Annex II

IUCLID5 manual for the preparation of PPORD notification dossiers

<u>Index</u>

INT	RODUCTION	3
1.	LEGAL ENTITIES	4
	Creating additional official Legal entity	4
	Downloading an official Legal entity and importing it into IUCLID 5	8
	Creating a Legal entity for customers to be listed in a PPORD notification	12
2.	REFERENCE SUBSTANCES	13
	Querying / updating Reference substances in your inventory	13
	Creating a Reference substance	16
3.	CREATING A SUBSTANCE DATASET	20
4.	ENTERING INFORMATION IN THE SUBSTANCE DATASET	23
	Section 1: General information	23
	1.1: Identification	23
	1.2: Composition	28
	1.3 Identifiers	30
	1.4: Analytical information	33
	1.8: Recipients	34
	1.9: Product and process oriented research and development	35
	Section 2: Classification and Labelling	36
	2.1. Global Harmonised System	36
	2.2 DSD – DPD	40
	Section 3: Manufacture, use and exposure	43
	3.3. Sites	43
	Sections 4 to 13	45

5.	CREATING A PPORD DOSSIER	.46
6.	EXPORTING A PPORD DOSSIER	.49
7.	UPDATING A DOSSIER	.51
	Updating the information	.51
	Attaching files as additional information	.51
	Creating the updated dossier	.54
8.	SUBMITTING A PPORD DOSSSIER TO ECHA	.56
	Sign-up procedure	.56
	Login to REACH-IT	.57
	Submission of a IUCLID 5 PPORD notification dossier	.58

INTRODUCTION

The purpose of this guide is to assist in the preparation of product and process orientated research and development (PPORD) dossiers using IUCLID 5.

The guide assumes that IUCLID 5 has been installed and that you have a user account assigned to the Legal entity created during the installation of IUCLID 5. If IUCLID 5 has not yet been installed, please consult the IUCLID 5 web site available at http://iuclid.eu. In this web site, you can download the software free of charge, and also find more comprehensive guidance about the use of IUCLID 5.

This manual provides a stepwise approach for the preparation and submission of a PPORD notification dossier:



1. LEGAL ENTITIES

The "Legal entities" are used in IUCLID 5 to provide contact details on the companies involved in processes under REACH. For the case of PPORD notifications, it is necessary to define the Legal entities of the notifier and its customers.

There are two types of Legal entities that can be created in IUCLID 5:

- "official" Legal entities, created on the IUCLID web site, for which a central management of company identifiers (UUID) is available: it enables to subsequently identify the company in a unequivocally manner. In general companies owning and/or submitting the data or the dossiers should be official Legal entities;
- "non official" Legal entities, created directly in IUCLID 5 for which there is no central management on the IUCLID web site of company identifiers. These should be used only in cases where an unequivocally identification of companies is not critical, e.g. for reporting information on a non EU manufacturer. It is however recommended to use as much as possible the "official" Legal entities obtained from the IUCLID web site or directly from the companies owning them.

For exemption under REACH due to PPORD the manufacturer or importer or producer of articles must notify the European Chemicals Agency (ECHA) of certain information, in particular his own contact details and those of his customers. Therefore you will be required (if you have not already done so) to create, on the IUCLID 5 web site, an official Legal entity for the PPORD notifier (either the manufacturer or importer or producer of articles for the substance on which the PPORD activity takes place). For the PPORD customers, it is recommended to also get from them or create on their behalf on the IUCLID 5 web site official Legal entities for a better management of the contact details.

The creation of an official Legal entity takes place during the installation and downloading of IUCLID 5 (for more details on how to download and install IUCLID 5 refer to <u>http://iuclid.eu</u>). Additional official Legal entities can be created in the IUCLID 5 web site and imported into your IUCLID 5 installation. If the official Legal entity you wish to link to the substance is a different Legal entity as the one specified during the IUCLID 5 installation you will need to create this official Legal entity.

Creating additional official Legal entity

• Go to http://iuclid.eu. Click on the "Get IUCLID 5" tab and sign in with your username and password. You will then see the following screen:



• Click on "Create new LEO".

