

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

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Article 5	Conditions for issue of an authorisation
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Article 7	Cancellation or modification of an authorisation
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ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT  
COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS

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ANNEX IA

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT  
COMMUNITY LEVEL FOR INCLUSION IN LOW-RISK BIOCIDAL PRODUCTS

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ANNEX IB

LIST OF BASIC SUBSTANCES WITH  
REQUIREMENTS AGREED AT COMMUNITY LEVEL

.....

ANNEX IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES

- 1. ....
- 2. ....

Dossier requirements

- I. ....
- II. ....
- III. ....
- IV. ....
- V. ....
- VI. ....
- VII. ....
- VIII. ....
- IX. ....
- X. ....
- I. APPLICANT
  - 1.1. ....
  - 1.2. ....
- II. IDENTITY
  - 2.1. ....
  - 2.2. ....
  - 2.3. ....
  - 2.4. ....
  - 2.5. ....

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	2.6.	.....
	2.7.	.....
	2.8.	.....
	2.9.	.....
	2.10.	.....
III.	PHYSICAL AND CHEMICAL PROPERTIES	
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	3.2.	.....
	3.3.	.....
	3.4.	.....
	3.5.	.....
	3.6.	.....
	3.7.	.....
	3.8.	.....
	3.9.	.....
	3.10.	.....
	3.11.	.....
	3.12.	.....
	3.13.	.....
IV.	ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION	
	4.1.	.....
	4.2.	.....
V.	EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES	
	5.1.	.....
	5.2.	.....
	5.3.	.....
	5.4.	.....
	5.5.	.....
	5.6.	.....
	5.7.	.....
	5.8.	.....
VI.	TOXICOLOGICAL AND METABOLIC STUDIES	
	6.1.	.....
	6.1.1.	.....
	6.1.2.	.....
	6.1.3.	.....
	6.1.4.	.....
	6.1.5.	.....
	6.2.	.....
	6.3.	.....
	6.4.	.....
	6.5.	.....
	6.6.	.....
	6.6.1.	.....
	6.6.2.	.....
	6.6.3.	.....
	6.6.4.	.....
	6.6.5.	.....
	6.6.6.	.....
	6.7.	.....
	6.8.	.....
	6.8.1.	.....

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- 6.8.2. ....
- 6.9. ....
  - 6.9.1. ....
  - 6.9.2. ....
  - 6.9.3. ....
  - 6.9.4. ....
  - 6.9.5. ....
  - 6.9.6. ....
  - 6.9.7. ....
  - 6.9.8. ....
- 6.10. ....
- VII. ECOTOXICOLOGICAL STUDIES
  - 7.1. ....
  - 7.2. ....
  - 7.3. ....
  - 7.4. ....
  - 7.5. ....
  - 7.6. ....
    - 7.6.1. ....
      - 7.6.1.1. ....
      - 7.6.1.2. ....
    - 7.6.2. ....
      - 7.6.2.1. ....
      - 7.6.2.2. ....
  - 7.7. ....
  - 7.8. ....
- VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT
  - 8.1. ....
  - 8.2. ....
  - 8.3. ....
  - 8.4. ....
  - 8.5. ....
    - 8.5.1. ....
    - 8.5.2. ....
    - 8.5.3. ....
    - 8.5.4. ....
  - 8.6. ....
- IX. CLASSIFICATION AND LABELLING
- X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

ANNEX IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS

- 1. ....
- 2. ....
- 3. ....

Dossier requirements

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I.	.....
II.	.....
III.	.....
IV.	.....
V.	.....
VI.	.....
VII.	.....
VIII.	.....
IX.	.....
X.	.....
I.	APPLICANT
1.1.	.....
1.2.	.....
II.	IDENTITY
2.1.	.....
2.2.	.....
2.3.	.....
III.	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES
3.1.	.....
3.2.	.....
3.3.	.....
3.4.	.....
3.5.	.....
3.6.	.....
3.7.	.....
3.8.	.....
3.9.	.....
IV.	METHODS OF IDENTIFICATION AND ANALYSIS
4.1.	.....
4.2.	.....
V.	INTENDED USES AND EFFICACY
5.1.	.....
5.2.	.....
5.3.	.....
5.4.	.....
5.5.	.....
5.6.	.....
5.7.	.....
5.8.	.....
5.9.	.....
5.10.	.....
5.11.	.....
VI.	TOXICOLOGICAL STUDIES
6.1.	.....
6.1.1.	.....
6.1.2.	.....
6.1.3.	.....
6.1.4.	.....
6.2.	.....
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6.4.	.....
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6.6.	.....

