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Environmental risk limits for triflusulfuron-methyl

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This investigation has been performed by order and for the account of Directorate-General for Environmental Protection, Directorate for Soil, Water and Rural Area (BWL), within the framework of the project 'Standard setting for other relevant substances within the WFD'.

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Rapport in het kort

Environmental risk limits for triflusulfuron-methyl

Dit rapport geeft milieurisicogrenzen voor het herbicide triflusulfuron-methyl in water. Milieurisicogrenzen zijn de technisch-wetenschappelijke advieswaarden voor de uiteindelijke milieukwaliteitsnormen in Nederland. De milieurisicogrenzen zijn afgeleid volgens de methodiek die is voorgeschreven in de Europese Kaderrichtlijn Water. Hierbij is gebruikgemaakt van de beoordeling in het kader van de Europese toelating van gewasbeschermingsmiddelen (Richtlijn 91/414/EEG), aangevuld met gegevens uit de openbare literatuur.

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1 Introduction

1.1 Background and scope of the report

In this report, environmental risk limits (ERLs) for surface water are derived for the herbicide triflusaluron-methyl. The derivation is performed within the framework of the project ‘Standard setting for other relevant substances within the WFD’, which is closely related to the project ‘International and national environmental quality standards for substances in the Netherlands’ (INS). Triflusaluron-methyl is part of a series of 25 pesticides that appeared to have a high environmental impact in the evaluation of the policy document on sustainable crop protection (‘Tussenevaluatie van de nota Duurzame Gewasbescherming’; MNP, 2006) and/or were selected by the Water Boards (‘Unie van Waterschappen’; project ‘Schone Bronnen’; <http://www.schonebronnen.nl/>).

The following ERLs are considered:

- Maximum Permissible Concentration (MPC) – the concentration protecting aquatic ecosystems and humans from effects due to long-term exposure
- Maximum Acceptable Concentration (MAC_{eco}) – the concentration protecting aquatic ecosystems from effects due to short-term exposure or concentration peaks.
- Serious Risk Concentration (SRC_{eco}) – the concentration at which possibly serious ecotoxicological effects are to be expected.

More specific, the following ERLs can be derived depending on the availability of data and characteristics of the compound:

| | |
|-------------------------------|---|
| MPC _{eco, water} | MPC for freshwater based on ecotoxicological data (direct exposure) |
| MPC _{sp, water} | MPC for freshwater based on secondary poisoning |
| MPC _{hh food, water} | MPC for fresh and marine water based on human consumption of fishery products |
| MPC _{dw, water} | MPC for surface waters intended for the abstraction of drinking water |
| MAC _{eco, water} | MAC for freshwater based on ecotoxicological data (direct exposure) |
| SRC _{eco, water} | SRC for freshwater based on ecotoxicological data (direct exposure) |
| MPC _{eco, marine} | MPC for marine water based on ecotoxicological data (direct exposure) |
| MPC _{sp, marine} | MPC for marine water based on secondary poisoning |
| MAC _{eco, marine} | MAC for marine water based on ecotoxicological data (direct exposure) |

1.2 Status of the results

The results presented in this report have been discussed by the members of the scientific advisory group for the INS-project (WK-INS). It should be noted that the Environmental Risk Limits (ERLs) in this report are scientifically derived values, based on (eco)toxicological, fate and physico-chemical data. They serve as advisory values for the Dutch Steering Committee for Substances, which is appointed to set the Environmental Quality Standards (EQSs). ERLs should thus be considered as proposed values that do not have any official status.

2 Methods

The methodology for the derivation of ERLs is described in detail by Van Vlaardingen and Verbruggen (2007), further referred to as the 'INS-Guidance'. This guidance is in accordance with the guidance of the Fraunhofer Institute (FHI; Lepper, 2005).

The process of ERL-derivation contains the following steps: data collection, data evaluation and selection, and derivation of the ERLs on the basis of the selected data.

2.1 Data collection

In accordance with the WFD, data of existing evaluations were used as a starting point. For triflurosulfuron-methyl, the evaluation report prepared within the framework of EU Directive 91/414/EC (Draft Assessment Report, DAR) was consulted (EC, 2007; further referred to as DAR). An on-line literature search was performed on TOXLINE (literature from 1985 to 2001) and Current contents (literature from 1997 to 2007). In addition to this, all potentially relevant references in the RIVM e-tox base and EPA's ECOTOX database were checked.

2.2 Data evaluation and selection

For substance identification, physico-chemical properties and environmental behaviour, information from the List of Endpoints of the DAR was used. When needed, additional information was included according to the methods as described in Section 2.1 of the INS-Guidance. Information on human toxicological threshold limits and classification was also primarily taken from the DAR.

Ecotoxicity studies (including bird and mammal studies) were screened for relevant endpoints (i.e. those endpoints that have consequences at the population level of the test species). All ecotoxicity and bioaccumulation tests were then thoroughly evaluated with respect to the validity (scientific reliability) of the study. A detailed description of the evaluation procedure is given in the INS-Guidance (see Section 2.2.2 and 2.3.2). In short, the following reliability indices were assigned:

- Ri 1: Reliable without restriction
'Studies or data ... generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline ... or in which all parameters described are closely related/comparable to a guideline method.'
- Ri 2: Reliable with restrictions
'Studies or data ... (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.'
- Ri 3: Not reliable
'Studies or data ... in which there are interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., unphysiologic pathways of application) or which were carried out or generated

according to a method which is not acceptable, the documentation of which is not sufficient for an assessment and which is not convincing for an expert judgment.’

