

Federal Department of Home Affairs FDHA **Federal Office of Public Health FOPH** Notification Authority for Chemicals

## e-Dossier: Guidance on electronic application for transitional authorisation A<sub>N</sub>

Opplications for a transitional authorisation A<sub>N</sub> can only be submitted for biocidal products that contain at least one notified active substance for which a decision on inclusion in the list in Annex 1 or 2 of the Ordinance on Biocidal Products (OBP; SR 813.12) is still outstanding.

Click here for more information about authorisation A<sub>N</sub>

Click here to view the "List of biocidal active substances"

- If the biocidal product only contains active substances listed in Annex 1 or 2 of the Ordinance on Biocidal Products, then an application for this biocidal product must be submitted using the <u>harmonised European procedure</u>. The following <u>transitional provisions</u> apply for biocidal products that have been placed on the Swiss market under a transitional authorisation.
- Before you can submit an electronic application, you will need to have access to the product register for chemicals (RPC). To obtain access, follow the instructions for <u>Opening a user account</u>.
- Go to the following web page: <u>www.rpc.admin.ch</u>



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#### <u>Colour codes</u>

Ø	Blue	. Information
U	Red	Interaction
U	Yellow	Help

#### Status overview

- "In progress" Data can only be entered/modified by the company
- "Under review" The e-dossier has been sent the company can only add missing documents



#### The public product register for chemicals (RPC) Language selection **Registered user name** Schweizerische Eidgenossenschaft Confédération suisse Product register for chemicals DE FR IT EN Oro Bieber (testfirma\_RPC) Logout MyAccount Confederazione Svizzera Confederaziun svizra Downloads New application / Enter notification $\, \sim \,$ Home Product search

#### Home

Searches					
Search Product search (preparation, parallel imported plant protection product, biocidal product or existing substance)	Parameter catalogue Collection of all ideal/default substances in the database.				

# New application / Enter notification Preparation Biocidal product Request application for a biocidal product Substance Registration application of a preparation Parallel imported plant protection product Substances listed in Annex XIV REACH Registration application of a parallel imported plant protection product Registration application of a parallel imported plant protection product Substances listed in Annex XIV REACH Reporting and applications pursuant to Annex 1.17 ORRChem

#### [en]Externe Links

Homepage notification authority for chemicals On this page you will find a lot of useful information (e.g. opening of a user account, training materials) Click for electronic submission of an application for a biocidal

#### product authorisation A<sub>N</sub>



## <u>Company data / Contact</u>

Product search Downloads New application / Enter no	tification ~	
 ocidal product	The cogwheel icon indicates the status "In progress": data can be entered/modified by the company.	Actions Deliver documents later
Company data/contact Product identifiers Characterization Company data/	contact The applicant is entered automatically.	Duplicate the product     Scard
Inaracteristics	Name testfirma_RPC Address Schwarzenburgstrasse 157	Confirmation
iHS labelling       ntended usage       Documents       Comments       jummary       jubmit	Click on "Add" to open a new form:         Page 5 – Create contact         Page 6 – Enter contact details         Page 7 – Chemical manufacturer         You can thus add contact information and edit the chemical manufacturer.	
/lenu	No entries	
Clanguage of authorisation German O French O Ita	Select the language in which the authorisation is to be issued.	

4



## <u>Company data / Contact – Create contact</u>

Schweizerische Eidgenossenschaft Confederation suisse Confederazione Svizzera Confederaziun svizra	ict register for chemicals		<b>9</b> D	oro Bieber (testfirma_RPC)	Logout MyAccount DE F	R IT EN
Home Product search Downloads	New application / Enter notification $  imes $					
🅸					Actions	
Image: Company data/contact         Image: Contact data data data data data data data	Contact information *	Contact	Q Sea	rch	Deliver documents later   Duplicate the product   Discard     Confirmation     Image: Product receipt (PDF)	
	Chemical manufacturer *	Person to be contacted in	Cancel Add contact Sa	ve		
	Save < Back Next >			Ţ		



