



# User Manual

# « Application Form Generator »

User Manual: « Application Form Generator »

Version 2\_A





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A. INTRODUCTION

# THE "**APPLICATION FORM GENERATOR**" SOFTWARE HAS TO BE INSTALLED LOCALLY ON YOUR PC.

That software will allow you to fill in the data required for your applications for authorisation concerning biocidal products (new application, renewal, extension, etc).

# 1. Useful information

There are "educational" help windows in each screen of the program. Those windows open by default but you can shut them if you don't need them.

💰 Application Form Generator v4 [I	Project Name: BiocideXX / Dossier Type: (B10m1) Nouvelle autorisation/identique Europe/même usage]	💶 🗗 🗙
File View Help		
ApplicationForm CTD Structure	Le demandeur	
🗂 Formulaire — 🗋 Le demandeur	Un peu d'explication	8
Le consultant     Le distributeur ou destinataire     Le distributeur ou destinataire     Le distributeur ou destinataire     Leicide     Lormposition     Caractérislques du biocide     Leiquetage     Etiquetage     Etiquetage     Liefucatif de l'utilisateur     L'efficacité du biocide	Dans cette fenétre, insérer les coordonnées du demandeur d'autorisation = responsable de la mise sur le marché en Belgiq Les éléments définis en vert sont ceux qui doivent être obligatoirement remplis. Le « n° BCE (banque carrefour des entreprises) » est obligatoire pour les sociétés dont le siège social est situé en Belgique Le « code langue » peut être donné à titre indicatif pour les sociétés belges. Si une personne de contact spécifique est responsable pour ce dossier, cliquer « oui » et insérer les coordonnées de la perso avec une adresse e-mail éventuelle qui pourra être utilisée pendant toute la procédure d'évaluation du dossier.	Cliquez ici pour fermer la fenêtre d'aide didactique
L'étude de résidu     Quantité biocide     Composants actifs	S'il n'y a pas de personne de contact, cliquer « non ».	
Biocide autorisé à l'étranger	BCE n°	
Formulaire, Le demandeurj	lings open by clicking the button on the right side of the scre	een.

The different headings close by clicking the <u>button</u> button on the right side of the screen.





To expand the tree structure, click 🔶 or double-click 👇 🗔 Le Biocide

🛃 Application Form Generator [Project Name: Produit / Dossier Type: B10m1]					
Le Biocide					

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This makes the different secondary headings appear on the screen.







### 2. How to add data to a table?

Application Form Generator v4 [P	roject Name: BiocideXX / D	ossier Type: (B10m1)	Nouvelle autorisation	/identique Europe/mé	me usage]				PX
File View Help									
ApplicationForm CTD Structure	Composition								
🗂 Formulaire	Un peu d'explication							*	-
- 🗋 Le demandeur								(2)	1
<ul> <li>Le consultant</li> <li>Le distributeur ou destinataire</li> </ul>	Analyse							8	
► C Le distributeur ou destinataire ► C Le biocide	Ajouter une attestation	d'analize confirmant	le teneur en compo	ante actife					
- Didentité du biocide	Ajouter une attestation	u analyse communan	re teneur en compos	anto actilo.					
Composition									
— 🗋 Caractéristiques du biocide	Un peu d'explication							*	R.
<ul> <li>Application du Biocide</li> <li>Etiquetage</li> </ul>	F								
Eliquette du produit	Composants Actif (% m/m)							8	
- Sécurité de l'utilisateur	nom substance en angl	nom commercial	numéro CAS	teneur %age m/m	range	numéro CE		ID	
— 🗋 L'efficacité du biocide									
– 🗋 L'étude de résidu		Supprimer				Ajouter			
<ul> <li>Quantité biocide</li> <li>Composants actifs</li> </ul>		-							
Biocide autorisé à l'étranger	Un peu d'explication							*	ñ.
	2								
	Documents composants a	ctifs						8	
						1			
	Ajouter une fiche de donn	ees de securne MSDS p	our chaque composant.				<u>a</u>		
	Composants non-actifs (%	en (en)						(2)	í l
	Composants non-actirs (%							×	
	nom chimique en nom i	commercial numéro	CAS teneur %age n	i/m range	numéro CE	fonction dans le bi rei	marque	ID	
			-						
		Supprimer				Ajouter			

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To **add or remove an** (active or inactive) **ingredient** in one of the tables above, you just have to click the "Ajouter" (add)/ "Supprimer" (remove) button to add or remove a line in the table.

#### <u>Example</u>

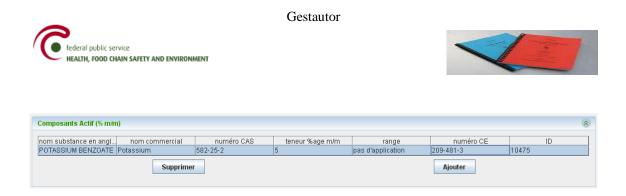
Composants Actif (% m/m)						
nom substance en angl	nom commercial	numéro CAS	teneur %age m/m	range	numéro CE	ID
POTASSIUM BENZOATE	Potassium	582-25-2	5	pas d'application	209-481-3	10475
Supprimer						

A new row appears in the "active substances" table where you can add data concerning a second active substance.

#### To add data to a column, click in the chosen cell.

	Composants Actif (% m/m)					8	
er.	nom substance en angl nom commercial	numéro CAS	teneur %age m/m	range	numéro CE	ID	
	Supprimer				Ajouter		

Composants Actif (% m/m)					۲
nom substance en anglais c	nom commercial	numéro CAS	teneur %age m/m	range	numéro CE
<u> </u>	Supprimer	1	1	Ajouter	
					6 - + + 1



Caution: If you do not add data to a table, there will always be a visible empty row. You cannot delete that empty row.

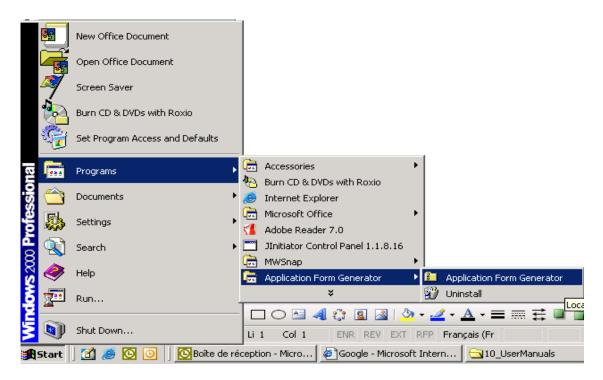




#### 3. How to start

1) Click on the "Start" button (in the lower left corner of your computer screen), then choose "Application Form Generator" in the list of programs;

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The program opens two different screens; the black screen must stay "OPEN". For more convenience, you may restore down the black screen and maximize the other one. (See arrow-pointer below)







🚰 Application Form Ge C:\ApplicationFor	merator rmGenerator≻java −jar ApplicationFormGenerator.jar	
Application Form	Generator	그凤즤
File CTD Structure ApplicationForm		

2) When the program is open, click on « file » and then « new »;

실 Applicatio	n Forn	n Generator	
File			
New	re		
Complete	prm		
Save			
Load			
	_		

3) In the window that appears, (see below)

- a) Choose the <u>language</u> of the application that will be submitted (French or Dutch). The language choice for the application is important because the chosen language will be used in all mail addressed to applicant as well as in the authorisation for the concerned product;
- b) Enter the <u>name</u> of the project, e.g. the trade name of the product for which an application for authorisation is submitted;
- c) Check if the <u>active substance(s)</u> in the submitted product is (are) already authorised in a biocidal product in Belgium. You can check this through the following link "recherche substances actives autorisées" (search authorized active substances). **!!Caution!!:** You cannot search these substances if you are not connected to the internet.
- d) If the <u>active substance(s)</u> is (are) already authorised in Belgium, click "Oui" (yes). If the <u>active substance(s)</u> is (are) not yet authorised in Belgium, click "Non" "no");
- e) Choose the <u>type of file</u> to be submitted in the scroll menu. If you want more details on the possible choices, click on the question mark (?);





f) Click **OK** to generate the electronic form and begin completing the spaces on the form and adding the required files.

