# CONCLUSION ON PESTICIDE PEER REVIEW

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

## Issued on 26 September 2008

**SUMMARY**

Bensulfuron is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within 6 months a conclusion on the risk assessment to the EU-Commission.

Italy being the designated rapporteur Member State submitted the DAR on bensulfuron in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 11 September 2006. The peer review was initiated on 24 November 2006 by dispatching the DAR for consultation of the Member States and the sole applicant United Phosphorus Limited. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in May-June 2008

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

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on rice for the control of broad-leaved weeds and *Cyperaceae* as proposed by the notifier. Full details of the GAP can be found in the attached list of endpoints.

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

The representative formulated product for the evaluation was Londax®, a water-dispersible granule (WG) containing 600 g/kg of bensulfuron-methyl which is a variant of bensulfuron[2].

The technical specification is not finalised, a data gap was identified for a revised specification. 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. Adequate methods are available to monitor bensulfuron-methyl residues in food/feed of plant origin, soil, surface water and air; however no monitoring methods were submitted for the metabolites set as part of the residue definition in ground water. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

In the mammalian metabolism studies, bensulfuron-methyl was rapidly but incompletely absorbed after oral administration. It was distributed mainly to the gastrointestinal tract, liver, kidneys and plasma and was extensively metabolised, showing no potential for accumulation. The acute toxicity was low, either by the oral, dermal or inhalation route; no eye or skin irritation was observed and no skin sensitisation potential was found in a Magnusson & Kligman test. The main target organ of bensulfuron-methyl was the liver upon short term or long term exposure in either the rat, mouse or dog species; the relevant NOAEL for both short term and long term exposure was the dose level of 19.9 mg/kg bw/day from the one-year dog study. No potential for neurotoxicity, genotoxicity or carcinogenicity was seen with bensulfuron-methyl; no reproductive or fertility effects were observed in a two-generation reproduction toxicity study. Some unspecific effects or delay in the development of rats were observed upon high dosing of bensulfuron-methyl without expressing maternal toxicity, in rabbits only decreased body weight was observed at maternal toxic doses.

The Acceptable Daily Intake (ADI) of bensulfuron-methyl was 0.2 mg/kg bw/day based on the 1-year dog study, applying a safety factor of 100; the Acceptable Operator Exposure Level (AOEL) was 0.12 mg/kg bw/day based on the same 1-year dog study, safety factor of 100, and applying a correction factor of 60 % for low oral absorption; no Acute Reference Dose (ARfD) was allocated. Dermal absorption was 5.9 % for the concentrate representative formulation and 7.2 % for the in-use spray dilution, based on an *in vivo* study in rat. The level of operator exposure calculated for the representative formulation Londax® (a water dispersible granule (WG) formulation containing 600 g/kg of bensulfuron-methyl), at a maximum dose rate of 0.06 kg bensulfuron-methyl/ha in rice was below the AOEL according to the UK POEM, only when the use of personal protective equipment (PPE) as gloves during mixing/loading and application was considered; according to the German model, estimated exposure was below the AOEL even when no PPE were worn. Estimated exposure of workers entering crops treated with bensulfuron-methyl was below the AOEL, without the use of PPE. Bystander exposure was low compared to the AOEL value.

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[2] Bensulfuron (IN-R9419): α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*o*-toluic acid

In metabolism studies with radio labelled bensulfuron-methyl in paddy rice, upon application to the water surface, levels of total radioactivity recovered in rice plants were very low and hence identification of residues was limited to the extractable radioactivity from foliage and straw. Neither intact bensulfuron-methyl nor bensulfuron was detected, but, though at very low levels, some metabolites could be identified that indicate a cleavage of the sulfonylurea bridge occurred. In the meeting of experts the need for further data on the nature of the residue in plants with foliar exposure and in rotational crops was identified. Therefore a residue definition for risk assessment and MRL setting purposes could only be proposed provisionally as bensulfuron-methyl.

Residue trials with post-emergence application to rice plants indicate that under practical conditions, residues of bensulfuron-methyl above the limit of quantification (LOQ) are not expected in rice grain, while in rice straw residues above the LOQ could be found in one trial.

In a confined rotational crop study total residues in the rotated crops did not exceed 0.01 mg/kg, however data indicated an increase of residues in rotated cereals with time and thus clarification on potential uptake of soil metabolites is required.

No significant residues are expected to occur in commodities to be processed or used in livestock diet, and therefore no further investigation in processing studies and livestock studies is required to support the representative uses in rice.

In a provisional chronic consumer exposure and risk assessment, based on the provisional residue definition for risk assessment, it was demonstrated that the maximum estimated dietary intake of residues of bensulfuron-methyl is well below (<1%) the toxicological reference value ADI. As no ARfD was allocated an acute risk assessment is not considered necessary.

Based on the available environmental fate and behaviour studies in aerobic soil and aerobic natural sediment water systems it was identified that bensulfuron-methyl and the breakdown products IN-F7880[3] (max 9.7% applied radioactivity (AR) in whole natural sediment water systems), bensulfuron (max 27.7% AR in soil), IN-J0290[4] (max 46% AR in soil), IN-N5297[5] (max 31.7% AR in whole natural sediment water systems), IN-DAT97[6] (max 9.9% AR in whole natural sediment water systems) and IN-D1R84[7] (max 18.2% AR in soil) needed environmental exposure assessments. In a sterilised natural water (indirect) aqueous photolysis study IN-T5831[8] was formed at up to 13.7% AR. An environmental exposure assessment was also completed for this metabolite. These observed formation fractions were used as the basis for calculating the available environmental exposure assessments. Bensulfuron-methyl was characterised as exhibiting moderate to high persistence, IN-F7880 low to medium persistence, bensulfuron low to moderate persistence, IN-J0290 low to moderate persistence, IN-N5297 low to medium persistence, IN-T5831 no data available but

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[3] IN-F7880: methyl 2-({[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}methyl)benzoate
[4] IN-J0290: 4,6-dimethoxypyrimidin-2-amine
[5] IN-N5297: methyl 2-(sulfamoylmethyl)benzoate
[6] IN-DAT97: {[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}acetic acid
[7] IN-D1R84: 2-(sulfamoylmethyl)benzoic acid
[8] IN-T5831: (4,6-dimethoxypyrimidin-2-yl)urea

considered to have moderate persistence on the basis of structural similarity to IN-J0290, IN-DAT97 moderate persistence and IN-D1R84 low to moderate persistence.

Mineralisation of both the phenyl and pyrimidine rings to carbon dioxide accounted for 12-39% AR after 95-119 days and 2-25% AR after 95-119 days respectively in the available aerobic studies. The formation of unextractable residues was a significant sink, accounting for 11-37 % AR (same radiolabels, results amalgamated) after 95-119 days in these studies. A data gap was identified for experimental data on the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions (that needs to include alkali soil conditions).

Bensulfuron-methyl was characterised as exhibiting medium to low mobility, IN-F7880 high to medium mobility, bensulfuron very high to low mobility, IN-J0290 high to low mobility, IN-N5297 very high to high mobility, and IN-D1R84 very high mobility. For IN-T5831 and IN-DAT97 no experimental data were available and a data gap was identified. The environmental exposure assessment was completed assuming that these two compounds (IN-T5831 and IN-DAT97) exhibited very high mobility. Using this assumption the assessment indicated that mitigation to reduce the potential for the exposure of groundwater may be necessary for these two metabolites for one of the applied for intended uses in situations represented by the MED-Rice sand groundwater scenario.

The information available was insufficient to enable a satisfactory environmental exposure assessment to be completed in line with agreed MED-Rice (2003) guidance[9], due to the data gaps identified above. A triggered higher tier exposure assessment for bensulfuron-methyl regarding natural surface water and sediment for situations represented by the MED-Rice sand soil scenario and for all scenarios where application is made before sowing the rice crop is missing. Whilst a higher tier exposure assessment regarding natural surface water and sediment for situations represented by the MED-Rice clay soil scenario for bensulfuron-methyl and post planting applications is available, the Member State experts did not accept the soil $DT_{50}$ used as input (field dissipation value) to the RICEWQ module of the simulations or the way the exposure concentrations (90th percentile 14 day TWA values) provided by the applicant had been calculated. The experts agreed that there was a data gap for 90th percentile 14 day TWA values to be represented in a way that has some meaning for an edge of field risk assessment. The approach used by the applicant in the available assessment mixed temporal and spatial factors in an inappropriate way, such that the resulting aquatic risk assessment does not demonstrate in which (if any) situations the active substance might be used without impacting on populations of aquatic species, which is what Member State experts agreed would be required to demonstrate compliance with annex VI criteria.

It can be concluded that the potential for bensulfuron-methyl to contaminate vulnerable groundwater above the parametric drinking water limit of 0.1μg/L from the applied for intended uses is low. For the known metabolites, based on the available data, there are indications that this is also the case

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[9] Sanco/1090/2000-rev.1 June 2003 Guidance document for environmental risk assessments of active substances used on rice in the EU for annex 1 inclusion. Document prepared by Working Group on MED-Rice.

when applications are made to paddies with a 10cm layer of water overlying the soil and for shallower paddy water depths in situations represented by the MED-Rice clay scenario. However in situations represented by the MED-Rice sand scenario where applications are made to paddies with <10cm overlying water it cannot be excluded with the available data that IN-5297, IN-T5831 and IN-DAT97 may be present in vulnerable groundwater at > 0. 1µg/L (calculations indicate concentrations up to 0.23µg/L). Therefore a non relevance assessment for these three metabolites was triggered, but these are not available. In the absence of data to assess the non relevance of these metabolites, the available groundwater exposure assessments indicate that risk management options may be effective at mitigating the potential for groundwater exposure by these metabolites in regions represented by the MED-Rice sand scenario. However the groundwater assessment for metabolites cannot be finalised until the data gap for experimental data on the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions (that needs to include alkali soil conditions) has been filled.

Bensulfuron-methyl is used as a herbicide and it is very toxic to aquatic and terrestrial plants. A low risk to the aquatic environment (algae and macrophytes) was not demonstrated using the submitted data and further refinement of the aquatic risk assessment is needed. The risk to non-target terrestrial plants in the off-field area needs to be mitigated. Risk mitigation comparable to an in-field no-spray buffer zone of 5 m is required to protect non-target terrestrial plants.
The risk to birds, mammals, fish and aquatic invertebrates, bees, non-target arthropods, earthworms, soil non-target macro- and micro-organisms, and biological methods of sewage treatment was assessed as low for the representative uses evaluated.

**Key words: bensulfuron, bensulfuron-methyl, 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 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Bensulfuron is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Italy as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Italy submitted the report of its initial evaluation of the dossier on bensulfuron, hereafter referred to as the draft assessment report, received by EFSA on 11 September 2006. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 24 November 2006 to the Member States and the main applicant United Phosphorus Limited as identified by the rapporteur Member State.

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

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

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

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

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

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

- the comments received,
- the resulting reporting table (rev 1-1 of 28 February 2008)

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

- the reports of the scientific expert consultation,
- the evaluation table (rev 2-1 of 22 September 2008).

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


# THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Bensulfuron is the ISO common name for α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*o*-toluic acid (IUPAC).
However the data submitted in the dossier relate to the variant bensulfuron-methyl, which is methyl α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*o*-toluate.

Bensulfuron belongs to the class of pyrimidinylsulfonylurea herbicides. Bensulfuron acts through inhibition of the enzyme acetolactate synthase (ALS) involved in the synthesis of branched-chain amino acids, leading to the cessation of cell division and subsequent growth processes in plants. Bensulfuron is primarily adsorbed through the leaves. Bensulfuron is used in rice for the control of broad-leaved weeds and *Cyperaceae*.

The representative formulated product for the evaluation was Londax®, a water-dispersible granule (WG) containing 600 g/kg of bensulfuron-methyl, registered under different trade names in Europe.

The representative uses evaluated comprise pre-sowing and post emergence applications with tractor-mounted spraying devices to control annual weeds (*Alisma plantago aquatica, Alisma lanceolata, Ammania coccinea, Bergia spp, Bolboschenus (Scirpus) maritimus, Schoenoplectus (Scirpus) mucronatus, Scirpus supinus, Butomus umbellatus, Cyperus spp., Lindernia spp., Heterantera reniformis, Heteranthera rotundifolia, Sparganium erectum, Typha spp*) in flooded rice from 2 to 5 days before sowing, or between growth stages of BBCH 12 up to BBCH 29 respectively; and post emergence applications in dry land rice between growth stages of BBCH 12 up to BBCH 29, one application per year, with maximum application rate of 60 g a.s./ha, in all Europe.

## SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of bensulfuron-methyl is still open as the experts at the PRAPeR Meeting 46 (May 2008) did not accept the technical specification for the active substance and proposed a data gap for the applicant to provide a revised specification, removing the impurities below 1 g/kg, or to provide more information on the QC data to support the specification.

The minimum purity of bensulfuron-methyl in the FAO specification 502/TC/2002 is 975 g/kg.

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 bensulfuron-methyl or the respective formulations. However, the following data gaps were identified:

- a GLP study for the determination of the vapour pressure
- a new calculation for Henry's law constant based on the vapour pressure

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

Adequate analytical methods based on HPLC-UV (CIPAC 502/TC/M, 502/WG/M) are available for the determination of bensulfuron-methyl in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material (HPLC-UV and GC-FID).

Sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor bensulfuron-methyl residues in food/feed of plant origin soil, surface water and air, however no monitoring methods were submitted for the metabolites set as part of the residue definition in ground water. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

Several analytical methods are available to monitor residues of bensulfuron-methyl in plant matrices, based on HPLC-UV, LC-MS and LC-MS/MS with LOQ of 0.01 mg/kg in rice grain and 0.05 mg/kg in rice straw.

Adequate HPLC-MS/MS methods are available to monitor residues of bensulfuron-methyl in soil with LOQ of 0.05 µg/kg.

An HPLC-MS/MS method is available to monitor bensulfuron-methyl in water (drinking water, surface water) with LOQ of 0.05 µg/L. No method has been submitted for the determination of metabolites IN-N5297[10], IN-T5831[11], IN-DAT97[12] in ground water and as a consequence a data gap was identified for an analytical method for the determination of the respective metabolites in drinking/ground water.

Residues of bensulfuron-methyl in air can be determined with HPLC-MS/MS with LOQ of 3 µg/m³ Analytical methods for the determination of residues in body fluids and tissues are not required as bensulfuron-methyl is not classified as toxic or highly toxic.

# 2. Mammalian toxicology

Bensulfuron-methyl was discussed at the PRAPeR Expert's Meeting on mammalian toxicology (PRAPeR 49) in June 2008.

No technical specification was agreed by the meeting on physical and chemical properties (PRAPER 46) and the toxicological profile of batches used in key studies was not provided; the meeting set a data gap for this information.

## 2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Bensulfuron-methyl was rapidly absorbed after oral dosing; peak plasma concentrations occurred 1 to 4 hours after a low dose of 20 mg/kg bw, and 4 to 12 hours after a high dose of 1000 mg/kg bw. Based on the amount of radioactivity recovered in urine, cage wash and tissues 96 hours after administration, the oral absorption from the gastrointestinal tract was estimated to be around 60 % (about 60 % in males and 65 % in females). Excretion through the bile was 16 to 29 % after 24 hours; however, this finding could not be used for the assessment of oral absorption as no determination of the urinary excretion was conducted in the same study.

Highest concentrations of active substance were found in the gastrointestinal content and tissue, liver, kidneys and plasma; 196 hours after dosing, less than 0.3 % of the dose remained in the tissue and carcass. At a low dose level, bensulfuron-methyl was excreted mainly by the urine (44 to 58 % of the dose); faeces represented 27 to 42 % of the excreted dose in 96 hours.

Extensive metabolism was observed mainly by *O*-demethylation and hydroxylation of the pyrimidine ring, as well as by sulphonamide cleavage. IN-F7880[13] was a major metabolite found in plasma, bile (8.3-13.7 % of administered dose), faeces (8.8-21.2 %) and urine (3.5-27.9 %). For some metabolites, toxicity studies were provided (see chapter 2.8), metabolite IN-N5297 was found in urine and faeces of rats at levels of 0.2 to 1.7 % of the administered dose; bensulfuron was also found in urine at levels of 0.6 to 1.8 % and in faeces at levels between < 0.05 to 1.2 %.

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[10] IN-N5297 : methyl 2-(sulfamoylmethyl)benzoate
[11] IN-T5831: (4,6-dimethoxypyrimidin-2-yl)urea
[12] IN-DAT97: {[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}acetic acid
[13] IN-F7880 : methyl 2-({[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}methyl)benzoate

## 2.2. ACUTE TOXICITY

Bensulfuron-methyl presented low acute toxicity, either by the oral, dermal or inhalation route; no skin or eye irritation was observed and no potential for skin sensitisation was seen in a Magnusson and Kligman test.

## 2.3. SHORT TERM TOXICITY

The oral short term effects of bensulfuron-methyl were investigated in a 90-day feeding study in rat, mice and dog, and a one-year feeding study in dog.

The main target organ of bensulfuron-methyl was the liver in rat, mouse and dog. In rat, slight effects were also observed on blood parameters and on cholesterol levels; the NOAEL was set at the 93 mg/kg bw/day dose level based on the liver and cholesterol effects seen at 475 mg/kg bw/day. In mouse, enlarged liver was associated with histopathological changes, mainly centrilobular swelling of hepatocytes that was not considered adverse by the rapporteur Member State. Upon an extensive discussion on the relevance of these findings, the experts agreed that they should be considered as adverse at the two highest dose levels from 387 mg/kg bw/day and up, and the NOAEL was set at 132 mg/kg bw/day. In dog, the relevant NOAEL was the dose level of **19.9 mg/kg bw/day** from the 1-year study based also on liver weight, clinical chemistry and histopathological changes.

## 2.4. GENOTOXICITY

A comprehensive data package of genotoxicity studies was submitted, including a gene mutation assay in bacterial and mammalian cells, a chromosome aberration test in human lymphocytes, a sister chromatid exchange test and unscheduled DNA synthesis *in vitro*; the *in vivo* genotoxic potential of bensulfuron-methyl was tested in a chromosome aberration test in rat bone marrow. One positive response occurred in an *in vitro* study (sister chromatid exchange) in the absence of metabolic activation, all other studies gave negative results; therefore no genotoxic potential was attributed to bensulfuron-methyl.

## 2.5. LONG TERM TOXICITY

Long term toxicity was examined in a two-year study in rat and in mouse.

In rat, the liver was again the target organ of bensulfuron-methyl, the high dose of 309 mg/kg bw/day produced decreased body weight, decreased haemoglobin concentration and histopathological changes in the liver with higher incidence after one year of treatment than at the end of the study. The NOAEL was the dose level of 30 mg/kg bw/day.

Initially in the draft assessment report, the rapporteur Member State proposed the highest dose tested in mice as the NOAEL of the study, the experts considered that the liver parameters (enlarged liver, masses, hepatocellular swelling and necrosis) were indicative of hepatic toxicity and set the NOAEL at the next lower dose level of 226 mg/kg bw/day.

No carcinogenic effect was observed in either rats or mice.

## 2.6. REPRODUCTIVE TOXICITY

Reproductive toxicity of bensulfuron-methyl was tested in a two-generation reproduction toxicity study in rat, and a developmental toxicity study in rat and in rabbit.

Reproduction toxicity

The main effect found in this study was decreased body weight in the $F_1$ parents and $F_1$ offspring, resulting in decreased pup body weight without apparent parental toxicity. Liver toxicity was not investigated in the study, but could be expected at the same dosing regime as the one used in the long term toxicity study. Considering the whole weight of evidence from other studies, the experts agreed that the decreased body weight of pups would be related to parental toxicity, therefore the NOAEL for both offspring and parental toxicity was set at the 250 ppm dose level, corresponding to 19.5 mg/kg bw/day dose intake for the parents and to 22.3 mg/kg bw/day for the offpring. No effect was observed on the fertility or reproductive parameters, the reproductive NOAEL was the highest dose tested of 1404.5 mg/kg bw/day.

Developmental toxicity

In the developmental toxicity study in rat, no maternal toxicity was found up to 2000 mg/kg bw/day (twice the limit dose for this type of test), but several skeletal variations were found in foetuses, as increased incidence of lumbar ribs, incompletely ossified hyoid bones and extra rib ossification centre. Investigations on maternal liver toxicity were limited to the analysis of liver weights, for which no effect was observed, but the experts noted that the period of dosing was very short (10 days) to obtain a good indication of liver toxicity (by liver weight change). The maternal NOAEL was 2000 mg/kg bw/day and the developmental NOAEL was 500 mg/kg bw/day. Considering the kind of effect observed (unspecific and characteristic of developmental delay) and the dose at which they appeared, the meeting did not consider it appropriate to propose a classification for bensulfuron-methyl related to developmental toxicity.

In rabbit, both maternal and foetal NOAELs were the dose level of 300 mg/kg bw/day, based on maternal mortality and decreased body weight, increased resorptions and reduced foetal weight at the highest dose level of 1500 mg/kg bw/day.

## 2.7. NEUROTOXICITY

No study was provided. Bensulfuron-methyl does not belong to a chemical group known to induce neurotoxicity, no concern was raised from the other general studies, and therefore no study was required.

## 2.8. FURTHER STUDIES

Metabolites

Supplementary studies were conducted on four rat metabolites of bensulfuron-methyl.

**IN-B6895-2**[14]

The approximate lethal dose (ALD) of this bensulfuron-methyl metabolite was estimated to be 11,000 mg/kg bw in male rat.

An Ames test gave negative results in *Salmonella typhimurium*.

**IN-N5297**

The approximate lethal dose (ALD) of this bensulfuron-methyl metabolite was estimated to be 7,500 mg/kg bw in male rat.

An Ames test gave negative results in *Salmonella typhimurium*.

**bensulfuron**

The approximate lethal dose (ALD) of this bensulfuron-methyl metabolite was estimated to be higher than 11,000 mg/kg bw in male rat.

An Ames test gave negative results in *Salmonella typhimurium*.

**IN-J290-17**[15]

The combined male and female oral $LD_{50}$ of this bensulfuron-methyl metabolite was 1200 mg/kg bw in rat.

A ten-dose oral subacute test produced moderate to severe initial weight loss and salivation at the dose level of 450 mg/kg bw/day in male rats.

This metabolite was negative in an Ames test in *Salmonella typhimurium* and *E. coli*.

## 2.9. MEDICAL DATA

Bensulfuron-methyl has been produced on a commercial scale for more than 17 years; the medical records of randomly selected employees at the manufacturing site from manufacturing, formulation and packaging areas did not indicate any occupational illness or symptoms associated with the active substance.

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

ADI

In the draft assessment report the rapporteur Member State proposed an ADI of 0.2 mg/kg bw/day based on the 1-year dog study presenting a NOAEL of 19.9 mg/kg bw/day with a safety factor of 100. This approach was agreed by the experts at the meeting. The **ADI for bensulfuron-methyl was established at 0.2 mg/kg bw/day**

AOEL

The approach followed for the ADI was considered applicable to the AOEL setting, the rapporteur Member State proposed an AOEL of 0.2 mg/kg bw/day based on the 1-year dog study and a safety

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[14] IN-B6895-2: 1*H*-2, 3-benzothiazin-4(3*H*)-one 2,2-dioxide or homosaccharin
[15] IN-J290-17: 4,6-dimethoxypyrimidin-2-amine

factor of 100. The approach was agreed by the experts; however a new value for oral absorption of 60 % was agreed by the meeting, therefore, the AOEL was corrected accordingly. **The resulting AOEL was 0.12 mg/kg bw/day.**

ARfD

The rapporteur Member State provided the rationale related to the ARfD in the addendum 1 to volume 3, considering that no ARfD was necessary for bensulfuron-methyl.

The experts agreed with the rapporteur Member State. **No ARfD was allocated.**

## 2.11. DERMAL ABSORPTION

Dermal absorption was investigated in an *in vivo* study in the rat conducted with the representative formulation Londax® (a water dispersible granule (WG) formulation containing 600 g bensulfuron-methyl/kg). The rapporteur Member State proposed to use the values obtained at the 10-hour time point, however as the excretion was still increasing at the 24-hour time point, the experts considered the latter more appropriate to derive the dermal absorption value. Accordingly, adding the radioactivity found in carcass, blood, urine, faeces and dosed skin at the 24-hour time point, dermal absorption is 5.9 % when handling the concentrate formulation and 7.2 % for the in-use spray dilution.

