

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium ammonium sulfate¹ (approved as aluminium ammonium sulphate)

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SUMMARY

Aluminium ammonium sulfate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004³, as amended by Commission Regulation (EC) No 1095/2007⁴.

Aluminium ammonium sulfate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009⁵, in accordance with Commission Implementing Regulation (EU) No 540/2011⁶, as amended by Commission Implementing Regulation (EU) No 541/2011⁷. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010⁸, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Portugal being the designated rapporteur Member State submitted the DAR on aluminium ammonium sulfate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 10 July 2008. The peer review was initiated on 16 December 2010 by dispatching the DAR for consultation of the Member States and on 7 August 2008 to the notifier Sphere Laboratories Ltd. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on aluminium ammonium sulfate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of aluminium ammonium sulfate as a repellent in agriculture, horticulture, amenity

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³ OJ L 379, 24.12.2004, p.13

⁴ OJ L 246, 21.9.2007, p.19

⁵ OJ L 309, 24.11.2009, p.1

⁶ OJ L 153, 11.6.2011, p.1

⁷ OJ L 153, 11.6.2011, p.187

⁸ OJ L 37, 10.2.2010, p.12

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areas and for amateur use, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified in the section identity, physical and chemical properties and analytical methods.

In the mammalian toxicology section, a data gap was identified for the lack of exposure estimates and risk assessment for the representative uses as seed dressing ('Curb Powder Formulation') and animal repellent in slug pellet formulation ('Curb Liquid Formulation').

A data gap was identified for the residues section to provide experimental data addressing the residue levels of aluminium ion in relevant representative crops (row crops, combinable crops, grassland) receiving foliar spray application at the worst case conditions (overall treatment, least favourable soil conditions, maximum seasonal application rate, latest growth stage at application). Only for uses as slug pellet formulations, as a seed treatment and as a barrier or spot trunk treatment of tree crops it can be reasonably assumed that aluminium residues resulting from the application of aluminium ammonium sulfate will be insignificant, and only provided treatment of fruit trees is conducted in a manner that precludes any contamination of the fruits. For all the other uses it is currently not possible to conclude without further data that the use of aluminium ammonium sulfate would not present a risk to consumers.

Concerning the environmental fate and behaviour, data gaps were identified to address the impact of the concentrations of transformation/dissociation products of aluminium ammonium sulfate in soil and surface water that arise from the use of aluminium ammonium sulfate. This is in the context of comparison to their background levels in the different environmental compartments, occurring naturally or from anthropogenic origin. These data gaps result in the environmental exposure/risk assessment being not finalised. Data gaps were identified for satisfactory information on mobility of the transformation/dissociation products of aluminium ammonium sulfate in soil, for predicted environmental concentrations (PEC) in surface water/sediment for aluminium ions and sulfate, and PEC in groundwater for the transformation/dissociation products of aluminium ammonium sulfate. A simplistic calculation performed by EFSA based on the worst case assumptions showed that there is a potential for the Drinking Water Directive requirement⁹ for the chemical parameter for aluminium (200 µg/L) to be exceeded. Some relevant information on the GAPs of the representative uses is inadequately reported to properly identify the worst case scenario (combination of crop, application rate, number of applications, timing, etc.) for the risk assessment. Information on the natural buffering capacity of surface water bodies in Europe to neutralize ammonia/ammonium and/or sulfate inputs potentially formed following the use of aluminium ammonium sulfate and on the possible adverse effects on aquatic organisms is required.

The risk assessment to non-target organisms cannot be concluded with the available data, with the exception of birds, mammals, non-target terrestrial plants and organisms involved in biological methods for sewage treatment plants.

KEY WORDS

Aluminium ammonium sulphate, aluminium ammonium sulfate, peer review, risk assessment, pesticide, repellent

⁹ Council Directive 98/83/EC on the quality of water intended for human consumption

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BACKGROUND

Aluminium ammonium sulfate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004¹⁰, as amended by Commission Regulation (EC) No 1095/2007¹¹.

Aluminium ammonium sulfate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009¹², in accordance with Commission Implementing Regulation (EU) No 540/2011¹³, as amended by Commission Implementing Regulation (EU) No 541/2011¹⁴. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010¹⁵ the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Portugal being the designated rapporteur Member State submitted the DAR on aluminium ammonium sulfate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 10 July 2008 (Portugal, 2008). The peer review was initiated on 16 December 2010 by dispatching the DAR for consultation and comments of the Member States and on 7 August 2008 to the notifier Sphere Laboratories Ltd. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 15 April 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a

¹⁰ OJ L 379, 24.12.2004, p.13

¹¹ OJ L 246, 21.9.2007, p.19

¹² OJ L 309, 24.11.2009, p.1

¹³ OJ L 153, 11.6.2011, p.1

¹⁴ OJ L 153, 11.6.2011, p.187

¹⁵ OJ L 37, 10.2.2010, p.12

repellent in agriculture, horticulture, amenity areas and for amateur use, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (19 April 2011),
- the Evaluation Table (5 December 2011),
- the report(s) of the scientific consultation with Member State experts,
- the comments received on the assessment of the points of clarification,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2011 containing all individually submitted addenda (Portugal, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Aluminium ammonium sulfate (IUPAC) is considered by the International Organization for Standardization not to require a common name. This substance was notified as aluminium ammonium sulphate but IUPAC now requires the “f” spelling for sulfur and its compounds.

The representative formulated products for the evaluation are ‘Curb Liquid Formulation’ a soluble concentrate (SL), containing 81.2 g/L aluminium ammonium sulfate dodecahydrate and ‘Curb Powder Formulation’, a water soluble powder (SP), containing 858 g/kg aluminium ammonium sulfate dodecahydrate, registered under different trade names in several EU countries.

The representative uses evaluated comprise spraying applications on numerous crops and grassland and seed dressing applications on various crops, as a repellent against birds; spray applications on grassland and amenity turf as a repellent against moles; and applications by hand or tractor-mounted equipment as an animal repellent in metaldehyde based slug pellet formulations. Full details of the GAP can be found in the list of end points in Appendix A. A general data gap is identified for detailed information on the GAPs of the representative uses in order to adequately identify the worst case scenario (combination of crop, application rate, number of applications, timing, etc.) for the risk assessment.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev. 4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004a).

It should be noted that the CAS No of the active substance aluminium ammonium sulfate in the Implementing Regulation¹⁶ is that of the aluminium ammonium sulfate dodecahydrate and the minimum purity is also expressed as dodecahydrate. The minimum purity of aluminium ammonium sulfate dodecahydrate is 960 g/kg which corresponds to 502 g/kg of anhydrous salt. No FAO specification exists.

