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

prosulfocarb

finalised: 27 July 2007

(version of 3 August 2007 with minor editorial changes in the list of endpoints)

SUMMARY

Prosulfocarb is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Sweden being the designated rapporteur Member State submitted the DAR on prosulfocarb in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 20 April 2005. Following a quality check on the DAR, the peer review was initiated on 7 October 2005 by dispatching the DAR for consultation of the Member States and the sole applicant Syngenta. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed during a written procedure in August – September 2006. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in January 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 27 June 2007 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a pre-emergence or early post-emergence herbicide as proposed by the notifier which comprise conventional field crop spraying to control grass weeds (*Apera spica-venti*, *Poa annua*, *Poa trivialis*, *Alopecurus myosuroides*, *Lolium multiflorum*) and broad-leaved weeds (*Galium aparine*, *Stellaria media*, *Lamium purpureum*, *Fumaria officinalis*, *Solanum nigrum*, Atriplex patula, *Chenopodium album*, *Thlaspi arvense*, *Veronica* spp., *Capsella bursa-pastoris*, *Myosotis arvensis*, *Anthemis* spp., *Viola arvensis*) in winter wheat and potatoes (a maximum rate of 4 kg as/ha).
The representative formulated products for the evaluation was "Boxer", an emulsifiable concentrate (EC) containing 800 g/L prosulfocarb.

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

The technical specification is still open waiting for confirmatory data.

Adequate methods are available to monitor prosulfocarb in the respective residue definitions. Residues of prosulfocarb in food and feed of plant origin can be determined by a multi method (DFG Method-S19) using GC-MSD and in soil, water and air by GC-MSD. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

The acute oral toxicity of prosulfocarb is moderate while the acute dermal or inhalation toxicity is low. Slight signs of skin- and ocular irritation were noted in rabbits, and skin sensitisation was shown in mice. In short-term toxicity studies, liver and kidney were found to be the target organs in rats and dogs. In addition, haemolytic anaemia was observed in dogs, with associated histopathological findings in the bone marrow and spleen. Available data do not support evidence of genotoxic or carcinogenic effects. In long-term toxicity studies, mainly reduced food consumption and decreased body weights were noted. No toxic effect on the reproductive parameters was demonstrated. However, there was some evidence of teratogenic potential but no convincing evidence for classification and adequate margins of safety were shown for the reference values. The Acceptable Daily Intake (ADI) is 0.005 mg/kg bw/d, the Acceptable Operator Exposure (AOEL) is 0.007 mg/kg bw/d and the Acute Reference Dose (ARfD) is 0.1 mg/kg bw. The level of operator exposure is below the AOEL with the use of personal protective equipment according to a field study.

Applied according to the representative uses in wheat and potatoes, prosulfocarb is extensively metabolised and in mature commodities no metabolite structurally related to the compound was identified. The ultimate degradation products are expected to be incorporated in the endogenous metabolism of the plant. The residue definition for monitoring and risk assessment is proposed to consist per default in prosulfocarb. MRLs for wheat and potatoes can be set at the Limit of Quantification. No residues are expected in rotational crops, processed plant commodities and in animal commodities. No risk for the consumer resulting from the use of prosulfocarb according to the representative uses is expected.

In soil under aerobic conditions prosulfocarb exhibits low to moderate persistence forming the minor soil metabolite prosulfocarb sulfoxide[2] (observed in studies at a maximum of 7.2% of prosulfocarb on a mass basis) which exhibits low persistence. Mineralisation to carbon dioxide accounted for 38 % of applied radioactivity (AR) after 96 days. The formation of unextractable residues was also a significant sink accounting for 27 % AR after 96 days. Under anaerobic soil conditions degradation was slower than under aerobic conditions but no novel breakdown products were identified. Prosulfocarb exhibits low to slight mobility in soil, prosulfocarb sulfoxide exhibits high mobility in

[2] 1-(benzylsulfinyl)-N,N-dipropylmethanamide

soil. There was no indication that adsorption of either prosulfocarb or prosulfocarb sulfoxide was pH dependant.

In natural sediment water systems prosulfocarb dissipated quite rapidly from water by partitioning to sediment where it subsequently degraded slowly exhibiting high persistence. The terminal metabolite, CO2, was the only significant degradation product accounting for 15-25 % AR at 70-107 days. Unextracted sediment residues were also a sink for radioactivity representing 7.3-23 % AR at study end (107 days). The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for prosulfocarb at steps 1-4, with spray drift mitigation being applied at step 4. These values are the basis for the risk assessment discussed in this conclusion. Additionally at step 4, for the runoff scenarios the applicant presented calculations where both spray drift and runoff were mitigated.

The potential for groundwater exposure from the applied for intended uses above the parametric drinking water limit of 0.1µg/L by parent prosulfocarb and its minor soil metabolite prosulfocarb sulfoxide, was concluded to be low, in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

The first-tier acute and short-term TERs for birds were above the trigger value of 10 but the long-term trigger of 5 was breached. The suggested risk refinements based on rate of decline of residues in plants, focal species and proportion of different food items in the diet (PD) were agreed in the meeting of experts. For mammals, the first tier acute TER was below the trigger of 10 for the small herbivore and all first tier long-term TERs were below the trigger of 5. As for birds, the refined risk assessment for mammals, based on rate of decline of residues in plants, focal species and proportion of different food items in the diet (PD), were agreed in the meeting of experts. The risk from uptake of contaminated drinking water was considered to be low since exposure of birds and mammals from contaminated drinking water was expected to be low. The accumulation of water in leaf axils and puddle formation were considered as unlikely since the product is applied at very early growth stages and sprayed at low volumes. A potential high risk was indicated for earthworm-eating birds and mammals. The refined risk assessment based on measured residues in earthworms resulted in TERs above the trigger of 5. The TERs for fish, daphnids and algae were about one order of magnitude below the trigger values of 100 and 10 based on FOCUS step 2 PECsw. No full FOCUS step3 scenario resulted in PECsw values low enough to achieve TERs above the Annex VI triggers for all groups of aquatic organisms.
Based on endpoints from laboratory studies, TERs below the Annex VI triggers were observed with FOCUS step 4 PECsw (10 m no spray buffer zone) in the scenarios D1, D2, D4, D5, D6, R1, R3, R4 (8 out of 9) for the use in winter wheat and in the scenarios R1, R2, R3 (3 out of 6) for the use in potato. Therefore it is concluded that a 10 m no-spray buffer zone is not sufficient as a risk mitigation measure in the majority of geoclimatic conditions represented by the FOCUS scenarios. Two mesocosm studies were submitted to refine the risk to aquatic organisms. The robustness of the results of the first study was questioned during the peer-review process. The experts in the PRAPeR

meeting agreed that a NOEAEC of 15 µg prosulfocarb/L could be derived from the new mesocosm study. No agreement was reached during the expert meeting on the safety factor which should be applied to the endpoint. If a safety factor of >3 is applied then the NOEAEC of 15 µg prosulfocarb/L would become the critical endpoint driving the risk assessment. The HQ values indicated a potential high in-field and off-field risk to non-target arthropods. Extended laboratory studies resulted in LR_{50}s below the suggested application rate of 4 kg prosulfocarb/ha but the LR_{50}s were higher than the expected exposure at 1m distance from the treated field. Therefore it was concluded by the expert meeting that recolonisation of the in-field area is likely to occur and the overall risk to non-target arthropods is sufficiently addressed. The TER values for non-target plants were calculated as 3 and 28 for pre- and post-emergence treatment. The use of an interception factor to estimate the pre-emergence exposure and the suggested lowering of the safety factor was not agreed by the expert meeting. Risk mitigation measures such as an in-field no spray buffer zone of 5 m was recommended. The risk to bees, earthworms, soil non-target micro-organisms and biological methods of sewage treatment was assessed as low for the representative uses evaluated.

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

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Prosulfocarb is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating Sweden as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Sweden submitted the report of its initial evaluation of the dossier on prosulfocarb, hereafter referred to as the draft assessment report, to the EFSA on 20 April 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 7 October 2005 to the Member States and the main applicant Syngenta as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in August – September 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings in January 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 27 June 2007 leading to the conclusions as laid down in this report.

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

In accordance with Article 11(4) of the Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

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

- the comments received
- the resulting reporting table (rev. 1-1 of 2 October 2006)

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

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 29 June 2007).

Given the importance of the draft assessment report including its addendum (compiled version of July 2007 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Vol. 3, B1, B5-B7, B9) which take into account mostly editorial changes. Since these revised documents still contain confidential information, the documents cannot be made publicly available. However, the information given can be found in the original draft assessment report together with the peer review report both of which are publicly available.

The Active Substance and the Formulated Product

Prosulfocarb is the ISO common name for *S*-benzyl dipropyl(thiocarbamate).

Prosulfocarb belongs to the class of thiocarbamate herbicides. Prosulfocarb is used for the selective control of a wide range of grass and broad-leaved weeds in winter wheat and potatoes. The mode of action of prosulfocarb is inhibition of lipid synthesis in the meristem.

The representative formulated product for the evaluation was "Boxer" registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying to control grass weeds (*Apera spica-venti, Poa annua, Poa trivialis, Alopecurus myosuroides, Lolium multiflorum*) and broad-leaved weeds (*Galium aparine, Stellaria media, Lamium purpureum, Fumaria officinalis, Solanum nigrum, Atriplex patula, Chenopodium album, Thlaspi arvense, Veronica spp., Capsella bursa-pastoris, Myosotis arvensis, Anthemis spp., Viola arvensis*) in winter wheat and potatoes.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of prosulfocarb as manufactured is 970 g/kg. No FAO specifications exist.

The manufacturing site of the technical material has been changed and a new specification was proposed with lower or equal maximum limits for the impurities and higher minimum active substance content. The new five batch data contain a new by-product, which was not included in the original specification of technical prosulfocarb. A data gap was proposed for the applicant to provide further information to justify the technical specification of the a.s. (data gap identified in the meeting of experts (PRAPeR 16)). Information to justify the new technical specification was provided (presented in addendum to Vol. 4 in May 2007) which was not peer review within the EU. EFSA created a new data gap for the applicant to provide quality control data from further production campaigns to allow a more sustainable assessment of the quality of technical prosulfocarb.
According to the equivalence assessment of the technical materials (Sanco/10597/2003 –rev. 7 final 2, Evaluation report, May, 2007), the RMS concluded that they can be regarded as equivalent. Due to the close similarity of the new impurity to prosulfocarb and the toxicological conclusions, the RMS concluded that the toxicological and the ecotoxicological profiles will be very similar to that of prosulfocarb, and that the occurrence of the new impurity would not increase the toxicity or ecotoxicity of the technical prosulfocarb. The new source was therefore considered to be equivalent to the original source and the risk assessment based on the original material should also cover the new technical material. This assessment was not peer reviewed.
Besides the specification, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of prosulfocarb or the respective formulations.

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

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of prosulfocarb in the technical material and in the representative formulations, as well as for the determination of the respective impurities in the technical material, however the PRAPeR 16 expert meeting (March 2007) agreed that a less harmful solvent should be used in the method for the determination of the plant protection product, which has been identified as a data gap and has to be addressed by the notifier. Besides that, enough data are available to ensure that quality control measurements of the plant protection products are possible.

Adequate analytical methods are available for the determination of prosulfocarb residues in food and feed of plant origin, soil, water, air. The DFG method S19 was validated for four representative

matrices: strawberry, potato, wheat and sunflower. Residues of prosulfocarb in soil, drinking and surface water and air are determined by gas chromatography with mass selective detection.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed. Analytical methods for the determination of residues in body fluids and tissues are not required.

2. Mammalian toxicology

Prosulfocarb was discussed by the experts in January 2007 (PRAPeR meeting 14, Round 3).

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

Absorption in rats is fairly rapid. Over 80% of the dose is excreted within 48 h, mainly in the urine (68% and 81% following single low and high dose, respectively) but also in the faeces (21% and 13% following single low and high dose, respectively). Potential for accumulation is low. Prosulfocarb is extensively metabolised by oxidation and conjugation, with at least 24 metabolites being detected in urine (mainly hippuric acid and benzylsulphonic acid).

2.2. Acute toxicity

Prosulfocarb has a moderate acute oral toxicity (rat LD_{50} 1820 mg/kg bw), and a low toxicity via the dermal and inhalation routes (rat dermal LD_{50} >2000 mg/kg bw, rat inhalative LC_{50} >4.72 mg/L). Clinical signs of cholinergic effects are noted in rats at a dose level of 1000 mg/kg bw and above. Slight skin and eye irritation is observed in rabbits, but no classification is required. Prosulfocarb is a skin sensitizer according to the Local Lymph Node Assay. Based on these results, the proposed classification is **Xn R22 'Harmful if swallowed', Xi R43 'May cause sensitisation by skin contact'.**

2.3. Short term toxicity

The short-term oral toxicity of prosulfocarb was investigated in rats and dogs (90-day studies). In both species, the main target organs were the liver and the kidney.
In the rat 90-day study, the agreed NOAEL is 1 – 2 mg/kg bw/day (males – females), based on reduced body weight gain (-15% in males, -16% in females compared to controls) noted at a dose level of 9-10 mg/kg bw/day (males-females). Histopathological changes in the liver and kidneys were observed at higher dose levels.
In the dog 90-day study, the agreed NOAEL is 30 mg/kg bw/day, based on increased liver/kidney weights, changes in biochemical parameters indicating liver and renal dysfunction and histopathological changes in the liver (females) and bone marrow (both sexes) noted at a dose level of 80 mg/kg bw/day. Clinical signs indicating general toxicity, reduced body growth, changes indicating haemolytic anaemia (with increased haemosiderin pigmentation in the spleen, increased reticulocyte levels and regenerative hyperplasia of the bone marrow erythroid tissue) and histopathological

changes in the liver (both sexes), kidneys (both sexes) and spleen (males) were noted at higher dose levels.

2.4. GENOTOXICITY

The potential genotoxicity of prosulfocarb has been investigated in an appropriate battery of tests *in vitro* and *in vivo.* Tests for gene mutations (Ames test, mouse lymphoma assay), chromosomal aberrations (cytogenetic assay in human lymphocytes) and DNA effects (unscheduled DNA synthesis) were conducted *in vitro*. A test for chromosomal aberration (bone marrow micronucleus in the mouse) was also conducted *in vivo*. All tests were negative except for a weak positive response in the presence of an S-9 activation system noted in a mouse lymphoma multiple endpoint test (forward mutation assay) when tested at toxic doses.

A new mouse lymphoma test (Clay P, 2005) has been discussed by the experts, showing negative results and confirming the conclusion that prosulfocarb does not pose an *in vivo* mutagenic or genotoxic concern to humans.

2.5. LONG TERM TOXICITY

The long term toxicity of prosulfocarb has been studied in rats and mice. The studies were considered acceptable by the RMS, but of restricted quality. In the rat study, the mortality rate was too high in every dose group at study termination (>50%). In the mouse study, the selected level of high dose was too low.

The 2-year rat study was considered acceptable by the experts since the survival in dosed animals was higher than in control animals, and there was no evidence of any compound related carcinogenic effect. An increased incidence of benign pheochromocytoma in the adrenal glands of male rats, within the historical control range for the conducting laboratory, was concluded to be not substance-related. The agreed NOAEL is 0.5 mg/kg bw/day, based on reduced body weight gain in females noted at a dose level of 2.3 mg/kg bw/day. Reduced body weight was noted in both sexes at higher dose levels.

In the 18-month mouse study, only minor effects on body weight were observed at the highest dose level tested (269 – 350 mg/kg bw/d). The increased incidence of lung tumours in females was considered by the experts as not substance-related after comparison with additional historical control data. As a conclusion, prosulfocarb is not considered oncogenic in the rat or the mouse.

2.6. REPRODUCTIVE TOXICITY

Reproductive toxicity of prosulfocarb was investigated in a two-generation study with rats. Developmental toxicity was investigated in rats and rabbits, the rabbit study was considered acceptable but of restricted quality due to high mortality in the highest dose group.

In the rat two-generation study, no effect on mating performance or fertility was noted. The agreed **parental NOAEL** is 0.5 mg/kg bw/day for males, based on kidney findings (increased weight and distal convoluted tubule hyperplasia with fibrosis), and reduced body weight growth noted at a dose level of 5 mg/kg bw/day. Reduced body weight gain (both sexes) and histopathological changes in the kidneys (both sexes) were observed at higher dose levels. The agreed **NOAEL for the offspring** is 5 mg/kg bw/day, based on decreased pup weights noted at a dose level of 50 mg/kg bw/day. The agreed **NOAEL for the reproductive parameters** is >50 mg/kg bw/day.

In the rat developmental study, the agreed **maternal NOAEL** is 10 mg/kg bw/day based on clinical signs, reduced body weight gain and elevated liver and kidney weights observed at a dose level of 50 mg/kg bw/day. The foetal findings at maternally toxic doses included a slight increase (not statistically significant) in the number of resorptions, no increases in the occurrence of external or soft tissues anomalies, and indications of delayed skeletal development (but within the historical control incidence). The proposed **developmental NOAEL** is 50 mg/kg bw/day based on reduced pup weights (more than 10%) noted at a dose level of 250 mg/kg bw/day.

