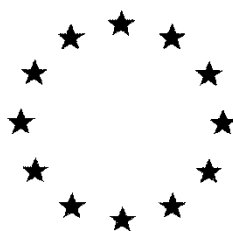


European Commission

**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.4

Rapporteur Member State: France
Co-Rapporteur Member State: Hungary

January 2013

Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt
Direction Générale de l'Alimentation
251, rue de Vaugirard
75732 PARIS Cedex 15
France

Table of contents

B.4. PROPOSALS FOR THE CLASSIFICATION AND LABELLING.....	3
B.4.1. PROPOSALS FOR THE CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE	3
B.4.1.1. Human health effect	3
B.4.1.2. Effects on environment.....	3
B.4.2. PROPOSALS FOR THE CLASIFICATION AND LABELLING OF THE PREPARATION (CA2735)	4
B.4.2.1. Human health effect	4
B.4.2.2. Effects on environment.....	5
B.4.3. REFERENCES RELIED ON.....	6

B.4. PROPOSALS FOR THE CLASSIFICATION AND LABELLING

B.4.1. PROPOSALS FOR THE CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE

B.4.1.1. Human health effect

Under Council Directive 67/548/EEC

B.4.1.1.1. Hazard symbol



B.4.1.1.2. Indication of danger

Xn Repr Cat 3

B.4.1.1.3. Risk phases

R63 R48/22

B.4.1.1.4. Safety phrases

S36/37

Under Regulation (EC) No 1272/2008



Warning

STOT RE 2 (H373), Repr. 2 (H361d)

B.4.1.1.5. Justification

Based on thyroid effects observed in several species, amitrole is classified as Xn, R48/22 (Harmful: danger of serious damage to health by prolonged exposure if swallowed) and H373 (May cause damage to thyroid through prolonged or repeated exposure, STOT-RE Cat. 2) in the regulation (EC) n°1272/2008.

Based on effects on the development observed in rabbits, the classification of amitrole as reprotoxic category 3 (Xn, Repr. Cat. 3 (R63)) is needed. Amitrole is classified reprotoxic category 2 according to the criteria of the regulation (EC) n°1272/2008 (H361d: Suspected of damaging the unborn child).

B.4.1.2. Effects on environment

B.4.1.2.1. Hazard symbol

According to directive 67/548	According to regulation 1272/2008
	

B.4.1.2.2. Indication of danger

According to directive 67/548	According to regulation 1272/2008
Dangerous for the environment (N)	Warning, GHS09

B.4.1.2.3. Risk phases

According to directive 67/548	According to regulation 1272/2008
R51/53, Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	Aquatic chronic 2, H411: Toxic to aquatic life with long lasting effects

B.4.1.2.4. Safety phrases

According to directive 67/548	According to regulation 1272/2008
S60, S61	P273, P391, P501

B.4.1.2.5. Justification

Aquatic toxicity data on the active substance are available for fish, daphnia, algae and aquatic plant.

Given that the acute toxicity value for daphnia (*daphnia magna*) and aquatic plant (*Lemna gibba*) is between 1 to 10 mg a.s./L, amitrole should carry the "N" symbol and "Dangerous to the environment" classification, along with the following risk phrase:

- R51/53, Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment..
- Aquatic chronic 2, H411: Toxic to aquatic life with long lasting effects (P273-P391-P501)

B.4.2. PROPOSALS FOR THE CLASIFICATION AND LABELLING OF THE PREPARATION (CA2735)**B.4.2.1. Human health effect**

Under Council Directive 99/45/EC

B.4.2.1.1. Hazard symbol**B.4.2.1.2. Indication of danger**

in Repr Cat 3

B.4.2.1.3. Risk phases

R63 R48/22 R36

B.4.2.1.4. Safety phrases

S36/37

Under Regulation (EC) No 1272/2008)



Warning

STOT RE 2 (H373), Repr. 2 (H361d), Eye Irrit. 2 (H319)

B.4.2.1.5. Justification

Based on the content of active substance in the preparation CA2735, classifications as Xn, Repr Cat 3 R63 (Repr. 2 H361d) and Xn, R48/22 (STOT RE2 H373) is required for the preparation. Moreover, based on the results of an eye irritation study performed on a preparation of similar composition, CA2735 needs to be classified as Xi, R36 (Eye Irrit. 2 H319).

B.4.2.2. Effects on environment**B.4.2.2.1. Hazard symbol**

According to directive 67/548	According to regulation 1272/2008
No pictogram	No pictogram

B.4.2.2.2. Indication of danger

According to directive 67/548	According to regulation 1272/2008
No signal word	No signal word

B.4.2.2.3. Risk phases

According to directive 67/548	According to regulation 1272/2008
R52/53 Harmful to aquatic life, may cause long-term adverse effects in the aquatic environment.	Aquatic chronic 3, H412: Harmful to aquatic life with long lasting effects

B.4.2.2.4. Safety phrases

According to directive 67/548	According to regulation 1272/2008
S60	P273, P501

B.4.2.2.5. Justification

Aquatic toxicity data on the formulation are available for fish, daphnia and algae.

Given that the acute toxicity value for daphnia (*daphnia magna*) is between 10 to 100 mg a.s./L, the formulation should carry “no symbol” and “no signal word” classification, along with the following risk phrase:

- R52/53, Harmful to aquatic life, may cause long-term adverse effects in the aquatic environment.
- Aquatic chronic 3, H412: Harmful to aquatic life with long lasting effects (P273- P501)

B.4.3. REFERENCES RELIED ON

Effects on environment

Refer to B.9.2 of the Ecotoxicology section.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.