

Application for approval of a disinfectant under The Diseases of Animals (Approved Disinfectants) (England) Order 2007 for the purposes of The Animal Health Act 1981

Before submitting an application please read all legislation relating to Defra Disinfectant Approvals, available on the AHVLA website at www.vla.defra.gov.uk

This form is to be used for:

- Submission of a disinfectant for efficacy testing for use under UK Animal Disease Orders as listed below (E). Please complete all sections of this form and send **three copies to the administration address on page 6**.
- Application for an approved disinfectant to be sold under a different name, i.e. approval for a back to back trade name. Please complete all sections of this form **except** sections 2.3 to 2.5 (no sample required) and section 3 (no charge for adding a trade name). **Send one copy to the administration address on page 6**.
- Applications for the two-yearly renewal of approval for currently listed Defra approved disinfectants. Please complete all sections of this form **except** sections 2.3 to 2.5 (no sample required) and section 3 (no charge at time of renewal). **Send one copy to the administration address on page 6**.

Please read these notes before completing this form.

A	For approval purposes, disinfectants are divided into five groups. These are four specific Animal Disease Orders, and one General category for approval for use where animal disease control legislation (other than the four specific Orders) made under the Animal Health Act or the European Communities Act requires the use of an approved disinfectant, for example The Transport of Animals (Cleansing and Disinfection) (England) (No.3) Order 2003, Number 1724. http://www.legislation.gov.uk/ukSI/2003/1724/contents/made
B	Applications are only accepted from the owner of the name and formulation of the disinfectant, henceforth referred to as the applicant. Approval, where given, is for a product as manufactured by the applicant. A separate application form must be completed for each product submitted for efficacy testing.
C	Applications will only be processed for products meeting the requirements of the Biocidal Products Directive (BPD). Submission of this form signed by the applicant signifies the applicant's compliance with the BPD requirements. Please see http://www.hse.gov.uk/biocides/bpd for details.
D	This application form must be completed and sent to the Administration Office address shown on page 6. The content will then be assessed and a decision made on the disinfectant's suitability for efficacy testing for the purpose of Defra Approval. You will be informed of the decision and successful applicants may then submit samples and payment. Please do not send samples or payment before you have received confirmation of your product's suitability from us.
E	Testing will commence upon payment of the required fee. Cheques or postal orders should be crossed and made payable to 'The Animal Health and Veterinary Laboratories Agency' and posted to the Shared Services Division address shown on page 6. Payment may be made by bank transfer. Please contact disinfectants@ahvla.gsi.gov.uk for bank details. Please reference all payments 'Defra Disinfectant Approvals FT1368'. Failure to do so may result in your payment being rejected. Cash cannot be accepted. Fees for efficacy testing cannot be refunded once testing has commenced. Please contact disinfectants@ahvla.gsi.gov.uk for details.
F	Sample requirements: samples must be sent to the Department of Bacteriology address shown on page 6. <ul style="list-style-type: none"> • Foot and Mouth Disease Orders – one 100ml liquid or 100g dry sample • Swine Vesicular Disease Regulations – one 100ml liquid or 100g sample • Diseases of Poultry Orders, and the Avian Influenza and Influenza of Avian Origin in Mammals Order – one 500ml or 500g sample • Tuberculosis Orders – one 500ml or 500g sample • General Orders – one 500ml or 500g sample You will be contacted if additional samples are required.
G	Disinfectants will be subject to random check tests. If the sample fails the check test at the approved dilution, approval for use under that Disease Order will be suspended and full revocation may follow in accordance with Article 6 of the Statutory Instrument.
H	Approval is granted for two years. Subsequent approval is subject to conditions including a renewal procedure that does not usually include submission of samples, but does require the applicant to provide key information to the AHVLA upon request. Failure to comply with the two-year renewals may result in revocation of the approval.
I	Approval is subject to an annual fee of £375 per approved Disease Order per product per year. Refer to The Disease of Animals (Approved Disinfectants) (Fees and Amendment) (England) Order 2011 No 1509. http://www.legislation.gov.uk/ukSI/2011/1509/made The fee is charged by the AHVLA to the manufacturer once the tested product is placed on the Defra List of Approved Disinfectants. http://disinfectants.defra.gov.uk/Default.aspx?Module=ApprovalsList_SI

3. Complete this table for new products only, i.e.: not trade name applications

Please complete this table for 'parent' products indicating which Order(s) you are applying for approval under, the dilution and the fee being paid.

* Solid products will be tested at a concentration of 1g to (x)mls of water

(1)	(2)	(3)	(4)	(5)
Test for approval for use under the following Orders	Fees per test (£)	Tick which types of approval are sought	*Dilution at which the preparation is to be used (expressed as 1 part to x parts water)	Fee (£)
(a) Foot-and-Mouth Disease	1,920			
(b) Swine Vesicular Disease	1,920			
(c) Diseases of Poultry and the Avian Influenza and Influenza of Avian Origin in Mammals:				
1. single dilution test or	1,040			
2. triple dilution test	1,400			
(d) Tuberculosis				
1. single dilution test or	1,300			
2. triple dilution test	1,620			
(e) General **				
1. single dilution test or	715			
2. triple dilution test	815			
(f) Administrative charge	1,000			1,000
			Sub-total	
			VAT at 20%	
			Grand total	(£)

** This category is for approval for use against animal diseases other than (a) to (d) under the appropriate legislation, and for general use where there is a statutory requirement for an approved disinfectant to be used.