The rabbit developmental study is considered acceptable but of restricted quality due to high mortality (animals killed due to abortions) in the high dose group. The agreed **maternal NOAEL** is 50 mg/kg bw/day, based on abortions and reduced body weight noted at a dose level of 250 mg/kg bw/day. The increase in abortions is concluded to be a secondary effect of the maternal toxicity.

Foetal data reveal one incidence of microphtalmia (1/49 = 2%) which is higher than the historical control incidence (0 – 1.2%). Due to the severe maternal toxicity at this dose level, it is impossible to determine if this uncommon effect is specific or incidental to treatment. At the experts' meeting, it was agreed that there was no convincing evidence for classification, and that adequate margins of safety were available for the proposed reference values (see 2.10). The agreed **developmental NOAEL** is 50 mg/kg bw/day.

2.7. NEUROTOXICITY

Prosulfocarb did not produce acute delayed neurotoxicity in hens. A NOAEL could not be determined because clinical signs as depression, diarrhoea and soft-shelled eggs were also noted at the low dose (970 mg/kg bw).

In an acute neurotoxicity study with Wistar rats, prosulfocarb did not inhibit cholinesterase (plasma, brain and erythrocyte) or cause any neurotoxicity. General toxicity was observed at 850 mg/kg bw as lower body weight, lower motor activity on day 1 and one death. Based on this study, the NOAEL for acute cholinergic effects is >850 mg/kg bw.

In a 14-day oral toxicity study in the Sprague-Dawley rat, the NOAEL was set at 40 mg/kg bw/day based on inhibition of erythrocyte cholinesterase activity (up to 21%) and clinical signs (salivation, urinary incontinence, and hunched posture). Clinical signs of salivation noted at lower dose levels were in the absence of other clinical signs not considered as an adverse effect.

The results of a new 90-day neurotoxicity study with Wistar rats (Rattray, 2005) were submitted in an addendum to the experts. The NOAEL was determined at 40 mg/kg bw/day based on reduced bodyweight (11%) noted in males at 200 mg/kg bw/day. The values for the brain cholinesterase inhibition at 200 mg/kg bw/day (15% in males) were discussed by the experts and not considered as consistent signs of neurotoxicity (all individual values were within the range of the control values). Finally, the agreed NOAEL for neurotoxicity after repeated exposure is 40 mg/kg bw/day, based on the 14-day rat study.

2.8. FURTHER STUDIES

Mechanistic studies: The effects of prosulfocarb on rat brain and human recombinant acetyl cholinesterase activity were studied in vitro. At the maximum concentration tested (0.1 mM), prosulfocarb did not inhibit rat brain acetyl cholinesterase, but inhibited the human recombinant enzyme activity of 30-38%. Relative potency of human and rat acetylcholinesterase could not be established.

Impurities: Information on the new specification was available in the addendum to Volume 4, Annex C (December 2006). The minimum purity increased, the level of some impurities decreased and a new impurity was identified. Based on the information available (Ames test negative, chromosome aberration test in vitro with human lymphocytes negative, acute oral study showing low toxicity), it is not expected that the new impurity would change the toxicological profile of the active ingredient taking also into account the low amount (0.5%). The experts concluded that the new source is equivalent to the old one.

Palatability study and pair feeding study:

The design of the palatability study was considered inadequate to determine the true reason for the avoidance of the treated diet. The paired feeding study in the rat was considered of restricted quality due to the small number of animals used (5/group). In addition, as no effects on bodyweight were observed in this study, the effect on bodyweight as a result of reduced palatability of prosulfocarb is considered inconclusive.

The notifier considers that these studies, together with evidence from the rat toxicology studies, form a weight of evidence for an effect of reduced palatability. This was discussed by the experts who concluded that the reduction of body weight in rats at low doses in several feeding studies is adverse since it is statistically significant, dose-related and above 10%. They didn't agree that this effect is caused solely by a reduced palatability of a diet containing prosulfocarb.

2.9. MEDICAL DATA

No adverse reactions occurring with prosulfocarb in research, development or formulation have been reported. There have been no known poisoning incidents and therefore no epidemiological studies have been considered necessary.

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

The **agreed ADI** is 0.005 mg/kg bw/day, based on the 2-year rat study, with the use of a safety factor of 100.

The **agreed AOEL** is 0.007 mg/kg bw/day, based on the 90-day rat study, with the use of a safety factor of 100 and adjustment for gastro-intestinal absorption of 72%.

Initially, the proposed ARfD was 0.01 mg/kg bw, based on the 90-day rat study, with the use of a safety factor of 100. In the experts' meeting, the **agreed ARfD** was 0.1 mg/kg bw based on the developmental toxicity study in the rat, with the use of a safety factor of 100. The main argument for this choice is that the maternal NOAEL is based on persistent body weight changes already at day 1 of treatment and persistent thereafter.

2.11. DERMAL ABSORPTION

The dermal absorption of prosulfocarb from an 80% (w/w) EC formulation ("Boxer") and 1/40 aqueous dilution has been assessed in three studies (in vivo absorption in rat, in vitro absorption in rat and in vitro absorption in human). The experts agreed with the revised calculations (Addendum to B.6, December 2006) taking into account the amount retained in the skin samples, resulting in dermal absorption values of 0.2% for the concentrate and 3.2% for the spray dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Boxer is an emulsifiable concentrate (EC) containing 800 g of prosulfocarb/L. It is used as a pre-emergent herbicide in small grain crops and potatoes, applied once a year.

Operator exposure

According to the intended uses submitted by the applicant, the maximum applied dose is 4 kg a.s./ha, and the spray volume ranges from 200 to 400 L of water/ha. The supported use is of tractor mounted equipment (hydraulic boom sprayer).

The estimated operator exposure for Boxer is above the AOEL, even with the use of PPE, according to both models (UK POEM model and German model).

Estimated exposure presented as % of AOEL (0.007 mg/kg bw/day), according to calculations with the German and UK POEM model. The used body weight of operator is 60 kg in the UK-POEM model and 70[3] kg in the German model. The assumed dermal absorption is 0.2% for the concentrate and 3.2% for the dilution.

Model	No PPE	PPE[1]	PPE[2]	PPE[3]
German	1170	1093	896	102
UK POEM	7093	6664	1316	-

PPE[1] : gloves during mixing/loading

PPE[2] : gloves during mixing/loading and application

PPE[3] : gloves during mixing/loading and application, coverall and sturdy footwear during application.

An operator exposure field study (Tribolet, 2004) during application of Boxer 800 EC with a tractor mounted hydraulic boom sprayer has been conducted in Germany. This study is considered as valid and appropriate by the experts. The results show that the levels of exposure are below the AOEL, with the use of proper PPE (coverall, gloves during mixing/loading, maintenance work and application): 5.0% of AOEL at the 75th percentile, 2.8% of AOEL using geometric mean values, and 51% of AOEL using maximum values.

[3] The RMS proposed to use 60 kg for the body weight value in the German model, but the experts agreed to use the standard assumption of 70 kg.

The exposure might have been slightly underestimated since no data was included for analysis on exposure to the feet. Assuming a correction factor of 1.03 for no use of boots the calculated total systemic exposure for prosulfocarb using maximum values will be 53% of AOEL (worst case scenario).

Bystander exposure

Predicted systemic exposure for a bystander is 3.7% of the AOEL. The exposure of bystanders outside the treatment areas should not give rise to concern.

Worker exposure

The calculations of exposure to re-entry workers indicate the predicted levels of systemic exposure are below the AOEL (0.3%).

EFSA notes: even if a low transfer coefficient has been used in the calculation, the use of a 500 times higher coefficient (more appropriate for cereals) would still give an exposure estimate below the AOEL for the workers.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of prosulfocarb has been investigated in potatoes, wheat, barley, and peas representing three crop groups (cereals, root vegetables and pulses). The application methods were soil treatment for peas and potatoes and early foliar post emergence application for cereals. Given these early applications, the Total Radioactive Residues (TRR) in edible plant parts were extremely low and mainly associated to endogenous plant materials. Neither prosulfocarb nor any structurally-related metabolites were detected. The metabolic pathway was determined on the basis of the residue pattern found in immature barley and consists of several routes involving hydrolysis, oxidation and dealkilation of the parent compound. Nine compounds including parent were in total identified.

The residue definition for monitoring and risk assessment is per default proposed to consist in prosulfocarb only as metabolism studies indicate that representative uses do not lead to quantifiable levels of any residual compound structurally related to the parent compound in the edible parts of these commodities.

This evidence is further supported by supervised residue trials where prosulfocarb residues were consistently below the Limit Of Quantification (LOQ) of the analysis method (0.01 mg/kg), in cereal grains (wheat, barley and rye) and potatoes. Sixty-seven trials where submitted for cereals and 22 for potatoes, among which a sufficient number where carried out in accordance with the proposed representative uses. Most of these trials were carried out in Northern Europe. For Southern Europe the information submitted does not strictly meet the amount required by the current guidelines, but is considered sufficient to confirm the expectation that no residues above the LOQ are present in wheat grain and potatoes. In straw residues were in the vast majority of cases below the LOQ of 0.01 mg/kg, and amounted 0.02 mg/kg in one trial. The reliability of these results is supported by storage stability studies demonstrating that prosulfocarb residues are stable under deep-freeze storage conditions for at least 18 months.

As no prosulfocarb residues are present in harvested commodities when applied according to the supported representative uses, studies investigating the effect of processing were not performed.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Because of the low to moderate soil persistence of prosulfocarb and its breakdown products (see section 4.1.2), and considering the delay for planting rotational crops, the potential for residues in subsequent crops is considered minimal. Therefore rotational crops studies were not required.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The potential exposure of livestock to residues of prosulfocarb through consumption of wheat grain and straw and/or potatoes is very low (below the trigger value of 0.1 mg/kg diet for the performance of metabolism studies). Therefore the metabolism of prosulfocarb in livestock has not been investigated. A residue definition and MRLs for animal products are not necessary.

3.3. CONSUMER RISK ASSESSMENT

No risk for the consumer resulting from the use of prosulfocarb according to the representative uses in wheat and potatoes is expected.

Chronic exposure

The chronic dietary exposure assessment has been based on the Theorical Maximum Daily Intake (TMDI) calculation model of WHO using the WHO typical European diet for adult consumers, the consumption pattern in UK for population subgroups of infants, toddlers, children and adults, which take into consideration high individual consumption levels as well as the German national diet for 4 to 6 years of age children. Residues in wheat and potatoes were considered to be at the level of proposed MRL. Based on these assumptions, the calculated TMDIs were below 5 % of the ADI in all examined populations of consumers.

Acute exposure

The acute exposure to residues of prosulfocarb in wheat and potatoes has been assessed according to the WHO model for conducting National Estimates of Short Term Intakes (NESTI). Large portion consumption data for adults and toddlers in UK were used. Calculations were carried out considering residues of prosulfocarb in composite samples of wheat grains and potatoes at the LOQ level as well as a variability factor of 7 for potatoes. Under these conditions all calculated NESTI were below the ARfD.

3.4. PROPOSED MRLS

Based on the results of the submitted supervised residue trials the MRL can be set at 0.01* mg/kg in both wheat and potatoes (* indicating that the MRL is set at the LOQ of the analysis method).

4. Environmental fate and behaviour

Prosulfocarb was discussed at the PRAPeR experts' meeting for environmental fate and behaviour (PRAPeR 12) in January 2007.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

In a soil experiment on a silty clay loam (pH 4.8 organic carbon (oc) 2.6%) carried out under aerobic conditions in the laboratory (50% maximum water holding capacity (MWHC)) in the dark, the predominant pathway of prosulfocarb degradation was microbially intermediated mineralisation (phenyl ring radiolabel) to carbon dioxide (38 % of applied radioactivity (AR) after 96 days). The formation of residues not extracted by water and acetone was also a significant sink for the applied radiolabel (27 %AR after 96 days). One minor (<10%AR) metabolite prosulfocarb sulfoxide[4] was formed at a maximum level of 6.8%AR after 18 days with its level declining to 2.8%AR after 96 days. However after 28 days the level was still at 5%AR, so in accordance with the guidance document on the assessment of the relevance of metabolites in groundwater[5] there is a need to complete a groundwater exposure assessment for this minor soil metabolite (see section 4.2.2). In the DAR the results of 2 experiments on the route of degradation carried out at 2 different laboratories were described (Stauffer and ADC laboratories). The results from these experiments were discussed in the meeting of experts. The experts concluded that only the results from the Stauffer experiment should be taken forward and relied on for regulatory purposes as there was not a good material balance in the ADC experiment (only the results from this (the Stauffer) experiment are described above). It was also noted that the number of sampling points in the Stauffer experiment (5) was the absolute minimum number necessary, so neither experiment was an optimum study design.

Under anaerobic conditions in soil, the route of degradation identified was essentially the same degradation pathway as described above for aerobic conditions.

In a laboratory soil photolysis study (phenyl ring label), the rate of degradation on light exposed air dried soil (actual soil moisture content not reported) was faster than in dark controls. No metabolites accounted for > 5%AR at any sampling point. Two metabolites were resolved by chromatography, one was identified as benzyl alcohol which accounted for 4.8%AR at 5.8 days (study end).

[4] 1-(benzylsulfinyl)-N,N-dipropylmethanamide
[5] SANCO/221/2000-rev.10-final 25 February 2003.

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

The rate of degradation of prosulfocarb was investigated under aerobic conditions at 20-22°C and a range of moisture contents in six soils (pH 4.8-7.5, oc 0.7–3.1%, texture loamy sand – silty clay loam). On the basis of the six available study results the single first order DT_{50} were 38.4 days (22°C at 50% MWHC, DT_{90} 128 days, see addendum, value from the Stauffer route experiment as agreed by the meeting of experts), 11 & 22 days (21.5°C, at 40% MWHC, DT_{90} 35 & 74 days) and 6.3-9.3 days (20°C and field capacity (pF2), DT_{90} 21 – 31 days). After normalisation to FOCUS reference conditions (20°C and field capacity (-10kPa or pF2)) this range of single first order DT_{50} is 6.3-40.3 days (geometric mean 11.9 days). Prosulfocarb is considered to exhibit low to moderate persistence.
The meeting of experts identified that there was no laboratory route / rate of degradation studies available that would allow an appropriate estimate to be made of the kinetic formation fraction of prosulfocarb sulfoxide from prosulfocarb. The reliable 'Stauffer' study design had too few sampling points to enable this kinetic analysis to be carried out. If in the future, for other uses of prosulfocarb, this value was necessary to provide a less conservative modelled leaching assessment for prosulfocarb sulfoxide, then further experimental data would be required. However for the applied for intended uses, the use of a conservative kinetic formation fraction of 100% did not identify a concern for groundwater exposure (see 4.2.2) so the EU level assessment can be satisfactorily completed without any further experimental data.

Under anaerobic soil conditions in the laboratory the single first order DT_{50} of prosulfocarb was roughly estimated to be 96 days (temperature not reported expected to be 22°C as required by the EPA guideline that was followed, only 4 sampling points available after the onset of anaerobic conditions).

The rate of degradation of the minor soil degradation product prosulfocarb sulfoxide was investigated using this degradation product as test substance under aerobic conditions in 3 soils at 20°C and field capacity (pF2) soil moisture (pH 4.8-7.7, oc 1.04–3.02%, texture sandy clay loam – silty clay loam). The estimated single first-order DT_{50} values were 1.6-3.9 days (DT_{90} 5.2-13 d) (see addendum to the DAR). Prosulfocarb sulfoxide is considered to exhibit low persistence.

Field dissipation studies where prosulfocarb was dosed at 4kg / ha in the autumn were provided from 4 field trial sites in Germany. Single first order DT_{50} were calculated to be 6.5-13 days (DT_{90} 22-48 days)

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

The adsorption / desorption of prosulfocarb was investigated in three soils. Calculated adsorption K_foc values varied from 1367 to 2339 mL/g, indicating that prosulfocarb exhibits low to slight mobility in soil (1/n 0.89 – 1.02). Following FOCUS guidance, as adsorption of prosulfocarb active substance had only been investigated in 3 soil (1 less than should have been provided) the experts from the member states agreed that the lowest adsorption K_foc value (1372 mL/g, 1/n 1.02) was the appropriate value to use in FOCUS modelling. The adsorption / desorption properties of the minor soil metabolite prosulfocarb sulfoxide was studied in three soils. Adsorption K_foc values were in the range of 50 – 68 mL/g indicating that prosulfocarb sulfoxide exhibits high mobility in soil (arithmetic mean 57 mL/g, 1/n 0.9-0.91, arithmetic mean 1/n 0.91, see addendum to the DAR). There was no indication that adsorption of either prosulfocarb or prosulfocarb sulfoxide was pH dependant based on the available information.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In laboratory sterile aqueous hydrolysis experiments at pH 5-9 prosulfocarb was stable at environmentally relevant temperatures. In a laboratory sterile aqueous photolysis experiment prosulfocarb was stable.

A ready biodegradability test (modified OECD 301B) indicated that prosulfocarb is considered ‘not readily biodegradeable’ following the criteria defined for the test.