New	×					
Image: FR One of the series						
Nom du Project: biocide						
Substance active déjà authorisée en Belgique						
Nouvelle autorisation/identique Europe/même usa 💌 🤉						
Ok Cancel						
Recherche substances actives authorisées (internet link)						

The above screen is the one where you will start entering the information required for your application for authorisation.

As you can see, you have to complete different headings!

According to the application type (see window below), some of those headings do not appear in the electronic application form as they are not necessary for that kind of application.

Please note that the green zones are <u>mandatory</u> in each form.





ApplicationForm CTD Structure	Le demandeur	
Formulaire	Un peu d'explication Dans cette fenêtre, insérer les coordonnées du demandeur d'autorisation = responsable de la mise sur le marché en Belgique. Les étéments définis en vert sont ceux qui doivent être obligatoirement remplis. Le « n° BCE (banque carrefour des entreprises) » est obligatoire pour les sociétés dont le siège social est situé en Belgique. Le « code langue » peut être donné à titre indicatif pour les sociétés belges.	۲
Etiquetage     Etiquetage     Sécurité de l'utilisateur     L'efficacité du biocide     L'éfficacité du biocide     Quantité biocide     Composants actifs	Si une personne de contact spécifique est responsable pour ce dossier, cliquer « oui » et insérer les coordonnées de la personne de contact avec une adresse e-mail éventuelle qui pourra être utilisée pendant toute la procédure d'évaluation du dossier. S'il n'y a pas de personne de contact, cliquer « non ».	
D Blocide autorisé à l'étranger	BCE n°	

You can make the file structure disappear at any moment under Application Form. To make those files disappear, you have to use the Hide Tree option in the menu. That option is useful if you cannot see the complete form on one screen. If the file structure disappears, there is more space for the form.

🛓	á Application Form Generator v1 [Project Name: BIOCIDE XYZ / Dossier Type: (B10m1) Nouvelle autorisation/identique Europe/même usage]						
File	View						
Ар	View tree CTD Structure	Le Demandeur					
F F	Hide tree	Un peu d'explication					
-   -	Le Consultant Le distributeur ou destinataire Le Biocide	BCE n°					
	] Biocide autorisé à l'étranger	Nom					
		Forme Juridique					

To make the file structure reappear, use View Tree option.







🙆 Application Form Generator v1 [Project Name: BIOCIDE XYZ / Dossier Type: (B10m1) Nouvelle autorisation/identique	Europe/même usage]
File View	
LeD View tree	
Hide tree	
Un peu a explication	
BCE n°	
Nom	
	I
Forme Juridique	

You can save the zones that have already been filled in at any moment by clicking on "file" and then "save".

🕌 Applicatio	orm Generator	_ 🗆 🗡
File		
New		
Complete	n	
Save		
Load <sup>K</sup>		

When all form zones have been filled in, you must check that all those zones have been filled in correctly by clicking on "**file, complete**".

If some zones have not been filled in correctly, error messages will appear on your screen.

Example of an error message: 'Completion Error List'

File View		
ApplicationForm CTD Structure Formulaire Le demandeur Le consultant Le distributeur ou destinataire	Formulaire	
- 📑 Le biocide	Completion Error List	
L Diocide autorisé à l'étranger	Erreurs dans ApplicationForm: Valeur non remplie. Nom > Formulaire > Le demandeur Valeur non remplie. Pays > Formulaire > Le distributeur ou destinataire > II y a un distributeur ou destinataire > Distributeur ou destinataire Le tableau Composants Actif (% m/m) n' est pas correctement rempli. > Formulaire > Le biocide > Composition Erreurs dans CTD Folder: Fichier avec syntax 'MSDS ** pas trouvé dans le répertoire /B10m1 compleet/CTDFolder/A9_safety/A91_MSDS/A911_MSDS_Biocidal Product/ Répertoire /B10m1 compleet/CTDFolder/A9_safety/A91_MSDS/A911_MSDS_Biocidal Product a moins que 2 fichiers	
	Cancel Complete	
	Cancel Complete	

This example contains the following errors:

The errors in the ApplicationForm correspond with the errors made in the form:





- The value for the zone 'Nom' (name) has not been not filled in. The place where this zone is situated is mentioned in the next line. In this example, the compulsory zone 'Name' has not been filled in under "Formulaire > le demandeur".
- The table 'Composants actifs (% m/m)' has not been filled in correctly. This table can be found under: "Formulaire > le biocide > Composition". You will receive this message if one or several columns of a compulsory table have not been filled in correctly.

The errors in the « CTD Folder » correspond with errors regarding the files that are missing or the files that do not start with the name that is required.

• The files of which the names start with MSDS have not been found in directory CTDFolder/A9\_Safety/A91\_MSDS/A911\_MSDS\_Biocidal Product. This directory must contain at least two of those files. The product's MSDS files are asked for in heading "Sécurité de l'utilisateur" (User safety). They must be added in both languages, that is in French **and** in Dutch.

It is not necessary to close the list of errors; you can move it on your screen and solve the problems one by one. When all problems have been solved, you have to click on 'Complete' until the message 'Complete successful' appears.

You can also close the list of errors and afterwards click on "file→complete".

📓 Application Form Generator v3 [P	roject Name: B10m1 complet / Dossier Type: B10m1]	×
File View		
ApplicationForm CTD Structure	Formulaire	
Product		
🗠 🚍 A2_admin		
🗢 🗂 A3_physical-chemical properties		
← 🛄 A4_efficacity		
- 🗋 A5_residu		
- 🗋 A7_toxsumm		
- 🗋 A8_ecotoxsumm		
🗠 🛄 A9_safety		
— 🗋 A10_other	Message 🛛 🔀	
	(i) Complete Successful	
	OK	

#### Once again, « green » zones are <u>mandatory</u>!!

At some stages, you have to add files. You can add those files by clicking on the window with a computer icon.

L'efficacité	۲
Ajouter les rapports de test d'efficacité.	





Through that window, you have access to the different documents saved on your PC.

<ul> <li>Caractèristiques du Bioci</li> <li>Application du Biocide</li> </ul>	Rechercher dans	: ICT-0090C (C:)			
<ul> <li>Etiquetage</li> <li>L'efficacité du biocide</li> <li>L'étude de résidu</li> <li>Quantité biocide</li> <li>Sécurité de l'utilisateur</li> <li>Composants actifs</li> <li>Biocide autorisé à l'étranger</li> </ul>	Recent Construction Desktop My Documents	MSSQL7 Cos-ng ORACLE OraHome_1 ORANT Profiel Program Files programs QUARANTINE SQLDeveloper	TEMP Temp lokaal Temp MeMU Eest TMPINST Uils Werkfolder WINNT TAUTOEXEC.BAT CONFIG.SYS	devicetable.log     d	:
	My Network Pl		voegen document.doc es fichiers	Ouvrir     Annuler	

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Click on the right file and then click on « Open » to add the file at the right place.

<u>Caution!</u> File name has to correspond exactly (correct capital letters and small letters are important!) to the defined norms. You can see those names in the "educational" help windows at every place you have to add files.

<u>Note</u>: only the <u>beginning</u> of file names, as mentioned in the help panels, is controlled. You can choose the <u>end</u> of the file names. Example: mentioning numbers by safety data sheet added, ... If you have to add several sheets, you must use that method because it is impossible to add a second file with the same name in the same folder.

! Before you begin completing the electronic form, file names to be added should be determined with the correct name on your computer to make things easier!