### <u>Company data / Contact – Enter contact details</u>

Confederaziun svizra	
Home     Product search     Downloads     New application / Enter notification	
Company data/contact   Image: Company data/contact   Image: Company data/contact   Image: Contact intervet   Image: Contact int	ions  Deliver documents later  Duplicate the product  Discard  rfirmation  Product receipt (PDF)



#### <u>Company data / Contact – Chemical manufacturer</u>

Schweizerische Eidgenossenschaft Confederation suisse Confederazione Svizzera Confederaziun svizra	ct register for chemicals	Doro Bieber (testfirma_RPC) Logout MyAccount DE FR IT EN
Home Product search Downloads	New application / Enter notification $\sim$	
<ul> <li>Company data/contact</li> <li>Product identifiers</li> </ul>	In this field, you can search for a company already present in the system. In exceptional cases, a missing company can be added using the option "Add".	Actions           Actions           Deliver documents later           Duplicate the product           Image: Discard
<ul> <li>(2) Product identifiers</li> <li>(3) Characteristics</li> <li>(4) Composition</li> <li>(5) Classification GHS</li> <li>(6) GHS labelling</li> <li>(7) Intended usage</li> <li>(8) Documents</li> <li>(9) Comments</li> <li>(10) Summary</li> <li>(11) Submit</li> </ul>	Registrant     Chemical manufacturer     Name     Address (postal code, city, country)     Contact information *     Sumitomo Chemical Co. Ltd   Shinkawa 2-Chome 27-1, - Tokyo, Giappone      Test Firma     Schwarzenburgstrasse 125, 3097 Liebefeld (BE), Svizzera     Cancel     Add        Chemical manufacturer *	Ave

Enter the search term and confirm by clicking on the search button. For incomplete terms, use a wildcard query (\*xxx).

A list of possible companies will appear. Click on the relevant entry to mark it and then click on "Save". The entry will now appear under "Chemical manufacturer".

N.B. More than one manufacturer can be specified.



#### **Product identifiers**

 6995-87, <mark>B</mark> iocidal	product	After saving, the CPID and the CPID is to be specified in any o	e primary name are added to the dataset correspondence relating to the biocidal	Actions
	·	product.		Durplicate the product
Company data/contact	Product identifiers			Discard
haracteristics	Primary name * Biocidical product Demo_2023 BIE	Name of the biocidal product		Confirmation
omposition assification GHS	Status In progress	Withdrawn from the market	Deleted on 	Product receipt (PDF)
IS labelling rended usage		[	The authorisation number is	
ocuments	Authorisation number 		assigned and managed by the	
omments mmary	Additional Tradename(s)	l	Authority.	
bmit	<ul> <li>Add</li> </ul>			
		No entries		
	EAN Number / Article number / primary key	Internal product ident	tifiers can be entered here.	
	Add			
		No entries		



#### <u>Product identifiers – EAN number / Article number / Primary key</u>

Schweizerische Eidgenossenschaft Confedération suisse Confederazione Svizzera Confederazion svizra	ct register for chemicals	😫 Doro Bieber (testfirma_RPC	.) Logout MyAccount DE FR IT EN
Home Product search Downloads	New application / Enter notification $\sim$		
Home     Product search     Downloads       Image: Company data/contact     Image: Company data/contact       Image: Composition     Image: Composition       Image: Composition     Image: Composition       Image: Composition     Image: Composition       Image: Comments     Image: Comments       Image:	New application / Enter notification ~	Cancel Add	Actions

Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

#### **Characteristics**

Confederazione Svizzera Confederazione Svizzera Confederazione Svizzera	uct register for chemicals	Doro Bieber (testfirma_RPC) Logout MyAccount DE FR IT EN
Home Product search Downloads	New application / Enter notification $$	
Product search     Downloads       Image: Biocidical product D       896995-87, Biocidal product D       896995-87, Biocidal product D       9 Composition       1       1       1       1       2       1       2       1       2       1       2       1       2       2       3       2       4       2       3       4       2       3       4       4       4       5       5       6       6       6       7       1       1       5       1       5       1       5       1       5       6       6       7       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1	New application / Enter notification ~	Actions         Indicate the user category/categories.         Confirmatio         Authorisation A <sub>N</sub> or Authorisation of identical products A <sub>N</sub> /A <sub>C</sub> or Authorisation for parallel trade A <sub>N</sub> Indicate the aggregate state of the product.         Indicate the aggregate state of the product.         In any case, select "Normal registration". Thus, even if the product is defacto a "Kit"!         Qualification         Image: Select "Normal registration". Thus, even if the product is defacto a "Kit"!
	Save < Back Next >	



