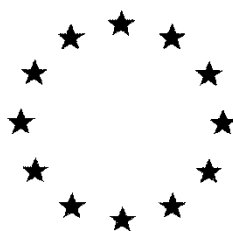


European Commission

**Second Programme for the Renewal of the Inclusion of Active Substances
in Annex I of Council Directive 91/414/EEC**



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) N° 1141/2010**

Amitrole

Volume 3 – Annex B.3

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January 2013

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B.3. DATA ON APPLICATION AND FURTHER INFORMATION

B.3.1. DATA ON APPLICATION RELEVANT TO ACTIVE SUBSTANCE

B.3.1.1. Function

Herbicide.

B.3.1.2. Effects on harmful organisms

B.3.1.2.1. Nature of the effects on harmful organisms

Non selective weed control.

B.3.1.2.2. Whether or not translocated in plants and if translocated whether such translocation is apoplastic, symplastic or both

Amitrole is systemic. It is rapidly absorbed by the leaves (mainly), but can be absorbed to a lesser extent by the roots. Once in the plants, it is translocated by both the xylem (apoplastic) and the phloem (symplastic). Weeds once treated with amitrole appear as whitening.

B.3.1.3. Field of use envisaged

Both agricultural (orchards, olive and vineyard) and non-agricultural (railways, roadsides, etc.)

B.3.1.4. Harmful organisms controlled and crops or products protected or treated

Amitrole is intended to control annual and perennial monocotyledonous and dicotyledonous weeds in orchards, olives, vineyards and non-cropped areas.

B.3.1.5. Mode of action

Amitrole belongs to the HRAC herbicide group F3. Amitrole mechanism of action inhibits carotenoid synthesis. At high dose, the synthesis of riboflavin and histidine is also indirectly inhibited. The target site is unknown.

B.3.1.6. Information on the occurrence or possible of the development of resistance and appropriate management strategies

Amitrole belongs to the HRAC herbicide group F3 (triazoles, ureas, isoxazolidiones) and to the triazole herbicides. Nowadays, cases of resistance to HRAC herbicide group F3 were identified for 5 species in the world including 3 species in Europe (Belgium). 4 of these species have developed cases of resistance to amitrole, 3 were in Europe (Belgium) in the 80s.

Due to the low number of resistance cases, the risk of development of resistance is considered as low. To decrease the risk, appropriate management strategies would be to recommend the use in sequence with herbicides with other modes of action or use in mixture with other herbicides.

B.3.2. FURTHER INFORMATION ON THE ACTIVE SUBSTANCE

B.3.2.1. Procedures for destruction or decontamination

B.3.2.1.1. Pyrolytic behavior of the active substance under controlled conditions at 800°C and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis

Amitrole does not contain any halogens.

B.3.2.1.2. Detailed instruction for safe disposal

Material containing Amitrole should be disposed of in accordance with existing local, state, and national official regulations concerning hazardous waste disposal (e.g. suitable incineration plants).

B.3.2.1.3. Methods other than controlled incineration for disposal of the active substance, contaminated packaging and contaminated materials

No other methods are currently available or known to the applicant.

B.3.2.2. Procedures for the decontamination of water in case of an accident

No specific measures available. Entry of Amitrole contaminated waters to drains and surface aquifer should be prevented.

In cases where larger amounts of the product have become unusable it should be checked in the first place (eventually with the manufacturer/supplier) whether utilization is still possible. Small amounts of the product and uncleaned empty packaging should be packed and sealed labeled and transferred to a suitable incinerator in an authorized special waste incinerator plant in accordance with the national/local regulations.

B.3.2.3. Recommended methods and precautions concerning handling, storage, transport of fire**B.3.3. DATA ON APPLICATION RELEVANT TO THE PLANT PROTECTION PRODUCT****B.3.3.1. Field of use**

CA2735 will be used for the weed control for both agricultural (orchards, olive and vineyard) and non-agricultural (railways, roadsides, etc.).

B.3.3.2. Effects on harmful organisms, expected mode of action

See B.3.1.2 and B.3.1.5 above.

