



**In Situ Generation of a biocidal product/substance**

**Application Form**

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| Please tick as appropriate | |
| * **Case Type 1 - generated by mixing 2+ precursor chemicals** |  |
| * **Case Type 2 - generated by 1+ biocidal precursor using a device** |  |
| * **Case Type 3 – coatings generating free radicals** |  |
| * **Case Type 4 - generated by a device/system using a commodity*[[1]](#footnote-1)* chemical or unmarketable pre-cursors** |  |

**Please revert to Page 17 for guidance to determine which case-type is relevant to your product**

*Application Check List – The application MUST include items 1-5 in word or pdf format. New customers MUST also include item 6. If any of these items are missing, the application will be rejected and sent back to applicant for re-submission.*

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| 1. Draft Irish label(s) (CLP/Article 69 of BPR compliant) |  |
| 1. REACH compliant Safety Data Sheet(s) for the active substance(s) |  |
| 1. REACH compliant Safety Data Sheet(s) for the product & precursor(s) |  |
| 1. REACH compliant Safety Data Sheet(s) for co-formulant(s) |  |
| 1. Letter(s) of Access or Supply to the active substance(s) on Article 95 |  |
| 1. Corporate Client System Form (new applicants/clients only) |  |

*The associated fee to be invoiced for this application is €300*

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| **Product Name** |  |
| **Active Substance(s)** |  |
| **Product type** |  |

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|  |  |  |
| Type Name |  | Date |

**Please fully complete all sections in this application form. An incomplete application form will result in your application being rejected.**

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| **Trivial Amendments Applications**  If this application is for a trivial amendment, please summarise the change(s) in the text box provided below. All amendments to the application form regarding the amendment requested must be in RED FONT.  **Summary of the Trivial Amendment:**  **Pesticide Control Division,**  **Department of Agriculture, Food and the Marine.**  Agriculture_MARK_MASTER_Std_Colour  S:\Pesticides\Biocides\Biocides webpage\images\biocides.jpg  ***Section 1: Notification Holder\* (person responsible for placing the product on the market)*** | | | | | |
| Company Name: | |  | | | |
| Address: | |  | | | |
| Company Tel: | |  | | Company email: |  |
| Company contact: | |  | | Contact Tel: |  |
| Contact email | |  | |  |  |
| DAFM Customer number (if available) | |  | | Purchase Order number (if available) |  |
| *\*If you are a new applicant/client with the Department of Agriculture, please also fill out the Corporate Customer System (CCS) form on the final page of this document.* | | | | | |
| ***Section 2: Product Information*** | | | | |
| Product name  (Trade name): | |  | | |
| Product-type(s): | |  | | |
| Product Function: | |  | | |
| Formulation type: | |  | | |

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| ***Section 3: Product Manufacturer*** | | | |
| Company Name: |  | | |
| Address: |  | | |
| Company Tel: |  | Company email: |  |
| Company contact: |  | Contact Tel: |  |
| Contact email: |  |  | |

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|  | | ***Section 4: Additional Product Information*** | | | | | | | | | | | | | | |
| Brief description of intended uses: | | |  |  | | | | | | | | | | | | |
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| For amateur use: | | | Yes | |  |  | No |  |  | For professional use: | Yes |  | No |  |  | |
|  | |  | | | | | | | | | | | | | | |
| For indoor use: | | | Yes | |  |  | No |  |  | For outdoor use: | Yes |  | No |  |  | |
|  | | |  | | | | | | | | | | | |  | |
| |  |  | | --- | --- | | If necessary please specify the use area further: | n/a | | | |  | | | | | | | | | | | |  | |
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| |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Is the AS/product made available on the market for sale and use as a;**   * “ready-to-use” product * “pre-cursors to allow end-user generate in-situ on site” (not for amateur use) | | | | | | | | | | | | | | Ready –to-use: | | Yes |  |  | No |  |  | In-situ by customer: | Yes |  | No |  |  | | | If generated in-situ, are the pre-cursors sold in a single pack or individually? | | | | | | | | | | | | | | Single pack: | | Yes |  |  | No |  |  | Individually: | Yes |  | No |  |  | |   ***Section 5: Labelling Information*** | | | | | | | | | | | | | | |
| Please attach to this completed application the draft product label for Ireland. It is important that the label is prepared in accordance with the classification, labelling and packaging provisions of Regulation (EC) 1272/2008 and Article 69 of the Biocidal Products Regulation EU 528/2012. | | | | | | | | | | | | | | |