If you want to add several documents at a time in the same heading, you can use the « shift » or « control » buttons to select several documents at a time.

Added files do not appear in the electronic form but only via the 'CTD Structure'.

You have to go to 'CTD Structure' to see the documents that have been added to your application. You have no access to the content of the documents in Application Form Generator.



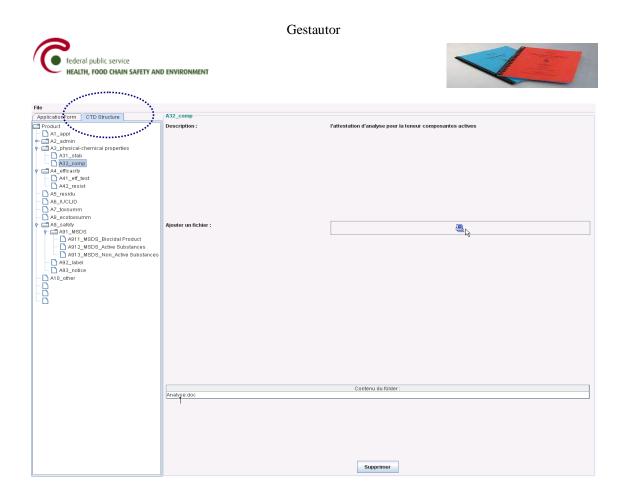


File		
ApplicationForm CTD Structure	A32_comp	
Product	Description :	l'attestation d'analyse pour la teneur composantes actives
A1_appl		
← 📑 A2_admin		
A3_physical-chemical properties		
A31_stab		
- 🗋 A32_comp 🖕		
🕈 🗂 A4_efficacity		
- 🗋 A41_eff_test 🔹		
A42_resist		
— 🗋 A5_residu		
- 🗋 A6_IUCLID		
- 🗋 A7_toxsumm		
- 🗋 A8_ecotoxsumm		
👇 🗂 A9_safety	Ajouter un fichier :	
— A911_MSDS_Biocidal Product		
N 1012 MCDC Latins Cubatanasa		

# It is also there that you can delete an added file.

	Contenu du folder :
Analyse.doc	
	Supprimer

Here is a global view of 'CTD Structure':



<u>Remark</u>: if applicant wants to provide other documents that can be useful in assessing the application but that are not required in the electronic form headings, these documents must be added via 'CTD Structure' under A10\_other.



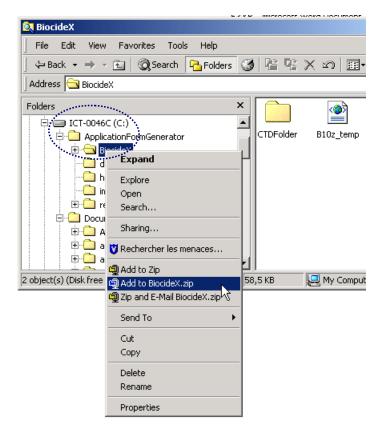




# 4. Last steps

When the registration of your product's application for authorization is done, you can make a "zip"-file of it. Here is how you do that:

- Using 'windows explorer', go to the place where the program 'Application Form Generator' is installed.
- Select the folder with the same name as your project (as given when you opened the electronic form).
- With a right click of your mouse, open the pop-up menu and save the whole folder (CTD Folder + xml file) in "Zip" format by clicking on "Add to BiocideX.zip"



If your folder has been transformed into a zip-file, you can send it by e-mail to the following address: info.gestautor@health.fgov.be

If you prefer sending the electronic file by mail (post), you have to copy the whole folder on a CD. In that case, it is not necessary to create a zip-file!

# B. COMPLETE FORM FOR ELECTRONICALLY SUBMITTING AN APPLICATION FOR AUTHORISATION FOR A BIOCIDAL PRODUCT





This part of the manual explains in detail the different headings for a new application for authorisation for a biocidal product.

For certain application types, the electronic form only contains the headings required for the chosen type of application and does not necessarily include all the headings listed below.







# 1. The Applicant

In this window, fill in the information of the authorisation applicant, which is by definition the person responsible for the putting on the market in Belgium.

The green elements are mandatory.

See screen below:

ApplicationForm CTD Structure	Le Demandeur	
📑 Formulaire	Un peu d'explication	۲
– 🗋 Le Demandeur – 🗋 Le Consultant	BCE n°	
<ul> <li>Le distributeur ou destinataire</li> </ul>		
• 📑 Le Biocide	Nom	
— 🗋 Biocide autorisé à l'étranger	Forme Juridique	
	Zone	
	Rue	
	Numéro	
	Boîte	
	Code Postal	
	Commune	
	Région	
	Pays	
		· · · · · · · · · · · · · · · · · · ·
	Téléphone	
	Fax	
	E-mail	
	Code langue	
	Il y a une personne de contact	• Oui
		🔾 Non
	Il y a une personne de contact	۲
	Prénom	
	Nom	
	Titre	<b></b>
	Fonction	
	Téléphone	
	GSM	
	Fax	
	E-mail	
	Utiliser l'adresse e-mail de la personne de contact pendant la procédure	⊖ Yes
		O No

[Formulaire, Le Demandeur]





Additional explanation concerning that screen:

- «  $BCE n^{\circ}$  » (Crossroads Bank for Enterprises number) is mandatory for enterprises with their head office in Belgium.

- « zone » may be filled in if the Belgian or foreign enterprise is installed in an industrial area.

- « **code langue** » (language code) can be filled in for information as far as Belgian enterprises are concerned.

- If a specific contact person is responsible for the application, click «  $\mathbf{oui}$  » (yes) and fill in the contact person information, including an <u>e-mail address</u> if there is one. This address will possibly be used through the whole application assessment procedure. If there is no specific contact person for that application, click « **non** » (no) and go to the next heading.





# 2. The Consultant

If a consulting enterprise is involved in submitting your application, click « **oui** » (yes). If there is no consulting enterprise involved, click « **non** » (no).

See screen below:

a un consultant	Oui		
l y a un consultant			
BCE n°			
Nom			
Forme Juridique			
Zone			
Rue			
Numéro			
Boite			
Code Postal			
Commune			
Région			
Pays			•
Téléphone			
Fax			
E-mail			
Code langue			
il y a une personne de contact	🖲 Oui		
	🔘 Non		
il y a une personne de contact			*
Prénom			
Nom			
Titre			•
Fonction			
Téléphone			
GSM			
Fax			
E-mail			
Utiliser l'adresse e-mail de la personne de contact pendant la procédure		) Yes	

That heading should be filled in the same way as for the applicant, taking the following remarks into account:

- « n° **BCE** » (Crossroads Bank for Enterprises number) is mandatory for enterprises with head office in Belgium.







- « **code langue** » (language code) can be filled in for information as far as Belgian enterprises are concerned.

- If a specific contact person, as a consultant, is responsible for the application, click « oui » (yes) and fill in the information of the contact person, as a consultant, including an <u>e-mail address</u> if there is one. This address will possibly be used through the whole application assessment procedure. If there is no specific contact person for that application, click « **non** » (no) and go to the next heading.





## 3. The Distributor or Addressee

This heading is **mandatory** for foreign enterprises with head offices in the European Union using one or more Belgian distributors or addressees to put their product on the market in Belgium.

This heading is **optional** for Belgian enterprises using one or more Belgian distributors or addressees to put their product on the market.

If there are one or more distributors or addressees, click « **oui** » (yes). If there is no distributor or addressee, click « **non** » (no).

See	screen	be	low:	

y a un Distributeur ou destinataire	© Oui ◯ Non	
l y a un Distributeur ou destinataire		(
Distributeur ou destinataire		۲
BCE n°		
Nom		
Forme juridique		
Zone		
Rue		
Numéro		
Boîte		
Code postal		
Commune		
Région		
Pays		
Téléphone	Required	
Fax		
E-mail		
Code langue		<b></b>
sous langue		
	Ajouter une zone : "Distributeur ou destinataire"	

If several distributors or addressees are involved in the putting on the market of that product in Belgium, click then on « <u>ajouter une zone</u> : **distributeur** ou **destinataire** » (Add a « distributor or addressee » field ).







