l/m^2 min max	g a.s./m^2 min max	
CLAIM: Triflumuron is a broad spectrum insect growth regulator (IGR), which acts during the moulting phases of insect development. The representative product is an insecticidal wettable powder containing 250 g/kg Triflumuron as a.s., used in animal houses (livestock and poultry houses) to control nuisance flies and litter beetles. The product is applied as a coarse spray after dispertion in water to the floor area of animal houses, to treat locations where flies or other insects may lay eggs USERS: Professionals The efficacy data presented in the dossier are adequate to show that Triflumuron is effective against the target species	Baycidal 25 WP	*Musca domestica* (housefly) *Alphitobius diaperinus* (litter beetle, lesser mealworm)	Wettable powder (WP) under PT 18 (Insecticide)	250 g/kg	Hand-held knapsack sprayer (low pressure)	Maximum of 5 applications per year at 2 g product/m^2 (0.5 g a.s./m^2)	Minimum interval of 14 days for second and third application, increased to 21 days for fourth and fifth applications No specified waiting or re-entry periods for personnel or animals	2.5 to 5 g/l (spray)* *up to 0.5 g/l where larger water volumes are required per m^2	0.1 l/m^2 (spray) where larger water volumes are required per m^2 (i.e. bedding or dry manure), applications can be made at up to 5 l/m^2	0.25 to 0.5 g/m² (spray)	Treatment is a preventative measure. Applications made to typical breeding areas before populations increase to above acceptable levels (typically over the period Jun to Sept) Lower application rates can be used in regions where lower temperatures mean that populations are typically lower. When control is achieved, rate (for flies) can be reduced to 0.25 g a.s./m^2 to maintain control at acceptable levels
					Watering can			0.5 g/l (watering can)	1 l/m^2 (watering can) where larger water volumes are required per m^2 (i.e. bedding or dry manure), applications can be made at up to 5 l/m^2	0.5 g/m² (watering can)	

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

List of studies for Active Substance (Doc. IIIA)

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 2.7. /01	Confidential	2001	Confidential (please refer to Doc I)	Yes	BCS
A 2.7. /02	Confidential	2005	Confidential (please refer to Doc I)	Yes	BCS
A 3.1.1 /01	[redacted]	1994	Melting point of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 3.1.1 /02	[redacted]	2002	The physical properties of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.3.1 /01 also filed: A 3.3.2 /01 also filed: A 3.3.3 /01 also filed: A 3.4.1 /02 also filed: A 3.6. /01	Yes	BCS
A 3.1.2 /01	[redacted]	2001	Density, surface Tension, Organic Solubility, Boiling Point and Henry Law Constant of SIR 8514 (Triflumuron) Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.3 /01 also filed: A 3.7. /01	Yes	BCS
A 3.1.3 /01	[redacted]	2001	Density, surface Tension, Organic Solubility, Boiling Point and Henry Law Constant of SIR 8514 (Triflumuron) Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.2 /01 also filed: A 3.7. /01	Yes	BCS
A 3.2. /01	[redacted]	1977	Vapour pressure curve of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 3.2. /02	[redacted]	2002	Vapour pressure, physical-chemical properties - Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted]	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			GLP, unpublished		
A 3.3.1 /01	[redacted]	2002	The physical properties of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.1 /02 also filed: A 3.3.2 /01 also filed: A 3.3.3 /01 also filed: A 3.4.1 /02 also filed: A 3.6. /01	Yes	BCS
A 3.3.2 /01	[redacted]	2002	The physical properties of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.1 /02 also filed: A 3.3.1 /01 also filed: A 3.3.3 /01 also filed: A 3.4.1 /02 also filed: A 3.6. /01	Yes	BCS
A 3.3.3 /01	[redacted]	2002	The physical properties of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.1 /02 also filed: A 3.3.1 /01 also filed: A 3.3.2 /01 also filed: A 3.4.1 /02 also filed: A 3.6. /01	Yes	BCS
A 3.4.1 /01	[redacted]	2001	Spectral Data Set of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.4.2 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.1 /02	[redacted]	2002	The physical properties of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.1 /02 also filed: A 3.3.1 /01 also filed: A 3.3.2 /01 also filed: A 3.3.3 /01 also filed: A 3.6. /01	Yes	BCS
A 3.4.2 /01	[redacted]	2001	Spectral Data Set of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.3 /01	[redacted]	2001	Spectral Data Set of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted]	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[redacted] GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.4 /01		
A 3.4.4 /01	[redacted]	2001	Spectral Data Set of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.3 /01	Yes	BCS
A 3.5. /01	[redacted]	2002	Water Solubility of SIR 8514 (Triflumuron) Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 3.6. /01	[redacted].	2002	The physical properties of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.1 /02 also filed: A 3.3.1 /01 also filed: A 3.3.2 /01 also filed: A 3.3.3 /01 also filed: A 3.4.1 /02	Yes	BCS
A 3.6. /02	[redacted]	1987	Dissoziationskonstante von Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 3.7. /01	[redacted]	2001	Density, surface Tension, Organic Solubility, Boiling Point and Henry Law Constant of SIR 8514 (Triflumuron) Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.1.2 /01 also filed: A 3.1.3 /01	Yes	BCS
A 3.9. /01	[redacted]	1982 Amended: 1994	Partition coefficient of Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 3.9. /02	[redacted]	2002	Determination of octanol-water partition coefficient of Triflumuron Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] Date: 05.05.2002 Non GLP, unpublished	Yes	BCS
A 3.10. /01	[redacted] [redacted] [redacted]	1986	Thermal stability of the agrochemical active ingredient Triflumuron Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted]	Yes	BCS

