NOTE FOR DISCUSSION WITH COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Updated version of the SPC template for single biocidal products

1.- Background and purpose of the document

(1) In accordance with the principles agreed in document CA-May14-Doc.5.6 – Final on the content of labels of single biocidal products with regard to the authorised uses in the SPC, the Commission services and the Coordination Group (CG) have been working on an updated version of the SPC template for single biocidal products.

(2) The annexed document takes into account the discussion held at CG-6 and the comments submitted by CG members after the meeting.

2.- Action requested

(3) The CA meeting is invited to discuss and endorse the updated version of the template, subject any additional change1 that the CG might agree at the CG-7 meeting on September 16th.

1 Should it be the case, an updated version of the template in track changes mode will be made available on Circabc after the CG meeting.
Annex:

Updated version of the SPC template for single biocidal products
Summary of product characteristics for a biocidal product

[Product name(s)]

Product type(s) [X]

[Authorisation number]

[R4BP reference number]
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### 1. Administrative information

#### 1.1. Trade name(s) of the product

<table>
<thead>
<tr>
<th>Trade name(s)</th>
<th></th>
</tr>
</thead>
</table>

#### 1.2. Authorisation holder

<table>
<thead>
<tr>
<th>Name and address of the authorisation holder</th>
<th>Name</th>
<th>Address</th>
<th>Authorisation number</th>
<th>Suffixes to the authorisation number linked to trade names</th>
<th>R4BP reference number</th>
<th>Date of the authorisation</th>
<th>Expiry date of the authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 1.3. Manufacturer(s) of the product

<table>
<thead>
<tr>
<th>Name of manufacturer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Address of manufacturer</td>
<td></td>
</tr>
<tr>
<td>Location of manufacturing sites</td>
<td></td>
</tr>
</tbody>
</table>

#### 1.4. Manufacturer(s) of the active substance(s)

<table>
<thead>
<tr>
<th>Active substance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of manufacturer</td>
<td></td>
</tr>
<tr>
<td>Address of manufacturer</td>
<td></td>
</tr>
<tr>
<td>Location of manufacturing sites</td>
<td></td>
</tr>
</tbody>
</table>

### 2. Product composition and formulation

#### 2.1. Qualitative and quantitative information on the composition of the product

<table>
<thead>
<tr>
<th>Common name</th>
<th>IUPAC name</th>
<th>Function</th>
<th>CAS number</th>
<th>EC number</th>
<th>Content (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Active substance</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. In case the product would have more than one name, all names can be provided in this field.

2. Where relevant for the Member State delivering a national authorisation. Insert rows as necessary.
### 2.2. Type of formulation


### 3. Hazard and precautionary statements

**Hazard statements**

**Precautionary statements**

### 4. Authorised use(s)

#### 4.1. Use description

**Table 1. Use # 1 – name of the use**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Where relevant, an exact description of the authorised use</th>
<th>Target organism(s) (including development stage)</th>
<th>Field(s) of use</th>
<th>Application method(s)</th>
<th>Application rate(s) and frequency</th>
<th>Category(ies) of users</th>
<th>Pack sizes and packaging material</th>
</tr>
</thead>
</table>

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3 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

4 According to Regulation (EC) 1272/2008, or where relevant, Directive 1999/45/EC. This section shall only include precautionary statements triggered by the CLP legislation. In accordance with paragraph 8 of document CA-May13-Doc.5.4, a precautionary statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

5 Copy this section as many times as necessary (one table per use, together with the relevant instructions for use, associated risk mitigation measures and where relevant, other directions for use that are use-specific). It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a single biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.
4.1.1. Instructions for use

4.1.2 Associated risk mitigation measures

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

5. General directions for use

5.1. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

5.2. Instructions for safe disposal of the product and its packaging

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6 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

7 Directions for use under this section are valid for any authorised uses.
5.3. Conditions of storage and shelf-life of the product under normal conditions of storage

6. Other information