検索期間：2010～2019年

区分 a に分類された文献とその理由

生活環境動植物及び家畜に対する毒性

1. Information on the study

Data point:	KCA 8.2.1
Report author	Antunes, A. M. *et al.*
Report year	2017
Report title	Gender-specific histopathological response in guppies *Poecilia reticulata* exposed to glyphosate or its metabolite aminomethylphosphonic acid
Document No	Journal of applied toxicology, 2017; 37:1098-1107
Guidelines followed in study	None
Deviations from current test guideline	Not applicable
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

The acute 96 hour-LC_{50} values for male and female guppies *P. reticulata* after exposure to glyphosate were 68.78 mg/L and 70.87 mg/L, respectively. The acute 96 hour-LC_{50} values for AMPA for male and female guppies were 180 mg/L and 164.3 mg/L, respectively.
In the material and methods part some important is missing. No information on preparation of test solution and application is given. Source and composition of media are unclear. Furthermore, there was no analytical verification of test concentrations reported. The study is considered as reliable with restrictions.

1. Information on the study

Data point:	KCA 8.2.8
Report author	Daam M.A *et al.*
Report year	2019
Report title	Lethal toxicity of the herbicides acetochlor, ametryn, glyphosate and metribuzin to tropical frog larvae
Document No	Ecotoxicology (2019) 28:707–715
Guidelines followed in study	OECD (2015) Test No. 241: the larval amphibian growth and development assay ASTM (2013) Standard guide for conducting the frog embryo teratogenesis assay-Xenopus (FETAX). ASTM E1439-12
Deviations from current test guideline	Not reported
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes / Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

The study investigated the acute toxicity of glyphosate to larvae of *Physalaemus cuvieri* and *Hypsiboas pardalis.* The LC_{50} for *Physalaemus cuvieri* and *Hypsiboas pardali* was determined to be 115 mg a.s./L and 106 mg a.s./L, respectively.

The study was conducted according to portions of OECD 241. However, validity criteria were not reported. It is unknown if the larvae were exposed to any other chemicals as no analysis of watershed water was provided.There was no analytical verification of test concentrations reported. The study is considered as reliable with restrictions.

1. Information on the study

Data point:	KCA 8.2.2.1
Report author	Rodrigues L. B. *et al.*
Report year	2019
Report title	Impact of the glyphosate-based commercial herbicide, its components and its metabolite AMPA on non-target aquatic organisms
Document No	Mutat Res Gen Tox En 842 (2019) 94-101
Guidelines followed in study	OECD 236
Deviations from current test guideline	Not reported
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

The acute toxicity of technical glyphosate and its metabolite aminomethylphosphonic acid (AMPA) to zebrafish embryos was investigated.

Glyphosate and AMPA caused no acute toxic effect (LC_{50}-96 h > 100 mg/L) in zebrafish.

The study was stated to have been conducted according to OECD guideline 236, but there is no information on hatching rates in the treatment and control groups, so exposure of the embryo without a potential barrier function of the chorion cannot be confirmed.

Concerning the validity of the study, four of the six validity criteria from the test guideline are mentioned in the paper (fertilization rate of embryo batches used was >90%, survival in the negative control group was > 90%, temperature was maintained at 26 ±1ºC and dissolved oxygen was at an acceptable level 8ppm). There is no information presented on the performance of the positive control group (3, 4-dichloroaniline) and no information provided on the hatching rates in the negative control group at 96 hours, which for the control group should exceed 80%. As these information are not presented and the fact that there was no analytical verification of test concentrations reported, this study considered as reliable with restrictions.

1. Information on the study

Data point:	KCA 8.2.1 / KCP 10.2.1
Report author	Gabriel U. U. *et al.*
Report year	2010
Report title	Toxicity of roundup (a glyphosate product) to fingerlings of *Clarias gariepinus*
Document No	Animal Research International (2010) 7(2):1184-1193
Guidelines followed in study	None
Deviations from current test guideline	Not applicable
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities (literature publication)
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

The effects of Roundup containing 360 g/l glyphosate (equivalent to 480g/L isopropylamine salt) were tested in an acute test with *C. gariepinus* fingerlings. The 96 hour-LC_{90} was determined to be 19.91 mg prod./L.