Section No / Reference No[5]	**Author(s)**[6]	**Year**	**Title**[7] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			Non GLP, unpublished		
A 3.11. /01	[redacted]	2001	Determination of Safety - relevant Data of ALSYSTIN Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.15. /01 also filed: A 3.16. /01	Yes	BCS
A 3.15. /01	[redacted]	2001	Determination of Safety - relevant Data of ALSYSTIN Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.11. /01 also filed: A 3.16. /01	Yes	BCS
A 3.16. /01	H[redacted], D.	2001	Determination of Safety - relevant Data of ALSYSTIN Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 3.11. /01 also filed: A 3.15. /01	Yes	BCS
A 3.17. /01	[redacted]	2002	Corrosion evaluation of Alsystin technical Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 4.1. /01	[redacted]	2001	Alsystin - Assay - HPLC, External Standard Bayer AG, Dormagen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.1. /02	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
A 4.1. /03	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
A 4.1. /04	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
A 4.2.1. /01	[redacted]	2003	Enforcement method 00792 for the determination of residues of Triflumuron in soil by HPLC-MS/MS Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 4.2.1. /02	[redacted]	1979	Provisional method for determination of SIR 8514 residues in plants, soil and water by high performance liquid chromatography (HPLC) and gas liquid chromatography (GLC) Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 4.2.3. /01	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 4.2.1. /03	[redacted]	1984	Method for HPLC determination of the insecticide Alsystin in plants, soil and water Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 4.2.3. /03	Yes	BCS
A 4.2.1. /04	[redacted]	1987	Modification M001 to method 00091:method for HPLC determination of the insecticide Alsystin in plants, soil and water Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.2.1. /05	[redacted]	1988	Method for the gas chromatographic determination of residues of the insecticide Triflumuron in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.2.1. /06	[redacted]	1988	Method for high performance liquid chromatographic determination of the insecticide Triflumuron in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.2.1. /07	[redacted]	1992	Modification M001 to method 00023: method for high performance liquid chromatographic determination of the insecticide Triflumuron in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.2.1. /08	[redacted]	2002	Triflumuron: Validation of an Analytical Method for Determination in Sediment Springborn Laboratories AG, Horn, Switzerland Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 4.2.2. /01	[redacted]	1993	Method for the determination of Triflumuron in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 4.2.2. /02	[redacted]	2003	Confirmation of enforcement method 00331 for the determination of Triflumuron in air Bayer CropScience AG, R[redacted]	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[redacted] GLP, unpublished		
A 4.2.3. /01	[redacted]	1979	Provisional method for determination of SIR 8514 residues in plants, soil and water by high performance liquid chromatography (HPLC) and gas liquid chromatography (GLC) Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 4.2.1. /02	Yes	BCS
A 4.2.3. /02	[redacted]	1990	Modification M005 to method 00130: method extension for leaching water Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.2.3. /03	[redacted]	1984	Method for HPLC determination of the insecticide Alsystin in plants, soil and water Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 4.2.1. /03	Yes	BCS
A 4.2.3. /04	[redacted]	1990	Method for determination of Triflumuron in drinking water using HPLC Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.2.3. /05	[redacted]	2002	Enforcement method 00697 for the determination of Triflumuron in drinking and surface water by HPLC-MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 4.3. /01	[redacted]	1986	Determination of BAY Vi 7533 (Triflumuron) in bovine tissues and milk Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.3. /02	[redacted]	1984	HPLC method for Alsystin TM in chicken tissues and eggs Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.3. /03	[redacted]	1987	Liquid chromatographic method for the determination of Alsystin (SIR 8514; Bay Vi 7533) in chicken fat	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished		
A 4.3. /04	[redacted]	1987	Supplement to HPLC method for the determination of Alsystin (SIR 8514; BAY Vi 7533) in chicken fat. RA-204; 04.03.1987 Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 4.3. /05	[redacted]	2002	Enforcement method 00757 for the determination of residues of Triflumuron in/on matrices of plant and animal origin by HPLC-MS/MS Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 5.3.1. /01	[redacted]	2006	Insect growth regulation with the best potential - Clear evidence in laboratory tests and field trials Publisher:Anon., Location:Anon., Journal:Anon., Volume:Anon., Issue:Anon., Pages:18-21, [redacted] Non GLP, published	No	
A 5.3.1. /02	[redacted]	1982	Laboratory evaluation of BAY SIR 8514 against the house fly (Diptera: Muscidae): Effects on immature stages and adult sterility Publisher: Entomological Society of America, Journal: Journal of Economic Entomology, Volume:75, Issue:4, Pages:657-661, [redacted] Non GLP, published	No	
A 5.4. /01	[redacted]	1980	Laboratory evaluation of SIR 8514, a new chitin synthesis inhibitor of the benzoylated urea class Publisher:Bayer AG, Location:Germany, Journal:Pflanzenschutz-Nachrichten, Volume:33, Issue:1, Pages:1-34, [redacted] Non GLP, published	No	
A 5.7.1. /01	[redacted]	2003	Information on the possible occurrence of the resistance or cross-resistance Bayer CropScience AG, [redacted] Non GLP, published	No	
A 5.7.1. /02	Anon.	2003	Literature search on Benzoylphenylurea and	Yes	BCS