The water-sediment study (2 systems studied at 20°C in the laboratory) demonstrated prosulfocarb dissipated quite rapidly from water by partitioning to sediment (double first order in parallel kinetic DT_{50} 0.6-1.5 days, DT_{90} 14-51 days) where it subsequently degraded slowly. In the total system, single first order DT_{50} were 139-331 days (with the longer DT_{50} being associated with the system with the higher oc sediment). No metabolites were identified and none accounted for >1% AR. The terminal metabolite, CO_2, was the most significant degradation product accounting for 15-25 % AR at 70-107 days). Residues not extracted from sediment by acetonitrile and methanol/water were also a sink for radioactivity representing 7.3-23 % AR at study end (107 days).

FOCUS surface water modelling was evaluated up to step 3 in the DAR and the peer review agreed the PEC at step 3 presented in the DAR were appropriate for use in risk assessment. The aquatic risk assessment requires risk mitigation to refine the levels of exposure calculated at step 3, so FOCUS surface water modelling at step 4 was evaluated in the addendum and discussed by the meeting of experts. The experts agreed that these step 4 calculations were appropriate for the drainage scenarios where the effect of no spray buffer zones of 5 and 10 m using the drift calculator in SWASH was used for calculations following FOCUS recommendations. For the runoff scenarios in addition to spray drift reduction, the effect of vegetative buffer strips in reducing runoff inputs was also included in the calculations. Pesticide masses and runoff volumes calculated by PRZM were reduced by 50% and 90% (also in the 20% of upstream catchment assumed to be treated when streams are defined for a scenario) before TOXSWA was run. The experts agreed with the mechanics of how the calculations had been carried out but considered there was uncertainty over the quantitative values ascribed to the effectiveness of vegetative buffer strips. These uncertainties and the effectiveness of vegetative buffer strips are discussed in detail in the EFSA PPR Panel opinion on the FOCUS landscape and mitigation report[6]. The experts therefore felt it would be useful if for the runoff scenarios calculations were also available where only spray drift inputs were mitigated. After the meeting these simulations were presented by the RMS in the addendum and EFSA is content the calculation procedure followed was correct. As the calculations follows standard agreed guidance, used input values and the application pattern and time window agreed as appropriate by the peer review[7], these PEC values where spray drift only is mitigated are considered as agreed values that are reliable to use in the EU level aquatic risk assessment. They are therefore included in appendix 1.5 of this document as agreed endpoints.

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

Groundwater modelling was available using FOCUS models and scenarios for the applied for intended uses of autumn applications pre or just post emergence to winter cereals and spring applications pre or just post emergence to potatoes. Simulations were carried out using FOCUSPELMO 3.3.2 for prosulfocarb (see DAR) and FOCUSPEARL 2.2.2 for both prosulfocarb and prosulfocarb sulfoxide (see addendum). The peer review concludes that the key compound properties that should be used in FOCUS leaching simulations were: a prosulfocarb normalised geomean soil single first order DT_{50} of 11.9 days, $K_{f}oc$ 1367 mL/g 1/n 1.02; a formation fraction for prosulfocarb sulfoxide from prosulfocarb of 100% (conservative value as no appropriate experimental data are available) and a prosulfocarb sulfoxide geomean soil single first order DT_{50} of 2.5 days and $K_{f}oc$ 56.7mL/g 1/n 0.91. The available FOCUSPELMO modelling used a more conservative input value (DT_{50} 41.4 days, other values as concluded appropriate by the peer review). In these parent prosulfocarb simulations annual average concentrations in leachate leaving the top 1m soil column were estimated to be <0.001 µg/L at all scenarios (significantly less than the parametric drinking water limit of 0.1µg/L)

The available FOCUSPEARL simulations used the key compound properties as concluded appropriate by the peer review with the exception of the parent prosulfocarb DT_{50} where a slightly lower value of 11.1 days was used. This small difference is not of concern and is slightly conservative with respect to the resulting concentrations calculated for prosulfocarb sulfoxide. In these simulations annual average concentrations in leachate leaving the top 1m soil column were estimated to be <0.001µg/L for both prosulfocarb and prosulfocarb sulfoxide at all scenarios (significantly less than the parametric drinking water limit of 0.1µg/L).

The potential for groundwater exposure from the applied for intended uses above the parametric drinking water limit of 0.1 µg/L by parent prosulfocarb and its minor soil metabolite prosulfocarb sulfoxide, is therefore concluded to be low, in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

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[6] Opinion of the Scientific Panel on Plant protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment *The EFSA Journal* (2006) 437, 1-30

[7] Though a slightly less conservative prosulfocarb geomean soil DT50 of 11.9 days would have been justified following FOCUS guidance rather than the slightly longer arithmetic mean value of 15.3 days used.

4.3. Fate and behaviour in air

Under controlled conditions of wind velocity (≥1-2 m/s) temperature (16-20°C) and humidity (relative humidity 42-57%) loss of applied radioactivity (assumed to be due to volatilisation) was 18% from soil and 47% from French bean leaves in 24 hours. This indicates that volatilisation potential particularly from leaves is significant. The vapour pressure of prosulfocarb (0.00079 Pa at 20°C) means that prosulfocarb would be classified under the national scheme of The Netherlands as slightly volatile, indicating some losses due to volatilisation would be expected. Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at 3.9 hours indicating the proportion of applied prosulfocarb that did volatilise would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Prosulfocarb was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 13) in January 2007. A data gap was identified to address the relevance of the new impurity SYN545019. The applicant submitted further information to address the relevance of this impurity in a not peer-reviewed addendum. Based on the assumption of 10 times higher toxicity of the new impurity to all groups of aquatic organisms the increase of toxicity of the new technical would be <5 times indicating equivalence of the technical material. The batches used in the ecotox studies were considered appropriate by the meeting to cover the proposed new technical specification.

5.1. Risk to terrestrial vertebrates

The representative uses evaluated are the uses as a herbicide in winter wheat (cereals early) and potatoes. The acute and short-term toxicity of prosulfocarb to birds is low with LD_{50} values of >2250 mg/kg bw and >1962 mg/kg bw. The acute and short-term TERs in the first tier risk assessment were above the Annex VI trigger of 10 except for large herbivorous birds for the use in cereals where the TER was >9. However the risk was considered as low for large herbivorous birds since the LD_{50} was based on the highest tested concentration and no mortality was observed at this concentration. The first-tier long-term TERs were in the range of 1.8 to 1.1 indicating a potential high long-term risk.

Summary of the risk assessment for birds

Active substance: Prosulfocarb	**1st tier TER**	**Proposed refinements**	**Conclusion of peer review**
Formulation: Boxer Scenario: cereals early			
Acute risk	LHB: >9 IB: >10.4	Not necessary for IB	Low acute risk was concluded also for herbivorous birds since no mortality was observed at the highest tested dose.
Short-term risk	LHB: 11.3 IB: 12.5	Not necessary	Low short-term risk

Active substance: Prosulfocarb	1st tier TER	Proposed refinements	Conclusion of peer review
Long- term/ reproductive risk	LHB: 1.8 IB: 1.1	LHB: Measured residue levels in cereals (whole plant), $\mathbf{f_{twa}}$ IB: **Focal species**: skylark (*Alauda arvensis*), **PD**: 13 % cereal grain, 54 % cereal leaves, 5 % weed seeds, 24 % broadleaved weeds, 3% arthropods (winter diet, relevant for the proposed winter applications) $\mathbf{f_{twa}}$ refinement for the plant material in the diet	LHB: refined TER = 24 IB: refined TER = 13
Formulation: Boxer Scenario: leafy crops (potatoes)			
Acute risk	IB: >10.4	Not necessary	Low acute risk
Short-term risk	IB: 12.5	Not necessary	Low short-term risk
Long-term risk	IB: 1.1	IB: **Focal species**: skylark (*Alauda arvensis*), **PD**: 20 % seeds, 50 % leaves, 30 % invertebrates (spring diet, relevant for the proposed application in spring) $\mathbf{f_{twa}}$ refinement for the plant material in the diet	 Refined TER: 17

LHB: Large herbivorous bird; IB: Insectivorous bird

The experts` meeting agreed to the choice of the focal species and the suggested refinements.

Summary of the risk assessment for mammals:

Active substance: Prosulfocarb	1st tier TER	Proposed refinements	Conclusion of peer review
Formulation: Boxer Scenario: cereals early			
Acute risk	SHM: 2.3	**Focal species**: Wood mouse (*Apodemus sylvaticus*); weight of evidence approach – residue decline is rapid, not possible for wood mice to consume enough in one food bout to reach a lethal dose. Some mitigation of the risk since wood mice are nocturnal and residues would decline until wood mice start to feed. **PD**: 25 % grasses and cereal shoots, 34 % cereal seeds, 14 % weed seeds, 21 % caterpillars, 5 % soil dwelling	The refined acute TER was calculated as 6.4 The meeting agreed that the weight of evidence is sufficient to conclude on a low acute risk to small herbivorous mammals taking into account all arguments (rapid residue decline, nocturnal feeding, low probability that mice take up a enough cereal shoots in one bout to reach a lethal dose, TERs of 22 and 24 are above the trigger on the basis of a mixed diet)

Active substance: Prosulfocarb	1st tier TER	Proposed refinements	Conclusion of peer review
		invertebrates (winter diet, relevant for the proposed use in winter wheat) **Focal species**: Hare (*Lepus europaeus*), acute TER = 11 without risk refinement.	In addition to the generic species (small herbivorous mammal) also a risk assessment for medium herbivorous mammals (hare) was conducted resulting in a first-tier TER of 11.
Long- term/ reproductive risk	SHM = 0.22	**Focal species**: Wood mouse (*Apodemus sylvaticus*); **PD**: 25 % grasses and cereal shoots, 34 % cereal seeds, 14 % weed seeds, 21 % caterpillars, 5 % soil dwelling invertebrates (winter diet, relevant for the proposed use in winter wheat), $\mathbf{f_{twa}}$ **Focal species**: Hare (*Lepus europaeus*), $\mathbf{f_{twa}}$:	SHM: long-term TER = 17 Hare: long-term TER = 14
Formulation: Boxer Scenario: leafy crops (potatoes)			
Acute risk	MHM: 11 SIM: 52	Not necessary	Low acute risk
Long-term risk	MHM: 1.2 SIM: 3.9	Refinement based on $\mathbf{f_{twa}}$ SIM: The substance is applied at a very early growth stage. Not sufficient shelter is available for shrews. Therefore it was considered unlikely that shrews spend all of their time foraging in potato fields.	MHM: long-term TER = 14 The submitted references provide some evidence that shrews do not prefer open habitats such as a potato field at very early growth stages. However it was not possible to quantify the PT. SIM are not an indicator species for the leafy crop scenario hence the risk assessment for SIM is not of relevance.

SHM: Small herbivorous mammal; MHM: Medium herbivorous mammal; SIM: Small insectivorous mammal

The long-term endpoint for mammals of 50 mg/kg bw/d based on the 2-generation rat study was discussed in the meeting. No effects on the number of offspring were observed at this concentration but body weight gain was affected at the dose level of 50 mg/kg bw/d. It was stated by the experts that effects on body weight are ecologically significant effects that would have an influence on survival and reproduction in nature. However the meeting considered the exposure situation in the 2-generation rat study as highly unrealistic in this particular case since prosulfocarb degrades very rapidly (DT_{50} on plant surfaces of 0.6 d) and is applied only once per growing season. Therefore the meeting suggested using the NOEC of 50 mg/kg bw/d in the risk assessment

The risk assessment for the uptake of contaminated drinking water was based on the PECsw values. The resulting TER values were far above the trigger values. A recalculation based on the 5-fold dilution of the sprayed solution resulted in acute TERs of >2.08 and 3.25 for birds and mammals. Exposure of birds and mammals was considered as low. Because the product is applied at very early growth stages it was considered that there would be no significant accumulation of water in leaf axils and that the formation of puddles on bare soil would be unlikely due to the low volume of the sprayed solution (20 – 40 mL/m^2). The experts` meeting agreed that puddle formation is unlikely and concluded that the risk to birds and mammals from uptake of contaminated drinking water is low.

The first-tier risk assessment for secondary poisoning of earthworm-eating birds and mammals indicated a potential high risk. The risk refinement was based on the bioconcentration factor derived from a study with earthworms. The TERs were calculated as >48 for birds and 14 for mammals. The meeting agreed to the proposed refinement and considered the risk to earthworm-eating birds and mammals as low.

No major metabolites were detected in the residue studies presented in the DAR and hence it was concluded by the experts that the risk from plant metabolites to herbivorous birds and mammals is low. However in an addendum to the residue section of the DAR from December 2006, revised March 2007 some metabolites were identified in a barley metabolism study. The most significant were 2C[8], 2B[9], 2D[10] and 2G[11] which were quantified to be in the range of 1.6 – 4.4 mg/kg 7 days after application, which is similar to the prosulfocarb (4.6 mg/kg). The toxophor (carbamate) is not present in the metabolites 2C, 2B and 2D suggesting a lower toxicity compared to the parent. Metabolite 2G is prosulfocarb conjugated with glucose suggesting a similar toxicity to prosulfocarb. Considering the low concentration of the metabolites in terms of absolute concentrations compared to the calculated amount of prosulfocarb immediately after application, it is likely that the risk is covered by the available risk assessment for prosulfocarb.

5.2. RISK TO AQUATIC ORGANISMS

The endpoints observed for aquatic organisms suggest a similar sensitivity of fish and daphnids. The lowest endpoint was observed in a study with green algae *Pseudokirchneriella subcapitata* (E_bC50 = 0.049 mg a.s./L). The acute and long-term TER values based on FOCUS step 2 PECs were below the Annex VI triggers for fish, daphnia, algae and aquatic plants. For *Chironomus riparius* the TERs were above the Annex VI trigger for potatoes in northern Europe and for winter wheat in southern Europe. The trigger was not met for the use of potatoes in southern Europe and winter wheat in northern Europe. No full FOCUS step3 scenario resulted in PECsw values low enough to achieve TERs above the Annex VI triggers for all groups of aquatic organisms.

[8] 6-(2-benzoyloxy-1-hydromethyl-ethoxy)-3,4,5-trihydroxy-tetrahydro-pyran-2-carboxylic acid
[9] 3-phenylmethanesulfinyl-2-(3,4,5-trihydroxy-6-hydroxymethyl-tetrahydro-pyran-2-yloxy)-propionic acid
[10] 3-benzylsulfanyl-2-(3,4,5-trihydroxy-6-hydroxydro-pyran-2-yloxy)propionic acid
[11] glucose conjugate of prosulfocarb.

Based on endpoints from laboratory studies, TERs below the Annex VI triggers were observed with FOCUS step 4 PECsw (10 m no spray buffer zone) in the scenarios D1, D2, D4, D5, D6, R1, R3, R4 (8 out of 9) for the use in winter wheat and in the scenarios R1, R2, R3 (3 out of 6) for the use in potato. Therefore it is concluded that a 10-m no-spray buffer zone is not sufficient as a risk mitigation measure in the majority of geoclimatic conditions represented by the FOCUS scenarios.

A mesocosm study was submitted and summarised in the DAR to address the potential high risk to aquatic organisms. The study was designed to observe the effects of pesticides used in a crop protection program of potatoes. Among other pesticides the microcosms were also exposed to prosulfocarb. The history of the mesocosm was not reported, no principal response curves were provided and identification of phytoplankton taxa was not provided in the study report. The robustness of the test results was questioned during the peer review and the applicant submitted a new mesocosm study focused on effects on zooplankton, phytoplankton and periphyton (see addendum). The experts discussed the endpoints derived from the new mesocosm study. Only statistically significant effects in two consecutive sampling time points were taken into account to derive the NOEC population for zooplankton. For cladocera (*Daphnia longispina*) the NOEC population was determined as 76 µg a.s./L. The lowest NOEC population for zooplankton was 15 µg a.s./L based on effects on the rotifer *Polyarthra remata*. The zooplankton community NOEC was estimated as 76 µg a.s./L. No agreement was reached on the NOEC population for periphytic algae. The algae *Tetraedon trigonum* was affected at all tested concentrations and on day 28 it was not present in the samples from the mesocosms at all treatment rates. However the abundance of this algae species in the mesocosms was generally very low and therefore it was difficult to detect statistically significant differences. Significant long-term effects on other periphyton green algae species were observed at 76 µg a.s./L and concerns were raised by some experts with regard to potential indirect effects on sediment dwelling invertebrates and species feeding on periphyton which were not investigated in the study.

The experts` meeting agreed to the suggested NOEC phytoplankton community of 15 µg a.s./L. The overall conclusion of the meeting was that a NOEAC of 15 µg a.s./L could be derived from the mesocosm study. No conclusion was reached on the safety factor which should be applied to the endpoint. It was acknowledged that the study is of high quality but it was considered by the meeting that one mesocosm with its specific composition of species and environmental conditions can only be representative for some types of aquatic ecosystems but not for all aquatic ecoystems in the vicinity of agricultural landscapes in Europe. Therefore it was suggested to use a safety factor at Member State level according to the representativeness of the mesocosm for their aquatic ecosystems. If Member States apply a safety factor of >3 then the endpoint of 15 µg a.s./L would become the critical endpoint driving the aquatic risk assessment.