## 4. The Biocide

# 4.1 Heading "Identité du biocide" (biocide identity)

#### Under "dénomination commerciale" (trade name)

In this window, fill in the trade name of the product in French, Dutch and German (if there is one). If the trade name is the same in all three languages, fill in the three fields with the same name.

The name should not contain one or several of the following characters:  $\setminus$  / : \* ? " < > |

If the name of your product contains one of those characters, you must mention this in an annexed document. Document to be added in folder A10\_other.

If the product has been given a code name and if that code is in the testing reports/documents that have been submitted, enter that code here so that the link can be made between the code and the application product.

Dénomination commerciale française	
Dénomination commerciale néerlandaise	
Dénomination commerciale allemande	
Nom de code	

#### **Under "fabricant" (producer)**

If the information concerning the producer head office is not different from the information concerning the applicant for authorisation, click « **non** » (no) next to that question. In this case, you nevertheless have to open the heading « coordonnées du siège social du fabricant différentes de celles du demandeur » (head office of producer information different from applicant information) and then enter the branch unit number ("numéro d'unité d'établissement") as defined by the Crossroad Bank for Enterprises.





ordonnées du siège social du fabricant différentes de celles du demandeur.	🔾 Oui	
	Non	
Coordonnées du siège social du fabricant différentes de celles du demandeur.		۲
Unité d'établissement du fabricant		۲
N° de l'unité d'établissement BCE		
Coordonnées de l'unité d'établissement différentes du siège social	🔾 Oui	
	🔾 Non	
Coordonnées de l'unité d'établissement différentes du siège social		۲

If the information concerning the producer head office is different from the information concerning the applicant for authorisation, click « **oui** » (yes) and fill in the fields in the window.

Le fabricant		۲
Un peu d'explication		۲
Coordonnées du siège social du fabricant différentes de celles du demandeur.	۱ Oui	
	○ Non	
Coordonnées du siège social du fabricant différentes de celles du demandeur.		8
BCE n°		
Nom		]
Forme Juridique		]
Zone		
Rue		
Numéro		
Boñe Code postal		
Commune		
Région		
Pays	· ·	]
Téléphone		]
Fax		]
E-mail		
Code langue	· · · · · · · · · · · · · · · · · · ·	· ]

Fill in the table above in the same way as the previous headings, taking the following remark into account:

- « n° **BCE** » (number in the Crossroads Bank for Enterprises) is mandatory for enterprises with head office in Belgium.





- « **code langue** » (language code) can be filled in for information as far as Belgian enterprises are concerned.

#### Under "Unité d'établissement du fabricant" (producer branch unit number)

As far as Belgian enterprises are concerned, enter the branch unit number of the producer as mentioned in the Crossroads Bank for Enterprises (**CBE**).

If the branch unit information is not different from the head office information, click « **non** » (no) and go to the next heading concerning the biocide « **composition** ».

Unité d'établissement du fabricant		۲
N° de l'unité d'établissement BCE		
Coordonnées de l'unité d'établissement différentes du siège social	🔾 Oui	
	Non	
Coordonnées de l'unité d'établissement différentes du siège social		۲

If the information concerning the branch unit is different from the information concerning the head office, click « **oui** » (yes) next to that question and fill in the window below where you have to enter the information concerning the branch unit.





<ul> <li>Oui</li> <li>Non</li> </ul>	
	8
	•





## 4.2 "Composition"

#### **Under "Analyse" (analysis)**

Composition	
Un peu d'explication	۲
Analyse	۲
Ajouter une attestation d'analyse confirmant le teneur en composants actifs.	<u> </u>
Un peu d'explication	۲

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Add here the analysis report justifying the active substance(s) concentration contained in the product. The analysis must be made by an independent laboratory on the product submitted for application. The **original** analysis report must be sent by mail (post).

The name of the file that will be added must begin with: Analyse (file visible under CTD Structure, A32\_comp)

#### **Under "Composants" (substances)**

Fill in the following tables listing all substances contained in the biocidal product, i.e. active substances (predefined list), non active substances (predefined list) and, if necessary, non active substances that are not listed.

The concentration of the different ingredients must be expressed in % m/m (mass/mass).

! All ingredients of the product must be registered until the product total percentage reaches 100 %.

#### **Under "Composants Actifs" (active substances)**

To add data to the table, you have to click on the left mouse button on the field where you want to enter a value.

Composants Actif (% m/m)						8
nom substance en anglais c	nom commercial	numéro CAS	teneur %age m/m	range	numéro CE	
	Supprimer			Ajouter		
Un peu d'explication						8
Documents composants actifs						8
Ajouter une fiche de donné	es de sécurité MSDS po	ur chaque composant.				

Here is how you complete the table:





1. First, enter in one of the three following columns the **active substance name in English** OR its **CAS** number OR its **EC** no. Example: if you choose to fill in the active substance name, it must correspond to the notification name as registered in the European lists. You can enter the name in small letters or in capital letters. When the name is found, the system will transform the name automatically into capital letters.

When you have completed <u>one</u> of those three columns, the system will automatically search in the substance list and fill in the 2 other columns.

Check if the substance found corresponds to the right substance.

The Column ID is also filled in by the system. This ID is used to identify the substance in the Gestautor system.

2. Enter manually the trade name of the selected active substance.

3. In the «*Teneur %age m/m* » (content percentage m/m) column, enter the concentration of each active substance (% m/m) contained in the product.

If there is a concentration range/margin, "**pas d'application**" (does not apply) must be written in that field and the « **range** » column has to be filled in.

4. The «*range* » column only has to be filled in if there is concentration range/margin and when only one concentration value cannot be given for the active substance. If that range does not apply to your product, write « pas d'application » in that column.

<u>As explained above</u>, if your product contains several active ingredients, add the needed number of rows using the "ajouter" (add) button. If you want to delete a needless row, click on "supprimer" (delete).

<u>Important remark:</u> Several substances on the predefined list of active substances may have the same CAS number and the same EC number but totally different notification names. In that case, you will have to search by active substance name and not by CAS number and CE number. The reason ifs that if you search by CAS number or CE number, the system will choose the first substance it finds in the list, which will not necessarily correspond to the right substance.

Under "documents composants actifs" (active substances documents), add the safety data sheets for

each active substance contained in your product using the computer icon.

The file name must begin with: MSDS (substance name) (file visible under CTD Structure, A912\_MSDS\_Active Substances)

#### **Under "Composants Non-Actifs" (non active substances)**

Just like for active substances, the concentration of the different ingredients must be expressed in % m/m (mass/mass).

The table must be filled in like the one for active substances, except that there is an additional field: "**fonction dans le biocide**" (function in the biocide) that you have to fill in by choosing a function in a scroll menu.







Composants non-actifs (% m/m)					and the second second	****	\$
						1. A.	
nom chimique en an nom commercial	numéro CAS	teneur %age m/m	range	numéro CE	fonction dans le bioc	remarque	
					adent anti peau 🛛 💌		
					agent anti peau 🛛 🔺		
Suppri	imer			Aj	agent anti-moussa		
					amérisant 📒		
					appât		
Un peu d'explication				1	colorant		۲
				- N	conservateur	1	
Documents composants non-actifs					épaississant	e de la companya de la	8
				· · · · · · · · · · · · · · · · · · ·	gaz propulseur 👻		
					gaz propuiseur	1.98 M	_
					· · · · · · · · · · · · · · · · · · ·	••	

If you choose "**autre**" (other), specify the real function of that substance in the "remarque" (remark) field. But if you choose a defined function in the scroll menu, write "pas d'application" (does not apply) in the "**remark**" field.

