

(a) Application for Defra approval of a disinfectant (DDA1)

Approval under The Diseases of Animals (Approved Disinfectants) (England) Order 2007 No. 448 (as amended), for the purposes of The Animal Health Act 1981 (as amended)

(i) APHA office use only

	Date received
S	Signed
F	Reference

(ii) When to use this form

Use this form if you manufacture a disinfectant and want to:

- submit your disinfectant for efficacy testing, for the purpose of Defra disinfectant approval
- apply for your approved disinfectant to be sold under another trade name (a 'back-to-back' approved trade name)
- apply for the biennial renewal of your disinfectant's Defra approval

Official – Sensitive – Commercial (once completed by the applicant) Before submitting an application, read the <u>guidance notes on how to fill out this form</u>.

Applications are voluntary. You do not need Defra approval to place a disinfectant on the market.

(iii) How to submit this form

To submit your application, email this completed form and your product's material safety data sheet (MSDS) to Defra Disinfectants Approvals Administration at APHA: disinfectant@apha.gov.uk.

If you have any questions or need to post your form, email disinfectant@apha.gov.uk.

We aim to reply within 5 working days.

Please do not send any samples until APHA requests them. Also, do not send this form in the post along with your samples.

(iv) Section 1: Manufacturer details

In this section, include details of the manufacturer.

To fill out this section, you must be either:

- an employee of the company that owns the formulation of the product you want APHA to test
- a third-party consultant commissioned by the manufacturer or owner of the formulation

To safeguard information about your product, APHA will send all correspondence to the contact listed in this section. If there is anyone else APHA can communicate with, send their details as soon as possible to Defra Disinfectants Approvals Administration at APHA: disinfectant@apha.gov.uk.

1.1	Company name
1.2	Employee or consultant name
1.3	Address of company, including postcode

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Official – Sensitive – Commercial (once completed by the applicant)
1.4 Address of manufacturing site, including postcode (if different to the address of manufacturing site, including postcode (if different to the address of manufacturing site, including postcode (if different to the address of manufacturing site, including postcode (if different to the address of manufacturing site, including postcode (if different to the address of manufacturing site, including postcode (if different to the address of manufacturing site, including postcode (if different to the address of manufacturing site).
company)
1.5 Telephone number (including international dialling code, if applicable)
(mercaning meericaning code, in approximation)
1.6 Email address
4.7. Company to MAT mumbers
1.7 Company's VAT number
(v) Section 2: Parent product information
In this section, include details about the 'parent' product.
in this section, include details about the parent product.
This is the product for which you are applying:
for Defra approval
for renewal of Defra approval
 to list under an additional trade name (a 'back-to-back' approved trade name)
2.1 Parent product name
This must be unique within the Defra list of approved disinfectants.
2.2 Physical form in which the disinfectant is to be tested and sold
Enter either liquid, gel, powder or tablet.
Sections 2.3 to 2.5 can be left blank when submitting this form and the sample
details confirmed at a later date.
2.3 Batch number of the disinfectant sample
2.3 Batch number of the distinectant sample
2.4 Date the sample was manufactured
2.4 Date the sample was manufactured
2.5 Expiry date of the disinfectant sample
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2.6 Storage instructions

How the sample should be stored. For example, 'at room temperature', 'kept cool' or 'in the
dark'.
2.7 Directions for use
How your customers should use the product.
2.8 Proposed use
The intended use of the product. Defra approves disinfectants for use on inanimate surfaces only. For topical application products, consult the Health and Safety Executive or
Veterinary Medicines Directorate for advice.
veterinary inedicines birectorate for advice.

2.9 Product composition

State the precise formulation of the product you want APHA to test. Use one line for each substance. Include dyes and perfumes.

You must include all substances in the product and state all percentages to 4 decimal places. The percentages of substances used in your product must total 100%.

Give the percentage purity of each raw material and the percentage of this raw material in your product. Do not correct for purity.

For example, you might use a 90% strength iodine. Your product might then be made up of 5% of this iodine plus 95% water. Give these percentages in the relevant columns of the form.

For the iodine, you would write:

Substance: Iodine

Percentage of active biocide in this substance: 90% pure

• Percentage of substance used in your product: 5%

Substance	CAS number	Percentage of active biocide in this substance	Percentage of substance used in your product	Active biocide or inert (non-biocidal) substance

O.C I	0 111 0	/		0
Official	– Sensitive – Comr	mercial (once comp	leted by the applica	ant)
2.10 I confirm the Signed	substances listed	in the above table	e total 100%	
2.11 Have you sub Type yes or no	omitted any addition	onal information w	vith this application	on?
Type yes of the				
(i)	Continu 2: N	4 4	-4!	
		ew test applic blications. Do not co		ı if you are
		n your approved pro		
		d like to apply for by nd challenge pathog		
3.1 Tests to order				
 dilution in pa 	arts – this is the dilu	r, you must write the ition at which APHA product is approve	should test your p	roduct and the

cost in pounds sterling – <u>see our efficacy testing fees</u>

Do not leave any fields empty. Enter NA (not applicable) or strike through tests not required.