### <u>Composition – Overview of components</u>

Confédé Confédé Confede	erische Eidgenossenscha ération suisse erazione Svizzera eraziun svizra	Produ	ct register for chemicals	Doro Bieber (testfirma_RPC)	) Logout MyAccount DE FR IT EN	
Home	Product search	Downloads	New application / Enter notification $ \sim$			
Bic 89699	ocidical pro 95-87, Bio any data/contact	oduct De cidal pro	emo_2023 BIE oduct		Actions	
2 Product 3 Charact	ct identifiers cteristics osition		Components ( Add	By clicking on "Add", you can open a new form ( <u>pp. 12–15</u> ) for adding components.	Confirmation	
5 Classif 6 GHS la 7 Intend	ication GHS Ibelling Ied usage		ID Name PA-370823-25 Honey	EC No.       CAS no.       Concentration ↓       B       C       D       I          8028-66-8       = 100 g/100 g       ▲       ●	Product receipt (PDF)	
(8) Docun (9) Comm (10) Summ (11) Submi	ients ary t	<	Add     Comments regarding the composition     Author of the composition	Summary of all components already recorded. The symbols under head has been designated as "declared" (D) or is a biocidal active substance You can click on components already recorded to edit or delete them. N.B. Details of the full composition must be given. Ranges must not be Biocidal active substances must always be designated as "declared"	lings "B" and "D" indicate whether a co (B). e used.	omponent
			Doro Bieber Save  Gack  Next  Relevant information a	bout the composition can be entered here.		

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### <u>Composition – Component search</u>

Schweizerische Eidgenossenschaft Confederation suisse Confederazione Svizzera Confederaziun svizra	emicals	<b>9</b> ¤	Doro Bieber (testfirma_RPC)	Logout MyAccount DE FR IT EN
Home Product search Downloads New application / E	Component search			
Biocidical product Demo_2023 B 896995-87, Biocidal product          1       Company data/contact         2       Product identifiers         3       Characteristics         4       Composition         5       Classification GHS         6       GHS labelling         7       Intended usage         8       Documents         10       Summary         11       Submit	<ul> <li>We recommend that you search with CAS or EC numbers where it may be that not all synonyms for a substance is Note: Substances which have CAS and / or EC numbers is reported to the Notification Authority for chemicals by will be reviewed and, if necessary, added to the database Name/CAS/EC/PAID honey</li> <li>Research reference substance () Research products</li> <li>ID Primary name</li> <li>370823-25 honey</li> <li>370823-25 Honey</li> <li>148985-22 HONEYOL</li> <li>116369-94 Honey, ext.</li> <li>140611-21 Honeybee, ext.</li> <li>141700-52 Honeycomb, ext.</li> <li>When the search has been completed,</li> </ul>	because substances have often many synonyms, ave been recorded in our database. and are not found in our database should be e-mail [cheminfo@bag.admin.ch] Such substances re. CAS no. EC No. 8028-66-8 8028-66-8 8028-66-8 8028-66-8 91052-92-5 293-255-4 84775-61-1 283-890-5 97553-34-9 307-191-2 all hits will appear in the list.		Actions          Deliver documents later         Duplicate the product         Discard         Confirmation         R. Product receipt (PDF)
Product register for chemicals 4.4.4-574 © 2023 Federal Office of Public Health (FOPH)   Hor	Click on the relevant component and a (p. 13 – Add components).	new form will open automatically	y	Legal Contact



#### <u>Composition – Add components</u>





#### **Composition – Component concentration**





#### Composition – GHS classification of components





### **GHS** classification





#### GHS labelling – Hazard and precautionary statements



Save (Back Next)

Data entry for GHS labelling: hazard and precautionary statements can be selected in the same way as hazard categories (GHS classification, p. 16). Please note the special case of "Hazard statements with placeholders" (Special case of hazard statements with placeholders, p. 18).