5.3. Risk to bees

Acute contact toxicity studies were conducted with technical and formulated prosulfocarb (SF245) showing similar toxicity of the a.s. when formulated (LD_{50} > 80 µg a.s./bee and >79.3 µg a.s./bee) The acute oral toxicity was tested with formulated prosufocarb only (LD_{50} 103 µg a.s./bee). The HQ values were below the Annex VI trigger of 50 indicating a low risk to bees from the representative uses evaluated.

5.4. Risk to other arthropod species

The studies with non-target arthropods were conducted with different formulations. The formulations were considered as similar enough to the lead formulation to use the results in the risk assessment for non-target arthropods. Standard laboratory tests were conducted with formulated prosulfocarb (YF10911) and the non-target arthropods *Aphidius rhopalosiphi* and *Typhlodromus pyri*. The in field HQ values were calculated as 96 and 7.6 and the off-field HQs were 2.6 and 0.21 indicating a potential high risk for non-target arthropods (except off-field for *T. pyri*).
Laboratory tests with formulated prosulfocarb (Boxer 80 EW) were also conducted with soil dwelling arthropods *Pterostichus melanarius* (carabid beetle) and the lycosid spiders *Pardosa sp*. and *Alopecosa sp*. No effects were observed on *Pterostichus melanarius* while 57% mortality was observed in the lycosid spiders when exposed to residues 1.5 h after a treatment equivalent to 4 kg a.s./ha. An extended laboratory study was conducted with *Aleochara bilineata* indicating that the LR_{50} is >4 kg a.s./ha. A semi-field test was conducted to address the potential high risk to lycosid spiders. No mortality was observed in the semi-field test following treatment with 4 kg a.s./ha. The RMS considered the risk to non-target arthropods as sufficiently addressed based on the assumption that predominantly soil dwelling arthropods would be exposed by the representative uses. However during the peer review this was questioned since application is suggested up to BBCH 11 and 21 for potatoes and cereals, respectively and hence the presence of leaf dwelling arthropods cannot be excluded. Extended laboratory studies were conducted with the formulations A-8646-C and 80 EC and *T. pyri*, *A. rhopalosiphi*, *Chrysoperla carnea*. In all studies the mortality was >50% at an application rate of 4 kg a.s./ha indicating a high in-field risk. The off-field risk to leaf dwelling arthropods was assessed as low since the expected exposure at 1m distance from the treated field (110.8 g a.s./ha) is lower than the LR_{50}s (*T. pyri*: 970 g a.s./ha, *A. rhopalosiphi*: 3081 g a.s./ha, *C. carnea*: 3627 g a.s./ha). Taking into account the very rapid decline of residues on plant surfaces (DT_{50} of 0.6 d on cereals) the experts´ meeting agreed that recolonisation of the in-field area is likely to occur. Overall it was concluded that the risk to non-target arthropods is low for the representative uses evaluated.

5.5. Risk to earthworms

The acute toxicity to earthworms was tested with technical prosulfocarb and one formulation (80 EW). A 28-d LC_{50} could also be estimated for the 80 EC formulation based on results from a study on bioaccumulation in earthworms. Chronic testing was considered not necessary because of the short half life of prosulfocarb in soil (field DT_{90} < 100d) and because only one application is proposed for the representative uses. The corrected LC_{50} for EW formulated prosulfocarb was in the range of 54.5 – 545 mg a.s./kg soil (no calculation possible since only these two concentrations were tested). The TERs were calculated as 13 (for technical prosulfocarb) and 10.2 – 102 (for the formulation). Overall it was concluded that the risk to earthworms is low for the representative uses evaluated.

5.6. Risk to other soil non-target macro-organisms

No studies required since the field DT_{90} of prosulfocarb in soil is <100 d and the product is applied only once a year.

5.7. Risk to soil non-target micro-organisms

No effects of >25 % on soil respiration and nitrification were observed in tests with technical prosulfocarb up to concentration of 53.3 mg a.s./kg soil dw (equivalent to an application rate of 40 kg a.s./ha) indicating a low risk to soil non-target micro-organisms for the representative uses evaluated.

5.8. Risk to other non-target-organisms (flora and fauna)

Herbicidal effects of the formulation Boxer on vegetative vigour and emergence were investigated in tests with 7 and 8 dicotyl plant species and with 4 monocotyl plant species. The lowest ER_{50} values were observed for tomato (*Lycopersicon esculentum*) ER_{50} (effect on biomass in seedling emergence test) = 0.335 kg a.s./ha and for oat (*Avena sativa*) ER_{50} (effect on biomass in vegetative vigour test) = 3.14 kg a.s./ha. The TERs were 3 and 28 for pre and post-emergence treatment based on PECs from spray drift at 1m distance. In the addendum the RMS suggested to take interception into account for the PEC calculation. The expert meeting did not agree to this approach since it is not in accordance with the guidance on terrestrial ecotoxicology and the vegetation in the field margins may differ considerably depending on the environmental conditions and agricultural practices in the different Member States. The applicant suggested lowering of the trigger of 5. This was not agreed by the meeting since only crop species were tested and the representativeness of these species with regard to the sensitivity of non-target plants in the off-field area is unclear. Risk mitigation measures such as an in-field no-spray buffer zone of 5 m was suggested by the meeting.

5.9. Risk to biological methods of sewage treatment

Technical prosulfocarb did not inhibit the growth of *Pseudomonas putida* at a concentration of 11.7 mg a.s./L. It is not expected that the concentrations of prosulfocarb in biological sewage treatment plants would reach a concentration of more than 11.7 mg a.s./L if the product is applied according to the GAP and therefore the risk to biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definition for risk assessment: prosulfocarb

Definition for monitoring: prosulfocarb

Water

<u>Ground water</u>

Definition for exposure assessment: prosulfocarb, prosulfocarb sulfoxide[12]

Definition for monitoring: prosulfocarb

<u>Surface water</u>

Definition for risk assessment: water: prosulfocarb
sediment: prosulfocarb

Definition for monitoring: prosulfocarb

<u>Air</u>

Definition for risk assessment: prosulfocarb

Definition for monitoring: prosulfocarb

<u>Food of plant origin</u>

Definition for risk assessment: prosulfocarb

Definition for monitoring: prosulfocarb

<u>Food of animal origin</u>

Definition for risk assessment: not necessary as the animal exposure is extremely low

Definition for monitoring: not necessary as the animal exposure is extremely low

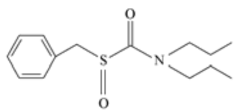
[12] 1-(benzylsulfinyl)-N,N-dipropylmethanamide

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
prosulfocarb	Low to moderate persistence ($DT_{50\ lab}$ = 6.3-40.3 d, 20°C, pF2 (normalised values)) DT_{50} field 6.5-13 days (German trial sites).	The risk to earthworms and soil micro-organisms was assessed as low.

Groundwater

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
prosulfocarb	Low to slight mobility ($K_{f}oc$ = 1367-2339 mL/g)	No	Yes	Yes	Very toxic to aquatic organisms particularly algae
prosulfocarb sulfoxide 	High mobility ($K_{f}oc$ = 50-68 mL/g)	No	No information available, no data required	No information available, no data required	No information available, no data required

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
prosulfocarb	See 5.2.

Air

Compound (name and/or code)	Toxicology
prosulfocarb	low acute toxicity by inhalation in rats (LD_{50} > 4.72 mg/L)

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

- A data gap was proposed for the applicant to present quality control data from further production campaigns to allow a more sustainable assessment of the quality of technical prosulfocarb.
- A data gap was proposed for the applicant to present information on the use of chloroform in the analytical method for the active ingredient determination in the formulations
- The ecotoxicological relevance of the new impurity in the new technical specification needs to be addressed (data gap identified in the meeting of experts (PRAPeR 13); relevant for all representative uses evaluated; an assessment was submitted by the applicant and included in a not peer-reviewed addendum to Vol. 4 in May 2007; refer to point 5).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a pre-emergence or early post-emergence herbicide as proposed by the notifier which comprise foliar spraying to control grass weeds (*Apera spica-venti, Poa annua, Poa trivialis, Alopecurus myosuroides, Lolium multiflorum*) and broad-leaved weeds (*Galium aparine, Stellaria media, Lamium purpureum, Fumaria officinalis, Solanum nigrum, Atriplex patula, Chenopodium album, Thlaspi arvense, Veronica spp., Capsella bursa-pastoris, Myosotis arvensis, Anthemis spp., Viola arvensis*) in winter wheat and potatoes (at a maximum rate of 4 kg as/ha).
The representative formulated products for the evaluation was "Boxer", an emulsifiable concentrate (EC) containing 800 g/L prosulfocarb.

Adequate methods are available to monitor prosulfocarb residues in food and feed of plant origin (winter wheat and potatoes).
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible.

Prosulfocarb has a moderate acute oral toxicity (**Xn, R22 Harmful if swallowed**), and is a skin sensitiser (**R43 May cause sensitisation by skin contact**). In short-term toxicity studies, liver and kidney were the target organs in rats and dogs. In addition, haemolytic anaemia was observed in dogs, with associated histopathological findings in the bone marrow and spleen. The relevant short term NOAEL is 1 – 2 mg/kg bw/d based on the 13-week rat study. Available data do not support evidence of genotoxic or carcinogenic effects. In long-term toxicity studies, mainly reduced food consumption and decreased body weights were noted. The relevant long term NOAEL is 0.5 mg/kg bw/d. No toxic effect on the reproductive parameters was demonstrated. In the developmental studies, there were some indications of delayed skeletal development in the rat, increase in abortions and increased

incidence of microphtalmia in the rabbit, at maternally toxic doses. It was concluded that there was no convincing evidence for classification and adequate margins of safety were shown for the reference values. No neurotoxic effect was observed up to 850 mg/kg bw in an acute rat study. Based on cholinergic signs in a 14-day rat study, the NOAEL for neurotoxicity after repeated exposure is 40 mg/kg bw/d.
The Acceptable Daily Intake (ADI) is 0.005 mg/kg bw/d, the Acceptable Operator Exposure (AOEL) is 0.007 mg/kg bw/d and the Acute Reference Dose (ARfD) is 0.1 mg/kg bw. The agreed dermal absorption values were 0.2% for the concentrate and 3.2% for the spray dilution. The level of operator exposure is below the AOEL with the use of personal protective equipment according to a field study.

Applied according to the representative uses in wheat and potatoes, prosulfocarb is extensively metabolised and in mature commodities no metabolite structurally related to the compound was identified. The ultimate degradation products are expected to be incorporated in the endogenous metabolism of the plant. The residue definition for monitoring and risk assessment is proposed to consist per default in prosulfocarb. MRLs for wheat and potatoes can be set at the Limit of Quantification. No residues are expected in rotational crops, processed plant commodities and in animal commodities. No risk for the consumer resulting from the use of prosulfocarb according to the representative uses is expected.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level. For the applied for intended uses, the potential for groundwater exposure by prosulfocarb or its soil metabolite prosulfocarb sulfoxide above the parametric drinking water limit of 0.1 µg/L, is low.

A potential high long-term risk to birds and a potential high acute and long-term risk to mammals were indicated in the first-tier risk assessment. The suggested risk refinements based on measured residues, focal species and proportion of different food items in the diet (PD) were agreed in the meeting of experts. The risk from uptake of contaminated drinking water was considered to be low since exposure of birds and mammals from contaminated drinking water was expected to be low. The refined risk assessment based on measured residues in earthworms resulted in TERs above the trigger of 5 for earthworm-eating birds and mammals. No full FOCUS step 3 scenario resulted in PECsw values low enough to achieve TERs above the Annex VI triggers for all groups of aquatic organisms. TERs below the Annex VI triggers were observed with FOCUS step 4 PECsw (10 m no spray buffer zone) in the scenarios D1, D2, D4, D5, D6, R1, R3, R4 (8 out of 9) for the use in winter wheat and in the scenarios R1, R2, R3 (3 out of 6) for the use in potato. Therefore it is concluded that a 10 m no-spray buffer zone is not sufficient as a risk mitigation measure in the majority of geoclimatic conditions represented by the FOCUS scenarios. Two mesocosm studies were submitted to refine the risk to aquatic organisms. The robustness of the results of the first study was questioned during the peer-review process. The experts in the PRAPeR meeting agreed that a NOEAEC of 15 µg prosulfocarb/L could be derived from the new mesocosm study. No agreement was reached which safety factor should be applied. If a safety factor of >3 is used then the NOEAEC of 15 µg prosulfocarb/L would become the endpoint driving the aquatic risk assessment. The HQ values indicated a potential high in-field and off-field risk to non-target arthropods. Extended laboratory studies resulted in LR_{50}s below the suggested application rate of 4 kg prosulfocarb/ha but the LR_{50}s were higher than the expected exposure at 1m distance from the treated field. Therefore it was concluded by the experts` meeting that recolonisation of the in-field area is likely to occur and the overall risk to non-target arthropods is sufficiently addressed. The TER values for non-target plants were calculated as 3 and 28 for pre- and post-emergence treatment. Risk mitigation measures such as an in-field no spray buffer zone of 5m was recommended. The risk to bees, earthworms, soil non-target micro-organisms and biological methods of sewage treatment was assessed as low for the representative uses evaluated.

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

- The operators have to use proper PPE (coverall, gloves during mixing/loading, maintenance work and application) in order to have an exposure below the AOEL (refer to point 2.12).
- Risk mitigation measures such as a no spray buffer zone of 10 m is required to achieve PECsw values low enough to result in scenarios (D3 for the use in winter wheat and D3, D4 and D6 for the use in potato) for which the risk to aquatic organisms is considered to be low.
- Risk mitigation measures such as an in-field no spray buffer zone of 5m is required to mitigate the risk to non-target plants.

Critical areas of concern

- A 10-m no-spray buffer zone is not sufficient as a risk mitigation measure in the majority of geoclimatic conditions represented by the FOCUS scenarios. TERs below the Annex VI triggers were observed with FOCUS step 4 PECsw (10 m no spray buffer zone) in the scenarios D1, D2, D4, D5, D6, R1, R3, R4 (8 out of 9) for the use in winter wheat and in the scenarios R1, R2, R3 (3 out of 6) for the use in potato.

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

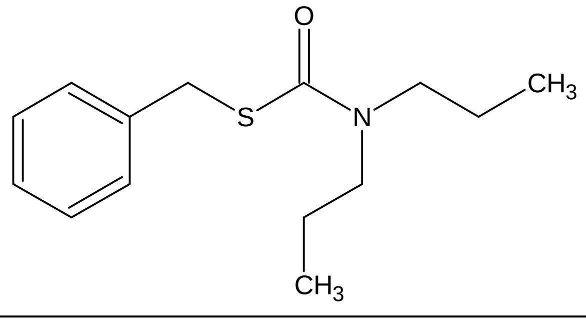
(Abbreviations used in this list are explained in appendix 2)

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

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

Rapporteur Member State	Sweden
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*S*-benzyl dipropyl(thiocarbamate)
Chemical name (CA) ‡	*S*-(phenylmethyl)-dipropylcarbamothioate
CIPAC No ‡	539
CAS No ‡	52888-80-9
EC No (EINECS or ELINCS) ‡	401-730-6
FAO Specification (including year of publication) ‡	No FAO specification available
Minimum purity of the active substance as manufactured ‡	970 Open point (confirmatory data needed)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Prosulfocarb as manufactured contains no relevant impurities
Molecular formula ‡	$C_{14}H_{21}NOS$
Molecular mass ‡	251.4
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	< -20 °C ± 0.5 °C, purity 99.6%
Boiling point (state purity) ‡	341 °C ± 0.5 °C, purity 99.6%
Temperature of decomposition (state purity)	Not applicable, since no decomposition occurs at the melting point or the boiling point
Appearance (state purity) ‡	Physical state and colour: Very pale straw-coloured transparent liquid with evidence of very fine particulate matter present at 20.5 ± 0.5 °C, purity 96.8% and 99.6% Odour: Strong, sulphurous, with a smoky resemblance at 23.0 ± 0.5°C, purity 99.6% Strong, with a slight amine resemblance, purity 96.8%
Vapour pressure (state temperature, state purity) ‡	7.9 x 10^{-4} Pa at 20 °C (purity: 99.6 %)
Henry's law constant ‡	1.52 x 10^{-2} Pa m^3 mol^{-1} at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	pH 6.1 ± 0.4: 13.0 ± 0.3 mg/L at 20 ± 0.5 °C (purity: 99.6 %) The solubility in water is not considered to be pH dependant
Solubility in organic solvents ‡ (state temperature, state purity)	>250 g/L at 20 ± 0.5 °C in all the tested solvents (acetone, 1,2-dichloroethane, ethyl acetate, n-heptane, methanol, n-octanol, xylene) (purity: 96.8%)
Surface tension ‡ (state concentration and temperature, state purity)	60.9 mN/m at 20.0 ± 0.5 °C (90% saturated solution)
Partition co-efficient ‡ (state temperature, pH and purity)	4.48 at pH 7.5 and 30 °C The partition coefficient is not considered to be pH dependant
Dissociation constant (state purity) ‡	Prosulfocarb does not have any mode of dissociation measurable within the pH ranges of the test methods (theoretical consideration)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	No absorbance maxima > 210 nm ε <10 at ≥ 295 nm
Flammability ‡	Flammability: Not required since prosulfocarb is a liquid Auto-ignition temperature: 358 ± 5 °C Flash point: 151 ± 2 °C (1013 mbar)
Explosive properties ‡	Not explosive (theoretical consideration)
Oxidising properties ‡ (state purity)	Not oxidising (theoretical consideration)