Non active ingredients that do not appear in the predefined list must not be added here but in the table below.

<u>Under</u> "documents composants non-actifs" (non active substances documents), add the safety data sheets for each non active substance contained in your product using the computer icon. The safety data sheets that must be added here are those corresponding to the substances added under the table "Composants Non-Actifs" (non active substances) coming from a predefined list. The name of the file must begin with: MSDS (substance name) (file visible under CTD Structure, A913\_MSDS\_Non\_Active Substances).

# <u>Under « Composants Non-Actifs pas définis dans la liste » (= non active substances that are not in the predefined list)</u>

The concentration of the different ingredients must be expressed in % m/m (mass/mass), just like for the « **composants actifs et non-actifs** » (active and non active substances).

The table must be filled in like the one for other ingredients. Every field in the table is mandatory. If you think that one of the fields is not necessary for a certain substance, please write "pas d'application" (does not apply) in the corresponding field.

In this particular case, you must fill in the chemical name, the **CAS** number and the **EC** number manually and there is no automatic search made by the programme, as there is no predefined list.

All substances contained in the product must be registered until the total percentage reaches 100 %.

<u>Under « Documents Composants Non-Actifs pas définis dans la liste » (= documents concerning</u> <u>non active substances that are not defined in the list)</u>, add the safety data sheets for each non active substance contained in your product using the computer icon. The safety data sheets that must be added here are those corresponding to the substances added under the table "Composants Non-Actifs pas définis dans la liste" (non active substances that are not defined in the list).

The file name must begin with: MSDS (substance name) (file visible under CTD Structure, A913\_MSDS\_Non\_Active Substances).





Composants Non-Actif pas définis dans la list	te (% m/m)						۲
nom chimique ou aut nom commercial (no	numéro CAS	teneur %age m/m	range	numéro CE	fonction dans le bioci	remarque	
Supp	rimer			Aj	jouter		
Documents composants non-actifs							\$
Ajouter une fiche de données de sécurité (M	SDS) pour chaque co	nposant			<u>e</u>		]







# 4.3 "Caractéristique du biocide" (biocide characteristics)

All details in this heading must be submitted.

aractéristiques du Biocide	
Un peu d'explication	(
Etat physique	
Etat physique	
Explication en cas d'autre	
Explication en cas d'autre	
Explication en cas d'autre Danger d'explosion Caractéristiques oxydantes	
Explication en cas d'autre Danger d'explosion Caractéristiques oxydantes Point de Fusion (°C)	
Explication en cas d'autre [ Danger d'explosion [ Caractéristiques oxydantes [ Point de Fusion (°C) [ Acidité/Alcalinité (pH) [	
Explication en cas d'autre [ Danger d'explosion [ Caractéristiques oxydantes [ Point de Fusion (°C) [ Acidité/Alcalinité (pH) [ Densité Relative (gr/cm <sup>3</sup> ) [	
Explication en cas d'autre       [         Danger d'explosion       [         Caractéristiques oxydantes       [         Point de Fusion (°C)       [         Acidité/Alcalinité (pH)       [         Densité Relative (gr/cm <sup>2</sup> )       [         Durée de conservation et       [	
Explication en cas d'autre       [         Danger d'explosion       [         Caractéristiques oxydantes       [         Point de Fusion (°C)       [         Acidité/Alcalinité (pH)       [         Densité Relative (gr/cm <sup>3</sup> )       [         Durée de conservation et la unité de durée       [	
Explication en cas d'autre [ Danger d'explosion [ Caractéristiques oxydantes [ Point de Fusion (°C) [ Acidité/Alcalinité (pH) [ Densité Relative (gr/cm <sup>2</sup> ) [ Durée de conservation et [ unité de durée [ Ajouter les tests de stabilité [	

If you cannot give one or more values for the product, complete « **pas d'application** » in the concerned field(s). In that case, join a letter for each of those missing values explaining the reasons why no value could be given. Such a letter must be added via CTD Structure, A10\_other, and must begin with the name: Argumentation (biocide name).

To get a definition of the different parameters mentioned above and to know which tests are necessary to obtain the required values/data, please consult the « Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products » (<u>http://ecb.jrc.it/biocides/</u>).

As far as the physical state of the biocide is concerned, just mention the formulation type, based on a coding system harmonised at international level which is already used for pesticides. You will find those codes in the « Manual on Development and Use of FAO Specifications for Plant Protection Products » which is based on the « Catalogue of pesticide formulations types and international coding system ».







You will find list of the codes on а http://www.fytoweb.fgov.be/FR/DOC/INLEIDING/Formuleringstype.htm . For a detailed description please of the codes. consult the following internet site http://www.insah.org/protectiondesvegetaux/csp/Annexe2.pdf.

If you cannot find any suitable code for your biocide, you can choose "autre" (other) in the scroll menu. In the "explication en cas d'autre" (explanation if "other") field, give a brief description of your product's physical appearance.

Concerning the product storage stability and its shelf-life, first indicate the shelf-life of the product (i.e. 1 year, 6 months,...) and then add one or several stability tests made on the product submitted for application , using the computer icon. Each test that is submitted has to establish the asserted shelf-life.

The name of the file must begin with: "Stabilité" or "Stabiliteit" (file visible under CTD Structure, A31\_stab)

The « **caractéristique technique** » (technical characteristics) field depends on the product type that has to be examined. Some additional technical characteristics can be submitted to allow a better evaluation of certain formulation types.

(example: flowability, wettability, surface tension, suspensibility, emulsion stability, ...).

If no additional technical characteristic is required for the product type submitted, indicate « **pas d'application** » (does not apply) under this heading.

The « **incompatibilité** » (incompatibility) field only has to be completed when the product cannot be mixed with specific substances or in the case of a mixture with 2 products. If this is not the case, indicate « **pas d'application** » (does not apply) under this heading.

<u>Remark</u>: if you have to fill in exponential values, please use the following form: <u>10 E -6</u> (instead of 10  $^{-6}$ )





# 4.4 "Application du biocide" (biocide application)

Indicate in this window the product types for which the application for authorisation is submitted.

Fill in one product at a time using the scroll menu and describe in detail, for each product type selected, the desired use(s) for that product in French and Dutch.

Type de Produit		(
Type de Produit		•
Usage		8
Usage (Français)		
Usage (Néerlandais)		
	Ajouter une zone : "Usage"	
	Ajouter une zone : "Type de Produit"	

If there are different possible uses for a selected product type, click on « **ajouter une zone 'Usage'** » (Add a 'Use' field) so that you can describe another use for that product in French and Dutch.

Usage	۲
Usage (Français)	
Usage (Néerlandais)	
	Remove
	Ajouter une zone : "Usage"

If there is a second product type for the concerned product, click « **ajouter une zone type de produit** » (add a 'product type' field) so that you can select the 2nd product type and describe the use(s) in French and Dutch.

<u>Under 'Description du biocide par type d'utilisateur'</u> (biocide description by type of user), there are two possible choices:

	Gestautor	
federal public service HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT		
Classification		۲
Classification	Pas classé	•
Description du biocide par type d'utilisateur	◯ Classe A ◉ Pas classé	
Description du biocide par type d'utilisateur		۲
Utilisateur professionnel	⊖ Oui ○ Non	
Utilisateur professionnel		۲
Grand public	<ul> <li>Oui</li> <li>Non</li> </ul>	
Grand public		۲

- Class A = product that may only be sold by registered sellers to approved or professional users
- Not classified = product sold to the general public and/or professionals without particular reseller/user registration

<u>Attention:</u> You must complete the classification twice: a first time using a list and a second time through indicating the class.

<u>If the product is a « class A product »</u>, the system will automatically complete « utilisateur professionnel : **ou**i » (professional user: yes) as the product is a class A product.