## 2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Londax ® is a water dispersible granule (WG) formulation containing 600 g bensulfuron-methyl/kg. It is a pre-sowing or post-emergence selective herbicide used in rice crops. Applications are performed via tractor mounted air blast sprayers (low crops) at a maximum dose rate of 0.06 kg bensulfuron-methyl/ha with a minimum application volume of 200 L/ha. Only one application per year is proposed.

The rapporteur Member State recalculated the operator, worker and bystander exposure in the addendum 2 to volume 3, B.6, taking into consideration the parameters agreed at the PRAPeR meeting.

Operator exposure

The operator exposure estimates were calculated using both the German and the UK POEM models. According to the German model assumptions, the body weight of operators is 70 kg and 20 ha are treated per day. According to the UK POEM, body weight of operators is 60 kg and 50 ha are treated per day, packaging of 1 kg was considered.

Estimated operator exposure presented as % of AOEL (0.12 mg/kg bw/day) in rice, application rate of 0.06 kg bensulfuron-methyl/ha

| Tractor-mounted (field crop) | No PPE | With PPE[a] during M/L & application |
|---|---|---|
| UK POEM | 258.5 | 4.6 |
| German model | 3.91 | 0.29 |

[a] PPE: gloves

According to the UK POEM, estimated exposure of operators is below the AOEL when personal protective equipment (PPE) is worn (gloves during mixing/loading and application); according to the German model, the estimated exposure of operators is below the AOEL even without the use of PPE.

Worker exposure

Estimation of worker exposure was performed according to the model developed by the German BBA (Krebs *et al.* 2000). Transfer factor of 5000 [$cm^2$/person/h] was considered; foliar dislodgeable residue per 1 kg bensulfuron-methyl/ha (FDR) of 3 [μg bensulfuron-methyl/$cm^2$/kg bensulfuron-methyl/ha], default value of 60 kg for worker body weight, dermal absorption of 5.9 %.
The resulting worker exposure estimate represents **5.4 % of the AOEL** of 0.12 mg/kg bw/day.
Therefore, after the spray solution has dried, the estimated exposure to bensulfuron-methyl during re-entry operations does not exceed the AOEL, even if no PPE are worn.

Bystander exposure

Estimation of bystander exposure considered both dermal exposure derived from available drift data (Ganzelmeier *et al.* 1995), and inhalation exposure derived from the German model operator exposure. The drift rate during spraying in orchard (high crops) at a distance of 7.5 m from the spray equipment was 2.6 %; a default surface area of 1 $m^2$/person was assumed. Using the proposed absorption rates of 7.2 % for dermal exposure (diluted spray) and 100 % for inhalation exposure, the estimated bystander exposure represents **0.3 % of the AOEL** of 0.12 mg/kg bw/day.

# 3.    Residues

Bensulfuron was discussed in the meeting of experts in residues in June 2008 (PRAPeR 50, round 10).
It is noted that the methyl ester, a variant of bensulfuron, was used in the residue studies. Thus the evaluated data belong to the variant bensulfuron-methyl and the reported residue levels are expressed as bensulfuron-methyl, unless otherwise specified.

## 3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

### 3.1.1. PRIMARY CROPS

The behaviour and metabolism of bensulfuron was investigated in Paddy rice using pyrimidinyl-[$^{14}$C]-labelled and phenyl-[$^{14}$C]-labelled bensulfuron-methyl applied as granules at a rate that was slightly exaggerated (1.5 N) compared to the notified representative application rate.

The meeting of experts considered the design of the available metabolism study is not representative of all notified uses. In the study the active substance was applied as granules to the water surface of a miniature paddy. The leaves of the plants therefore did not come in direct contact with the substance. This is however expected to occur during a post-emergence broadcast application at the maximum tillering stage, as intended with the notified uses. Therefore the experts proposed the notifier to either conduct a new metabolism study considering foliar exposure or, if applicable, to provide comparative data on other sulfonylurea herbicides with similar use patterns in order to clarify the nature of residues upon a foliar application.

In the submitted study, total radioactivity in mature rice grain was very low (0.003 mg/kg) and an attempt of identification was unsuccessful. Though the total residues were also low in immature and mature foliage (0.009 mg/kg), attempts were made to identify the radioactivity readily extractable from the plant matrix. Upon analysis of foliage extracts neither bensulfuron-methyl nor bensulfuron was detected. Metabolites identified at different sampling intervals were very similar in structure, indicating cleavage of the sulfonylurea bridge was a major step in metabolism of bensulfuron-methyl. None of the identified metabolites was present in significant amounts in the immature or mature plants, however accurate quantitation was not possible due to the very low levels. For the same reason the nature of non-extractable residues was not further investigated.

Based on the information available, that might only support a pre-emergence use on rice, a metabolic pathway was proposed for bensulfuron-methyl that involves O-demethylation of a methoxy group on the pyrimidine ring (IN-F7880) and/or cleavage of the pyrimidine ring from the benzyl moiety, yielding metabolites sulphonamide (IN-N5297), homosaccharin (IN-B6895-2) and pyrimidine amine (IN-J0290). All metabolites identified were also seen in the rat metabolism study.

It can be concluded that, in a scenario where foliar exposure of rice plants does not occur, bensulfuron or its methyl ester is not a major component of the residue in the crop, but metabolites or degradation products formed by cleavage of the sulfonylurea bridge do occur. None of the identified metabolites were present in rice plants in significant amounts following a treatment under the conditions used in the available study. Further data to confirm the relevance of these results to all possible scenarios of use of bensulfuron-methyl in rice are still required. Moreover a final plant residue definition is pending further data on the nature of the residue in rotated crops, in particular other cereal crops.

Therefore it was agreed in the meeting of experts that the residue definition for risk assessment and monitoring purposes should currently be provisional, and has been proposed by default as bensulfuron-methyl.

To investigate the residue levels of bensulfuron-methyl in treated rice, residue trials were conducted in major rice production areas in southern Europe, 10 on flooded rice and 4 on dry land rice. Bensulfuron-methyl, single formulated or co-formulated with metsulfuron, was applied according to GAP criteria. Grain and straw samples were taken at maturity of the crop at PHIs ranging from 67 to 144 days. A total of 13 trials were considered valid and acceptable for further assessment. The results are supported by valid freezer storage stability data in rice matrices and validated analytical methods. Residues were always below the LOQ in grain (0.01 mg/kg and 0.02 mg/kg, respectively) and mostly in straw samples (0.05 mg/kg) with one exception where residues of 0.1 mg/kg were found.

Since levels of bensulfuron-methyl in rice grain were always below the LOQ of the analytical method, no studies on the level and nature of residues in processed grain are required.

### 3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Some soil metabolites of bensulfuron-methyl were found to be moderately persistent, and moreover data on their toxicity is limited (for details refer to chapter 4.1). Therefore, the investigation of potential residues in succeeding crops was considered a necessary step in the assessment of the notified representative uses.

The residue behaviour of bensulfuron in succeeding and rotational crops was investigated in a confined rotational crop study. Field plots were treated with pyrimidine and phenyl-labelled bensulfuron-methyl in a mixture of sand and water at a rate corresponding to the notified application rate and aged for 120 days. Soil to a depth of 15 cm was transferred to greenhouse pots, and model crops of the categories cereals (wheat), root and tuber crops (beets, onions, garlic) and leafy crops (cabbage) were planted. Crop samples were taken at different stages of maturity. The total radioactive residues in all crops and matrices were generally low (below or at 0.01 mg/kg), but the meeting of experts noticed that there was an increase of the TRR values mostly in wheat along with the sampling time intervals up to final harvest. Due to the low residue levels, identification of metabolites in the crop samples was not attempted.

The major part of the metabolites identified in soil was not found in the primary plant metabolism study, and some of them were not identified either in rat metabolism. Therefore, the experts recommended that further investigation on metabolite identity should be carried out in rotated crops considering the potential for uptake of soil metabolites.

Hence a new data gap was proposed for the requirement of further metabolite identification, in particular in the rotated cereals (wheat). A final plant residue definition is pending the submission of these data (see also chapter 3.1.1 above).

## 3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

With regard to the notified representative use in rice no significant residues are expected to occur in livestock diet, and therefore the submission of livestock studies was not a requirement. Studies on the metabolism of orally administered phenyl-labelled bensulfuron-methyl in lactating goats and phenyl-labelled and pyrimidine-labelled bensulfuron-methyl in laying hens were submitted and summarised in the DAR for future reference but not peer reviewed.

The meeting of experts concluded that with regard to the notified representative use a livestock residue definition for risk assessment and monitoring does not need to be proposed.

## 3.3. CONSUMER RISK ASSESSMENT

The chronic dietary risk assessment for consumers is based on the **provisionally** proposed residue definition, the currently proposed MRL (see 3.4 below) and on consumption data from the WHO/GEMS Food European diet, the WHO cluster diets and national consumption data from Germany and UK, respectively.

The TMDI from the consumption of rice grain for all considered consumer groups (adults, toddlers, and children) are all significantly below (< 1%) the allocated ADI of 0.2 mg/kg bw/day for bensulfuron-methyl. As no ARfD was allocated an acute risk assessment is not considered necessary.

**Note:** The risk assessment presented above is pending confirmation on the residue definition for risk assessment. Moreover there is a potential for consumer exposure to residues in ground water used as drinking water, however an accurate assessment is currently pending the submission of further data in the areas of toxicology and environmental fate and behaviour.

## 3.4. PROPOSED MRLS

The MRL proposal is based on the **provisionally** proposed residue definition for monitoring.

In supervised residue trials in rice no residues of bensulfuron-methyl were determined above the LOQ of 0.02 mg/kg and thus the MRL currently proposed for rice grain is 0.02* mg/kg.

No MRLs are proposed for food of animal origin.

# 4. Environmental fate and behaviour

The bensulfuron-methyl variant of bensulfuron was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 47 in May 2008.

## 4.1. FATE AND BEHAVIOUR IN SOIL

### 4.1.1. ROUTE OF DEGRADATION IN SOIL

Soil experiments (3 different soils) were carried out under aerobic conditions in the laboratory (20-25°C 40-70% maximum water holding capacity (MWHC)) in the dark.  Mineralisation to carbon

dioxide of the applied phenyl ring-^{14}C-radiolabel accounted for 13-39 % of the applied radiolabel (AR) after 95-119 days. These values for the pyrimidine ring-^{14}C-radiolabel were 2-25% AR. The formation of residues not extracted by supercritical fluid (ammonia:carbon dioxide:acetone) extraction or basified methylene chloride /methanol were a sink for the applied radiolabels (accounting for 11-25% AR after 95-119 days and 13-26% AR after 95-119 days respectively). The major (>10 AR) extractable breakdown products present were: bensulfuron (max. 27.7% AR at 31 days), IN-D1R84[16] (max. 18.2% AR at 122 days) IN-J0290 (max. 46% AR at 245 days) and IN-N5297 (max. 21% AR at 56 days).

Though information on the route of degradation under aerobic not flooded conditions was available in a further three soils, the results from these experiments were concluded (by the RMS in the DAR) as being unreliable regarding the route of degradation, as recoveries of the applied radioactivity was low and the basic extraction conditions utilised in the study resulted in the formation of at least 1 major metabolite that was an artefact of the extraction conditions used. The peer review agreed that the results from these experiments should not be relied on regarding the route of degradation (but could be used to estimate degradation rates of bensulfuron-methyl, see section 4.1.2).

As the applied for intended use of bensulfuron-methyl is for rice, the relevant EU MED-Rice (2003) guidance[17] requires that aerobic laboratory flooded soil degradation studies are provided on at least 2 soils. Such experiments were not included in the applicant's dossier. The Member State experts discussed if the 'aerobic aquatic metabolism study' (Hunt, 1986) evaluated by the RMS in section B.8.4.4 of the DAR, might be sufficient to provide the necessary information for the exposure assessment that should come from aerobic laboratory flooded soil degradation studies. The conclusion of the experts was that this would not be appropriate. The main deficiencies identified in the study design were that deionised water and not a paddy water had been utilised and that the Japanese and USA soils used did not have soil properties that were representative of EU rice soils. The experts therefore confirmed the conclusion that the RMS had presented in the DAR that there was a data gap for aerobic laboratory flooded soil degradation studies on at least 2 soils that are representative of EU rice growing soils. The peer review had also noted that all the available reliable soil degradation studies where bensulfuron-methyl was dosed had been carried out using acidic soils (pH 5.2-6.7) and generally EU rice soils had neutral / alkaline pH (up to pH 8.5). They therefore identified that in any new experiments that might be provided in the future, a neutral / alkaline soil should be investigated.

Data on anaerobic degradation in an experiment on a single silt loam soil (25°C) identified that bensulfuron-methyl degrades at a comparable, though slightly slower rate than under aerobic conditions and formed the major breakdown products: bensulfuron (max. 15% AR at 252 days), IN-J0290 (max. 18% AR at 175 days) and IN-N5297 (max. 16% AR at 56 days) already identified under aerobic conditions (see addendum 1 to B.8 of the DAR pages 3-6 where corrected results tables for

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[16] IN-D1R84: 2-(sulfamoylmethyl)benzoic acid
[17] Sanco/1090/2000-rev.1 June 2003 Guidance document for environmental risk assessments of active substances used on rice in the EU for annex 1 inclusion. Document prepared by Working Group on MED-Rice.

this experiment are presented). In a laboratory soil photolysis study on air dried soil, the breakdown product IN-N5297 (also formed in the dark), as well as the novel breakdown product IN-T5831 were identified. The degradation of bensulfuron-methyl was significantly faster in irradiated samples than in the dark controls. As the applied for intended use recommends applications are made when 5-10 cm of water are present in the paddies and that this water must be retained for at least 15 days, photolysis at the surface of dry soil is unlikely to be an important process regarding the uses that are assessed in this conclusion.

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

The rate of degradation of bensulfuron-methyl was estimated from the results of the studies described in 4.1.1 above. Single first order $DT_{50}$ from the three soils used to characterise the aerobic route of degradation were: 25 days (20°C 50%MWHC), 89 and 89 days (both 25°C 70%MWHC). These values for the other 3 soils were 65, 90 and 102 days (25°C 70%MWHC).

Under anaerobic laboratory conditions (25°C, flooded, experiment already described at 4.1.1 above) a single first order whole system $DT_{50}$ for bensulfuron-methyl of 118 days was estimated.

Experiments were available that determined laboratory (aerobic, dark, 20°C, 40%MWHC) single first order soil $DT_{50}$ for 5 breakdown products (bensulfuron, IN-J0290, IN-N5297, IN-F7880 and IN-D1R84). The peer review agreed the endpoints from these studies as set out in appendix 1. With the exception of those for IN-D1R84, these $DT_{50}$ were not used in the environmental exposure assessment PEC calculations as total system aerobic sediment water $DT_{50}$ values were considered the most pertinent values to utilise in exposure calculations for the applied for intended use on rice (see section 4.2.1). For IN-D1R84 the single first order soil $DT_{50}$ that were used in PEC calculations were: 3, 11, 17 and 19 days (geomean value 10.2 days). These soil degradation values for the metabolites (as listed in appendix 1, longest $DT_{90}$ 208 days for IN-N5297) do provide the necessary reassurance that the accumulation potential of the metabolites will be low in the periods when paddies are drained and when other crops are being grown in rotation with rice.

Field paddy dissipation studies (with rice cultivated) were provided from 3 sites in northern Italy where applications were made in July in 3 consecutive years, to flooded soil, when rice was at the end of the tillering growth stage. Static water was held in the paddy for the first 5 days after application, subsequently the water was allowed to flow through the treated paddies. Paddy water single first order $DT_{50}$ (accepted by the experts probably represent an estimate of degradation) were 1.5 to 6 days. These values estimated from sampled soil cores were 4, 7, 12 and 14 days (values from 1 site for 3 years and a second site in one year, for other years / the third site it was not possible to estimate any $DT_{50}$ as the level of residues present was too low). Experts considered that these paddy soil $DT_{50}$ had to be considered as dissipation rates as after 5 days the water flow through the paddies was started and then loss from soil would include desorption and flow out of the paddy as

well as degradation. They therefore concluded that it was not appropriate to use these field soil $DT_{50}$ in process based models that require a true degradation rate (i.e. RICEWQ). The experts considered that if in the future the applicant were to choose to conduct further European field studies to obtain more realistic soil degradation rate estimates than might be obtained from laboratory studies (that might subsequently be utilised in process based models such as RICEWQ), then they should design a study that would enable degradation rates to be estimated. Therefore any study design aimed at determining a degradation rate should not mimic the GAP (i.e. not include water flow through the paddy after 5 days) as had been done in the available European field experiments currently in the dossier.

The longest available laboratory bensulfuron-methyl single first order whole system sediment water $DT_{50}$ of 59 days (see section 4.2.1) was agreed by the experts from the Member States as the best available value (there being a data gap for aerobic flooded soil studies) and an arithmetic mean $K_foc$ of 315mL/g (see section 4.1.3) for use in step 1 MED-Rice (2003) PEC soil calculations. For the breakdown products the same approach was used (longest single first order whole system sediment water $DT_{50}$ and arithmetic mean $K_foc$) with the exception (as discussed above) that for IN-D1R84, which was not formed in the sediment water system, a geometric mean soil $DT_{50}$ of 10.2 days was used. The maximum observed formation fraction for breakdown products (in any fate study) was used as the basis for the PEC soil for the breakdown products. This was accepted by the experts as the best possible approach available for calculating these PEC, whilst there was a data gap for aerobic flooded soil studies. These clarifications on these calculations can be found on pages 10-13 of addendum 1 to B.8 of the DAR. The key table of input parameters is Table B.8.5 on page 13 of addendum 1. These input parameters and the resulting PEC can also be found in appendix 1 of this conclusion.

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

The adsorption / desorption of bensulfuron-methyl was investigated in 4 soils in satisfactory US EPA guideline batch adsorption experiments. Calculated adsorption $K_foc$ values varied from 205 to 561 mL/g, (arithmetic mean 315 mL/g) (1/n 0.88 – 0.97, arithmetic mean 0.92). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of IN-F7880 was investigated in 5 soils in satisfactory OECD 106 guideline batch adsorption experiments. Calculated adsorption $K_foc$ values varied from 75 to 472 mL/g, (arithmetic mean 206 mL/g) (1/n 0.9 – 1.14, arithmetic mean 1.0). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of IN-J0290 was investigated in 5 soils in satisfactory OECD 106 guideline batch adsorption experiments. Calculated adsorption $K_foc$ values varied from 58 to 1460

mL/g, (arithmetic mean 458 mL/g) (1/n 0.71 – 0.85, arithmetic mean 0.80). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of IN-N5297 was investigated in 5 soils in satisfactory OECD 106 guideline batch adsorption experiments. Calculated adsorption $K_f oc$ values varied from 15 to 92 mL/g, (arithmetic mean 36.4 mL/g) (1/n 0.91 – 0.94, arithmetic mean 0.92). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of bensulfuron was investigated in 5 soils in satisfactory OECD 106 guideline batch adsorption experiments. Calculated adsorption $K_f oc$ values varied from 28 to 580 mL/g, (arithmetic mean 225 mL/g) (1/n 0.89 – 0.93, arithmetic mean 0.90). There was no evidence of a correlation of adsorption with pH.

The adsorption / desorption of IN-D1R84 was investigated in 5 soils in satisfactory OECD 106 guideline batch adsorption experiments. Calculated adsorption $K_f oc$ values varied from 6 to 21 mL/g, (arithmetic mean 9.4 mL/g) (1/n 0.45– 0.84, arithmetic mean 0.71). There was no evidence of a correlation of adsorption with pH.

No adsorption / desorption data were available for IN-T5831 and IN-DAT97. In PEC calculations a value of 9 mL/g was assumed (that measured for IN-D1R84) as a conservative approach. However as risk management to protect groundwater from potential contamination appears necessary consequent to using this conservative assumption for one of the recommended situations for applying products (where paddy water depth is shallower than 10cm), EFSA has included a data gap in this conclusion for adsorption estimates for IN-T5831 and IN-DAT97. See section 4.2.2 for further discussion.

## 4.2. FATE AND BEHAVIOUR IN WATER

### 4.2.1. SURFACE WATER AND SEDIMENT

Bensulfuron-methyl was essentially stable under sterile hydrolysis conditions at 25°C at pH 7. At pH 4 a single first order $DT_{50}$ of 6 days was calculated. At pH 9 this value was 141 days. Under acidic conditions the breakdown products formed were IN-J0290 and IN-N5297. Under alkaline conditions bensulfuron was formed.

In a laboratory study where direct aqueous photolysis of bensulfuron-methyl was investigated under sterile pH 5, 7 and 9 conditions, bensulfuron-methyl was essentially stable at pH 7 and 9. At pH 5 the rate of degradation was similar to that expected from hydrolysis but unlike the results of the hydrolysis study, no major breakdown products were produced, indicating that IN-J0290 and IN-N5297 are photolabile. In sterile laboratory aqueous photolysis investigations with natural waters that were adjusted to have a pH of 7 (note clarifications relating to this study can be found on pages

16-17 of addendum 1 to B.8 of the DAR) i.e. where indirect sterile aqueous photolysis was investigated, bensulfuron-methyl degraded with single first order $DT_{50}$ of 10 to 89 test system days which can be equated to ca. 18 to 166 days of midday summer sunlight at 52°N, the water with the higher amount of suspended solids had the longer half life. In this study the degradation product IN-T5831 was formed at 13.4-14 % AR at days 7-14 in the natural water with more suspended solids where bensulfuron-methyl degraded more slowly.

A ready biodegradability test (OECD 301B) indicated that bensulfuron-methyl is 'not readily biodegradable' using the criteria defined by the test.

In dark water-sediment studies (2 systems studied at 20°C in the laboratory, sediment pH 5.2 and 5.8, water pH 7.4 and 7.7) bensulfuron-methyl degraded with first order whole system $DT_{50}$ 37 and 59 days. The metabolites IN-J0290 (max. 19.7 and 8.2% % AR at 130 days and 40 days respectively, relatively equally distributed between water and sediment) and IN-N5297 (max. 31.7 and 16.1% AR at 130 days and 50 days respectively, primarily in water) were the major transformation products. Metabolites approaching 10% AR in the whole water sediment system were IN-DAT97 (which accounted for a maximum of 9.9 and 3.6 % AR at days 50 and 40 respectively, primarily in water); IN-F7880 (which accounted for a maximum of 9.7 and 5.3 % AR at days 40 and 70 respectively, primarily in water) and IN-D1R84 (which accounted for a maximum of 4.7 and 9.9 % AR at days 130, primarily in water). Single first order whole system $DT_{50}$ were estimated where possible for these metabolites and bensulfuron with the kinetic model defined assuming each was formed directly from bensulfuron-methyl, the values estimated were IN-J0290 21.1 days (associated kinetic formation fraction 0.304), IN-N5297 30.8 days (associated kinetic formation fraction 0.363), IN-DAT97 34.6 and 37.8 days (associated kinetic formation fractions 0.162 and 0.092), IN-F7880 39.2 and 79.1 days (associated kinetic formation fraction 0.178 and 0.087) and bensulfuron 6.9 and 3.5 days (associated kinetic formation fractions 0.291 and 0.501). The kinetic fitting associated with these estimates are presented on pages 26-33 of addendum 1 to B.8 of the DAR. The terminal metabolite, $CO_2$, accounted for 12 to 15% AR of the pyrimidine ring radiolabel and 12 to 22 % AR of the phenyl ring radiolabel by 100 days. Residues not extracted from sediment by ammonium carbonate:acetone were a significant sink representing 25 to 37 % AR and 14 to 31% AR at 100 days for the two radiolabels respectively.

An acceptable light exposed laboratory aerobic sediment water experiment was evaluated by the RMS in the DAR, the peer review agreed the endpoints from this study as being reliable. As the endpoints from the study were not used in the environmental exposure calculations they are not discussed further in this conclusion.

With regard to the MED-Rice (2003) step 1 surface water and sediment PEC calculations, the experts accepted the available calculations as the best possible approach available for calculating these step 1 PEC, whilst there was a data gap for aerobic flooded soil studies. See section 4.1.2 where the

selection of the substance input parameters is already discussed.  The resulting PEC surface water and sediment can be found in appendix 1.