Section No / Reference No[5]	**Author(s)**[6]	**Year**	**Title**[7] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			resistance Bayer CropScience AG, [redacted] Non GLP, unpublished		
A 5.7.1. /03	[redacted]	1996	Field evaluation of Triflumuron and methomyl for control of the housefly Musca domestica Danish Pest Infestation Laboratory, Lyngby, Denmark Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 5.10.2. /02	Yes	BCS
A 5.7.2. /01	[redacted]	2004	Insecticide mode of action classification: A key to insecticide resistance management Publisher: for more information from the customer see page note, Location: Salt Lake City, UT, USA, Journal: Insecticide Resistance Action Committee (IRAC), [redacted] Non GLP, published also filed: B 5.11.2. /01	No	
A 6.1.1. /01	[redacted]	1977	SIR 8514 - Acute toxicity studies Bayer AG, Wuppertal, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.1.2 /01 also filed: A 6.1.4. /01 also filed: A 6.11. /01	Yes	BCS
A 6.1.1. /[redacted]	[redacted]	1981	SIR 8514 - Acute toxicity for sheep after oral administration [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.1.1. /03	[redacted]	2002	Triflumuron technical (Alsystin) - An acute oral LD_{50} study in the rat [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.1.2 /01	[redacted]	1977	SIR 8514 - Acute toxicity studies [redacted] Bayer CropScience AG, [redacted] 1 Non GLP, unpublished also filed: A 6.1.1. /01 also filed: A 6.1.4. /01 also filed: A 6.11. /01	Yes	BCS
A 6.1.2 /02	[redacted]	2002	Triflumuron technical (Alsystin) - An acute dermal LD_{50} study in the rat [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.1.3. /01	[redacted]	2002	SIR 8514 (common-name: Triflumuron) - Study on acute inhalation toxicity in rats	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			according to OECD no. 403 [redacted] Bayer CropScience AG, [redacted] GLP, unpublished		
A 6.1.4. /01	[redacted]	1977	SIR 8514 - Acute toxicity studies [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.1.1. /01 also filed: A 6.1.2 /01 also filed: A 6.11. /01	Yes	BCS
A 6.1.4. /02	[redacted]	2002	Technical Triflumuron - Primary skin irritation study in rabbits [redacted] U[redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.1.4. /03	[redacted]	2002	Technical Triflumuron - Primary eye irritation study in rabbits [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.1.5. /01	[redacted]	1982	Delayed dermal sensitization of SIR 8514 [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.1.5. /02	[redacted]	1997	SIR 8514 - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according Magnusson and Kligman) [redacted] Bayer CropScience AG, [redacted]1 GLP, unpublished	Yes	BCS
A 6.2. /01	[redacted]	2002	[Trifluoromethoxyaniline-UL-14C]Triflumuron. Distribution of the total radioactivity in male rats determined by quantitative whole body autoradiography [redacted] G[redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.2. /02	[redacted]T.	2003	The metabolism of Triflumuron in rats [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.2. /03	[redacted].	1985	Excretion and metabolism of Alsystin TM in rats [redacted] Bayer CropScience AG,	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[redacted] [redacted] Non GLP, unpublished		
A 6.2. /04	[redacted]	1983	Triflumuron (SIR 8514) - Biotransformation of [2-chlorophenyl-ul-14C)Triflumuron in rats. Characterization and preliminary identification of metabolites in urine and feces [redacted] Bayer CropScience AG, [redacted] [redacted] Non GLP, unpublished	Yes	BCS
A 6.2. /05	[redacted]	1983	Triflumuron (SIR 8514): Biokinetics of [2-chlorobenzoyl-ring-U-14C]-Triflumuron in rats [redacted] Bayer CropScience AG, [redacted] [redacted] Non GLP, unpublished	Yes	BCS
A 6.2. /06	[redacted]	1984	Triflumuron (SIR 8514) - Characterization of erythrocyte-bound radioactivity under in vivo and in vitro conditions [redacted] Bayer CropScience AG, [redacted] [redacted] Non GLP, unpublished	Yes	BCS
A 6.2. /07	[redacted]	1984	The metabolism of Alsystin TM by lactating dairy goats [redacted] Bayer CropScience AG, [redacted] [redacted] Non GLP, unpublished	Yes	BCS
A 6.2. /08	O[redacted]	1983	The metabolism and excretion of Alsystin TM-chlorophenyl-ul-14C by chickens [redacted] Bayer CropScience AG, [redacted] [redacted]-1 Non GLP, unpublished	Yes	BCS
A 6.3.1 /01	[redacted]	1978	SIR 8514 - Subacute oral cumulative toxicity study on rats [redacted] Bayer CropScience AG, [redacted] [redacted]-1 Non GLP, unpublished	Yes	BCS
A 6.3.2 /01	[redacted]	1978	SIR 8514 - Subacute dermal cumulative toxicity study on rabbits [redacted] Bayer CropScience AG, [redacted] [redacted] Non GLP, unpublished	Yes	BCS
A 6.3.2 /02	[redacted]	1990	SIR 8514 (proposed common name: Triflumuron) - Subacute dermal toxicity study on rabbits [redacted] Bayer CropScience AG, [redacted] [redacted] GLP, unpublished	Yes	BCS
A 6.3.3 /01	[redacted]	1979	SIR 8514 - Subacute inhalation study on rats [redacted]	Yes	BCS

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			Bayer CropScience AG, [redacted] Non GLP, unpublished		
A 6.3.3 /02	[redacted]	1981	SIR 8514 065 EC 059 B - Subacute inhalational toxicity study on rats [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.4.1. /01	[redacted]	1981	SIR 8514 (Triflumuron) - Subchronic toxicological study on rats (feeding experiment over three months) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.4.1. /02	[redacted]	1983	SIR 8514 (Triflumuron) - Subchronic toxicological study with rats (feeding study over three months) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	A 6.4.1. /02
A 6.4.1. /03	[redacted]	1984	SIR 8514 (proposed common name Triflumuron) - Subchronic study of toxicity to rats (three-month feeding study) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	A 6.4.1. /03
A 6.4.1. /04	[redacted]	1980	SIR 8514 - Subchronic toxicity study on dogs (thirteen-week feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	A 6.4.1. /04
A 6.5. /01	[redacted]	1984 Amended: 1988	SIR 8514 (Triflumuron) - Chronic toxicity study on rats (2-year feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.7. /01	Yes	A 6.5. /01
A 6.5. /02	[redacted]	1984 Amended: 1988	SIR 8514 (suggested common name: Triflumuron) - Chronic toxicity study on mice (2-year feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.7. /02	Yes	BCS
A 6.5. /03	[redacted]	1984 Amended: 1989	SIR 8514 (proposed common name: Triflumuron) - Chronic oral toxicity study on dogs (12- month feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS

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A 6.5. /04	[redacted]	1984 Amended: 1989	SIR 8514 (proposed common name: Triflumuron): Chronic oral toxicity to dogs / supplementary study (12-month feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.6.1. /01	[redacted]	1979	SIR 8514 - Salmonella/microsome test for point mutagenic effects [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.6.1. /02	[redacted]	1983	Mutagenicity evaluation of SIR 8514 (c.n. Triflumuron) in the reverse mutation induction assay with Saccharomyces cervisiae strains S138 and S211alpha [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.6.1. /03	[redacted]	1983	SIR 8514 (proposed c.n. Triflumuron) - POL test on E. coli to evaluate for DNA damage [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.6.1. /04	[redacted]	1988	Alsystin technical (Bay SIR 8514) - Salmonella/mammalian-microsome plate incorporation mutagenicity assay (Ames test) [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.6.1. /05	[redacted]	1991	SIR 8514 - Salmonella/microsome test [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.6.2. /01	[redacted]	1992	Chromosome aberration assay in human lymphocytes in vitro with SIR 8514 [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	A 6.6.2. /01
A 6.6.2. /02	[redacted]	1988	Alsystin technical - Unscheduled DNA synthesis in rat primary hepatocytes [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	A 6.6.2. /02
A 6.6.2. /03	[redacted]	1988	Alsystin technical - Sister chromatid exchange assay in Chinese hamster ovary (CHO) cells [redacted],	Yes	A 6.6.2. /03

