

Commission Implementing Regulation (EU) 2018/1258 of
18 September 2018 granting a Union authorisation for the biocidal
product family Ecolab Iodine PT3 Family (Text with EEA relevance)

- Article 1 A Union authorisation is granted to Ecolab Deutschland GmbH
for...
- Article 2 This Regulation shall enter into force on the twentieth day...
Signature

ANNEX

Summary of product characteristics for a biocidal product family

Ecolab Iodine PT3 Family
Product type 3 — Veterinary hygiene (Disinfectants)
Authorisation number: EU-0018398-0000
R4BP asset number: EU-0018398-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION
 - 1.1. Family name
 - 1.2. Product type(s)
 - 1.3. Authorisation holder
 - 1.4. Manufacturer(s) of the biocidal products
 - 1.5. Manufacturer(s) of the active substance(s)
2. PRODUCT FAMILY COMPOSITION AND FORMULATION
 - 2.1. Qualitative and quantitative information on the composition of the family...
 - 2.2. Type(s) of formulation

PART II

SECOND INFORMATION LEVEL — META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION
 - 1.1. Meta SPC 1 identifier
 - 1.2. Suffix to the authorisation number
 - 1.3. Product type(s)
2. META SPC 1 COMPOSITION
 - 2.1. Qualitative and quantitative information on the composition of the meta...
 - 2.2. Type(s) of formulation of the meta SPC 1
3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1
4. AUTHORISED USE(S) OF THE META SPC 1
 - 4.1. Use description

- 4.1.1. Use-specific instructions for use
- 4.1.2. Use-specific risk mitigation measures
- 4.1.3. Where specific to the use, the particulars of likely direct...
- 4.1.4. Where specific to the use, the instructions for safe disposal...
- 4.1.5. Where specific to the use, the conditions of storage and...
- 5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1
 - 5.1. Instructions for use
 - 5.2. Risk mitigation measures
 - 5.3. Particulars of likely direct or indirect effects, first aid instructions...
 - 5.4. Instructions for safe disposal of the product and its packaging...
 - 5.5. Conditions of storage and shelf-life of the product under normal...
- 6. OTHER INFORMATION
- 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1...
 - 7.1. Trade name(s), authorisation number and specific composition of each individual...
 - 7.2. Trade name(s), authorisation number and specific composition of each individual...

META SPC 2

- 1. META SPC 2 ADMINISTRATIVE INFORMATION
 - 1.1. Meta SPC 2 identifier
 - 1.2. Suffix to the authorisation number
 - 1.3. Product type(s)
- 2. META SPC 2 COMPOSITION
 - 2.1. Qualitative and quantitative information on the composition of the meta...
 - 2.2. Type(s) of formulation of the meta SPC 2
- 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2
- 4. AUTHORISED USE(S) OF THE META SPC 2
 - 4.1. Use description
 - 4.1.1. Use-specific instructions for use
 - 4.1.2. Use-specific risk mitigation measures
 - 4.1.3. Where specific to the use, the particulars of likely direct...
 - 4.1.4. Where specific to the use, the instructions for safe disposal...
 - 4.1.5. Where specific to the use, the conditions of storage and...
- 5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2
 - 5.1. Instructions for use
 - 5.2. Risk mitigation measures
 - 5.3. Particulars of likely direct or indirect effects, first aid instructions...
 - 5.4. Instructions for safe disposal of the product and its packaging...
 - 5.5. Conditions of storage and shelf-life of the product under normal...
- 6. OTHER INFORMATION
- 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2...
 - 7.1. Trade name(s), authorisation number and specific composition of each individual...
 - 7.2. Trade name(s), authorisation number and specific composition of each individual...