There is no analytical verification of test concentrations reported and thus the reliability of the endpoint is questionable. The appearance of mucus accumulation on the skin and gills and skin pigmentation recorded in fish in the holding / stock vessels is a clear indicator of stress. Therefore, the condition of the fish used in the test is questionable. The study was not conducted in accordance with a recognised test guideline and was not performed under conditions of GLP. Furthermore, the purity of the formulation roundup is not clearly given as the specification in the full text contains some typing errors. The study is considered reliable with restrictions.

1. Information on the study

Data point:	KCA 8.2.1
Report author	Gholami Syedkolaei S.J. *et al*. (Seyed Jalil Gholami)
Report year	2013
Report title	Toxicity evaluation of Malathion, Carbaryle and Glyphosate in common carp fingerlings (Cyprinus carpio, Linnaeus, 1758).
Document No	Journal of Veterinary Research (2013), Volume 68, Number 3, pp. 257-267
Guidelines followed in study	OECD 203
Deviations from current test guideline	None
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities.
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

The acute 96 hours- LC_{50} for common carp fingerlings was determined to be 6.75 mg/L by static exposure to glyphosate at 5 test concentrations between 5.5 and 9.5 mg/L.

The test was conducted according to OECD 203, but validity criteria are missing. No information on the test item such as purity is given. The results for the control are not stated. Furthermore, there was no analytical verification of test concentrations reported. The study is considered as reliable with restrictions.

1. Information on the study

Data point:	KCA 8.2.2 / KCA 8.2.5
Report author	Levine S.L. *et al.*
Report year	2015
Report title	Aminomethylphosphonic acid has low chronic toxicity to *Daphnia magna* and *Pimephales promelas*
Document No	Environmental Toxicology and Chemistry (2015), Vol. 34, No. 6, pp. 1382-1389
Guidelines followed in study	OECD 211, OECD 210
Deviations from current test guideline	None
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable

2. Assessment and conclusion

Assessment and conclusion by applicant:

Chronic toxicity tests of the glyphosate environmental metabolite aminomethylphosphonic acid (AMPA) were performed with fathead minnow (*Pimephales promelas*) and *Daphnia magna*.
During a 21-d exposure period under semi-static test conditions the effects on survival, growth, and reproduction of the cladoceran *Daphnia magna* were determined resulting in a no-observed-effect concentration (NOEC) of 15 mg AMPA/L. During a 33-d exposure period under continuous renewal test conditions the effects on time to hatch, hatching success, posthatch growth and survival of the fish *Pimephales promelas* were assessed resulting in an NOAEC of 12 mg AMPA/L, the highest tested concentration. Test methodology followed the procedure outlined in the OECD 210 test guideline for *P. promelas*. For the chronic test on *Daphnia magna* the OECD 211 guideline is mentioned in the full text.

The study is well documented and all relevant information, e.g. information on the test item, test design, application method and implementation of the study, is available. In addition, a chemical analysis of test solutions was performed. All information for evaluation of the study is given. The study is considered as reliable.

1. Information on the study

Data point:	KCA 8.2.1
Report author	Schweizer M. *et al.*
Report year	2019
Report title	How glyphosate and its associated acidity affect early development in zebrafish (*Danio rerio)*
Document No	PeerJ, (2019) Vol. 7, pp. e7094
Guidelines followed in study	OECD Guideline 236
Deviations from current test guideline	None
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

For Zebrafish (*Danio rerio*) embryos acutely exposed to glyphosate at concentrations between 1.69 and 1690.7 mg glyphosate/L (10 µM to 10 mM) for 96 hours post fertilization (hpf) the LC_{10} and LC_{50} values (96 hpf) were calculated to be 65.1 mg a.s./L (385 µM) and 98.4 mg a.s./L (582 µM), respectively (in unbuffered glyphosate medium). Regarding heart rates the EC_{10} was 7.27 mg a.s./L (43 µM). Concerning hatching rate, 96 hpf -EC_{10} and EC_{50} values were 26.2 mg a.s./L (155 µM) and 37.9 (224 µM), respectively. For developmental delays at 24 hpf the EC10 was 21.3 mg a.s./L (126 µM). The test was conducted according to OECD 236 test guideline.