- Ri 4: Not assignable

‘Studies or data ... which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).’

All available studies were summarised in data-tables, that are included as Annexes to this report. These tables contain information on species characteristics, test conditions and endpoints. Explanatory notes are included with respect to the assignment of the reliability indices.

With respect to the DAR, it was chosen not to re-evaluate the underlying studies. In principle, the endpoints that were accepted in the DAR were also accepted for ERL-derivation with Ri 2, except in cases where the reported information was too poor to decide on the reliability or when there was reasonable doubt on the validity of the tests. This applies especially to DARs prepared in the early 1990s, which do not always meet the current standards of evaluation and reporting.

In some cases, the characteristics of a compound (i.e. fast hydrolysis, strong sorption, low water solubility) put special demands on the way toxicity tests are performed. This implies that in some cases endpoints were not considered reliable, although the test was performed and documented according to accepted guidelines. If specific choices were made for assigning reliability indices, these are outlined in Section 3.3 of this report.

Endpoints with Ri 1 or 2 are accepted as valid, but this does not automatically mean that the endpoint is selected for the derivation of ERLs. The validity scores are assigned on the basis of scientific reliability, but valid endpoints may not be relevant for the purpose of ERL-derivation (e.g. due to inappropriate exposure times or test conditions that are not relevant for the Dutch situation).

After data collection and validation, toxicity data were combined into an aggregated data table with one effect value per species according to Section 2.2.6 of the INS-Guidance. When for a species several effect data were available, the geometric mean of multiple values for the same endpoint was calculated where possible. Subsequently, when several endpoints were available for one species, the lowest of these endpoints (per species) is reported in the aggregated data table.

2.3 Derivation of ERLs

For a detailed description of the procedure for derivation of the ERLs, reference is made to the INS-Guidance. With respect to the selection of the final MPC_{water}, some additional comments should be made:

2.3.1 Drinking water

The INS-Guidance includes the MPC for surface waters intended for the abstraction of drinking water (MPC_{dw, water}) as one of the MPCs from which the lowest value should be selected as the general MPC_{water} (see INS-Guidance, Section 3.1.6 and 3.1.7). According to the proposal for the daughter directive Priority Substances, however, the derivation of the AA-EQS (= MPC) should be based on direct exposure, secondary poisoning, and human exposure due to the consumption of fish. Drinking water was not included in the proposal and is thus not guiding for the general MPC value. The exact way of implementation of the MPC_{dw, water} in the Netherlands is at present under discussion within the framework of the “AMvB Kwaliteitseisen en Monitoring Water”. No policy decision has been taken yet, and the MPC_{dw, water} is therefore presented as a separate value in this report. The MPC_{water} is thus

derived considering the individual MPCs based on direct exposure ($MPC_{eco, water}$), secondary poisoning ($MPC_{sp, water}$) or human consumption of fishery products ($MPC_{hh\ food, water}$); derivation of the latter two is dependent on the characteristics of the compound.

Related to this, is the inclusion of water treatment for the derivation of the $MPC_{dw, water}$. According to the INS-Guidance (see Section 3.1.7), a substance specific removal efficiency related to simple water treatment should be derived in case the $MPC_{dw, water}$ is lower than the other MPCs. For pesticides, there is no agreement as yet on how the removal fraction should be calculated, and water treatment is therefore not taken into account. In case no A1 value is set in Directive 75/440/EEC, the $MPC_{dw, water}$ is set to the general Drinking Water Standard of 0.1 $\mu\text{g/L}$ for organic pesticides as specified in Directive 98/83/EC.

3 Derivation of environmental risk limits for triflusulfuron-methyl

3.1 Substance identification, physico-chemical properties, fate and human toxicology

3.1.1 Identity

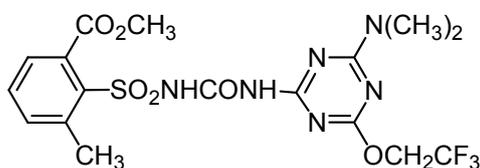


Figure 1. Structural formula of triflusulfuron-methyl.

Table 1. Identification of triflusulfuron-methyl.

| Parameter | Name or number | Source |
|---------------------------|---|----------|
| Common/trivial/other name | triflusulfuron-methyl | EC, 2007 |
| Chemical name | Methyl 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-m-toluate (IUPAC) | EC, 2007 |
| CAS number | [126535-15-7] | EC, 2007 |
| EC number | not assigned | EC, 2007 |
| SMILES code | <chem>O=C(OC)c1cccc(c1S(=O)(=O)NC(=O)Nc2nc(nc(OCC(F)(F)F)n2)N(C)C)C</chem> | |
| Use class | Post-emergence selective herbicide | EC, 2007 |
| Mode of action | Inhibition of the enzyme acetolactate synthase (ALS) involved in the synthesis of branched-chain amino acids. | EC, 2007 |
| Authorised in NL | Yes | |
| Annex 1 listing | No | |

3.1.2 Physico-chemical properties

Table 2. Physico-chemical properties of triflusulfuron-methyl.