IUCLID5 - Microsoft Intern	et Explorer provided by ECHA			
File Edit View Favorites To	ools Help			<u>At</u>
🌀 Back 🔹 🕥 🕤 📓 💈	🛾 🏠 🔎 Search 🤺 Favorites 🥝 🔗 - 🎍	i 🛛 • 🔜 🛍 🦓		
Address 🛃 http://ecbwbiu5.jrc.it/ii	ndex.php?fuseaction=home.showAddLeox&type=private			💌 🛃 Go 🛛 Links 🎇
				Welcome Steven Buchanan (StevenBuchanan)
	Home IUCLID 5 Project Get IUCLID 5	Get Support Pre-Regi	stration News About Us	
	U	ser Info Download LEO	Creation Your LEOs	
	Legal Entity Object (LEO) Cre	ation		
	A Legal entity can be an individual, an ii research organisation, a partnership (no which you have already created a LEO.	ndustrial or commercial or n exhaustive enumeratior	ganisation (including SMEs), a university, a ı). Edit here the data about a Legal entity f	or
	Organisation information - Ger	neral		
	IUCLID 4 PIN (if available):			
	Company name (*):			
	DUNS number:			
	VAT number:			
	Organisation information - Lec	al entity contact		
	Phone number:			
	Fax number:			
	E-Mail address:			
	Legal entity web site:			
	Street:			
	Street 2:			
	Postal code:			
	City / Town:			
	Region / County:			
	Country:	other: -	~	
Done				Internet

- Complete as many of the fields as possible. In addition to the Company name, it is important that in the "Organisation information Legal entity contact" block the following fields are completed:
 - o Phone and/or Fax number
 - o E-mail address
 - o Street
 - o Postal code
 - o City/Town
 - o Country
- Click on the "Next" button.

IUCLID5 - Microsoft Internet	et Explorer provided by ECHA						
File Edit View Favorites To	pols Help						
🔇 Back 🔹 🕥 - 💌 🙎) 🟠 🔎 Search Favorites	• 🥝 🔗 🎍	🗵 • 🔜 🎇 🦓				
Address 🔊 http://ecbwbiu5.jrc.it/ir	ndex.php?fuseaction=home.showAddLec	ox&type=private					💌 🄁 Go 🛛 L
		15				Wel Log	come name surname (username1) <u>out</u>
	ERNATIONAL UNIFORM CHEMICAL INFORM	ATION DATABASE					English (en) 💌
	Home IUCLID 5 Project	Get IUCLID 5	Get Support Pre-Regis	tration News	About Us		
		Us	er Info Download <mark>LEO (</mark>	Creation Your L	EOs		
	Legal Entity Obje	ct (LEO) Crea	tion				
	A Legal entity can be a research organisation, a which you have already	n individual, an ind a partnership (non r created a LEO.	dustrial or commercial or exhaustive enumeration	ganisation (inclu). Edit here the	ding SMEs), a universi data about a Legal en	ty, a itity for	
	Organisation infor	mation - Gen	eral				
	IUCLID 4 PIN (if availab	le):					
	Company name (*):		CompanyB				
	DUNS number:		963852741				
	VAT number:		BE0999999999				
	Organisation infor	mation - Lega	al entity contact				
	Phone number:		+123456789				
	Fax number:		+129876543				
	E-Mail address:		name@CompanyB.eu				
	Legal entity web site:		http://www.companyb.eu				
	Street:		Bakerstreet 1				
	Street 2:						
	Postal code:		123456				
	City / Town:		Helsinki				
	Region / County:						
	Country:		Finland - Fl		*		

• In the "Organisation Information – Contact Person" complete as many of the fields as possible. In particular it is important that the following fields are completed:

- o Organisation
- o First Name
- o Last Name
- Phone and/or mobile and/or fax number
- o E-mail address
- o Street
- o Postal code
- o City/Town and/or Region/County
- o Country.