Concerning the validity criteria in the OECD 236, despite the stated > 80% mortality in the positive control (>30% required) there are no details presented to confirm the level of mortality. The fertilisation rate of the batch of eggs used was not reported. Finally, acute endpoints based on developmental delay and heart rate are not relevant to an EU level risk assessment for Annex I renewal purposes.

The test design is adequately described, however, there was no analytical verification of test concentrations reported. The study is considered as reliable with restrictions.

1. Information on the study

Data point:	KCA 8.3.1.3 / KCP 10.3.1.5
Report author	Thompson H. M. *et al.*
Report year	2014
Report title	Evaluating Exposure and Potential Effects on Honeybee Brood (*Apis mellifera*) Development Using Glyphosate as an Example
Document No	Integr Environ Assess Manag (2014), 10: 463-470
Guidelines followed in study	Oomen et al. 1992
Deviations from current test guideline	Not applicable
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable

2. Assessment and conclusion

Assessment and conclusion by applicant:

The Oomen et al. (1992) approach was used to quantify at residues in relevant matrices (pollen, nectar, and larvae) following application of glyphosate at 2.88 kg a.e./ha (400 L water/ha) to flowering *Phacelia tenacetifolia* in large glasshouses. Then brood feeding tests following the Oomen approach, were conducted by feeding 1 L treated sucrose solution at 75 / 150 and 301 mg glyphosate a.e./L directly to honeybee colonies.

The study is adequately described and all information to evaluate the study are available. At the time the study was conducted, there were no field level test guidelines adopted for use in the EU. The test did follow a recognised approach and is considered fit for purpose. The study is considered as reliable.

1. Information on the study

Data point:	KCA 8.2.7
Report author	Tian Y. *et al.*
Report year	2015
Report title	Growth inhibition of two herbicides on Spirodela polyrhiza
Document No	Nongyao kexue yu guanli (Pesticide Science and Administration), 2015, Vol. 36 (issue 3), pp. 61-65
Guidelines followed in study	OECD 221
Deviations from current test guideline	Not reported
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable with restrictions

2. Assessment and conclusion

Assessment and conclusion by applicant:

The effects of glyphosate to the aquatic macrophyte *Spirodela polyrhiza* was tested in a semi-static exposure of 7 days at concentrations between 8.4 and 20.902 mg/L. The 7 day-EC_{50} value was determined to be 12.817 mg/L.

This study was conducted to guideline but not to GLP. The test concentrations were not analytically verified and thus the exact exposure concentrations of the aquatic macrophyte are unknown. Therefore, the study should considered as reliable with restrictions.

1. Information on the study

Data point:	KCA 8.4.1 / KCA 8.4.2.1 / KCA 8.5
Report author	von Mérey G. *et al.*
Report year	2016
Report title	Glyphosate and aminomethylphosphonic acid chronic risk assessment for soil biota
Document No	Environmental Toxicology and Chemistry (2016), Vol. 35, No. 11, pp. 2742-2752
Guidelines followed in study	OECD 222; OECD 226; OECD 232; OECD 216
Deviations from current test guideline	Earthworm cocoons were not counted, in accordance with OECD 222.
GLP/Officially recognised testing facilities	No, not conducted under GLP/Officially recognised testing facilities
Acceptability/Reliability:	Yes/Reliable

2. Assessment and conclusion

Assessment and conclusion by applicant:

The aim of the paper was to evaluate potential effects of Glyphosate, Glyphosate salt and AMPA on earthworm, soil mites, springtails and soil micro-organisms.

The studies have been conducted according to recognised guidelines and validity criteria were presented. Test substance information, test organism origin, study designs and toxicity effects were adequately described. The study is considered reliable.