| Parameter | Unit | Value | Remark | Reference |
|----------------------|--------------------------|--------------------------------|----------------------------------|--------------|
| Molecular weight | [g/mol] | 492.43 | | EC, 2007 |
| Water solubility | [g/L] | pH 3: 0.0011 g/L | purity 98.6%, 25 °C | EC, 2007 |
| | | pH 5: 0.0038 g/L | purity 98.6%, 25 °C | |
| | | pH 7: 0.26 g/L | purity 98.6%, 25 °C | |
| | | pH 9: 11 g/L | purity 98.6%, 25 °C | |
| pK _a | [-] | 4.4 | 25 °C | EC, 2007 |
| log K _{ow} | [-] | 2.3 | pH dependent | EC, 2007 |
| | | 3.56 | pH 5; 95.6% purity | |
| | | 3.08 | MlogP, ion-corrected | |
| | | 3.94 | ClogP, ion-corrected | |
| log K _{oc} | [-] | 3.94 | EPIWIN, ion-corrected | US EPA, 2007 |
| | | 1.67 | K _{oc} 47 L/kg (median) | EC, 2007 |
| Vapour pressure | [Pa] | 6.0 x 10 ⁻¹⁰ | 25°C, purity 95.6% | EC, 2007 |
| Melting point | [°C] | 159 °C – 162 °C | purity 98.9 % | EC, 2007 |
| Boiling point | [°C] | not relevant | | EC, 2007 |
| Henry's law constant | [Pa.m ³ /mol] | pH 3: 2.69 x 10 ⁻⁷ | 20°C | EC, 2007 |
| | | pH 5: 7.78 x 10 ⁻⁸ | 20°C | |
| | | pH 7: 1.14 x 10 ⁻⁹ | 20°C | |
| | | pH 9: 2.69 x 10 ⁻¹⁰ | 20°C | |

The estimated log K_{ow} of 3.94 is selected as the worst-case value for ERL-derivation.

3.1.3 Behaviour in the environment

Table 3. Selected environmental properties of triflusulfuron-methyl.

| Parameter | Unit | Value | Remark | Reference |
|------------------------|--|-------|--------|-----------|
| Hydrolysis half-life | DT50 [d] | 3.7 | pH 5 | EC, 2007 |
| | | 32 | pH 7 | |
| | | 36 | pH 9 | |
| Photolysis half-life | DT50 [d] | 3.8 | pH 5 | EC, 2007 |
| | | 13.9 | pH 7 | |
| | | 24.6 | pH 9 | |
| Readily biodegradable | | no | | EC, 2007 |
| Water/sediment systems | DT50 [d] | 21-39 | system | EC, 2007 |
| Relevant metabolites | IN-W6725 = methyl saccharin | | | EC, 2007 |
| | IN-D8526 = triazine amine | | | |
| | IN-E0Q47 = N-desmethyl triazine amine | | | |
| | IN-66036 = N-desmethyl triflusulfuron-methyl | | | |

3.1.4 Bioconcentration and biomagnification

An overview of the bioaccumulation data for triflurosulfuron-methyl is given in Table 4.

Table 4. Overview of bioaccumulation data for triflurosulfuron-methyl.

| Parameter | Unit | Value | Remark | Reference |
|------------|---------|-------|--------------------------------------|--------------------|
| BCF (fish) | [L/kg] | 446 | QSAR with log K_{ow} 3.94 | Veith et al., 1979 |
| BMF | [kg/kg] | 1 | Default value for log $K_{ow} < 4.5$ | |

3.1.5 Human toxicological threshold limits and carcinogenicity

Triflurosulfuron-methyl is proposed to be classified Carcinogenic cat.3 in the DAR, and R40 is assigned. The ADI was set at 0.04 mg/kg_{bw}/d, based on the NOAEL of 4.0 mg/kg_{bw}/d from a two-year study in the rat, with a safety factor of 100.

3.2 Trigger values

This section reports on the trigger values for ERLwater derivation (as demanded in WFD framework).

Table 5. Triflurosulfuron-methyl: collected properties for comparison to MPC triggers.

| Parameter | Value | Unit | Method/Source | Derived at section |
|------------------------|-----------|--------|--|--------------------|
| Log $K_{p,susp-water}$ | 0.67 | [-] | $K_{OC} \times f_{OC,susp}$ ¹ | K_{OC} : 3.1.2 |
| BCF | 446 | [L/kg] | | 3.1.4 |
| BMF | 1 | [-] | | 3.1.4 |
| Log K_{OW} | 3.94 | [-] | | 3.1.2 |
| R-phrases | R 40, R53 | [-] | | 3.1.5 |
| A1 value | 1 | [µg/L] | Total pesticides | |
| DW standard | 0.1 | [µg/L] | General value for organic pesticides | |

¹ $f_{OC,susp} = 0.1 \text{ kg}_{OC}/\text{kg}_{solid}$ (EC, 2003).

- triflurosulfuron-methyl has a log $K_{p, susp-water} < 3$; derivation of $MPC_{sediment}$ is not triggered.
- triflurosulfuron-methyl has a log $K_{p, susp-water} < 3$; expression of the MPC_{water} as $MPC_{susp, water}$ is not required.
- triflurosulfuron-methyl has a log $K_{ow} \geq 3$; assessment of secondary poisoning is triggered.
- triflurosulfuron-methyl has an R40 classification. Therefore, an MPC_{water} for human health via food (fish) consumption ($MPC_{hh \text{ food, water}}$) should be derived.
- For triflurosulfuron-methyl, no specific A1 value or Drinking Water Standard is available from Council Directives 75/440, EEC and 98/83/EC, respectively. Therefore, the general Drinking Water Standard for organic pesticides applies.