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			[redacted] Bayer CropScience AG, [redacted] GLP, unpublished		
A 6.6.3. /01	[redacted]	1989	SIR 8514 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	A 6.6.3. /01
A 6.6.3. /02	[redacted].	1988	Alsystin technical - CHO/HGPRT mutation assay [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.6.4. /01	[redacted]	1978	SIR 8514 - Micronucleus test on mouse to evaluate SIR 8514 for mutagenic potential [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.6.6. /01	[redacted]	1978	SIR 8514 - Dominant lethal study on male mouse to test for mutagenic effects [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.7. /01	[redacted]	1984 Amended: 1988	SIR 8514 (Triflumuron) - Chronic toxicity study on rats (2-year feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.5. /01	Yes	BCS
A 6.7. /02	[redacted] [redacted] [redacted]	1984 Amended: 1988	SIR 8514 (suggested common name: Triflumuron) - Chronic toxicity study on mice (2-year feeding experiment) [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.5. /02	Yes	BCS
A 6.8.1. /01	[redacted]	1987	SIR 8514 - Study of embryotoxic effects on rats after oral administration (proposed common name: Triflumuron) [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.8.1. /02	[redacted]	1987	SIR 8514 - Study of embryotoxic effects on rabbits after oral administration (proposed common name: Triflumuron) [redacted] Bayer CropScience AG, [redacted]	Yes	BCS

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			GLP, unpublished		
A 6.8.2. /01	[redacted]	1983 Amended: .2003	SIR 8514 (c.n. Triflumuron; Alsystin active ingredient) - Multigeneration study on rats [redacted]ny Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.10. /01	[redacted]	1980	p-aminotrifluoroanisol (Trifluoromethyl-4-aminophenyether) - Study for occupational toxicity [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.10. /02	[redacted]	1982	N,N-bis-(trifluoromethoxyphenyl) urea and 4-trifluoromethoxyaniline (potential components of SIR 8514) - Study for potential hemotoxic effect [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.10. /03	[redacted]	1984	4-trifluoromethoxyaniline - KLU 2996B - Salmonella/microsome test for point mutagenic effects [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.10. /04	[redacted]	1985	4-Trifluoromethoxyaniline - KLU 2996B - Pol A1 test on E. coli for DNA modification [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.10. /05	[redacted]	1985	4-trifluoromethoxyaniline - KLU 2996B - Micronucleus test on the mouse to evaluate for mutagenic effect [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 6.11. /01	[redacted]	1977	SIR 8514 - Acute toxicity studies [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.1.1. /01 also filed: A 6.1.2 /01 also filed: A 6.1.4. /01	Yes	BCS
A 6.12.1. /01	[redacted]	1990	Your inquiry regarding information on human health hazards to workers associated with the manufacture or formulation of Alsystin [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 6.12.1. /02	[redacted]	2005	Occupational medical experiences with Triflumuron in the CI-Plant, Dormagen	Yes	BCS

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			[redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 6.7.2. /02		
A 6.12.1. /03	[redacted]	2005	Occupational medical experiences with Triflumuron in the FL-Plant, Dormagen [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 6.7.2. /01	Yes	BCS
A 6.15.3. /01	[redacted]	1986	Residue levels of Triflumuron (BAY Vi 7533) in milk and tissue of bovine [redacted] Bayer CropScience AG, [redacted]	Yes	MOB
A 6.15.3. /02	[redacted]	1984	Radioactive residues of 14-C-Alsystin TM in rotational crops [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.1.1.1.1. /01	[redacted]	1984	Hydrolysis of Alsystin in sterile aqueous buffer solutions [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.1.1.1.1. /02	[redacted]	2003	Hydrolysis of [trifluoromethoxphenyl-UL-14C] Triflumuron at 25 C in sterile aqueous buffer solution of pH9 Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /01	[redacted]	2003	Photolysis of Triflumuron in sterile aqueous buffer pH 7 Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /02	[redacted]	1991	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of Triflumuron in water Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /03	[redacted]	2002	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water: 2-Chlorobenzamide (photodegradation product of Triflumuron) Bayer AG, Bayer CropScience, Monheim, Germany Bayer CropScience AG,	Yes	BCS

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			[redacted] GLP, unpublished		
A 7.1.2.2.2. /01	[redacted]	1997	Degradation and metabolism of Triflumuron in the water-sediment system Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /02	[redacted]	2003	Calculation of DT_{50} values of Triflumuron and its metabolites 4-Trifluoromethoxyphenylurea and 2-Chlorobenzoic Acid in water and sediment based on results of a water-sediment study Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.1. /01	[redacted]	2002	Aerobic degradation/metabolism of Triflumuron in soil Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.2.1. /02	[redacted]	1983 Amended: 1984	Degradation of 14C-Alsystin in soil Mobay Chemical Corporation, USA Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.1. /03	[redacted]	2005	[Phenoxy-UL-14C]Triflumuron: Aerobic soil degradation in one EU soil Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 7.2.2.1. /03	Yes	BCS
A 7.2.1. /04	[redacted]	1980	SIR 8514; air; soil; Germany; BBA Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.1. /05	[redacted]	1980, Amended: 1991	SIR 8514; air; soil; Germany; BBA Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.2.1. /01	[redacted]	2003	Calculation of DT_{50} values of Triflumuron and its metabolites 4-trifluoromethoxyphenylurea and 2-chlorobenzoic acid in soil under aerobic conditions Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.2.1. /02	[redacted]	2002	Recalculation of Triflumuron half-lives in soil according to 1st order kinetics and corrected to 20 C and pF 2 (laboratory study) Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.2.1. /03	Hei[redacted]	2005	[Phenoxy-UL-14C]Triflumuron: Aerobic soil	Yes	BCS