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

Summary of representative uses evaluated *

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Winter wheat	Northern and Southern Europe	Boxer	F	Weeds	EC	800 g/L	Boom sprayer	Pre em. up to BBCH 21	1	N/A	1-2	200-400	4.0	N/A	
Potatoes	Northern and Southern Europe	Boxer	F	Weeds	EC	800 g/L	Boom sprayer	Pre em. up to BBCH 11	1	N/A	1-2	200-400	4.0	N/A	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval N/A: not applicable

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

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	GC-FID
Impurities in technical as (analytical technique)	GC-FID
Plant protection product (analytical technique)	GC-FID Open point (to replace chloroform)

Analytical methods for residues (Annex IIA, point 4.2)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Multi method DFG Method-S19 GC-MSD 0.01 mg/kg (strawberry, potato, wheat and sunflower)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	GC-MSD 0.02 mg/kg
Water (analytical technique and LOQ)	GC-MSD 0.1 µg/L (drinking , ground, river and sea water)
Air (analytical technique and LOQ)	GC-MSD 0.00015 mg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not required since prosulfocarb is not classified as toxic or highly toxic

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

	RMS/peer review proposal
Active substance	None

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Fairly rapid but limited to approximately 72% following a single low dose in rats (based on excretion in urine, cage wash, tissues and carcasses).
Distribution ‡	Widely distributed (highest levels found in kidneys, liver and blood). Elevated levels in fat of high dose female rats.
Potential for accumulation ‡	Low potential for accumulation.
Rate and extent of excretion ‡	Fairly rapid (>80% of low dose excreted within 48 hrs). Approximately 68% and 21% of the single low dose was excreted over 5 days in urine and faeces, respectively.
Metabolism in animals ‡	Extensively metabolised. Two major pathways: 1. Oxidation of the α-benzyl carbon and glycine conjugation of the intermediates to form hippuric acid. 2. Oxidation of the sulphur with further oxidation of intermediates to form benzylsulphonic acid.
Toxicologically relevant compounds ‡ (animals, plants and environment)	Parent compound.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1820 mg/kg bw (males) 1958 mg/kg bw (females)	**R22**
Rat LD_{50} dermal ‡	>2000 mg/kg bw for both sexes combined	
Rat LC_{50} inhalation ‡	>4.72 mg/L (maximum attainable concentration, 4 hrs, whole body).	
Skin irritation ‡	Not irritating.	
Eye irritation ‡	Not irritating.	
Skin sensitisation ‡	Sensitising (Local Lymph Node Assay)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Reduced bw and bw gain (rat, dog) and reduced food consumption (rat). Target organs at higher doses: liver (rat, dog), kidneys (rat, dog) and bone marrow (dog). Cholinergic effects (rat). Haematolytic anaemia associated with histopathological changes in spleen (dog).	
Relevant oral NOAEL ‡	1 mg/kg bw/day (13-week rat)	
Relevant dermal NOAEL ‡	No data- not required.	

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

Relevant inhalation NOAEL ‡	No data- not required.

Genotoxicity ‡ (Annex IIA, point 5.4)

……………………………………………….	No genotoxic potential.

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

Target/critical effect ‡	Reduced bw and bw gain (rat) and reduced food consumption (rat).
Relevant NOAEL ‡	0.5 mg/kg bw/day (2-year rat) 269 mg/kg bw/day (18-m mouse)
Carcinogenicity ‡	Non- carcinogenic in rats and mice.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental effects (rat): reduced bw and food consumption, kidney effects (increased weight and histopathological changes). Effects on pups (rat): reduced pup weight at parental toxic dose. No reproductive effects.
Relevant parental NOAEL ‡	0.5 mg/kg bw/day (rat, 2-gen study)
Relevant reproductive NOAEL ‡	>50 mg/kg bw/day (rat, 2-gen study)
Relevant offspring NOAEL ‡	5 mg/kg bw/day (rat, 2-gen study)

Developmental toxicity

Developmental target / critical effect ‡	Maternal effects: clinical signs (rat), reduced bw gain (rat), reduced bw (rabbit), reduced food consumption (rat, rabbit), increased abortions (rabbit), elevated kidney and liver weights (rat). Effects on offspring: reduced pup weights (rat)
Relevant maternal NOAEL ‡	10 mg/kg bw/day (rat) 50 mg/kg bw/day (rabbit)
Relevant developmental NOAEL ‡	50 mg/kg bw/day (rat, rabbit)

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

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL for the acute neurotoxicity and cholinergic effects observed is >850 mg/kg bw.	
Repeated neurotoxicity ‡	NOAEL 40 mg/kg bw/day based on cholinergic effects (with salivation, urinary incontinence) (14-day oral rat)	
Delayed neurotoxicity ‡	No potential to produce acute delayed neurotoxicity in hens.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	The effects of prosulfocarb on rat brain and human recombinant acetylcholinesterase activity was studied *in vitro*. Prosulfocarb did not inhibit rat brain homogenate acetylcholinesterase *in vitro* at concentrations up to 0.1 mM. Nor did it inhibit human recombinant acetylcholinesterase *in vitro* at concentrations up to 30 µM. Only a modest inhibition of the human recombinant enzyme was observed for the maximum dose of prosulfocarb tested (0.1 mM).
Studies performed on metabolites or impurities ‡	Impurity SYN545019 Not oral LD_{50} > 2000 mg/kg bw; Ames test negative; chromosome aberrations in human lymphocytes: negative

Medical data ‡ (Annex IIA, point 5.9)

……………………………………………….	No health surveillance information available. Since 1983 no reports of accidents in the safety department of the manufacturer.

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

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.005 mg/kg bw/day	2-year oral toxicity study in rats, supported by the multi-generation study in rats	100
AOEL (short-term systemic) ‡	0.007 mg/kg bw/day	90-day oral toxicity study in rats.	100 Adjustment for gastrointestinal absorption of 72%.
ARfD (acute reference dose)‡	0.1 mg/kg bw	developmental toxicity study in rats	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Boxer 800 EC	Concentrate: 0.2% Spray dilution 3.2% Based on *in vivo* (rat) and *in vitro* (rat and human) dermal absorption studies.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	<u>German Mode</u> 1170% of AOEL without PPE 101% of AOEL with gloves during mix/load and appl., coverall and sturdy footwear during appl. <u>UK model</u>: 7093% of AOEL without PPE 1316% with gloves during mix/load and appl. <u>Field study</u>: Boxer 800 EC; coverall, gloves during mixing/loading, maintenance work and application; systemic exposure of up to 53% of the AOEL with PPE (closed cabin used)
Workers	Estimated systemic exposure: 0.3% of the AOEL.
Bystanders	Estimated systemic exposure: 3.7% of the AOEL.

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

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

Active substance: prosulfocarb	RMS/peer-review proposal		ECB decision
	Xn;	Harmful	Xn; R22, R43
	R22	Harmful if swallowed	(ATP 29)
	R43	May cause sentitisation by skin contact	

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

Appendix 1.4: Residues

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

Plant groups covered	Foliar treatment (early post emergence application): Cereals (wheat, barley), Soil treatment: Root vegetables (potato) and pulses (pea).
Rotational crops	Not required given the low to moderate persistence of prosulfocarb in soil.
Metabolism in rotational crops similar to metabolism in primary crops?	Assessment not required
Processed commodities	Not required as no residues are present in raw commodities.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Assessment not required
Plant residue definition for monitoring	Prosulfocarb
Plant residue definition for risk assessment	Prosulfocarb
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Not required due to the extremely low exposure of livestock
Time needed to reach a plateau concentration in milk and eggs	Assessment not required
Animal residue definition for monitoring	Assessment not required
Animal residue definition for risk assessment	Assessment not required
Conversion factor (monitoring to risk assessment)	Assessment not required
Metabolism in rat and ruminant similar (yes/no)	Assessment not required
Fat soluble residue: (yes/no)	Assessment not required

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

…………………………………………………	The DT_{90} values for prosulfocarb in soil, under field conditions, are between 22 and 48 days. As prosulfocarb shows no potential for accumulation, no detectable residues in succeeding crops are expected.

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

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

…………………………………………………	Wheat grain, wheat straw and forage: stable at -18°C for at least 25 months. Potato: stable at -18°C for at least 18 months. Pea and dry bean: stable at -18°C for at least 18 months.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Residue levels in feeding studies (dose level: mg/kg) Mean (max) mg/kg		
Muscle	N/R	N/R	N/R
Liver	N/R	N/R	N/R
Kidney	N/R	N/R	N/R
Fat	N/R	N/R	N/R
Milk	N/R		
Eggs		N/R	

N/R=Not required

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

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

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL estimated from trials according to the intended use		STMR (b)	HR (c)
				MRL – 1 (R_{max})	MRL – 2 (R_{ber})		
Potatoes	Northern and Southern Europe	14 trials: PHI = 28 – 82, 14 x <0.01		0.01	0.02	0.01	0.01
Cereals	Northern and Southern Europe	8 trials: PHI = 97 – 292, 8x <0.01	The trials were conducted on winter wheat (3), spring wheat (2), winter barley (1), spring barley (1) and winter rye (1).	0.01	0.02	0.01	0.01
Wheat straw	Northern and Southern Europe	6 trials: PHI = 94 - 261, 5x <0.01, 1x0.02,				0.01	0.01

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

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

ADI	0.005 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	1.5% (adult, 60 kg bw)
TMDI (% ADI) according to national (to be specified) diets	2.5% (German model – girl, 13.5 kg bw) 2.3% (UK model – adult, 70.1 kg bw) 3.0% (UK model – child, 43.6 kg bw) 1.7% (UK model – toddler, 14.5 kg bw) 4.1% (UK model – infant, 8.7 kg bw)
IEDI (WHO European Diet) (% ADI)	Not calculated (TMDI < 100%)
NEDI (specify diet) (% ADI)	Not calculated (TMDI < 100%)
Factors included in IEDI and NEDI	Calculations not performed (TMDI < 100%)
ARfD	0.1 mg/kg
IESTI (% ARfD)	Not calculated
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Current WHO methodology and UK acute consumption data: Max 2.1% (potato in toddlers)
Factors included in IESTI and NESTI	Highest residue (HR)

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
--	--	--	--	--

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

Potato	0.01* mg/kg
Wheat	0.01* mg/kg

* LOQ

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

Appendix 1.5: Fate and bahaviour in the Environment

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

Mineralization after 100 days ‡	38% after 96 days, [^{14}C-phenyl]-label, n=1
Non-extractable residues after 100 days ‡	27% after 96 days, [^{14}C-phenyl]-label, n=1
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Prosulfocarb sulfoxide 5.0-6.8% at 2 consecutive measurements.

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

Anaerobic degradation ‡	
Mineralization after 100 days	39 % of the radioactivity present at the onset of anaerobic conditions was mineralised 68 days after the onset of anaerobic conditions (96-28 days) [^{14}C-phenyl]-label, n= 1
Non-extractable residues after 100 days	16 % after 68 days anaerobic conditions preceded by 28 days aerobic conditions [^{14}C-phenyl]-label, n= 1
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None
Soil photolysis ‡	DT_{50} = 97 d summer sunlight at 50°N
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

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

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[1]	pH	t. oC / % w/w MWHC in the study	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silty clay loam		4.8	22°/ 26	38.4/128	40.3	0.97	SFO
Heavy loamy sand		5.7	21.5 °C/9.6 §	11 / 35	9.5	0.84	SFO
Medium loamy sand		5.4	21.5 °C/9.6§	22 / 74	18.9	0.89	SFO
Silt loam		7.0	20 °C/49.8	6.3 / 21	6.3	0.955	SFO
Sandy clay loam		6.5	20 °C/33.3	6.7 / 22	6.7	0.979	SFO
Silty clay loam		7.5	20 °C/30.9	9.3 / 31	9.3	0.937	SFO
Geometric mean				12.4 / 41	11.9		
Arithmetic mean				15.6/ 52	15.2		

§§ calculated based on 40% of FOCUS default WHC for loamy sand of 24%w/w.

Met 1 **Prosulfocarb sulfoxide**	Aerobic conditions							
Soil type	X1	pH	t. oC / % WHC at pF2	DT_{50}/ DT_{90} (d)	f. f. kdp/ kf	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
sandy clay loam		4.8	20/32.2	2.7 / 8.8	2.7	0.99	SFO	
loam		7.0	20/44.0	1.6 / 5.2	1.6	0.99	SFO	
silty clay loam		7.7	20/27.6	3.9 / 13.0	3.9	0.99	SFO	
Geometric mean				2.5 / 8.4	2.5			
Arithmetic mean				2.7 / 9.0	2.7			

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

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

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sand (bare soil)	Speyer, Germany		6.4	25	6.5	22	0.83	SFO	
Loam/sandy loam (bare soil)	Varendorf, Germany		6.7	10	9.9	33	0.99	SFO	
Loam/sandy loam (bare soil)	Varendorf, Germany		6.7	10	10	33	0.98	SFO	
Clay loam (bare soil)	Hernigersdorf, Germany		6.8	30	11	35	0.98	SFO	
Silty clay loam (bare soil)	Romerberg, Germany		7.4	10	13	48	0.94	SFO	
Geometric mean/median					9.8	33			
Arithmetic mean					10.1	34.2			

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not relevant

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[13]	pH	t. °C / flooded	DT_{50} / DT_{90} (d)		St. (r^2)	Method of calculation
Silty clay loam		4.8	Temperature not reported.	96/221	Indicative value based on only 4 data points	0.95	SFO

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

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc* (mL/g)	1/n
Sand	0.5	6.0	-	-	11.7	2339	0.896
Silt loam	1.8	5.6	-	-	24.7	1372	0.966
Clay-clay loam	2.4	7.3	-	-	32.8	1367	1.023
Arithmetic mean					23.1	1693	0.96
pH dependence, Yes or No			No				

* as results from only three soils were available the lowest value is appropriate for use in FOCUS modelling (Kfoc 1367ml/g, 1/n 1.0)

Metabolite ‡ **Prosulfocarb sulfoxide**							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
sandy clay loam	2.9	5.9	2.55	88	1.98	68	0.90
loam	2.0	7.1	1.23	61	1.02	50	0.91
silty clay loam	2.9	4.8	1.84	63	1.50	52	0.91
Arithmetic mean					1.50	56.7	0.91
pH dependence, Yes or No			No				

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

Column leaching ‡	No reliable study, as the LOQ in the available study for the leachate was high at 5µg/L, however there is no data gap as results from adequate soil batch adsorption studies are available. Leachate: <5 µg/L (<0.64% of applied) The result is only considered as supportive information.
Aged residues leaching ‡	No reliable study (only 1 cm columns; packed; eluted with water, not CaCl2)
	Leachate: <2% total residues/radioactivity in leachate (prosulfocarb sulfoxide, benzoic acid, polar compounds) 0.02 – 0.12% active substance The result is only considered as supportive information.
Lysimeter/ field leaching studies ‡	No studies available, not required

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

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 13days Kinetics: 1st order Field or Lab: representative worst case from field studies.
Application data	Crop: winter wheat and potatoes Depth of soil layer: 5 cm Soil density 1.5g/cm^3 % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Interval (d): Not relevant Application rate(s): 4000 g as/ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		5.33		-	
Short term	24h	5.08	5.19	-	-
	2d	4.83	5.06	-	-
	4d	4.38	4.80	-	-
Long term	7d	3.77	4.45	-	-
	28d	1.33	2.77	-	-
	50d	0.45	1.86	-	-
	100d	0.038	1.00	-	-
Plateau concentration		Not relevant			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: No significant hydrolysis (<10 %) was observed at 25 °C and 40 °C after 31 days.
	pH 7: No significant hydrolysis (<10 %) was observed at 25 °C and 40 °C after 31 days.
	pH 9: No significant hydrolysis (<10 %) was observed at 25 °C and 40 °C after 31 days.

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

Photolytic degradation of active substance and metabolites above 10 % ‡	No photodecomposition was observed at pH 7.0 and 20 ± 3 °C
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not relevant since no photo degradation occurs
Readily biodegradable ‡ (yes/no)	Not ready biodegradable.

Degradation in water / sediment

Parent	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Old Basin	7.9	7.5	20	381 / too long to predict; 331 / too long to predict		0.6 / 13.9	 0.848	Not determined		DFOP SFO
Virginia Water	7.9	7.2	20	147 / too long to predict; 139 / too long to predict		1.5 / 51.1	 0.838	Not determined		DFOP SFO
Geometric mean				214		0.95 / 26.6		-		SFO/DFOP
Arithmetic mean						264		1.05 / 32.5		

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Old Basin	7.9	7.5	25% after 107 days (end of study)	23% after 107 days	
Virginia Water	7.9	7.2	14.8% after 70 days 9.6% after 107 days (end of study)	10% after 70 days	7.3% after 107 days (end of study)

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

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

Parent Parameters used in FOCUSsw step 3	Molecular weight (g/mol): 251.4 Water solubility (mg/L): 13 Kfoc (L/kg): 1367 (worst case from 3 soils) DT_{50} soil (d): 11.1 (comparable to the geometric mean normalised to pF2, 20°C of 11.9) DT_{50} water (d): 1000 (default worst case value for slowly degradable substances) DT_{50} sediment (d): 331 (worst case from sediment water studies) DT_{50} whole system (d): 331 (worst case from sediment water studies) Crop interception (%): Given by the Pesticide Application Timer (PAT) in the model Vapour pressure: 7.9 × 10-4 Koc: 1367 (worst case from 3 soils) 1/n: 1.0 (corresponding to Kfoc)
Application rate	Crop: Winter wheat and potatoes Number of applications: 1 Interval (d): Not relevant Application rate(s): 4000 g a.s./ha Application window: 8 September – 17 December for wheat; 1 March – 26 May (21 August*) for potatoes, * denotes that 2 crops/year are grown in the D6 scenario.