3.3 Toxicity data and derivation of ERLs for water

3.3.1 MPC_{eco, water} and MPC_{eco, marine}

An overview of the selected freshwater toxicity data for triflurosulfuron-methyl is given in Table 6. There are no valid marine toxicity data available. Detailed toxicity data for triflurosulfuron-methyl are tabulated in Appendix 2.

With respect to macrophyta, the following should be noted. For *Lemna gibba* and *Mycrophyllum aquaticum*, EC₅₀ and NOEC-values are available from a 14-days test. In view of the generation time of these species, 14 days is considered as chronic. However, when omitting the EC₅₀s from the acute dataset, the most sensitive species group would not be included in the derivation of the MAC. It is considered that the 14-days EC₅₀s are representative for shorter test durations, and therefore, the data are treated as acute.

Table 6. Triflurosulfuron-methyl: selected freshwater toxicity data for ERL derivation.

| Chronic^a | | Acute^a | |
|--|-----------------------------|--|---------------------------|
| Taxonomic group | NOEC/EC10 (µg/L) | Taxonomic group | L(E)C50 (µg/L) |
| Algae | | Algae | |
| <i>Pseudokirchneriella subcapitata</i> | 36 ^b | <i>Pseudokirchneriella subcapitata</i> | 215 ^f |
| Cyanobacteria | | Cyanobacteria | |
| <i>Anabaena flos-aquae</i> | 1000 ^c | <i>Anabaena flos-aquae</i> | 2800 ^g |
| Crustacea | | Crustacea | |
| <i>Daphnia magna</i> | 13270 ^d | <i>Daphnia magna</i> | 600000 |
| Macrophyta | | Macrophyta | |
| <i>Lemna gibba</i> | 1.3^e | <i>Lemna gibba</i> | 2.8^h |
| Pisces | | <i>Mycrophyllum aquaticum</i> | 18 ⁱ |
| <i>Onchorhynchus mykiss</i> | 57700 | Pisces | |
| | | <i>Onchorhynchus mykiss</i> | 730000 |
| | | <i>Lepomis macrochirus</i> | 760000 |

^a For detailed information see Appendix 2. Bold values are used for ERL derivation.

^b endpoint biomass in the absence of growth rate data for the active substance

^c preferred endpoint growth rate

^d geometric mean of 11000 and 16000 µg/L; endpoint reproduction

^e geometric mean of 1.5, 1.3 and 1.0 µg/L; preferred endpoint growth rate

^f preferred endpoint growth rate

^g preferred endpoint growth rate

^h geometric mean of 3.50, 2.82 and 2.15 µg/L; preferred endpoint growth rate

ⁱ based on nominal concentration with shoot length as endpoint

3.3.1.1 Treatment of fresh- and saltwater toxicity data

ERLs for freshwater and marine waters should be derived separately. For pesticides, data can only be combined if it is possible to determine with high probability that marine organisms are not more sensitive than freshwater organisms (Lepper, 2005). For triflurosulfuron-methyl, no marine toxicity data are available and ERLs for the marine compartment cannot be derived.

3.3.1.2 Mesocosm and field studies

Mesocosm and field studies were not available.

3.3.1.3 Derivation of MPC_{eco, water} and MPC_{eco, marine}

The base set is complete. Chronic data are available for five species in the taxonomic groups of fish, crustacea, algae, cyanobacteria and macrophyta. An assessment factor of 10 is applied to the lowest NOEC of 1.3 µg/L for macrophyta. The MPC_{eco, water} is 0.13 µg/L.

Due to the absence of marine data, the MPC_{eco, marine} cannot be derived.

3.3.2 MPC_{sp, water} and MPC_{sp, marine}

Triflurosulfuron-methyl has a $\log K_{ow} \geq 3$, the assessment of secondary poisoning is triggered. The available toxicity data for mammals and birds are presented in Appendix 4. In Table 7, the MPC_{oral} is derived applying the appropriate assessment factors to the data. No default assessment factors are available for 8- and 12-days NOEC for mammals, and a 5-days NOEC for birds. In these cases, a factor of 300 is used.

Table 7. triflurosulfuron-methyl: selected mammal and bird data for ERL derivation

| Species ^a | Exposure time | Criterion | Effect concentration (mg/kg _{diet}) | Assessment factor | MPC _{oral} (mg/kg _{diet}) |
|----------------------|---------------|-----------|---|-------------------|--|
| Mammals | | | | | |
| Rat | 8 d | NOEC | 2400 | 300 | 8 |
| Rat | 90 d | NOEC | 100 | 90 | 1.1 |
| Rat | 90 d | NOEC | 2000 | 90 | 22.2 |
| Rat | 2 year | NOEC | 750 | 30 | 25 |
| Rat | 2-gen | NOEC | 100 | 30 | 3.3 |
| Mouse | 18 m | NOEC | 500 | 30 | 16.7 |
| Rabbit | 12 d | NOEC | 2997 | 300 | 10 |
| Dog | 90 d | NOEC | 4000 | 90 | 44.4 |
| Birds | | | | | |
| Bobwhite quail | 21 w | NOEC | 250 | 30 | 8.3 |
| Mallard duck | 5 d | NOEC | 562 | 300 | 1.9 |
| Mallard duck | 20 w | NOEC | 250 | 30 | 8.3 |

^a For detailed information see Appendix 4. Bold values are used for ERL derivation.