Then you have to open the « utilisateur professionnel » window and fill in the following items:

- under « **emballage** » (packaging), complete table as follow, for all possible packaging of your product:

- "Unité" (unit) : choose from the proposed scroll menu (kg, g, l, ml)
- "Nombre" (number) : indicate the packaging capacity (content)
- "sorte" (type): choose from the proposed scroll menu. If nothing corresponds to the product packaging, choose « **autres** » (other) and complete the field « **emballage non standard** » (no standard packaging)
- "Emballage non standard" (no standard packaging): to be completed only if it is a special packaging that does not appear in "**sorte**".

If it is a standard packaging, indicate in this field: "pas d'application" (does not apply).

Utilisateur professionnel		<ul><li>Oui</li><li>Non</li></ul>	
Utilisateur professionnel			8
Emballage			۲
Unité	Nombre	Sorte	Emballage non standard
Supp	primer	A	jouter







- under "**mode d'emploi par usage/exposition à l'utilisateur**" (instructions by use/exposure to user), fill in all fields under this heading in a very detailed way in French and Dutch.

Add as many « mode d'emploi par usage/exposition à l'utilisateur » fields as necessary.

!! It goes without saying that the number of additional fields to be added will depend on the number of (professional) uses defined at the level of the chosen product types at the top of the window.

<u>*Remark*</u>: The packaging period of use in case of intensive use has to be completed <u>for each type of packaging</u> defined in the packaging table.

Mode d'emploi par usage/ exposition à l'utilisateur)	\$
Informations en français	8
Commentaire	
mode d'emploi	
Acte préparatoire Manière d'utiliser	
Fréquence d'utilisation	
Dose prescrite exposition à l'utilisateur	
Durée d'application unique Durée d'utilisation d'un emballage lors	
de l'utilisation intensive	
Désignation quantitative et/ou qualitative d'une durée d'application unique	
a une auree a application unique	

If the product is not classified ("pas classé"), choose the concerned type of user: professional user and/or general public by ticking "**oui**" (yes) or "**non**" (no) where required.

Open appropriate windows and fill in as described above for "**emballage**" (packaging) and "**mode d'emploi/exposition à l'utilisateur**" (instructions by use/exposure to user).





# 4.5 "Étiquetage selon" (Labelling) • Envelore • E

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a) "Etiquetage" (Labelling) according to the old directives 'Préparations dangereuses'

#### Under "symboles de danger" (danger symbols):

-Etiquetage			
Symboles de Danger			۲
		Symboles de danger	
	Supprimer	Ajouter	

Indicate the danger symbol(s) to be attributed to the product using the scroll menu. Click on the line with your mouse to activate the scroll menu.

Symboles de Danger	۲
Symboles de danger	
O: Comburant	-
O; Comburant	
C; Corrosif	
N; Dangereux pour l'environnement	
E; Explosif	=
F+; Extrêmement inflammable	
F; Facilement inflammable	
Xi; Irritant	
Xn; Nocif	-

If several danger symbols correspond to the preparation, insert additional zone(s). To add zones, click "Ajouter" (Add).

Symboles de Danger	۲
O: Comburant	oles de danger
Supprimer	Ajouter

If no danger symbol applies to the submitted product, do not complete the zone.

#### Under "phrases R" (R phrases):

User Manual: « Application Form Generator »



Indicate the risk phrase(s) (R) to be attributed to the submitted product using the scroll menu.

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 Phrases-R R1: Explosif à l'état sec	>	Phrases-R	* •	
R1: Explosif à l'état sec	Supprimer		Ajouter	

If several R-phrases apply to product, insert additional zone(s) using the "Ajouter" (Add) button.

Phrases-R	۲
R1; Explosif à l'état sec	<b>v</b>
R4; Forme des composés métalliques explosifs très sensibles	
Supprimer	Ajouter

If no R phrase applies to that product, do not complete the zone.

#### Under "phrases S usage professionnel" (S phrases for professional use):

If your product is meant for professional use, complete the following heading where you have to fill in the security (S) phrase(s) to be attributed to the product for its professional use.

For some S phrases the title is not complete and specifications typical of the product have to be added by the producer. As far as those phrases are concerned, add those specifications where required in French and in Dutch.

If several S phrases for professional use correspond to the product, insert one ore more additional zones using the "Ajouter" (add) button.

If no S phrase for professional use applies to that product, do not complete that field.







Phrases-S usage professionnel			\$
Phrases-S usage professionnel	Spécifications (français)	Spécifications (néerlandais)	
Supprimer		Ajouter	

#### Under "phrases S usage grand public" (S phrases for use by the general public):

Complete the table following the same principles as for the S-phrases for professional use, but only if your product is meant to be used by the general public.

<u>*Remark:*</u> Choosing the type of user under the heading "biocide application" (professional and/or general public) automatically determines which "S-phrases" fields have to be completed under the heading "etiquette" (labelling).

<u>*Example*</u>: if you choose "professional user" for your product under "biocide application", you only have to fill in the part on "S-phrases for professional use" under the heading « étiquette » (labelling) and not the part concerning "S-phrases for use by the general public".

b) "Etiquetage" (Labelling) according to the new CLP system

## Under "Classes et catégories de danger" (Hazard Classes and Categories):

Classes et catégories de danger + Pictogrammes de danger	8
Classes et catégories de dang	er + Pictogrammes de danger
Supprimer	Ajouter

Indicate the danger classes and categories with the corresponding danger picture to be attributed to the submitted product using the scroll menu.

If several danger classes and categories apply to your product, insert additional zone(s) using the "Ajouter" (Add) button.

If no danger classe and category apply to your product, do not complete the zone.

## Under "Mentions de danger et mentions d'avertissement" (H-Statements and signal words):

Indicate the H-statements and signal words to be attributed to the submitted product using the scroll menu.

Mentions de danger et mentions d'averti	ssement		۲
Phrase-H	Mentions d'avertissement	Spécifications (français)	Spécifications (néerlandais)
Sup	orimer	A	jouter

If several H-statements and signal words apply to your product, insert additional zone(s) using the "Ajouter" (Add) button.

If no H-statement and signal word apply to your product, do not complete the zone.

For some H-statements and signal words the title is not complete and specifications typical of the product have to be added by the producer. As far as those phrases are concerned, add those





specifications where required in French and in Dutch. (e.g. H350... (*mentionner les voies d'exposition*)).

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#### **Under "Mentions de danger supplémentaires" (EUH-Statements):**

Mentions de danger supplémentaires			\$
Phrase-EUH	Spécifications (français)	Spécifications (néerlandais)	Ę
Supprimer		Ajouter	
Constitute annutana una successioned			*
Conseils de prudence usage professionnel			~
Phrases-P usage professionnel	Spécifications (français)	Spécifications (néerlandais)	-
Supprimer		Ajouter	
Conseils de prudence usage grand public			\$
Phrases-P usage grand public	Spécifications (français)	Spécifications (néerlandais)	
Supprimer	1	Ajouter	

# 4.6 Label of the product

<u>Under "Projet d'étiquette" (labelling project)</u>, insert a labelling project for your product using the computer icon.

If your product is meant for professional use <u>and</u> for use by the general public, you have to add a labelling project for each of the concerned uses <u>in French and in Dutch</u>.

The names of the files must begin with: "Etiquette professionnelle", "Etiquette grand public", "Etiket groot publiek" or "Etiket professioneel" (files visibles under CTD Structure, A92\_label).

Projet d'étiquette	۲
Ajouter un projet d'étiquette pour l'utilisation professionnelle.	

<u>Pour rappel</u>, the labelling project must include all the elements required by Articles 39 and 40 of the Royal Decree of 22 May 2003.

# 4.7 "Sécurité de l'utilisateur" (user safety):



Under this heading, add a **safety data sheet** for the submitted biocidal product using the computer icon. The safety data sheet must be added <u>in French and in Dutch</u>.