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	[redacted]		degradation in one EU soil Bayer CropScience AG, [redacted] GLP, unpublished also filed: A 7.2.1. /03		
A 7.2.2.1. /04	[redacted]	1996	Calculation of DT-50 values of metabolites of Triflumuron in soil under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.2.1. /05	[redacted]	2003	Degradation and metabolism of [phenyl-UL-14C] 2-chlorobenzoic acid in three different soils under aerobic conditions Staatl. Lehr- u. Forschungsanstalt fuer Landwirtschaft, Neustadt/Weinstr., Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.2.2.4. /01	[redacted]	1986	Anaerobic aquatic metabolism of 14C-Alsystin Mobay Chemical Corporation, USA Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.2.4. /02	[redacted]	1986 Amended: .2002	Photodecomposition of 14C-Alsystin on soil Mobay Chemical Corporation, USA Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.3.1. /01	[redacted]	2002	Adsorption/desorption of Triflumuron in four soil types Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.2.3.1. /02	[redacted]	2002	Adsorption/desorption of Triflumuron on soil Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.2.3.1. /03	[redacted]	1989	Adsorption of Triflumuron to soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
A 7.2.3.1. /04	[redacted]	2003	Adsorption/desorption of 4-trifluoromethoxyphenyl-urea (metabolite of Triflumuron) on soils Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.2.3.1. /05	[redacted]	2003	Adsorption/desorption of 2-chlorobenzoic acid (metabolite of Triflumuron) on soils Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.3.1. /01	[redacted]	2002	Calculation of the chemical lifetime of	Yes	BCS

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	[redacted]		Triflumuron in the troposphere Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished		
A 7.3.2. /01	[redacted]	1993 Amended: 1993	Determination of the volatilization of Triflumuron in a field experiment Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
A 7.4.1.1. /01	[redacted]	2002	Triflumuron (SIR 8514): Acute toxicity limit test with rainbow trout (Oncorhynchus mykiss) under flow-through conditions [redacted], [redacted] Bayer CropScience AG, [redacted] Date: 17.05.2002 GLP, unpublished	Yes	A 7.4.1.1. /01
A 7.4.1.1. /02	[redacted]	2002	Acute toxicity of Triflumuron to fish (Lepomis macrochirus) [redacted] Bayer CropScience AG, [redacted] Date: 03.06.2002 GLP, unpublished	Yes	A 7.4.1.1. /02
A 7.4.1.2. /01	[redacted]	2002	Acute toxicity of Triflumuron (tech.) to water fleas (Daphnia magna) under semistatic test conditions [redacted] Bayer CropScience AG, [redacted] Date: 10.04.2002 GLP, unpublished	Yes	A 7.4.1.2. /01
A 7.4.1.2. /02	[redacted]	1998	Acute toxicity of 2-chlorobenzoic acid to water fleas (Daphnia magna) [redacted] Bayer CropScience AG, [redacted] Date: 06.10.1998 GLP, unpublished	Yes	A 7.4.1.2. /02
A 7.4.1.2. /03	[redacted]	2003	Acute toxicity of SIR 8514-2-chloro benzamide (tech.) to water fleas (Daphnia magna) Bayer CropScience AG, [redacted] Date: 13.03.2003 GLP, unpublished	Yes	A 7.4.1.2. /03
A 7.4.1.2. /04	[redacted]	1998	Acute toxicity of 4(trifluoromethoxy)-phenylurea to water fleas (Daphnia magna) [redacted] Bayer CropScience AG, [redacted] Date: 06.10.1998 GLP, unpublished	Yes	A 7.4.1.2. /04
A 7.4.1.3. /01	[redacted]	1990	Growth inhibition of green algae (Scenedesmus subspicatus) by Triflumuron	Yes	A 7.4.1.3. /01

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			(tech.) [redacted] Bayer CropScience AG, [redacted] Date: 02.02.1990 GLP, unpublished		
A 7.4.1.4. /01	[redacted]	2001	Triflumuron - Toxicity to bacteria [redacted] Bayer CropScience AG, [redacted] Date: 12.02.2001 GLP, unpublished	Yes	A 7.4.1.4. /01
A 7.4.2. /01	[redacted]	1990	Triflumuron bioconcentration in fish [redacted] Bayer CropScience AG, [redacted] Date: 15.11.1990 GLP, unpublished	Yes	A 7.4.2. /01
A 7.4.3.2. /01	[redacted]	2002	Triflumuron (SIR 8514): Early life-stage limit test with fathead minnow (Pimephales promelas) under flow-through conditions [redacted] Bayer CropScience AG, [redacted] Date: 17.05.2002 GLP, unpublished	Yes	A 7.4.3.2. /01
A 7.4.3.4. /01	[redacted]	1990	Influence of Alsystin WP 25 on the reproduction rate of water fleas [redacted] Bayer CropScience AG, [redacted]-1 Date: 27.03.1990 GLP, unpublished	Yes	A 7.4.3.4. /01
A 7.4.3.5. /01	[redacted]	2003	Outdoor aquatic microcosm study of the ecological effects and environmental fate of Triflumuron SC 480 [redacted] Bayer CropScience AG, [redacted]1 Date: 16.05.2003 GLP, unpublished	Yes	A 7.4.3.5. /01
A 7.4.3.5. /02	[redacted]	2005	Evaluation of the report: Outdoor aquatic microcosm study of the ecological effects and environmental fate of triflumuron SC 480, 16 May 2003 [redacted] Bayer CropScience AG, [redacted] Date: 17.05.2005 Non GLP, unpublished	Yes	A 7.4.3.5. /02
A 7.4.3.5.1. /01	[redacted]	1996	Influence of Triflumuron (tech.) on development and emergence of larvae of Chironomus riparius in a water-sediment system [redacted] Bayer CropScience AG, [redacted]	Yes	A 7.4.3.5.1. /01

