Section A6.2	Metabolism studies in mammals.		
Annex Point IIA6.2	6.2 Dermal absorption		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only	
Other existing data [X]	Technically not feasible [] Scientifically unjustified []		
Limited exposure []	Other justification []		
Detailed justification:	Studies on the dermal toxicity of dichlofluanid show that the toxicity via the dermal route is low compared to the oral toxicity of dichlofluanid.	X	
	The dermal absorption of dichlofluanid has been studied using a solvent-based formulation containing approx. 0.6 % dichlofluanid. This formulation represents a guide recipe for dichlofluanid-containing wood preservatives. The respective study (Roper & Sherratt, 2004) is therefore summarised and discussed in the product-related parts of this dossier, i.e., Documents III-B and II-B.	X	
	An additional study using the active substance in an organic solvent was not done, because due to the low concentration of the active substance in the guide recipe and the type of formulation used therein it can be assumed that the percentage of dermal penetration obtained from the above mentioned study represents a reasonable worst case value, which can be used for risk assessment purposes.		
Undertaking of intended data submission []	-		
	Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
	EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	16/08/05		
Evaluation of applicant's justification	The dermal absorption of dichlofluanid has been studied using a mineral oil formulation containing approx. 0.6 % dichlofluanid. This is not the exact formulation put forward for risk characterisation, but is considered provide relevant information.		
	Single and repeated-dose dermal studies conducted with dichlofluar provided no evidence that dichlofluanid can cross the skin. It is also that dichlofluanid has limited water solubility. Overall; technical dichlofluanid is predicted to have limited dermal penetration potent	o noted	
Conclusion			
Remarks	The UK CA agrees with the applicant, that a dermal penetration study, conducted with the a.s. is unnecessary, and the waiving argument is acceptable.		

BAYER CHEMICALS AG DICTION UNITED TO 100/2004	BAYER CHEMICALS AG	Dichlofluanid	06/2004
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Section A6.2	Metabolism studies in mammals.
Annex Point IIA6.2	6.2 Dermal absorption
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	Give date of comments submitted
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	