B.3.3.3. Details of intended uses

Crop and/or situation (a)	Member State	Product Name	F G 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 a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/ha)	Water l/ha min max	Kg a.i./ha min max (*) (g/ha)		
Orchards (citrus fruits, pome and stone fruits, assorted fruits-edible or inedible peel, tree nuts)	All MS	CA 2735	F	Non selective control of annual and perennial monocotyledones and dicotyledones weeds (growth stage 40-60)	Soluble concentrate (SL)	229 g:L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	94-75	1 (or several splitted applications)	2-3 months	0.24-1	300 to 500	1.2-3	35	CA2735 is applied either once per year at 2977 gai/ha (ie 13 L product/ha) or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.
Grapes (table and vine)	All MS	CA 2735	F	Non selective control of annual and perennial monocotyledones and dicotyledones weeds (growth stage 40-60)	Soluble concentrate (SL)	229 g:L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	92-79	1 (or several splitted applications)	2-3 months	0.24-1	300 to 500	1.2-3	42	CA2735 is applied either once per year at 2977 gai/ha (ie 13 L product/ha) or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.
Olives	South EU MS	CA 2735	F	Non selective control of annual and perennial monocotyledones and dicotyledones weeds (growth stage 40-60)	Soluble concentrate (SL)	229 g:L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	Spring and autumn	1-2 (or several splitted applications)	2-3 months	0.18-0.5	300 to 500	0.9-1.375	35	CA2735 is applied either once or twice per year at 1375 gai/ha (ie 6 L product/ha) or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.
Non crop uses (impermeable and permeable surfaces: road, railways)	All MS	CA 2735	F	Non selective control of annual and perennial monocotyledones and dicotyledones weeds (growth stage 40-60)	Soluble concentrate (SL)	229 g:L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	Not applicable	1 (or several splitted applications)	2-3 months	0.36-1	300 to 500	1.8-3	-	CA2735 is applied either once per year at 2977 gai/ha (ie 13 L product/ha) or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.

B.3. Data on application and further information

- * For uses where the column „Remarks“ in 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 classification (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 N° 2, 1989
- (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
- (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. fluoroxypryr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-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 125 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

B.3.3.4. Application rate

Please refer to B.3.3.3. (Details of intended uses) of this document.

B.3.3.5. Concentration of active substance in material used

Please refer to B.3.3.3. (Details of intended uses) of this document.

B.3.3.6. Application method

Please refer to B.3.3.3. (Details of intended uses) of this document.

B.3.3.7. Number and timing of applications and the protection period where relevant***B.3.3.7.1. Maximum number of applications and their timing***

Please refer to B.3.3.3. (Details of intended uses) of this document.

B.3.3.7.2. For each application, growth stages of the crop or plants to be protected

Please refer to B.3.3.3. (Details of intended uses) of this document.

B.3.3.7.3. For each application, development stage of the harmful organisms concerned

Weeds should be treated in the vegetative phase.

B.3.3.7.4. Duration of protection afforded by each application

The long-lasting action of amitrole, due to the slow destruction of weeds preventing any new emergence of weeds, has a duration of about 2-3 months.

B.3.3.7.5. Duration of protection afforded by the maximum number of applications

See above.

B.3.3.8. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops***B.3.3.8.1. Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops***

No waiting period between application and planting of rotational or succeeding crops is required. CA2735 is used on perennial crops (orchards and vineyards) and on non-cropped areas.

B.3.3.8.2. Limitations on choice of succeeding crops

See above.

B.3.3.8.3. Description of damage to rotational crops

See above.

B.3.4. FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCTS

B.3.4.1. Packaging and compatibility with the preparation***B.3.4.1.1. Description of the packaging and materials used***

Primary packaging	
Type:	Jerrican
Capacity:	5 L
Material:	High Density Polyethylene (HDPE).
Size (diameter x height):	L=193 mm l=142 mm H=305 mm
Inner layer	none
Product Volume (Brimful capacity)	5.950±100mL
Type of closure and seals	HDPE screw cap with tamper-proof collar/ Triple sealed joint (PE).
Size of opening	Large opening 63 mm ASTM.
Weight	200±5g

Primary packaging	
Type:	Jerrican
Capacity:	20 L
Material:	High Density Polyethylene (HDPE).
Size (diameter x height):	L= 286 ± 4 mm l = 249± 4 mm H=405 ± 5 mm
Inner layer	HDPE
Product Volume (Brimful capacity)	22.3L
Type of closure and seals	HDPE screw cap with tamper-proof collar/ Triple sealed joint (PE).
Size of opening	63 mm
Weight	980g

Primary packaging	
Type:	Jerrican
Capacity:	5 L
Material:	PET
Size:	Height: 319.50 mm Diameter: 174 mm
Wall Thickness (Minimum)	0.25 mm
Product Volume (Brimful)	5625 +/-50 mL
Type of closure and seals	Inviolable KS 63
Size of opening	59.7 mm
Weight	135±3g
Total height neck	41 mm
Ext. diameter thread	63.4 mm
Inner diameter neck	59.7 mm

B.3.4.1.2. Suitability of the packaging and closures

The above-mentioned packaging and closures are suitable for containing, handling and transporting CA2735. Please refer to the UN registration document.