The file name has to begin with: MSDS (biocide name) (files visible under CTD Structure, A911\_MSDS\_biocidal product)

You also have to add a first aid **leaflet** in compliance with the writing instructions given by the Poison Centre ("Centre antipoison"). You can get those instructions as well as the form concerning the leaflet by following <u>this link</u>. You can find the first aid writing instructions below on that page (Word file) and the form concerning the leaflet (Excel file).

When you write that leaflet, it is important that you adhere to the lay-out imposed by the Poison Centre. The leaflet has to be added <u>in French and in Dutch</u> using the computer icon.

The file name has to begin with: «Notice » or «Bijsluiter » (files visible under CTD Structure, A93\_notice)

## 4.8 "Efficacité du biocide" (biocide effectiveness):

Under "But visé par le produit" (product goal):

L'efficacité du biocide		
But visé par le produit		۲
But visé par le produit autre	<b>A</b>	Commentaire si but = autre
Supprimer		Ajouter

Insert in this window the product goal(s) using the scroll menu. If the product has several goals, insert additional zone(s) using the "Ajouter" (add) button.

If the product goal does not correspond to a predefined choice, select "**autre**" (other) and explain why in the comment field.

#### **Under "organisme cible" (target organism):**





Organisme cible	۲
Organisme cible	
Effets sur l'organisme cible (Français)	
Effets sur l'organisme cible (Néerlandais)	
Effets secondaires indésirables ou involontaires (Français)	
Effets secondaires indésirables ou involontaires (Néerlandais)	
Commentaire si autres organismes cibles (Français)	
Commentaire si autres organismes cibles (Néerlandais)	
	Ajouter une zone : "Organisme cible"

Fill in the data required under this heading. ("organisme cible visé" (targeted organism), "effets" (effects) and "effets secondaires" (secondary effects)). If an organism targeted by the product does not appear in the predefined list of target organisms, choose "autre" (other) and complete the field "commentaire si autres organismes cibles' (comment if other target organisms) in French and Dutch. If your product is effective against several target organisms, insert an additional zone by clicking "ajouter une zone : organisme cible" (add a zone: target organism).

#### Under Efficacité et résistance (Potency and resistance):

L'efficacité			۲
Ajouter les rapports de test d'efficacité.		<b>e</b>	
Résistance			۲
Ajouter les rapports de test et documentation concernant la résistance.			

As far as "**efficacité**" (potency) is concerned, join all potency test reports concerning the biocidal product using the computer icon. Each target of the product has to be established by potency testing. The tests must be carried out on the submitted product and a comprehensive description of the testing method is required.

The name of the file(s) must begin with : « Efficacité » ou « Werkzaamheid » (files visible under CTD Structure, A41\_eff).

As far as "**résistance**" is concerned, data concerning the product possible resistance to active substances are asked. The data may come from testing results from tests carried out on products in the same product type or from literature.

The name of the file(s) must begin with: « Résistance » ou « Resistentie » (files visible under CTD Structure, A42\_resist).





# 4.9 « étude de résidu » (residue study):

A residue study is mandatory for biocides when their use can lead to residue in foodstuffs, drinks or food intended for animals (e.g. products of type 3 (stall disinfectants), 4 (disinfectants used in the food sector), 8 (wood used in food transport), 18 (for insecticides used in stalls or on cattle when there is a possibility that actives substances are found in meat and/or milk and/or eggs, ...).

If your product is intended for the above uses, you have to add a residue study on the submitted product to your application file, using the computer icon. If your product is not intended for the above applications, do not complete that heading.

The name of the file(s) must begin with: « Résidu » or « Résidu » (file visible under CTD Structure, A5\_residu)

L'étude de résidu	2
Ajouter l'étude de résidu.	

*Example*: For type 3 and type 4 products: you have to provide a study on the residue quantities remaining on surfaces that have been in contact with the above mentioned foodstuffs after using the product.

Kind of study that you have to submit: In the residue study, different materials (like stainless steel, glass or other material used in food (-processing) industry have to be treated according to the product instructions for use. Those materials are then rinsed several times.

The first and second rinsing water will then be analysed to determine the quantities of remaining active and non active substances in that rinsing water.

If those quantities are small enough or under the detection limit, one can conclude that there is no risk for the consumer.





# 4.10 "Quantité biocide" (biocide quantity):

In this window, give an estimation of the commercial quantities that will yearly be put on the Belgian market for the submitted biocidal product.

Estimation des quantités commerciales de biocide sur le plan national		
Unité	<b></b>	
Volume		

**Under "Unité" (unit)**: choose unit of measurement (ex. : l, kg, ...) **Under "Quantité"(quantity**): give a figure





# 4.11 "Composants actifs" (active components)

In this window fill in the properties of each active substance present in the biocidal product. Insert the name of the first active substance contained in the product, based on the same principle as the one used to fill in the table under "Composition". Just fill in its **name** or its **CAS number** or its **CE number** and the two other values automatically appear in the table.

*We remind you that* the names on the list correspond to the names as they appear on the European lists of notified substances (in English, capital letters).

Composants actifs			
Un peu d'explication			۲
Composants actifs			8
Composants Actif (% m/m)			۲
nom substance en anglais comme notifié	numéro CAS	numéro CE	
h.	·	·	

**<u>Under "Le fabricant" (producer)</u>**, fill in the required data:







e Fabricant		
Un peu d'explication		۲
oordonnées du siège social du fabricant différentes de celles du d	lemandeur 🔾 Oui	
	⊖ Non	
Coordonnées du siège social du fabricant différentes de celles du demar	ideur	۲
actéristiques		
Jn peu d'explication		۲
Caractéristiques		۲
poids moléculaire (g/mol)		
point de fusion (°C)		
point d'ébullition (°C)		
pression de vapeur (Pa) à 20°C		
solubilité dans l'eau (mg/l) à 20°C		
Log Pow		
S'il s'agit d'un aérosol, distribution de la grandeur des particules		
Constante de la loi d'Henry (Pa.m³/mol)		
Log Koc		
Densité relative (g/cm³)		
Degré de pureté (en %)		
Degré de pureté (commentaire)		
iers ajoutés		
	<ul> <li>IUCLID</li> <li>Résumés tox/écotox</li> </ul>	
	<ul> <li>IUCLID et résumés tox/écotox</li> </ul>	

If the active substance producer also is the applicant for authorisation, answer "**non**" (no) to the question. Nevertheless open the window "le fabricant est autre que le demandeur" (producer is not the applicant) and directly fill in the branch unit number ("numéro d'unité d'établissement").

If the active substance producer is <u>not</u> the applicant for authorisation, answer « **oui** » (yes) to the question. Open the window "le fabricant est autre que le demandeur" (producer is not the applicant) and directly fill in all the required data.

In that case, you have to add an **access letter** from the active substance producer. With this letter, the active substance producer grants access to toxicological/ecotoxicological data he owns to applicant. That access would preferably refer to the IUCLID data concerning that active substance that have been given for the notification or the European file summary submitted to the different Member States when it has been declared admissible by the reporting Member State. The **original** access letter has to be sent by post.

The file name has to begin with: "Lettre d'accès (substance name)" or "Toegangsbrief (substance name)" (file visible under CTD Structure, A26\_access).

Then fill in the active substance producer's data, i.e. the head offices data.

User Manual: « Application Form Generator »







The "**BCE** n°" (Crossroads Bank for Enterprises number) is mandatory for enterprises with their head offices in Belgium.

The "code langue" (language code) can be filled in for information as far as Belgian enterprises are concerned.

<u>Under "Unité d'établissement du fabricant"</u> (producer branch unit number), fill in – for Belgian companies – the producer branch unit number as defined in the Crossroads Bank for Enterprises (BCE).

