Section A4.2 **Annex Point IIA, IV.4.2**	**Analytical Methods for Detection and Identification** *d) Residues in Animal and human body fluids and tissues*	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	An analytical method for animal tissues (fish) has been submitted (Hellstern, 2007; Annex Point IIA4.2). A method for human body fluids and tissues is not deemed necessary, since OIT is instable in body fluids and tissues. This was shown for the analytical method in fish tissue (Hellstern, 2007). During fortification experiments, fish tissue needed to be sterilised in order to inhibit the very rapid dissipation of OIT in non-sterile tissue. Similar observations had already been made in the ADME study (Wenker, 2007; Annex Point IIA6.2/01). OIT after oral dosing to rats was rapidly and extensively converted to a large number of metabolites. No parent compound was identified. From its chemical reactivity towards nucleophiles (see DocIII-A 5) it is not expected that parent compound could be detected in animal or human body fluids or tissues after oral, dermal or inhalation exposure (see DocII-A3.1). Besides, oral exposure to OIT can be excluded during manufacture and use of OIT. OIT is corrosive and does not cause systemically adverse effects (see DocII-A). In summary, OIT will not be present in human body fluids and tissues and therefore an analytical method for those matrices is not deemed meaningful or necessary.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*03/11/2009*	
Evaluation of applicant's justification	Justification is acceptable when considered with the fish study. The toxicological assessment confirms that OIT dissipates rapidly in body tissues and fluids. In addition, OIT does not cause systemic toxicity. The metabolites observed are not regarded as of a concern and no method for body fluids is regarded as necessary.	
Conclusion	*Acceptable*	

Section A4.2	**Analytical Methods for Detection and Identification**
Annex Point IIA, IV.4.2	*d) Residues in Animal and human body fluids and tissues*
Remarks	A method is not regarded as necessary based on the toxicological evaluation.
	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	