N.B. The precautionary statements given for biocidal products are determined independently by the future authorisation holder, who is responsible for ensuring that they are correct; they will not be reviewed by the Authority.



#### GHS labelling – Special case of hazard statements with placeholders





#### GHS labelling – Hazard pictograms





#### Intended use

Confi Confi Confi	édération suisse ederazione Svizzera ederaziun svizra	Produ	ct register for chemicals		Doro Bieber (testfirma_RPC) Logout MyAccount DE FR IT EN	
Home	Product search	Downloads	New application / Enter notification $ \sim$			
Home Bi 8969 1 Corr 2 Proc 3 Chas 4 Corr 5 Class 6 GHS 7 Inter 8 Docc 9 Corr 10 Sum 11 Subr	Product search ocidical pro 295-87, Bio apany data/contact duct identifiers racteristics aposition sification GHS labelling inded usage uments iments mary mit	Downloads	New application / Enter notification ~ emo_2023 BIE oduct Intended usage Product type >  01 Human hygiene disinfectants ~  02 Disinfectants and algaecides not intended for d 02-06 Disinfectants: Althlete's foot prophylax 0 02-07 Instrument disinfection 0 02-08 Disinfectants: Sterilisation 0 02-09 Surface disinfection general 0 02-10 Disinfectants: Surfaces for medical use, 0 02-11 Industrial surface disinfection; Air conditioning, r	irect application to humans or animals	Fields of application   Select all   Deselect all   Indoor   Outdoor   Use on the skin   Select all   Deselect all   Discord	lication
			O2-13 Surface disinfection for solariums     O2-14 Household disinfection (exclusively)		Ireatment     Prevention	
			Save < Back Next >		Select the applicable subheadings for the relevant biocidal product type(s) the options displayed on the right may change accordingly.	);



#### **Documents**

Schweizerische Eidgenossenschaft Confederation suisse Confederazione Svizzera Confederaziun svizra	er for chemicals	\rm Doro Bieber (te	stfirma_RPC) Logout MyAccount DE FR IT EN
HomeProduct searchDownloadsNew appImage: Description of the searchDownloadsNew appImage: Description	Dication / Enter notification ~	Click on "Add" to navigate to your personal files; select formats (such as Word, Excel and PDF) are acceptable. dropping it over the "Add" button	the required files and add using "Open". Most conventional file You are even able to add documents by Drag & Drop by
1       Company data/contact         2       Product identifiers         3       Characteristics         4       Composition         5       Classification GHS         6       GHS labelling         7       Intended usage	d document Oownload all files Type	N.B. Use transparent file names! For example: "SDS_E»         Date ↓       Access level       Actions         14.08.2023 14:18       Author & federal authorities       €       €	<pre>, "Study_EN1650", "Label_front" Confirmation R Product receipt (PDF)</pre>
B Documents       9 Comments       10 Summary       11 Submit	Under "Actions", uploaded files	can be removed. Click to rename documents, select the de lication for authorisation A <sub>N</sub> :	ocument type and set access rights.
	<ul> <li>Signed printout of the last part of the label (including</li> <li>A draft of the label (including</li> <li>Safety data sheet</li> <li>If appropriate, documentation</li> <li>Where appropriate, document</li> <li>The completed additional document</li> <li>Excel template for identifying</li> </ul>	age of the RPC record ( <u>Product receipt, p. 27</u> ) g information and instructions for use) on of efficacy (disinfectants and wood preservatives) ntation of the product labelling ocument <u>"Further data for an electronic application for a</u> og the active substance supplier included in the Art. 95 I	<u>authorisation A<sub>N</sub>"</u> l <mark>ist (<u>cf. information required under Art. 62d OBP</u>).</mark>



