ANNEX B

Metconazole

B.4 Proposals for classification and labelling

B.4.1 Proposals for the classification and labelling of the active substance (Annex IIA 10)

Table B.4.1-1 : Classification and labelling of metconazole made by the Rapporteur

Classification :	Xn; R22 : Harmful if swallowed Xn; R63 : Possible risk of harm to the unborn child (Dev. Cat 3) N; R51 : Toxic to aquatic organisms R53 : May cause long-term effects in the aquatic environment
Labelling :	
Hazard symbols :	Xn , N
Indications of danger :	Harmful and Dangerous for the Environment
Risk phrases :	R22-63-51/53
Safety phrases :	S36/37-46-60-61

Table B.4.1-2 : Justification for the proposal made by the Rapporteur concerning the classification and labelling of Metconazole

Proposed classification	**Justification**
Xn : R22	Based upon the acute oral toxicity in both the rat (LD_{50}=595-727) and the mouse (LD_{50}=410-718)
Xn : R63	Based upon the increased incidence of hydrocephaly in the rabbit developmental study at 10 mg/kg bw/d, in the absence of maternal toxicity
N: R51/53	Based upon the toxicity for *Salmo gairdneri* ($LC_{50, 72h}$ = 2.1 mg a.s./L), *Daphnia magna* (EC_{50} = 4.2 mg a.s./l), *Selenastrum capricornutum* (E_bC_{50} = 1.7 mg a.s./L, E_rC_{50} = 2.2 mg a.s./L). The active substance is not readily biodegradable (2 - 5% Theoretical CO_2 being evolved in 28 days).

B.4.2 Proposals for the classification and labelling of CARAMBA 60 SL (Annex IIIA 12.3)

Table B.4.2-1 : Classification and labelling of formulation CARAMBA 60 SL made by the Rapporteur

Classification :	R10 : Flammable Xi ; R36 : Irritating to eyes Xi ; R37 : Irritating to respiratory system Xi ; R38 : Irritating to skin R43 : May cause sensitisation by skin contact Xn ; R63 : Possible risk of harm to the unborn child (Dev. Cat 3) Xn ; R65 : Harmful: may cause lung damage if swallowed N ; R50 : Toxic to aquatic organisms R53 : May cause long-term effects in the aquatic environment
Labelling :	
Hazard symbols :	Xn , N
Indications of danger :	Flammable, Irritant, Sensitizing, Harmful and Dangerous for the Environment
Risk phrases :	R10-36/37/38-43-63-65-50/53
Safety phrases :	S2-24/25-36/37-60-61-62

Table B.4.2-2 : Justification for the proposal made by the Rapporteur concerning the classification and labelling of CARAMBA 60 SL

Proposed classification	**Justification**
R10	Based upon the flash point determination = 43°C
Xi ; R36	Based upon the irreversible corneal effects on d21 in the eye irritation study
Xi ; R37	Based upon signs of irritation of the upper airways in the acute inhalation study, and carry-over of the labelling of a solvent, present at 26% w:w (>20%)
Xi ; R38	Based upon the observed erythema in the skin irritation study
R43	Based upon the positive skin reactions in the guinea pig maximisation assay
Xn ; R63	Carry-over of the labelling of the a.s. (teratogenic effects in rabbit developmental study), present at 7% w:w (>5%).
Xn ; R65	Carry-over of the labelling of the aromatic solvent (aspiration hazard), present at 22% w:w (>10%) (pending physico-chemical tests)
N ; R50/53	Given the toxicity for *Oncorhynchus mykiss* (LC_{50} = 14.83 mg/L) , *Daphnia magna* (EC_{50} = 0.365 mg/L), *Selenastrum capricornutum* (E_bC_{50} = 5.13 mg/L, E_rC_{50} = 8.38 mg/L). The active substance is not readily biodegradable.

B.4.3 References relied on

(i) European Directive 67/548/EEC of 27 june 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
Annex II (Symbols and Indications of danger), Annex III (R-phrases), Annex IV (S-phrases) and Annex VI (General criteria)

(ii) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
Annex I (Evaluation methods Physico-chemistry), Annex II (Evaluation methods Human Health), Annex III (Evaluation methods Environmental Health), Annex V (Particular dispositions)