The lowest MPC_{oral, duck} for Mallard ducks is 1.9 mg/kg_{diet}, based on a short-term toxicity study. There are, however, also long-term data available, which according to the INS-Guidance prevail over the short-term study. The MPC_{oral, duck} for Mallard ducks based on the long-term test is 8.3 mg/kg_{diet}. For rats, there are also chronic data available which prevail over the short-term tests. The 2-year study is considered less reliable because in this study there was a high mortality and effects on body weight were observed in females only. The MPC_{oral, rat} is therefore set to 3.3 mg/kg_{diet}, and this value is selected for MPC-derivation.

The MPC_{sp, water} = MPC_{oral, min} / (BCF × BMF) = 3.3 / (446 × 1) = 7.4 × 10⁻³ mg/L = 7.4 µg/L.

Because toxicity data for marine predators are generally not available, the MPC_{oral, min} as derived above is used as a representative for the marine environment also. To account for the longer food chains in the marine environment, an additional biomagnification step is introduced (BMF₂). This factor is the same as given in Table 4. The MPC_{sp, marine} = MPC_{oral, min} / (BCF × BMF₁ × BMF₂) = 3.3 / (446 × 1 × 1) = 7.4 × 10⁻³ mg/L = 7.4 µg/L.

3.3.3 MPC_{hh food, water}

Derivation of MPC_{hh food, water} for triflusaluron-methyl is triggered (Table 5). The MPC_{hh food} is calculated from the ADI (0.04 mg/kg_{bw}/d), a body weight of 70 kg and a daily fish consumption of 115 g, as $MPC_{hh\ food} = 0.04 \times 0.1 \times 70 / 0.115 = 2.4 \text{ mg/kg}$.

Subsequently the MPC_{hh food, water} is calculated as $2.4 / (BCF_{fish} \times BMF_1) = 2.4 / (446 \times 1) = 5.4 \times 10^{-3} \text{ mg/L} = 5.4 \text{ } \mu\text{g/L}$.

3.3.4 MPC_{dw, water}

The Drinking Water Standard is 0.1 $\mu\text{g/L}$. Thus, the MPC_{dw, water} is also 0.1 $\mu\text{g/L}$.

3.3.5 Selection of the MPC_{water} and MPC_{marine}

The lowest value of the routes included (see Section 2.3.1) is the ecotoxicological MPC_{eco, water}. The MPC_{water} = 0.13 $\mu\text{g/L}$.

No MPC_{marine} can be selected due to the absence of data.

3.3.6 MAC_{eco}

3.3.6.1 MAC_{eco, water}

The MAC_{eco} is based on the acute toxicity data. The base set is complete. Triflusaluron-methyl has a potential to bioaccumulate ($\log K_{ow} \geq 3$), has a known mode of action and the potentially most sensitive species groups (algae and macrophyta) are included in the dataset. Therefore, the default assessment factor of 100 applies. It is considered justified to lower this assessment factor to 10 because of the following:

- There is no concern for effects due to bioaccumulation, because toxicity for fish is low (LC₅₀ 730 – 760 mg/L) and bioaccumulation is considered not relevant for macrophytes.
- Five EC₅₀ values are available for *Lemna gibba* and one for *Mycrophyllum aquaticum*. *L. gibba* is the most sensitive of the two species, selected EC₅₀ values are 2.15, 2.82 and 3.50 $\mu\text{g/L}$ with a geometric EC₅₀ of 2.8 $\mu\text{g/L}$. It is assumed that this most sensitive species will be protected by a assessment factor of 10.

The MAC_{eco, water} is therefore set to 0.28 $\mu\text{g/L}$.

3.3.6.2 MAC_{eco, marine}

Due to the absence of marine data, the MAC_{eco, marine} cannot be derived.

3.3.7 SRC_{eco, water}

NOECs are available for five taxa, including algae, *Daphnia* and fish. The SRC_{eco, water} is therefore derived as the geometric mean of all available NOECs with an assessment factor of 1. The SRC_{eco, water} is 514 $\mu\text{g/L}$ (data fit a log-normal distribution).

3.4 Toxicity data and derivation of ERLs for sediment

The log $K_{p, \text{susp-water}}$ of triflusaluron-methyl is below the trigger value of 3, therefore, ERLs are not derived for sediment

4 Conclusions

In this report, the risk limits Maximum Permissible Concentration (MPC), Maximum Acceptable Concentration for ecosystems (MAC_{eco}), and Serious Risk Concentration for ecosystems (SRC_{eco}) are derived for triflurosulfuron-methyl in water. No risk limits were derived for the marine compartment because data were not available. Derivation of risk limits for sediment was not triggered.

The ERLs that were obtained are summarised in the table below. The MPC value that was set for this compound until now, is also presented in this table for comparison reasons. It should be noted that this is an indicative MPC ('ad-hoc MTR'), derived using a different methodology and based on limited data.

Table 7. Derived MPC, MAC_{eco} , and SRC values for triflurosulfuron-methyl.

| ERL | Unit | MPC | MAC_{eco} | SRC |
|-----------------------------|------|-------------------|-------------------|-------------------|
| Water, old ^a | µg/L | 0.23 | - | - |
| Water, new ^b | µg/L | 0.13 | 0.28 | 5.1×10^2 |
| Drinking water ^b | µg/L | 0.1 ^c | - | - |
| Marine | µg/L | n.d. ^d | n.d. ^d | - |

^a indicative MPC ('ad-hoc MTR'), source: Helpdesk

Water http://www.helpdeskwater.nl/emissiebeheer/normen_voor_het/zoeksysteem_normen/

^b The $MPC_{dw, water}$ is reported as a separate value from the other MPC_{water} values ($MPC_{eco, water}$, $MPC_{sp, water}$ or $MPC_{hh food, water}$). From these other MPC_{water} values (thus excluding the $MPC_{dw, water}$) the lowest one is selected as the 'overall' MPC_{water} .

