Section A9 Classification and labelling

Annex Point IIA9

Official use only

1 CLASSIFICATION PROPOSAL

1.1	**Classification proposal**	Hazard symbol(s):	T+; N	
		Indication of danger:	Very toxic, dangerous to the (aquatic) environment	
		Risk phrase(s):	R 26/27/28/50	X
		Safety phrases:	S 2/13/20/21/27/28/36/37/38/39/45/61	
1.2	**Justification of the proposals**	R 26/27/28	These phrases derive from the result of the studies on acute toxicity in rats, and dermal irritation in rabbits.	

Remarks:

The studies on inhalation toxicity resulted in 4h-LC_{50} values in the ranges of 0.12–0.42 mg/l (A6.1.3/01) and 0.16–1.4 mg/l (A6.1.3/02, 03), respectively, resulting in a classification as very toxic (T+) and R phrase R26.

The rat acute dermal study resulted in a LC_{50} value of < 3mg/kg body weight, resulting in a classification as very toxic (T+) and R phrase R27.

The oral rat acute study resulted in an LD_{50} of 0.25 mg/kg body weight, resulting in a classification as very toxic (T+) and R phrase R28.

R50 is derived from the results of studies on aquatic toxicity (fish and daphnia LC_{50}/EC_{50} < 1 mg/l)

2 LABELLING PROPOSAL

2.1	**Labelling proposal**	Hazard symbol(s):	T+; N	
		Indication of danger:	Very toxic by inhalation, in contact with skin and if swallowed, dangerous to the (aquatic) environment	
		Risk phrase(s):	R 26/27/28/50	X
		Safety phrases:	S 2/13/20/21/27/28/36/37/38/39/45/61	

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	2 October 2005
Conclusion	Based on an overall evaluation of the dossier the following classification is proposed: Risk phrases: R 26/27/28, 48/23/24/25, 50/53, 61 Safety phrases: S 53-45-60-61
Reliability	Not applicable.
Acceptability	Not applicable.
Remarks	It should be noted that Flocoumafen accumulates in body tissues. This might indicate a concern for offspring exposed to flocoumafen through breast milk. Classification of the substance with R64 might be considered. However, there is no indication that Flocoumafen can be preferentially excreted via breast milk. There are no toxicokinetic data that suggest any relevant levels of Flocoumafen in breast milk, cumulation of dose would lead to intensive haemorrhaging with subsequent lethality of maternal animals prior to any effect being exerted on the offspring in multi-generation studies. Furthermore, there is no evidence in humans indicating a risk to babies during the lactation period. As a consequence classification with R64 is not proposed.

	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	