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| ***Section 6: Packaging Informationmust be completed if applicable*** | | |
| **Pack type(s)** | **Packaging**  **material(s)** | **Pack**  **size(s)** |
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|  |  |  |
| *\*Insert additional rows if required* | | |

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| ***Section 7: Primary Distributor(s) & Marketing Company\**** | | | |
| **Distributor**  **Company Name (1):** |  | | |
| Address: |  | | |
| Company Tel: |  |  |  |
|  |  | | |
| **Company Name (2):** |  | | |
| Address: |  | | |
| Company Tel: |  | Company email: |  |
|  |  | | |

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| **Marketing Company**  **Company Name:** |  | | |
| Address: |  | | |
| Company Tel: |  | Company email: |  |

*\*Insert lines for each distributor, if required*

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| ***Section 8: Account Holder (company responsible for paying the notification and annual fees)\**** | | | |
| Company Name: | |  | | |
| Address: | |  | | |
| Company Tel: | |  | Company email: |  |
| Company contact: | |  | Contact Tel: |  |
| Contact email | |  |  |  |
| DAFM Customer number | |  | Purchase Order number |  |

*\* If you are a new applicant/client with the Department of Agriculture, please also fill out the Corporate Customer System (CCS) form on the final page of this document.*

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| ***Section 9: Art 95 listed Active Substance Manufacturer(s)\*- not require for Case-type 4*** | | | | | | |
| **Active Substance (1):** |  | |  | |  | |
| Nano Material: | Yes No | | |  | | |  |
| Company name: |  | | | | | |
| Address: |  | | | | | |
| Company Tel: |  | Company email: | | | |  |
|  |  | | | | | |
| *\* Insert lines for each additional active substance, if required* | | | | | | |

***Section 10A: Product Specification for devices***

***Is your device case-type 2 or case-type 4: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

Please complete below if your product/substance is generated through a **device/system**

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| --- |
| *Technical details of device or in situ generation (e.g. parameters to generate active substance, details of device settings that generate the required active substance(s) concentrations)* |
| **Parameters that influence the output of the device, add/delete parameters as necessary.**     |  |  | | --- | --- | | **Parameter** | **Settings** | | Flow rate |  | | Current |  | | Temperature |  | | pH |  | | Humidity |  | | Variable composition of air and water used |  | |  |  | |  |  |   **Other relevant operating conditions required for the proper functioning of the device**   |  |  | | --- | --- | | **Parameter** | **Specification** | | Water hardness |  | | Organic matter content |  | |  |  | |  |  | |

***Section 10B: Operating range of AS/BP generated in-situ***

**Please complete the following in relation to in situ generated products generated from devices using precursor chemicals**

For Case-type 2, 3 and 4 ONLY - A biocidal product generated in-situ can generate a range of concentrations. These concentrations are equivalent to application rates for standard biocidal products, and therefore a single application for a single product will cover the application rates generated by the device.