B.3.4.1.3. Resistance of the packaging material to its contents

The integrity of the test containers versus the influence of the formulation was evaluated during the accelerated storage stability study which was performed in original commercial container for 14 days at 54°C, which correspond to the material intended for trading.

B.3.4.2. Procedures for cleaning application equipment

B.3.4.2.1. Procedures for cleaning application equipment and protective clothing

Application equipment: clean with water or, if necessary, with water and detergent. Wash out the container thoroughly and empty the washings into the spray-tank. The container should be punctured and disposed of safely; it should not be re-used for any other purpose.

After use, tanks and spray equipment should be thoroughly washed through with detergent and clean water. Take care not to contaminate surface waters with washings.

Protective clothing: Wash with water and detergent.

Contaminated water should be disposed off in agreement with local regulations.

B.3.4.2.2. Effectiveness of the cleaning procedures

Two studies were performed for checking the effectiveness of cleaning procedures, measuring the potential residues of Amitrole or ammonium thiocyanate in the tanks after washing with a commercial tank cleaner of with water. Both studies are summarized below.

Comb (2009) investigated the effectiveness of the cleaning procedure on the elimination of amitrole residues in spray tanks.

This study was performed to determine the efficiency of the normal procedures used for cleaning spray tanks (one polypropylene, one stainless steel) after use with CA2210.

The test was conducted in accordance with accepted principles in order to meet the requirements of European Council Directive 91/414/EEC (Annex III) as amended by European Commission Directive 94/37/EC.

The test substance was added to the tanks at the maximum recommended application level (equivalent to 16 L of formulation/100 L of water). The contents of the tanks were discarded and each tank was then subjected to two separate five stage cleaning procedures: one with a commercial sprayer-cleaner in the procedure and one using water only throughout the procedure.

The amount of CA2210 present was negligible by the end of both of the prescribed cleaning procedures.

It was therefore concluded that the washing procedures used in this study were adequate for the cleaning of polypropylene and stainless steel spray tanks.

Comb (2010) also checked the effectiveness of the cleaning procedure on the elimination of ammonium thiocyanate residues in spray tanks.

A study had been performed at Huntingdon Life Sciences to determine the efficiency of the normal procedures used for cleaning spray tanks after use (Huntingdon Life Sciences Study No. NUF0455). Portions of the wash samples from the original study had been stored frozen and the purpose of this study was to analyse the samples for the presence of the compound, ammonium thiocyanate.

The test was conducted in accordance with accepted principles in order to meet the requirements of European Council Directive 91/414/EEC (Annex III) as amended by European Commission Directive 94/37/EC.

The original study was performed to determine the efficiency of the normal procedures used for cleaning spray tanks (one polypropylene, one stainless steel) after use with CA2210. The test substance was added to the tanks at the maximum recommended application level (equivalent to 16 L of formulation/100 L of water). The contents of the tanks were discarded and each tank was then subjected to two separate five stage cleaning procedures: one with a commercial sprayer-cleaner in the procedure and one using water only throughout the procedure.

The amount of ammonium thiocyanate present was negligible by the end of both of the prescribed cleaning procedures.

It was therefore concluded that the washing procedures used in this study were adequate for the cleaning of the component from the polypropylene and stainless steel spray tanks.

B.3.4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

B.3.4.3.1. Pre-harvest interval (in days) for each relevant crop

Given the residue data base, a Pre Harvest Interval of 42 and 35 days in vines and orchards, respectively, will allow not to exceed the MRL set up in the regulation 149/2008/EC.

B.3.4.3.2. Re-entry period (in days) for livestock, to areas to be grazed

A re-entry period for livestock is not applicable because neither vineyards nor orchards (including olives) are used for grazing.

B.3.4.3.3. Re-entry period (in hours or days) for man to crops, buildings or spaces treated

As the estimated exposure for workers is far lower than the AOEL, no risk to workers is anticipated and a re-entry period is therefore not needed.

B.3.4.3.4. Withholding period (in days) for animal feedingstuffs

There is no need for fixing a withholding period for animal feeding stuff. Apples, grapes and olives are not given to cattle. In addition, no quantifiable residue was found at harvest.