#### **Comments**

Home Product search D	ownloads New application / Enter notification ~				
Biocidical prod 896995-87, Biocic	uct Demo_2023 BIE al product	Α	Actions	ter	
<ol> <li>Company data/contact</li> <li>Product identifiers</li> <li>Characteristics</li> <li>Composition</li> <li>Classification GHS</li> </ol>	Comments		Duplicate the product Discard Confirmation R Product receipt (PDF)	t 	^
<ul> <li>6 GHS labelling</li> <li>7 Intended usage</li> <li>8 Documents</li> <li>9 Comments</li> <li>10 Summary</li> <li>11 Submit</li> </ul>	Save < Back Next >	>			

Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

#### <u>Summary</u>

Confederaziun svizra Confederaziun svizra	Opro Bieber (testfirma_RPC) Logout MyAccount DE FR IT EN
Home     Product search     Downloads     New application / Enter notification	
Biocidical product Demo_2023 BIE 896995-87, Biocidal product    Ocmpany data/contact Product identifiers Characteristics Composition Classification GHS Classification GHS Classification GHS Classification GHS Contact identifiers Summary Obcuments Contact information Ferm of address	o far. Actions Deliver documents later Duplicate the product Discard Confirmation Product receipt (PDF)

Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra

#### **Corrections**

iome Product search Downloads	New application / Enter notification $ \sim $		
Biocidical product E 396995-87, Biocidal product	Demo_2023 BIE roduct		Actions ^
) Company data/contact 2 Product identifiers	Characteristics		Discard
Characteristics Composition Classification GHS GHS labelling T Intended usage	Validation error 1 At least one users category must be indicated.		Characteristics
) Documents ) Comments ) Summary 1) Submit	Authorisation procedure * Authorisation AN  Aggregate state / formulation type * Encapsulated granule  Type  Kit © Normal registration		
	Descriptors is / contains	Qualification	
	nanomaterial 🚯	Yes	·
	When you click on the "Summary" button in the	menu, validation errors and warnings v	will be displayed.



Home

Product search

#### Submit – Send application

Downloads

Once you have entered all the relevant data and checked the box to confirm submission of all the required documents, the electronic application can be sent. The status will then change from "In progress" to "Under review" (Provide further information, p. 26), and the application will be forwarded to the Notification Authority for Chemicals.

The application cannot be sent until all the errors listed have been rectified (Corrections, p. 24).

New application / Enter notification  $\, \sim \,$ 

896995-87, Biocid	al pr <mark>o</mark> duct	Actions Deliver documents later	
<ol> <li>Company data/contact</li> <li>Product identifiers</li> </ol>	Submit	Duplicate the product  Discard	
<ul> <li>2) Product identifiers</li> <li>3) Characteristics</li> <li>4) Composition</li> <li>5) Classification GHS</li> <li>6) GHS labelling</li> <li>7) Intended usage</li> <li>8) Documents</li> <li>9) Comments</li> <li>10) Summary</li> <li>11) Submit</li> </ul>	<ul> <li>Please note the new procedure for applications!</li> <li>For changes to existing applications, please consult the instructions on the <u>Notification Authority website</u></li> <li>For new applications:</li> <li>Before you submit your application, you must complete the documents listed below and upload them to the "Documents" tab:</li> <li>In hereby confirm that all the documents listed below have been submitted to the product register for chemicals (RPC) (incomplete documents will lead to additional charges determined by the amount of work they cause):</li> <li>a. Signed printout of the last page of the record from the RPC (in PDF format)*</li> <li>b. A draft of the label (including information and instructions for use)</li> <li>c. Safety data sheet</li> <li>d. If appropriate, documentation of efficacy (disinfectants and wood preservatives)</li> <li>e. Where appropriate, documentation of the product labelling</li> <li>f. Additional document "<i>Further Data</i>"</li> <li>g. Provision of proof of the source of the active substance in accordance with Art. 95 EU-BPR, either with the following form or by enclosing a letter of conformity from the supplier. Form Declaration Art. 95 BPR (PDF, 63 kB, 30.11.2020). See also : Provision of evidence required under Article 55 EU-BPR 528/2012</li> <li>* Upload after sending using "Deliver documents later"</li> </ul> After the electronic application has been sent through the product register for chemicals (RPC), the following information must be e-mailed to the Notification Arubrity for Chemicals (cheminfo@bag.admin.ch): <ul> <li>a. Proprietary name and CPID number of the biocidal product</li> <li>b. Confirmation that this is the first application for an authorisation A<sub>N</sub> or an application for a change to an existing authorisations A<sub>N</sub>.</li> </ul> It is no longer necessary to submit product and/or application documents by post (with the exception of the letter of access/transfer request).	Confirmation  Product receipt (PDF)	