Crop: Winter wheat

FOCUS STEP 3 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	1-day TWA	Global max (= initial)
D1	Ditch	1st	25.7	Not used for risk	58.2
D1	Stream	1st	22.4	assessment	11.5
D2	Ditch	1st	25.7		46.2
D2	Stream	1st	22.9		40.2
D3	Ditch	1st	25.2		9.45
D4	Pond	1st	0.875		4.31
D4	Stream	1st	21.9		4.10
D5	Pond	1st	0.875		4.22
D5	Stream	1st	23.6		5.58

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

FOCUS STEP 3 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	1-day TWA	Global max (= initial)
D6	Ditch	1st	25.5		29.6
R1	Pond	1st	2.23		11.6
R1	Stream	1st	25.9		8.89
R3	Stream	1st	32.4		490
R4	Stream	1st	16.8		7.16

Crop: potatoes

FOCUS STEP 3 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	1-day TWA	Global max (= initial)
D3	Ditch	1st	20.9	Not used for	9.91
D4	Pond	1st	0.847	risk assessment	2.82
D4	Stream	1st	17.5		0.872
D6	Ditch	1st	20.7		5.00
D6	Ditch	2nd	21.1		25.3
R1	Pond	1st	1.51		7.08
R1	Stream	1st	14.5		6.06
R2	Stream	1st	19.2		278
R3	Stream	1st	34.3		16.5

Parent Parameters used in FOCUSsw step 4 - mitigation of spray drift as well as run-off	Molecular weight (g/mol): 251.4 Water solubility (mg/L): 13.2 Kfoc (L/kg): 1367 (worst case from 3 soils) DT_{50} soil (d): 11.1 (comparable to the geometric mean normalised to pF2, 20°C of 11.9) DT_{50} water (d): 1000 (default worst case value for slowly degradable substances) DT_{50} sediment (d): 331 (worst case from sediment water studies) Crop interception (%): Given by the Pesticide Application Timer (PAT) in the model Vapour pressure: 6.9 x 10^{-3} Koc: 1367 (worst case from 3 soils) 1/n: 1.0 (corresponding to Kfoc)

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

Application rate	Crop: Winter wheat and potatoes Number of applications: 1 Interval (d): Not relevant Application rate(s): 4000 g a.s./ha Application window: 10 September – 6 December for wheat; 1 March – 17 May (25 July*) for potatoes, * denotes that 2 crops/year are grown in the D6 scenario.
Risk mitigation	5 m and 10 m vegetated buffer strips assumed, to reduce spray drift and run-off. Loading via run-off (water volume as well as pesticide mass) thereby assumed to be reduced by 50% (5 m buffer) and 90% (10 m buffer).

Crop: Winter wheat - 5 m vegetated buffer strip - assumed to reduce loading via spray drift as well as run-off

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
D1	Ditch	1st	7.03	TWA not used	22.2
D1	Stream	1st	8.19	for risk assessment	4.99
D2	Ditch	1st	7.04		15.4
D2	Stream	1st	8.38		16.5
D3	Ditch	1st	6.84		2.57
D4	Pond	1st	0.759		4.74
D4	Stream	1st	8.00		1.51
D5	Pond	1st	0.760		4.37
D5	Stream	1st	8.64		2.04
D6	Ditch	1st	11.7		8.41
R1*	Pond	1st	2.25		12.6
R1*	Stream	1st	14.3		4.79
R3*	Stream	1st	**18.2**		**274**
R4*	Stream	1st	8.86		4.46

*Results for scenario considered uncertain by the peer review.

Crop: Winter wheat - 10 m vegetated buffer strip - assumed to reduce loading via spray drift as well as run-off

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

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
D1	Ditch	1st	3.77	TWA not used	13.6
D1	Stream	1st	4.34	for risk assessment	4.43
D2	Ditch	1st	3.77		9.37
D2	Stream	1st	4.46		9.34
D3	Ditch	1st	3.63		1.36
D4	Pond	1st	0.546		3.85
D4	Stream	1st	4.24		0.802
D5	Pond	1st	0.548		3.52
D5	Stream	1st	4.58		1.09
D6	Ditch	1st	**11.7**		5.45
R1*	Pond	1st	2.14		11.7
R1 *	Stream	1st	3.23		1.07
R3*	Stream	1st	4.48		**55.1**
R4*	Stream	1st	3.25		0.989

*Results for scenario considered uncertain by the peer review.

Crop: potatoes - 5 m vegetated buffer strip - assumed to reduce loading via spray drift as well as run-off

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
D3	Ditch	1st	6.86	TWA not used	3.29
D4	Pond	1st	0.756	for risk assessment	3.01
D4	Stream	1st	7.38		0.369
D6	Ditch	1st	6.78		1.65
D6	Ditch	2nd	6.92		9.60
R1*	Pond	1st	1.62		8.91
R1*	Stream	1st	7.00		3.89
R2*	Stream	1st	8.08		**114**
R3*	Stream	1st	**19.4**		10.7

*Results for scenario considered uncertain by the peer review.

Crop: potatoes - 10 m vegetated buffer strip - assumed to reduce loading via spray drift as well as run-off

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

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
D3	Ditch	1st	3.64	TWA not used	1.75
D4	Pond	1st	0.544	for risk assessment	2.17
D4	Stream	1st	3.91		0.197
D6	Ditch	1st	3.59		0.874
D6	Ditch	2nd	3.67		5.09
R1*	Pond	1st	1.49		8.07
R1*	Stream	1st	3.24		0.856
R2*	Stream	1st	4.28		**22.8**
R3*	Stream	1st	**4.55**		2.33

*Results for scenario considered uncertain by the peer review.

Parent Parameters used in FOCUSsw step 4 - mitigation of spray drift only	Molecular weight (g/mol): 251.4 Water solubility (mg/L): 13.2 Kfoc (L/kg): 1367 (worst case from 3 soils) DT_{50} soil (d): 15.3 (arithmetic mean from 6 lab soils, data refitted to SFO-kinetics and most of the values normalised to pF2, 20°C) DT_{50} water (d): 1000 (default worst case value for slowly degradable substances) DT_{50} sediment (d): 331 (worst case from sediment water studies) Crop interception (%): Given by the Pesticide Application Timer (PAT) in the model Vapour pressure: 7.9×10^{-7} Koc: 1367 (worst case from 3 soils) 1/n: 1.0 (corresponding to Kfoc)
Application rate	Crop: Winter wheat and potatoes Number of applications: 1 Interval (d): Not relevant Application rate(s): 4000 g a.s./ha Application window: 10 September – 6 December for wheat; 1 March – 17 May (25 July*) for potatoes, * denotes that 2 crops/year are grown in the D6 scenario.
Risk mitigation	5 m and 10 m spray drift buffer zone, to reduce spray drift.

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

Crop: Winter wheat - 5 m buffer zone to reduce loading via spray drift only

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
R1	Pond	1st	2.60	TWA not used	14.5
R1	Stream	1st	27.4	for risk assessment	9.86
R3	Stream	1st	**34.4**		**569**
R4	Stream	1st	21.2		10.6

Crop: Winter wheat - 10 m buffer zone to reduce loading via spray drift only

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
R1	Pond	1st	2.48	TWA not used	13.7
R1	Stream	1st	27.4	for risk assessment	9.83
R3	Stream	1st	**34.4**		**569**
R4	Stream	1st	21.2		10.6

Crop: potatoes - 5 m buffer zone to reduce loading via spray drift only

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
R1	Pond	1st	1.92	TWA not used	10.7
R1	Stream	1st	15.4	for risk assessment	8.90
R2	Stream	1st	9.18		**255**
R3	Stream	1st	**36.5**		23.1

Crop: potatoes - 10 m buffer zone to reduce loading via spray drift only

FOCUS STEP 4 Scenario	Water body	Crop	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
			Global max (= initial)	X-day TWA	Global max (= initial)
R1	Pond	1st	1.78	TWA not used	9.87
R1	Stream	1st	15.4	for risk assessment	8.86
R2	Stream	1st	9.18		**255**
R3	Stream	1st	**36.5**		23.0

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

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: PELMO (prosulfocarb) and PEARL (prosulfocarb and metabolite prosulfocarb sulfoxide) Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva. Crop: Winter wheat (pre-emergent) and potatoes (pre-emergent) Prosulfocarb: Soil DT_{50lab} PELMO: 41.4 days (A worst case value from lab, normalised to pF2, 20°C was used. This value was from a study not accepted for estimation of DT_{50} and is not in accordance with FOCUS. However modelling with the correct geometric mean value of 11.9 days would not have altered the result). Soil DT_{50lab} PEARL: 11.1 days (comparable to the geometric mean normalised to pF2, 20°C of 11.9 days) Kf_{oc} PELMO: Prosulfocarb 1367 (worst case from 3 soils) Kfom PEARL: 792.9 (worst case from 3 soils) $^1/_n$= 1.0 (worst case from 3 soils, corresponding to Kfoc/Kfom). Prosulfocarb sulfoxide: Soil DT_{50lab}: 2.7 d (comparable to correct geometric mean value of 2.5 d) Kfom: 32.9 (mean value) 1/n: 0.906 (mean value) Formation fraction from parent: 1.0
Application rate	Application rate: 4000 g/ha. No. of applications: 1 Time of application (month or season): 13 Sept – 24 Nov for winter and 24 Jan – 3 May for potatoes

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

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

	The models predicted that prosulfocarb or the metabolite prosulfocarb sulfoxide would not be found at concentrations greater than 0.001 µg l^{-1}, at 1 m depth, in any Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva scenarios.

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

Direct photolysis in air ‡	Not studied - no data requested @Latitude: .... Season: .... DT_{50} ....
Quantum yield of direct phototransformation	Not required
Photochemical oxidative degradation in air ‡	DT_{50} of 3.9 hours derived by the Atkinson method of calculation
Volatilisation ‡	From plant surfaces: 46.7% had volatilised from leaf surfaces after 24 hours
	From soil surfaces: 18% had volatilised after 24 hours
Metabolites	No available data – no data requested

PEC (air)

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

$PEC_{(a)}$

Maximum concentration	Negligible except at the time of application

@ If direct photolysis data is provided, information on the latitude etc. should be included.

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

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil:	Prosulfocarb
	Surface Water:	Prosulfocarb
	Sediment:	Prosulfocarb
	Ground water:	Prosulfocarb (Note the levels of prosulfocarb sulfoxide in soil triggers the need for ground-water exposure to prosulfocarb sulfoxide to be assessed. Further assessment for prosulfocarb sulfoxide would be required for different use patterns/use on other crops)
	Air:	Prosulfocarb

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

Soil (indicate location and type of study)	No data provided - none requested
Rain water (indicate location and type of study)	South of Sweden, samples were collected during May-June and September-October 2002 and 2003. Prosulfocarb was detected in four out of ten samples in 2002 and in five out of twelve samples in 2003. The maximum concentration was 0.3 µg/L in 2002 and 0.4 µg/L in 2003. Deposition was calculated to be 6.6 and 14.1 µg/m^2 in the two years respectively.
Surface water (indicate location and type of study)	No data provided - none requested
Ground water (indicate location and type of study)	No data provided - none requested
Air (indicate location and type of study)	No data provided - none requested

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

Not readily biodegradable

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

Appendix 1.6: Effects on non-target Species

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds				
Bobwhite Quail, *Colinus virginianus*	a.s.	Acute	LD_{50} >2250	
	Preparation	Acute	No data available – no data required	
Mallard duck, *Anas platyrhynchos*	a.s.	Short-term	LD_{50} >1505.6	>5620
Mallard duck, *Anas platyrhynchos*	a.s.	Long-term	NOEL= 131	1000
Mammals				
Rat	a.s.	Acute	LD_{50} = 1820	
	Preparation	Acute	No data available	
	Metabolite 1	Acute	No metabolites of concern	
Rat	a.s.	Long-term	NOAEL = 50	
Additional higher tier studies No study available – no studies requested				

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

Winter wheat, 4000 g a.s./ha pre- or early postemergence

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivor / early	Acute	249.9	**>9.0**	10
Small insectivor / early	Acute	216.3	>10.4	10
Large herbivor / early	Short-term	133.8	11.3	10
Small insectivor / early	Short-term	120.6	12.5	10
Large herbivor / early	Long-term	70.9	**1.8**	5
Small insectivor / early	Long-term	120.6	**1.1**	5
Earthworm-eating bird	Long-term	31.6	**4.1**	5
Fish-eating bird	Long-term	2.4	55	5
Exposure via drinking water (puddles/leaves)	Acute	1080	**>2.08**	10
Exposure via drinking water (surface water)[1]	Acute	0.14	>16000	10
Exposure via drinking water (surface water)[1]	Long term	0.14	936	5

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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Higher tier refinement (Birds)				
Large herbivor /early	Long-term	5.5[2]	24	5
Skylark, spring application	Long term	7.8[3]	17	5
Skylark, autumn application	Long term	10.1[4]	13	5
Earthworm-eating bird	Long-term	2.72[5]	48	5
Tier 1 (Mammals)				
Small herbivor /early	Acute	790	**2.3**	10
Medium herbivor /early	Acute	159	11.4	10
Insectivor /early	Acute	35.3	51.6	10
Small herbivor /early	Long-term	224	**0.22**	5
Medium herbivor /early	Long-term	45.1	**1.2**	5
Insectivor /early	Long-term	12.8	**3.9**	5
Earthworm-eating mammals	Long-term	40.2	**1.2**	5
Fish eating mammals	Long-term	1.43	35	5
Exposure via drinking water (puddles/leaves)	Acute	560	**3.25**	10
Exposure via drinking water (surface water)[1]	Acute	0.073	24900	10
Exposure via drinking water (surface water)[1]	Long term	0.073	686	5
Higher tier refinement (Mammals)				
Woodmouse (only insects)	Acute	25.8	71	10
Woodmouse (only weed seeds)	Acute	62.6	29	10
Woodmouse (only cereal grain)	Acute	7.83	230	10
Woodmouse (cereal shoots)[6]	Acute	284	**6.4**	10
Woodmouse (mixed diet, spring/autumn)	Acute	82.1/75.5	22/24	10
Woodmouse (mixed diet, spring/autumn)	Long-term	5.2/3.0[7]	9.7/17	5
Medium herbivor (rabbit/hare)	Long-term	3.5[2]	14	5
Earthworm-eating mammals	Long-term	3.45[5]	14	5

[1] Based on FOCUS Step 1 PECsw, see addendum.
[2] Based on residue decline data (Devine, 2004, see DAR) on winter cereals (DT_{50} = 0.6 days leading to ftwa = 0.0412 and a concentration in food of 12.5 mg/kg).
[3] Based on mixed diet of skylark in May according to Green (1978) as cited by Roeloefs et al, 2005, see addendum.
[4] Based on mixed diet of skylark in autumn according to Donald et al. 2001, see addendum.
[5] Based on earthworm bioaccumulation study and 21 d twa PEC in soil, see addendum.
[6] This scenario is considered as relevant for post-emergence applications only. Based on FIR/bw of 0.5, assumed as maximum amount per feeding bout, and a PT factor of 1.0. The resulting TER value is considered to be overly conservative since woodmice are nocturnal, allowing for residue declination before start of exposure, see adden.
[7] Based on a mixed diet of woodmouse in autumn according to Pelz (1989) and a DT_{50} of 0.6 days in vegetation, see addendum.