The applicant also provided higher tier surface water and sediment PEC calculations for just the active substance bensulfuron-methyl.  The peer review did not accept these PECs noting the following issues:

- The MED-Rice step 1 surface water and sediment PEC calculations indicated that situations represented by sand soils gave higher concentrations, however the scenarios constructed for the higher tier calculations only addressed the apparently less vulnerable clay soil situations. The sand soil situation needs to be assessed as well.  The applicant was given the opportunity to address this before the meeting of experts but chose not to.

- The higher tier calculations did not address the applied for intended use before sowing.  Only post emergence uses where 50% crop interception was assumed were assessed.  The pre-emergence pattern of use needs to be assessed as well.  The applicant was given the opportunity to address this before the meeting of experts but chose not to.

- The soil $DT_{50}$ used as input of 12 days is not appropriate.  With the available data a value of 59 days or possible 47 days (geomean of 37 and 59 days) should have been used, as the RICEWQ model needs a degradation rate and the value of 12 days is a dissipation rate (see section 4.1.2 where this is discussed further).

- The experts could not accept the way the 90th percentile 14 day time weighted averages for each scenario had been calculated from the daily model outputs as they include every 14 day time period including those at times of year far removed from the application window.  This has the effect of producing low 90th percentile concentrations as the distribution contains an unwarranted number of low concentration days.  These 90th percentile values bear no relation to a 90th percentile exposure concentration that any 1 generation of aquatic plants in an ecosystem would be exposed to, which is what is required for risk assessment. The applicant was given the opportunity to address this before the meeting of experts but chose not to.

- The experts confirmed that the process of amalgamating geographically different (from Portugal to Greece) climate scenarios to produce an overall 50th percentile of 90th percentile values is unacceptable in a risk assessment, as no single ecosystem of aquatic plants (the protection goal) will ever be exposed to hydrology and consequent exposure concentrations that reflect an average of such geographically different climates.  Also there is no precedent of agreeing to use any kind of 50th percentile value in EU level aquatic risk assessments.

Relevant data gaps in relation to the provision of higher tier surface water and sediment PEC estimates were therefore identified.  These can be found under the 'list of studies to be generated' section of this conclusion.  Whilst the experts had the reservations as set out above regarding this higher tier modelling it should be noted that (with the exception of the limited only clay soil texture range defined) the experts did not identify significant issues with the scenarios (climate and catchment descriptions) that the applicant had devised and defined for the models as described on pages 13 to 16 of addendum 1 to B.8 of the DAR.

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

The applied for representative use of pre-emergence applications to rice were calculated for application to 1 and 10cm deep paddy water using the MED-Rice (2003) step 1 method, with a modification to account for a mass of inflowing water that equalled that defined as being lost by infiltration below 1m. The substance property input parameters used were those already outlined as having been used to calculate PEC soil as already discussed at section 4.1.2 above. The peer review accepted these PEC calculations with these substance input parameters as representing the best possible approach available (in the knowledge that a data gap for aerobic flooded soil studies was identified, the results from which might trigger modified calculations).

Bensulfuron-methyl was calculated to be present in leachate leaving the top 1m soil layer at a 120 day (scenario defined flooding period) average concentration of <0.0391μg/L in both the step 1 defined clay and sand soil scenarios when applications were made to 1 and 10cm deep paddy water. This was also the case for the clay scenario for all the assessed metabolites (IN-F7880, bensulfuron, IN-D1R84, IN-J0290, IN-N5297, IN-T5831 and IN-DAT97) where these concentrations were calculated to be <0.007μg/L. For the sand scenario with 10cm overlying water, the metabolite concentrations calculated to be present in leachate leaving the top 1m soil layer over the 120 day scenario defined flooding period were <0.0524μg/L. For the sand scenario with 1cm overlying water, these metabolite concentrations were calculated to be: 0.0154, <0.0001, 0.0629, <0.0001, 0.154, 0.126 and 0.229 respectively. On the basis of these calculations it cannot be excluded that the metabolites IN-N5297, IN-T5831 and IN-DAT97 could be present in groundwater above the parametric drinking water limit of 0.1μg/L when applications are made as requested to paddies where the overlying water is < 10cm deep. Consequently an updated groundwater exposure assessment, (using measured soil adsorption values for IN-T5831 and IN-DAT97, data gap) and or groundwater non relevance assessment for IN-T5831 and IN-DAT97 and a groundwater non relevance assessment for IN-N5297, should be provided or risk management measures would appear to be necessary to protect groundwater from potential contamination by these three metabolites. Management of the minimum depth of paddy water, to which products containing bensulfuron-methyl should be applied, would appear to be an appropriate measure on the basis of the available calculations.

## 4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of bensulfuron-methyl (about $2.8 \times 10^{-12}$ Pa at 25°C, non-GLP study) means that bensulfuron-methyl would be classified under the national scheme of The Netherlands as very slightly volatile, indicating losses due to volatilisation would not 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 0.61 hours (assuming an atmospheric hydroxyl radical concentration of $1.5 \times 10^{6}$ radicals $cm^{-3}$). This Atkinson half life indicates that any

small proportion of applied bensulfuron-methyl that did reach the upper atmosphere (for example as aerosols formed at the time of spraying) would be unlikely to be subject to long range atmospheric transport.

# 5. Ecotoxicology

The bensulfuron-methyl variant of bensulfuron was discussed at the PRAPeR experts' meeting for ecotoxicology PRAPeR 48 (subgroup 2) in May 2008 on the basis of the draft assessment report and the addendum 1 (B.9.). The representative use evaluated is pre-sowing or post-emergence application as a herbicide in rice.

## 5.1. RISK TO TERRESTRIAL VERTEBRATES

The submitted studies with bensulfuron-methyl suggested a low acute and short-term toxicity to birds. No mortality was observed up to the highest tested doses (acute $LD_{50}$ > 2510 mg/kg bw, short-term $LD_{50}$ > 1678 mg a.s./kg bw/d). The long-term toxicity (reproduction) NOEC was 83 mg a.s./kg bw/d. The acute and long-term (reproductive) toxicity of bensulfuron-methyl to mammals is low (acute $LD_{50}$ >5000 mg/kg bw, long-term NOEL = 20.9 mg a.s./kg bw/d). The TERs were calculated for a large herbivorous bird, a small herbivorous mammal, a small insectivorous bird and a small insectivorous mammal according to SANCO 4145/2000. The TERs were above the Annex VI trigger values of 10 and 5 indicating a low risk to birds and mammals. The first-tier TERs for earthworm-eating birds and mammals were >5 indicating a low risk. The risk of secondary poisoning was assessed for crayfish-eating birds and mammals since *Procambarus clarkii* is known to inhabit rice paddies and the BCF for crayfish of 1.6 was higher than for fish. The resulting TERs for crayfish-eating birds and mammals were >5. The risk assessment for the uptake of contaminated drinking water was based on the concentration of bensulfuron-methyl in the paddy water of 0.0192 mg/L. The long-term TER was well above the trigger of 5 for birds and mammals.

Overall it is concluded that the risk to birds and mammals is low for the representative use of bensulfuron-methyl.

No risk assessment was conducted for birds and mammals for the uptake of plant metabolites. The risk from uptake of plant metabolites is assumed to be low considering that the acute TERs for bensulfuron-methyl are significantly above the trigger. It was considered as unlikely that the metabolites would be more than one order of magnitude more acutely toxic to birds and mammals as bensulfuron-methyl.

## 5.2. RISK TO AQUATIC ORGANISMS

Algae and aquatic plants were the most sensitive organisms tested. The lowest endpoint driving the aquatic risk assessment was observed in a study with *Lemna gibba* ($ErC_{50}$ = 0.0008 mg a.s./L). Bensulfuron-methyl is of low acute toxicity to fish and aquatic invertebrates. NOECs of 1.5 mg a.s./L (early life stage test with *Oncorhynchus mykiss*) and 12 mg a.s./L (*Daphnia magna* reproduction)

were observed on the long-term time scale. The studies with the formulation DPX-F5384 60WG (a water dispersible granule (WG) formulation containing 600 g bensulfuron-methyl / kg) suggested that the toxicity of bensulfuron-methyl was not increased when formulated.

The aquatic risk assessment was based on the concentrations in the rice paddies ($PEC_{pw}$ of 0.0192 mg a.s./L) and concentrations in ditches receiving the outflow of the rice paddies ($PEC_{sw}$ of 0.00175 mg a.s./L). The acute and long-term TERs for fish and aquatic invertebrates were significantly above the Annex VI triggers of 100 and 10 even with the higher in-field $PEC_{pw}$. The first-tier off-field TERs for algae and aquatic plants were 4.4 and 0.4 indicating a high risk. The RMS suggested using the 14-d time weighted average $PEC_{sw}$ values to refine the risk assessment. This was agreed by the experts since the endpoint for *Lemna sp*. is based on growth effects. A range of aquatic higher plant species were tested in screening tests on herbicidal activity. It was further proposed by the RMS to consider in the refined risk assessment that Lemna was the most sensitive species and to take into account recovery of *Lemna gibba*. The experts agreed that the herbicidal screening data suggested that *Lemna gibba* is one of the most sensitive plant species tested. However, it was not accepted to take recovery of *Lemna gibba* into account to refine the risk assessment since other macrophytes with lower recovery potential would not be covered by such a refinement. Based on the 14-d TWA $PEC_{sw}$ of 0.000998 mg a.s./L (clay scenario) and 0.00161 mg a.s./L (sand scenario) the resulting TERs for *Lemna gibba* would be 0.8 and 0.49, respectively. The suggested refinement of the exposure estimation was rejected by the experts on fate and behaviour (see point 4.2.1.). Also the TERs for algae would still be below the trigger of 10 on the basis of the 14-d TWA $PEC_{sw}$ values. A high risk to primary producers cannot be excluded on the basis of the available data. Therefore a data gap was identified for further refinement of the aquatic risk assessment.

The study with *Chironomus riparius* was considered not valid by the experts since it was not conducted with the most sensitive life stages. It was agreed in the expert meeting that no new study is required since the toxicity of bensulfuron-methyl to invertebrates is low and a study with *Chironomus riparius* would not be triggered.

The toxicity of the metabolites IN-J0290, IN-N5297, IN-D1R84, bensulfuron, IN-T5831, IN-F7880 and IN-DAT97 to aquatic organisms was several orders of magnitude lower compared to bensulfuron-methyl. The TERs based on the in-field $PEC_{pw}$ were significantly above the Annex VI triggers indicating a low risk to aquatic organisms

The risk of bioaccumulation in aquatic food chains was assessed as low for bensulfuron-methyl. The bioconcentration factors observed in studies with fish (*Salmo gairdneri*, *Cyprinus carpio*) and crayfish (*Procambarus clarkii*) were in the range of <0.9 to 1.6 (whole body BCF).

Overall it is concluded that the risk to the aquatic environment is high on the basis of the submitted information and further refinement of the risk assessment is required.

## 5.3. RISK TO BEES

Technical bensulfuron-methyl is of low toxicity to bees. The acute $LD_{50}$ values for oral and contact exposure are >51.4 µg a.s./bee and >100 µg a.s./bee, respectively. The acute oral and contact HQ values were significantly below the Annex VI trigger of 50 indicating a low risk to bees from the representative use evaluated.

## 5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory tests were conducted with the formulation DPX-F5384 60WG and *Aphidius rhopalosiphi* and *Typhlodromus pyri*. The observed $LR_{50}$ values were >600 g a.s./ha. The in-field and off-field HQ values were well below the trigger of 2 indicating a low risk to non-target arthropods for the representative uses of bensulfuron-methyl.

## 5.5. RISK TO EARTHWORMS

Bensulfuron-methyl and the soil metabolites IN-J0290, IN-N5297, IN-D1R84, bensulfuron, IN-F7880 were of low acute toxicity to earthworms with $LC_{50}$ values of >1000 mg a.s./kg soil. The TERs based on maximum initial PECsoil values were several orders of magnitude above the trigger of 10. Since bensulfuron is applied only once per season, and the field $DT_{90}$ is less than 100 days for bensulfuron-methyl, and the lab $DT_{90}$s of its metabolites were less than 1 year, and considering the large margin of safety on the acute time scale, it was considered not necessary to conduct long-term (reproduction) studies with earthworms. Overall it is concluded that the risk to earthworms is low for the metabolites for which ecotox data were available. No data were submitted for the soil-photolysis metabolites IN-T5831 and IN-DAT97. Since these metabolites occur at a maximum of 16% and 9.9% in the soil photolysis study, the risk to soil dwelling organisms needs to be addressed.

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

A risk assessment for soil non-target macro-organisms is not triggered since the field $DT_{90}$ is less than 100 days. The risk to earthworms and soil micro-organisms was assessed as low and the results from studies with non-target arthropods indicated a low toxicity to arthropods. Therefore no studies with soil non-target macro-organisms are triggered and the risk is considered to be low.

## 5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

Effects on soil nitrification and respiration were <25% at concentrations of up to 5 times the calculated initial PECsoil for bensulfuron-methyl and the soil metabolites IN-J0290, IN-N5297, IN-D1R84, bensulfuron, IN-F7880 . Overall it is concluded that the risk to soil micro-organisms is low for the metabolites for which ecotox data were made available. No data were submitted for the soil-photolysis metabolites IN-T5831 and IN-DAT97. Since these metabolites occur at a maximum of 16% and 9.9% in the soil photolysis study, the risk to soil dwelling organisms needs to be addressed.

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

Effects of bensulfuron-methyl on seedling emergence and vegetative vigour was investigated in 4 monocotyledon and 6 dicotyledon plant species. The lowest endpoint ($ER_{50} = 2.08$ g a.s./ha) was observed for soybean (*Glycine max*). The TERs for cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean and tomato (*Lycopersicon esculentum*) were below the trigger of 5 at a distance of 1 m from the treated field. The TERs were >5 (6.1 for soybean) at a distance of 5m. Therefore risk mitigation such as an in-field no spray buffer zone of 5 m is suggested for the representative uses evaluated.

## 5.9.  RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Respiration of activated sewage sludge was not affected up to the highest tested concentration of 100 mg a.s./L. It is considered unlikely that bensulfuron-methyl would enter sewage treatment plants at concentrations exceeding 100 mg a.s./L if applied according to the GAP. Therefore the risk to biological methods of sewage treatment is considered to be low for the representative uses.

# 6.     Residue definitions

**Soil**

Definition for risk assessment: a data gap needs to be filled before this can be finalised, based on the current data: bensulfuron-methyl, IN-F7880, bensulfuron, IN-J0290, IN-N5297, IN-T5831, IN-DAT97 and IN-D1R84

Definition for monitoring: data gaps needs to be filled before this can be finalised, based on the current data: bensulfuron-methyl

**Water**

**Ground water**

Definition for exposure assessment: data gaps needs to be filled before this can be finalised, based on the current data: bensulfuron-methyl, IN-F7880, bensulfuron, IN-J0290, IN-N5297, IN-T5831, IN-DAT97 and IN-D1R84

Definition for monitoring: data gaps need to be filled before this can be finalised, based on the current data: bensulfuron-methyl, IN-N5297, IN-T5831 and IN-DAT97

**Surface water**

Definition for risk assessment: surface water: data gaps needs to be filled before this can be finalised, based on the current data: bensulfuron-methyl, IN-F7880, bensulfuron, IN-J0290, IN-N5297, IN-T5831, IN-DAT97 and IN-D1R84

Sediment: bensulfuron-methyl and IN-J0290.

Definition for monitoring: data gaps needs to be filled before this can be finalised, based on the current data: bensulfuron-methyl

**Air**

Definition for risk assessment: bensulfuron-methyl

Definitions for monitoring: bensulfuron-methyl

**Food of plant origin**

Definition for risk assessment: bensulfuron-methyl - provisional (for details refer to 3.1.1)

Definition for monitoring: bensulfuron-methyl - provisional (for details refer to 3.1.1)

**Food of animal origin**

Definition for risk assessment: not required for the representative use assessed

Definition for monitoring: not required for the representative use assessed

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

**Soil**

| Compound (name and/or code) | Persistence | Ecotoxicology |
|---|---|---|
| bensulfuron-methyl | | The risk to earthworms and soil-micro organisms was assessed as low. |
| IN-F7880 | Low to medium persistence<br><br>Single first order $DT_{50}$ 39-79 days (20°C aerobic sediment water)<br><br>Single first order $DT_{50}$ 4.1-30.5 days (20°C, 50%MWHC soil moisture aerobic soil) | The risk to earthworms and soil micro-organisms was assessed as low. |
| bensulfuron (IN-R9419) | Low to moderate persistence<br><br>Single first order DT50 3.5-7 days (20°C aerobic sediment water)<br><br>Single first order DT50 8-54 days (20°C, 50%MWHC soil moisture aerobic soil) | The risk to earthworms and soil micro-organisms was assessed as low. |
| IN-J0290 | Low to moderate persistence<br><br>Single first order DT50 21.1 days (20°C aerobic sediment water) | The risk to earthworms and soil micro-organisms was assessed as low. |

| | | |
|---|---|---|
| | Single first order DT50 3-19 days (20°C, 50%MWHC soil moisture aerobic soil) | |
| IN-N5297 | Low to medium persistence<br><br>Single first order DT50 31 days (20°C aerobic sediment water)<br><br>Single first order DT50 4-63 days (20°C, 50%MWHC soil moisture aerobic soil) | The risk to earthworms and soil micro-organisms was assessed as low. |
| IN-T5831 | No data available, based on structural similarity to IN-J0290 21.1 days was used for assessment (moderate persistence). | No data available. Data gap |
| IN-DAT97 | Moderate persistence<br><br>Single first order DT50 35-38 days (20°C aerobic sediment water) | No data available. Data gap |
| IN-D1R84 | Low to moderate persistence<br><br>Single first order DT50 3-19 days 20°C, 50%MWHC soil moisture aerobic soil) | The risk to earthworms and soil micro-organisms was assessed as low. |

**Ground water**

| Compound (name and/or code) | Mobility in soil | > 0.1 µg / L 1m depth for the representative uses (at least one MED-Rice scenario or relevant lysimeter) | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|---|---|---|---|---|---|
| bensulfuron-methyl | medium to low mobility $K_{foc}$ 205-561 mL/g | No | Yes | Yes | Yes |
| IN-F7880 | high to medium mobility $K_{foc}$ 75-472 mL/g | No | No | No data, is a major metabolite of the rat found in plasma, bile, urine and faeces; as assessment is not triggered data not required | No |
| bensulfuron (IN-R9419) | Very high to low mobility $K_{foc}$ 28-580 mL/g | No | No | The ALD was 11000 mg/kg bw in male rat, an Ames test was negative; is a minor rat metabolite found in plasma, urine and faeces; as assessment is not triggered no further data required | No |

| Compound (name and/or code) | Mobility in soil | > 0.1 μg / L 1m depth for the representative uses (at least one MED-Rice scenario or relevant lysimeter) | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|---|---|---|---|---|---|
| IN-J0290 | high to low mobility $K_{foc}$ 58-1460 mL/g | No | No | The acute oral $LD_{50}$ was 1200 mg/kg bw in rat, an Ames test was negative; is a minor rat metabolite found only in faeces; as assessment is not triggered no further data required | No |
| IN-N5297 | very high to high mobility $K_{foc}$ 15-92 mL/g | Yes up to 0.154μg/L but only for the sand scenario when paddy water depths at application are <10cm | No | The ALD was 7500 mg/kg bw in male rat, an Ames test was negative; is a minor rat metabolite found in urine and faeces; insufficient data to conclude on its relevance, data gap. | No |
| IN-T5831 | Data gap | Yes up to 0.126μg/L but only for the sand scenario when paddy water depths at application are <10cm | No | No data, not identified in rat metabolism; no conclusion possible on its relevance | No |

| Compound (name and/or code) | Mobility in soil | > 0.1 µg / L 1m depth for the representative uses (at least one MED-Rice scenario or relevant lysimeter) | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|---|---|---|---|---|---|
| IN-DAT97 | Data gap | Yes up to 0.229µg/L but only for the sand scenario when paddy water depths at application are <10cm | No | No data, not identified in rat metabolism; no conclusion possible on its relevance | No |
| IN-D1R84 | very high mobility $K_{foc}$ 6-21 mL/g | No | No | No data, not identified in rat metabolism; as assessment is not triggered, data not required | No |

**Surface water and sediment**

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| bensulfuron-methyl | Very toxic and high risk to aquatic organisms (*Lemna gibba* ErC$_{50}$ = 0.0008 mg a.s./L) |
| IN-F7880 | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |
| bensulfuron (IN-R9419) | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |
| IN-J0290 | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |
| IN-N5297 | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |
| IN-T5831 | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |
| IN-DAT97 | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |
| IN-D1R84 | Several orders of magnitude less toxic to aquatic organisms compared to bensulfuron-methyl. Low risk to aquatic organisms. |

**Air**

| Compound (name and/or code) | Toxicology |
|---|---|
| Bensulfuron-methyl | Inhalation rat $LC_{50} > 7.5$ mg/L air/4 h, whole body as a suspension of particulate, no classification proposed |

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

- Revised technical specification for the active substance, removing the impurities below 1 g/kg, or to provide more information on the QC data to support the specification (relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1)

- GLP study for the determination of the vapour pressure (relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1)

- A new calculation for Henry's law constant based on the GLP vapour pressure study (relevant for all representative uses evaluated, date of submission unknown, data gap identified by the experts of the PRAPeR 46 meeting, May 2008; refer to chapter 1)

- Monitoring method(s) for the determination of the metabolites IN-N5297, IN-T5831, IN-DAT97, set as part of the residue definition in ground water (relevant for all representative uses evaluated; date of submission unknown, data gap identified by EFSA after the finalisation of the residue definitions for monitoring, August 2008; refer to chapter 1 and point 6)

- Information on the impurity profile of the batches used in key toxicological studies (relevant for all representative uses evaluated; date of submission unknown, data gap identified by the experts of the PRAPeR 49 meeting, June 2008; refer to chapter 2)

- The applicant should either conduct a new metabolism study in rice considering foliar exposure or, if applicable, provide comparative data on other sulfonylurea herbicides with similar use patterns in order to clarify the nature of residues upon a foliar application (relevant for all representative uses with post-emergence application, date of submission unknown, data gap identified by the experts of the PRAPeR 50 meeting, June 2008; refer to chapter 3).

- Further investigation on metabolite identity should be carried out in rotated crops, in particular rotated cereals, considering the potential for uptake of soil metabolites (relevant for all representative uses evaluated, date of submission unknown, data gap identified by the experts of the PRAPeR 50 meeting, June 2008; refer to chapter 3)

- A mammalian toxicological assessment on the relevance of the groundwater metabolite IN-N5297. (relevant for the representative use on rice but only required to confirm non relevance where applications are applied to rice paddies with less than a 10cm water depth in situations represented by the MED-Rice sand soil scenario; submission date proposed by the notifier: unknown; data gap identified by EFSA when drafting this conclusion; refer to point 4.2.2)

- Aerobic laboratory flooded soil degradation studies, taking into account the EU MED-Rice guidance on at least 2 soils. One of the soils investigated should have a neutral/alkaline pH

(relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; data gap confirmed by the experts of the PRAPeR 47 meeting, May 2008; refer to point 4.1.1)

- Reliable soil adsorption estimates for IN-T5831 and IN-DAT97, on at least 3 soils. (relevant for all the representative uses evaluated but only required to refine exposure estimates where applications are applied to rice paddies with less than a 10cm water depth; submission date proposed by the notifier: unknown; data gap identified by EFSA when drafting this conclusion; refer to point 4.1.3)

- Higher tier exposure assessments (PEC) for surface water and sediment for bensulfuron-methyl from applications pre-sowing of the rice crop; submission date proposed by the notifier: unknown; data gap confirmed by the experts of the PRAPeR 47 meeting, May 2008; refer to point 4.2.1)

- Higher tier RICEWQ/RIVWQ simulations for sand soil scenarios to calculate PEC in surface water and sediment for bensulfuron-methyl (necessary for the post emergence pattern of use). All $DT_{50}$ selected for use as input into this modelling to be clearly justified; submission date proposed by the notifier: unknown; data gap confirmed by the experts of the PRAPeR 47 meeting, May 2008; refer to point 4.2.1)

- New RICEWQ/RIVWQ simulated 90th percentile 14 day TWA surface water values for bensulfuron-methyl to be calculated and presented for each clay scenario and year (higher tier scenarios, i.e. soil, catchment and climate definitions as already defined and used in the applicants dossier) but only include 14 day periods when predicted TWA concentrations are > 0.04μg/L (1/20 of the *Lemna* EC50), when calculating the 90th percentile. Pertinent to PEC in surface water and sediment and the aquatic risk assessment for the post emergence pattern of use. The bensulfuron-methyl soil $DT_{50}$ used as input should be a true degradation value and not a dissipation rate; submission date proposed by the notifier; unknown; data gap confirmed by the experts of the PRAPeR 47 meeting, May 2008; refer to point 4.2.1)

- The aquatic risk assessment needs further refinement. (relevant for all representative uses evaluated; data gap identified in the meeting of experts, PRAPeR 48 in May 2008; submission date proposed by the notifier unknown; refer to point 5.2).