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			[redacted] Date: 23.07.1996 GLP, unpublished		
A 7.4.3.5.1. /02	[redacted]	2003	Chironomus riparius 28-day chronic toxicity test with SIR 8514-2-chlorobenzoic acid in a water-sediment system using spiked water [redacted] Date: 20.03.2003 GLP, unpublished	Yes	A 7.4.3.5.1. /02
A 7.4.3.5.1. /03	[redacted]	2003	Chironomus riparius 28-day chronic toxicity test with SIR 8514-2-chloro benzamide in a water-sediment system using spiked water [redacted] Date: 14.03.2003 GLP, unpublished	Yes	A 7.4.3.5.1. /03
A 7.4.3.5.1. /04	[redacted]	2002	Influence of Triflumuron-4 (trifluoromethoxy)-phenylurea on development and emergence of larvae of Chironomus riparius in a water-sediment system [redacted] Bayer CropScience AG, [redacted] Date: 28.08.2002 GLP, unpublished	Yes	A 7.4.3.5.1. /04
A 7.5.1.1. /01	[redacted]	1987	Influence of Alsystin (Triflumuron) on the microbial mineralization of carbon in soils [redacted] Bayer CropScience AG, [redacted] Date: 26.05.1987 Non GLP, unpublished	Yes	A 7.5.1.1. /01
A 7.5.1.1. /02	[redacted]	1988	Influence of Alsystin (Triflumuron) on the microbial mineralization of nitrogen in soils [redacted] Bayer CropScience AG, [redacted] Date: 12.02.1988 Non GLP, unpublished	Yes	A 7.5.1.1. /02
A 7.5.1.1. /03	[redacted]	1990	Influence of the commercial product Alsystin 480 SC on the soil respiration after amendment with glucose [redacted] Bayer CropScience AG, [redacted] Date: 28.09.1990 GLP, unpublished	Yes	A 7.5.1.1. /03
A 7.5.1.1. /04	[redacted]	1990	Influence of the commercial product Alsystin 480 SC on nitrogen turnover in soil [redacted] Bayer CropScience AG, [redacted] Date: 28.09.1990 GLP, unpublished	Yes	A 7.5.1.1. /04
A 7.5.1.1. /05	[redacted]	2001	Influence of the metabolite Triflumuron-2-chlorobenzoic acid on the microbial mineralization of nitrogen in soils [redacted]	Yes	A 7.5.1.1. /05

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			Bayer CropScience AG, [redacted] Date: 15.03.2001 GLP, unpublished		
A 7.5.1.1. /06	[redacted]	2001	Influence of the metabolite Triflumuron-4-trifluoromethoxy-phenylurea on the microbial mineralization of nitrogen in soils [redacted] Bayer CropScience AG, [redacted] Date: 15.03.2001 GLP, unpublished	Yes	A 7.5.1.1. /06
A 7.5.1.2. /01	[redacted]	1986	Acute toxicity of Triflumuron (tech.) to earthworms (Eisenia foetida) [redacted] Bayer CropScience AG, [redacted] Date: 23.12.1986 GLP, unpublished	Yes	A 7.5.1.2. /01
A 7.5.1.2. /02	[redacted]	2001	Acute toxicity of SIR 8514-2-chlorobenzoic acid to the earthworm Eisenia andrei in an artificial soil test [redacted] Bayer CropScience AG, [redacted] Date: 19.12.2001 GLP, unpublished	Yes	A 7.5.1.2. /02
A 7.5.1.2. /03	[redacted]	2001	Acute toxicity of SIR 8514-4(trifluormethoxy)-phenylurea to the earthworm Eisenia andrei in an artifical soil test according to the OECD Guideline No. 207 (1984) [redacted], Bayer CropScience AG, [redacted] Date: 25.07.2001 GLP, unpublished	Yes	A 7.5.1.2. /03
A 7.5.1.3. /01	[redacted]	2001	Herbicidal screening data for triflumuron SC 480 Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Date: 07.06.2001 Non GLP, unpublished	Yes	A 7.5.1.3. /01
A 7.5.2.1. /01	[redacted]	2002	SIR 8514-2-chlorobenzoic acid: Acute and reproduction toxicity to the collembolan species Folsomia candida [redacted] Bayer CropScience AG, [redacted] Date: 03.07.2002 GLP, unpublished	Yes	A 7.5.2.1. /01
A 7.5.2.1. /[redacted]	[redacted]	2001	Acute and reproduction toxicity of SIR 8514-4(trifluormethoxy)-phenylurea to the Collembolan species Folsomia candida according to the ISO Guideline 11267 (1999) [redacted] Bayer CropScience AG, [redacted]	Yes	A 7.5.2.1. /02

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Edition Number: M-065204-01-1 Date: 06.08.2001 GLP, unpublished		
A 7.5.2.2. /01	[redacted]	2001	Herbicidal screening data for Triflumuron SC 480 [redacted] Bayer CropScience AG, [redacted] Date: 07.06.2001 Non GLP, unpublished	Yes	A 7.5.2.2. /01
A 7.5.3.1.1. /01	[redacted]	1982	Acute oral LD_{50} of BAY SIR 8514 to bobwhite quail [redacted] Bayer CropScience AG, [redacted] Date: 23.04.1982 Non GLP, unpublished	Yes	A 7.5.3.1.1. /01
A 7.5.3.1.2. /01	[redacted]	1981	Acute dietary LC^{50} of SIR 8514 technical to mallard ducks [redacted] Bayer CropScience AG, [redacted] Date: 21.10.1981 Non GLP, unpublished	Yes	A 7.5.3.1.2. /01
A 7.5.3.1.2. /02	[redacted]	1981	Acute dietary LC^{50} of SIR 8514 technical to bobwhite quail [redacted] Bayer CropScience AG, [redacted] Date: 21.10.1981 Non GLP, unpublished	Yes	A 7.5.3.1.2. /02
A 7.5.3.1.2. /03	[redacted]	2002	Technical Triflumuron: a subacute dietary LC^{50} with northern bobwhite [redacted] Bayer CropScience AG, [redacted] Date: 01.11.2002 GLP, unpublished	Yes	A 7.5.3.1.2. /03
A 7.5.3.1.3. /01	[redacted]	1983	Effect of Triflumuron on bobwhite quail reproduction [redacted] Bayer CropScience AG, [redacted] Date: 24.10.1983 Non GLP, unpublished	Yes	A 7.5.3.1.3. /01
A 7.5.3.1.3. /02	[redacted]	1983	Effects of Triflumuron on mallard duck reproduction [redacted] Bayer CropScience AG, [redacted] Date: 21.10.1983 Non GLP, unpublished	Yes	A 7.5.3.1.3. /02
A 8.1. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1,	Yes	A 8.1. /01

Section No / Reference No[5]	**Author(s)**[6]	**Year**	**Title**[7] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01		
A 8.3. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	A 8.3. /01
A 8.4. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	A 8.4. /01
A 8.5.1. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	A 8.5.1. /01
A 8.5.2. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	A 8.5.2. /01
A 8.5.3. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01	Yes	A 8.5.3. /01

