



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Aluminium ammonium sulphate

SANCO/2985/08 – rev. 1

01 August 2008

FINAL

Review report for the active substance **aluminium ammonium sulphate**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
28 October 2008

in view of the inclusion of aluminium ammonium sulphate in Annex I of Directive
91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of aluminium ammonium sulphate, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 1112/2002⁽¹⁾ laying down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, and Regulation (EC) No 2229/2004⁽²⁾ have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Aluminium ammonium sulphate is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, Sphere Laboratories Ltd notified to the Commission of their wish to secure the inclusion of the active substance aluminium ammonium sulphate in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated Portugal as rapporteur Member State to carry out the assessment of aluminium ammonium sulphate on the basis of the dossiers submitted by the notifier. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required, as well as for other parties with regard to further technical and scientific information was 30 June 2005.

¹ OJ No L 168, 27.06.2002, p.14.

² OJ No L 379, 24.12.2004, p.13. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

Sphere Laboratories Ltd submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore, Sphere Laboratories Ltd was considered to be the sole data submitter.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, Portugal submitted in June 2008 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of aluminium ammonium sulphate in Annex I to the Directive.

In accordance with the provisions of Article 24 of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Sphere Laboratories Ltd being the sole data submitter, on 7 August 2008 by making it available.

On the basis of the provisions of Article 24a of Regulation 2229/2004 as last amended by Regulation (EC) 1095/2007 the Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from Member States.

In accordance with the provisions of Article 24b and Article 25 (1) a of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the Commission referred on 28 October 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 28 October 2008.

The present review report contains the conclusions of the final examination by the Standing Committee.

2. Purposes of this review report

This review report, including the background document appendices thereto, has been developed in support of the Directive **2008/127/EC**³ concerning the inclusion of aluminium ammonium sulphate in Annex I to Directive 91/414/EEC. The Commission shall request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest. When the Member States decide on individual plant protection products containing aluminium ammonium sulphate they shall take into account this review report in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI. However, when the EFSA has delivered its view on the draft review report, the Commission shall revise it.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

³ Commission Directive 2008/127/EC (OJ L 344, 20.12.2008, p. 89)

In accordance with the provisions of Article 26 of Regulation (EC) No 2229/2004, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the draft assessment report, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 24a of Regulation 2229/2004 is that there are clear indications that it may be expected that aluminium ammonium sulphate does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007.

These indications are however subject to compliance with the particular requirements in sections 4 and 5 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each aluminium ammonium sulphate containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these indications were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The review has concluded that there are acceptable exposure scenarios for consumers, operators, workers and bystanders which require however to be confirmed for each plant protection products in accordance with the relevant sections of the above-mentioned uniform principles.

It has also been concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and biological properties

The main properties of aluminium ammonium sulphate are given in Appendix I.

It has been established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in volume 1, page 85 of this report. The EFSA will deliver its view on this review report by 31 December 2010 at the latest.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing aluminium ammonium sulphate

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn.

7. List of studies to be generated

Further studies which were at this stage considered necessary were identified in the level 4 of the Draft Assessment Report.

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

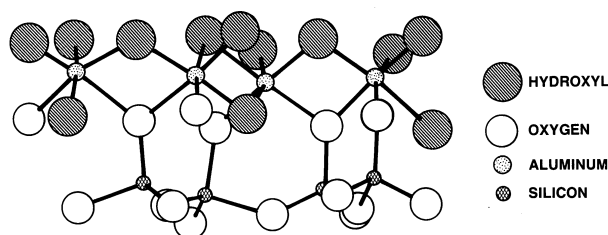
The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for aluminium ammonium sulphate in Annex I of the Directive.

APPENDIX I

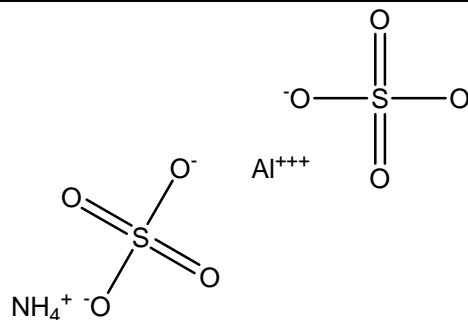
Identity; physical and chemical properties

ALUMINIUM AMMONIUM SULPHATE

Common name (ISO)	Aluminium ammonium sulphate
Chemical name (IUPAC)	Aluminium ammonium sulphate
Chemical name (CA)	Aluminium ammonium sulphate
CIPAC No	<i>-not allocated</i>
CAS No	7784-26-1
EEC No	2320553
FAO SPECIFICATION	<i>-not allocated</i>
Minimum purity	960 g/kg
Molecular formula	$(\text{NH}_4)_2\text{Al}_2(\text{SO}_4)_4 \cdot 24\text{H}_2\text{O}$
Molecular mass	906 g/mol



Structural formula



APPENDIX II

List of uses supported by available data

ALUMINIUM AMMONIUM SULPHATE

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between appl. (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Curb Crop Spray Powder MAFF 02480															
Seed dressing (various crops)	Northern and Southern Europe	Curb Crop Spray Powder	F	Birds (various seed eating species)	SP	880 g/kg	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 rate 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

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between appl. (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Row crops	Northern and Southern Europe	Curb Crop Spray Powder	F	Birds (various species)	SP	880 g/kg	Applied by hand held sprayers(amateur) 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 Crop Spray Powder	F	Birds (various species)	SP	880 g/kg	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.
Grassland	Northern and Southern Europe	Curb Crop Spray Powder	F	Birds (various species)	SP	880 g/kg	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 Crop Spray Powder	F	Birds (various species)	SP	880 g/kg	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															

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between appl. (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Grassland and Amenity turf.	Northern and Southern Europe	Curb Liquid	F	Moles (dogs)	SL	83 g/L	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	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 Profession. 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.

* For uses where the column "Remarks" is marked in grey further consideration is necessary.
Uses should be crossed out when the notifier no longer supports this use(s).

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
 (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
 (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

- (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. fluoroxypr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialicarb-isopropyl).**
 (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 (k) Indicate the minimum and maximum number of application possible under practical conditions of use
 (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

<p>(f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(m) PHI - minimum pre-harvest interval</p>
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