Active substance 1

|  |  |
| --- | --- |
| Please identify the **minimum** active substance content generated in situ: |  |
| Please identify the **maximum** active substance content generated in situ: |  |

Active substance 2\*

|  |  |
| --- | --- |
| Please identify the **minimum** active substance content generated in situ |  |
| Please identify the **maximum** active substance content generated in situ |  |

*\* Insert lines for each additional active substance, if required*

***Section 11A: Case* Type 1** - generated by mixing 2+ precursor chemicals (Refer to Page 16 and 18 for more information)

***Precursor 1 Product Specification. Is this a Biocidal pre-cursor Yes/No \_\_\_\_* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

***Precursor 2 Product Specification (if applicable). Is this a Biocidal pre-cursor Yes/No \_\_\_* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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|  |  |  |  |  |  |  |  |  |
| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

*\* Where the application is for a biocidal product generated in situ from 2 or more precursor products, please add an additional specification table for each precursor product*

***Final Specification of AS generated in-situ*  Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product type** | **Identity of Active Substance generated in-situ** | **CAS No** | **Purity of active substance (g/kg)** | **Content of ‘pure active substance’ in the product (as a quantity) units = g/kg, g/L etc** | **Content of active substance in the product (as a %) units = w/w OR %v/v** | **Manufacturer of AS** | **SDS Attached Yes/No** | **LoA Attached Yes/No** |
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| **Identity of impurities (other than AS) generated in-situ** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** |  |  |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

**Section 11B: Case Type 2 –** generated by 1+ biocidal precursor using a device. Section 10A & 10B must be completed. (Refer to Page 17 and 18 for more information)

***Precursor 1 Product Specification* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |
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| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

***Precursor 2 Product Specification (if applicable)* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

*\* Where the application is for a biocidal product generated in situ from 2 or more precursor products, please add an additional specification table for each precursor product*

***Final Specification of AS generated in-situ*  Name:\_\_\_\_­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product type** | **Identity of Active Substance generated in-situ** | **CAS No** | **Purity of active substance (g/kg)** | **Content of ‘pure active substance’ in the product (as a quantity) units = g/kg, g/L etc** | **Content of active substance in the product (as a %) units = w/w OR %v/v** | **Manufacturer of AS** | **SDS Attached Yes/No** | **LoA Attached Yes/No** |
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| **Identity of impurities (other than AS) generated in-situ** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

**Section 11C: Case Type 3 *–*** generated in situ based on a coating that was exposed to UV light generating free radicals. Section 10A & 10B must be completed. (Refer to Page 17 and 18 for more information)

***Precursor 1 Product Specification* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

***Precursor 2 Product Specification (if applicable)* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

*\* Where the application is for a biocidal product generated in situ from 2 or more precursor products, please add an additional specification table for each precursor product*

***Final Specification of AS generated in-situ* Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product type** | **Identity of Active Substance generated in-situ** | **CAS No** | **Purity of active substance (g/kg)** | **Content of ‘pure active substance’ in the product (as a quantity) units = g/kg, g/L etc** | **Content of active substance in the product (as a %) units = w/w OR %v/v** | **Manufacturer of AS** | **SDS Attached Yes/No** | **LoA Attached Yes/No** |
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| **Identity of impurities (other than AS) generated in-situ** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

**Section 11D: Case Type 4 –** generated by a device/system using a commodity chemical or unmarketable pre-cursors. Section 10A & 10B must be completed. (Refer to Page 17 and 19 for more information)

***Precursor 1 Product Specification – This is not a biocidal pre-cursor* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

***Precursor 2 Product Specification (if applicable)* Product Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Identity of Co-formulants in the pre-cursor product** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
|  |  |  |  |  |  |  |  |  |
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| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

*\* Where the application is for a biocidal product generated in situ from 2 or more precursor products, please add an additional specification table for each precursor product*

***Final Specification of AS generated in-situ* Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product type** | **Identity of Active Substance generated in-situ** | **CAS No** | **Purity of active substance (g/kg)** | **Content of ‘active substance’ in the product (as a quantity) units = g/kg, g/L etc** | **Content of active substance in the product (as a %) units = w/w OR %v/v** | **Manufacturer of AS** | **SDS Attached Yes/No** | **LoA Attached Yes/No** |
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| **Identity of impurities (other than AS) generated in-situ** | **Trade name (if applicable)** | **CAS No** | **Function of the co-formulant** | **Content of co-formulant in the product (as a quantity) units = g/kg, g/L etc** | **Content of co-formulant in the product (as a %) units = w/w OR %v/v** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant** |
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|  |  |  |  |  |  |  |  |  |
| **Total (4 decimal places max)** |  |  |  |  |  |  |  |  |

*NB: the total quantities for the pink and green columns must add up to 1000 and 100, respectively.*

**Annex 1 - Completeness check**

1. **Are sections 1 – 11 fully complete?**
2. **Is the information in this application form identical to the information on the draft product label, specifically:**
   1. **Product Name**
   2. **Name of Active Substance(s)**
   3. **Active Substance(s) Content**
   4. **Product type**
3. **Is the product specification in section 10 correct and the units identified?**
   1. **The Red column adds up to 1000**
   2. **The Green column add up to 100**

**Incomplete/incorrect application forms may be rejected as they lead to longer processing times, which results in a longer application queue. The quality of your application has a direct effect on the numbers of applications we can process.**

**Applicants will be asked to submit additional information within a specific time period, if this is not received on time the application will be rejected. Please note no reminder emails will be sent.**

**CCS COMPANY REGISTRATION FORM (New Customer) CCS CR/CY**

*Please complete this form fully and return to the Business Area which issued it to you. Please submit bank details if you intend to receive payments from the Department of Agriculture, Food and the Marine (DAFM)*

|  |  |
| --- | --- |
| \* VAT No: And/Or \* COMPANY IDENTIFIER:  \* COMPANY NAME: | |
| TRADING NAME: | |
| \* NATIONALITY: \* LANGUAGE | |
| CONTACT NAME: | |
| \* POSTAL ADDRESS  EIRCODE: | |
| BUSINESS ADDRESS (if different)  EIRCODE: | |
| TELEPHONE: \*MOBILE:  \* EMAIL ADDRESS FAX NO: | |
| TAX CLEARANCE DETAILS  ACCESS CODE: TRN: | |
| **Withholding Tax □ *(tick box)***  **If your business provides a Professional Service, it is subject to Professional Services Withholding Tax. (PSWT)** (see [www.revenue.ie](http://www.revenue.ie) for more information)  **Tax Type: Corporation Tax ⬜ Income Tax ⬜** | **Relevant Contract Tax □ *(tick box)***  **If your business relates to Construction, Forestry or Meat Processing Industries, payments are subject to Relevant Contracts Tax. (RCT)** (see [www.revenue.ie](http://www.revenue.ie) for more information) |
| Signature: Date: | |
| *Any fields denoted by an asterisk are mandatory and must be completed* | |
| **Return to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Business Area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **For Official Use Only – To be completed by DAFM Business Area**  **Select Farmer Status (for statistical purposes) Full Time:** □ **Part time:** □ **Non Farmer** □ **X**  **Business Role: \_\_\_Supplier\_\_\_\_\_\_ Business ID: \_\_\_\_\_\_\_\_\_\_\_\_\_ Start date: \_\_\_\_1.1.21\_\_**  **Is this Company to be set up as** Accounts Payable⬜ **OR** Accounts Receivable ⬜ X  (DAFM pays customer) (Customer pays DAFM)  **Tax Clearance details: Access Code and TRN verified? Yes** □ **No** □  **Liability for RCT established? Yes** □ **No** □  **Liability for PSWT established?: Yes** □ **No** □  **Prepared by: Approved by:**  **Business Area: Business Area:**  **Grade: Grade:**  **Phone No : Phone No:**  **Date:** **Date:** | |

**Annex II – Text from CA-July19-Doc.4.1-Final**

**Management of product authorisation for in situ cases**

* 1. **In situ generated active substance[[2]](#footnote-2)** in this document means the AS generated in situ, as per the definitions in Articles 3(1)(c) of the BPR and 3(1) of REACH (i.e. including any impurity deriving from the in situ generation process used, such as reaction by-product, unreacted precursors, etc. Output = in situ generated active substance).
  2. **In situ biocidal products falling under the first indent of the definition of a biocidal product**: ***any substance or mixture, in the form in which it is supplied to the user,*** *consisting of, containing or* ***generating one or more active substances****, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action* (emphasis added).
  3. **In situ biocidal products falling under the second indent of the definition of a biocidal product):** ***any substance or mixture, generated from substances or mixtures*** *which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action* (emphasis added).
  4. **In situ generation** means the reaction of one or more precursors to generate the AS at the place of use for direct application without isolation, purification, storage or transport[[3]](#footnote-3).
  5. **In situ generation process** means the whole process leading to the in situ generation, including those parameters that may affect the chemical reactions and impact the qualitative and quantitative composition of the formulations containing the precursors (e.g. including impurities, etc…) and/or concentration of the in situ AS generated.
  6. **Precursor** is a substance or mixture (formulation containing the precursor(s)) as supplied to the user, from which an active substance (including free radicals) is generated *in situ*.
  7. **'Device'** designates the equipment or technology used in the in situ generation process[[4]](#footnote-4). This device may enable the users to set the values of the parameters that may affect the chemical reactions and the composition of the AS generated in situ. Devices are not authorised.
  8. **In situ generation system ('IGS')** means a system generating an in situ AS that covers the combination of:
     + The [formulation(s) containing the] precursor(s), which have to meet the conditions specified in the AS approval,
     + the relevant parameters affecting the generation process, including those to be applied in the relevant devices (if any) and,
     + the AS generated in situ which has to meet any condition specified in the AS approval and which includes any impurities, such as reaction by-products and/or any unreacted precursors, (the so-called “output” of the IGS).

For the purpose of the authorisation of biocidal products for in situ generated ASs under either the first or the second indent (as defined above), the terms and conditions of the product authorisation and the SPC should specify all the relevant elements integrating the IGS that are involved in the generation of the in situ generated AS.

***3.1 Case-types of in situ biocidal products***

1. Document “*CA-March15-Doc.5.1-Final revised on 23 June 2015*” clarifies that:
   1. Under the first indent of the definition of biocidal product under article 3 (1) (a), the [formulation containing] the precursor will be authorised as biocidal product
   2. Under the second indent of the definition of biocidal product under article 3 (1) (b), the active substance generated in situ will be authorised as biocidal product
2. When authorising in situ generated biocidal products, the following case-types[[5]](#footnote-5) could be considered (see Annex I):
   1. ***In situ biocidal products falling under the first indent of the definition:***
      * Case-type 1: the in situ biocidal products involve an IGS only based on the mixing of two or more [formulations containing the] precursors without using a device (e.g. active bromine generated from sodium bromide and sodium hypochlorite)[[6]](#footnote-6);
      * Case-type 2: the in situ biocidal products involve an IGS based on one or more [formulations containing the] precursors used in a device (e.g. active bromine generated from sodium bromide by electrolysis);
      * Case-type 3: the in situ biocidal products involve an IGS based on a coating that when exposed to light generates free radicals;
   2. ***In situ biocidal products falling under the second indent of the definition:***
      * Case-type 4: the in situ biocidal products involve an IGS generating an in situ AS from a [formulation containing the] precursor not placed on the market for biocidal purposes and using a device[[7]](#footnote-7) (e.g. “ozone” generated from ambient air by an ozone generator or “active chlorine” generated from salt "not supplied for biocidal purposes[[8]](#footnote-8)" by electrolysis through a device).
3. ***Case-type 1 with no device*** (see Annex III):

The authorised product is either a single [formulation containing the] precursor or a combination of 2 formulations containing the precursors marketed in a single packaging. In case a combination of 2 (or more) [formulations containing the] precursors are marketed in a single packaging, only one authorisation is needed.

A specified variation in the composition of the single formulation containing the precursor can establish a BPF.

A specified variation in the composition of the formulations containing the two (or more) precursors can establish a BPF.