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 aluminium ammonium sulfate or the representative formulations. Data gaps were identified for information about the origin and purity of starting materials used in the manufacturing process, for information about the method used for the determination of the active substance in the batch analysis and for a method to confirm the sulfate anion of the active substance. A data gap was also identified for the determination of the persistence of foaming of the preparations to be diluted with water. The main data regarding the identity of aluminium ammonium sulfate and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of aluminium ammonium sulfate in the technical material and in the representative formulations.

Pending on the residue definition for monitoring, analytical method(s) to determine this compound in food of plant and animal origin might be required (see section 3). The need for methods of analysis for monitoring this compound in soil and water have been waived due to the nature of the compound, however a data gap was identified for a monitoring residue analytical method for air due to the spray applications.

¹⁶ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186

A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance document was followed in the production of this conclusion: SANCO/222/2000 rev. 7 (European Commission, 2004b).

With the exception of some acute toxicity and mutagenicity studies, most of the data submitted by the notifier are published reviews performed by third parties on different aluminium salts. The raw data and original studies were not part of the dossier for aluminium ammonium sulfate and therefore these reviews could not be considered for the peer review.

For the derivation of the reference values, the same approach than for aluminium sulfate was agreed, based on the use of the EFSA opinion on the safety of aluminium from dietary intake (EFSA, 2008). Aluminium is considered to be the most toxic compound for which reference values have to be derived, resulting in an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) of 0.14 mg/kg bw/(day) and an Acceptable Operator Exposure Level (AOEL) of 0.002 mg/kg bw/d based on the Tolerable Weekly Intake (TWI) for aluminium of 1 mg/kg bw/week. For the AOEL, a correction factor of 1% is applied for the oral absorption, and 5 working days per week are considered. In the absence of data for the representative formulations, the dermal absorption of aluminium is considered to be the same as the oral absorption, i.e. 1%.

The predicted **operator** exposure in all scenarios with tractor application and in tree crops with hand-held application was below the AOEL with the use of PPE in the German model (gloves and RPE during mixing and loading; gloves, broad-brimmed headwear, coverall, sturdy foot wear, with or without RPE during application) and in the UK POEM (gloves during mixing/loading and application). The exposure for hand-held application of 'Curb Liquid Formulation' in grassland and amenity turf exceeds the AOEL even with the use of PPE in the UK POEM (129% of the AOEL with the use of gloves during mixing/loading and application; impermeable coveralls during application) and a high risk was identified. No estimates were provided for the exposure during seed dressing (with 'Curb Powder Formulation') and during use as an animal repellent in slug pellet formulation (with 'Curb Liquid Formulation'), therefore data gaps were identified. The worst case estimate for **worker** exposure in row crops, combinable crops, grassland and tree crops (for 'Curb Powder Formulation') is below the AOEL with the use of gloves. This will also cover the re-entry in grassland and amenity turf (treated with 'Curb Liquid Formulation') since a much lower application rate is supported. The **bystander** exposure is below the AOEL for row crops, combinable crops, grassland and tree crops (for 'Curb Powder Formulation'), and is assumed to cover bystander exposure in grassland and amenity turf (for 'Curb Liquid Formulation') as well.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document SANCO/1607/VI/97 rev. 2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004 and 2007).

Specific studies to evaluate residues in plants upon the use of aluminium ammonium sulfate as a plant protection product were not submitted. In aqueous conditions, aluminium ammonium sulfate dissociates immediately into aluminium sulfate and ammonium sulfate. The nitrogenous portion of ammonium sulfate is likely to undergo bioaccumulation in proteins, and sulfate might be further metabolised according to known processes in living matter. On the contrary, aluminium ion will be very stable and thus will not metabolise or form degradation products. Upon foliar application, transportation and distribution of aluminium ion in plants is expected to be limited and residues are likely to occur only on treated plant surfaces.

As for the toxic potential of aluminium, Provisional Tolerable Weekly Intakes (PTWIs) were set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). On this basis the peer review of aluminium sulfate concluded on an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) of 0.14 mg/kg bw/(day) for aluminium (EFSA, 2010). Consequently, the consumer exposure to aluminium ion residues resulting from the use of aluminium ammonium sulfate on crops will have to be determined in order to conduct a consumer risk assessment. The plant residue definition for consumer risk assessment is aluminium ion.

Estimates of theoretical maximum aluminium ion residues following a single foliar application of aluminium ammonium sulfate were provided for selected crops (brassicas, legumes, grass) in the Addendum to the DAR (Portugal, 2011) and were used for livestock and consumer exposure assessment. The current assessment indicates a possible exceedance of the ARfD of 0.14 mg/kg bw and the trigger value (0.01 mg/kg DM) for further metabolism data on livestock, respectively. The relevant information on the representative uses has been inadequate to properly identify the worst case scenarios (raw and combinable crops, application rate, number of applications, growth stage at application). Moreover, no limit was set regarding the number of applications per season. Therefore, the estimates provided by the RMS should be considered as a rough indication only and are not exhaustive. Without further data, it is not possible to conclude that the use of aluminium ammonium sulfate according to the requested use pattern involving spray application to row crops, combinable crops, and grassland would not present a risk to consumers. Hence, a data gap was identified for data addressing the residue levels of aluminium ion in relevant representative crops upon foliar spray treatment under worst case conditions (i.e., considering the overall treatment, the least favourable soil conditions, the envisaged maximum seasonal application rate, the latest growth stage at application, etc...) and addressing the natural background levels in untreated crops grown under identical conditions. Depending on the results of these trials, further consideration of the residue situation in livestock might become necessary.

As for the uses as slug pellet formulations or as a seed dressing it can be reasonably assumed that residues of aluminium ion resulting from the application of aluminium ammonium sulfate will be insignificant. As for the use with barrier or a trunk treatment of tree crops, residues are expected to be insignificant if application to fruit trees is conducted in a manner that precludes any contamination of fruits (e.g. when fruits are not present), or else residue data in fruit trees will have to be provided.

Whether the setting of a residue definition for monitoring is necessary will have to be further considered upon receipt and evaluation of the required residue trials.

It should also be highlighted that based on the lowest tier assessment performed by EFSA (see section 4) the Drinking Water Directive limit of 200 µg/L for the aluminium ion might be exceeded following the use of aluminium ammonium sulfate leading to an exceedance of the tolerable daily intake for exposure of the consumers through drinking water (>20% of the ADI for all categories of consumers).