- A risk assessment for soil dwelling organisms is required for the soil metabolites IN-T5831 and IN-DAT97. (relevant for all representative uses evaluated; data gap identified after the meeting of experts when drafting this conclusion; submission date proposed by the notifier; unknown; refer to point 5.5. and 5.7)

## CONCLUSIONS AND RECOMMENDATIONS

### Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprise pre-sowing and post emergence applications with tractor-mounted spraying devices to control annual weeds (*Alisma plantago aquatica, Alisma lanceolata, Ammania coccinea, Bergia spp, Bolboschenus (Scirpus) maritimus, Schoenoplectus (Scirpus) mucronatus, Scirpus supinus, Butomus umbellatus, Cyperus spp., Lindernia spp., Heterantera reniformis, Heteranthera rotundifolia, Sparganium erectum, Typha spp*) in flooded rice from 2 to 5 days before sowing, or between growth stages of BBCH 12 up to BBCH 29 respectively; and post emergence applications in dry land rice between growth stages of BBCH 12 up to BBCH 29, one application per year, with maximum application rate of 60 g a.s./ha, in all Europe.

The technical specification is not finalised, a data gap was identified for a revised specification.
The representative formulated product for the evaluation was Londax®, a water-dispersible granule (WG) containing 600 g/kg of bensulfuron-methyl, registered under different trade names in Europe.

The technical specification is not finalised, a data gap was identified for a revised specification.
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. Adequate methods are available to monitor bensulfuron-methyl residues in food/feed of plant origin, soil, surface water and air, however no monitoring methods were submitted for the determination of the metabolites set as part of the residue definition in ground water. Analytical method for food of animal origin is not required due to the fact that no residue definition is proposed.

In the mammalian metabolism studies, bensulfuron-methyl was rapidly but incompletely absorbed after oral administration. It was distributed mainly to the gastrointestinal tract, liver, kidneys and plasma and was extensively metabolised, showing no potential for accumulation. The acute toxicity was low, either by the oral, dermal or inhalation route; no eye or skin irritation was observed and no skin sensitisation potential was found in a Magnusson & Kligman test. The main target organ of bensulfuron-methyl was the liver upon short term or long term exposure in either the rat, mouse or dog species; the relevant NOAEL for both short term and long term exposure was the dose level of 19.9 mg/kg bw/day from the one-year dog study. No potential for neurotoxicity, genotoxicity or carcinogenicity was seen with bensulfuron-methyl; no reproductive or fertility effects were observed in a two-generation reproduction toxicity study. Some unspecific effects or delay in the development of rats were observed upon high dosing of bensulfuron-methyl without expressing maternal toxicity, in rabbits only decreased body weight was observed at maternal toxic doses.

The Acceptable Daily Intake (ADI) of bensulfuron-methyl was 0.2 mg/kg bw/day, the Acceptable Operator Exposure Level (AOEL) was 0.12 mg/kg bw/day and no Acute Reference Dose (ARfD) was allocated. The level of operator exposure was below the AOEL according to the UK POEM, only when the use of personal protective equipment (PPE) was considered; according to the German model, estimated exposure was below the AOEL even when no PPE were worn. Estimated exposure of workers entering crops treated with bensulfuron-methyl was below the AOEL, without the use of PPE. Bystander exposure was low compared to the AOEL value.

In metabolism studies with radio labelled bensulfuron-methyl in paddy rice, upon application to the water surface, levels of total radioactivity recovered in rice plants were very low and hence identification of residues was limited to the extractable radioactivity from foliage and straw. Neither intact bensulfuron-methyl nor bensulfuron was detected, but, though at very low levels, some metabolites could be identified that indicate a cleavage of the sulfonylurea bridge occurred. In the meeting of experts the need for further data on the nature of the residue in plants with foliar exposure and in rotational crops was identified. Therefore a residue definition for risk assessment and MRL setting purposes could only be proposed provisionally as bensulfuron-methyl.

Residue trials with post-emergence application to rice plants indicate that under practical conditions, residues of bensulfuron-methyl above the limit of quantification (LOQ) are not expected in rice grain, while in rice straw residues above the LOQ could be found in one trial.

In a confined rotational crop study total residues in the rotated crops did not exceed 0.01 mg/kg, however data indicated an increase of residues in rotated cereals with time and thus clarification on potential uptake of soil metabolites is required.

No significant residues are expected to occur in commodities to be processed or used in livestock diet, and therefore no further investigation in processing studies and livestock studies is required to support the representative uses in rice.

In a provisional chronic consumer exposure and risk assessment, based on the provisional residue definition for risk assessment, it was demonstrated that the maximum estimated dietary intake of residues of bensulfuron-methyl is well below (<1%) the toxicological reference value ADI. As no ARfD was allocated an acute risk assessment is not considered necessary.

The information available was insufficient to enable a satisfactory environmental exposure assessment to be completed. Experimental data on the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions (that needs to include alkali soil conditions) is missing. A triggered higher tier exposure assessment for bensulfuron-methyl regarding natural surface water and sediment for situations represented by the MED-Rice sand soil scenario and for all scenarios where application is made before sowing the rice crop is missing (the applicant was given the opportunity to provide these calculations before the meeting of experts but chose not to provide them). Whilst a higher tier exposure assessment regarding natural surface water and sediment for situations represented by the MED-Rice clay soil scenario for bensulfuron-

methyl and post planting applications is available, the Member State experts did not accept the soil $DT_{50}$ used as input (field dissipation value) to the RICEWQ module of the simulations or the way the exposure concentrations ($90^{th}$ percentile 14 day TWA values) provided by the applicant had been calculated. (Note the applicant was given the opportunity to update these calculations before the meeting of experts but chose not to update them). The experts agreed that there was a data gap for $90^{th}$ percentile 14 day TWA values to be represented in a way that has some meaning for an edge of field risk assessment. The approach used by the applicant in the available assessment mixed temporal and spatial factors in an inappropriate way, such that the resulting aquatic risk assessment does not demonstrate in which (if any) situations the active substance might be used without impacting on populations of aquatic species, which is what Member State experts agreed would be required to demonstrate compliance with annex VI criteria.

It can be concluded that the potential for bensulfuron-methyl to contaminate vulnerable groundwater above the parametric drinking water limit of 0.1µg/L from the applied for intended uses is low. For the known metabolites, based on the available data, there are indications that this is also the case when applications are made to paddies with a 10cm layer of water overlying the soil and for shallower paddy water depths in situations represented by the MED-Rice clay scenario. However in situations represented by the MED-Rice sand scenario where applications are made to paddies with <10cm overlying water it cannot be excluded with the available data that IN-5297, IN-T5831 and IN-DAT97 may be present in vulnerable groundwater at > 0. 1µg/L (calculations indicate concentrations up to 0.23µg/L). Consequently a data gap was identified for soil adsorption information in at least three soils for IN-T5831 and IN-DAT97. Therefore a non relevance assessment for at least IN-5297 (calculated concentrations up to 0.15µg/L) and based on the available data in the dossier all three of these metabolites were triggered, but these are not available. In the absence of data to assess the non relevance of these metabolites, the available groundwater exposure assessments indicate that risk management options may be effective at mitigating the potential for groundwater exposure by these metabolites in regions represented by the MED-Rice sand scenario. However the groundwater assessment for metabolites cannot be finalised until the data gap for experimental data on the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions (that needs to include alkali soil conditions) has been filled.

Bensulfuron-methyl is used as a herbicide and it is very toxic to aquatic and terrestrial plants. A high risk to the aquatic environment (algae and macrophytes) was indicated from the submitted data and further refinement of the aquatic risk assessment is needed. The risk to non-target terrestrial plants in the off-field area needs to be mitigated. Risk mitigation comparable to an in-field no-spray buffer zone of 5 m is required to protect non-target terrestrial plants.

The risk to birds, mammals, fish and aquatic invertebrates, bees, non-target arthropods, earthworms, soil non-target macro- and 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**

- To protect groundwater from the potential for contamination by metabolites IN-N5297, IN-T5831 and IN-DAT97 in rice growing areas where predominantly more sandy soils occur applications of bensulfuron-methyl should not be made when water depths in the paddies are less than 10cm (refer to point 4.2.2).
- Risk mitigation comparable to a 5 m in-field no-spray buffer zone is required to protect non-target plants in the off-field area (refer to point 5.2.).

# Critical areas of concern

- Data gaps for experimental data on identity of metabolites of bensulfuron-methyl in rotated crops, in particular cereals, and upon post-emergence application to cereals (rice) need to be filled before the consumer exposure and risk assessment can be taken forward and finalised.
- A data gap for experimental data on the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions (that needs to include alkali soil conditions) needs to be filled before the environmental exposure estimates for both bensufuron methyl and its breakdown products can be taken forward and finalised.
- High risk to the aquatic environment. The risk assessment for bensulfuron-methyl needs further refinement.

**Appendix 1 – list of endpoints**

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

### List of End Points

**Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling**

| | |
|---|---|
| Active substance (ISO Common Name) | Bensulfuron<br>Data were provided and evaluated for the variant bensulfuron-methyl |
| Function (*e.g.* fungicide) | Herbicide |

| | |
|---|---|
| Rapporteur Member State | Italy |

**Appendix 1 – list of endpoints**

**Identity (Annex IIA, point 1)**

| | |
|---|---|
| Chemical name (IUPAC) ‡ | α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*o*-toluic acid (bensulfuron)<br><br>methyl α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*o*-toluate   (bensulfuron-methyl) |
| Chemical name (CA) ‡ | methyl 2-[[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl]benzoate |
| CIPAC No ‡ | 502.201 |
| CAS No ‡ | 83055-99-6 |
| EC No (EINECS or ELINCS) ‡ | 401-340-6 |
| FAO Specification (including year of publication) ‡ | 502/TC/2002 |
| Minimum purity of the active substance as manufactured ‡ | Open |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | None |
| Molecular formula ‡ | $C_{16}H_{18}N_4O_7S$ |
| Molecular mass ‡ | 410.4 g/mol |
| Structural formula ‡ |  |
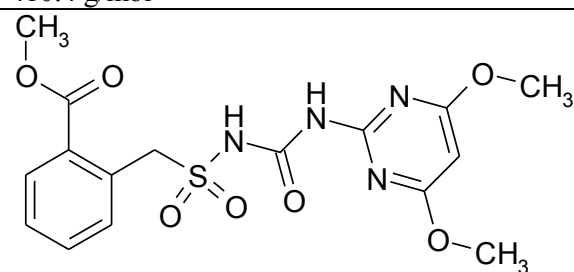
**Appendix 1 – list of endpoints**

**Physical and chemical properties** (Annex IIA, point 2)

| | |
|---|---|
| Melting point (state purity) ‡ | 179.4 °C (98.3%) |
| Boiling point (state purity) ‡ | Decomposes before boiling |
| Temperature of decomposition (state purity) | Approximately 245°C (98.3%) |
| Appearance (state purity) ‡ | White solid (technical product: 98.3%) |
| Vapour pressure (state temperature, state purity) ‡ | Study required |
| Henry's law constant ‡ | Study |
| Solubility in water (state temperature, state purity and pH) ‡ | Solubilities at 25°C (99.5%)<br>pH 5: 2.1 mg/l<br>pH 7: 67 mg/l<br>pH 9: 3100 mg/l |
| | Solubility at 20°C (99.5%)<br>Unbuffered distilled water: 6.65 mg/ml at 20°C |
| Solubility in organic solvents ‡<br>(state temperature, state purity) | Solubilities at 20°C (99.3%)<br>Acetone: 5.10 g/L<br>Acetonitrile: 3.75 g/L<br>Dichloromethane: 18.4 g/L<br>Dimethylformamide: 70.8 g/L<br>Ethyl acetate: 1.75 g/L<br>n-Heptane: $3.62 \times 10^{-4}$ g/L<br>Methanol: 0.765 g/L<br>1-Octanol: $7.47 \times 10^{-2}$ g/L<br>o-Xylene: 0.229 g/L |
| Surface tension ‡<br>(state concentration and temperature, state purity) | $74.9 \times 10^{-3}$ N/m (90 % saturated solution and at 20.3°C) (97.9%) |
| Partition co-efficient ‡<br>(state temperature, pH and purity) | Parent (experimental) (99.5%):<br>pH 5: log $P_{ow}$ = 2.18 at 25°C<br>pH 7: log $P_{ow}$ = 0.79 at 25°C<br>pH 9: log $P_{ow}$ = -0.99 at 25°C |
| | Impurities/Metabolites (calculated):<br>IN-J0290 (pyrimidine amine): log $P_{ow}$ = 0.95<br>IN-N5297 (sulfonamide): log $P_{ow}$ = 0.47 |
| Dissociation constant (state purity) ‡ | pKa = 5.2 at 20°C (99.0%) |
| UV/VIS absorption (max.) incl. ε ‡<br>(state purity, pH) | Absorption (max): 239 nm at pH 7:<br>$\varepsilon$ = 784 l × mol-1 × cm-1 at 290 nm at pH 7 (98.3%) |
| Flammability ‡ (state purity) | Not highly flammable (98.66%) |
| Explosive properties ‡ (state purity) | Negative; Not explosive (98.66%) |
| Oxidising properties ‡ (state purity) | Not oxidising (structural argument) |

![efsa logo - European Food Safety Authority]

*EFSA Scientific Report* **(2008) 178, 1-102**
**Conclusion on the peer review of bensulfuron**

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## Appendix 1 – list of endpoints

### Summary of representative uses evaluated (*Bensulfuron-methyl*)*

| Crop and/ or situation (a) | Member State, Country or Region | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | | Application | | | | Application rate per treatment (for explanation see the text in front of this section) | | | PHI (days) (m) | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of as (i) | method kind (f-h) | growth stage & season (j) | number min/ max (k) | interval between applications (min) | kg as/hL (l) min – max | water L/ha min – max | kg as/ha (l) min – max | | |
| Rice | Italy Spain France (South) Greece Portugal Hungary | Londax® Sectar® Testar® | F | Broadleaved weeds and Cyperaceae | WG | 600 a.s.g/kg | Flooded Rice Broadcast terrestrial | **Pre-sowing** application 5-2 days before sowing.  **Post-emergence** Application to be made between 20 to 45 days after sowing. (Depending on locale, this may be between BBCH12 two leaves and BBCH 29 maximum tillers) | 1 | N/A | 0.012 – 0.030 | 200-400 | 0.048-0.060 | Normal Maturity (BBCH 89) | Flooded: (5-10 cm) water  Do not apply within 60 days of harvest.  [1][2] [3] |

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## Appendix 1 – list of endpoints

| Crop and/ or situation (a) | Member State, Country or Region | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | | Application | | | | Application rate per treatment (for explanation see the text in front of this section) | | | PHI (days) (m) | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of as (i) | method kind (f-h) | growth stage & season (j) | number min/ max (k) | interval between applications (min) | kg as/hL (l) min – max | water L/ha min – max | kg as/ha (l) min – max | | |
| Rice | Italy Spain France (South) Greece Portugal Hungary | Londax® Sectar® Testar® | F | Broadleaved weeds and Cyperaceae | WG | 600 a.s.g/kg | Saturated soil with 0-1 cm of water Broadcast terrestrial | **Post-emergence** Application to be made between 20 to 50 days after sowing. (Depending on locale, this may be between BBCH 12 two leaves and BBCH 29 maximum tillers) | 1 | NA | 0.012 – 0.030 | 200-400 | 0.048-0.060 | Normal Maturity (BBCH 89) | Soil will be flooded with 5-10 cm of water from 2 to 5 days after the treatment and water will be kept in rice paddy for at least 15 days. Do not apply within 60 days of harvest.  [1] [2] [3] |

[1] The exposure assessment could not be finalised in section 4.

[2] A high risk to the aquatic environment was indicated, data gap for further refinement of the aquatic risk assessment

[3] The consumer risk assessment is not finalised.

## Appendix 1 – list of endpoints

| | |
|---|---|
| ∗ 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). | (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).** |
| (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) | (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 |
| (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds | (k) Indicate the minimum and maximum number of application possible under practical conditions of use |
| (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 | (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 |
| (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench | (m) PHI - minimum pre-harvest interval |
| (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated | |

**Appendix 1 – list of endpoints**

**Methods of Analysis**

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

| | |
|---|---|
| Technical as (analytical technique) | Bensulfuron-methyl is determined by reversed-phase HPLC, using UV detection at 236 nm. Confidential Attachment in Volume 4 Annex C |
| Impurities in technical as (analytical technique) | High boiling impurities are determined by reversed-phase HPLC using UV detection at 230 nm, whereas solvents are determined by GC/FID. Confidential Attachment in Volume 4 Annex C |
| Plant protection product (analytical technique) | Same method used in Technical as. The inert ingredients included in Londax® are not expected to interfere with the extraction and analysis of bensulfuron-methyl residues in any matrix. Therefore, no residue analytical methods have been developed specifically for bensulfuron-methyl 60WG. |

**Analytical methods for residues** (Annex IIA, point 4.2)

**Residue definitions for monitoring purposes**

| | |
|---|---|
| Food of plant origin | Bensulfuron-methyl (provisional) |
| Food of animal origin | Not required for the representative use assessed |
| Soil | Bensulfuron-methyl (provisional) |
| Water   surface | Bensulfuron-methyl (provisional) |
|            drinking/ground | Bensulfuron-methyl (provisional)-IN-N5297, IN-T5831, IN-DAT97 |
| Air | Bensulfuron-methyl |

**Appendix 1 – list of endpoints**

**Monitoring/Enforcement methods**

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Bensulfuron-methyl is extracted by homogenisation in an aqueous ammonium carbonate solution. Extracts are purified and concentrated by solid-phase extraction (SPE). Analysis options are reversed-phase HPLC utilising: <br> - column switching with UV detection (primary method), or <br> - electrospray with selected ion monitoring mass spectrometry (ILV; enforcement method; LC/ESI/MS; SIM molecular 411m/e) <br> - electrospray tandem mass spectrometry (confirmatory method; LC/ESI/MS/MS; mass transitions 411->149m/e and 411->182m/e). <br><br> The Limit of Quantitation (LOQ) is 0.010 mg/kg in rice grain and 0.050 mg/kg in rice straw. |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not needed. A foodstuff of animal origin method was not required because bensulfuron-methyl residues ≥0.1 mg/kg do not occur in any feed items or products of animal origin after the application of bensulfuron-methyl under normal agricultural practice based on metabolism studies. |
| Soil (analytical technique and LOQ) | Bensulfuron-methyl in soil is extracted in 90% ammonium carbonate/10% methanol solution using a wrist-action shaker. Extracts are purified and concentrated by SPE. The analyte is eluted from the SPE cartridge, partitioned into ethyl acetate, evaporated to dryness, and reconstituted for reversed-phase LC/ESI/MS/MS analysis. The Limit of Quantitation (LOQ) is 0.050 μg/kg. |
| Water (analytical technique and LOQ) | Bensulfuron-methyl in water is extracted, purified, and concentrated by SPE. The analyte is eluted from the SPE cartridge, evaporated to dryness, and reconstituted for reversed-phase LC/ESI/MS/MS analysis. The limit of Quantitation (LOQ) is 0.050 μg/L. <br><br> No method has been submitted for the determination of IN-N5297, IN-T5831, IN-DAT97 in water. |

**Appendix 1 – list of endpoints**

| | |
|---|---|
| Air (analytical technique and LOQ) | Bensulfuron-methyl is adsorbed on XAD-2 adsorbent from ambient and warm/humidified air and desorbed in acetonitrile. Analysis is by reversed-phase LC/ESI/MS/MS. The Limit of Quantitation (LOQ) is 3.0 $\mu$g/m³. |
| Body fluids and tissues (analytical technique and LOQ) | Not needed. A body fluids and tissues method was not required because bensulfuron-methyl and its metabolites are not classified as highly toxic or toxic to humans and would not bio-accumulate in human tissues. |

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

| | |
|---|---|
| | RMS/peer review proposal |
| Active substance | Not classified |

**Appendix 1 – list of endpoints**

**Impact on Human and Animal Health**

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

| | |
|---|---|
| Rate and extent of absorption ‡ | Rapid but limited. 60 and 65 % in male and female rats, respectively, based on urine, cage wash and tissues minus gastrointestinal tract content within 196 hours after 20 mg/kg bw dose level |
| Distribution ‡ | Widely and uniformly distributed. Less than 0.3 % of the dose remained in all tissues and carcass 196 hours after dose administration |
| Potential for accumulation ‡ | No potential for accumulation |
| Rate and extent of excretion ‡ | Excretion in urine and faeces essentially complete by 48 to 72 hours after administration, independent of sex, dose level, radiolabel, or single or multiple dosing. After single or multiple low dose the percent of dose excreted was 44-58 % of dose in urine and 27-42 % in faeces. Biliary excretion 24 hours after dose administration was 29 % and 16 % in male and female rats, respectively |
| Metabolism in animals ‡ | Undergoes extensive metabolism in rats primarily by *O*-demethylation and hydroxylation of the pyrimidine ring as well as sulfonamide cleavage |
| Toxicologically relevant compounds ‡ (animals and plants) | Bensulfuron-methyl |
| Toxicologically relevant compounds ‡ (environment) | Bensulfuron-methyl |

**Acute toxicity (Annex IIA, point 5.2)**

| | | |
|---|---|---|
| Rat $LD_{50}$ oral ‡ | > 5000 mg/kg bw | |
| Rabbit $LD_{50}$ dermal ‡ | > 2000 mg/kg bw | |
| Rat $LC_{50}$ inhalation ‡ | > 7.5 mg/L air/4 hour (whole body, suspension of particulate) | |
| Skin irritation ‡ | Non-irritant | |
| Eye irritation ‡ | Non-irritant | |
| Skin sensitisation ‡ | Non-sensitiser (Magnusson & Kligman test) | |

**Appendix 1 – list of endpoints**

**Short term toxicity (Annex IIA, point 5.3)**

| Target / critical effect | Hepatotoxicity and hepatocyte hypertrophy in rats, dogs and mice |
|---|---|
| Relevant oral NOAEL ‡ | 90-day rat: 93 mg/kg bw/day |
| | 90-day mouse:132 mg/kg bw/day |
| | 1-year dog: 19.9 mg/kg bw/day |
| Relevant dermal NOAEL ‡ | No data; not required |
| 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 | Liver hypertrophy and histopathological changes |
|---|---|
| Relevant NOAEL ‡ | 2-year rat: 30 mg/kg bw/day |
| | 2-year mouse: 226 mg/kg bw/day |
| Carcinogenicity ‡ | No carcinogenic potential |

**Reproductive toxicity (Annex IIA, point 5.6)**

**Reproduction toxicity**

| Reproduction target/critical effect | Parental toxicity: body weight and liver effects (liver effects seen in 2-year rat study) | |
|---|---|---|
| | Reproductive toxicity: no effect | |
| | Offspring's toxicity: lower pup weight and liver effects | |
| Relevant parental NOAEL ‡ | 19.5 mg/kg bw/day | |
| Relevant reproductive NOAEL ‡ | 1404.5 mg/kg bw/day | |
| Relevant offspring NOAEL ‡ | 22.3 mg/kg bw/day | |

**Appendix 1 – list of endpoints**

**Developmental toxicity**

| Developmental target / critical effect ‡ | Rat: | |
|---|---|---|
| | Maternal toxicity: none | |
| | Development toxicity: unspecific delay of development | |
| | Rabbit: | |
| | Maternal & developmental toxicity: reduced body weight | |
| Relevant maternal NOAEL ‡ | Rat: 2000 mg/kg bw/day | |
| | Rabbit: 300 mg/kg bw/day | |
| Relevant developmental NOAEL ‡ | Rat: 500 mg/kg bw/day | |
| | Rabbit: 300 mg/kg bw/day | |