Save K Back Next >



<u>Submit – Provid</u>	<u>e further information</u>	The eye icon indicates the status "Under review":		
Schweizerische Eidgenossenschaft Confederation suisse Confederazione Svizzera Confederaziun svizra	uct register for chemicals	As the e-dossier has been sent, only missing documents can added by the company ( <u>p. 27</u> ).	now be	MyAccount DE FR IT EN
Home     Product search     Downloads       Image: Organization of the search     Downloads     Downloads	New application / Enter notification ~ Demo_2023 BIE oduct Registrant	▲	Succ The forw chen	ess X application for authorisation has been arded to the notification authority for nicals.
<ul> <li>3 Characteristics</li> <li>4 Composition</li> <li>5 Classification GHS</li> <li>6 GHS labelling</li> <li>7 Intended usage</li> </ul>	N Ad	CLD C-100485 lame testfirma_RPC dress Schwarzenburgstrasse 157 3003 Bern Bern Svizzera	Confi (only time)	rmation of transmission appears for a short
B Documents	Contact information			
<ul> <li>9 Comments</li> <li>10 Summary</li> <li>11 Submit</li> </ul>	Form of add N Language for correspond Telepi	dress Iame Helpdesk ASChem ence German hone +41 <b>%</b>	>	

After the electronic application has been submitted via the product register for chemicals (RPC), an e-mail must be sent to the Notification Authority for Chemicals (cheminfo@bag.admin.ch), indicating:

- a. the proprietary name and CPID number of the biocidal product and
- b. whether this is an initial application for authorisation  $A_N$  or an application for a change to an existing authorisation  $A_N$ .

Product and/or application documents no longer need to be sent by post (except for a letter of access or transfer to a new authorisation holder).



#### **Deliver documents later**

Schweizerische Eidgenossenschaft Confederation suisse Confederazione Svizzera Confederaziun svizra	Ict register for chemicals	estfirma_RPC) Logout MyAccount DE FR IT EN
Home Product search Downloads	New application / Enter notification $$	
<ul> <li>Biocidical product E 896995-87, Biocidal pr</li> <li>Company data/contact</li> <li>Product identifiers</li> <li>Characteristics</li> <li>Composition</li> <li>Classification GHS</li> <li>GHS labelling</li> <li>Intended usage</li> </ul>	Demo_2023 BIE oduct Registrant Deliver documents later Additional documents can be submitted using the option "Deliver documents later". Procedure as for Documents, p. 21.	Actions
8 Documents	Contact information	
<ul> <li>Gomments</li> <li>Summary</li> <li>Submit</li> </ul>	Form of address Name Helpdesk ASChem Language for correspondence German Telephone +41 E-mail cheminfo@bag.ch S	>
	Product	
	Primary name Biocidical product Demo_2023 BIE CPID 896995-87 Product type Biocidal product Status Under examination Authorisation number	
	Save < Back Next >	



#### **General information**

- During the review process or after receiving the official decision, please do not add any documents unless you are requested to do so by the Authority.
- You are likely to incur additional charges if dossiers are incomplete.
- If you have any queries, please do not hesitate to contact us:

Federal Office of Public Health FOPH Notification Authority for Chemicals Schwarzenburgstrasse 157, CH-3003 Bern Tel. +41 (0)58 462 73 05 (Mon/Tue/Thu: 09:00 – 12:00) cheminfo@bag.admin.ch www.notificationauthority.admin.ch

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