

Application Form for Biocidal Product

Notification

Product Name
Active
Substance(s)
Product type

Biocidal product A
Active Substance 1; Active Substance 2
PT 2, 4

Commented [A1]: All relevant information in this form must be reflected on the label

Any future changes to a notified product that require a change to this applications form will require a trivial amendment to be submitted

Commented [A2]: This product name and active substance information must be the exact same as the details on the product label

Please fully complete all sections in this application form

*Application Check List – The application **MUST** include items 1-5. 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.*

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

<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input type="checkbox"/>

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

- **Biocidal product**
- **Biocidal product that are a treated article that has a primary biocidal function**

Please tick as appropriate

Applicant name

Print Name

01/05/2019

Date

Commented [A3]: No requirement to print and sign the form. Applications can be submitted in a word version for ease of transcription to the register. Please do not submit scanned forms

Department of Agriculture, Food and the Marine
Pesticide Control Division



An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine



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Section 1: Notification Holder* (person responsible for placing the product on the market)

Company Name: **A General Biocide Company**

Address: **General Road, Newtown, Co Dublin, Ireland Y12345**

Company Tel: **+ 353 1 234 5678** Company email: **queries@general.biocides.ie**

Company contact: **Mr Joe Bloggs** Contact Tel: **+ 353 1 234 5678**

Contact email: **Joe.Bloggs@general.biocides.ie**

DAFM Customer number (if available): **300012345** Purchase Order number (if available): **123456**

Commented [A4]: All section of the application form must be completed**Commented [A5]:** Found at the top of previous DAFM invoices (N/A for new application)

**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): **Biocidal product A**

Product-type(s): **PT 2, 4**

Product Function: **Sanitiser**

Formulation type: **Soluble concentrate (SL)**

Commented [A6]: Consult [ECHA website](#) for the list and description of product types**Commented [A7]:** Consult the [Formulation codes](#) document on the OECD website**Section 3: Product Manufacturer**

Company Name: **As Notification holder**

Address:

Company Tel: Company email:

Company contact: Contact Tel:

Contact email:

Section 4: Additional Product Information

Brief description of intended uses: **A sanitizer disinfectant for work surfaces, for the control of bacteria and viruses (including H2N1) used in hospitals, public areas and food industrial manufacturing sites.**

Commented [A8]: The brief description of intended uses should reflect all the Product Type identified in section 2. This text should be placed on the label to inform the end-user what areas the product can be used.

The text in this draft covers both PT2 and PT 4 use

For amateur use: Yes No For professional use: Yes No

For indoor use: Yes No For outdoor use: Yes No

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If necessary please specify the use area further:

n/a

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.

Section 6: Packaging Information*

Pack type(s)	Packaging material(s)	Pack size(s)
Plastic Bottle contained in a wall mounted dispenser	Bottle: LDPE, Wall Dispenser: PP	250ml, 500ml.
Plastic Bottle for desk use contained in a pump action dispenser	Bottle: LDPE Dispenser: PP	100ml, 200ml, 250ml.
Spray bottle	Bottle: PP	200ml

*Insert additional rows if required

Section 7: Primary Distributor(s) & Marketing Company*

Distributor Company Name (1): Distributor IE

Address: New Industrial Estate, Newtown, Co Dublin.

Company Tel: +353 1 98765 4321 Company email: General@DistributorIE.ie

Company Name (2): n/a

Address:

Company Tel: _____ Company email: _____

Marketing Company Company Name: As distributor company

Address:

Company Tel: _____ Company email: _____

Commented [A9]: The final product label must include:

- The CLP classification as per section 2 of the Product SDS. This should be included in a separate text box with pictograms and hazard statements.
 - The PCS number (assigned to the product during processing) must be added to the bottom right hand corner of the CLP text box.
 - The exact name and content of each active substance
 - The name and address of the notification holder
 - The relevant instructions for use
 - The formulation type (consistent with section 2 of this form)
- The text 'Use biocides safely and sustainably. It is illegal to use this product for uses or in a manner other than prescribed on this label. Dispose of content/container in accordance with local regulations. Poisons Information: For information or to reports a poisoning incident contact the nations poisons Information Centre (01 8092166).'

Commented [A10]: Child proof fastening must be used on all amateur product classified as corrosive.

**Insert lines for each distributor, if required*

Section 8: Account Holder (company responsible for paying the notification and annual fees)*

Company Name: As Notification holder

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.*

Section 9: Active Substance Manufacturer(s)***Active Substance (1):** Active substance 1Nano Material: Yes No Company name: A chemical companyAddress: New Road, Oldtown, Co Cork.Company Tel: +353 21 456789 123 Company email: sales@achemco.ie**Active Substance (2):** Active substance 2Nano Material: Yes No Company name: ACME Chemical CompanyAddress: Old Road, Newtown, London UKCompany Tel: +44 789 123 456 Company email: Sales@acmechemicalco.co.uk**Active Substance (3):** N/aNano 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	

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

Technical details of device or in situ generation (e.g. parameters to generate active substance)

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Section 10: Product Specification continued. *

Product type	Identity of <u>Active Substance</u> in the product	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	Letter of access (LoA) or supply Attached Yes/No
2, 4	AS 1	123-12-3	500 g/kg	200 g/kg	20.0 % w/w	A chemical company	yes	yes
2, 4	AS 2	456-45-6	1000 g/kg	11.48 g/kg	1.148 % w/w	ACME Chemical company	yes	yes

Commented [A11]: Purity must be a specific figure not a range. This can be obtained from the AS manufacturer

Commented [A12]: 'Active substance' content: the amount of active including impurities. This value **must** be on the product label

Identity of <u>Co-formulants</u> (other than AS) in the 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
Co formulant 1	na	789-78-9	Colour	2 g/kg	0.2 % w/w	no	no	X company
Co formulant 2	na	654-65-4	Solvent	786.52 g/kg	78.652 % w/w	yes	yes	Y company
Total				1000 g/kg	100 % w/w			

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

Commented [A13]: Applications can only be accepted if the red column adds up to 1000 and the green column adds up to 100.
Red: (200+11.48+2+786.52=1000)
Green: (20+1.148+0.2+78.652=100)

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Completeness check

Commented [A14]: Please review application form before submitting to DAFM

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

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.

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.