**Neurotoxicity (Annex IIA, point 5.7)**

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

**Other toxicological studies (Annex IIA, point 5.8)**

| Mechanism studies ‡ | No data, not required |
|---|---|
| Studies performed on metabolites or impurities ‡ | **Metabolites:** |
| | <u>IN-B6895-2:</u> |
| | Rat approximate lethal dose (ALD): 11000 mg/kg bw |
| | Negative in an *in vitro* Ames test |
| | <u>IN-N5297:</u> |
| | Rat ALD: 7500 mg/kg bw |
| | Negative in an *in vitro* Ames test |
| | <u>Bensulfuron:</u> |
| | Rat ALD: > 11000 mg/kg bw |
| | Negative in an *in vitro* Ames test |

**Appendix 1 – list of endpoints**

> IN-J290-17:
>
> Rat $LD_{50}$: 1200 mg/kg bw
>
> Negative in an *in vitro* Ames test

**Medical data ‡ (Annex IIA, point 5.9)**

> No detrimental effects on health of manufacturing personnel

**Summary (Annex IIA, point 5.10)**

| | Value | Study | Safety factor |
|---|---|---|---|
| ADI ‡ | 0.20 mg/kg bw/day | Dog, 1-year study | 100 |
| AOEL ‡ | 0.12 mg/kg bw/day | Dog, 1-year study | Overall 166.7* (100 + 60 %)* |
| ARfD ‡ | Not allocated; not necessary | - | - |

 * correction for low oral absorption (60 %)

**Dermal absorption ‡ (Annex IIIA, point 7.3)**

Londax® - bensulfuron-methyl 60WG

> Concentrate: 5.9 %
>
> Spray dilution: 7.2 %
>
> Based on in vivo rat study

**Appendix 1 – list of endpoints**

**Exposure scenarios (Annex IIIA, point 7.2)**

| Operator | The estimated exposure from Londax® (application rate of 0.06 kg bensulfuron-methyl/ha) according to the German model was below the AOEL even without PPE; according to the UK POEM, exposure is below the AOEL only if PPE are worn. | |
|---|---|---|
| | German Model: field crop | % of AOEL |
| | No PPE | 3,91 % |
| | with PPE (gloves during mixing/loading and application) | |
| | | 0,29 % |
| | UK POEM: field crop | |
| | No PPE | 258,5 % |
| | with PPE (gloves during mixing/loading and application) | |
| | | 4,6 % |
| Workers | No risk identified for the proposed uses (5.4 % of the AOEL) | |
| Bystanders | No risk identified for the proposed uses (0.3 % of the AOEL) | |

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

| | RMS/peer review proposal |
|---|---|
| Substance classified (bensulfuron-methyl) | No classification proposed |

**Appendix 1 – list of endpoints**

**Residues**

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

| | |
|---|---|
| Plant groups covered | Cereals (rice, soil treatment); foliar treatment not covered (new data necessary) |
| Rotational crops | Wheat, cabbage, onions, garlic and beets |
| Metabolism in rotational crops similar to metabolism in primary crops? | Not possible to conclude (data necessary) |
| Processed commodities | Not required since no significant, no analytically determinable residues occur in the plant or plant product to be processed. |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Not applicable since no processing studies have to be performed |
| Plant residue definition for monitoring | Bensulfuron-methyl (provisional) |
| Plant residue definition for risk assessment | Bensulfuron-methyl (provisional) |
| 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 applicable for the representative use |
| Time needed to reach a plateau concentration in milk and eggs | Not applicable for the representative use |
| Animal residue definition for monitoring | Not applicable for the representative use |
| Animal residue definition for risk assessment | Not applicable for the representative use |
| Conversion factor (monitoring to risk assessment) | None |
| Metabolism in rat and ruminant similar (yes/no) | Not applicable since no livestock metabolism study is required |
| Fat soluble residue: (yes/no) | No |

**Appendix 1 – list of endpoints**

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

| Further metabolites identification in the rotated crops (wheat) is required. |
| --- |

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

| Rice grain: up to 42 months at $-24\ ^0$C, rice straw up to 18 months at $-20\ ^0$C. |
| --- |

**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 $\geq 0.1$ 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 $\geq 0.01$ mg/kg in edible tissues (yes/no) | No | No | No |
|  | Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) | | |
|  | Residue levels in matrices: Mean (max) mg/kg | | |
| Muscle | No data, not required | No data, not required | No data, not required |
| Liver | No data, not required | No data, not required | No data, not required |
| Kidney | No data, not required | No data, not required | No data, not required |
| Fat | No data, not required | No data, not required | No data, not required |
| Milk | No data, not required | | |
| Eggs | | No data, not required | |

**Appendix 1 – list of endpoints**

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

| Crop | Northern or Mediterranean Region, field or glasshouse, and any other useful information | Trials results relevant to the representative uses (a) | Recommendation/comments | MRL estimated from trials according to the representative use | HR (c) | STMR (b) |
|---|---|---|---|---|---|---|
| Rice grain | S, flooded land | 3 x < 0.01 mg/kg; 6 x < 0.02 mg/kg | MRL can be proposed | 0.02 mg/kg | 0.02 mg/kg | 0.01 mg/kg |
| Rice straw | S, flooded land | 3 x < 0.05 mg/kg | | n/a | 0.05 mg/kg | 0.05 mg/kg |
| Rice grain | S, saturated land | 4 x < 0.01 mg/kg | MRL can be proposed | 0.01 mg/kg | 0.01 mg/kg | 0.01 mg/kg |
| Rice straw | S, saturated land | 3 x < 0.05 mg/kg; 1 x 0.1 mg/kg | | n/a | 0.1 mg/kg | 0.05 mg/kg |

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

**Appendix 1 – list of endpoints**

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

| | |
|---|---|
| ADI | 0.2 mg/kg bw/day |
| TMDI (% ADI) according to WHO European diet | **Note:** Risk assessment not finalised; based on provisional residue defintion for risk assessment <br><br> WHO/GEMS European diet, 2003: 0.000004 mg/kg/day (<0.1%) <br><br> WHO/GEMS Cluster Consumption Diets, 2005 <br> Cluster B: 0.000011 mg/kg/day (<0.1%) <br> Cluster E: 0.000004 mg/kg/day (<0.1%) <br> Cluster F: 0.000004 mg/kg/day (<0.1%) <br> Cluster: D 0.000011 mg/kg/day (<0.1%) |
| TMDI (% ADI) according to national (to be specified) diets | **Note:** Risk assessment not finalised; based on provisional residue defintion for risk assessment <br><br> UK Consumer Exposure Model, 2006 <br> Adult: 0.000045 mg/kg/day (<1%) <br> Infant:  0.000056 mg/kg/day (<1%) <br> Toddler: 0.000094 mg/kg/day (<1%) <br> 4-6 years old child:  0.000074 mg/kg/day  (<1%) <br> 7-10 years old child: 0.0001 mg/kg/day (<1%) <br> 11-14 years old child: 0.000078 mg/kg/day (<1%) <br> 15-18 years old child: 0.000053 mg/kg/day (<1%) <br> Vegetarian: 0.00004 mg/kg/day (<1%) <br> Elderly/own home: 0.000023 mg/kg/day (<1%) <br> Elderly/residential: 0.0000097 mg/kg/day (<1%) <br> German model: <br> 2-5 years old child: 0.000005 mg/kg/day (<0.1%) |
| IEDI (WHO European Diet) (% ADI) | Not required since TMDI is below 100% |
| NEDI (specify diet) (% ADI) | Not required since TMDI is below 100% |
| Factors included in IEDI and NEDI | Not required since IEDI, NEDI not necessary |
| ARfD | Not applicable |
| IESTI (% ARfD) | Not applicable |
| NESTI (% ARfD) according to national (to be specified) large portion consumption data | Not applicable |
| Factors included in IESTI and NESTI | Not applicable |

**Appendix 1 – list of endpoints**

**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 | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

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

| Rice grain | 0.02* mg/kg **Note:** provisional proposal since based on provisional residue defintion for monitoring |
| --- | --- |
| | |

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure

**Appendix 1 – list of endpoints**

**Fate and Behaviour in the Environment**

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

| | |
|---|---|
| Mineralization after 100 days | Phenyl: 13.0% (after 95 days), 14.2-39% (after 119 days) <br> Pyrimidine: 2-25% (after 95-119 days) |
| Non-extractable residues after 100 days | Phenyl: 11-24.9% (after 95-119 days) <br> Pyrimidine: 13-25.7% (after 95-119 days) |
| Relevant metabolites - name and/or code, % of applied (range and maximum) | IN-R9419 (27.7%); IN-D1R84 (18.2%); IN-J0290 (pyrimidine amine, 46%); IN-F7880 (4.30%), IN-N5297 (sulphonamide, 21%) |

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

| | |
|---|---|
| Anaerobic degradation | $DT_{50}$ of bensulfuron-methyl (phenyl label): 118 days (average, n=1) <br> IN-N5297, IN-J0290, and IN-R9419 major degradation products |
| Soil photolysis | Average $DT_{50}$ = 27 days with continuous irradiation; Adjusted $DT_{50}$ =44-64 days with a 12-hour photo-period <br> Major degradation products: IN-N5297 (sulfonamide) IN-T5831 (pyrimidinyl urea) |

## Appendix 1 – list of endpoints

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

| Method of calculation | Software program ModelManager® (ver. 1.1, Cherwell Scientific Limited). Non linear SFO |
|---|---|
| Laboratory studies (range or median, with n value, with $r^2$ value) | |

$DT_{50lab}$ (25°C, aerobic): **bensulfuron-methyl**

| Soil | MWHC[b] | %OC | $pH_w$ | $DT_{50}$ (d) | $r^2$ |
|---|---|---|---|---|---|
| Silt loam | 70% | 2.4 | 5.6 | 89 | 0.978 |
| Silt loam | 70% | 1.0 | 6.7 | 89 | 0.941 |
| Sandy loam | | 70% | 1.2 | 5.2 | 65 0.875 |
| Clay loam | 70% | 6.1 | 6.1 | 102 | 0.809 |
| Silt loam | 70% | 1.1 | 6.5 | 90 | 0.84 |

$DT_{50lab}$ (20°C, aerobic)

| Soil | MWHC | %OC | pH | DT | r |
|---|---|---|---|---|---|
| Loamy sand | | 50% | 0.5 | 5.2 | 25 0.957 |

$DT_{50lab}$ (20°C, aerobic) **IN-J0290**

| Soil | MWHC[b] | %OC | pHw | $DT_{50}$(d) | $r^2$ |
|---|---|---|---|---|---|
| Sandy loam F | 50% | 0.8 | 8.0 | 19 | 0.936 |
| Sandy loam | 50% | 0.3 | 5.5 | 18 | 0.880 |
| Loamy sand | 50% | 2.5 | 6.7 | 3 | 0.995 |
| Silt loam | 50% | 1.0 | 6.1 | 13 | 0.864 |

$DT_{50lab}$ (20°C, aerobic) **IN-N5297**

| Soil | MWHC[b] | %OC | $pH_w$ | $DT_{50}$ (d) | $r_2$ |
|---|---|---|---|---|---|
| Sandy loam | 50% | 0.8 | 8.0 | 7 | 0.995 |
| Sandy loam | 50% | 0.3 | 5.5 | 63 | 0.924 |
| Loamy sand | 50% | 2.5 | 6.7 | 4 | 0.997 |
| Silt loam | 50% | 1.0 | 6.1 | 45 | 0.951 |

**Appendix 1 – list of endpoints**

| $DT_{50lab}$ (20°C, aerobic) **IN-R9419** | | | | | |
|---|---|---|---|---|---|
| Soil | $MWHC^b$ | %OC | $pH_w$ | | $DT_{50}$ (d) $r^2$ |
| Sandy loam | 50% | 1.0 | 8.1 | 20 | 0.960 |
| Sandy loam | 50% | 0.6 | 5.8 | 29 | 0.950 |
| Loamy sand | 50% | 2.1 | 5.9 | 8 | 0.975 |
| Silt loam | 50% | 1.2 | 6.2 | 20 | 0.877 |
| Loamy sand | 50% | 0.5 | 5.2 | 54* | >0.957 |

\* associated kinetic formation fraction from a.s. 0.51

| $DT_{50lab}$ (20°C, aerobic) **IN-D1R84** | | | | | |
|---|---|---|---|---|---|
| Soil | $MWHC^b$ | %OC | $pH_w$ | $DT_{50}$ | (d) $r^2$ |
| Sandy loam | 50% | 1.0 | 8.1 | 11 | 0.981 |
| Sandy loam | 50% | 0.6 | 5.8 | 17 | 0.934 |
| Loamy sand | 50% | 2.1 | 5.9 | 3 | 0.958 |
| Silt loam | 50% | 1.2 | 6.2 | 19 | 0.970 |

| $DT_{50lab}$ (20°C, aerobic) **IN-F7880** | | | | | |
|---|---|---|---|---|---|
| Soil | $MWHC^b$ | %OC | $pH_w$ | $DT_{50}$ (d) | r2 |
| Sandy loam | 50% | 1.0 | 8.1 | 4.1 | 0.994 |
| Sandy loam | 50% | 0.6 | 5.8 | 18.8 | 0.957 |
| Loamy sand | 50% | 2.1 | 5.9 | 5.6 | 0.958 |
| Silt loam | 50% | 1.2 | 6.2 | 20.2 | 0.947 |
| Loamy sand | 50% | 0.5 | 5.2 | 30.5* | >0.957 |

\* associated kinetic formation fraction from a.s. 0.1
[b] MWHC = Maximum Water Holding Capacity (0 bar)

| $DT_{90lab}$ (25°C, aerobic): **bensulfuron-methyl** | | | | | |
|---|---|---|---|---|---|
| Soil | $MWHC^b$ | %OC | $pH_w$ | $DT_{90}$ (d) | $r^2$ |
| Silt loam | 70% | 2.4 | 5.6 | 294 | 0.978 |
| Silt loam | 70% | 1.0 | 6.7 | 294 | 0.941 |
| Sandy loam | 70% | 1.2 | 5.2 | 214 | 0.875 |
| Clay loam | 70% | 6.1 | 6.1 | 339 | 0.809 |
| Silt loam | 70% | 1.1 | 6.5 | 297 | 0.84 |

| $DT_{90lab}$ (20°C, aerobic) | | | | | |
|---|---|---|---|---|---|
| Loamy sand | 50% | 0.5 | 5.2 | 84 | 0.957 |

| $DT_{90lab}$ (20°C, aerobic) **IN-J0290** | | | | | |
|---|---|---|---|---|---|
| Soil | $MWHC^b$ | %OC | pHw | $DT_{90}$ | (d) $r^2$ |
| Sandy loam F | | 50% | 0.8 | 8.0 | 63 0.936 |
| Sandy loam | 50% | 0.3 | 5.5 | 60 | 0.880 |
| Loamy sand | 50% | 2.5 | 6.7 | 10 | 0.995 |
| Silt loam | 50% | 1.0 | 6.1 | 42 | 0.864 |

**Appendix 1 – list of endpoints**

| | | | | | |
|---|---|---|---|---|---|
| $DT_{90lab}$ (20°C, aerobic) **IN-N5297** | | | | | |
| Soil | $MWHC^b$ | %OC | $pH_w$ | $DT_{90}$ (d) $r_2$ | |
| Sandy loam | 50% | 0.8 | 8.0 | 23 | 0.995 |
| Sandy loam | 50% | 0.3 | 5.5 | 208 | 0.924 |
| Loamy sand | 50% | 2.5 | 6.7 | 13 | 0.997 |
| Silt loam | 50% | 1.0 | 6.1 | 148 | 0.951 |
| $DT_{90lab}$ (20°C, aerobic) **IN-R9419** | | | | | |
| Soil | $MWHC^b$ | %OC | $pH_w$ | $DT_{90}$ (d) | $r^2$ |
| Sandy loam | 50% | 1.0 | 8.1 | 65 | 0.960 |
| Sandy loam | 50% | 0.6 | 5.8 | 95 | 0.950 |
| Loamy sand | 50% | 2.1 | 5.9 | 27 | 0.975 |
| Silt loam | 50% | 1.2 | 6.2 | 65 | 0.877 |
| Loamy sand | 50% | 0.5 | 5.2 | 181 | >0.957 |
| $DT_{90lab}$ (20°C, aerobic) **IN-D1R84** | | | | | |
| Soil | $MWHC^b$ | %OC | pHw | $DT_{90}$ (d) | $r^2$ |
| Sandy loam | 50% | 1.0 | 8.1 | 35 | 0.981 |
| Sandy loam | 50% | 0.6 | 5.8 | 55 | 0.934 |
| Loamy sand | 50% | 2.1 | 5.9 | 11 | 0.958 |
| Silt loam | 50% | 1.2 | 6.2 | 62 | 0.970 |
| $DT_{90lab}$ (20°C, aerobic) **IN-F7880** | | | | | |
| Soil | $MWHC^b$ | %OC | $pH_w$ | $DT_{90}$ (d) | r2 |
| Sandy loam | 50% | 1.0 | 8.1 | 13.5 | 0.994 |
| Sandy loam | 50% | 0.6 | 5.8 | 62.4 | 0.957 |
| Loamy sand | 50% | 2.1 | 5.9 | 18.4 | 0.958 |
| Silt loam | 50% | 1.2 | 6.2 | 67.1 | 0.947 |
| Loamy sand | 50% | 0.5 | 5.2 | 101 | >0.957 |
| $^b$ MWHC = Maximum Water Holding Capacity (0 bar) | | | | | |
| $DT_{50lab}$ (10°C, aerobic): Not relevant | | | | | |
| DT50lab (25°C, anaerobic): **bensulfuron-methyl** | | | | | |
| Soil | $MWHC^b$ | %OC | pHw | $DT_{50}$ (d) $r^2$ | |
| Silt loam | N/A | 1.1 | 7.0 | 118 | 0.880 |
| Degradation in the saturated zone: Not required | | | | | |

Field studies (state location, range or median with n value)

| $DT_{50f}$: | | | |
|---|---|---|---|
| **Water** | $pH_w$ | $DT_{50}$ (d) | $r^2$ |
| Ceretto Lomellina (94) | 7.5-8.3 | 2 | 0.834 |
| Ceretto Lomellina (95) | 8.2-8.9 | 1.5 | 0.947 |
| Ceretto Lomellina (96) | 7.5-8.2 | 3 | |

**Appendix 1 – list of endpoints**

| | | | | |
|---|---|---|---|---|
| | 0.708 | | | |
| Villarboit (94) | 7.6-8.6 | 4 | | 0.985 |
| Villarboit (95) | 7.3-7.9 | 3 | | 0.927 |
| Villarboit (96) | 7.3-8.5 | 3 | | 0.892 |
| Rosate (94) | 8.5-8.6 | 5 | | 0.721 |
| Rosate (95) | 7.3-8.7 | 5 | | 0.973 |
| Rosate (96) | 6.9-7.8 | 6 | | 0.908 |
| **Soil** | **%OC** $\underline{r^2}$ | **pHs** | **DT$_{50}$** | **(d)** |
| Ceretto  Lomellina (94) | 0.937 | 0.8 | 6.2 | 12 |
| Ceretto Lomellina (95) | 0.843 | 0.8 | 6.2 | 4 |
| Ceretto Lomellina (96) | 0.963 | 0.8 | 6.2 | 7 |
| Villarboit (94) | 1.2 | 5.7 | 14 | 0.983 |

DT$_{90f}$:

| **Water** | **pH$_w$** | | **DT$_{90}$ (d)** | $\underline{r^2}$ |
|---|---|---|---|---|
| Ceretto  Lomellina (94) | | | 7.5-8.3 | 7 |
| | 0.834 | | | |
| Ceretto Lomellina (95) | | | 8.2-8.9 | 5 |
| | 0.947 | | | |
| Ceretto Lomellina (96) | | | 7.5-8.2 | 10 |
| | 0.709 | | | |
| Villarboit (94) | 7.6-8.6 | | 12 | 0.985 |
| Villarboit (95) | 7.3-7.9 | | 10 | 0.927 |
| Villarboit (96) | 7.3-8.5 | | 11 | 0.892 |
| Rosate (94) | 8.5-8.6 | | 18 | 0.721 |
| Rosate (95) | 7.3-8.7 | | 18 | 0.973 |
| Rosate (96) | 6.9-7.8 | | 19 | 0.908 |
| **Soil** | **%OC** $\underline{r^2}$ | **pH$_s$** | **DT$_{90}$** | **(d)** |
| Ceretto Lomellina (94) | 0.937 | 0.8 | 6.2 | 39 |
| Ceretto Lomellina (95) | 0.843 | 0.8 | 6.2 | 14 |
| Ceretto Lomellina (96) | 0.963 | 0.8 | 6.2 | 23 |
| Villarboit (94) | 1.2 | 5.7 | 48 | 0.983 |

| | |
|---|---|
| Soil accumulation and plateau concentration: | Not relevant |

## Appendix 1 – list of endpoints

**Soil adsorption/desorption (Annex IIA, point 7.1.2)**

$K_f/K_{oc}$
(mL/g)

| **Bensulfuron-methyl** | | | | | |
|---|---|---|---|---|---|
| Soil | OC% | pH | $K_f$ | $K_{foc}$ | l/n |
| Sandy loam | 1.2 | 6.5 | 2.5 | 205 | 0.89 |
| Sandy loam | 0.6 | 6.6 | 1.4 | 219 | 0.88 |
| Silt loam | 4.4 | 5.2 | 12 | 276 | 0.97 |
| Silt loam | 2.5 | 5.4 | 14 | 561 | 0.93 |
| Arithmetic mean | | | | 315 | |
| | | | | | 0.92 |
| **IN-F7880** | | | | | |
| Soil | OC% | pH | $K_f$ | $K_{foc}$ | l/n |
| Sandy loam | 1.0 | 8.1 | 1.6 | 161 | 0.92 |
| Sandy loam | 0.6 | 5.8 | 0.5 | 75 | 0.90 |
| Loamy sand | 2.2 | 5.9 | 3.1 | 140 | 1.14 |
| Silt loam | 1.0 | 6.1 | 2.2 | 181 | 1.01 |
| Clay loam | 3.0 | 5.6 | 14.2 | 472 | 1.05 |
| Arithmetic mean | | | | 206 | |
| | | | | | 1.0 |
| **IN-J0290** | | | | | |
| Soil | OC% | pH | $K_f$ | $K_{foc}$ | l/n |
| Sandy loam | 0.7 | 7.8 | 0.90 | 123 | 0.79 |
| Loamy sand | 0.5 | 5.2 | 2.3 | 452 | 0.81 |
| Loamy sand | 2.1 | 6.7 | 1.2 | 58 | 0.85 |
| Silt loam | 1.2 | 6.1 | 2.35 | 196 | 0.82 |
| Silt loam | 3.1 | 5.5 | 45.3 | 1460 | 0.71 |
| Arithmetic mean | | | | 458 | |
| | | | | | 0.80 |
| **IN-N5297** | | | | | |
| Soil | OC% | pH | $K_f$ | $K_{foc}$ | l/n |
| Sandy loam | 0.7 | 7.8 | 0.14 | 20 | 0.92 |
| Loamy sand | 0.5 | 5.2 | 0.074 | 15 | 0.92 |
| Loamy sand | 2.1 | 6.4 | 0.40 | 19 | 0.94 |
| Silt loam | 1.2 | 5.8 | 0.43 | 36 | 0.93 |
| Silt loam | 3.1 | 5.5 | 2.8 | 92 | 0.91 |
| Arithmetic mean | | | | 36.4 | |
| | | | | | 0.92 |
| **IN-R9419** | | | | | |
| Soil | OC% | pH | $K_f$ | $K_{foc}$ | l/n |
| Sandy loam | 1.0 | 8.1 | 0.3 | 28 | 0.93 |
| Sandy loam | 0.6 | 5.8 | 1.49 | 248 | 0.89 |
| Loamy sand | 2.2 | 5.9 | 1.86 | 84.5 | 0.91 |
| Silt loam | 1.0 | 6.1 | 1.87 | 187 | 0.89 |
| Clay loam | 3.0 | 5.6 | 17.4 | 580 | 0.89 |
| Arithmetic mean | | | | 225 | |
| | | | | | 0.90 |