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- VII. ECOTOXICOLOGICAL STUDIES
  - 7.1. ....
  - 7.2. ....
  - 7.3. ....
- VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE...
  - 8.1. ....
  - 8.2. ....
  - 8.3. ....
  - 8.4. ....
  - 8.5. ....
  - 8.6. ....
  - 8.7. ....
  - 8.8. ....
- IX. CLASSIFICATION, PACKAGING AND LABELLING
- X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

#### ANNEX IIIA

##### ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES

- 1. ....
- 2. ....
- III. PHYSICAL AND CHEMICAL PROPERTIES
  - 1. ....
  - 2. ....
- IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION
  - 1. ....
- VI. TOXICOLOGICAL AND METABOLIC STUDIES
  - 1. ....
  - 2. ....
  - 3. ....
  - 4. ....
  - 5. ....
  - 6. ....
  - 7. ....
- VII. ECOTOXICOLOGICAL STUDIES
  - 1. ....
  - 2. ....
  - 3. ....
  - 4. ....
  - 5. ....
  - 6. ....
- VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT
  - 1. ....

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XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. ....
  - 1.1. ....
  - 1.2. ....
  - 1.3. ....
  - 1.4. ....
  - 1.5. ....
  - 1.6. ....
  - 1.7. ....
  - 1.8. ....
  - 1.9. ....
2. ....

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. ....
  - 1.1. ....
  - 1.2. ....
  - 1.3. ....
  - 1.4. ....
2. ....
  - 2.1. ....
  - 2.2. ....
3. ....
4. ....

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. ....
  - 1.1. ....
  - 1.2. ....
  - 1.3. ....
2. ....
  - 2.1. ....
  - 2.2. ....
  - 2.3. ....
  - 2.4. ....
3. ....
  - 3.1. ....
  - 3.2. ....
  - 3.3. ....
  - 3.4. ....
4. ....
  - 4.1. ....
5. ....

ANNEX IIIB

ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS

1. ....
2. ....

- 3. ....
- XI. FURTHER HUMAN HEALTH-RELATED STUDIES
  - 1. ....
    - 1.1. ....
    - 1.2. ....
  - 2. ....
- XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT
  - 1. ....
  - 2. ....
- XIII. FURTHER ECOTOXICOLOGICAL STUDIES
  - 1. ....
    - 1.1. ....
  - 2. ....
    - 2.1. ....
      - 2.1.1. ....
      - 2.1.2. ....
      - 2.1.3. ....
    - 2.2. ....
  - 3. ....
    - 3.1. ....
    - 3.2. ....
    - 3.3. ....
    - 3.4. ....
    - 3.5. ....
    - 3.6. ....
    - 3.7. ....
      - 3.7.1. ....
      - 3.7.2. ....
  - 4. ....

#### ANNEX IVA

#### DATA SET FOR ACTIVE SUBSTANCES

- 1. ....
- 2. ....
- 3. ....
- 4. ....
- 5. ....

#### Dossier requirements

- I. IDENTITY OF THE MICRO-ORGANISM
  - 1.1. ....
  - 1.2. ....
  - 1.3. ....