If the branch unit data are the same as the head office data, click "**non**" (no) and go to the following heading ("caractéristiques") concerning the properties of the active substance.

If the branch unit data are different from the head office data, click "oui" (yes) and fill in the following window concerning the branch unit data. The "code langue" (language code) can be filled in for information as far as Belgian enterprises are concerned.

Under "caractéristiques" (properties):





in peu d'explication	3
aractéristiques	¢
poids moléculaire (g/mol)	
point de fusion (°C)	
point d'ébullition (°C)	
ression de vapeur (Pa) à 20°C	
solubilité dans l'eau (mg/l) à 20°C	
.og Pow	
S'il s'agit d'un aérosol, distribution de la grandeur des particules	
Constante de la loi d'Henry (Pa.m³/mol)	
.og Koc	
Densité relative (g/cm³)	
Degré de pureté (en %)	
Degré de pureté (commentaire)	[]

Fill in this heading with the required values taking the units of measures into account. If you cannot give one or more active substances, complete « **pas d'application** » in the concerned field(s). In that case, join a letter for each of those missing values explaining the reasons why no value could be given. Such a letter must be added via CTD Structure, A10\_other, and must begin with the name: 'Argumentation (active substance name)' or 'argumentatie (active substance name)'.

Under '	<b>'fichiers</b>	ajoutés"	(ioined	files):

chiers ajoutés		
	Résumés tox/écotox	
	IUCLID et résumés tox/écotox	
Fichiers ajoutés		۲
Les noms des fichiers doivent correspondre à JUCLID (nom subs	stance), Tox résumé (nom substance) ou Ecotox résumé (nom substance)	
Ajouter le dossier IUCLID.		
Ajouter un résumé des données toxicologiques.		
Ajouter un résumé des données écotoxicologiques.		

As far as the active substance is concerned, choose from the files that have been added to the application:

- either the **IUCLID** file submitted at the moment of the active substance notification;
- or a **summary** from the active substance producer, which must include data on the <u>toxicological</u> and ecotoxicological properties of that substance;
- or **both documents** IUCLID file + producer summary are submitted in the application for authorisation file.

When you have made your choice, add the required document(s).





The name of the files must begin with: IUCLID (substance name), Tox résumé (substance name) or Ecotox résumé (substance name) (files visible under CTD Structure, A6\_IUCLID (as far as IUCLID file is concerned) or A7\_toxsumm (as far as the toxicological properties summary is concerned) or A8\_ecotoxsumm (as far as the ecotoxicological properties summary is concerned).

If the product contains several active substances, click « **ajouter une zone composants actifs** » (add an active component field) and fill in the window like you did it for the previous active substance.

**Important remark:** If the producer - and not the applicant for authorisation - submits the physicochemical properties of the active substance and/or the tox/ecotox summary and/or the IUCLID file, the applicant for authorisation must write in the concerned fields that those data will be provided by the producer. The applicant for authorisation must join in each case - instead of the required documents - a letter explaining that the producer will submit the IUCLID file and/or the tox/ecotox summary. The letter must bear the name of the required document.





## 5. Biocide authorised abroad:

Fill in the trade name of the product under which it is authorised in the other Member State of the European Union.

Gestautor

Choose the Member State where the product has been authorised using the scroll menu.

Bio	ocide autorisé à l'étranger		
E	Biocide autorisé à l'étranger	8	
	Un peu d'explication	۲	
		۲	
	Nom commercial		
	Etat membre dans lequel ce biocide est autorisé	<b>•</b>	

## **Under "Type de produit" (product type):**

Type de Produit		\$
Type de Produit		
Usage	8	
Usage (Français)		
Usage (Néerlandais)		
	Ajouter une zone : "Usage"	
	yaar aa	
	Ajouter une zone : "Type de Produit"	

Fill in the product type(s) for which the product has been authorised in the other Member State. Fill in one product type at a time using the scroll menu and describe thoroughly for each selected product type the use(s) of that product authorised in the other Member State in French and in Dutch.

If several uses have been authorised for a product type, click "**ajouter une zone: usage**" (add a "use" field) so that you can describe the other authorised use of that product in French and in Dutch.

If another product type has been authorised in the other Member State, click "**ajouter une zone: type de produit**" (add a "product type" field) so that you can select the other authorised product type and describe the authorised use(s) in French and in Dutch.





## Under "Composition":

You must give the product composition as authorised in the Member State.

mposants actifs (%)	,					(
om en anglais co	nom commercial	numéro CAS	teneur (%age m	m) range	numéro EC	ID
	Supprimer		1		Ajouter	
mposants non-actifs	s (% m/m)					(
m chimique en a	nom commercial	numéro CAS	teneur (%age m.	m) range	numéro EC	ID
·	Supprimer				Ajouter	
tres composants no	on-actifs (% m/m)					(
om chimique ou autr	e nom commercia	l numér	o CAS ten	eur (%age m/m)	range	numéro EC
	Supprimer		I		Ajouter	1

Add in the right tables the names of active components, non active components and other non active components (only for those that do not appear yet in the list of non active components) following the instructions described above in biocide « composition ».

The concentration of the different ingredients must be expressed in % m/m (mass/mass).

! All substances of the product must be registered until the product total percentage reaches 100 %.

<u>Under "documents à ajouter"</u> (documents to be added), add the required documents using the computer icon.

Un peu d'explication		Gestautor	
Accuments à ajouter Un peu d'explication Un peu d'e			
Un peu d'explication			
Ajouter une copie certifiée de l'acte d'autorisation original.       Image: Comparison of the sector d'autorisation original.         jouter une traduction certifiée de l'acte d'autorisation original.       Image: Comparison of the sector d'autorisation original.         (obligé sauf si l'acte d'autorisation est en français, néerlandais ou anglais)       Image: Comparison of the sector de sect	ocuments à ajouter		
jouter une traduction certifiée de l'acte d'autorisation original.          (obligé sauf si l'acte d'autorisation est en français, néerlandais ou anglais)         Ajouter une déclaration sur l'honneur.	Un peu d'explication		۲
(obligé sauf si l'acte d'autorisation est en français, néerlandais ou anglais)	Ajouter une copie certifiée de l'acte d'autorisatio	n original.	
Njouter une déclaration sur l'honneur.	Njouter une traduction certifiée de l'acte d'autorisation	original.	
	(obligé sauf si l'acte d'autorisation est en français, né	erlandais ou anglais)	
ijouter une étiquette approuvée dans l'autre état membre.	Ajouter une déclaration sur l'honneur.		
	Ajouter une étiquette approuvée dans l'autre éta	t membre.	
Ajouter une zone : "Biocide autorisé à l'étranger"		Aiouter une zone · "Biocide autorisé à l'étranger"	

#### The following **<u>original documents</u>**:

the certified copy of the ORIGINAL authorisation act, an ORIGINAL statement on honour ( = letter stating that the product authorised in the other Member State is identical to the biocidal product submitted for authorisation in Belgium) as well as a label APPROVED in the other Member State, must be sent **by post** 

and an electronic version of these documents (with a correct name) must be added to the form as required above.

<u>*Remark*</u>: the certified translation of the authorisation act is mandatory if its original language is not French, Dutch or English.

As far as the documents to add are concerned, the file name respectively has to begin with:

- « Autorisation à l'étranger » or « Buitenlandse toelating » See under CTD Structure, A22\_act
- « Autorisation traduction » or « Vertaling toelating » See under CTD Structure, A23\_transl
- « Déclaration honneur » or « Verklaring erewoord » See under CTD Structure, A24\_letter
- « Etiquette à l'étranger » or « Etiket buitenland » See under CTD Structure, A25\_foreign label

If the product submitted for authorisation has been authorised in several Member States, click « **ajouter une zone biocide autorisé à l'étranger** » (add a "biocide authorized abroad" field). In that case, fill in the newly created field with the data concerning the authorization given in the other Member State.