

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
IIIA 3.1 Function	Biological larvicide.	
IIIA 3.2 Field of use envisaged	Main Group 3: Pest control.	
IIIA 3.3 Product types(s) and category of users which the micro-organism should be listed in Annex I, IA or IB.	Product type 18: Insecticide. <i>Bti</i> (Strain AM65-52) is intended for use by both professional and non-professional users.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Evaluation by Rapporteur Member State	
Date	September 2007
Materials and methods	Not applicable
Conclusion	Not applicable
Reliability	Not applicable
Acceptability	Not applicable
Remarks	None
Comments from ...	
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<b>IIIA 3.4</b> <b>Method of production and quality control</b>	Information concerning the production method of <i>Bti</i> (Strain AM65-52) is confidential to Valent BioSciences and is presented in the confidential attachment under Point IIIA 3.4.	

<b>Evaluation by Competent Authorities</b>	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
<b>Evaluation by Rapporteur Member State</b>	
<b>Date</b>	September 2007
<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Not applicable
<b>Remarks</b>	See evaluation of Confidential Information
<b>Comments from ...</b>	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

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<p><b>IIIA 3.5</b> <b>Information on the occurrence or possible occurrence of the development of resistance of the target organism</b></p>	<p>In the laboratory, resistance has been developed for several insects to the <i>Bt</i> subspecies <i>kurstaki</i>, <i>aizawai</i>, <i>entomocidus</i> and <i>tenebrionis</i> (<i>san diego</i>) and individual Cry toxins from the subspecies <i>kurstaki</i>, <i>aizawai</i>, <i>entomocidus</i> and <i>israelensis</i>. However, despite repeated attempts, significant resistance to whole cultures of <i>Bt israelensis</i> has not been achieved. The difficulty of generating resistance results from the involvement of Cyt toxins, which appear capable of overcoming resistance generated to individual or multiple Cry toxins. Cross resistance between <i>Bt</i> toxins has been found, but does not automatically occur. In most cases, with the exception of <i>Bt israelensis</i>, resistance to <i>Bt</i> was developed in the laboratory in less than 20 generations.<sup>1</sup></p>	

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<b>Date</b>	September 2007
<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Not applicable
<b>Remarks</b>	None
Comments from ...	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

<sup>1</sup> Glare, T.R. and O'Callaghan, M. 2000. *Bacillus thuringiensis*: Biology, Ecology and Safety, John Wiley and Sons Ltd, pp 17-19.

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<b>IIIA 3.6</b> <b>Methods to prevent loss of virulence of the seed stock of the micro-organism</b>	Information concerning methods to preserve the seed stock is confidential to Valent BioSciences and is presented in the confidential attachment under Point IIIA 3.6.	

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<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Not applicable
<b>Remarks</b>	See evaluation of Confidential Information
<b>Comments from ...</b>	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<b>IIIA 3.7</b> <b>Recommended methods and precautions concerning handling, storage, transport or fire</b>	<p>Store under cool, dry and well-ventilated conditions. Keep away from food, drink and animal feed stuffs. Keep away from heat.</p> <p>There are no restrictions for <i>Bti</i> (Strain AM65-52) concerning transport by land, sea or air.</p> <p>In case of fire use extinguishing media appropriate to surrounding conditions: dry chemical powder, carbon dioxide, foam, sand, or water are all suitable.</p>	(X)

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<b>Date</b>	September 2007
<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Partially acceptable (see below)
<b>Remarks</b>	(X) Precautions for operator and safety/ risk phrases are to be reported
<b>Comments from ...</b>	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<p><b>IIIA 3.8</b> <b>Procedures for destruction or decontamination</b></p>	<p><i>Bti</i> (Strain AM65-52) and any associated contaminated packaging should be disposed of by incineration, or in accordance with governmental or local authority regulations. These are standard procedures and no further detailed instructions are required. If further advice is required contact the manufacturer.</p> <p>The delta-endotoxins present in <i>Bti</i> (Strain AM65-52) are rapidly degraded in the environment and are harmless to non-target species and humans. <i>Bti</i> (Strain AM65-52) is not infective and does not multiply in the environment. No special requirements are therefore needed for decontamination.</p> <p>If further advice is needed the manufacturer should be contacted.</p>	(X)

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<b>Date</b>	September 2007
<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Partially acceptable
<b>Remarks</b>	The re-entry period continues to call out for protective equipment.
<b>Comments from ...</b>	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<b>IIIA 3.9</b> <b>Measures in case of an accident</b>	<p><i>Bti</i> (Strain AM65-52) is harmless to non-target species and humans and therefore no special requirements are needed to render the micro-organism harmless. However, in case of an accident it is recommended that spillage should be recovered and placed in an appropriate container for disposal. The spillage area should be washed using bleach or dilute detergent.</p> <p>If further advice is needed the manufacturer should be contacted.</p>	

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Evaluation by Rapporteur Member State	
<b>Date</b>	September 2007
<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Not acceptable
<b>Remarks</b>	None
Comments from ...	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<b>IIIA 3.10</b> <b>Procedures for waste management</b>	<i>Bti</i> (Strain AM65-52) and any associated contaminated packaging should be disposed of by incineration, or in accordance with governmental or local authority regulations. These are standard procedures and no further detailed instructions are required.  If further advice is required contact the manufacturer.	

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Evaluation by Rapporteur Member State	
<b>Date</b>	September 2007
<b>Materials and methods</b>	Not applicable
<b>Conclusion</b>	Not applicable
<b>Reliability</b>	Not applicable
<b>Acceptability</b>	Partially acceptable
<b>Remarks</b>	More details should be provided
Comments from ...	
<b>Date</b>	
<b>Results and discussion</b>	
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	



SECTION IIIA 3	FURTHER INFORMATION ON THE MICRO-ORGANISM	Official use only
<b>IIIA 3.11</b> <b>Monitoring plan to be used for the active micro-organism including handling, storage, transport and use</b>	<b>JUSTIFICATION FOR NON-SUBMISSION OF DATA</b>	
<b>Other existing data</b> [ ] <b>Limited exposure</b> [X]	<b>Technically not feasible</b> [ ] <b>Scientifically unjustified</b> [ ] <b>Other justification</b> [ ]	
<b>Detailed justification:</b>	<p><i>Bacillus thuringiensis</i> subsp <i>israelensis</i> is a common naturally occurring micro-organism with worldwide distribution. The species has been detected both in soil and on insects and plants and will be indigenous to intended areas of application. The vegetative cells and insecticidal toxins of <i>Bacillus thuringiensis</i> subsp <i>israelensis</i> are readily degraded in the environment and although the spores are more persistent they do not germinate readily and do not multiply in the environment. Furthermore, <i>Bacillus thuringiensis</i> subsp <i>israelensis</i> is not toxic or infective to mammals and other non-target organisms.</p> <p>Monitoring for <i>Bti</i> (Strain AM65-52) during handling, storage, transport and use is therefore not considered necessary.</p>	
<b>Undertaking of intended data submission</b> [ ]	Not applicable.	
<b>EVALUATION BY COMPETENT AUTHORITIES</b>		
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>		
<b>Date</b> <b>Evaluation of applicant's justification</b> <b>Conclusion</b> <b>Remarks</b>	September 2007 Partially acceptable Methodology to achieve identification at strain level is available, although it has been considered that monitoring is not required. Re-entry levels, with protective equipment, have been suggested at 3 days intervals. Paragraph should be re-phrased and completed	
<b>COMMENTS FROM OTHER MEMBER STATE</b>		
<b>Date</b> <b>Evaluation of applicant's justification</b> <b>Conclusion</b> <b>Remarks</b>		