Solid products will be tested at a concentration of 1g plus the number of millilitres of water you choose.

State the dilution in parts, such as 1 part disinfectant plus 50 parts of water.

Efficacy test	Dilution in parts (fill in this column)	Cost in pounds sterling (fill in this column)
Foot and mouth disease virus		
Swine vesicular disease virus		
Poultry diseases, avian influenza and influenza of avian origin in mammals:		

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Official – Sensitive – Commercial (once completed by the applicant) single dilution Poultry diseases, avian influenza and influenza of avian origin in mammals: triple dilution Tuberculosis disease: single dilution Tuberculosis disease: triple dilution Other notifiable disease requirements: single dilution Other notifiable disease requirements: triple dilution 3.2 Total cost, including the administrative fee State the total cost for all tests you are applying for, in pounds sterling. Include the administrative fee for new tests.

(vii) Section 4: Trade name approval (back-to-back approved trade names)

Leave this section blank for new applications.

You must wait for efficacy tests on the parent product before requesting a back-to-back trade name approval.

Fill in this section if you have an approved disinfectant and wish to:

- make it available under a different trade name
- supply it to a distributor who will make it available under a different trade name

This is known as a 'back-to-back' approved trade name.

The disinfectant must be identical to the product originally tested and approved.

It is an offence to label and market a product as Defra approved unless the name has been added to the <u>approved disinfectants list</u>.

If you would like to apply for more than one back-to-back approved trade name, make copies of this section.

4.1 Proposed new trade name

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This must be unique with the **Defra list of approved disinfectants**. Write it exactly as you would like it to appear on the list. For example, use upper or lower case characters 4.2 Distributor company name 4.3 Distributor company address (including postcode) 4.4 Distributor company representative's name 4.5 Distributor company representative's email 4.6 Distributor company representative's telephone number 4.7 Distributor company representative's signature 4.8 Date of signature 4.9 Have you supplied any additional information with this application? Type yes or no.

(viii) Section 5: Applicant's declaration

If your disinfectant is approved by Defra, you must still adhere to other legal requirements, such as on classification, packaging, labelling and provision of information on dangerous goods for supply and transport – read information and guidance on Health and Safety Executive (HSE) website.

It is an offence to make a false claim on this application form.

I confirm, on behalf of the company named in section 1.1, that the product named on this form is compliant with all relevant legislation for it to be marketed and sold in Great Britain.

5.1 Company name	
5.2 Applicant's name	
5.3 Date of application	
5.4 Applicant's signature Add your signature electronically by typing your name. You	ı do not need a wet signature.

(ix) Confidentiality of data

APHA and delivery partners carrying out testing will treat commercial information you supply as confidential. We will only use the personal data you supply during this application – on this form or separately – to contact you and process your application.

This data will be:

- stored on a database so that APHA can commission testing and maintain the list of approved disinfectants
- shared with laboratories that carry out statutory testing

Official – Sensitive – Commercial (once completed by the applicant) If a disinfectant you manufacture or distribute is approved by Defra, the name and address you provide will be publicly available on the approved disinfectants list.

(x) Labels

If you are submitting disinfectant samples to APHA as part of this application, you must use these label templates for the inner and outer packaging.

If you fail to comply with these instructions and the legal requirements outlined in section 5, APHA will reject the samples and halt your application.

Please do not send this form in the post along with your samples. Read our guidance above on how to submit this form.

(A) If your labels already comply

If you are submitting a market-ready container with labels and pictograms that already comply, contact Defra Disinfectants Approvals Administration at APHA for instructions on submitting samples:

Email: disinfectant@apha.gov.uk

For example, this may happen if your product is already listed and marketed as Defra approved and you want to apply for additional or further approval testing.

(B) Outer package label

Disinfectant Samples				
Delivery address:	Bacteriology Depa Defra Disinfectant Animal and Plant H Woodham Lane Addlestone Surrey KT15 3NB	Approvals (b	• ,	
Disinfectant Name				
Batch Number		Expiry Date		
Contents (sample volume)		1	1	
MSDS enclosed (tick)	Compliant with CLP Regulations (tick)		ck)	
Signed :				

(C) Inner package label (sample container)

Disinfectant Samples for Defra Approval Efficacy Testing			
Disinfectant Name			
Batch Number		Expiry Date	
Sender:			
Company Name:			
Contents: samples (tick to confirm tests required and sample volumes enclosed)			
FMDV			
SVDV			
DoP	single		
	triple		
ТВ	single		
	triple		
GO	single		
	triple		
MSDS enclosed (tick)		Compliant with CLP Regulations (tick)	
Signed :			