^c provisional value pending the decision on implementation of the $MPC_{dw, water}$, (see Section 2.3.1)

^d n.d. = not derived due to lack of data

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Appendix 1. Detailed aquatic toxicity data

Table A1.1. Acute toxicity of triflurosulfuron-methyl to freshwater organisms.

| Species | Species properties | A | Test type | Test compound | Purity [%] | Test water | pH | T [°C] | Hardness CaCO ₃ [mg/L] | Exp. time | Criterion | Test endpoint | Value [mg/L] | Value [µg/L] | Ri | Notes | Reference |
|--|---------------------------------|---|-----------|---------------|------------|------------|----|-----------|-----------------------------------|-----------|-----------|----------------|--------------|--------------|----|----------|------------------------|
| Algae | | | | | | | | | | | | | | | | | |
| <i>Pseudokirchneriella subcapitata</i> | 9.69 x 10 ⁴ cells/mL | N | S | technical | >97 | | | 24 ± 1 | | 24-48 h | EC50 | growth rate | 1.00 | 1000 | 3 | 17,10,12 | EC, 2007 |
| <i>Pseudokirchneriella subcapitata</i> | 9.69 x 10 ⁴ cells/mL | N | S | technical | >97 | | | 24 ± 1 | | 72 h | EC50 | biomass | 0.50 | 500 | 2 | 17,10 | EC, 2007 |
| <i>Pseudokirchneriella subcapitata</i> | 3000 cells/mL | Y | S | technical | 98.7 | | | 24 ± 2 | | 120 h | EC50 | biomass | 0.05 | 46 | 2 | 4,10 | EC, 2007 |
| <i>Pseudokirchneriella subcapitata</i> | 10 ⁴ cells/mL | N | S | formulation | 50 | | | 24 ± 2 | | 72 h | EC50 | cell density | 0.03 | 31 | 2 | 9 | EC, 2007 |
| <i>Pseudokirchneriella subcapitata</i> | 10 ⁴ cells/mL | N | S | formulation | 50 | | | 24 ± 2 | | 72 h | EC50 | biomass | 0.04 | 36 | 2 | 9 | EC, 2007 |
| <i>Pseudokirchneriella subcapitata</i> | 10 ⁴ cells/mL | N | S | formulation | 50 | | | 24 ± 2 | | 72 h | EC50 | growth rate | 0.22 | 215 | 2 | 9 | EC, 2007 |
| Cyanobacteria | | | | | | | | | | | | | | | | | |
| <i>Anabaena flos-aquae</i> | 10 ⁴ cells/mL | N | S | technical | 98.7 | | | | | 96 h | EC50 | cell density | 1.46 | 1460 | 2 | 10 | EC, 2007 |
| <i>Anabaena flos-aquae</i> | 10 ⁴ cells/mL | N | S | technical | 98.7 | | | | | 96 h | EC50 | biomass | 1.31 | 1310 | 2 | 10 | EC, 2007 |
| <i>Anabaena flos-aquae</i> | 10 ⁴ cells/mL | N | S | technical | 98.7 | | | | | 96 h | EC50 | growth rate | 2.80 | 2800 | 2 | 10 | EC, 2007 |
| <i>Anabaena flos-aquae</i> | | N | S | formulation | 98.7 | | | | | 96 h | EC50 | | 0.12 | 123 | 4 | 11 | EC, 2007 |
| Crustacea | | | | | | | | | | | | | | | | | |
| <i>Daphnia magna</i> | | Y | S | technical | 95.6 | | | 20.2-20.4 | | 48 h | EC50 | immobilisation | > 960 | > 960000 | 2 | 1,9 | EC, 2007 |
| <i>Daphnia magna</i> | | Y | S | formulation | 49.8 | | | 20.2-20.3 | | 48 h | EC50 | immobilisation | 600 | 600000 | 2 | 1,3,9 | EC, 2007 |
| <i>Daphnia magna</i> | | | S | technical | 95.6 | well | 8 | 20.1-21.0 | 86 | 48 h | EC50 | immobilisation | 460 | 460000 | 3 | 5,6,9 | Post and Linders, 1995 |
| Macrophyta | | | | | | | | | | | | | | | | | |
| <i>Lemna gibba</i> | | Y | S | technical | 98.7 | | | | | 14 d | EC50 | growth rate | 0.00350 | 3.50 | 2 | 7,10,14 | EC, 2007 |
| <i>Lemna gibba</i> | | Y | S | technical | 98.7 | | | | | 14 d | EC50 | biomass | 0.00440 | 4.40 | 2 | 7,10,14 | EC, 2007 |
| <i>Lemna gibba</i> | | Y | S | technical | 98.7 | | | 25 ± 2 | | 14 d | EC50 | growth rate | 0.00282 | 2.82 | 2 | 4,10,14 | EC, 2007 |
| <i>Lemna gibba</i> | | Y | S | formulation | 50 | | | | | 14 d | EC50 | growth rate | 0.00215 | 2.15 | 2 | 9,14 | EC, 2007 |
| <i>Lemna gibba</i> | | Y | S | formulation | 50 | | | | | 14 d | EC50 | biomass | > 0.0025 | > 2.5 | 2 | 9,14 | EC, 2007 |
| <i>Mycriophyllum aquaticum</i> | | N | S | formulation | 25 | | | | | 14 d | EC50 | shoot length | 0.01800 | 18 | 2 | 4,8,14 | EC, 2007 |
| Pisces | | | | | | | | | | | | | | | | | |
| <i>Cyprinus carpio</i> | 2.4 cm | Y | S | technical | 95.6 | | 8 | 21.6-22.1 | | 96 h | LC50 | mortality | > 830 | > 830000 | 2 | 1,9 | EC, 2007 |
| <i>Lepomis macrochirus</i> | 2.6 cm | Y | S | technical | 95.6 | | 8 | 22.5-22.7 | | 96 h | LC50 | mortality | 760 | 760000 | 2 | 1,9 | EC, 2007 |
| <i>Onchorhynchus mykiss</i> | <5 cm | Y | S | technical | 95.6 | | 8 | 10.6-12.4 | | 96 h | LC50 | mortality | 730 | 730000 | 2 | 1,9 | EC, 2007 |
| <i>Onchorhynchus mykiss</i> | <5 cm | Y | S | formulation | 49.8 | | 8 | 12.2-12.5 | | 96 h | LC50 | mortality | 75 | 75000 | 2 | 1,2,9,11 | EC, 2007 |

