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# APPROVAL

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## Summary

Substance	BioWorma
Application type	To reissue an approval for a hazardous substance under clause 4 of Schedule 7 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Considered by	The Chief Executive <sup>1</sup> of the Environmental Protection Authority ("the EPA")
Decision	Approved for reissue
Date of reissue	30 April 2021
Approval code	<b>HSR101166</b>
Hazard classification	Designed for biocidal action

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<sup>1</sup> The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act

## Decision

- 1.1. Pursuant to clause 4 of Schedule 7 of the Act, I have considered this approval to reissue.
- 1.2. I have considered the matters raised in sections 4 to 8 of the Act but, given the nature of the reissue is administrative, there are no further considerations required in order to achieve the purpose of the Act.
- 1.3. I consider it appropriate to reissue approval HSR101166 with the controls set out in the Appendix in accordance with clause 4 of Schedule 7 of the Act. Therefore the reissued approval is now made under section 29 of the Act, in accordance with clause 4(5) of Schedule 7, and Schedule 7 no longer applies to the reissued approval. Given the hazard classification system comes into effect from 30 April 2021, this decision will have effect from that date.
- 1.4. The transitional provisions of the Labelling Notice, Safety Data Sheets Notice and Packaging Notice apply to this reissued approval for the transitional period which begins on the date of reissue and ends on 30 April 2025.



Signed by:

Date: 16 April 2021

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Dr Allan L Freeth  
Chief Executive, EPA

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## Appendix: Controls applying to HSR101166

### Hazardous substances and new organisms (HSNO) default controls

Control code	EPA Notice	Notice / Part description
LAB	Labelling Notice 2017	<a href="#">Requirements for labelling of hazardous substances</a>
PKG	Packaging Notice 2017	<a href="#">Requirements for packaging of hazardous substances</a>
SDS	Safety Data Sheets Notice 2017	<a href="#">Requirements for safety data sheets for hazardous substances</a>
DIS	Disposal Notice 2017	<a href="#">Requirements for disposing hazardous substances</a>
HPC1	Hazardous Property Controls Notice 2017 Part 1	<a href="#">Preliminary provisions</a>
HPC3	Hazardous Property Controls Notice 2017 Part 3	<a href="#">Requirements for hazardous substances in a place other than a workplace</a>
HPC4A	Hazardous Property Controls Notice 2017 Part 4A	<a href="#">Substances that are hazardous to the environment: Site and storage controls</a>
HPC4B	Hazardous Property Controls Notice 2017 Part 4B	<a href="#">Use of substances that are hazardous to the environment</a>
HPC4C	Hazardous Property Controls Notice 2017 Part 4C	<a href="#">Qualifications required for application of substances that are hazardous to the environment</a>

### HSNO additional controls and modifications to controls

Control Description	Varied / Additional Control	Control
HPC4B	Variation to Hazardous Property Controls Notice Part 4B	<p>Clause 52(1) of the Hazardous Property Controls Notice applies to this substance as if it had a classification in the hazard class hazardous to the aquatic environment but clause 52(2) of the Hazardous Property Controls Notice does not apply.</p> <p>The maximum application rate of this substance is <math>3.0 \times 10^4</math> spores/kg bw (equivalent to 6 g BioWorma/100 kg bw and 100 g Livamol/100 kg bw).</p>
Use restrictions	Additional control	This substance must only be used as a veterinary medicine.

Control Description	Varied / Additional Control	Control
Label - additional labelling requirements	Additional control	Statements are required to be placed on the label equivalent to the following: <ul style="list-style-type: none"> <li>• Potential respiratory or skin sensitiser.</li> <li>• This substance must not be applied into or onto water.</li> <li>• Animals must not be allowed onto surface waters while receiving this substance as treatment.</li> <li>• The maximum application rate of this substance is 3.0 x 10<sup>4</sup> spores/kg bw (equivalent to 6 g BioWorma/100 kg bw and 100 g Livamol/100 kg bw).</li> <li>• This substance must only be used as a veterinary medicine.</li> </ul>
Application method restrictions	Additional control	Animals must not be allowed onto surface waters while receiving these substances as treatment.