

<b>Section A6</b>		<b>Studies on other routes of administration</b>	
<b>Annex Point A6.11</b>			
<b>JUSTIFICATION FOR NON-SUBMISSION OF DATA</b>			Official use only
<b>Other existing data</b> [ ]	<b>Technically not feasible</b> [ ]	<b>Scientifically unjustified</b> [x]	
<b>Limited exposure</b> [ ]	<b>Other justification</b> [ ]		
<b>Detailed justification:</b>	<p>According to the 'Technical Guidance Document on data requirements' this is an additional data requirement and under IIIA 6.11 the following is cited:</p> <p>“· For existing substances, data (if already existing) by alternative routes should be submitted by the applicant.</p> <p>· New studies will be required only in exceptional cases.</p> <p>· Studies on parenteral routes may supplement the information received from toxicokinetic studies and give valuable information e.g. in cases when the gastrointestinal absorption of the chemical in question is poor.</p> <p>· E.g. acute toxicity studies on intraperitoneal, intravenous subcutaneous and intramuscular routes, where conducted, should be submitted.</p> <p>· A scientific judgement is required to decide whether any supplementary studies are needed (see Chapter 1.2, point 4).”</p> <p>The dossier contains studies on respiratory, dermal, and oral exposure.</p>		
<b>Undertaking of intended data submission</b> [ ]	Not applicable		
<b>Evaluation by Competent Authorities</b>			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>			
<b>Date</b>	2008/07/09		
<b>Evaluation of applicant's justification</b>	Applicant's version is acceptable.		
<b>Conclusion</b>	Applicant's version is acceptable.		
<b>Remarks</b>	None		
<b>COMMENTS FROM OTHER MEMBER STATE</b> <i>(specify)</i>			
<b>Date</b>	<i>Give date of comments submitted</i>		
<b>Evaluation of applicant's justification</b>	<i>Discuss if deviating from view of rapporteur member state</i>		
<b>Conclusion</b>	<i>Discuss if deviating from view of rapporteur member state</i>		
<b>Remarks</b>			