**Appendix 1 – list of endpoints**

$K_d$
(mL/g)

| **IN-D1R84** | | | | | |
|---|---|---|---|---|---|
| Soil | OC% | pH | $K_f$ | $K_{foc}$ | l/n |
| Sandy loam | 1.0 | 8.1 | 0.0173 | 2 | 0.45 |
| Sandy loam | 0.6 | 5.8 | 0.123 | 21 | 0.84 |
| Loamy sand | 2.2 | 5.9 | 0.133 | 6 | 0.71 |
| Silt loam | 1.0 | 6.1 | 0.103 | 10 | 0.77 |
| Clay loam | 3.0 | 5.6 | 0.231 | 8 | 0.78 |
| Arithmetic mean | | | | 9.4 | |
| | 0.71 | | | | |

**Bensulfuron-methyl**:
AMR 254-84: ($K_d$ and $K_{oc}$ values were recalculated by notifier from raw data)

| Soil | OC% | pH | $K_d$ | $K_{oc}$ |
|---|---|---|---|---|
| Sandy loam | 1.2 | 6.5 | 2.9 | 241 |
| Sandy loam | 0.6 | 6.6 | 1.6 | 250 |
| Silt loam | 4.4 | 5.2 | 13.3 | 303 |
| Silt loam | 2.5 | 5.4 | 7.2 | 689 |

| **IN-J0290** | | | | |
|---|---|---|---|---|
| Soil | OC% | pH | $K_d$ | $K_{oc}$ |
| Sandy loam | 0.7 | 7.8 | 1.71 | 245 |
| Loamy sand | 0.5 | 5.2 | 4.76 | 952 |
| Loamy sand | 2.1 | 6.7 | 2.01 | 96 |
| Silt loam | 1.2 | 6.1 | 4.69 | 391 |
| Silt loam | 3.1 | 5.5 | 212 | 6849 |

| **IN-N5297** | | | | |
|---|---|---|---|---|
| Soil | OC% | pH | $K_d$ | $K_{oc}$ |
| Sandy loam | 0.7 | 7.8 | 0.17 | 25 |
| Loamy sand | 0.5 | 5.2 | 0.09 | 18 |
| Loamy sand | 2.1 | 6.4 | 0.48 | 23 |
| Silt loam | 1.2 | 5.8 | 0.54 | 45 |
| Silt loam | 3.1 | 5.5 | 3.86 | 125 |

| **IN-R9419** | | | | |
|---|---|---|---|---|
| Soil | OC% | pH | $K_d$ | $K_{oc}$ |
| Sandy loam | 1.0 | 8.1 | 0.33 | 33 |
| Sandy loam | 0.6 | 5.8 | 2.04 | 341 |
| Loamy sand | 2.2 | 5.9 | 2.49 | 113 |
| Silt loam | 1.0 | 6.1 | 2.65 | 265 |
| Clay loam | 3.0 | 5.6 | 25.9 | 862 |

**Appendix 1 – list of endpoints**

| IN-D1R84 | | | | |
|---|---|---|---|---|
| Soil | OC% | pH | $K_d$ | $K_{oc}$ |
| Sandy loam | 1.0 | 8.1 | 0.09 | 9 |
| Sandy loam | 0.6 | 5.8 | 0.19 | 32 |
| Loamy sand | 2.2 | 5.9 | 0.30 | 14 |
| Silt loam | 1.0 | 6.1 | 0.19 | 19 |
| Clay loam | 3.0 | 5.6 | 0.47 | 16 |
| **IN-F7880** | | | | |
| Soil | OC% | pH | $K_d$ | $K_{oc}$ |
| Sandy loam | 1.0 | 8.1 | 2.2 | 222 |
| Sandy loam | 0.6 | 5.8 | 0.7 | 65 |
| Loamy sand | 2.2 | 5.9 | 2.1 | 95 |
| Silt loam | 1.0 | 6.1 | 2.2 | 187 |
| Clay loam | 3.0 | 5.6 | 13.5 | 449 |

| pH dependence (yes/no) (if yes, type of dependence) | No |
|---|---|

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

| Column leaching | No data available not required |
|---|---|
| Aged residues leaching | No data available not required |
| Lysimeter/field leaching studies | No data available not required |

## Appendix 1 – list of endpoints

**PEC (soil) (Annex IIIA, point 9.1.3)**

| Method of calculation | |
|---|---|
| | Tier 1: Med-Rice (2003)<br>Foliar interception: 0%<br>Compound   Max formation   Kfoc   Total W/S $DT_{50}$<br>Bensulfuron<br>methyl          100              315        59 days<br>IN-F7880     9.7              206        79.1<br>IN-R9419    27.7             225        6.9<br>IN-J0290     46.0             458        21.1<br>IN-N5297    31.7             36          30.8<br>IN-T5831     13.7             3.96       21.1<br>IN-DAT97    9.9              9            37.8<br>IN-D1R84    18.2             9            10.2<br><br>For IN-D1R84 the geomean from aerobic soil study was used. For IN-T5831 the same $DT_{50}$ as for IN-J0290 was used (structurally similar metabolite<br><br>Higher tier: RICEWQ 1.64 and RIVWQ 2.02<br>Bensulfuron-methyl: $K_{oc}$= 315, paddy water $DT_{50}$: 4 days, paddy soil $DT_{50}$: 12 days (field study), foliar interception 50%<br>60 g a.s./ha to flooded paddies |

**$PEC_{SOIL}$ (paddy soil) in the Med-Rice clay scenario (µg/kg dry weight) – 10 cm water**

| Chemical | Actual or TWA (µg/kg) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 4 | 7 | 14 | 21 | 28 | 42 | 50 | 100 |
| bensulfuron methyl | Actual | 64.7 | 64.0 | 63.3 | 61.8 | 59.6 | 54.9 | 50.6 | 46.6 | 39.5 | 36.0 | 20.0 |
| | TWA | -- | 64.4 | 64.0 | 63.2 | 62.2 | 59.7 | 57.4 | 55.2 | 51.1 | 49.0 | 38.1 |
| IN-F7880 | Actual | 5.51 | 5.46 | 5.42 | 5.32 | 5.18 | 4.88 | 4.58 | 4.31 | 3.81 | 3.56 | 2.29 |
| | TWA | - | 5.49 | 5.46 | 5.42 | 5.35 | 5.19 | 5.03 | 4.89 | 4.61 | 4.46 | 3.67 |
| IN-R9419 | Actual | 16.1 | 14.6 | 13.2 | 10.8 | 7.99 | 3.96 | 1.96 | 0.970 | 0.238 | 0.106 | 0.0007 |
| | TWA | -- | 15.4 | 14.6 | 13.3 | 11.6 | 8.67 | 6.73 | 5.40 | 3.77 | 3.19 | 1.61 |
| IN-D1R84 | Actual | 0.826 | 0.772 | 0.721 | 0.630 | 0.514 | 0.319 | 0.198 | 0.123 | 0.0476 | 0.0276 | 0.0009 |
| | TWA | -- | 0.799 | 0.773 | 0.724 | 0.658 | 0.533 | 0.440 | 0.370 | 0.273 | 0.235 | 0.122 |
| IN-J0290 | Actual | 11.9 | 11.6 | 11.2 | 10.5 | 9.48 | 7.54 | 5.99 | 4.76 | 3.00 | 2.31 | 0.447 |
| | TWA | -- | 11.7 | 11.6 | 11.2 | 10.7 | 9.57 | 8.62 | 7.80 | 6.47 | 5.86 | 3.50 |
| IN-N5297 | Actual | 4.62 | 4.52 | 4.42 | 4.22 | 3.95 | 3.37 | 2.88 | 2.46 | 1.80 | 1.50 | 0.487 |
| | TWA | -- | 4.57 | 4.52 | 4.42 | 4.28 | 3.96 | 3.68 | 3.43 | 2.99 | 2.77 | 1.84 |
| IN-T5831 | Actual | 0.572 | 0.554 | 0.536 | 0.502 | 0.454 | 0.361 | 0.287 | 0.228 | 0.144 | 0.111 | 0.0214 |
| | TWA | -- | 0.563 | 0.554 | 0.536 | 0.511 | 0.458 | 0.413 | 0.374 | 0.310 | 0.281 | 0.168 |
| IN-DAT97 | Actual | 0.670 | 0.658 | 0.646 | 0.623 | 0.590 | 0.518 | 0.456 | 0.401 | 0.310 | 0.268 | 0.107 |
| | TWA | -- | 0.664 | 0.658 | 0.646 | 0.629 | 0.591 | 0.556 | 0.524 | 0.467 | 0.439 | 0.307 |

**Appendix 1 – list of endpoints**

**PEC$_{soil}$ (paddy soil) in the Med-Rice sand scenario (µg/kg dry weight) - ) – 10 cm water**

| Chemical | Actual or TWA (µg/kg) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 4 | 7 | 14 | 21 | 28 | 42 | 50 | 100 |
| bensulfuron methyl | Actual | 54.4 | 53.7 | 53.1 | 51.9 | 50.1 | 46.2 | 42.5 | 39.2 | 33.2 | 30.2 | 16.8 |
| | TWA | -- | 54.1 | 53.8 | 53.2 | 52.2 | 50.2 | 48.2 | 46.4 | 42.9 | 41.1 | 32.0 |
| IN-F7880 | Actual | 4.36 | 4.32 | 4.28 | 4.21 | 4.10 | 3.86 | 3.63 | 3.41 | 3.02 | 2.81 | 1.81 |
| | TWA | -- | 4.34 | 4.32 | 4.28 | 4.23 | 4.10 | 3.98 | 3.86 | 3.65 | 3.53 | 2.90 |
| IN-R9419 | Actual | 12.9 | 11.7 | 10.6 | 8.66 | 6.41 | 3.17 | 1.57 | 0.777 | 0.190 | 0.0852 | 0.0006 |
| | TWA | -- | 12.3 | 11.7 | 10.6 | 9.30 | 6.95 | 5.39 | 4.32 | 3.02 | 2.56 | 1.29 |
| IN-D1R84 | Actual | 0.437 | 0.408 | 0.381 | 0.333 | 0.271 | 0.169 | 0.105 | 0.0651 | 0.0252 | 0.0146 | 0.0005 |
| | TWA | -- | 0.422 | 0.408 | 0.382 | 0.348 | 0.282 | 0.233 | 0.195 | 0.144 | 0.124 | 0.0642 |
| IN-J0290 | Actual | 10.5 | 10.1 | 9.81 | 9.19 | 8.32 | 6.61 | 5.26 | 4.18 | 2.64 | 2.03 | 0.392 |
| | TWA | -- | 10.3 | 10.1 | 9.82 | 9.36 | 8.40 | 7.57 | 6.85 | 5.68 | 5.14 | 3.07 |
| IN-N5297 | Actual | 2.76 | 2.70 | 2.64 | 2.52 | 2.36 | 2.02 | 1.72 | 1.47 | 1.07 | 0.897 | 0.291 |
| | TWA | -- | 2.73 | 2.70 | 2.64 | 2.56 | 2.37 | 2.20 | 2.05 | 1.79 | 1.66 | 1.10 |
| IN-T5831 | Actual | 0.302 | 0.293 | 0.283 | 0.265 | 0.240 | 0.191 | 0.152 | 0.121 | 0.0761 | 0.0585 | 0.0113 |
| | TWA | -- | 0.298 | 0.293 | 0.283 | 0.270 | 0.242 | 0.218 | 0.198 | 0.164 | 0.148 | 0.0886 |
| IN-DAT97 | Actual | 0.354 | 0.348 | 0.342 | 0.329 | 0.312 | 0.274 | 0.241 | 0.212 | 0.164 | 0.142 | 0.0566 |
| | TWA | -- | 0.351 | 0.348 | 0.342 | 0.335 | 0.312 | 0.294 | 0.277 | 0.247 | 0.232 | 0.162 |

**Maximum value of PEC$_{soil}$ (paddy soil) in Med-Rice sand & clay scenario (µg/kg dry weight) – 1 cm water**

| Compound | Clay scenario (PEC$_{soil}$ µg/kg) | Sand scenario (PEC$_{soil}$ µg/kg) |
|---|---|---|
| Bensulfuron-methyl | 78.2 | 76.0 |
| IN-F7880 | 7.23 | 6.99 |
| IN-R9419 | 20.8 | 20.1 |
| IN-D1R84 | 4.18 | 2.88 |
| IN-J0290 | 13.6 | 13.4 |
| IN-N5297 | 11.7 | 10.0 |
| IN-T5831 | 2.90 | 2.00 |
| IN-DAT97 | 3.39 | 2.34 |

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

| Hydrolysis of active substance and relevant metabolites (DT$_{50}$) (state pH and temperature) | pH4: DT$_{50}$=6.1 days at 25°C Major metabolites that were formed: IN-J0290 (98.3%) for pyrimidine label and IN-N5297 (98.6%) for phenyl label |
|---|---|
| | pH7: Stable at 25°C |

**Appendix 1 – list of endpoints**

| Photolytic degradation of active substance and relevant metabolites | pH9: 141 days at 25°C<br>Major metabolite that was formed: IN-R9419, at 15.5% for pyrimidine label and 14.6% for phenyl label |
|---|---|
| | Photolytic degradation of [phenyl(U)$^{14}$C]label was used at pH 5, 7, and 9; [pyrimidine-2-$^{14}$C] label was used at pH 9. Continuous direct sunlight (global radiation 285-2800 nm) for up to 30 days.<br><br>**pH**　　　　　　$DT_{50}$　　　　**Corrected $DT_{50}$**<br>5 (phenyl)　　　　13　　　　　　>1000<br>7 (phenyl)　　　251　　　　　　505<br>9 (phenyl)　　　223　　　　　　405<br>9 (pyrimidine)　286　　　　　　>1000<br>No major metabolites were observed |
| | Photolytic degradation of bensulfuron-methyl was determined in natural water and pH 7 buffer solution<br>Continuous irradiatiom xenon arc lamp for 15 days.<br><br>**Water source**　　　　　　　$DT_{50}$　　$R^2$<br>Cavrini Farm Pond water　　　10　　0.824<br>Ten-Mile Creek water　　　　89　　0.876<br>Irradiated sterile buffer　　　29　　0.848<br>Non-irradiated sterile buffer　stable　　nd |

**Appendix 1 – list of endpoints**

| Photolytic degradation of bensulfuron-methyl was determined in a simulated paddy system and pH 7 buffer solution | | |
|---|---|---|
| **Water/sediment source** | $DT_{50}$ | $R^2$ |
| *Total systems*: | | |
| Irradiated Cavrini Farm Pond system | 12.7 | |
| | 0.993 | |
| Non-irradiated Cavrini Farm Pond system | | 33.1 |
| | 0.936 | |
| Irradiated Lonoke system | 14.2 | |
| | 0.944 | |
| Non-irradiated Lonoke system | 35.9 | |
| | 0.963 | |
| *Water*: | | |
| Irradiated Cavrini Farm Pond water | 7.7 | |
| | 0.987 | |
| Non-irradiated Cavrini Farm Pond water | | 14.3 |
| | 0.937 | |
| Irradiated Lonoke water | 6.7 | |
| | 0.930 | |
| Non-irradiated Lonoke water | 15.8 | |
| | 0.991 | |
| Irradiated sterile buffer | 50.3 | |
| | 0.937 | |

| Readily biodegradable (yes/no) | No | |
|---|---|---|

Degradation in water/sediment
- $DT_{50}$ water

| **Pavia (loamy sand)** | **Vercelli (silt loam)** |
|---|---|
| *Bensulfuron-methyl* | |
| 21 d | 16 d |
| *IN-J0290* | |
| 55.3 d | 74.6 d |
| *IN-N5297* | |
| Not major met. | 106 d |
| *IN-F7880* | |
| 60.6 d | Not major met. |
| *IN-DAT97* | |
| 54.3 d | 394 d |
| *IN-R9419* | |
| 9.1 d | 7.0 d |

**Appendix 1 – list of endpoints**

| - DT$_{90}$ water | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
|---|---|---|
| | *Bensulfuron-methyl* | |
| | 69 d | 52 d |
| | *IN-J0290* | |
| | 184 d | 254 d |
| | *IN-N5297* | |
| | Not major met. | 353 d |
| | *IN-F7880* | |
| | 201 d | Not major met. |
| | *IN-DAT97* | |
| | 180 d | n.a. |
| | *IN-R9419* | |
| | 30.1 d | 23.2 d |
| - DT$_{50}$ whole system | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| | *Bensulfuron-methyl* | |
| | 37 d | 59 d |
| | *IN-J0290* | |
| | Not major met. | 21.1 d ff from a.s. 0.302 |
| | *IN-N5297* | |
| | Not major met. | 30.8 d ff from a.s. 0.363 |
| | *IN-F7880* | |
| | 39.2 d ff from a.s. 0.178 | 79.1 d ff from a.s. 0.087 |
| | *IN-DAT97* | |
| | 34.6 d ff from a.s. 0.162 | 37.8 ff from a.s. 0.092 |
| | *IN-R9419* | |
| | 6.9 d ff from a.s. 0.291 | 3.5 d ff from a.s. 0.501 |
| - DT$_{90}$ whole system | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| | *Bensulfuron-methyl* | |
| | 122 d | 195 d |
| | *IN-N5297* | |
| | Not major met. | 102 d |
| | *IN-F7880* | |
| | 115 d | 263 d |
| | *IN-DAT97* | |
| | 115 d | 126 d |
| | *IN-R9419* | |
| | 22.9 d | 11.6 d |

## Appendix 1 – list of endpoints

| Mineralisation | *Pyrimidine label*: | |
|---|---|---|
| | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| | 16.7% (130d) | 16.6% (130d) |
| | *Phenyl label*: | |
| | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| | 26.1% (130d) | 14.9% (130d) |
| Non-extractable residues | *Pyrimidine label*: | |
| | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| | 25% (100d) | 43% (130d) |
| | *Phenyl label*: | |
| | Pavia | Vercelli |
| | 14% (100d) | 32%(130d) |
| Distribution in water / sediment systems (active substance) | *Phenyl & Pyrimidine labels* | |
| | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| | Total 7.6-7.9% (130d) | 23.3-24.9% (130d) |
| | Water 0.3-0.4% (130d) | 5.1 - 6.9% (130d) |
| | Sediment 7.3-7.5% (130d) | 18.0-18.2% (130d) |
| Distribution in water / sediment systems (metabolites) | Relevant metabolites that were formed >10% in Pavia and Vercelli systems (in total system): | |

**IN-J0290**

| *Pyrimidine* | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
|---|---|---|
| Total | 19.7% (130d) | 8.2% (40d) |
| Water | 10.1% (70d) | 5.1% (0d) |
| Sediment | 18.4% (130d) | 4.7% (40d) |

**IN-DAT97**

| *Pyrimidine* | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
|---|---|---|
| Total | 9.9% (50d) | 3.6% (40d) |
| Water | 8.4% (50d) | 3.0% (40d) |
| Sediment | 1.9% (100d) | 0.9% (100d) |
| *Phenyl label:* | | |
| Total | 1.4 (50d) | 0.5% (70d) |
| Water | 1.4% (50d) | 0.5% (70d) |
| Sediment | 1.9% (100d) | 0.9% (100d) |

**Appendix 1 – list of endpoints**

| **IN-F7880** | | |
|---|---|---|
| *Pyrimidine* | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| Total | 9.71% (40d) | 4.5% (70d) |
| Water | 9.04% (40d) | 2.9% (70d) |
| Sediment | 4.11% (21d)% | 1.62% (70d) |
| *Phenyl* | | |
| Total | 9.51%(70d) | 5.34% (70d) |
| Water | 5.42%(70d) | 2.5% (130d) |
| Sediment | 4.09% (70d) | 3.0% (70d) |

| **IN-N5297** | | |
|---|---|---|
| *Pyrimidine* | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| Total | N/A | N/A |
| Water | N/A | N/A |
| Sediment | N/A | N/A |
| *Phenyl label:* | | |
| Total | 31.73% (130d) | 16.13%(50d) |
| Water | 27.30% (130d) | 10.28% (50d) |
| Sediment | 4.43% (130d) | 5.85% (50d) |

| **IN-D1R84** | | |
|---|---|---|
| *Pyrimidine* | **Pavia (loamy sand)** | **Vercelli (silt loam)** |
| Total | N/A | N/A |
| Water | N/A | N/A |
| Sediment | N/A | N/A |
| *Phenyl label:* | | |
| Total | 4.17% (130d) | 9.95%(130d) |
| Water | <1.62% (130d) | 7.31% (130d) |
| Sediment | 2.55% (130d) | 2.64% (130d) |

**Appendix 1 – list of endpoints**

**PEC (surface water)** (Annex IIIA, point 9.2.3)

| Method of calculation | Tier 1:  Med-Rice (2003) Foliar interception: 0% |
|---|---|

Tier 1:  Med-Rice (2003)
Foliar interception: 0%

| Compound | Max formation | $K_{foc}$ | Total W/S $DT_{50}$ |
|---|---|---|---|
| Bensulfuron methyl | 100 | 315 | 59 days |
| IN-F7880 | 9.7 | 206 | 79.1 |
| IN-R9419 | 27.7 | 225 | 6.9 |
| IN-J0290 | 46.0 | 458 | 21.1 |
| IN-N5297 | 31.7 | 36 | 30.8 |
| IN-T5831 | 13.7 | 3.96 | 21.1 |
| IN-DAT97 | 9.9 | 9 | 37.8 |
| IN-D1R84 | 18.2 | 9 | 10.2 |

For IN-D1R84 the geomean from aerobic soil study was used. For IN-T5831 the same DT50 as for IN-J0290 was used (structurally similar metabolite

| Application rate | 60 g a.s./ha to flooded paddies |
|---|---|
| Main routes of entry | drainage water from treated paddy and spray drift |

**$PEC_{PW}$ (paddy water) in the Med-Rice clay scenario (µg/L)**

| Chemical | Actual or TWA (µg/L) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 4 | 7 | 14 | 21 | 28 | 42 | 50 | 100 |
| bensulfuron methyl | Actual | 11.4 | 11.3 | 11.2 | 10.9 | 10.5 | 9.69 | 8.92 | 8.22 | 6.97 | 6.35 | 3.53 |
| | TWA | -- | 11.4 | 11.3 | 11.2 | 11.0 | 10.5 | 10.1 | 9.73 | 9.02 | 8.64 | 6.72 |
| IN-F7880 | Actual | 1.49 | 1.47 | 1.46 | 1.44 | 1.40 | 1.31 | 1.24 | 1.16 | 1.03 | 0.959 | 0.619 |
| | TWA | -- | 1.48 | 1.47 | 1.46 | 1.44 | 1.40 | 1.36 | 1.32 | 1.24 | 1.20 | 0.990 |
| IN-R9419 | Actual | 3.99 | 3.61 | 3.26 | 2.67 | 1.97 | 0.977 | 0.484 | 0.239 | 0.0587 | 0.0263 | 0.0002 |
| | TWA | -- | 3.79 | 3.61 | 3.28 | 2.86 | 2.14 | 1.66 | 1.33 | 0.931 | 0.789 | 0.397 |
| IN-D1R84 | Actual | 5.10 | 4.77 | 4.45 | 3.87 | 3.17 | 1.97 | 1.22 | 0.761 | 0.294 | 0.171 | 0.0057 |
| | TWA | -- | 4.93 | 4.77 | 4.46 | 4.06 | 3.29 | 2.72 | 2.28 | 1.68 | 1.45 | 0.750 |
| IN-J0290 | Actual | 1.45 | 1.40 | 1.36 | 1.27 | 1.15 | 0.914 | 0.726 | 0.577 | 0.364 | 0.280 | 0.0542 |
| | TWA | -- | 1.42 | 1.40 | 1.36 | 1.29 | 1.16 | 1.05 | 0.947 | 0.785 | 0.711 | 0.424 |
| IN-N5297 | Actual | 7.13 | 6.97 | 6.82 | 6.52 | 6.09 | 5.21 | 4.45 | 3.80 | 2.77 | 2.32 | 0.752 |
| | TWA | -- | 7.05 | 6.98 | 6.82 | 6.60 | 6.12 | 5.68 | 5.29 | 4.61 | 4.28 | 2.84 |
| IN-T5831 | Actual | 3.53 | 3.42 | 3.31 | 3.10 | 2.81 | 2.30 | 1.77 | 1.41 | 0.889 | 0.683 | 0.132 |
| | TWA | -- | 3.47 | 3.42 | 3.31 | 3.15 | 2.83 | 2.55 | 2.31 | 1.92 | 1.73 | 1.03 |
| IN-DAT97 | Actual | 4.13 | 4.06 | 3.99 | 3.84 | 3.64 | 3.20 | 2.82 | 2.48 | 1.92 | 1.65 | 0.661 |
| | TWA | -- | 4.10 | 4.06 | 3.99 | 3.88 | 3.65 | 3.43 | 3.24 | 2.88 | 2.71 | 1.90 |

