#### STATUTORY INSTRUMENTS

#### 2001 No. 880

#### **HEALTH AND SAFETY**

### The Biocidal Products Regulations 2001

Made - - - - 7th March 2001
Laid before Parliament 16th March 2001
Coming into force 6th April 2001

#### THE BIOCIDAL PRODUCTS REGULATIONS 2001

#### PART I

#### **GENERAL**

- 1. Citation and commencement
- 2. Interpretation
- 3. Application

#### PART II

#### **ACTIVE SUBSTANCES**

- 4. Placing on the market of active substances
- 5. Applications concerning new active substances
- 6. Assessment of applications concerning new active substances
- 7. Applications for variation or renewal of the inclusion of active substances in Annex I, IA or IB

#### PART III

#### **BIOCIDAL PRODUCTS**

- 8. Prohibitions
- 9. Authorisation of a biocidal product
- 10. Registration of a low-risk biocidal product
- 11. Mutual recognition of authorisations
- 12. Mutual recognition of registrations
- 13. Provisional authorisation
- 14. Provisional registration
- 15. Emergency authorisation
- 16. Research and development

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- 17. Experimental authorisation
- 18. Frame-formulations
- 19. Revocation of authorisations and registrations
- 20. Modification and review of authorisations and registrations
- 21. Notification of new information
- 22. Emergency prohibition or restriction

#### DART IV

#### USE OF INFORMATION

- 23. Data protection for active substances
- 24. Data protection for biocidal products
- 25. Co-operation in the use of information
- 26. Confidentiality
- 27. Treatment of confidential information
- 28. Exchange of information
- 29. Notification of information to the National Poisons Information Service

#### PART V

#### PACKAGING, LABELLING AND ADVERTISEMENTS

- 30. Packaging
- 31. Labelling
- 32. Samples, models and drafts
- 33. Advertisements

#### PART VI

#### MISCELLANEOUS AND GENERAL

- 34. General provisions on applications for authorisations and registrations
- 35. Files on applications
- 36. Appeals
- (8) In this regulation, "the appropriate person" means—
- 37. Tests
- 38. Enforcement, offences and civil liability
- 39. Fees
- 40. Transitional provisions
- 41. Extension outside Great Britain
- 42. Amendments

Signature

SCHEDULE 1 — BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS

#### SCHEDULE 2 — REGULATIONS RELATING TO BIOCIDAL PRODUCTS

#### SCHEDULE 3 — DETERMINATIONS OF THE MINISTERS

- 1. Subject to paragraph 2, the Ministers have determined that the...
- 2. In making the determinations referred to in paragraph 1, the...
- 3. The Ministers have determined, according to the relevant requirements in...
- 4. The Ministers have determined—(a) the physical and chemical properties...

## SCHEDULE 4 — INFORMATION TO BE CONTAINED IN A DOSSIER SUBMITTED IN SUPPORT OF AN APPLICATION FOR THE REGISTRATION OF A BIOCIDAL PRODUCT

- 1. The name and address of the applicant.
- 2. The name and address of the manufacturer of the biocidal...
- 3. The name and address of the manufacturer of the active...
- 4. The trade name of the biocidal product.
- 5. The name of each substance in the biocidal product, including...
- 6. The physical and chemical properties of the biocidal product relating...
- 7. The product-type and field of use of the biocidal product....
- 8. The intended category of users.
- 9. The intended method of use.
- 10. Efficacy data.
- 11. Analytical methods.
- 12. The classification, packaging and labelling of the biocidal product, including...
- 13. Where the biocidal product is a substance or preparation dangerous...

# SCHEDULE 5 — MATTERS IN RESPECT OF WHICH ADDITIONAL CONDITIONS MAY BE IMPOSED ON THE MUTUAL RECOGNITION OF AN AUTHORISATION OR A REGISTRATION OF A BIOCIDAL PRODUCT

- 1. Directions for use of the biocidal product in question, including...
- 2. Particulars of any likely direct or indirect adverse side effects...
- 3. Directions for safe disposal of the biocidal product in question...
- 4. The period of time needed for the biocidal effect.
- 5. The interval to be observed between— (a) applications of the...
- 6. Particulars for adequate cleaning of equipment.
- 7. Particulars concerning precautionary measures during use, storage and transport, such...
- 8. Information on any specific dangers to the environment, including protection...

#### SCHEDULE 6 — NON-CONFIDENTIAL INFORMATION

- 1. The name and address of the applicant for the authorisation...
- 2. The name of the biocidal product.
- 3. The name and address of the manufacturer of the biocidal...
- 4. The name and address of the manufacturer of the active...
- 5. The name and content of the active substance in the...
- 6. The name of any other substance in the biocidal product...
- 7. Physical and chemical data concerning the biocidal product and the...
- 8. Any ways of rendering harmless the biocidal product and the...
- 9. A summary of the results of the tests, referred to...
- 10. Recommended methods and precautions to reduce dangers from handling, storage,...
- 11. Safety data sheets.
- 12. Methods of analysis necessary to enable the Ministers to make...
- 13. Methods of disposal of the biocidal product and its packaging....
- 14. Procedures to be followed and measures to be taken in...
- 15. First aid and medical advice to be given in the...

