



Defra disinfectant approval scheme

Application for approved disinfectant trade certificate

This application is for the issue of a document for trade purposes that certifies a disinfectant has been approved on behalf of Defra under 'the relevant Disinfectant Approval Order', namely:

- the Diseases of Animals (Approved Disinfectants) (England) Order 2007
- the Diseases of Animals (Approved Disinfectants) (Scotland) Order 2008
- the Diseases of Animals (Approved Disinfectants) (Wales) Order 2007

The Animal and Plant Health Agency (APHA) is an executive agency of the Department for Environment, Food and Rural Affairs (Defra). It approves disinfectants on behalf of Defra as set out in the relevant Disinfectant Approval Order. The purpose of an approval under this legislation is to confirm the disinfectant is effective in controlling certain pathogens under laboratory conditions. Where legislation requires the use of a disinfectant approved by Defra, only a disinfectant listed as having been approved under this order may be used.

Manufacturers marketing disinfectants in the UK have a duty to understand and comply with relevant legislation including the GB- Biocide Products Regulations (BPR) and general chemicals legislation. The GB-BPR replaces the EU-BPR in England, Scotland and Wales. Arrangements for Northern Ireland are covered in the Northern Ireland Protocol (contact Northern Ireland and the Health and Safety Executive (HSE) for details).



These regulations:

- enable the GB-BPR to be enforced in the UK
- appoint a competent authority (the HSE)
- set maximum penalties for non-compliance
- enable the HSE to recover the costs of services they provide, from those who benefit from them, through a fees system

Transitional arrangements were also required to enable parts of legacy systems (EU-BPD and the UK Control of Pesticides Regulations (COPR) 1986) to remain in place until affected products are brought under the product authorisation requirements in the new GB-BPR.

In making an application for a disinfectant to be approved by Defra under the relevant Disinfectant Approval Order the applicant is required to confirm by signing the DDA1 form that they have and will continue to execute their legal duties and comply with relevant legislation for the manufacture, sale, labelling and safety of their products. These legal duties include as a minimum:

- ensuring the formulation complies with the GB-BPR for Product Type 3 (Veterinary Hygiene Products) or such transitional arrangements as required by the UK HSE
- ensuring the product complies with any applicable general chemicals and consumer legislation including the Classification, Labelling and Packaging of Substances and Mixtures Regulation (CLP regulation), where appropriate the General Products Safety Regulations (GPSR), and the GB-BPR requirements
- informing the National Poisons Information Service (NPIS)
- depending on the specific intended usage of the product, that they comply with any other relevant national requirements that apply



Animal & Plant Health Agency

disinfectant@apha.gov.uk
Official-Sensitive (commercial)
once completed by the applicant

More information about the requirements of the GB-BPR can be obtained from HSE biocides team:

Chemicals Regulation Directorate (CRD)
Health and Safety Executive
4N.G Redgrave Court
Merton Road
Bootle
Merseyside
L20 7HS
United Kingdom
Email: pa.biocides@hse.gov.uk
Website: <http://www.hse.gov.uk/biocides/index.htm>

The manufacturer must inform APHA of the formulation of the product and any change of formula for the approved product (no matter how small) must result in a fresh application for approval.

In requesting the issue of a trade certificate, the applicant is required to reaffirm their compliance with these obligations. The applicant must ensure the product continues to comply with the conditions of its original approval.

I draw your attention to the requirements of product labelling and other restrictions set out in the Conditions of Defra approval. Where a back-to-back approved product is intended for international markets and the packaging is not in the English language, the translated label text must have the same meaning as that set out in the conditions of the parent product.

For each product for which a trade certificate requested, a fee of £177.60 is payable for up to 10 copies.



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I agree on behalf of *(insert company name or stamp)*

to the conditions contained in this letter and confirm that disinfectant

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_____’

complies with all relevant legislation for it to be marketed and sold in Great Britain.

Company representative’s signature (the addressee):

Company representative’s name:

Date: