**Application Form for Biocidal Product Notification/Trivial Amendment**

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

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

|  |
| --- |
| Please tick one of the following boxes as appropriate for the application. |
| * **Biocidal Product Notification**
 |  |
| * **Trivial Amendment**
 |  |
| * **Biocidal product that is a treated article that has a primary biocidal function**
 |  |

The associated fee to be invoiced for this application is **€300. Application(s) will not be processed until the invoice is paid in full.**

**Application Check List**

The application MUST include items 1-6 listed below. New customers MUST also include item 7.

If any of these items are missing, the application may be rejected and sent back to applicant for re-submission.

|  |  |
| --- | --- |
|  |  |
| 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
 |  |
| 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. Toxicology Report (If applicable)
 |  |
| 1. Corporate Client System Form (New applicants/clients only)
 |  |

**All supporting documentation (Items 1-7) must be in English**.

**Please Read** – page 11-12 below for common issues before completing application form

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Print Name  |  | Date |

**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.**





|  |
| --- |
| ***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](https://www.pcs.agriculture.gov.ie/media/pesticides/content/biocides/GCPF%20Formulation%20Codes.pdf):*(AL, SL, etc.)* |  |
|  |  |
| UFI Code (if known): |  |

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

|  |
| --- |
| ***Section 4: Additional Product Information***(Each PT listed in section 2 must be described, 1800 Characters Max) |
| Brief description of intended uses  |  |
|  |
|  |
|  |
| For amateur use: | Yes |  | No |  |  | For professional use: | Yes |  | No |  |  |
|  |
| For indoor use: | Yes |  | No |  |  | For outdoor use: | Yes |  | No |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| For Fogging/Misting Use^: | Yes |  | No |  |  | Toxicology report attached: | Yes |  | No |  |  |
|  | Please note that if you answered ‘**Yes’** above, and the product is intended to be applied via a fog or a mist, a ^[toxicology report](https://www.pcs.agriculture.gov.ie/media/pesticides/content/biocides/disinfectantsandsanitisersforcovid-19/FoggingMisting250620.pdf) **must** be submitted for a risk assessment to be carried out for that use. |
| If necessary, please specify the use area further: |  |
|  |

|  |
| --- |
| ***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. See final page for specific labelling requirements which must be on the final label submitted to complete the notification. |

|  |
| --- |
| ***Section 6: Packaging Information\**** |
| **Pack type(s)** | **Packaging** **material(s)** | **Pack** **size(s)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| *\*Insert additional rows if required* |

|  |
| --- |
| ***Section 7a: Primary Distributor(s)***  |
| **Distributor****Company Name (1):** |  |
| Address: |  |
| Company Tel: |  | Company email: |  |
|  |  |
| **Company Name (2):** |  |
| Address: |  |
| Company Tel: |  | Company email: |  |
| *\*Insert lines for each distributor, if required* |  |

***Section 7b: Marketing Company***

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

|  |
| --- |
| ***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 the company named here is 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 9: Active Substance Manufacturer(s)\**** |
| **Active Substance (1):** |  |  |  |
| Nano Material:  | Yes No |  |  |
| Company name: |  |
| Address: |  |
| Company Tel: |  | Company email: |  |
|  |  |
| **Active Substance (2):** |  |  |  |
| Nano Material:  | Yes No |
| Company name: |  |
| Address: |  |
| Company Tel: |  | Company email: |  |
|  |  |
| **Active Substance (3):** |  |  |  |
| Nano Material:  | Yes No |
| Company name: |  |
| Address: |  |
| Company Tel: |  | Company email: |  |
|  |

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

***Section 10: Product Specification***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Is your product a wipe:  | Yes |  | No |  |  |

If yes, please complete

|  |  |
| --- | --- |
| Wipe Material |  |
| Weight of wipe |  |

***Section 10: Product Specification continued. \****

***Please specify units below in the content of “Active Substance” (previously known as technical content) columns in red and green***

***For information on using the correct units, please refer to the table on page 10 of this document - ‘Common Issues Identified’.***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product type** **(PT)** | **Identity of Active Substance in the product***(as Listed on the* [*review programme*](https://echa.europa.eu/information-on-chemicals/biocidal-active-substances)**)** | **CAS No**  | **Purity of active substance (g/kg)** | **Content of “active substance” in the product**  | **Units g/kg, g/L etc.**  | **Content of “active substance” in the product (as a %) units = w/w OR %v/v**  | **Units****%w/w,****%w/v,****Etc.** | **Manufacturer of AS**  | **SDS Attached Yes/No** | **Letter of access****(LoA) or supply Attached Yes/No** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|   |  |   |   |   |  |  |  |  |   |   |
|   |  |   |   |   |  |  |  |  |   |   |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Identity of Co-formulants (other than AS) in the product**  | **Trade name (if applicable)**  | **CAS No**  | **Function of the co-formulant**  | **Content of co-formulant in the product**  | **Units g/kg, g/L etc.**  | **Content of co-formulant in the product (as a %) units = w/w OR %v/v**  | **Units****%w/w,****%w/v,****Etc.** | **Substance of concern Yes/No** | **SDS Attached Yes/No** | **Manufacturer of the co-formulant**  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |   |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |   |   |

*NB: the total quantities for the pink and green columns must add up to 1000.00g/Kg and 100.00%, respectively.*

*\* Where the application is for a biocidal product generated in situ from 2 or more precursor products, a separate* [*application form*](https://www.pcs.agriculture.gov.ie/media/pesticides/content/biocides/biocidalproducts/In-situ%20Application%20form%20for%20Biocidal%20Product%20Notifications%20240524.docx) *is required.*

**Completeness check**

1. **Are sections 1 – 10 fully complete?**
2. **Are all supporting documents included?**

|  |  |
| --- | --- |
|  |  |
| 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**
 |  |
| 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. **Toxicology report (If applicable)**
 |  |
| 1. **Corporate Client System Form (new applicants/clients only)**
 |  |

1. **Is the information in this application form consistent with the draft product label, specifically:**
	1. **Product Name**
	2. **Name of Active Substance(s)**
	3. **Active Substance(s) Content**
	4. **Product type**
2. **Is the product specification in section 10 correct and the units identified?**
	1. **The Red column adds up to 1000.00**
	2. **The Green column add up to 100.00%**

**Applications can only be accepted if section 10 is completed correctly**

**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.**

**In order to complete the product notification, applicants may be required to submit additional information/documentation within a specific time period. Please note that no reminder emails will be sent.**

**If no information/documentation is received within the specific time period, the application will be rejected.**

**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 DETAILSACCESS 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:**  |

**Common issues identified**

* The notified product can ONLY be used as described on the product label; all other uses are considered illegal uses.
* Biocidal products cannot be applied in the presence of food or animals or people, if a product is applied to disinfect for example to a mushroom tunnel or a hatchery or hospital room, the food/animals/people, should be removed if there is any risk of contact with the product. This is particularly important for products used with foggers/misting as it is not possible to prevent contact with the food/animal/person.

The only exception to this rule is for PT 3 & PT 19 products which can be directly applied to animals and PT 1 which can be directly applied to humans and the risk assessments take this into account.

* The Active Substance (AS) **must** be presented on the label **exactly as listed on the register**. This is only as described in the review programme and can be found on the ECHA website, link in table above. We can only accept the “common name” and no other format. Please be aware that naming of AS changes as a result of evaluation of the AS and the products. If the name of the AS changes following an approval decision or for any other reason, you MUST update your label/SDS to reflect the change in the name which will appear on the register following the change. If a change takes place and the label is not updated, your product will be removed from sale if identified on sale during enforcement activities if the name on the label does not match the name on the register. If it your responsibility to keep up to date with the review programme and know the status of the substances in your products at all times.
* The trade name/product name of the biocidal product listed on the register, as presented on the application form must read identical to the product label. The final product label must read top to bottom uninterrupted. Product names can differ by just one character so it **must** be extremely clear that the name on the label is the same as the name on the register, the tradename on the product label should not be disrupted with marketing claims for example. The marketing claims need to be moved to a different area on the label, or the marketing claims need to form part of the trade name if you do not wish to move them.
* All Product Types (PTs) **must** be described on the product label and include instructions for use for **each of those PT’s**. If the instructions are not on the label, the PT should be removed from the application form.
* The units used on the label must reflect the units on the Register. You can choose one of the following four ways to present your product on your label and the register. There is no opportunity to select from more than one row, for e.g., g/kg on register and %v/v on label.

|  |  |  |
| --- | --- | --- |
|  | Units entered on the PRS | Automatically converted to below units on PRS |
| 1 | g/kg | %w/w |
| 2 | g/L | %w/v |
| 3 | mL/L | %v/v |
| 4 | mL/kg | %v/w |

* If your product is a wipe, the wipe itself does not need to be included in the table in section 10. The table should only incorporate the liquids that are used to impregnate the wipes.
* Letters of Access/Supply. An official LoA must be submitted for each AS in the product. Alternatively, a Letter of Supply (LoS) will suffice (Only if submitted before the Date of Approval, after the date of approval, we must receive a LoA). The LoS must be accompanied with a recent invoice (within 12 months of the date of submission) to show proof of active purchase from the article 95 listed supplier.
* **Final Label Requirements,** all items below **must** be listed on the final label

|  |
| --- |
| 1. The CLP classification as prescribed in section 2.2 of the product SDS. This should be included in a separate text box with pictograms, hazard statements and precautionary statements.
2. The **PCS\* No. xxxxxx** must be placed in the bottom right-hand corner of the CLP information text box.
3. The exact name and content of the active substance(s*)* as Listed on the [review programme](https://echa.europa.eu/information-on-chemicals/biocidal-active-substances)
4. The notification holder company name and address
5. The relevant instructions for use of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each Product Type use provided for in the notification.
6. The type of formulation (e.g. AL other liquid to be applied undiluted)
7. The formulation batch number or designation and the expiry date relevant to normal conditions of storage.
8. Label version number.
9. The following statements must also be placed on the label:
* Use biocides safely and sustainably. This product should be used in accordance with the product label.
* Dispose of contents/container in accordance with local regulations
* Poisons Information: For information or to report a poisoning incident contact The National Poisons Information Centre (01 8092166)

10) A valid UFI code (See link to NPIC\* FAQ Document: [Poisons Centre - Ireland FAQ](https://poisons.ie/contact-us/)) (See link to other NPIC guidance also [Industry / Manufacturers - National Poisons Information Centre of Ireland](https://poisons.ie/industry-manufacturers/) , [Product Registration - National Poisons Information Centre of Ireland](https://poisons.ie/industry-manufacturers/product-registration/) )11) User category, where restricted to Professional Use only.12) If accompanied by a leaflet, the sentence ‘Read attached instructions before use’. 13) Please add the following information to the **label for concentrated products ONLY** which require dilution by the user (including pods and tablets).* Clear instructions for dilution and dilution rates. Lines on refill bottles are recommended for amateur products.
* The ‘shelf life’ of the diluted product, “The diluted product is only effective for x days/weeks and must be disposed of and refreshed after x days/weeks”.

**Note: Underlined items may be placed on the inside of the label where space is restricted.** |