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

Potatoes, 4000 g a.s./ha pre or early postemergence

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Small insectivor	Acute	216.3	>10.4	10
Small insectivor	Short-term	120.6	12.5	10
Small insectivor	Long-term	120.6	**1.1**	5
Earthworm-eating bird	Long-term	31.6	**4.1**	5
Fish-eating bird	Long-term	2.4	55	5
Exposure via drinking water (puddles/leaves)	Acute	1080	**>2.08**	10
Exposure via drinking water (surface water)[1]	Acute	0.14	>16000	10
Exposure via drinking water (surface water)[1]	Long-term	0.14	936	5
Higher tier refinement (Birds)				
Skylark, spring application	Long term	7.8[2]	17	5
Earthworm-eating bird	Long-term	2.72[3]	48	5
Tier 1 (Mammals)				
Small herbivor	Acute	790	**2.3**	10
Medium herbivor	Acute	159	11.4	10
Insectivor	Acute	35.3	51.6	10
Small herbivor	Long-term	224	**0.22**	5
Medium herbivor	Long-term	45.1	**1.2**	5
Insectivor	Long-term	12.8	**3.9**	5
Earthworm-eating mammals	Long-term	40.2	**1.2**	5
Fish eating mammals	Long-term	1.43	35	5
Exposure via drinking water (puddles/leaves)	Acute	560	**3.25**	10
Exposure via drinking water (surface water)[1]	Acute	0.073	24900	10
Exposure via drinking water (surface water)[1]	Long term	0.073	686	5
Higher tier refinement (Mammals)				
Woodmouse (only insects)	Acute	25.8	71	10
Woodmouse (only weed seeds)	Acute	62.6	29	10
Woodmouse (grass weeds)[4]	Acute	284	**6.4**	10
Woodmouse (mixed diet, spring)	Acute	82.1	22	10
Woodmouse (mixed diet, spring)	Long-term	5.2[5]	9.7	5
Medium herbivor (rabbit/hare)	Long-term	3.5[6]	14	5
Earthworm-eating mammals	Long-term	3.45[3]	14	5

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

[1] Based on FOCUS Step 1 PECsw, see addendum.
[2] Based on mixed diet of skylark in May according to Green (1978) as cited by Roeloefs et al, 2005, see addendum.
[3] Based on earthworm bioaccumulation study and 21 d twa PEC in soil, see addendum.
[4] Based on FIR/bw of 0.5, assumed as maximum amount per feeding bout, and a PT factor of 1.0. The resulting TER value is considered to be overly conservative since woodmice are nocturnal, allowing for residue declination before start of exposure, see addendum.
[5] Based on a mixed diet of woodmouse in spring according to Pelz (1989) and a DT_{50} of 0.6 days in vegetation, see addendum.
[6] Based on residue decline data (Devine, 2004, see DAR) on winter cereals (DT_{50} = 0.6 days leading to ftwa = 0.0412 and a concentration in food of 12.5 mg/kg).

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

Group	**Test substance**	**Time-scale (Test type)**	**Endpoint**	**Toxicity[1] (mg/L)**
Laboratory tests				
Fish				
Rainbow trout, *Oncorhynchus mykiss*	a.s.	96 h (flow-through)	Mortality, EC_{50}	**0.84** (nom)
Rainbow trout, *Oncorhynchus mykiss*	a.s.	96 h (dynamic simulating DT_{50} =1.5 d)	Mortality, EC_{50}	4.3 (24-h LC_{50} calculated based on DT_{50} = 6.2 d in mesocosm study)
Rainbow trout, *Oncorhynchus mykiss*	a.s.	21 d (flow-through)	Toxic symptoms, NOEC	0.31 (mm)
Bluegill sunfish, *Lepomis macrochirus*	SC-0574 80EC	96 hr (static)	Mortality, EC_{50}	2.2 (2.8 mg formulation/L, (nom)[1]
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	**0.51** (mm)
Daphnia magna	a.s.	21 d (semi static)	Reproduction, NOEC	0.045 (mm)
Daphnia magna	A-8545 C	48 h (static)	Mortality, EC_{50}	**0.42** (0.52 mg formulation/L, (mm)
Sediment dwelling organisms				
Chironomus riparius	a.s.	25 d (static)	NOEC	1.25 (nom, water spiked)

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	**0.049** ($_{mm}$) 0.120 ($_{mm}$)
Pseudokirchneriella subcapitata	80% EC	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.066 (0.084 mg formul/L, $_{mm}$) 0.114 (0.142 mg formul/L, $_{mm}$)
Higher plant				
Lemna gibba	a.s.	14 d (static)	Fronds, EC_{50}	0.69 ($_{mm}$)
Lemna gibba	Preparation	14 d (static)	Fronds, EC_{50}	No data
Higher tier tests A mesocosm study was conducted to refine the risk assessment for invertebrates and algae				

[1] supportive only, since test conc not verified.

Microcosm or mesocosm tests
<u>Mesocosm study evaluated in DAR (Arts et al, 2003)</u>: The study was initiated on 22 April 2002 in the Netherlands. Four ditches served as controls, two ditches received a low spray drift emission of 0.2%, and in three ditches each a spray drift emission of 1% and 5%, respectively of a field application rate of 3200 g prosulfocarb/ha (corresponding to nominal concentrations of 3, 15 and 76 µg/L respectively). The study lasted for 24 weeks but only results from the first 5 weeks were used since later other pesticides were applied to the ditches. Measurements: Prosulfocarb was analysed in water and in sediment and macrophytes of ditches with the highest application rate. DT50 values were 4.7 - 7.6 days in the water, and 15.8 and 11.9 days in the sediment and macrophytes, respectively. Temperature, pH and DO was measured 3 times a week. Plankton samples were taken every 3 weeks (-1, 2 and 5 weeks). Of the zooplankton taxa Cladocera were identified to species level. Remaining taxa (e.g., Copepoda, Ostracoda and Rotifera) were identified to the lowest practical taxonomic level. Phytoplankton were identified to the lowest practical taxonomic level. 1 L was collected for Chl-a analysis. <u>3 µg/L</u>: No significant effects <u>15 µg/L</u>: No significant effects on the measurement endpoints for zooplankton, macroinvertebrates, phytoplankton or macrophytes could be demonstrated. The pH decreased slightly for nine days after treatment. <u>76 µg/L</u>: No effects observed on the measurement endpoints for zooplankton, macroinvertebrates or macrophytes which could be attributed to prosulfocarb. The pH decreased for 16 days after treatment. On three occasions there were decreases in dissolved oxygen concentration, but not on consecutive sampling occasions. Significant increase of Flagellatae five weeks after application, a trend of an effect was already visible after 2 weeks. Effects were classified according to GD (SANCO 3268 rev 3). NOEAEC = 76 µg/L based on only short term effects on Flagellatae at this concentration. A safety factor of 5 is proposed.

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

Treatment rate (% of 3200 g a.s./ha)	Initial conc. (µg/L)	Phytoplankton (Flagellatae)	Macrophytes	pH/DO	Zooplankton	Macro-invertebrates
0.2	3.0	1	1	1	1	1
1	15	2↑	1	2↓	1	1
5	76	3↑	1	2-3↓	1	1

Class 1 = effect could not be demonstrated; Class 2 = slight effect; Class 3 = effect is pronounced short-term; ↓= decrease; ↑= increase

<u>Microcosm study evaluated in Addendum to DAR (van Wijngaarden, 2006)</u>:

A single application of prosulfocarb was made on the 23 May, 2006, to enclosures in a constructed ditch, The Netherlands. All treatments, including the controls, were in triplicate. Treatments were 3, 15, 76 and 380 µg a.s./L. Prosulfocarb was applied as EC formulation (A8545C) diluted in water to the water surface of the enclosures followed by gentle mixing. The experiment lasted for 8 weeks (58 days) after treatment.

Measurements: Prosulfocarb was analysed in the water; 2 h after treatment the average concentrations was 94% of nominal. On avergae, 42% of the initial concentrations was measured after 7 days. At the end of the experiment, 1-4% was measured in the 3 highest treatments (<LOQ in the lowest). Temperature, pH, dissolved oxygen (DO) and electrical conductivity (EC) were measured pre-treatment and at 7 dates thereafter.

Phytoplankton and zooplankton were collected days -8, -1, 3, 7, 14, 21, 28, 42 and 56 (though zooplankton collected d 14, 28 and 56 not analysed). Periphyton substrates were collected d -1, 7, 14, 21, 28, 42, 56. Macrophyte coverage was visually examined d -6, 15, 33, 43 and 58, and biomass was determined at study end.

94 phytoplankton taxa were collected, and 54 periphyton (chlorophyta dominating in both), and 46 zooplankton taxa were identified (rotifers dominating).

<u>3 µg a.s./L</u>: No consistent effects observed.

<u>15 µg a.s./L</u>: NOECcommunity for phytoplankton. Short-term reduction in periphytic green alga *Tetraedon trigonum* though difficult to interpret.

<u>76 µg a.s./L</u>: NOECcommunity for periphyton. Pronounced short-term effects at the phytoplanktonic community level. Pronounced short-term effects in phytoplankton populations (*S. cuspidatus*, *A. spiralis* [decrease] and *S. alternans* [increase]). Long-term reduction in *T. trigonum*. Also long-term reduction in periphytic green alga *A. spiralis* though not statistically significant (trend). Short-term effect in periphytic chlorophyll-a. Pronounced short-term effect [increase] for rotifer *Polyarthra remata*.

<u>380 µg a.s./L</u>: NOECcommunity for zooplankton and NOEC for community metabolism (function). Pronounced long-term effects for phytoplanktonic species (*A. spiralis*, *Euastrum sp*.) and at the phytoplanktonic community level. Pronounced short-term effects in phytoplanktonic taxa (*S. cuspidatus*, *S. mansfeldtii*, Cosmarium sp. [decrease] and *S. alternans*) and periphytic *P. vulgaris* [increase]. Pronounced short-term effects at the periphyton community level. Short-term effect in periphytic chlorophyll-a. Long-term reductions in periphytic *T. trigonum* and *A. spiralis* (trend). Pronounced short-term effect in the cladoceran *D. longispina* [decrease] and in the rotifer *P. remata* [increase].

Overall conclusion: NOECcommunity 15 µg a.s./L based on effects in phytoplankton.
NOECpopulation could not be allocated (difficulties to interpret data on periphytic T.trigonum).
NOEAEC 15 µg a.s./L.

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

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

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Winter wheat, 4000 g a.s./ha, pre- emergence or early post emergence. Short termTER values shown in bold are less than the relevant Annex VI trigger value.

FOCUS Scenario	Maximum PEC_{SW} value (μg a.s. L^{-1})	Fish *Oncorhynchus mykiss*	Aquatic invertebrates *Daphnia magna*	Algae *Selenastrum subspicatus*
		LC_{50} = 840 µg/L[1]	EC_{50} = 420 µg/L[2]	EC_{50} = 49 µg/L[3]
D1 – Ditch	25.7	**33**	**16**	**1.9**
D1 – Stream	22.4	**38**	**38**	**2.2**
D2 – Ditch	25.7	**33**	**16**	**1.9**
D2 – Stream	22.9	**37**	**18**	**2.1**
D3 – Ditch	25.2	**33**	**17**	**1.9**
D4 – Pond	0.875	960	479	56
D4 – Stream	21.9	**38**	**19**	**2.2**
D5 – Pond	0.875	960	479	56
D5 – Stream	23.6	**36**	**18**	**2.1**
D6 – Ditch	25.5	**33**	**16**	**1.9**
R1 – Pond	2.23	377	188	22
R1 – Stream	25.9	**32**	**16**	**1.9**
R3 – Stream	32.4	**26**	**13**	**1.5**
R4 – Stream	16.8	**50**	**25**	**2.9**

[1] previously used 24-h LC_{50} 4300 µg/L from a modified exposure study where dissipation from the water phase was simulated (DT_{50} =6.15 d) replaced by standard 96-h LC_{50} 840 µg/L as agreed at expert meeting.
[2] previously used EC_{50} 510 µg/L replaced by data from a new formulation study EC_{50} 419 µg/L (see Addendum)
[3] previously used EC_{50} 66 µg/L replaced by data from ew study EC_{50} 49 µg/L (see Addendum).

Potatoes, 4000 g a.s./ha, pre- emergence or early post emergence. Short term TER values shown in bold are less than the relevant Annex VI trigger value.

FOCUS Scenario	Maximum PEC_{SW} value (μg a.s. L^{-1})	Fish *Oncorhynchus mykiss*	Aquatic invertebrates *Daphnia magna*	Algae *Selenastrum subspicatus*
		LC_{50} = 840 µg/L[1]	EC_{50} = 420 µg/L[2]	EC_{50} = 49 µg/L
D3 – Ditch	20.9	**40**	**20**	**2.3**
D4 – Pond	0.847	992	495	58
D4 – Stream	17.5	**48**	**24**	**2.8**
D6 – Ditch 1st	20.7	**41**	**20**	**2.4**

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

FOCUS Scenario	Maximum PEC_{SW} value (µg a.s. L^{-1})	Fish *Oncorhynchus mykiss*	Aquatic invertebrates *Daphnia magna*	Algae *Selenastrum subspicatus*
		LC_{50} = 840 µg/L[1]	EC_{50} = 420 µg/L[2]	EC_{50} = 49 µg/L
D6 – Ditch 2nd	21.1	**40**	**20**	**2.3**
R1 – Pond	1.51	556	277	32
R1 – Stream	14.5	**58**	**29**	**3.4**
R2 – Stream	19.2	**44**	**22**	**2.6**
R3 –Stream	34.3	**24**	**12**	**1.4**

[1] previously used 24-h LC_{50} 4300 µg/L from a modified exposure study where dissipation from the water phase was simulated (DT_{50} =6.15 d) replaced by standard 96-h LC_{50} 840 µg/L as agreed at expert meeting.
[2] previously used EC_{50} 510 µg/L replaced by data from a new formulation study EC_{50} 419 µg/L (see Addendum)
[3] previously used EC_{50} 66 µg/L replaced by data from ew study EC_{50} 49 µg/L (see Addendum).

Winter wheat, 4000 g a.s./ha, pre- emergence or early post emergence. Long term TER values shown in bold are less than the relevant Annex VI trigger value.

FOCUS Scenario	Maximum PEC_{SW} value (µg a.s. L^{-1})	Fish *Oncorhynchus mykiss*	Aquatic invertebrates *Daphnia magna*	Sediment dwellers *Chironomus riparius*	Aq. plant *Lemna gibba*
		NOEC = 310 µg/L	NOEC = 45 µg/L	NOEC = 1250 µ/L	EC_{50} = 690 µg/L
D1 – Ditch	25.7	12.0	**1.8**	48.6	26.8
D1– Stream	22.4	13.8	**2.0**	55.8	30.8
D2 – Ditch	25.7	12.1	**1.8**	48.6	26.8
D2– Stream	22.9	13.5	**2.0**	54.6	30.1
D3 – Ditch	25.2	12.3	**1.8**	49.6	27.4
D4 – Pond	0.875	354	51.4	1429	789
D4– Stream	21.9	14.2	**2.1**	57.1	31.5
D5 – Pond	0.875	354	51.4	1429	789
D5– Stream	23.6	13.1	**1.9**	53.0	29.2
D6 – Ditch	25.5	12.2	**1.8**	49.0	27.1
R1 – Pond	2.23	139	20.2	560	309
R1 – Stream	25.9	12.0	**1.7**	48.3	26.6
R3 – Stream	32.4	**9.6**	**1.4**	38.6	21.3
R4 – Stream	16.8	18.5	**2.7**	74.4	41.1

Potatoes, 4000 g a.s./ha, pre- emergence or early post emergence. Long term TER values shown in bold are less than the relevant Annex VI trigger value.

FOCUS Scenario	Maximum PECSW value (µg a.s. /L)	Fish *Oncorhynchus mykiss*	Aquatic invertebrates *Daphnia magna*	Sediment dwellers *Chironomus riparius*	Aq. plant *Lemna gibba*
		NOEC = 310 µg/L	**NOEC = 45 µg/L**	**NOEC = 1250 µg/L**	**EC50 = 690 µg/L**
D3 – Ditch	20.9	14.8	**2.2**	59.8	33.0
D4 – Pond	0.847	366	53.1	1476	815
D4–Stream	17.5	17.7	**2.6**	71.4	39.4
D6–Ditch 1st	20.7	15.0	**2.2**	60.4	33.3
D6 Ditch 2nd	21.1	14.7	**2.1**	59.2	32.7
	1.51	205	29.8	829	457
R1 – Stream	14.4	21.4	**3.1**	86.2	47.6
R2 – Stream	19.2	16.1	**2.3**	65.1	35.9
R3 –Stream	34.3	**9.0**	**1.3**	36.4	20.1

FOCUS Step 4

Refined aquatic risk assessment for aquatic invertebrates and algae using FOCUS Step 4 modelling - mitigation of spray drift as well as run-off by distance

Acute TER values for aquatic organisms at 5 m and 10 m buffer zone in winter wheat. TER values shown in bold are lower than the relevant Annex VI trigger value of 10/100. Mitigation of spray drift as well as run-off.