4. Complete this table for trade name (back to back) approvals only

4.1 Please complete the following table indicating the Orders under which the parent product is pending or already approved for use under, the approved dilution and the date (if applicable), that the product was approved.

	Date of approval
• Foot and Mouth Disease Orders in the proportion of one part of this preparation to _____ parts of water.	_____
• Swine Vesicular Disease Order in the proportion of one part of this preparation to _____ parts of water.	_____
• Diseases of Poultry Order and the Avian Influenza and Influenza of Avian Origin in Mammals Order in the proportions of one part of this preparation to _____ parts of water.	_____
• Tuberculosis Orders in the proportions of one part of this preparation to _____ parts of water.	_____
• Approval for use against diseases other than the above under the appropriate legislation made under the Animal Health Act 1981 in the proportions of one part of this preparation to _____ parts of water.	_____

Manufacturers of an approved disinfectant may make it available under different trade names or supply it to customers wishing to make it available under their own trade names. The disinfectant approved and supplied must be identical to the sample tested. Please give the trade names already used for your product as well as new trade names for which approval is being sought. Also provide the names and addresses of companies wishing to distribute your product under their own trade names. A disinfectant must not be marked as approved until its name appears on the list published on the Defra website at <http://www.defra.gov.uk>

4.2 Trade names to appear on the list published on the website.	Company name	Address, e-mail and telephone number	Name and signature of company representative

Please tick if any information has been supplied separately

Approval of disinfectants by the Secretary of State does not relieve manufactures of their obligation to obtain other statutory or non-statutory clearance, or of their general responsibilities to users of their products. Attention is also drawn to legal requirements regarding classification, packaging, labelling and provision of information on dangerous goods, both for supply and transport. Advice on these may be sought from the Health and Safety Executive www.hse.gov.uk

It is an offence to make an approved disinfectant available which is labelled incorrectly. Every container in which an approved disinfectant is supplied must bear a label containing the information at 4.1

It is an offence to make a false claim on this application form and may result in approval of your product being revoked.

Company Representative's Signature (*person named at 1.1*)

Date

Signed on behalf of (*company name*)

Confidentiality of data

Commercial information supplied to Defra and laboratories carrying out testing will be treated as confidential. Any personal data supplied on this form or provided separately by you in connection with this application will be used to contact you and process your application. Such data will be stored on a database for the purpose of administering the disinfectant approvals mechanism and disclosed to the laboratories that undertake statutory testing. Names and addresses of manufacturers and distributors of disinfectants approved for statutory use under the Animal Health Act will be publically available on the Defra website.

When you have received confirmation of the assessment described at D, send two further copies of the application form to:

Defra Disinfectant Approvals
Bacteriology Administration Office (Stewart Stockman Building)
Animal Health and Veterinary Laboratories Agency
Woodham Lane, New Haw, Addlestone
Surrey KT15 3NB

NB: For trade name approvals only (section 4) send only one copy of this form.

Send the required samples (see F) of the disinfectant and three copies of the health and safety data sheet to:

Department of Bacteriology (Building 17)
Animal Health and Veterinary Laboratories Agency
Woodham Lane
New Haw, Addlestone
Surrey KT15 3NB

Send cheques and postal orders referenced as described in E, to:

Shared Services – Accounts Receivable
PO Box 347, York YO1 7PX

We aim to acknowledge receipt of your application within five working days.

The labels below should be completed and used to label the packages and sample container in which samples are sent to the Animal Health and Veterinary Laboratories Agency.

Outer Package Label	
Disinfectant samples for Defra approval	
To: Department of Bacteriology, Animal Health and Veterinary Laboratories Agency, Addlestone, Surrey KT15 3NB	
Name of disinfectant <input type="text"/>	
<hr/>	
Tests required:	Foot-and-Mouth Disease..... <input type="checkbox"/>
<i>(tick appropriate box)</i>	Swine Vesicular Disease <input type="checkbox"/>
	Diseases of Poultry and the Avian Influenza and Influenza of Avian Origin in Mammals:
	• Single dilution <input type="checkbox"/>
	• Triple dilution <input type="checkbox"/>
	Tuberculosis:
	• Single dilution <input type="checkbox"/>
	• Triple dilution <input type="checkbox"/>
	General Purpose:
	• Single dilution <input type="checkbox"/>
	• Triple dilution <input type="checkbox"/>



Inner Sample Container Label	
Disinfectant samples for Defra approval	
To: Department of Bacteriology, Animal Health and Veterinary Laboratories Agency, Addlestone, Surrey KT15 3NB	
Name of disinfectant <input type="text"/>	
<hr/>	
Batch no	<input type="text"/>
Date of manufacture	<input type="text"/>
Expiry date	<input type="text"/>
Company representative signature <input type="text"/>	