NOTES

- | | |
|--|---|
| 1 based on mean measured concentrations | 8 not performed under GLP, not according to test guideline |
| 2 150 mg formulation/L | 9 according to OECD guidelines |
| 3 1200 mg formulation/L | 10 according to US-EPA pesticide assessment Guidelines |
| 4 measured but based on nominal since initial mean measured concentrations were >80% of nominal | 11 formulation > factor 3 more active than active substance and is therefore not used for calculating the geomean |
| 5 not measured, based on nominal concentrations | 12 growth calculated over 24 h only |
| 6 precipitation at all test concentrations | 13 endpoint not given |
| 7 based on nominal; mean measured concentrations were slightly under 80%, but concentrations very stable in time | 14 the EC50 of this test is considered as acute, the NOEC as chronic |

Table A1.2. Chronic toxicity of triflurosulfuron-methyl to freshwater organisms.

| Species | Species properties | A | Test type | Test compound | Purity [%] | Test water | pH | T [°C] | Hardness CaCO ₃ [mg/L] | Exp. time | Criterion | Test endpoint | Value [mg/L] | Value [µg/L] | Ri | Notes | Reference | |
|--|--------------------|---|-----------|---------------|------------|------------|---------|-----------|-----------------------------------|-----------|-----------|-------------------|--------------|--------------|----|--------------|------------------------|--|
| Algae | | | | | | | | | | | | | | | | | | |
| <i>Pseudokirchneriella subcapitata</i> | | N | S | technical | >97 | | | | | 120 h | NOEC | | 0.13 | 125 | 4 | 9,10 | EC, 2007 | |
| <i>Pseudokirchneriella subcapitata</i> | | Y | S | technical | 98.7 | | | 24 ± 2 | | 120 h | NOEC | biomass | 0.04 | 36 | 2 | 9,10 | EC, 2007 | |
| <i>Pseudokirchneriella subcapitata</i> | | N | S | formulation | 50 | | | 24 ± 2 | | 72 h | NOEC | cell density | 0.01 | 5 | 2 | 8,9 | EC, 2007 | |
| <i>Pseudokirchneriella subcapitata</i> | | N | S | formulation | 50 | | | 24 ± 2 | | 72 h | NOEC | biomass | 0.01 | 5 | 2 | 8,9 | EC, 2007 | |
| <i>Pseudokirchneriella subcapitata</i> | | N | S | formulation | 50 | | | 24 ± 2 | | 72 h | NOEC | growth | 0.01 | 10 | 2 | 8,9 | EC, 2007 | |
| Cyanobacteria | | | | | | | | | | | | | | | | | | |
| <i>Anabaena flos-aquae</i> | | N | S | technical | 98.7 | | | | | 96 h | NOEC | cell density | 1 | 1000 | 2 | 10 | EC, 2007 | |
| <i>Anabaena flos-aquae</i> | | N | S | technical | 98.7 | | | | | 96 h | NOEC | biomass | < 1 | < 1000 | 2 | 10 | EC, 2007 | |
| <i>Anabaena flos-aquae</i> | | N | S | technical | 98.7 | | | | | 96 h | NOEC | growth rate | 1 | 1000 | 2 | 10 | EC, 2007 | |
| Crustacea | | | | | | | | | | | | | | | | | | |
| <i>Daphnia magna</i> | | Y | R | technical | 95.6 | well | 6.8-8.0 | 19.2-19.9 | | 21 d | NOEC | reproduction | 11 | 11000 | 2 | 1,3,4,6,9,10 | EC, 2007 | |
| <i>Daphnia magna</i> | | Y | | formulation | 49.8 | well | 8.5 | 19.6-20.8 | | 21 d | NOEC | reproduction | 16 | 16000 | 2 | 5,9 | Post and Linders, 1995 | |
| Macrophyta | | | | | | | | | | | | | | | | | | |
| <i>Lemna gibba</i> | | Y | S | technical | 98.7 | | | | | 14 d | NOEC | growth rate | 0.00150 | 1.5 | 2 | 7,10,11 | EC, 2007 | |
| <i>Lemna gibba</i> | | Y | S | technical | 98.7 | | | | | 14 d | NOEC | biomass | 0.00200 | 2.0 | 2 | 7,10,11 | EC, 2007 | |
| <i>Lemna gibba</i> | | Y | S | technical | 98.7 | | | 25 ± 2 | | 14 d | NOEC | growth rate | 0.00127 | 1.3 | 2 | 6,10,11 | EC, 2007 | |
| <i>Lemna gibba</i> | | Y | S | formulation | 50 | | | | | 14 d | NOEC | growth rate | 0.00100 | 1.0 | 2 | 10,11 | EC, 2007 | |
| <i>Lemna gibba</i> | | Y | S | formulation | 50 | | | | | 14 d | NOEC | biomass | ≥ 0.0015 | ≥ 1.5 | 2 | 10,11 | EC, 2007 | |
| Pisces | | | | | | | | | | | | | | | | | | |
| <i>Onchorhynchus mykiss</i> | | Y | F | technical | 95.6 | | | | | 21 d | NOEC | mortality | ≥ 210 | ≥ 210000 | 2 | 1,9 | EC, 2007 | |
| <i>Onchorhynchus mykiss</i> | | Y | F | technical | 95.72 | | | 9.3-11.0 | | 97 d | NOEC | mortality, growth | 57.70 | 57700 | 2 | 1,2,9 | EC, 2007 | |