4. Environmental fate and behaviour

Little information based on literature review was provided on the fate and behaviour of aluminium ammonium sulfate in the environmental compartments. Aluminium ammonium sulfate is an inorganic salt that does not degrade in soil. It dissociates immediately in water to its two component salts (aluminium sulfate and ammonium sulfate). Environmental exposure of the transformation/dissociation products such as aluminium salts, ammonium and sulfate ions to soil and surface waters may occur. The notifier claimed that aluminium is the only element of the active substance of environmental concern and therefore predicted environmental concentrations (PEC) in soil and surface waters for aluminium only were provided in the DAR. The amount of aluminium applied in a single application was compared to the total aluminium content of the planet's crust (about 8% by weight). As the form of soil Al is a key factor in its potential bioavailability and toxicity, a quantitative assessment of the amount of soluble Al^{3+} species added to soil as result of application of aluminium ammonium sulfate with respect to background levels of these species in soil was

considered necessary. Additionally, some relevant information on the GAPs (as defined in the “Summary of representative uses evaluated”) of the representative uses is inadequately reported to properly identify the worst case scenario (combination of crop, application rate, number of applications, timing, etc.) for the risk assessment. As a consequence, data gaps were identified for PECs in soil (top 5 cm of the soil profile assuming a soil bulk density of 1.5 g/cm³) for aluminium ammonium sulfate components and for information on background levels of the transformation/dissociation products of aluminium ammonium sulfate in grassland and agricultural soil occurring naturally or from anthropogenic origin to be compared with these PECs. A limited qualitative assessment on the mobility of aluminium in soils has been reported in the DAR, but the primary scientific literature source of this information was not clear. A data gap was also identified for satisfactory information on the mobility of the transformation/dissociation products of aluminium ammonium sulfate (i.e. soluble species of aluminium, nitrate and nitrite) in soil if the data are considered necessary to address the potential of groundwater contamination.

Calculations of the PEC in surface water and sediment for aluminium for the two formulations for field crops and fruit crops according to “Drift Calculator” (version not specified) were provided by the notifier. However, because only spray drift was considered as the entry route to the water body, and because of the data gap identified for details on the GAP, these PECs could not be considered acceptable. A data gap was identified also for PEC in surface water/sediment for ammonia and sulfate ions originating from the representative uses of aluminium ammonium sulfate in comparison with the estimated levels of natural occurrence and as contributions from fertilizer uses of these elements. Consequently, information on the natural buffering capacity of surface water bodies in Europe to neutralize ammonia/ammonium and/or sulfate inputs potentially formed following the use of aluminium ammonium sulfate and on the possible adverse effects on aquatic organisms is required. These data gaps result in the environmental exposure and risk assessments being not finalised. Additionally, a data gap was identified for a groundwater exposure assessment of the transformation/dissociation products of aluminium ammonium sulfate to compare against the parametric drinking water limits set by the EU Drinking Water Directive¹⁷ for these inorganic compounds. A simplistic calculation performed by EFSA based on the worst case in terms of aluminium ammonium sulfate rate on trees (17.6 kg a.s./ha, 1 application a year, 50% crop interception), assuming that 100% of aluminium applied to soil will leach to groundwater, showed that the Drinking Water Directive requirement for aluminium (200 µg/L) might be exceeded (see Appendix A for details). Using the same approach and considering the total amount of sulfur applied to soil (= 4.75 kg S/ha) it can be concluded that it is unlikely that the limit of 250 mg/L for sulfate will be exceeded following the use of aluminium ammonium sulfate. It should be noted that PEC_{gw} calculations as reported in Appendix A are valid for the representative use on trees with a single application of 17.6 kg a.s./ha and, because of the data gap on the GAPs, it can not be concluded if this assessment would cover the worst case scenario.

5. Ecotoxicology

An acute valid toxicity study to mammals was submitted. Various overviews of toxicity studies to birds, aquatic organisms and soil micro-organisms from scientific literature were submitted. The notifier was requested to provide the original studies, however original study reports were not submitted and therefore these data could not be used in the risk assessment.

A weight of evidence approach was used to address the risk assessment for birds and mammals from exposure to aluminium ammonium sulfate. Aluminium ammonium sulfate is used as a repellent for birds and mammals. Results of available efficacy tests submitted for birds and mammals corroborate the repellent properties of the active substance. Additionally, based on the available toxicity study (LD₅₀ > 2000 mg as/kg bw) the acute toxicity to mammals is low. Consequently, it can be concluded that the risk of aluminium ammonium sulfate to birds and mammals can be considered as low for all representative uses.

¹⁷ Council Directive 98/83/EC on the quality of water intended for human consumption

Aquatic toxicity studies considered necessary to fulfil the Annex II data requirements were not submitted, and consequently a data gap was identified. Exposure to surface water bodies cannot be excluded (see data gap in section 4). Pending on this data gap, in particular whether the exposure to the environment will be higher than the natural background levels in water, the risk assessment for aquatic organisms from the exposure of aluminium ion, ammonia and sulfate ions (ammonium sulfate and aluminium sulfate) and nitrate and nitrite (pending on predicted groundwater level exposure), needs to be addressed for all representative uses.

The exposure to bees and non-target arthropods cannot be excluded for the representative uses. Therefore, the risk assessment for bees and non-target arthropods needs to be addressed and data gaps were identified.

Exposure to soil is likely. Pending on the outcome of the data gaps in section 4, in particular whether the exposure to environment arising from the representative uses will be higher than the natural background levels in soil, the risk of aluminium ammonium sulfate components to soil organisms (earthworms, and soil non-target macro and micro-organisms) needs to be addressed and data gaps were identified.

The risk to non-target terrestrial plants and to organisms involved in biological methods for sewage treatment plants was considered to be low.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
aluminium ion	no data, data not required	Data gap
sulfate	no data, data not required	Data gap

6.2. Ground water

Compound (name and/or code)	Mobility in soil	Chemical and indicator parameters set by Council Directive 98/83/EC on the quality of water intended for human consumption	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
aluminium ion	no data, data required if necessary to address the potential for groundwater contamination	A simplistic calculation performed by EFSA for the representative use on tree crops suggested that the limit of 200 µg/L might be exceeded following the use of aluminium ammonium sulfate.	Yes	Yes	No data available. Data gap.

sulfate	no data, data not required	A simplistic calculation performed by EFSA for the representative use on tree crops suggested that the limit of 250 mg/L will not be exceeded following the use of aluminium ammonium sulfate.	No data available. Not required.	No data available. Not required	No data available. Not required.
nitrate	no data, data required if necessary to address the potential for groundwater contamination	no data, data required (limit 50 mg/L)	No data available, pending on predicted groundwater level.	No data available, pending on predicted groundwater level.	No data available pending on predicted groundwater level.
nitrite	no data, data required if necessary to address the potential for groundwater contamination	no data, data required (limit 0.5 mg/L)	No data available pending on predicted groundwater level.	No data available, pending on predicted groundwater level.	No data available pending on predicted groundwater level.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
aluminium ion	No data available. Data gap.
ammonia/ammonium	No data available. Data gap.
sulfate	No data available. Data gap.