1. ***Case-type 2 using precursors marketed with biocidal purposes[[9]](#footnote-9) and a device***

Where the [formulation containing the] precursor(s) is the biocidal product (case-type 2), an application can be made for a single BP. The dilution made with the precursor and the settings of the device can lead to a range of in use concentration of the in situ AS (e.g. X-Y%). The actual concentration of the active substance generated in situ will depend on parameters like the composition of the incoming water (temperature, pH, hardness, soiling, etc.) or air and the settings of the device. Variation in the generated AS concentration is considered as in use concentration and is allowed when authorising case-type 2 IGS as a single BP.

An application for a BPF can be made in case similar products with a specified variation in the formulation containing the precursor(s) will be used to generate the in situ AS.

1. ***Case-type 3 - coating generating free radicals:***

Each coating (the biocidal product) will have its own composition and as such, it can be authorised as a single biocidal product with different in use concentrations of the free radicals.

Several individual products (coatings) with a specified variation in their composition can be combined in a BPF provided that the conditions in Article 3(1)(s) of the BPR are met.

1. ***Case-types 4 using commodity[[10]](#footnote-10)chemical not marketed for biocidal purposes or unmarketable precursors and a device***

Where the in situ generated AS is the biocidal product (case-type 4), this AS can be authorised as a single BP and have a concentration range depending on device settings, flow, temperature, the distance from the generator, etc. This range is connected to the specific way the AS is generated (e.g. to (a) specific device(s) or technology). No ‘specified variations’ can be determined by the applicant for it to be considered as a ‘group of products’ as the final composition depends on environmental conditions and device settings and there is no intention to have a group of different products with similar uses.

Since the in situ generated AS is authorised, one or more devices could generate the same product (AS range) and could be listed in the use of the product (see section 4 below).

An application for a BPF can be made combining several BPs provided that the conditions of article 3(1)(s) and the specifications of the approval are respected.

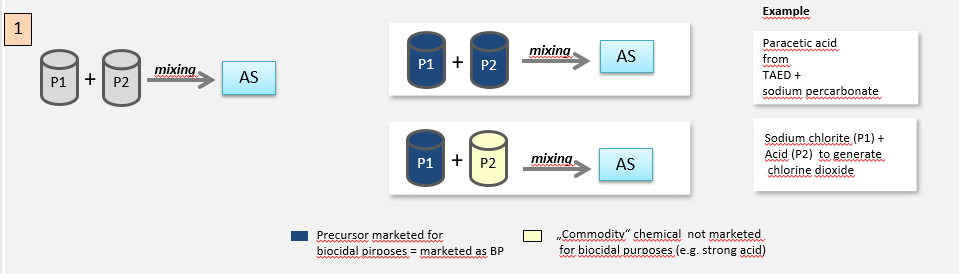
1. Where relevant, following information is required in the context of in situ generation:
   1. The reference specifications or reference to the relevant standards and corresponding standard (if applicable) of the precursors that are used in the IGS.
   2. A detailed description of the parameters that influence the “output” of the device (e.g. temperature, pH, humidity, variable composition of air and water used, etc.)[[11]](#footnote-11) and of any other relevant operating condition (e.g. water hardness or organic matter content) required for a proper functioning of the IGS involving the in the in situ biocidal product.
   3. The relevant analytical (e.g. measurements), technical (e.g. alarm) or procedural (e.g. maintenance) instructions aiming at ensuring that the IGS involving the in situ biocidal products will be properly used and that the in situ AS concentration will remain within the limits of the authorisation. This information is also important for the user and enforcement authorities in order to enable them to verify that the output of the device complies with the authorisation.

