

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European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

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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

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ANNEX IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES

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Dossier requirements

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- IX.
- X.
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 - 1.2.
- II. IDENTITY
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 - 2.3.
 - 2.4.
 - 2.5.

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X.	SUMMARY AND EVALUATION OF SECTIONS II TO IX	

ANNEX IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS

1.
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3.

Dossier requirements

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III.
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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
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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...
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 - 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

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- 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.
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- 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

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 - 2.4.
- 3.
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 - 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.
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ANNEX IVA

DATA SET FOR ACTIVE SUBSTANCES

- 1.
- 2.
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Dossier requirements

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

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	1.3.1.
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	1.3.4.
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II.	BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM	
	2.1.
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III.	FURTHER INFORMATION ON THE MICRO-ORGANISM	
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IV.	ANALYTICAL METHODS	
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V.	EFFECTS ON HUMAN HEALTH	
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	5.1.3.
	5.1.4.
	5.2.
	5.2.1.
	5.2.2.
	5.2.2.1.
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	5.2.2.3.
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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.

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5.5.

END OF TIER II

5.6.

VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

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6.2.

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6.2.2.

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VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT

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7.1.3.

7.2.

7.3.

VIII. EFFECTS ON NON-TARGET ORGANISMS

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8.3.

8.4.

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8.7.2.

8.7.3.

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IX. CLASSIFICATION AND LABELLING

X. SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS...

ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS

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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

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III. DATA ON APPLICATION

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IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

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V.	ANALYTICAL METHODS	
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VI.	EFFICACY DATA	
VII.	EFFECTS ON HUMAN HEALTH	
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	7.1.3.
	7.2.
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	7.2.2.
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	7.5.
	7.6.
VIII.	RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED	
IX.	FATE AND BEHAVIOUR IN THE ENVIRONMENT	
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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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EVALUATION

General principles

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Effects on humans

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Effects on animals

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Effects on the environment

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Unacceptable effects

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Efficacy	
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Summary	
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DECISION MAKING

General principles

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Effects on humans

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Effects on animals

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Effects on the environment

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Water

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Soil

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Air

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Effects on non-target organisms

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Unacceptable effects
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Efficacy
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Summary
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OVERALL INTEGRATION OF CONCLUSIONS

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