6.4. Air

Compound (name and/or code)	Toxicology
aluminium ammonium sulfate	No data available

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Detailed information on the GAPS of the representative uses in order to adequately identify the worst case scenario (combination of crop, application rate, number of applications, timing, etc.) (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see all sections)
- Information about the origin and purity of starting materials used in the manufacturing process (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Information about the method used for the determination of the a.s. in the batch analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Method to confirm the sulfate anion of the a.s. (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Foam persistence of the preparations to be diluted with water (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Monitoring residue analytical method for air (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Operator, worker and bystander exposure estimates from the use as seed dressing (with 'Curb Powder Formulation') and from the use as an animal repellent in the slug pellet formulation (with 'Curb Liquid Formulation') (relevant for two representative uses; submission date proposed by the notifier: unknown; see section 2)
- Data addressing the residue levels of aluminium ion in relevant representative crops upon foliar spray treatment under worst case conditions (i.e. considering overall treatment, the least favourable soil conditions, the envisaged maximum seasonal application rate, the latest growth stage at application, etc...) and addressing natural background levels in untreated crops grown under identical conditions (relevant for the representative uses in row crops, combinable crops, grassland; submission date proposed by the notifier: unknown; see section 3)
- Predicted environmental concentrations (PEC) in soil of the transformation/dissociation products of aluminium ammonium sulfate to be compared with the background levels in grassland and agricultural soil occurring naturally or from anthropogenic origin (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Satisfactory information on the mobility of the transformation/dissociation products of aluminium ammonium sulfate (i.e. soluble species of aluminium, nitrate and nitrite) in soil if the data are considered necessary to address the potential of groundwater contamination (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Satisfactory information to address the potential for the transformation/dissociation products of aluminium ammonium sulfate to reach surface water systems and compare the PECs to the amounts which might occur from typical fertiliser application uses and background levels. Additionally, information on the natural buffering capacity of surface water bodies in Europe to

neutralize ammonia/ammonium and/or sulfate inputs potentially formed following the use of aluminium ammonium sulfate and on the possible adverse effects on aquatic organisms is required (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4 and 5)

- Predicted environmental concentrations (PEC) in groundwater of the transformation/dissociation products of aluminium ammonium sulfate to be compared against the EU parametric values of the Drinking Water Directive 98/83/EC (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)
- Aquatic toxicity studies that are considered necessary to fulfil the Annex II data requirements directly related to classification (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown ; see section 5)
- Pending on the data gap on section 4, in particular, whether the exposure to environment will be higher than the natural background levels in water, the risk assessment for aquatic organisms from the exposure of aluminium ion, ammonia and sulfate ions (ammonium sulfate and aluminium sulfate) and nitrate and nitrite (pending on predicted groundwater level exposure), needs to be addressed (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown ; see section 5)
- Risk assessment for bees and non-target arthropods (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown ; see section 5)
- Pending on the data gap in section 4, in particular whether the exposure to the environment arising from the representative uses will be higher than the natural background levels in soil, the risk of aluminium ammonium sulfate to soil organisms needs to be addressed (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown ; see section 5)

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

- Personal protective equipment is needed for the operators and workers (see section 2):
 - For the tractor application of 'Curb Powder Formulation' on row crops, combinable crops, grassland, tree crops
 - For the tractor application of 'Curb Liquid Formulation' on grassland and amenity turf
 - For the hand-held application of 'Curb Powder Formulation' to tree crops
- Barrier or trunk application to fruit trees must be conducted in a manner that precludes any contamination of fruits (e.g. when fruits are not present) (see section 3).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. Risk assessment for the operators, workers and bystanders from the use of 'Curb Powder Formulation' in seed dressing, and from the use of 'Curb Liquid Formulation' as an animal repellent in slug pellet formulation.
2. For the use of aluminium ammonium sulfate following foliar application on row crops, combinable crops and grassland, it is currently not possible to conclude without further data that the use of aluminium ammonium sulfate would not present a risk to consumers
3. Based on the available data, it is not possible to conclude if the amounts of the transformation/dissociations products of aluminium ammonium sulfate such as aluminium ions, sulfates, nitrates and nitrites formed following the use of aluminium ammonium sulfate will be negligible with respect to environmental background levels.
4. The groundwater exposure assessment of the transformation/dissociation products of aluminium ammonium sulfate to be compared against the EU parametric values of the Drinking Water Directive 98/83/EC.
5. The risk assessment to non-target organisms cannot be concluded with the available data, with the exception of birds, mammals, non-target terrestrial plants and organisms involved in biological methods for sewage treatment plants.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

- None

9.3. Overview of the concerns for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		seed dressing (various crops)	Row crops	Combinable crops (grains, pulses, oilseed rape)	Grassland	Tree crops	Grassland and amenity turf
Operator risk	Risk identified						X
	Assessment not finalised	X ¹					
Worker risk	Risk identified						
	Assessment not finalised	X ¹					
Bystander risk	Risk identified						
	Assessment not finalised	X ¹					
Consumer risk	Risk identified						
	Assessment not finalised		X ²	X ²	X ²		
Risk to wild non target terrestrial vertebrates	Risk identified						
	Assessment not finalised						
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified						
	Assessment not finalised	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵
Risk to aquatic organisms	Risk identified						
	Assessment not finalised	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵	X ⁵
Groundwater exposure active substance	Legal parametric value breached						
	Assessment not finalised						
Groundwater exposure metabolites	Legal parametric value breached					X	
	Parametric value of 10µg/L ^(a) breached						
	Assessment not finalised	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴	X ⁴
Comments/Remarks							