META SPC 3

- 1. META SPC 3 ADMINISTRATIVE INFORMATION
 - 1.1. Meta SPC 3 identifier

- 1.2. Suffix to the authorisation number
 - 1.3. Product type(s)
 2. META SPC 3 COMPOSITION
 - 2.1. Qualitative and quantitative information on the composition of the meta...
 - 2.2. Type(s) of formulation of the meta SPC 3
 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3
 4. AUTHORISED USE(S) OF THE META SPC 3
 - 4.1. Use description
 - 4.1.1. Use-specific instructions for use
 - 4.1.2. Use-specific risk mitigation measures
 - 4.1.3. Where specific to the use, the particulars of likely direct...
 - 4.1.4. Where specific to the use, the instructions for safe disposal...
 - 4.1.5. Where specific to the use, the conditions of storage and...
 - 4.2. Use description
 - 4.2.1. Use-specific instructions for use
 - 4.2.2. Use-specific risk mitigation measures
 - 4.2.3. Where specific to the use, the particulars of likely direct...
 - 4.2.4. Where specific to the use, the instructions for safe disposal...
 - 4.2.5. Where specific to the use, the conditions of storage and...
 5. GENERAL DIRECTIONS FOR USE OF THE META SPC 3
 - 5.1. Instructions for use
 - 5.2. Risk mitigation measures
 - 5.3. Particulars of likely direct or indirect effects, first aid instructions...
 - 5.4. Instructions for safe disposal of the product and its packaging...
 - 5.5. Conditions of storage and shelf-life of the product under normal...
 6. OTHER INFORMATION
 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3...
 - 7.1. Trade name(s), authorisation number and specific composition of each individual...
- META SPC 4
1. META SPC 4 ADMINISTRATIVE INFORMATION
 - 1.1. Meta SPC 4 identifier
 - 1.2. Suffix to the authorisation number
 - 1.3. Product type(s)
 2. META SPC 4 COMPOSITION
 - 2.1. Qualitative and quantitative information on the composition of the meta...
 - 2.2. Type(s) of formulation of the meta SPC 4
 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4
 4. AUTHORISED USE(S) OF THE META SPC 4
 - 4.1. Use description
 - 4.1.1. Use-specific instructions for use
 - 4.1.2. Use-specific risk mitigation measures
 - 4.1.3. Where specific to the use, the particulars of likely direct...
 - 4.1.4. Where specific to the use, the instructions for safe disposal...
 - 4.1.5. Where specific to the use, the conditions of storage and...
 5. GENERAL DIRECTIONS FOR USE OF THE META SPC 4
 - 5.1. Instructions for use
 - 5.2. Risk mitigation measures
 - 5.3. Particulars of likely direct or indirect effects, first aid instructions...

- 5.4. Instructions for safe disposal of the product and its packaging...
- 5.5. Conditions of storage and shelf-life of the product under normal...
- 6. OTHER INFORMATION
- 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4...
 - 7.1. Trade name(s), authorisation number and specific composition of each individual...

META SPC 5

- 1. META SPC 5 ADMINISTRATIVE INFORMATION
 - 1.1. Meta SPC 5 identifier
 - 1.2. Suffix to the authorisation number
 - 1.3. Product type(s)
- 2. META SPC 5 COMPOSITION
 - 2.1. Qualitative and quantitative information on the composition of the meta...
 - 2.2. Type(s) of formulation of the meta SPC 5
- 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5
- 4. AUTHORISED USE(S) OF THE META SPC 5
 - 4.1. Use description
 - 4.1.1. Use-specific instructions for use
 - 4.1.2. Use-specific risk mitigation measures
 - 4.1.3. Where specific to the use, the particulars of likely direct...
 - 4.1.4. Where specific to the use, the instructions for safe disposal...
 - 4.1.5. Where specific to the use, the conditions of storage and...
- 5. GENERAL DIRECTIONS FOR USE OF THE META SPC 5
 - 5.1. Instructions for use
 - 5.2. Risk mitigation measures
 - 5.3. Particulars of likely direct or indirect effects, first aid instructions...
 - 5.4. Instructions for safe disposal of the product and its packaging...
 - 5.5. Conditions of storage and shelf-life of the product under normal...
- 6. OTHER INFORMATION
- 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5...
 - 7.1. Trade name(s), authorisation number and specific composition of each individual...

META SPC 6

- 1. META SPC 6 ADMINISTRATIVE INFORMATION
 - 1.1. Meta SPC 6 identifier
 - 1.2. Suffix to the authorisation number
 - 1.3. Product type(s)
- 2. META SPC 6 COMPOSITION
 - 2.1. Qualitative and quantitative information on the composition of the meta...
 - 2.2. Type(s) of formulation of the meta SPC 6
- 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6
- 4. AUTHORISED USE(S) OF THE META SPC 6
 - 4.1. Use description
 - 4.1.1. Use-specific instructions for use
 - 4.1.2. Use-specific risk mitigation measures
 - 4.1.3. Where specific to the use, the particulars of likely direct...
 - 4.1.4. Where specific to the use, the instructions for safe disposal...

- 4.1.5. Where specific to the use, the conditions of storage and...
- 5. GENERAL DIRECTIONS FOR USE OF THE META SPC 6
 - 5.1. Instructions for use
 - 5.2. Risk mitigation measures
 - 5.3. Particulars of likely direct or indirect effects, first aid instructions...
 - 5.4. Instructions for safe disposal of the product and its packaging...
 - 5.5. Conditions of storage and shelf-life of the product under normal...
- 6. OTHER INFORMATION
- 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6...
 - 7.1. Trade name(s), authorisation number and specific composition of each individual...

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (See end of Document for details)*

- (1) [OJ L 167, 27.6.2012, p. 1.](#)
- (2) Commission delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council ([OJ L 301, 17.11.2017, p. 1.](#)).
- (3) ECHA opinion of 12 December 2017 on the Union authorisation of Ecolab Iodine PT3 Family (ECHA/BPC/177/2017).

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