NOTES

- | | |
|--|--|
| 1 based on mean measured concentrations | 7 based on nominal; mean measured concentrations were slightly under 80%, but concentrations very stable in time |
| 2 61 days post-hatch | 8 formulation > factor 3 more active than active substance and is therefore not used |
| 3 dissolved oxygen exceeded the theoretical saturation value on some occasions | 9 according to OECD guidelines |
| 4 variation in pH (>0.3 unit) | 10 according to US-EPA pesticide assessment Guidelines |
| 5 based on nominal since initial mean measured concentrations were >80% of nominal | 11 NOECs from this test are considered as chronic, EC50s as acute |
| 6 lacking information on temp, pH was found in the milieuefiche | |

Appendix 2. Detailed bird and mammal toxicity data

Table A2.1. Toxicity of triflurosulfuron-methyl to birds and mammals.

| Species | Species properties (age, sex) | Purity [%] | Application route | Exp. time | Criterion | Test endpoint | NOAEL [mg/kg _{bw} /d] | NOAEC/LC50 Diet [mg/kg _{diet}] | Ri | Notes | Reference |
|----------------|-------------------------------|------------|-------------------|-----------|-----------|----------------|--------------------------------|--|----|-------|-----------|
| birds | | | | | | | | | | | |
| Bobwhite quail | 10 d | 95.6 | diet | 5 d | LC50 | mortality | | ≥ 5620 | 2 | 1 | EC, 2007 |
| Bobwhite quail | 19 w | 95.6 | diet | 21 w | NOEC | reproduction | | 250 | 2 | 1 | EC, 2007 |
| Mallard duck | 10 d | 95.6 | diet | 5 d | NOEC | body weight | | 562 | 2 | 1 | EC, 2007 |
| Mallard duck | 22 w | 95.6 | diet | 20 w | NOEC | reproduction | | 250 | 2 | 1 | EC, 2007 |
| mammals | | | | | | | | | | | |
| rat | Sprague-Dawley ♂,♀ | 95.8 | diet | 90 d | NOAEC | body weight | | 100 | 2 | 1 | EC, 2007 |
| rat | Sprague-Dawley ♂,♀ | 98.7 | diet | 90 d | NOAEC | body weight | | 2000 | 2 | 1 | EC, 2007 |
| rat | Sprague-Dawley ♀ | 95.6 | diet | 2 y | NOAEC | body weight | | 750 | 2 | 1,3 | EC, 2007 |
| rat | Sprague-Dawley ♂ | 95.6 | diet | 14 d | NOAEL | body weight | < 1000 | < 20000 | 2 | 2 | EC, 2007 |
| rat | Sprague-Dawley ♂ | 95.6 | gavage | 28 d | NOAEL | body weight | ≥ 5 | ≥ 50 | 2 | 2 | EC, 2007 |
| rat | Sprague-Dawley ♂,♀ | 95.6 | diet | 2-gen | NOAEC | body weight | | 100 | 2 | 1 | EC, 2007 |
| rat | Sprague-Dawley ♀ | 95.6 | gavage | 8 d | NOAEL | teratogenicity | 120 | 2400 | 2 | 2 | EC, 2007 |
| mouse | CD1 ♂,♀ | 91.9 | diet | 90 d | NOAEC | body weight | | ≥ 7500 | 2 | 1 | EC, 2007 |
| mouse | CD1 ♂,♀ | 91.9 | diet | 90 d | NOAEC | mortality | | ≥ 7500 | 2 | 1 | EC, 2007 |
| mouse | CD1 ♂,♀ | 95.6 | diet | 18 m | NOAEC | body weight | | 150 | | 1 | EC, 2007 |
| rabbit | Hra:(NZW)SPF ♀ | 95.6 | gavage | 12 d | NOAEL | teratogenicity | 90 | 2997 | 2 | 2 | EC, 2007 |
| dog | Beagle ♂,♀ | 95.6 | diet | 90 d | NOAEC | body weight | | 4000 | 2 | 1 | EC, 2007 |
| dog | Beagle ♂,♀ | 95.6 | diet | 90 d | NOAEC | body weight | | ≥ 3500 | 2 | 1 | EC, 2007 |

NOTES

- 1 NOAEC based on dietary concentrations in test
- 2 NOAEC calculated with default conversion factor
- 3 considerable mortality in all groups; effect on body weight not present in males

Appendix 3. References used in the appendices

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