Representative use		Animal repellent in metaldehyde based slug pellet formulations
Operator risk	Risk identified	
	Assessment not finalised	X ¹
Worker risk	Risk identified	
	Assessment not finalised	X ¹
Bystander risk	Risk identified	
	Assessment not finalised	X ¹
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X ⁵
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X ⁵
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L ^(a) breached	
	Assessment not finalised	X ⁴
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 4 and 6 for further information. A column is greyed out if there is a concern for that specific use.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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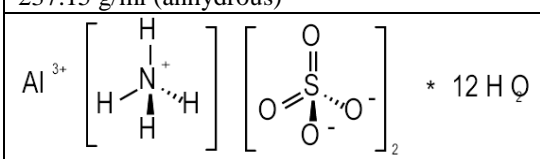
APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	aluminium ammonium sulfate ammonium aluminium sulfate (unless otherwise stated the following data relate to the variant dodecahydrate) (No ISO common name)
Function (e.g. fungicide)	Repellent
Rapporteur Member State	Portugal
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	aluminium ammonium sulfate
Chemical name (CA) ‡	aluminium ammonium sulfate
CIPAC No ‡	840
CAS No ‡	7784-26-1 (dodecahydrate) 7784-25-0 (anhydrous)
EC No (EINECS or ELINCS) ‡	232-055-3 (dodecahydrate)
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	960 g/kg (expressed as dodecahydrate) 502 g/kg (anhydrous)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities
Molecular formula ‡	$(\text{NH}_4)\text{Al}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$
Molecular mass ‡	453.33 g/mol (dodecahydrate) 237.15 g/mol (anhydrous)
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	94.5 °C (100.7%)
Boiling point (state purity) ‡	200 °C
Temperature of decomposition (state purity)	Decomposition begins at temperatures of approximately 87 °C with the loss of water crystallisation. Above 193°C decomposition occurs with the release of ammonium. Aluminium sulfate decomposes at 1000 °C, sulfur trioxide is lost, leaving an aluminium oxide residue.
Appearance (state purity) ‡	White crystalline powder.
Vapour pressure (state temperature, state purity) ‡	It is anticipated that the vapour pressure of the a.s. will be very low
Henry's law constant ‡	The a.s has a low volatility from water since vapour pressure is negligible.
Solubility in water (state temperature, state purity and pH) ‡	104.67 g/L (20°C) (100.7%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (100.7%) heptane < 10 <i>p</i> -xylene < 10 1,2-dichloroethane < 10 methanol < 10 acetone < 10 ethyl acetate < 10 glycerol 67-80 The literature indicate that the a.s. is insoluble in most common organic solvents with the exception of glycerol
Surface tension ‡ (state concentration and temperature, state purity)	Not relevant.
Partition co-efficient ‡ (state temperature, pH and purity)	log P _{O/W} = - 2.0 (aluminium sulfate) Expected to be very low since aluminium ammonium sulfate dodecahydrate is practically insoluble in organic solvents.
Dissociation constant (state purity) ‡	As aluminium ammonium sulfate dodecahydrate is an inorganic ionic compound it is fully dissociated in water.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not relevant
Flammability ‡ (state purity)	Not flammable
Explosive properties ‡ (state purity)	Not explosive
Oxidising properties ‡ (state purity)	Not oxidising

Summary of representative uses evaluated (*aluminium ammonium sulfate*)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (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 min-max (l)	water L/ha min – max	kg as/ha min – max (l)		
Curb Crop Spray Powder MAFF 02480															
Seed dressing (various crops)	Northern and Southern Europe	Curb Powder Formulation	F	Birds (various seed eating species)	SP	858 g/kg (dodeca hydrate)	Applied by hand (amateur) or seed dressing machinery (professional)	To seed at planting. Season of application dependent on crop establishment pattern.	1	Not applicable	Not applicable.	Not applicable	Dependent on the seed size and drilling rate.	Not specified	The rates of application are as follows Seed rate Product hectare rate 125 kg 500 g per and over 50 kg 75 to 500 g per 125 kg 25 kg 25 to 500 g per 75 kg 17 kg Below 500 g per 25 kg 10 kg
Row crops	Northern and Southern Europe	Curb Powder Formulation	F	Birds (various species)	SP	858 g/kg (dodeca hydrate)	Applied by hand held sprayers(amate ur) or Tractor drawn/mounted sprayers (professional)	When crops are under attack (seedlings up to and including mature crops)	Not specified - depends on infestation pressure.	Usually a minimum of 14 days but may be reduced if heavy rain occurs	7.04	250	17.6	Not specified	Barrier or overall treatment. (Overall treatment only used on high value crops such as plant breeding trials)
Combinable crops (grains, pulses, oilseed rape)	Northern and Southern Europe	Curb Powder Formulation	F	Birds (various species)	SP	858 g/kg (dodeca hydrate)	Applied by tractor drawn/mounted sprayers (professional)	BBCH 00-11 early season BBCH 80-98 late season	Not specified depends on infestation pressure	Usually a minimum of 14 days but may be reduced if heavy rain occurs	7.04	250	17.6	Not specified	Overall or barrier treatment.

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (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 min-max (l)	water L/ha min – max	kg as/ha min – max (l)		
Grassland	Northern and Southern Europe	Curb Powder Formulation	F	Birds (various species)	SP	858 g/kg (dodecahydrate)	Applied by tractor drawn/mounted sprayers (professional)	Not applicable. The level of protection required depends on the use of the grassland	Not specified	Usually a minimum of 14 days but may be reduced if heavy rain occurs	7.04	250	17.6	Not specified	Overall or barrier treatment following re-seeding.
Tree crops	Northern and Southern Europe	Curb Powder Formulation	F	Birds (various species)	SP	858 g/kg (dodecahydrate)	Applied by tractor drawn/mounted sprayers (professional)	Hand held equipment or tractor drawn mistblowers	Not specified	Usually a minimum of 14 days but may be reduced if heavy rain occurs	7.04	250	17.6	Not specified	Fruit - Barrier or spot trunk treatment. Forestry - Overall (nursery stock) Barrier or spot treatment (field transplants).
Curb Liquid Crop Spray MAFF 03164															
Grassland and Amenity turf.	Northern and Southern Europe	Curb Liquid Formulation	F	Moles (dogs)	SL	81.2 g/L (dodecahydrate)	Tractor mounted spray or pedestrian controlled sprayer	Mown turf throughout the growing season	Not specified – application as soon as infestation or reinfestation occurs	Not specified – dependent on pest activity	0.830 – 1.0375	200 – 250	max 2.075	Not specified	Barrier or spot treatment.
Animal repellent in metaldehyde based slug pellet formulations	Northern and Southern Europe	Curb Liquid Formulation	F & G.	Companion animals (dogs) and non target rodents.	SL	20.0 L/ton of pellets during manufacture	Slug pellets are applied by hand (amateur) or tractor mounted equipment	Incorporation in pellets	Not specified. Slug pellet application number depends on the susceptibility of the crop to be protected and the level of protection required. (Max number will be dependent on number of metaldehyde applications permitted/crop)	Not applicable	Not applicable	Amateur use = 0.0498g a.s./ha Professional use = 0.0249 g a.s./ha	Not specified but identical to slug pellet formulations	Animal repellent in metaldehyde based slug pellet formulations	The inclusion of an effective animal repellent is a condition of approval for metaldehyde based slug pellet formulations in the UK to prevent accidental poisoning of non-target animal species.