# SCHEDULE 7 — INFORMATION RELATING TO BIOCIDAL PRODUCTS TO BE GIVEN TO THE COMMISSION AND TO THE COMPETENT AUTHORITIES

- 1. The name of the applicant for, or the person to...
- 2. The trade name of the biocidal product.
- 3. The name and amount of each active substance which the...
- 4. The name and amount of each substance which the biocidal...
- 5. The product-type for the biocidal product and the use for...
- 6. The type of formulation of the biocidal product, namely whether...
- 7. Any proposed limits on residues which have been determined by...
- 8. Any conditions subject to which the authorisation or registration was...
- 9. The reasons for the modification or cancellation of an authorisation...
- 10. Whether the biocidal product is a low-risk biocidal product or...

## SCHEDULE 8 — INFORMATION TO BE NOTIFIED TO THE NATIONAL POISONS INFORMATION SERVICE

- 1. The name of the biocidal product.
- 2. If the biocidal product is authorised or registered under these...
- 3. The date on which the biocidal product was first placed...
- 4. The name, address and telephone number and any e-mail address...
- 5. A description of the packaging of the biocidal product, including...
- 6. The pH, physical state and colour of the biocidal product....
- 7. The identity of the ingredients of the biocidal product, and...
- 8. The effects on human health of contact with the biocidal...
- 9. Particulars of the likely direct or indirect adverse side effects...
- 10. Any other information relating to the health and safety of...

#### SCHEDULE 9 — INFORMATION TO BE INCLUDED ON LABELS

- 1. The identity of the active substance in the biocidal product...
- 2. The authorisation or registration number allocated to the biocidal product...
- 3. The type of formulation of the biocidal product, namely whether...
- 4. The use for which the biocidal product is authorised or...
- 5. Directions for use of the biocidal product, including its dose...
- 6. Particulars of likely direct or indirect adverse side effects and...
- 7. Directions for safe disposal of the biocidal product and its...
- 8. The number or other reference assigned by the manufacturer of...
- 9. The period of time needed for the biocidal effect.
- 10. The interval to be observed between—(a) applications of the...
- 11. Instructions for adequate cleaning of equipment for use with the...
- 12. Instructions concerning precautionary measures during use, storage and transport, such...
- 13. Any restriction on the category of persons who may use...
- 14. Information on any specific dangers to the environment, including protection...

#### SCHEDULE 10 — APPEALS

#### PART I

- 1. In this Schedule—(a) "appeal" means an appeal under regulation...
- 2. The appropriate person shall direct that an appeal shall be...
- 3. Before the determination of an appeal, the appointed person shall...
- 4. An appointed person may give such directions as he thinks...
- 5. The appropriate person may pay to an appointed person such...

#### PART II

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- 6. An appeal brought pursuant to regulation 36(1)(j) shall be heard...
- 7. (1) Subject to the following sub-paragraphs of this paragraph, a...
- 8. (1) Not later than 28 days before the date of...
- 9. (1) The parties shall be entitled to appear at the...
- 10. (1) Where a government department has expressed in writing to...
- 11. (1) Except as otherwise provided in this Part of this...
- 12. (1) Where, after the close of the hearing, the appointed...
- 13. The appointed person shall notify the determination on the appeal,...

#### SCHEDULE 11 — ENFORCEMENT, OFFENCES AND CIVIL LIABILITY

- 1. Interpretation
- 2. Application of the 1974 Act
- 3. Offences
- 4. Limitation on entry to domestic premises in certain circumstances
- 5. Allocation of enforcement responsibility

#### SCHEDULE 12 — FEES

- 1. On the making of an application to the Ministers under...
- 2. There shall be payable by the applicant to the Ministers...
- 3. The applications to the Ministers referred to in paragraph 2...
- 4. There shall be payable by the applicant to the Ministers...
- 5. There shall be payable by a person who provides information...
- 6. There shall be payable by a person who requests a...
- 7. On receipt of— (a) an application referred to in paragraph...
- 8. The amount estimated in accordance with paragraph 7 shall be...
- 9. On the determination of the application, completion of the evaluation...
- 10. If the cost referred to in paragraph 9 is greater...
- 11. If the cost referred to in paragraph 9 is less...
- 12. In estimating or stating the cost of carrying out any...

#### SCHEDULE 13 — TRANSITIONAL PROVISIONS

- 1. In this Schedule—"COPR 1986" means the Control of Pesticides...
- 2. Subject to paragraphs 3 and 4, where a decision is...
- 3. These Regulations shall not apply to a biocidal product—
- 4. Where there is more than one unlisted active substance in...
- 5. Where— (a) there is made a decision referred to in...
- 6. Where— (a) there is made a decision referred to in...
- 7. During—(a) the period of time in which an application...
- 8. Where—(a) there is made a decision referred to in...
- 9. During—(a) the period of time in which an application...
- 10. Where— (a) no application is made in accordance with paragraph...
- 11. Where—(a) an application is made in accordance with paragraph...
- 12. Where— (a) there is made a decision referred to in...
- 13. Where— (a) there is made a decision referred to in...
- 14. The Ministers shall—(a) notify in writing the holder of...
- 15. A certificate of exemption granted pursuant to paragraph 6, 7,...
- 16. An exemption certificate granted in accordance with paragraph 15—

**Explanatory Note**