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	1.3.1.	.....
	1.3.2.	.....
	1.3.3.	.....
	1.3.4.	.....
	1.4.	.....
	1.4.1.	.....
	1.4.2.	.....
	1.4.3.	.....
II.	BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM	
	2.1.	.....
	2.1.1.	.....
	2.1.2.	.....
	2.2.	.....
	2.2.1.	.....
	2.2.2.	.....
	2.3.	.....
	2.4.	.....
	2.5.	.....
	2.6.	.....
	2.7.	.....
	2.8.	.....
	2.9.	.....
	2.10.	.....
	2.11.	.....
III.	FURTHER INFORMATION ON THE MICRO-ORGANISM	
	3.1.	.....
	3.2.	.....
	3.3.	.....
	3.4.	.....
	3.5.	.....
	3.6.	.....
	3.7.	.....
	3.8.	.....
	3.9.	.....
	3.10.	.....
	3.11.	.....
IV.	ANALYTICAL METHODS	
	4.1.	.....
	4.2.	.....
V.	EFFECTS ON HUMAN HEALTH	
	TIER I	
	5.1.	.....
	5.1.1.	.....
	5.1.2.	.....
	5.1.3.	.....
	5.1.4.	.....
	5.2.	.....
	5.2.1.	.....
	5.2.2.	.....
	5.2.2.1.	.....
	5.2.2.2.	.....
	5.2.2.3.	.....
	5.2.3.	.....

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	5.2.4.	.....
	5.2.5.	.....
	5.2.5.1.	.....
	5.2.6.	.....
	5.2.7.	.....
	END OF TIER I	
	TIER II	
	5.3.	.....
	5.4.	.....
	5.5.	.....
	END OF TIER II	
	5.6.	.....
VI.	RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED	
	6.1.	.....
	6.2.	.....
	6.2.1.	.....
	6.2.2.	.....
	6.3.	.....
VII.	FATE AND BEHAVIOUR IN THE ENVIRONMENT	
	7.1.	.....
	7.1.1.	.....
	7.1.2.	.....
	7.1.3.	.....
	7.2.	.....
	7.3.	.....
VIII.	EFFECTS ON NON-TARGET ORGANISMS	
	8.1.	.....
	8.2.	.....
	8.2.1.	.....
	8.2.2.	.....
	8.2.3.	.....
	8.2.4.	.....
	8.3.	.....
	8.4.	.....
	8.5.	.....
	8.6.	.....
	8.7.	.....
	8.7.1.	.....
	8.7.2.	.....
	8.7.3.	.....
	8.8.	.....
IX.	CLASSIFICATION AND LABELLING	
X.	SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS...	

ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS

1. ....

2. ....

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- 3. ....
- 4. ....
- 5. ....

Dossier requirements

I. IDENTITY OF THE BIOCIDAL PRODUCTS

- 1.1. ....
- 1.2. ....
- 1.3. ....
- 1.4. ....
- 1.5. ....
- 1.6. ....

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

- 2.1. ....
- 2.2. ....
  - 2.2.1. ....
  - 2.2.2. ....
- 2.3. ....
- 2.4. ....
- 2.5. ....
- 2.6. ....
- 2.7. ....
  - 2.7.1. ....
  - 2.7.2. ....
  - 2.7.3. ....
  - 2.7.4. ....
  - 2.7.5. ....
  - 2.7.6. ....
  - 2.7.7. ....
- 2.8. ....
  - 2.8.1. ....
  - 2.8.2. ....
  - 2.8.3. ....

III. DATA ON APPLICATION

- 3.1. ....
- 3.2. ....
- 3.3. ....
- 3.4. ....
- 3.5. ....
- 3.6. ....
- 3.7. ....
- 3.8. ....
- 3.9. ....
- 3.10. ....
- 3.11. ....
- 3.12. ....

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

- 4.1. ....
- 4.2. ....

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	4.3.	.....
	4.4.	.....
	4.5.	.....
	4.6.	.....
	4.6.1.	.....
	4.6.2.	.....
	4.7.	.....
V.	ANALYTICAL METHODS	
	5.1.	.....
	5.2.	.....
VI.	EFFICACY DATA	
VII.	EFFECTS ON HUMAN HEALTH	
	7.1.	.....
	7.1.1.	.....
	7.1.2.	.....
	7.1.3.	.....
	7.2.	.....
	7.2.1.	.....
	7.2.2.	.....
	7.2.3.	.....
	7.3.	.....
	7.4.	.....
	7.5.	.....
	7.6.	.....
VIII.	RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED	
IX.	FATE AND BEHAVIOUR IN THE ENVIRONMENT	
X.	EFFECTS ON NON-TARGET ORGANISMS	
	10.1.	.....
	10.2.	.....
	10.3.	.....
	10.4.	.....
	10.5.	.....
	10.6.	.....
	10.7.	.....
	10.7.1.	.....
	10.7.2.	.....
	10.7.3.	.....
	10.8.	.....
XI.	CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT	
XII.	SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS...	