<p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(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).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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Methods of Analysis

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

Technical as (analytical technique)

a) Complexometric titration
b) ammonium ion – titration
aluminium - atomic absorption spectroscopy
method to confirm the SO_4^{-2} anion of the active substance needs to be submitted

Impurities in technical as (analytical technique)

Atomic absorption spectroscopy

Plant protection product (analytical technique)

ammonium ion – titration
aluminium - atomic absorption spectroscopy

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin

Pending, no residue definition is currently proposed.

Food of animal origin

Pending, no residue definition currently proposed.

Soil

No residue definition is proposed.

Water surface

No residue definition is proposed.

drinking/ground

No residue definition is proposed.

Air

aluminum ammonium sulfate

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

Open

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

Open

Soil (analytical technique and LOQ)

Not required

Water (analytical technique and LOQ)

Not required

Air (analytical technique and LOQ)

Required

Body fluids and tissues (analytical technique and LOQ)

Not required

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

Active substance

RMS/peer review proposal

None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Insufficient data available – not required 1% for aluminium (EFSA, 2010)
Distribution ‡	Insufficient data available – not required
Potential for accumulation ‡	Insufficient data available – not required.
Rate and extent of excretion ‡	Insufficient data available – not required
Metabolism in animals ‡	No data available – not required
Toxicologically relevant compounds ‡ (animals and plants)	Aluminium
Toxicologically relevant compounds ‡ (environment)	Aluminium

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral ‡ (Curb Powder, 88.8% a.s)	>2000 mg/kg bw	
Rat LD ₅₀ dermal ‡ (Curb Powder, 88.8% a.s)	>2000 mg/kg bw	
Rat LC ₅₀ inhalation ‡	No data available – not required	
Skin irritation ‡ (Curb Powder, 88.8% a.s)	Non irritant	
Eye irritation ‡ (Curb Powder, 88.8% a.s)	Non irritant	
Skin sensitisation ‡	No data available – not required	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Insufficient data available – not required	
Relevant oral NOAEL ‡	Insufficient data available – not required	
Relevant dermal NOAEL ‡	No data available – not required	
Relevant inhalation NOAEL ‡	No data available – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Negative in two Ames Test	
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Insufficient data available – not required	
Relevant NOAEL ‡	Insufficient data available – not required	
Carcinogenicity ‡	Insufficient data available – not required	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡

Insufficient data available – not required

Relevant parental NOAEL ‡

Insufficient data available – not required

Relevant reproductive NOAEL ‡

Insufficient data available – not required

Relevant offspring NOAEL ‡

Insufficient data available – not required

Developmental toxicity

Developmental target / critical effect ‡

Insufficient data available – not required

Relevant maternal NOAEL ‡

Insufficient data available – not required

Relevant developmental NOAEL ‡

Insufficient data available – not required

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡

Insufficient data available – not required

Repeated neurotoxicity ‡

Delayed neurotoxicity ‡

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡

Insufficient data available – not required

Studies performed on metabolites or impurities ‡

No data available – not required

Medical data ‡ (Annex IIA, point 5.9)

No data available – not required

Summary (Annex IIA, point 5.10)

ADI ‡

Value	Study	Safety factor
0.14 mg Al/kg bw/d	TWI* of 1 mg Al/kg bw/week	1
0.002 mg Al/kg bw/d	TWI* of 1 mg Al/kg bw/week	1% oral absorption, 5 working days/week
0.14 mg Al/kg bw	TWI* of 1 mg Al/kg bw/week	1

AOEL ‡

ARfD ‡

* TWI: Tolerable Weekly Intake (EFSA, 2008)

Dermal absorption ‡ (Annex IIIA, point 7.3)

Curb Powder Formulation

1% based on the oral absorption value (EFSA, 2010)

Curb Liquid Formulation

Exposure scenarios[#] (Annex IIIA, point 7.2)

Operator	Exposure estimates to AI (% AOEL) for Curb Powder Formulation , according to the German model:	No PPE	PPE
	Tractor - tree crops	960	85*
	Tractor – row crops, combinable crops (grains, pulses and oilseed rape), grassland	750	93**
	Hand-held – tree crops	690	69*
	Seed dressing	No estimates provided, data gap	
	Exposure estimates to AI (% AOEL) for Curb Liquid Formulation , according to the UK POEM:	No PPE	PPE
	Tractor – grassland and amenity turf	327	57 ^{\$}
	Hand-held – grassland and amenity turf	507	129 ^{\$\$}
	Slug pellet formulation	No estimates provided, data gap	
	Workers	For re-entry in tree crops (worst case for row crops, combinable crops, grassland and amenity turf): 31% of AOEL with gloves (Krebs, 1996)	
Bystanders	During application in tree crops (also worst case for row crops, combinable crops, grassland and amenity turf): 29% of AOEL (Rautman, 2001)		

[#] considering a conversion factor of 27(MW AI)/453 (MW AAS) for the AI content in the formulations

* PPE (personal protective equipment): gloves and respiratory protective equipment (RPE) during mixing/loading (M/L) and application (A); broad-brimmed head wear, coverall and sturdy foot wear during A

** PPE: gloves and RPE during M/L; gloves, broad-brimmed headwear, coverall and sturdy footwear during A

^{\$} PPE: gloves during M/L and A

^{\$\$} PPE: gloves during M/L and A; impermeable coveralls during A

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

Aluminium ammonium sulfate	RMS/peer review proposal
	No classification is proposed.

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

Plant groups covered	None. Not required.
Rotational crops	None. Not required.
Metabolism in rotational crops similar to metabolism in primary crops?	Not required.
Processed commodities	Not required.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not required.
Plant residue definition for monitoring	No residue definition is currently proposed. Pending the outcome of the identified data gap.
Plant residue definition for risk assessment	Aluminium ion
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	None, pending the outcome of the identified data gap.
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Pending, no residue definition is currently proposed.
Animal residue definition for risk assessment	Pending, no residue definition is currently proposed.
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	Not considered

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

Not required. Residues will be addressed by data in representative primary crops. Accumulation of Aluminium in crops by uptake from soil is expected only in very rare cases.