Scenario	Max PEC ug a.s./L	Max PEC ug a.s./L	Fish LC_{50} = 840 µg/L[1]		*Daphnia* EC_{50} =420 µg/L[2]		Algae EC_{50} = 49 ug/L	
	(5 m buffer)	(10 m buffer)	5 m buffer	10 m buffer	5 m buffer	10 m buffer	5 m buffer	10 m buffer
D1 - Ditch	7.03	3.77	119	223	**59.5**	110.9	**7.0**	13.0
D1 - Stream	8.19	4.34	103	194	**51.0**	**96.3**	**6.0**	11.3
D2 - Ditch	7.04	3.77	119	223	**59.4**	110.9	**7.0**	13.0
D2 - Stream	8.38	4.46	100	188	**49.9**	**93.7**	**5.8**	11.0
D3 - Ditch	6.84	3.63	123	231	**61.1**	115	**7.2**	13.5
D4 - Pond	0.759	0.546	1107	1538	551	766	64.6	89.7
D4 - Stream	8	4.24	105	198	**52.3**	**98.6**	**6.1**	11.6
D5 - Pond	0.76	0.548	1105	1533	550	763	64.5	89.4
D5 - Stream	8.64	4.58	**97**	183	**48.4**	**91.3**	**5.7**	10.7
D6 - Ditch	11.7	11.7	**72**	**72**	**35.7**	**35.7**	**4.2**	**4.2**

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

Scenario	Max PEC ug a.s./L	Max PEC ug a.s./L	Fish LC_{50} = 840 µg/L[1]		*Daphnia* EC_{50} =420 µg/L[2]		Algae EC_{50} = 49 ug/L	
	(5 m buffer)	(10 m buffer)	5 m buffer	10 m buffer	5 m buffer	10 m buffer	5 m buffer	10 m buffer
*R1 - Pond	2.25	2.14	373	393	186	195	21.8	22.9
*R1 - Stream	14.3	3.23	**59**	260	**29.2**	129	**3.4**	15.2
*R3 - Stream	18.2	4.48	**46**	188	**23.0**	**92.3**	**2.7**	10.9
*R4 - Stream	8.86	3.25	**95**	258	**47.2**	129	**5.5**	15.1

[1] standard 96-h LC_{50} 840 µg/L as agreed at expert meeting.
2 Endpoint adjusted from formulation endpoint of 520ug/L based on an 80% nominal concentration factor
*Results for scenario considered uncertain by the peer review.

Acute TER values for aquatic organisms at 5 m and 10 m buffer zone in potatoes. TER values shown in bold are less than the relevant Annex VI trigger value of 10/100. Mitigation of spray drift as well as run-off.

Scenario	Max PEC ug a.s./L	Max PEC ug a.s./L	Fish LC_{50} = 840 µg/L[1]		*Daphnia* EC_{50} = 420 ug/L[2]		Algae EC_{50} = 49 ug/L	
	(5 m buffer)	(10 m buffer)	5 m buffer	10 m buffer	5 m buffer	10 m buffer	5 m buffer	10 m buffer
D3 - Ditch	6.86	3.64	122	231	**60.9**	115	**7.1**	13.5
D4 - Pond	0.756	0.544	1111	1544	553	768	64.8	90.1
D4 - Stream	7.38	3.91	114	215	**56.6**	107	**6.6**	12.5
D6 - Ditch	6.78	3.59	124	234	**61.7**	116	**7.2**	13.6
D6 - Ditch[a]	6.92	3.67	121	229	**60.4**	114	**7.1**	13.4
*R1 - Pond	1.62	1.49	519	564	258	281	30.2	32.9
*R1 - Stream	7	3.24	120	259	**59.7**	129	**7.0**	15.1
*R2 - Stream	8.08	4.28	104	196	**51.7**	**97.7**	**6.1**	11.4
*R3 - Stream	19.4	4.55	**43**	185	**21.5**	**91.9**	**2.5**	10.8

[1] standard 96-h LC_{50} 840 µg/L as agreed at expert meeting.
[2] Endpoint adjusted from formulation endpoint of 520ug/L based on an 80% nominal concentration factor
[a] Two potato crops in one season was assumed for this scenario. These figures are for the second crop.
*Results for scenario considered uncertain by the peer review.

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

Chronic TER values for aquatic invertebrates at 5 m and 10 m for wheat, based on the available NOEC for *Daphnia magna*, 0.045 mg as/L. TER values shown in bold are less than the relevant Annex VI trigger value of 10. Mitigation of spray drift as well as run-off.

FOCUS Scenario	Wheat			
	Max PEC Value ug a.s./L (5 m buffer)	Max PEC Value ug a.s./L (10 m buffer)	Invertebrate Chronic TER (5 m Buffer)	Invertebrate Chronic TER (10 m Buffer)
D1 - Ditch	7.03	3.77	**6.4**	11.9
D1 - Stream	8.19	4.34	**5.5**	10.4
D2 - Ditch	7.04	3.77	**6.4**	11.9
D2 - Stream	8.38	4.46	**5.4**	10.1
D3 - Ditch	6.84	3.63	**6.6**	12.4
D4 - Pond	0.759	0.546	59.3	82.4
D4 - Stream	8	4.24	**5.6**	10.6
D5 - Pond	0.76	0.548	59.2	82.1
D5 - Stream	8.64	4.58	**5.2**	**9.8**
D6 - Ditch	11.7	11.7	**3.8**	**3.8**
*R1 - Pond	2.25	2.14	20.0	21.0
*R1 - Stream	14.3	3.23	**3.1**	13.9
*R3 - Stream	18.2	4.48	**2.5**	10.0
*R4 - Stream	8.86	3.25	**5.1**	13.8

*Results for scenario considered uncertain by the peer review.

Chronic TER values for aquatic invertebrates at 5 m and 10 m for potatoes, based on the available NOEC for Daphnia magna, 0.045 mg as/L. TER values shown in bold are less than the relevant Annex VI trigger value of 10. Mitigation of spray drift as well as run-off.

FOCUS Scenario	Potatoes			
	Max PEC Value ug a.s./L (5 m buffer)	Max PEC Value ug a.s./L (10 m buffer)	Invertebrate Chronic TER (5 m Buffer)	Invertebrate Chronic TER (10 m Buffer)
D3 - Ditch	6.86	3.64	**6.6**	12.4
D4 - Pond	0.756	0.544	59.5	82.7
D4 - Stream	7.38	3.91	**6.1**	11.5
D6 - Ditch	6.78	3.59	**6.6**	12.5
D6 - Ditcha	6.92	3.67	**6.5**	12.3

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

FOCUS Scenario	Potatoes			
	Max PEC Value ug a.s./L (5 m buffer)	Max PEC Value ug a.s./L (10 m buffer)	Invertebrate Chronic TER (5 m Buffer)	Invertebrate Chronic TER (10 m Buffer)
*R1 - Pond	1.62	1.49	27.8	30.2
*R1 - Stream	7	3.24	**6.4**	13.9
*R2 - Stream	8.08	4.28	**5.6**	10.5
*R3 - Stream	19.4	4.55	**2.3**	**9.9**

[a] Two potato crops in one season was assumed for this scenario. These figures are for the second crop.
*Results for scenario considered uncertain by the peer review.

Refined aquatic risk assessment for aquatic invertebrates and algae using FOCUS Step 4 modelling - mitigation only of spray drift by distance

Acute TER values for aquatic organisms at 5 m and 10 m buffer zone in winter wheat. TER values shown in bold are lower than the relevant Annex VI trigger value of 10/100. Mitigation of spray drift only.

Scenario	Max PEC ug a.s./L	Max PEC ug a.s./L	Fish LC_{50} = 840 µg/L1		Daphnia EC_{50} =420 µg/L2		Algae EC_{50} = 49 ug/L	
	(5 m buffer)	(10 m buffer)	5 m buffer	10 m buffer	5 m buffer	10 m buffer	5 m buffer	10 m buffer
R1 - Pond	2.60	2.48	323	339	162	169	19	20
R1 - Stream	27.4	27.4	**31**	**31**	**15**	**15**	**1.8**	**1.8**
R3 - Stream	34.4	34.4	**24**	**24**	**12**	**12**	**1.4**	**1.4**
R4 - Stream	21.2	21.2	**40**	**40**	**20**	**20**	**2.3**	**2.3**

1 standard 96-h LC_{50} 840 µg/L as agreed at expert meeting.
2 *Endpoint adjusted from formulation endpoint of 520ug/L based on an 80% nominal concentration factor*

Acute TER values for aquatic organisms at 5 m and 10 m buffer zone in potatoes. TER values shown in bold are less than the relevant Annex VI trigger value of 10/100. Mitigation of spray drift only.

Scenario	Max PEC ug a.s./L	Max PEC ug a.s./L	Fish LC_{50} = 840 µg/L[1]		*Daphnia* EC_{50} = 420 ug/L[2]		Algae EC_{50} = 49 ug/L	
	(5 m buffer)	(10 m buffer)	5 m buffer	10 m buffer	5 m buffer	10 m buffer	5 m buffer	10 m buffer
R1 - Pond	1.92	1.78	438	472	219	236	26	28
R1 - Stream	15.4	15.4	**55**	**55**	**27**	**27**	**3.2**	**3.2**
R2 - Stream	9.18	9.18	**91**	**91**	**46**	**46**	**5.3**	**5.3**
R3 - Stream	36.5	36.5	**23**	**23**	**12**	**12**	**1.3**	**1.3**

[1] standard 96-h LC_{50} 840 µg/L as agreed at expert meeting.
[2] *Endpoint adjusted from formulation endpoint of 520ug/L based on an 80% nominal concentration factor*

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

Chronic TER values for aquatic invertebrates at 5 m and 10 m for wheat, based on the available NOEC for Daphnia magna, 0.045 mg as/L. TER values shown in bold are less than the relevant Annex VI trigger value of 10. Mitigation of spray drift only.

FOCUS Scenario	**Wheat**			
	Max PEC Value ug a.s./L (5 m buffer)	**Max PEC Value ug a.s./L (10 m buffer)**	**Invertebrate Chronic TER (5 m Buffer)**	**Invertebrate Chronic TER (10 m Buffer)**
R1 - Pond	2.60	2.48	17	18
R1 - Stream	27.4	27.4	**1.6**	**1.6**
R3 - Stream	34.4	34.4	**1.3**	**1.3**
R4 - Stream	21.2	21.2	**2.1**	**2.1**

Chronic TER values for aquatic invertebrates at 5 m and 10 m for potatoes, based on the available NOEC for Daphnia magna, 0.045 mg as/L. TER values shown in bold are less than the relevant Annex VI trigger value of 10. Mitigation of spray drift only.

FOCUS Scenario	**Potatoes**			
	Max PEC Value ug a.s./L (5 m buffer)	**Max PEC Value ug a.s./L (10 m buffer)**	**Invertebrate Chronic TER (5 m Buffer)**	**Invertebrate Chronic TER (10 m Buffer)**
R1 - Pond	1.92	1.78	23	25
R1 - Stream	15.4	15.4	**2.9**	**2.9**
R2 - Stream	9.18	9.18	**4.9**	**4.9**
R3 - Stream	36.5	36.5	**1.2**	**1.2**

Bioconcentration				
	Active substance	Met. 1	Met. 2	Met. 3
$logP_{O/W}$	4.48			
Bioconcentration factor (BCF)[1] ‡	X* 700 (whole fish) 480 (fillet) 1100 (viscera)			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	1.7 ± 0.12			
(CT_{90})	5.6 ± 0.40			
Level and nature of residues (%) in organisms after the 14 day depuration phase	1% of total at day 28			

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

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

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s.	No data	>80
Preparation SF245[1]	103.4 (a.s.)	>79.3 (a.s.)
Metabolite 1	-	-
Field or semi-field tests No data – no data required		

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

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

Winter wheat and potatoes, 4000 g/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	<50	50
a.s.	oral	-	50
Preparation SF245	Contact	<50	50
Preparation SF245	oral	39	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri	Preparation YF10911	Mortality	524
Aphidius rhopalosiphi	Preparation YF10911	Mortality	41.8

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

Winter wheat and potatoes, 4000 g/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Preparation YF10911	*Typhlodromus pyri*	524	7.6	0.21	2
Preparation YF10911	*Aphidius rhopalosiphi*	41.8	96	2.6	2

[1] indicate distance assumed to calculate the drift rate

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

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration[1]	Dose (g/ha)	Mortality Reproduction	% adverse effect	Trigger value
Typhlodromus pyri	Proto-nymph	Preparation A-8545-C	60-4000 initial	LR_{50} = 970 g a.s./ha NOER = 500 g a.s./ha	59% mortality at 1000 g a.s./ha	50%
Aphidius rhopalosiphi	adult	Preparation 80EC	500-4000 initial	LR_{50} = 3081g a.s./ha NOER, no reliable value	57% mortality at 4000 g a.s./ha	50%
Crysoperla carnea	larvea	Preparation A-8545-C	60-4000 initial	LR_{50} = 3627 g a.s./ha NOER = 1000 g a.s./ha	53% mortality at 4000 g a.s./ha	50%
Aleochara bilineata	adult	Preparation A-8545-C	60-4000 initial	LR_{50} >4000 g a.s./ha NOER = 4000 g a.s./ha	No effects	50%
Pterostichus melanarius	adult	Preparation 80EW	4000 initial	No effects	No effects	50%
Pardosa sp. and *Alopecosa sp.*	adult	Preparation 80EC	4000 initial	57% mortality after 6 days	57% mortality	50%

[1] all test formulations considered as equivalent to the representative EU formulation, see Annex C

Field or semi-field tests
Pardosa sp. were tested in semi-field enclosures at 4000 g a.s./ha on bare soil and newly emerged winter wheat. No significant effects on mortality compared to control was observed.

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia foetida	a.s.	Acute 14 days	LC_{50corr} = 71.8 mg a.s./kg d.w.soil[1]
	a.s.	Chronic 8 weeks	No data – studies not required
Eisenia foetida	Preparation (80EW)	Acute	LC_{50corr} = >54.5 mg a.s./kg d.w.soil[1]
	Preparation (80EC)	Acute	LC_{50corr} = >3 mg a.s./kg d.w.soil[1]
	Preparation	Chronic	No data – studies not required

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

Test organism	Test substance	Time scale	End point[1]
Other soil macro-organisms			
Soil mite	a.s.		No data – studies not required
	Preparation		No data – studies not required
Collembola			
	a.s.	Chronic	No data – studies not required
	Preparation		No data – studies not required
Soil micro-organisms			
Nitrogen mineralisation	a.s.		<25% effect at day 42 at 5.33 and 53.3 mg a.s./kg d.w.soil (4 and 40 kg a.s/ha)
Carbon mineralisation	a.s. ‡		<25% effect at day 42 at 5.33 and 53.3 mg a.s./kg d.w.soil (4 and 40 kg a.s/ha)
Field studies[2]			
No data – studies not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate:

Test organism	Test substance	Time scale	Soil PEC initial	Soil PEC twa	TER	Trigger
Earthworms						
Eisenia foetida	a.s.	Acute	5.33 mg a.s/kg		13	10
		Chronic	-	-	-	5
	Preparation (80EW)[1]	Acute	5.33 mg a.s/kg		>10.2	10
		Chronic	-	-		5
Other soil macro-organisms						
Soil mite	a.s.	-	-	-	-	-
	Preparation	-	-	-	-	-
Collembola	a.s.	-	-	-	-	-
	Preparation	-	-	-	-	-
Refined risk assessment -						

[1] considered to be equivalent to the representative formulation for the EU assessment, see Annex C.

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

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

Preliminary screening data

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g a.s./ha)[2] vegetative vigour	ER_{50} (g a.s./ha) emergence	Distance (m)	Exposure (g/ha)[1]	TER	Trigger
Tomato, *Lycopersicon esculentum*	Preparation 80EC		335	1	110.8	**3**	5
Tomato, *Lycopersicon esculentum*	Preparation 80EC		335	5	22.8	15	5
Oat, *Avena. sativa*	Preparation 80EC	3140		1	110.8	28	5
Oat, *Avena. sativa*	Preparation 80EC	3140		5	22.8	138	5

[1] Based on 2.77% drift at 1 m and 0.57% at 5 m.

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

No additional studies available

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

Test type/organism	Endpoint
Activated sludge	No study available
Pseudomonas sp	No effect on growth at 11.7 mg a.s./L (water solubility 13 mg/L)

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

Compartment	Ecotoxicologically relevant residue
soil	Prosulfocarb
water	Prosulfocarb
sediment	Prosulfocarb
groundwater	None

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

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

	RMS/peer review proposal		ECB decision
Active substance	N,	Harmful	
	R50/53	Very toxic to aquatic organism, may cause long-term adverse effects in the aquatic environment	
Preparation	N,	Harmful	
	R50/53	Very toxic to aquatic organism, may cause long-term adverse effects in the aquatic environment	

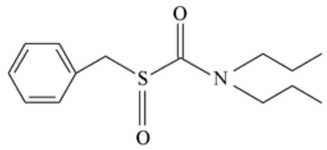
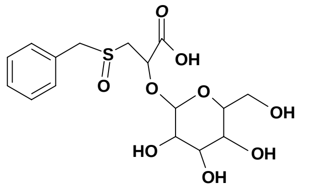
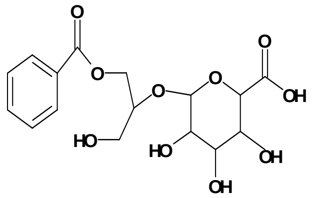
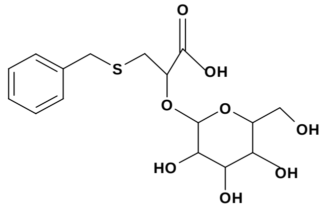
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

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

LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Prosulfocarb sulfoxide	1-(benzylsulfinyl)-N,N-dipropylmethanamide	
2B	3-phenylmethanesulfinyl-2-(3,4,5-trihydroxy-6-hydroxymethyl-tetrahydro-pyran-2-yloxy)-propionic acid	
2C	6-(2-benzoyloxy-1-hydromethyl-ethoxy)-3,4,5-trihydroxy-tetrahydro-pyran-2-carboxylic acid	
2D	3-benzylsulfanyl-2-(3,4,5-trihydroxy-6-hydroxydro-pyran-2-yloxy)propionic acid	
2G glucose conjugate of prosulfocarb.