## Appendix 1 – list of endpoints

**PEC$_{PW}$ (paddy water) in the Med-Rice sand scenario (μg/L)**

| Chemical | Actual or TWA (μg/L) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **1** | **2** | **4** | **7** | **14** | **21** | **28** | **42** | **50** | **100** |
| bensulfuron methyl | Actual | 19.2 | 19.0 | 18.7 | 18.3 | 17.7 | 16.3 | 15.0 | 13.8 | 11.7 | 10.7 | 5.9 |
| | TWA | -- | 19.1 | 19.0 | 18.7 | 18.4 | 17.7 | 17.0 | 16.4 | 15.1 | 14.5 | 11.3 |
| IN-F7880 | Actual | 2.35 | 2.33 | 2.31 | 2.27 | 2.21 | 2.08 | 1.96 | 1.84 | 1.63 | 1.52 | 0.979 |
| | TWA | -- | 2.34 | 2.33 | 2.31 | 2.28 | 2.21 | 2.15 | 2.08 | 1.97 | 1.90 | 1.56 |
| IN-R9419 | Actual | 6.39 | 5.78 | 5.23 | 4.28 | 3.16 | 1.57 | 0.775 | 0.383 | 0.0940 | 0.0421 | 0.0003 |
| | TWA | -- | 6.08 | 5.79 | 5.26 | 4.59 | 3.43 | 2.66 | 2.14 | 1.49 | 1.26 | 0.636 |
| IN-D1R84 | Actual | 5.39 | 5.04 | 4.71 | 4.11 | 3.35 | 2.08 | 1.29 | 0.804 | 0.311 | 0.180 | 0.0060 |
| | TWA | -- | 5.21 | 5.04 | 4.72 | 4.29 | 3.48 | 2.87 | 2.41 | 1.78 | 1.53 | 0.793 |
| IN-J0290 | Actual | 2.54 | 2.46 | 2.38 | 2.23 | 2.02 | 1.60 | 1.28 | 1.01 | 0.640 | 0.492 | 0.0952 |
| | TWA | -- | 2.50 | 2.46 | 2.38 | 2.27 | 2.04 | 1.84 | 1.66 | 1.38 | 1.25 | 0.745 |
| IN-N5297 | Actual | 8.53 | 8.34 | 8.15 | 7.79 | 7.28 | 6.22 | 5.32 | 4.54 | 3.31 | 2.77 | 0.898 |
| | TWA | -- | 8.43 | 8.34 | 8.16 | 7.89 | 7.31 | 6.80 | 6.33 | 5.52 | 5.12 | 3.39 |
| IN-T5831 | Actual | 3.73 | 3.61 | 3.50 | 3.27 | 2.97 | 2.36 | 1.87 | 1.49 | 0.940 | 0.722 | 0.140 |
| | TWA | -- | 3.67 | 3.61 | 3.50 | 3.34 | 2.99 | 2.70 | 2.44 | 2.02 | 1.83 | 1.09 |
| IN-DAT97 | Actual | 4.37 | 4.29 | 4.22 | 4.06 | 3.85 | 3.38 | 2.98 | 2.62 | 2.02 | 1.75 | 0.699 |
| | TWA | -- | 4.33 | 4.30 | 4.22 | 4.11 | 3.86 | 3.63 | 3.42 | 3.05 | 2.86 | 2.00 |

**PEC$_{SW}$ (receiving ditch water) in the Med-Rice clay scenario (μg/L)**

| Chemical | Actual or TWA (μg/L) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **1** | **2** | **4** | **7** | **14** | **21** | **28** | **42** | **50** | **100** |
| bensulfuron methyl | Actual | 1.08 | 1.07 | 1.06 | 1.03 | 0.997 | 0.918 | 0.846 | 0.779 | 0.661 | 0.602 | 0.334 |
| | TWA | -- | 1.08 | 1.07 | 1.06 | 1.04 | 0.998 | 0.959 | 0.923 | 0.854 | 0.819 | 0.637 |
| IN-F7880 | Actual | 0.140 | 0.139 | 0.138 | 0.135 | 0.132 | 0.124 | 0.117 | 0.110 | 0.0970 | 0.0905 | 0.0584 |
| | TWA | -- | 0.140 | 0.139 | 0.138 | 0.136 | 0.132 | 0.128 | 0.124 | 0.117 | 0.114 | 0.0934 |
| IN-R9419 | Actual | 0.239 | 0.216 | 0.195 | 0.160 | 0.118 | 0.0585 | 0.0290 | 0.0143 | 0.0035 | 0.0016 | 0.0000 |
| | TWA | -- | 0.227 | 0.216 | 0.197 | 0.171 | 0.128 | 0.0994 | 0.0798 | 0.0557 | 0.0472 | 0.0238 |
| IN-D1R84 | Actual | 0.340 | 0.318 | 0.297 | 0.259 | 0.211 | 0.131 | 0.0817 | 0.0507 | 0.0196 | 0.0114 | 0.0004 |
| | TWA | -- | 0.329 | 0.318 | 0.298 | 0.271 | 0.220 | 0.181 | 0.152 | 0.112 | 0.0968 | 0.0500 |
| IN-J0290 | Actual | 0.126 | 0.122 | 0.118 | 0.111 | 0.100 | 0.0796 | 0.0632 | 0.0502 | 0.0317 | 0.0244 | 0.0047 |
| | TWA | -- | 0.124 | 0.122 | 0.118 | 0.113 | 0.101 | 0.0910 | 0.0824 | 0.0684 | 0.0619 | 0.0369 |
| IN-N5297 | Actual | 0.602 | 0.589 | 0.576 | 0.551 | 0.514 | 0.440 | 0.376 | 0.321 | 0.234 | 0.196 | 0.0635 |
| | TWA | -- | 0.596 | 0.589 | 0.576 | 0.557 | 0.517 | 0.480 | 0.447 | 0.390 | 0.362 | 0.239 |
| IN-T5831 | Actual | 0.281 | 0.272 | 0.263 | 0.246 | 0.223 | 0.177 | 0.141 | 0.112 | 0.0706 | 0.0543 | 0.0105 |
| | TWA | -- | 0.276 | 0.272 | 0.263 | 0.251 | 0.225 | 0.203 | 0.184 | 0.152 | 0.138 | 0.0823 |
| IN-DAT97 | Actual | 0.354 | 0.347 | 0.341 | 0.329 | 0.311 | 0.274 | 0.241 | 0.212 | 0.164 | 0.141 | 0.0565 |
| | TWA | -- | 0.351 | 0.347 | 0.341 | 0.332 | 0.312 | 0.294 | 0.277 | 0.247 | 0.232 | 0.162 |

### Appendix 1 – list of endpoints

**PEC$_{SW}$ (receiving ditch water) in the Med-Rice sand scenario (µg/L)**

| Chemical | Actual or TWA (µg/L) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **1** | **2** | **4** | **7** | **14** | **21** | **28** | **42** | **50** | **100** |
| bensulfuron methyl | Actual | 1.75 | 1.73 | 1.71 | 1.67 | 1.61 | 1.48 | 1.37 | 1.26 | 1.07 | 0.972 | 0.540 |
| | TWA | -- | 1.74 | 1.73 | 1.71 | 1.68 | 1.61 | 1.55 | 1.49 | 1.38 | 1.32 | 1.03 |
| IN-F7880 | Actual | 0.215 | 0.214 | 0.212 | 0.208 | 0.203 | 0.191 | 0.179 | 0.169 | 0.149 | 0.139 | 0.897 |
| | TWA | -- | 0.214 | 0.214 | 0.212 | 0.209 | 0.203 | 0.197 | 0.191 | 0.180 | 0.174 | 0.144 |
| IN-R9419 | Actual | 0.371 | 0.336 | 0.303 | 0.248 | 0.184 | 0.0909 | 0.0450 | 0.0223 | 0.0055 | 0.0024 | 0.0000 |
| | TWA | -- | 0.353 | 0.336 | 0.306 | 0.266 | 0.199 | 0.154 | 0.124 | 0.0866 | 0.0734 | 0.0369 |
| IN-D1R84 | Actual | 0.359 | 0.336 | 0.314 | 0.274 | 0.223 | 0.139 | 0.0862 | 0.0536 | 0.0207 | 0.0120 | 0.0004 |
| | TWA | -- | 0.347 | 0.336 | 0.314 | 0.286 | 0.232 | 0.191 | 0.161 | 0.119 | 0.102 | 0.0528 |
| IN-J0290 | Actual | 0.210 | 0.204 | 0.197 | 0.185 | 0.167 | 0.133 | 0.106 | 0.0839 | 0.0530 | 0.0407 | 0.0079 |
| | TWA | -- | 0.207 | 0.204 | 0.197 | 0.188 | 0.169 | 0.152 | 0.138 | 0.114 | 0.103 | 0.0617 |
| IN-N5297 | Actual | 0.716 | 0.700 | 0.684 | 0.654 | 0.611 | 0.522 | 0.446 | 0.381 | 0.278 | 0.232 | 0.0754 |
| | TWA | -- | 0.708 | 0.700 | 0.684 | 0.662 | 0.614 | 0.570 | 0.531 | 0.463 | 0.430 | 0.284 |
| IN-T5831 | Actual | 0.296 | 0.287 | 0.278 | 0.260 | 0.236 | 0.187 | 0.149 | 0.118 | 0.0746 | 0.0573 | 0.0111 |
| | TWA | -- | 0.292 | 0.287 | 0.278 | 0.265 | 0.238 | 0.214 | 0.194 | 0.161 | 0.146 | 0.0868 |
| IN-DAT97 | Actual | 0.373 | 0.367 | 0.360 | 0.347 | 0.328 | 0.289 | 0.254 | 0.223 | 0.173 | 0.149 | 0.0597 |
| | TWA | -- | 0.370 | 0.367 | 0.360 | 0.350 | 0.329 | 0.310 | 0.292 | 0.260 | 0.244 | 0.171 |

### PEC (sediment)

| | |
|---|---|
| Method of calculation | Tier 1: Med-Rice (2003) <br> Foliar interception: 0% <br><br> Compound  Max formation  K$_{foc}$   Total W/S DT$_{50}$ <br> Bensulfuron <br> methyl      100          315       59 days <br> IN-F7880    9.7          206       79.1 <br> IN-R9419    27.7         225       6.9 <br> IN-J0290    46.0         458       21.1 <br> IN-N5297    31.7         36        30.8 <br> IN-T5831    13.7         3.96      21.1 <br> IN-DAT97    9.9          9         37.8 <br> IN-D1R84    18.2         9         10.2 <br><br> For IN-D1R84 the geomean from aerobic soil study was used. For IN-T5831 the same DT50 as for IN-J0290 was used (structurally similar metabolite |
| Application rate | 60 g a.s./ha to flooded paddies |

## Appendix 1 – list of endpoints

**PEC$_{SED}$ (receiving ditch sediment) in the Med-Rice clay scenario (µg/kg dry weight)**

| Chemical | Actual or TWA (µg/kg) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 4 | 7 | 14 | 21 | 28 | 42 | 50 | 100 |
| bensulfuron methyl | Actual | 4.51 | 4.46 | 4.41 | 4.31 | 4.16 | 3.83 | 3.53 | 3.25 | 2.76 | 2.51 | 1.39 |
| | TWA | -- | 4.49 | 4.46 | 4.41 | 4.33 | 4.16 | 4.00 | 3.85 | 3.56 | 3.41 | 2.65 |
| IN-F7880 | Actual | 0.415 | 0.412 | 0.408 | 0.401 | 0.391 | 0.367 | 0.346 | 0.325 | 0.288 | 0.268 | 0.173 |
| | TWA | -- | 0.414 | 0.412 | 0.408 | 0.403 | 0.391 | 0.379 | 0.368 | 0.348 | 0.336 | 0.277 |
| IN-R9419 | Actual | 0.761 | 0.688 | 0.622 | 0.509 | 0.376 | 0.186 | 0.0922 | 0.0457 | 0.0112 | 0.0050 | 0.0000 |
| | TWA | -- | 0.724 | 0.689 | 0.626 | 0.546 | 0.408 | 0.317 | 0.254 | 0.178 | 0.150 | 0.0757 |
| IN-D1R84 | Actual | 0.0533 | 0.0498 | 0.0466 | 0.0406 | 0.0331 | 0.0206 | 0.0128 | 0.0080 | 0.0031 | 0.0018 | 0.0001 |
| | TWA | -- | 0.0516 | 0.0499 | 0.0467 | 0.0424 | 0.0344 | 0.0284 | 0.0238 | 0.0176 | 0.0152 | 0.0078 |
| IN-J0290 | Actual | 0.697 | 0.674 | 0.652 | 0.611 | 0.554 | 0.440 | 0.349 | 0.278 | 0.175 | 0.135 | 0.0261 |
| | TWA | -- | 0.685 | 0.674 | 0.653 | 0.622 | 0.558 | 0.503 | 0.455 | 0.378 | 0.342 | 0.204 |
| IN-N5297 | Actual | 0.366 | 0.358 | 0.350 | 0.335 | 0.313 | 0.267 | 0.228 | 0.195 | 0.142 | 0.119 | 0.0386 |
| | TWA | -- | 0.362 | 0.358 | 0.350 | 0.339 | 0.314 | 0.292 | 0.272 | 0.237 | 0.220 | 0.146 |
| IN-T5831 | Actual | 0.0440 | 0.0426 | 0.0412 | 0.0386 | 0.0350 | 0.0278 | 0.0221 | 0.0175 | 0.0111 | 0.0085 | 0.0016 |
| | TWA | -- | 0.0433 | 0.0426 | 0.0412 | 0.0393 | 0.0353 | 0.0318 | 0.0288 | 0.0239 | 0.0216 | 0.0129 |
| IN-DAT97 | Actual | 0.0554 | 0.0544 | 0.0535 | 0.0515 | 0.0488 | 0.0429 | 0.0377 | 0.0332 | 0.0257 | 0.0222 | 0.0089 |
| | TWA | -- | 0.0549 | 0.0544 | 0.0535 | 0.0520 | 0.0489 | 0.0460 | 0.0434 | 0.0387 | 0.0363 | 0.0254 |

**PEC$_{SED}$ (receiving ditch sediment) in the Med-Rice sand scenario (µg/kg dry weight)**

| Chemical | Actual or TWA (µg/kg) | Days after application | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0 | 1 | 2 | 4 | 7 | 14 | 21 | 28 | 42 | 50 | 100 |
| bensulfuron methyl | Actual | 7.19 | 7.11 | 7.02 | 6.86 | 6.62 | 6.10 | 5.62 | 5.18 | 4.39 | 4.00 | 2.22 |
| | TWA | -- | 7.15 | 7.11 | 7.02 | 6.90 | 6.63 | 6.37 | 6.13 | 5.68 | 5.44 | 4.23 |
| IN-F7880 | Actual | 0.634 | 0.628 | 0.623 | 0.612 | 0.596 | 0.561 | 0.528 | 0.496 | 0.439 | 0.409 | 0.264 |
| | TWA | -- | 0.631 | 0.628 | 0.623 | 0.615 | 0.597 | 0.579 | 0.562 | 0.531 | 0.513 | 0.422 |
| IN-R9419 | Actual | 1.17 | 1.06 | 0.960 | 0.785 | 0.581 | 0.287 | 0.142 | 0.0704 | 0.0173 | 0.0077 | 0.0001 |
| | TWA | -- | 1.12 | 1.06 | 0.966 | 0.842 | 0.630 | 0.489 | 0.392 | 0.274 | 0.232 | 0.117 |
| IN-D1R84 | Actual | 0.0563 | 0.0526 | 0.0491 | 0.0429 | 0.0350 | 0.0217 | 0.0135 | 0.0084 | 0.0032 | 0.0019 | 0.0001 |
| | TWA | -- | 0.0544 | 0.0526 | 0.0493 | 0.0448 | 0.0363 | 0.0300 | 0.0252 | 0.0186 | 0.0160 | 0.0083 |
| IN-J0290 | Actual | 1.14 | 1.10 | 1.06 | 0.996 | 0.902 | 0.717 | 0.570 | 0.453 | 0.286 | 0.220 | 0.0425 |
| | TWA | -- | 1.12 | 1.10 | 1.06 | 1.01 | 0.910 | 0.820 | 0.742 | 0.616 | 0.558 | 0.333 |
| IN-N5297 | Actual | 0.435 | 0.426 | 0.416 | 0.398 | 0.372 | 0.318 | 0.271 | 0.232 | 0.169 | 0.141 | 0.0459 |
| | TWA | -- | 0.430 | 0.426 | 0.416 | 0.403 | 0.373 | 0.347 | 0.323 | 0.282 | 0.261 | 0.173 |
| IN-T5831 | Actual | 0.0465 | 0.0450 | 0.0435 | 0.0407 | 0.0369 | 0.0293 | 0.0233 | 0.0185 | 0.0117 | 0.0090 | 0.0017 |
| | TWA | -- | 0.0457 | 0.0450 | 0.0435 | 0.0415 | 0.0372 | 0.0336 | 0.0304 | 0.0252 | 0.0228 | 0.0136 |
| IN-DAT97 | Actual | 0.0585 | 0.0575 | 0.0564 | 0.0544 | 0.0515 | 0.0453 | 0.0398 | 0.0350 | 0.0271 | 0.0234 | 0.0094 |
| | TWA | -- | 0.0580 | 0.0575 | 0.0564 | 0.0549 | 0.0516 | 0.0486 | 0.0458 | 0.0408 | 0.0383 | 0.0268 |

For presentation purposes, PEC values were rounded to three significant figures or to a maximum of four decimal places.

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

## Appendix 1 – list of endpoints

| Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter) | Annual average calculation based on Med-Rice (2003). Two water depths considered: 1 cm and 10 cm. Tier 1: Med-Rice (2003) Foliar interception: 0% |||||
|---|---|---|---|---|---|
| | Compound | Max formation | $K_{foc}$ | Total W/S $DT_{50}$ ||
| | Bensulfuron methyl | 100 | 315 | 59 days ||
| | IN-F7880 | 9.7 | 206 | 79.1 ||
| | IN-R9419 | 27.7 | 225 | 6.9 ||
| | IN-J0290 | 46.0 | 458 | 21.1 ||
| | IN-N5297 | 31.7 | 36 | 30.8 ||
| | IN-T5831 | 13.7 | 3.96 | 21.1 ||
| | IN-DAT97 | 9.9 | 9 | 37.8 ||
| | IN-D1R84 | 18.2 | 9 | 10.2 ||
| | For IN-D1R84 the geomean from aerobic soil study was used. For IN-T5831 the same DT50 as for IN-J0290 was used (structurally similar metabolite |||||
| Application rate | 60 g a.s./ha |||||

**PEC (gw)**

| Compound | Annual average $PEC_{GW}$ (µg/L)[a,b] | | |
|---|---|---|---|
| | Clay scenario | Sand scenario | Sand scenario |
| | 10 and 1 cm water | 10 cm water | 1 cm water |
| bensulfuron-methyl | 0.0000 | 0.0391 | 0.0356 |
| IN-F7880 | 0.0000 | 0.0149 | 0.0154 |
| IN-R9419 | 0.0000 | 0.0000 | 0.0000 |
| IN-D1R84 | 0.0000 | 0.0126 | 0.0629 |
| IN-J0290 | 0.0000 | 0.0000 | 0.0000 |
| IN-N5297 | 0.0000 | 0.0633 | 0.1545 |
| IN-T5831 | 0.0000 | 0.0275 | 0.126 |
| IN-DAT97 | 0.0003 (0.0007 with 1 cm water) | 0.0524 | 0.229 |

**Appendix 1 – list of endpoints**

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

| | |
|---|---|
| Direct photolysis in air | No data, not required |
| Quantum yield of direct phototransformation | 0.00003 in sterile pH 7 buffer |
| Photochemical oxidative degradation in air ($DT_{50}$) | $DT_{50}$: 0.611 hours based on 12-hr day; $1.5 \times 10^6$ OH radicals per $cm^3$ |
| Volatilization | From plant surfaces: Bensulfuron-methyl is a non-volatile crystalline solid. The vapour pressure is less than $3 \times 10^{-12}$ Pa at 20°C, and volatilization is not expected. |
| | From soil: volatilization is not expected. |

**PEC** (air)

| | |
|---|---|
| Method of calculation | - |

**PEC$_{(a)}$**

| | |
|---|---|
| Maximum concentration | Negligible based on experts judgement |

**Residues requiring further assessment**

| | |
|---|---|
| Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered | Based on the currently available information (cannot be finalised until a data gap is filled)<br><br>Soil: Bensulfuron-methyl, IN-F7880, bensulfuron (IN-R9419), IN-J0290, IN-N5297, IN-T5831, IN-DAT97, IN-D1R84<br>Surface water: Bensulfuron-methyl, IN-F7880, bensulfuron (IN-R9419), IN-J0290, IN-N5297, IN-T5831, IN-DAT97, IN-D1R84<br>Sediment: Bensulfuron-methyl, IN-J0290<br><br>Groundwater: Bensulfuron-methyl, IN-F7880, bensulfuron (IN-R9419), IN-J0290, IN-N5297, IN-T5831, IN-DAT97, IN-D1R84<br>Air: bensulfuron-methyl |

**Appendix 1 – list of endpoints**

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

| | |
|---|---|
| Soil (indicate location and type of study) | Italy, with SIGMA 60DF<br>Type of study: Monitoring of surface and groundwaters in Italy in the district of East and West Sesia (Italy) to evaluate contamination by bensulfuron-methyl<br>Soil samples were collected at the rice field in East and West of Sesia at the piezometer site. Samples were taken every 0.5 meters for the first 5 meters and every meter for the next 15 meters<br>The two –year study of bensulfuron-methyl indicated that bensulfuron-methyl had no impact in the entire water systems of the region. No phenomena of accumulation, mobility into groundwater, and persistence were observed. |
| Surface water (indicate location and type of study) | Italy, with DPX-JM206 60WG (SIGMA 60DF)<br>Type of study: Monitoring of surface and ground waters in Italy in the district of East and West Sesia to evaluate contamination by bensulfuron-methyl.<br>Location: Four surface water samples from East Sesia and two from West Sesia, Italy.<br>The two–year study of bensulfuron-methyl indicated that bensulfuron-methyl had no impact in the entire water systems of the region. No phenomena of accumulation, mobility into groundwater, and persistence were observed. The presence of bensulfuron-methyl in surface water is limited to the period of application (about 30 days between mid-May and mid-June), and is influenced by precipitation and /or regulation of the water in the chambers. The maximum concentration found in water was 0.32 ppb in the Marcova and 0.16 ppb in the Sesia in the proximity of the mouth of the Roggione di Sartirana on June 2, 1998.<br><br>Italy, with SIGMA 60DF<br>Two surface water monitoring studies were made to evaluate the environmental fate of bensulfuron-methyl following use of DPX-JM206 60WG herbicide used during rice production in Italy. The selected surface water sampling locations represent main irrigation channels and permanent waterways that receive drainage from rice paddies surrounding Vercelli, Italy. The data show that bensulfuron-methyl is only detectable in the waterways during the two months following application of DPX- |

**Appendix 1 – list of endpoints**

| | |
|---|---|
| | JM206 60WG, and that the concentrations are very low (<0.7 µg/L) even during that two-month period. Monitoring results from these two studies support the conclusion that bensulfuron-methyl does not pose a significant threat of persistent contamination in the waterways of the monitored area. DuPont-15347 |
| Ground water (indicate location and type of study) | Italy with DPX-JM206 60WG Type of study: Monitoring of surface and groundwater in Italy in the district of East and West Sesia to evaluate contamination by bensulfuron-methyl. Location: Groundwater from East and West Sesia, Italy was sampled using 6 piezometers adjacent to a 1.5-ha rice paddy treated with SIGMA. The two –year study of bensulfuron-methyl indicated that bensulfuron-methyl had no impact in the entire water systems of the region. No phenomena of accumulation, mobility into groundwater, and persistence were observed. The presence of bensulfuron-methyl in surface water is limited to the period of application (about 30 days between mid-May and mid-June), and is influenced by precipitation and /or regulation of the water in the chambers. The maximum concentration found in water was 0.32 ppb in the Marcova and 0.16 ppb in the Sesia in the proximity of the mouth of the Roggione di Sartirana on June 2, 1998 |
| Air (indicate location and type of study) | Not relevant |