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

Not required. Aluminium is considered to be very stable.

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

Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

Ruminant:	Poultry:	Pig:
Conditions of requirement of feeding studies		
open	open	open
open	open	open
open	open	open
Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant)		
Residue levels in matrices : Mean (max) mg/kg		
open	open	open
open	open	open
open	open	open
open	open	open
open		
	open	

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/ Southern/ region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representative use	HR (c)	STMR (b)
Row crops	N & S	Data required		Open	Open	Open
Combinable crops	N & S	Data required		Open	Open	Open
Grassland	N & S	Data required		Open	Open	Open

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

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

ADI	0.14 mg/kg bw/day (for aluminium ion resulting from the aluminium ammonium sulfate as animal repellent)
TMDI (% ADI) according to WHO European diet	Pending refined consumer exposure assessment upon submission of residue data
TMDI (% ADI) according to national (to be specified) diets	Pending refined consumer exposure assessment upon submission of residue data
IEDI (WHO European Diet) (% ADI)	Pending refined consumer exposure assessment upon submission of residue data
Factors included in IEDI and NEDI	Pending refined consumer exposure assessment upon submission of residue data
ARfD	0.14 mg/kg bw (for aluminium ion resulting from the aluminium ammonium sulfate as animal repellent)
IESTI (% ARfD)	Pending refined consumer exposure assessment upon submission of residue data Based on the theoretical calculation of the maximum residue levels of aluminium ion recovered in brassica and legume vegetables and on a single foliar treatment (SP formulation) at a dose rate of 17.6 kg as/ha (<i>ca.</i> 1 kg Al/ha), an exceedance of the ARfD was identified.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Pending refined consumer exposure assessment upon submission of residue data
Factors included in IESTI and NESTI	Pending refined consumer exposure assessment upon submission of residue data

Note: Based on the lowest tier assessment performed by EFSA (see section 4) the Drinking Water Directive limit of 200 µg/L for the aluminium ion might be exceeded following the use of aluminium ammonium sulfate leading to an exceedance of the tolerable daily intake for the exposure of the consumers through drinking water (>20% of the ADI for all categories of consumers).

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
Pending the outcome of the identified data gap.				

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

MRLs currently not proposed.

Pending the outcome of the identified data gap.

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

Mineralization after 100 days ‡	Not applicable to an active substance that is inorganic
Non-extractable residues after 100 days ‡	Not applicable to an active substance that is inorganic
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not applicable to this active substance that is inorganic Aluminium ammonium sulfate dissociates in water to its two component salts (aluminium sulfate and ammonium sulfate).

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

Anaerobic degradation ‡	
Mineralization after 100 days	Not applicable to an active substance that is inorganic
Non-extractable residues after 100 days	Not applicable to an active substance that is inorganic
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable to an active substance that is inorganic

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

Laboratory studies ‡

Parent	Aerobic conditions
	Not applicable to an active substance that is inorganic

Met 1	Aerobic conditions
	Not applicable

Field studies ‡

Parent	Aerobic conditions
	Not applicable

Met 1	Aerobic conditions
	Not applicable

pH dependence ‡
(yes / no) (if yes type of dependence)

Not applicable

Soil accumulation and plateau concentration ‡

Not applicable

Laboratory studies ‡

Parent	Anaerobic conditions
	Not applicable

Met 1	Anaerobic conditions
	Not applicable

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡	Not applicable
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Metabolite 1 ‡	Not applicable
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Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Data gap: satisfactory information on the mobility of the transformation/dissociation products of aluminium ammonium sulfate in soil if considered necessary to address the potential for groundwater contamination.

Column leaching ‡

Not applicable

Not applicable

Aged residues leaching ‡

Not applicable

Not applicable

Not applicable

Lysimeter/ field leaching studies ‡

Not applicable

PEC (soil) (Annex IIIA, point 9.1.3)

Data gap: PEC soil of the transformation/dissociation products of aluminium ammonium sulfate to be compared with the background levels in grassland and agricultural soil occurring naturally or from anthropogenic origin

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

pH 5: Not applicable

pH 7: Not applicable

pH 9: Not applicable

Photolytic degradation of active substance and metabolites above 10 % ‡

Not applicable

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

Not applicable

Readily biodegradable ‡
(yes/no)

No – aluminium is an element and cannot degrade

Degradation in water / sediment

Parent	Not applicable
Mineralization and non extractable residues	pH dependent. At environmentally relevant pH values hydroxyaluminium compounds naturally form soluble hydroxides.

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

Data gap: Satisfactory information to address the potential for the transformation/dissociation products of aluminium ammonium sulfate to reach surface water systems and compare the PECs to the amounts which might occur from typical fertiliser application uses.

Additionally, information on the natural buffering capacity of surface water bodies in Europe to neutralize ammonia and/or sulfate inputs potentially formed following the use of aluminium ammonium sulfate and on the possible adverse effects on aquatic organisms is required.

Powder and liquid formulations.

Parent	-			
Method of calculation	-			
Application rate	-			
PEC(sw)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	No calculations have been conducted in this section, since no DT ₅₀ could be derived. In addition the behaviour of aluminium in the aquatic environment is highly dependent on the pH of the water and its cation content.			
Short term 24h				
2d				
4d				
Long term 7d				
14d				
21d				
28d				
42d				

PEC sediment

Powder and liquid formulations.

Parent	-			
Method of calculation	-			
Application rate	-			
PEC(sed)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	No calculations have been conducted in this section, since no DT ₅₀ could be derived. In addition the behaviour of aluminium in the aquatic environment is highly dependent on the pH of the water and its cation content.			
Short term 7d				
14d				
Long term 32d				
60d				
90d				
120d				
152d				

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

Data gap: PEC in groundwater of the transformation/dissociation products of aluminium ammonium sulfate such as nitrates and nitrites to be compared against the EU parametric values of the Drinking Water Directive 98/83/EC.

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

In line with the assessments for other inorganic compounds, a simplistic calculation was performed by EFSA based on the following assumptions (a data gap was identified for clarifications on the GAP of the representative uses applied for):

Scenario: tree crops
Application: 17.6 kg a.s./ha sprayed (equivalent to 1.05 kg Al/ha based on dodecahydrated molecular mass)

Crop interception: 50%

Total water volume percolated at 1 m depth determined in Sevilla scenario for apples: 1490.92 L/m² (FOCUS PELMO)

The total amount of Al applied to soil in 26 years with 50% foliar interception is:

[Al] → 1.05 x 26 x 0.5 = 13.65 kg Al/ha

$$PEC_{GW\ Al} = \frac{(Al) \times 10^6}{Water\ volume \times 10^4} = 0.91\ mg/L = 910\ \mu g/L.$$

This first tier calculation shows that the limit of 200 µg/L set by Council Directive 98/83/EC on the quality of water intended for human consumption might be exceeded following the use of aluminium ammonium sulfate.