Section No / Reference No[5]	**Author(s)[6]**	**Year**	**Title[7]** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			also filed: A 8.5.4. /01 also filed: A 9. /01		
A 8.5.4. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 9. /01	Yes	A 8.5.4. /01
A 9. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01	Yes	A 9. /01
A 8.1. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	BCS
A 8.3. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	BCS
A 8.4. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	BCS
A 8.5.1. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished	Yes	BCS

Section No / Reference No[5]	Author(s)[6]	Year	Title[7] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01		
A 8.5.2. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	BCS
A 8.5.3. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.4. /01 also filed: A 9. /01	Yes	BCS
A 8.5.4. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 9. /01	Yes	BCS
A 9. /01	Anon.	2005	Triflumuron TC Bayer CropScience AG, Report No.: M-089421-03-1, Edition Number: M-089421-03-1 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.4. /01 also filed: A 8.5.1. /01 also filed: A 8.5.2. /01 also filed: A 8.5.3. /01 also filed: A 8.5.4. /01	Yes	BCS

List of studies for Biocidal Product (Doc. IIIB)

Section No / Reference No[8]	Author(s)[9]	Year	Title[10] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
B 2.2. /01	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /02	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /03	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /04	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /05	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /06	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /07	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /08	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /09	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 2.2. /10	Confidential	[redacted]	Confidential (please refer to Doc I)	Yes	BCS
B 3.1.1. /01	[redacted]	2005 Amended: 2005	Amendment No.: 1 - Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.1.2. /01	[redacted]	2005 Amended: .2005	Amendment No.: 1 - Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.1.3. /01	[redacted]	2005 Amended: .2005	Amendment No.: 1 - Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.2. /01	[redacted] [redacted] [redacted]	2005	Determination of explosion properties, flammability, ability for slef heating, relative self-ignition temperature of baycidal WP 25 Rhodia, Lyon, France Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 3.3. /01 also filed: B 3.4. /01	Yes	BCS
B 3.3. /01	[redacted] [redacted]	2005	Determination of explosion properties,	Yes	B 3.3. /01

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	[redacted]		flammability, ability for slef heating, relative self-ignition temperature of baycidal WP 25 Rhodia, Lyon, France Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 3.2. /01 also filed: B 3.4. /01		
B 3.4. /01	[redacted] [redacted] [redacted]	2005	Determination of explosion properties, flammability, ability for slef heating, relative self-ignition temperature of baycidal WP 25 Rhodia, Lyon, France Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 3.2. /01 also filed: B 3.3. /01	Yes	B 3.4. /01
B 3.5. /01	[redacted]	2005 Amended: 2005	Amendment No.: 1 - Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	B 3.5. /01
B 3.6. /01	[redacted]	2005 Amended: 2005	Amendment No.: 1 - Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.8. /01	Yes	BCS
B 3.7. /01	[redacted]	2005	Storage stability of Triflumuron WP25 - [Packaging material: Al-composite foil] - Interim report - New Version Interim report Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 3.8. /01	[redacted]	2005, Amended: 2005	Amendment No.: 1 - Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01	Yes	BCS

Section No / Reference No[8]	Author(s)[9]	Year	Title[10] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
B 3.11. /01	[redacted]	2005	Physical, chemical and technical properties of a WP-Formulation Triflumuron WP25 - particle size distribution Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
B 4.1. /01	[redacted]	1989	Determination of Triflumuron in Formulations Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 4.1. /02	[redacted]	2004	Validation of HPLC-method 2001-0011401-89 -Determination of Triflumuron in Formulations- Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 4.1. /03	[redacted]	2005	Validation of HPLC-method 2001-0011401-89 -Determination of Triflumuron in Formulations- Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /01	[redacted]	1993	Field trials to determine the efficacy of various treatment programmes against stable flies in the lower Rhine district and upper franconia, Germany, 1993 Bayer AG, Leverkusen, Germany Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /02	[redacted]	1996	Field evaluation of Triflumuron and methomyl for control of the housefly Musca domestica Danish Pest Infestation Laboratory, Lyngby, Denmark Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 5.7.1. /03	Yes	BCS
B 5.10.2. /03	Salin, C., Delettre, Y. R. and Vernon, P.	2003	Controlling the mealworm Alphitobius diaperinus (Coleoptera Tenebrionidae) in broiler and turkey houses: field trials with a combined insecticide treatment: insect growth regulator and pyrethroid Publisher: Entomological Society of America, Location:Anon., Journal: Journal of Economical Entomology, Volume:96, Issue:Anon., Pages:126-130, Report No.: BES-EH-Mo-00323, Edition Number: M-267027-01-1 Non GLP, published	No	
B 5.10.2. /04	[redacted]	1998	Efficiency tests in natural conditions of Baycidal (Triflumuron) and Solfac (cyfluthrine) against Coleoptera in poultry and turkey breeding systems Universite de Rennes, Rennes, France Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS

Section No / Reference No[8]	Author(s)[9]	Year	Title[10] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
B 5.10.2. /05	[redacted]	1997	Population biology of Alphitobius diaperinus (Coleoptera: Tenebrionidae) - Efficiency tests in natural conditions of Baycidal (Triflumuron) and Solfac (cyfluthrine) against Coleoptera in poultry breeding systems Universite de Rennes I, CNRS, Paimpont, France Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /06	[redacted]	1998	Field trial with Baycidal WP 25 (Triflumuron) against litter beetles, especially Alphitobius diaperinus (Panzer), in a Danish parent flock poultry farm Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /07	[redacted]	1998	Efficacy of Baycidal 25 WP and Solfac 10 WP against the litter beetle Alphitobius diaperinus in poultry IRATI, Lasarte-Oria, Spain Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /08	[redacted]	1993	To determine the efficacy of Triflumuron against larvae of Musca domestica in the laboratory Bayer, South Africa Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /09	Weaver, J. E., Kondo, V. A.	1987	Laboratory evaluation of insect growth regulators in producing lesser mealworm mortality and egg infertility Publisher:Anon., Location:Anon., Journal: Journal of Agricultural Entomology, Volume:4, Issue:3, Pages:233-245, Report No.: M-269042-01-1, Edition Number: M-269042-01-1 Non GLP, published	No	
B 5.10.2. /10	[redacted]	1996	Evaluation of the activity of the formulation Baycidal 25 WP on Alphitobius diaperinus in the laboratory Instituto de Entomologia Agraria, Milan University, Italy Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.10.2. /11	[redacted]	1986	Evaluation of Alsystin 250 WP for the control of lesser mealworm (Alphitobius diaperinus) by two applications/mixing regimes Bayer Australia Ltd., Botany, Australia Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 5.11.2. /01	Staetz, C. A.	2004	Insecticide mode of action classification: A key	No	