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

| |
|---|
| Not ready biodegradable - candidate for R53 |

**Appendix 1 – list of endpoints**

**Effect on non target species**

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

| | |
|---|---|
| Acute toxicity to birds | LD50= >2510 mg/kg bw (male and female mallard duck) |
| Acute toxicity to mammals | LD50 = >5000 mg/kg bw (rat) |
| Dietary toxicity to birds | LC50 of > 5620 ppm(mallard duck, bobwhite quail) >1678 mg a.s./kg bw/day, bobwhite quail >1690 mg a.s./kg bw/day, mallard duck |
| Reproductive toxicity to birds | NOEC = 560 ppm (83 mg a.s./kg bw/day, mallard duck) |
| Reproductive toxicity to mammals | NOEL = 250 ppm (20.9 mg a.s./kg bw/day, rat) |

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

| Application rate (kg a.s./ha) | Crop | Category (*e.g.,* insectivorous bird) | Time-scale | TER | Annex VI Trigger |
|---|---|---|---|---|---|
| 0.06 | Rice | Large herbivorous bird | Acute | >669 | 10 |
| 0.06 | Rice | Insectivorous bird | Acute | >772 | 10 |
| 0.06 | Rice | Small herbivorous mammal | Acute | >422 | 10 |
| 0.06 | Rice | Insectivorous mammal | Acute | >9434 | 10 |
| 0.06 | Rice | Large herbivorous bird | Short-term | >835 | 10 |
| 0.06 | Rice | Insectivorous bird | Short-term | >927 | 10 |
| 0.06 | Rice | Large herbivorous bird | Long-term | 78.3 | 5 |
| 0.06 | Rice | Insectivorous bird | Long-term | 45.9 | 5 |
| 0.06 | Rice | Small herbivorous mammal | Long-term | 6.22 | 5 |
| 0.06 | Rice | Insectivorous mammal | Long-term | 108 | 5 |

**Effects on aquatic species (most sensitive species of each group)** (Annex IIA, point 8.2, Annex IIIA, point 10.2)

| | |
|---|---|
| Microcosm or mesocosm tests | Not required |

**Appendix 1 – list of endpoints**

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

| Group | Test substance | Time-scale | Endpoint | Toxicity (mg a.s./L) |
|---|---|---|---|---|
| Laboratory tests | | | | |
| *Oncorynchus mykiss* | Active substance | 96 hours | Mortality $LC_{50}$ | >66 |
| *Procambarus clarki* | Active substance | 96 hours | Mortality $LC_{50}$ | >71 |
| *Oncorynchus mykiss* | Active substance | 90 days | ELS NOEC | 1.5 |
| *Daphnia magna* | Active substance | 21 days | Immobilisation NOEC | 12 |
| *Lemna gibba* | Active substance | 14 days | Growth $EC_{50}$ | 0.0008 |
| *Selenastrum capricornutum* | DPX-F5384 60WG | 72 hours | Growth rate $EC_{50}$ | 0.0077 |
| *Oncorynchus mykiss* | IN-J0290 | 96 hours | Mortality $LC_{50}$ | >97 |
| *Oncorynchus mykiss* | IN-N5297 | 96 hours | Mortality $LC_{50}$ | >118 |
| *Daphnia magna* | IN-J0290 | 48 hours | Immobilisation $EC_{50}$ | >100 |
| *Daphnia magna* | IN-N5297 | 48 hours | Immobilisation $EC_{50}$ | >117 |
| *Daphnia magna* | IN-J0290 | 21 days | Immobilisation NOEC | 24.9 |
| *Daphnia magna* | IN-N5297 | 21 days | Reproduction NOEC | 12.7 |
| *Selenastrum capricornutum* | IN-J0290 | 72 hours | Growth rate $EC_{50}$ | > 120 |
| *Selenastrum capricornutum* | IN-D1R84 | 72 hours | Growth $EC_{50}$ | 36.2 |
| *Selenastrum capricornutum* | IN-N5297 | 72 hours | Growth $EC_{50}$ | >120 |
| *Selenastrum capricornutum* | IN-F7880 | 72 hours | Growth $EC_{50}$ | 32.3 |
| *Selenastrum capricornutum* | IN-DAT97 | 72 hours | Growth $EC_{50}$ | 26.9 |
| *Selenastrum capricornutum* | IN-T5831 | 72 hours | Growth $EC_{50}$ | 41.1 |
| *Selenastrum capricornutum* | IN-R9419 | 72 hours | Growth $EC_{50}$ | 26.4 |
| *Lemna gibba* | IN-J0290 | 14 days | Growth $EC_{50}$ | >100 |
| *Lemna gibba* | IN-N5297 | 14 days | Growth $EC_{50}$ | >120 |
| *Lemna gibba* | IN-F7880 | 14 days | Growth $EC_{50}$ | 1.18 |
| *Lemna gibba* | IN-T5831 | 14 days | Growth $EC_{50}$ | 97.9 |
| *Lemna gibba* | IN-R9419 | 14 days | Growth $EC_{50}$ | 6.2 |
| *Lemna gibba* | IN-D1R84 | 14 days | Growth $EC_{50}$ | >130 |
| *Lemna gibba* | IN-DAT97 | 14 days | Growth $EC_{50}$ | 79.1 |

**Appendix 1 – list of endpoints**

**Acute Tier 1 TERs for aquatic organisms exposed to the maximum Med-Rice PEC in paddy water (PEC$_{pw}$)**

| Test Substance | Test organism | EC$_{50}$ or LC$_{50}$ (mg a.s./L) | Max. PEC$_{pw}$ (mg a.s./L)$^a$ | TER | Annex VI Trigger |
|---|---|---|---|---|---|
| Active substance | *Oncorhynchus mykiss* | >66 | 0.0192 | >3438 | 100 |
| Active substance | *Procambarus clarki* | >71 | 0.0192 | >3698 | 100 |
| DPX-JM206 60WG | *Chironomus tentans* | >125 | 0.0192 | >6510 | 100 |
| DPX-F5384 60WG | *Selenastrum capricornutum* | 0.0077 | 0.0192 | 0.4 | 10 |
| Active substance | *Lemna gibba* | 0.0008 | 0.0192 | **0.04** | 10 |

$^a$ Determined using the Tier 1 Med-Rice (2003) calculation method.

**Acute Tier 1 TERs for aquatic organisms exposed to maximum PEC in paddy water (PEC$_{pw}$) of metabolites of Bensulfuron-methyl**

| Test Substance | Test organism | Toxicological endpoint (mg/L) | Max. PEC$_{pw}$ (mg/L)$^a$ | TER | Annex VI Trigger |
|---|---|---|---|---|---|
| IN-J0290 | *Oncorhynchus mykiss* | >97 | 0.00254 | >38189 | 100 |
| | *Daphnia magna* | >100 | 0.00254 | >39370 | 100 |
| | *Selenastrum capricornutum* | >120 | 0.00254 | >47244 | 10 |
| | *Lemna gibba* | >100 | 0.00254 | >39370 | 10 |
| IN-N5297 | *Oncorhynchus mykiss* | >118 | 0.00853 | >13833 | 100 |
| | *Daphnia magna* | >117 | 0.00853 | >13716 | 100 |
| | *Selenastrum capricornutum* | >120 | 0.00853 | >14068 | 10 |
| | *Lemna gibba* | >120 | 0.00853 | >14068 | 10 |
| IN-D1R84 | *Selenastrum capricornutum* | 36.2 | 0.00539 | 6716 | 10 |
| | *Lemna gibba* | >130 | 0.00539 | >24119 | 10 |
| IN-R9419 | *Selenastrum capricornutum* | 26.4 | 0.00639 | 4131 | 10 |
| | *Lemna gibba* | 6.2 | 0.00639 | 970 | 10 |
| IN-T5831 | *Selenastrum capricornutum* | 41.1 | 0.00373 | 11018 | 10 |
| | *Lemna gibba* | 97.9 | 0.00373 | 26247 | 10 |
| IN-F7880 | *Selenastrum capricornutum* | 13.5 | 0.00235 | 5745 | 10 |

**Appendix 1 – list of endpoints**

| | | | | | |
|---|---|---|---|---|---|
| IN-DAT97 | *Lemna gibba* | 1.18 | 0.00235 | 502 | 10 |
| | *Selenastrum capricornutum* | 26.9 | 0.00437 | 6155 | 10 |
| | *Lemna gibba* | 79.1 | 0.00437 | 18101 | 10 |

[a] Determined using the Tier 1 Med-Rice (2003) model

**Summary of long-term Tier 1 TERs for aquatic organisms exposed to maximum PEC in paddy water (PECpw) of Bensulfuron-methyl**

| Test Substance | Test organism | NOEC (mg a.s./L) | Max. PEC$_{pw}$ (mg a.s./L)[a] | TER | Annex VI Trigger |
|---|---|---|---|---|---|
| Active substance | *Oncorhynchus mykiss* | 1.5 | 0.0192 | 78 | 10 |
| Active substance | *Daphnia magna* | 12 | 0.0192 | 625 | 10 |

[a] Determined using the Tier 1 Med-Rice (2003) model

**Summary of long-term Tier 1 TERs for aquatic organisms exposed to maximum PEC in the paddy water (PECpw) of Bensulfuron-methyl metabolites**

| Test Substance | Test organism | NOEC (mg a.s./L) | Max. PEC$_{pw}$ (mg a.s./L)[a] | TER | Annex VI Trigger |
|---|---|---|---|---|---|
| IN-J0290 | *Daphnia magna* | 24.9 | 0.00254 | 9803 | 10 |
| IN-N5297 | *Daphnia magna* | 12.7 | 0.00853 | 1489 | 10 |

[a] Determined using the Tier 1 Med-Rice (2003) model

**Summary of Tier 1 TERs for algae and *Lemna* exposed to Bensulfuron-methyl in ditches receiving outflow from treated rice paddies**

| Test substance | Test organism | EC$_{50}$ (mg a.s./L) | Max. PEC$_{sw}$ (mg a.s./L)[a] | TER | Annex VI trigger |
|---|---|---|---|---|---|
| Active substance | *Selenastrum capricornutum* | 0.0077 | 0.00175 | 4.4 | 10 |
| Active substance | *Lemna gibba* | 0.0008 | 0.00175 | **0.46** | 10 |

[a] Determined using the Tier 1 Med-Rice (2003) calculation method.

**Appendix 1 – list of endpoints**

**Bioconcentration**

| | |
|---|---|
| Bioconcentration factor (BCF) | 1.6 (*Procambarus clarkii*) |
| Annex VI Trigger for the bioconcentration factor | 1000 |
| Clearance time (CT$_{50}$) | 327 |
| (CT$_{90}$) | Not applicable |
| Level of residues (%) in organisms after the 14-day depuration phase | Not applicable; will not accumulate (<0.4mg/g $^{14}$C) |

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

| | |
|---|---|
| Acute oral toxicity | LD$_{50}$ of >51.41μg a.s./bee |
| Acute contact toxicity | LD$_{50}$ of >100 μg a.s. /bee |

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

| Application rate (kg a.s./ha) | Crop | Route | Hazard quotient | Annex VI Trigger |
|---|---|---|---|---|
| Laboratory tests | | | | |
| 0.06 | Rice | oral | <1.2 | 50 |
| | | contact | <0.6 | 50 |

| | |
|---|---|
| Field or semi-field tests | Not triggered |

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

| Species | Stage | Test Substance | Dose (g a.s./ha) | Endpoint | Effects |
|---|---|---|---|---|---|
| Laboratory tests | | | | | |
| *Aphidius rhopalosiphi* | Nymph | DPX-F5384 60WG | 60, 300, 600 | LR$_{50}$ | >600 |
| *Typhlodromus pyri* | Adult | DPX-F5384 60WG | 60, 300, 600 | LR$_{50}$ | >600 |

**Hazard quotients Tier 1 for the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*** (Annex IIIA, point 10.5)

| Test organism | Application rate | LR$_{50}$ | In-field HQ | Off-field HQ* | Trigger |
|---|---|---|---|---|---|
| *Aphidius rhopalosiphi* | 0.060 kg a.s./ha | >600 g a.s./ha | <0.1 | <0.0028 | 2 |
| *Typhlodromus pyri* | 0.060 kg a.s./ha | >600 g a.s./ha | <0.1 | <0.0028 | 2 |

* calculated with 2.77% drift at 1 m

**Appendix 1 – list of endpoints**

| Field or semi-field tests | Not requested |
|---|---|

**Effects on earthworms** (Annex IIA, point 8.4, Annex IIIA, point 10.6)

| | **Bensulfuron-methyl** |
|---|---|
| Acute toxicity | LC$_{50}$ >1000 mg a.s./kg soil dry wt |
| Reproductive toxicity | Not required |
| | **IN-D1R84** |
| Acute toxicity | LC$_{50}$ >1000 mg a.s./kg soil dry wt |
| Reproductive toxicity | Not required |
| | **IN-F7880** |
| Acute toxicity | LC$_{50}$ >1000 mg a.s./kg soil dry wt |
| Reproductive toxicity | Not required |
| | **IN-N5297** |
| Acute toxicity | LC$_{50}$ >1000 mg a.s./kg soil dry wt |
| Reproductive toxicity | Not required |
| | **IN-R9419** |
| Acute toxicity | LC$_{50}$ >1000 mg a.s./kg soil dry wt |
| Reproductive toxicity | Not required |
| | **IN-J0290** |
| Acute toxicity | LC$_{50}$ >1000 mg a.s./kg soil dry wt |
| Reproductive toxicity | Not required |

**Toxicity/exposure ratios for earthworms** (Annex IIIA, point 10.6)

| Test substance | Crop | Time-scale | LC$_{50}$ (mg a.s./kg soil dry wt) | TER | Annex VI Trigger |
|---|---|---|---|---|---|
| Active substance | Rice | acute | >1000 | >15 456 | 10 |
| IN-D8526 | Rice | acute | >1000 | >181 488 | 10 |
| IN-F7880 | Rice | acute | >1000 | >62 112 | 10 |
| IN-N5297 | Rice | acute | >1000 | >1.21 x 10$^6$ | 10 |
| IN-R9419 | Rice | acute | >1000 | >84 034 | 10 |
| IN-J0290 | Rice | acute | >1000 | >216 450 | 10 |

**Appendix 1 – list of endpoints**

**Effects on other soil non-target macro-organisms** (Annex IIA, point 8.6, Annex IIIA, point 10.6.2)

> Other non-target macro-organisms are not expected to be at risk from exposure to residues Bensulfuron-methyl 60WG. Evidence from earthworms, honeybees, and beneficial arthropods toxicity tests suggest low toxicity of Bensulfuron-methyl 60WG residues to non-target invertebrate fauna. Therefore, Bensulfuron-methyl 60WG, when applied according to Good Agricultural Practice, is expected to pose little acute or long-term risk to soil non-target macro-organisms and no further testing is warranted.

**Effects on soil micro-organisms** (Annex IIA, point 8.5, Annex IIIA, point 10.7)

| | |
|---|---|
| Nitrogen mineralization | No significant effects at 5x field application rate (500g Bensulfuron-methyl 60WG/ha) |
| Carbon mineralization | No significant effects at 5x field application rate (500g Bensulfuron-methyl 60WG/ha) |

**Effects on non-target plants** (Annex IIA, point 8.6)

| Species | Test Substance | Time-scale | End point | Toxicity |
|---------|----------------|------------|-----------|----------|
| Ten plants | DPX-F5384 60WG | Seedling emergence and growth 21 days | $ER_{50}$ | 2.41 g a.s./ha (Oilseed rape) |
| Ten plants | DPX-F5384 60WG | Vegetative vigour 21 days | $ER_{50}$ | 2.08 g a.s./ha (Soybean) |

**Appendix 1 – list of endpoints**

**Toxicity/exposure ratios for non-target plants (Tier 2 deterministic approach and refinement)**

|  | 21 days $ER_{50}$ (g a.s./ha) | Exposure (g a.s./ha) | TER | Trigger value |
|---|---|---|---|---|
| Seedling emergence | 2.41 | 1.66[a] | **1.45** | 5 |
| Seedling emergence | 2.41 | 0.342[b] | 7.05 | |
| Vegetative vigour | 2.08 | 1.66[a] | **1.3** | 5 |
| Vegetative vigour | 2.08 | 0.342[b] | 6.1 | |

[a]60 g a.s./ha (application rate) x 2.77% (spray drift rate for a distance of 1 m of the field edge)

[b]60 g a.s./ha (application rate) x 0.57% (spray drift rate for a distance of 5 m of the field edge)

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

| Test type/organism | Endpoint |
|---|---|
| Activated sludge | $EC_{50}$ >100 mg/l |
| Pseudomonas sp | no data available – not required |

**Classification and proposed labelling** (Annex IIA, point 10)

with regard to ecotoxicological data

| | |
|---|---|
| Symbol: | N |
| Risk phrase | R50/53 |
| Safety phrase | S60, S61 |

**Appendix 2 – abbreviations**

# APPENDIX 2 – ABBREVIATIONS

| | |
|---|---|
| ADI | acceptable daily intake |
| ALD | approximate lethal dose |
| ALS | acetolactate synthase |
| AOEL | acceptable operator exposure level |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| a.s. | active substance |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| bp | boiling point |
| bw | body weight |
| °C | degree Celsius (centigrade) |
| CA | Chemical Abstract |
| CAS | Chemical Abstract Service |
| CIPAC | Collaborative International Pesticide Analytical Council Limited |
| cm | centimetre |
| d | day |
| DAR | draft assessment report |
| DM | dry matter |
| dpi | days past inoculation |
| $DT_{50}$ | period required for 50 percent dissipation (define method of estimation) |
| $DT_{90}$ | period required for 90 percent dissipation (define method of estimation) |
| dw | dry weight |
| DWQG | drinking water quality guidelines |
| $\varepsilon$ | 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 |
| F | field |
| $F_0$ | parental generation |
| $F_1$ | filial generation, first |
| $F_2$ | filial generation, second |

## Appendix 2 – abbreviations

| | |
|---|---|
| FAO | Food and Agriculture Organisation of the United Nations |
| FID | flame ionisation detector |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| f(twa) | time weighted average factor |
| g | gram |
| GAP | good agricultural practice |
| GC | gas chromatography |
| GC-EC | gas chromatography with electron capture detector |
| GC-FID | gas chromatography with flame ionisation detector |
| GC-MS | gas chromatography-mass spectrometry |
| GC-MSD | gas chromatography with mass-selective detection |
| GLC | gas liquid chromatography |
| GLP | good laboratory practice |
| GM | geometric mean |
| GS | growth stage |
| h | hour(s) |
| H | Henry's Law constant (calculated as a unitless value) (see also K) |
| ha | hectare |
| hL | hectolitre |
| HPLC | high pressure liquid chromatography |
| | or high performance liquid chromatography |
| HPLC-MS | high pressure liquid chromatography – mass spectrometry |
| HPPLC | high pressure planar liquid chromatography |
| HPTLC | high performance thin layer chromatography |
| HQ | hazard quotient |
| I | indoor |
| ID | ionisation detector |
| IEDI | international estimated daily intake |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| inh | inhalation |
| k | kilo |
| K | Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H)13 |
| $K_{ads}$ | adsorption constant |
| $K_{des}$ | apparent desorption coefficient |
| $K_{oc}$ | organic carbon adsorption coefficient |
| $K_{om}$ | organic matter adsorption coefficient |

## Appendix 2 – abbreviations

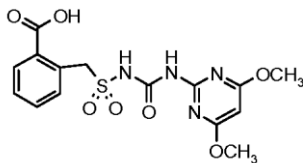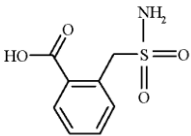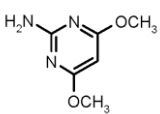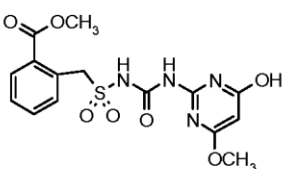| | |
|---|---|
| kg | kilogram |
| L | litre |
| LAN | local area network |
| LC | liquid chromatography |
| LC-MS | liquid chromatography-mass spectrometry |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry |
| $LC_{50}$ | lethal concentration, median |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LOAEL | lowest observable adverse effect level |
| LOD | limit of detection |
| LOEC | lowest observable effect concentration |
| LOEL | lowest observable effect level |
| LOQ | limit of quantification (determination) |
| m | metre |
| M | molar |
| MAF | multiple application factor |
| μm | micrometer (micron) |
| MC | moisture content |
| μg | microgram |
| mg | milligram |
| MHC | moisture holding capacity |
| min | minute(s) |
| mL | millilitre |
| mm | millimetre |
| mN | milli-Newton |
| mo | month(s) |
| mol | Mol |
| MOS | margin of safety |
| mp | melting point |
| MRL | maximum residue limit or level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| n | normal (defining isomeric configuration) |
| NAEL | no adverse effect level |
| nd | not detected |
| NEDI | no effect daily intake (mg/kg body wt/day) |
| NEL | no effect level |
| NERL | no effect residue level |

## Appendix 2 – abbreviations
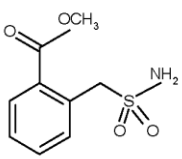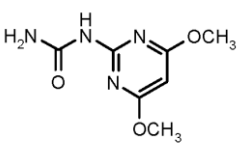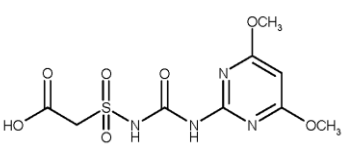
| | |
|---|---|
| NESTI | national estimated short term intake |
| ng | nanogram |
| NIR | near-infrared-(spectroscopy) |
| nm | nanometer |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOED | no observed effect dose |
| NOEL | no observed effect level |
| OC | organic carbon content |
| OM | organic matter content |
| Pa | Pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| $PEC_A$ | predicted environmental concentration in air |
| $PEC_S$ | predicted environmental concentration in soil |
| $PEC_{SW}$ | predicted environmental concentration in surface water |
| $PEC_{GW}$ | predicted environmental concentration in ground water |
| pH | pH-value |
| PHED | pesticide handler's exposure data |
| PHI | pre-harvest interval |
| $pK_a$ | negative logarithm (to the base 10) of the dissociation constant |
| PNEC | predicted no effect concentration |
| ppb | parts per billion ($10^{-9}$) |
| PPE | personal protective equipment |
| ppm | parts per million ($10^{-6}$) |
| ppp | plant protection product |
| PT | proportion of diet obtained in the treated area |
| QC | quality control |
| r | correlation coefficient |
| $r^2$ | coefficient of determination |
| RfD | reference dose |
| RH | relative humidity |
| RPE | respiratory protective equipment |
| rpm | reversed phase material |
| s | second |
| SF | safety factor |
| SFC | supercritical fluid chromatography |

## Appendix 2 – abbreviations

| | |
|---|---|
| SOP | standard operating procedure |
| sp | species (only after a generic name) |
| spp | subspecies |
| sq | square |
| STMR | supervised trials median residue |
| t | tonne (metric ton) |
| $t_{1/2}$ | half-life (define method of estimation) |
| TC | technical material |
| TER | toxicity exposure ratio |
| TK | technical concentrate |
| TMDI | theoretical maximum daily intake |
| TWA | time weighted average |
| UV | ultraviolet |
| WHO | World Health Organisation |
| WG | water dispersible granule |
| wk | week |
| wt | weight |
| yr | year |

**Appendix 3 – used compound code(s)**

## APPENDIX 3 – USED COMPOUND CODE(S)

| Code/Trivial name | Chemical name | Structural formula |
|---|---|---|
| bensulfuron IN-R9419 IN-R9419-1 | α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-o-toluic acid |  |
| IN-D1R84 | 2-(sulfamoylmethyl)benzoic acid |  |
| IN-J0290 IN-J290-17 | 4,6-dimethoxypyrimidin-2-amine |  |
| IN-F7880 | methyl 2-({[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}methyl)benzoate |  |
| IN-N5297 IN-N5297-1 | methyl 2-(sulfamoylmethyl)benzoate |  |
| IN-T5831 | (4,6-dimethoxypyrimidin-2-yl)urea |  |
| IN-DAT97 | {[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}acetic acid |  |

**Appendix 3 – used compound code(s)**

| IN-B6895-2 homosaccharin | 1H-2, 3-benzothiazin-4(3H)-one 2,2-dioxide |  |