Using the same approach and considering the total amount of sulfur applied to soil (= 4.75 kg S/ha based on a worst case assumption for the anhydrous molecular mass) and assuming that 100% is oxidised to sulfates and 100% of sulfates will leach to groundwater and the equivalence in SO₄²⁻ (1 S₈ giving 8 SO₄²⁻), the estimated PEC_{gw} for sulfates is:

[S] → 4.75 x 26 x 0.5 = 61.75 kg S/ha

[SO₄²⁻] → 61.75 x 8 x (96.1/256.6) = 185 kg SO₄²⁻/ha

$$PEC_{GW\ SO_4^{2-}} = \frac{(SO_4^{2-}) \times 10^6}{Water\ volume \times 10^4} = 12.4\ mg/L.$$

This first tier calculation shows that the limit of 250 mg/L set by Council Directive 98/83/EC on the quality of water intended for human consumption might not be exceeded following the use of aluminium ammonium sulfate.

PEC_(gw) From lysimeter / field studies

Parent	Not applicable.
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Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	aluminium ammonium sulfate is not volatile
Quantum yield of direct phototransformation	Not available
Photochemical oxidative degradation in air ‡	Not available
Volatilisation ‡	Not available
Metabolites	Not available

PEC (air)

Method of calculation	Not volatile therefore not calculated
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PEC_(a)

Maximum concentration	Not volatile therefore not calculated
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Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	<p>Soil: aluminium ions, sulfate</p> <p>Surface water: aluminium ions, ammonia/ammonium, sulfate</p> <p>Sediment: aluminium ions</p> <p>Groundwater: aluminium ions, sulfate, nitrates, nitrites</p> <p>Air: aluminium ammonium sulfate</p>
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Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available.
Ground water (indicate location and type of study)	Aluminium concentrations in surface and ground water are routinely monitored by national authorities and private water supply companies.
Air (indicate location and type of study)	<p>Not available.</p> <p>Environmental atmospheric pollution (dust etc) is routinely monitored by national authorities.</p>

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

Biodegradability assessment not applicable
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Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
<i>Indicate species.</i>	a.s.	Acute	-	
	Preparation	Acute	-	-
Mammals ‡				
rat	Aluminium ammonium sulfate	Acute	>2000mg/kg	-
rat				-
mouse				-
	Preparation	Acute	-	-
	a.s.	Long-term	-	-
Additional higher tier studies ‡				
-				

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

Not necessary.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹ (mg/L)
Laboratory tests ‡				
Fish. Data gap				
Aquatic invertebrate. Data gap				
Algae species (specify). Data gap				
Microcosm or mesocosm tests				
None available				

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

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC _i ¹ (mg/L)	distance	TER	Annex VI Trigger
Field crops; 20kg/ha ⇔ 1.192kg Al/ha.							
Powder formulation – Fruit crops; 20kg/ha ⇔ 1.192kg Al/ha.							
Liquid formulation - Field crops; 25L/ha ⇔ 0.124kg Al/ha							
Liquid formulation - Fruit crops; 25L/ha ⇔ 0.124kg Al/ha							

¹No reliable PEC_{sw} values were available in the fate section. Data gap identified.

Bioconcentration	
	Active substance
logP _{O/W}	log P _{O/W} = - 2.0 (aluminium sulfate) (literature) Expected to be very low since aluminium ammonium sulfate dodecahydrate is practically insoluble in organic solvents.
Bioconcentration factor (BCF) ¹ ‡	Not applicable does not bioaccumulate
Annex VI Trigger for the bioconcentration factor	Not applicable
Clearance time (days) (CT ₅₀)	Not applicable
(CT ₉₀)	Not applicable
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not applicable

¹only required if log P_{O/W} >3.

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

Test substance	Acute oral toxicity (LD ₅₀ µg/bee)	Acute contact toxicity (LD ₅₀ µg/bee)
a.s. ‡	No data available. Data gap	No data available. Data gap
Preparation	No data available	No data available
Field or semi-field tests	No data available	

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	Not applicable	50
a.s.	oral	Not applicable	50
Preparation	Contact	Not applicable	50
Preparation	oral	Not applicable	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR ₅₀ g/ha)
<i>Typhlodromus pyri</i> ‡	No data available. Data gap	Mortality	
<i>Aphidius rhopalosiphi</i> ‡	No data available. Data gap	Mortality	

Crop and application rate

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field	Trigger
	<i>Typhlodromus pyri</i>	Not applicable			2
	<i>Aphidius rhopalosiphi</i>	Not applicable			2

Field or semi-field tests
No data available

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

Test organism	Test substance	Time scale	End point
Earthworms			
	No data available. Data gap.		
Other soil macro-organisms			
Soil mite	No data available. Data gap.		
Collembola			
	No data available		
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡	Data gap	
Carbon mineralisation	a.s. ‡	Data gap	
Field studies			
No data available			

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
					10
Other soil macro-organisms					
Soil mite	Data gap.				
Collembola	Data gap.				

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

Preliminary screening data

Not required

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

Test type/organism	end point
Activated sludge	BOD <50% in presence of 2.8mg Al/L as aluminium sulfate.
<i>Pseudomonas sp</i>	

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

Compartment	
soil	No data available.

water	No data available.
sediment	No data available.
groundwater	No data available.

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

Active substance	RMS/peer review proposal
	Data gap.
Preparation	RMS/peer review proposal
	-

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
μg	microgram
μm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BOD	biological oxygen demand
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT ₅₀	period required for 50 percent disappearance (define method of estimation)
DT ₉₀	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC ₅₀	effective concentration (biomass)
EC ₅₀	effective concentration
ECHA	European Chemical Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER ₅₀	emergence rate/effective rate, median
ErC ₅₀	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K _{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K _{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC ₅₀	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in ground water
PEC _{sed}	predicted environmental concentration in sediment
PEC _{soil}	predicted environmental concentration in soil
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK _a	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
PTWI	provisional tolerable weekly intake
QSAR	quantitative structure-activity relationship
r ²	coefficient of determination
RAC	raw agricultural commodity
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t _{1/2}	half-life (define method of estimation)
TER	toxicity exposure ratio
TER _A	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
TWI	tolerable weekly intake
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year