B.3.4.3.5. Waiting period (in days) between application and handling treated products

As the estimated exposure for workers is far lower than the AOEL, no risk to workers is anticipated and a re-entry period is therefore not needed.

B.3.4.3.6. Waiting period (in days) between last application and sowing or planting succeeding crops

There is no need for fixing a waiting period between last application and sowing or planting, amitrole will be used on perennial crops or on non-cropped areas.

B.3.4.3.7. Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

No specific agricultural, plant health and/or environmental conditions have to be respected except the manufacturer recommendations.

B.3.4.4. Recommended methods and precautions concerning handling, storage, transport or fire of the plant protection product

B.3.4.4.1. Emergency measures in case of an accident

Please refer to the material safety data sheet of CA2735.

First aid for contamination by the product:

- o If the incident involves workers and operatives, wear protective clothes and PVC gloves, and remove any affected personnel from the work-zone. Move to a well-ventilated place and protect from hypothermia. Do not administer anything orally and do not induce vomiting. Seek medical attention or contact the appropriate toxic substances treatment centre. In case of ingestion, seek immediate medical

attention and show container or label. In case of contact with eyes, rinse immediately with plenty of water for approximately 15 minutes. If redness or irritation persists, consult an eye specialist.

- o Medical note: no known antidote, treat symptomatically with supportive therapy.
- o Absorb as much spilled liquid on to a suitable inert substances such as earth, sand, sawdust, and peat.
- o Sweep up and place in a labelled container for disposal by a licensed operator. Small quantities may be buried in an approved area where there is no risk of contamination of ground or surface water, and large quantities may be disposed of by controlled high temperature incineration with effluent scrubbing. Observe local legislation at all times.

Packaging:

- o Empty the contents into the spray-tank, rinse and puncture the container so that it cannot be re-used. Eliminate empty cartons and containers in compliance with local and national legislation.
- o If the packaging is damaged, but the contents are not leaking, return to the agent/distributor for disposal. If the contents are leaking from the containers, adsorb onto inert materials, and place everything into an approved container, seal, label and send to a licensed contractor for disposal.

B.3.4.4.2. First aid measures

First aid:	Remove victim from area of exposure. Wash away remainder with plenty of water.
Inhalation:	Remove victim to fresh air. If breathing is difficult give artificial respiration. Get medical attention.
Ingestion:	DO NOT INDUCE VOMITING. Wash out mouth with plenty of water. Get medical attention. Never give anything by mouth to an unconscious person.
Skin contact:	Wash thoroughly with plenty of water. Remove contaminated or soaked clothes immediately. In case of irritations (reddening etc.) consult physician. Inappropriate cleaning agents: solvents, diluents.
Eye contact:	Remove contact lenses. Rinse thoroughly with plenty of water for 15 minutes. Contact physician if necessary.
Note to physician:	There is no specific antidote. Treat symptomatically and give supportive therapy.
Protection of first-aiders:	Use appropriate protection

B.3.4.4.3. Procedures for safe disposal of the plant protection product and its packaging

Environmental precautions:	Do not discharge into the environment.
After spillage and/or leakage:	Absorb in sand or other inert material. Dispose of this material and its container at hazardous or special waste collection point.
European waste codes:	
	02 01 08 agrochemical waste containing dangerous substances
	07 04 01 Aqueous washing liquids and mother liquors
	20 01 19 Pesticides

Recommendation: Follow official regulations for suitable combustor and for deposit on suitable landfill.

After triple rinsing the empty container, consult with the agent/distributor to see if they will take back empty packaging. If not, make the packaging unusable by puncturing and dispose of in normal industrial or household refuse systems. Empty cartons and combustible packing materials can be burnt if local regulations permit, or recycled.

B.3.4.4.4. Evaluation of further information on the active substance and plant protection product

B.3.5. REFERENCES RELIED ON**B.3.5.1. References relevant to the active substance****B.3.5.2. References relevant to the plant protection product**

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
IIIA 4.2.2/01	Comb, A.	2009	Determination of the efficiency of the normal procedures used for cleaning spray tanks after use of CA 2210. HLS report n° NUF0455. GLP Not published	Y	NUFAR M
IIIA 4.2.2/02	Comb, A.	2010	Analysis of tank cleaning samples for presence of ammonium thiocyanate. HLS report n° KPN0058 GLP Not published	Y	NUFAR M