## ANNEX V

### BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)(a) OF THIS DIRECTIVE

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MAIN GROUP 1: Disinfectants and general biocidal products  
Product-type 1: Human hygiene biocidal products

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Product-type 2: Private area and public health area disinfectants and...  
Product-type 3: Veterinary hygiene biocidal products  
Product-type 4: Food and feed area disinfectants  
Product-type 5: Drinking water disinfectants

MAIN GROUP 2: Preservatives

Product-type 6: In-can preservatives  
Product-type 7: Film preservatives  
Product-type 8: Wood preservatives  
Product-type 9: Fibre, leather, rubber and polymerised materials preservatives  
Product-type 10: Masonry preservatives  
Product-type 11: Preservatives for liquid-cooling and processing systems  
Product-type 12: Slimicides  
Product-type 13: Metalworking-fluid preservatives

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides  
Product-type 15: Avicides  
Product-type 16: Molluscicides  
Product-type 17: Piscicides  
Product-type 18: Insecticides, acaricides and products to control other arthropods...  
Product-type 19: Repellents and attractants

MAIN GROUP 4: Other biocidal products

Product-type 20: Preservatives for food or feedstocks  
Product-type 21: Antifouling products  
Product-type 22: Embalming and taxidermist fluids  
Product-type 23: Control of other vertebrates

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION  
OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

Definitions  
Introduction  
Evaluation  
Decision-making  
Overall integration of conclusions

DEFINITIONS

- (a) Hazard identification
- (b) Dose (concentration) — response (effect) assessment
- (c) Exposure assessment
- (d) Risk characterisation
- (e) Environment

INTRODUCTION

- 1. ....
- 2. ....

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- 4. ....
- 5. ....
- 6. ....
- 7. ....
- 8. ....
- 9. ....
- 10. ....
- 11. ....
- 12. ....
- 13. ....

**EVALUATION**

General principles

- 14. ....
- 15. ....
- 16. ....
- 17. ....
- 18. ....
- 19. ....

Effects on humans

- 20. ....
- 21. ....
- 22. ....
- 23. ....
- 24. ....
- 25. ....
- 26. ....
- 27. ....
- 28. ....
- 29. ....
- 30. ....
- 31. ....
- 32. ....
- 33. ....
- 34. ....

Effects on animals

- 35. ....

Effects on the environment

- 36. ....
- 37. ....
- 38. ....
- 39. ....
- 40. ....
- 41. ....
- 42. ....
- 43. ....
- 44. ....
- 45. ....
- 46. ....
- 47. ....

Unacceptable effects

- 48. ....

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49.	.....
50.	.....
Efficacy	
51.	.....
52.	.....
Summary	
53.	.....
54.	.....

## DECISION MAKING

### General principles

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56.	.....
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58.	.....
59.	.....
60.	.....
61.	.....
62.	.....
63.	.....
64.	.....
65.	.....
66.	.....
67.	.....

### Effects on humans

68.	.....
69.	.....
70.	.....
71.	.....
72.	.....
73.	.....
74.	.....
75.	.....

### Effects on animals

76.	.....
77.	.....

### Effects on the environment

78.	.....
79.	.....
80.	.....

### Water

81.	.....
82.	.....
83.	.....
84.	.....

### Soil

85.	.....
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### Air

86.	.....
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### Effects on non-target organisms

87.	.....
88.	.....
89.	.....

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Unacceptable effects  
90. ....  
91. ....  
Efficacy  
92. ....  
93. ....  
Summary  
94. ....

**OVERALL INTEGRATION OF CONCLUSIONS**

95. ....  
96. ....  
97. ....