Section No / Reference No[8]	Author(s)[9]	Year	Title[10] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			to insecticide resistance management Publisher: for more information from the customer see page note, Location: Salt Lake City, UT, USA, Journal: Insecticide Resistance Action Committee (IRAC), [redacted] Non GLP, published also filed: A 5.7.2. /01		
B 6.1. /01	[redacted]	[redacted]	Confidential (please refer to Doc I)	Yes	B 6.1. /01
B 6.1.1. /01	[redacted]	1979	Acute oral toxicity of BAY SIR 8514 25% wettable powder to rats [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished	Yes	BCS
B 6.1.1. /02	[redacted] [redacted] [redacted]J.	1980	SIR 8514 25 WP 032 A: Study of formulation toxicity [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 6.1.2 /01 also filed: B 6.1.3. /01 also filed: B 6.2. /01	Yes	BCS
B 6.1.2 /01	[redacted] [redacted] [redacted]	1980	SIR 8514 25 WP 032 A: Study of formulation toxicity [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 6.1.1. /02 also filed: B 6.1.3. /01 also filed: B 6.2. /01	Yes	BCS
B 6.1.3. /01	[redacted] [redacted] [redacted]J.	1980	SIR 8514 25 WP 032 A: Study of formulation toxicity [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 6.1.1. /02 also filed: B 6.1.2 /01 also filed: B 6.2. /01	Yes	BCS
B 6.1.3. /02	[redacted] [redacted] [redacted]	1987	Acute inhalation toxicity study with Alsystin 25% Wettable Powder dust in Sprague-Dawley rats [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
B 6.2. /01	[redacted] [redacted] [redacted]	1980	SIR 8514 25 WP 032 A: Study of formulation toxicity [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: B 6.1.1. /02 also filed: B 6.1.2 /01	Yes	BCS

Section No / Reference No[8]	**Author(s)**[9]	**Year**	**Title**[10] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			also filed: B 6.1.3. /01		
B 6.2. /02	[redacted]	1991	SIR 8514 25 WP 03823/0142 H (c.n.: Triflumuron (proposed)) - Study for skin and eye irritation/corrosion in rabbits [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
B 6.3. /01	[redacted]	2005	SIR 8514 25 WP (Project: Triflumuron (SIR 8514)) - Local lymph node assay in mice (LLNA/IMDS) [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
B 6.4. /01	[redacted]	2002	In vivo percutaneous absorption of [14C]-Triflumuron formulated as SC 480 in rats [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
B 6.4. /02	[redacted]	2003	In vitro percutaneous absorption study with [14C] Triflumuron formulated as SC480 through human and rat skin membranes using flow through diffusion cells [redacted] Bayer CropScience AG, [redacted] GLP, unpublished	Yes	BCS
B 6.7.2. /01	[redacted]	2005	Occupational medical experiences with Triflumuron in the FL-Plant, Dormagen [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.12.1. /03	Yes	BCS
B 6.7.2. /02	[redacted]	2005	Occupational medical experiences with Triflumuron in the CI-Plant, Dormagen [redacted] Bayer CropScience AG, [redacted] Non GLP, unpublished also filed: A 6.12.1. /02	Yes	BCS
B 7.7.1.1. /01	[redacted]	1982	Acute toxicity of SIR 8514 25% wettable powder to bluegill and rainbow trout [redacted] USA Bayer CropScience AG, [redacted] Date: 22.01.1982 GLP, unpublished	Yes	BCS
B 7.7.1.1. /02	[redacted]	1981	Acute toxicity of SIR 8514 25% wettable powder to Daphnia magna [redacted] Bayer CropScience AG, [redacted]	Yes	BCS

Section No / Reference No[8]	Author(s)[9]	Year	Title[10] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Date: 13.10.1981 Non GLP, unpublished		
B 7.7.1.1. /03	[redacted]	1987	Growth inhibition of green algae (Scenedesmus subspicatus) caused by Triflumuron 25 WP [redacted] Bayer CropScience AG, [redacted] Date: 11.02.1987 GLP, unpublished	Yes	BCS
B 8.1. /01	Anon.	2005	Baycidal 25 WP Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-269039-01-1, Edition Number: M-269039-01-1 Non GLP, unpublished also filed: B 8.2. /01 also filed: B 8.3. /01 also filed: B 8.4. /01 also filed: B 8.5. /01 also filed: B 9. /01	Yes	BCS
B 8.2. /01	Anon.	2005	Baycidal 25 WP Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-269039-01-1, Edition Number: M-269039-01-1 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.3. /01 also filed: B 8.4. /01 also filed: B 8.5. /01 also filed: B 9. /01	Yes	BCS
B 8.3. /01	Anon.	2005	Baycidal 25 WP Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-269039-01-1, Edition Number: M-269039-01-1 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.2. /01 also filed: B 8.4. /01 also filed: B 8.5. /01 also filed: B 9. /01	Yes	BCS
B 8.4. /01	Anon.	2005	Baycidal 25 WP Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-269039-01-1, Edition Number: M-269039-01-1 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.2. /01 also filed: B 8.3. /01 also filed: B 8.5. /01 also filed: B 9. /01	Yes	BCS
B 8.5. /01	Anon.	2005	Baycidal 25 WP Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-269039-01-1, Edition Number: M-269039-01-1 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.2. /01 also filed: B 8.3. /01 also filed: B 8.4. /01 also filed: B 9. /01	Yes	BCS
B 9. /01	Anon.	2005	Baycidal 25 WP Bayer CropScience SA, Lyon, France	Yes	BCS

Section No / Reference No[8]	**Author(s)**[9]	**Year**	**Title**[10] **Source (where different from company) Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
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