**Annex I**

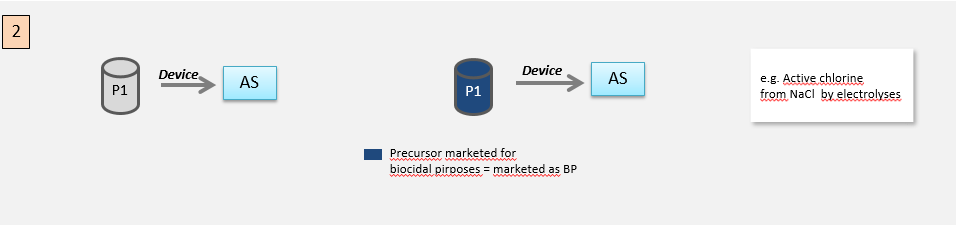
**Case-types for in situ biocidal products**

1. In situ products falling under the first indent of the definition:

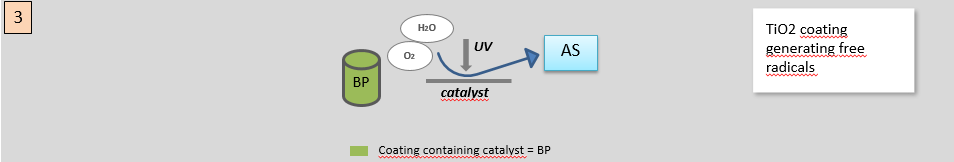
**Case-type 1**: the in situ biocidal products involve an IGS based on the mixing of two or more [formulations containing the] precursors.



**Case-type 2**: the in situ biocidal products involve an IGS based on one or more [formulations containing the] precursors used in a device.

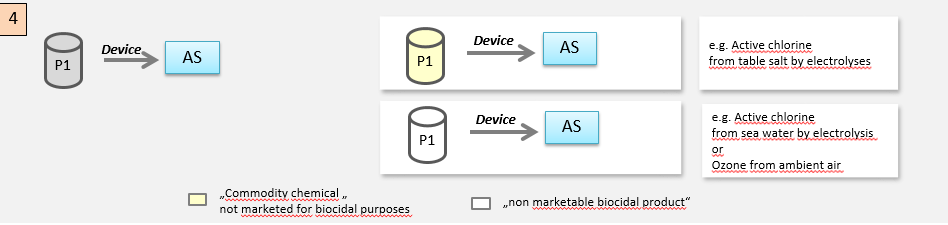


**Case-type 3**: the in situ biocidal products involve an IGS based on a coating that when exposed to ultraviolet light generates free radicals out of air and/or water.



2. In situ products falling under the second indent of the definition:

**Case-type 4**: the in situ biocidal products involve an IGS generating the in situ AS from [formulations containing the] precursors that are not placed on the market for biocidal purposes and using a device.



1. Well-known and widely used REACH registered industrial chemical not marketed for biocidal purposes [↑](#footnote-ref-1)
2. The concept of “technical active substance” in the ECHA’s recommendation, when updated, will be aligned to this document (i.e. in line with the legal definition of “active substance” in the BPR and of a “substance” under REACH). [↑](#footnote-ref-2)
3. An 'in situ generation' situation is not applicable when the active substance generated is bottled prior to its placing on the market. [↑](#footnote-ref-3)
4. Except dosing systems only used to control the ratio of precursors [↑](#footnote-ref-4)
5. These case-types should not be considered as an exhaustive list. [↑](#footnote-ref-5)
6. See section II.1 in Annex II as a particular case of case-type 1. [↑](#footnote-ref-6)
7. Based on current knowledge, there is no possibility to generate an in situ AS without a device for case-type 4 [↑](#footnote-ref-7)
8. See section II.2 in Annex II as a particular case of case-type 1. [↑](#footnote-ref-8)
9. CA-May15 doc5.a (precursors placed on the market for biocidal purposes) [↑](#footnote-ref-9)
10. Well-known and widely used REACH registered industrial chemical not marketed for biocidal purposes [↑](#footnote-ref-10)
11. Any on-site variation of these parameters that might result in a concentration and quality of the in situ AS beyond the authorised concentration and quality is not allowed. [↑](#footnote-ref-11)