and hot	ndex.php?fuseaction=home.showAddLeox2&type=p	private	Sec. 1
			Welcome name surname (username1) Logout
	ERNATIONAL UNIFORM CHEMICAL INFORMATION DATA	Base	English (en
EUROPEAN COMMISSION	Home IVCLID 5 Project Get IV	CLID 5 Get Support Pre-Registration News About	ıt Us
		User Info Download LEO Creation Your LEOs	
	Enter data about the person th	at will act as primary contact for the Legal Entity.	
	Organisation:	Company B	
	Department:	Regulatory affairs	
	Title:	Mr	
	First name:	Name	
	Last name:	Sumame	
	Phone number:	+123456789	
	Phone humber.		
	Mobile number:	+050123456789	
	Mobile number: Fax number:	+050123456789 +129876543	
	Mobile number: Fax number: E-Mail address:	+050123456789 +129876543 name@companyB.eu	
	Mobile number: Fax number: E-Mail address: Street:	+060123456789 +129876543 name@companyB.eu Bakerstreet 1	
	Mobile number: Fax number: E-Mail address: Street: Street 2:	+060123456789 +129876543 name@companyB.eu Bakerstreet 1	
	Mohie number: Fax number: E-Mail address: Street: Street 2: Postal code:	+060123456789 +129876543 name@companyB.eu Bakerstreet 1 123456	
	Phone Handbar Mobile number: Fax number: E-Mail address: Street: Street 2: Postal code: City / Town:	+050123456789 +129876543 name@companyB.eu Bakerstreet 1 123456 Helsinki	
	Note Handar Mobile number: Fax number: E-Mail address: Street: Street 2: Postal code: City / Town: Region / County:	+050123456789 +129676543 name@companyB.eu Bakerstreet 1 123456 Helsinki	

• Click on the "Submit" button.

You have now created your official Legal entity.

Downloading an official Legal entity and importing it into IUCLID 5

• Click on the "Get IUCLID 5" tab from the IUCLID 5 home page and click on "Your LEOs" link.

IUCLID5 - Microsoft Internet Explorer provided by ECHA			
File Edit. View Favorites Tools Help			
Address Thtp://ecbwbu5.rr.kt/index.php?fuseaction=home.vourLeoxsStype=private			So So
		Welcome name s Logout	urname (username1)
			English (en) 💌
EUROPEAN COMMISSION Home IUCLID 5 Project Get IUCLID 5 Get Support Pre-Registration News	ws About Us		
Your LEOS			
Legal entity Name UUID Country Adv	ddress Edit	t LEOX	
CompanyB 10C5-0eb52f1c-e51f-4a77-a4ea- Finland - Hel- e059480a94d3 FI 1	elsinki, Bakerstreet <mark>Edit</mark>	Download	
			Legal notice

- Click "Download". You will download a "Legal entity Object" (or LEO) that contains the information of your official Legal entity. However, it is still not linked to your local IUCLID 5 installation.
- In the main task panel of IUCLID 5, click on "Import".

Note: this import procedure applies to Legal entities other than your own one under which you have executed the installation process of IUCLID 5.

• Use the browser window to select the new LEO you created.

ify content carefully before importing	
elect the import file	
	٩,
Overwrite mode	
) never	
always	
🔾 ask user	
) ask user	

• Press "Next" in the following windows. A confirmation message will appear. Press "Finish".

🚼 Imp	ort assista	int				
Please s Verify ci	elect the .i5 ontent care	z file to be fully befor	imported e importing			\$
Im poi	t Doci 🏢 Com	ument panyB /	Endpoint	Last modification 2008-04-18 21:0	Compared to data	Validation
			<u>.</u>			
]-2-[3		< <u>B</u> ack	Next >	inish <u>C</u> ancel
P	repare the i	mport				

• Now you have to assign this new Entity to your user. Go to "User management" in the main task panel.



• In the user management screen select the user to which you want to associate this new official Legal entity.

<u>Eile E</u> dit <u>Go W</u> indow <u>H</u> elp <u>P</u> lugins	
O O ♠ H = Z ⊡ > + i	
🚑 All users	🤱 PPORD notifier – – last login: (Never) from (Nowhere)
💠 PPORD notifier 🛛 🚱	
🔏 PPORD notifier	Suspended
	Login name PPORD notifier
	Full name
	Set password
	Remarks

• Now go to "Assign Legal entities" and press the 🕩 button. A query window will appear. Type the name of the official Legal entity you want to assign and press "Search".

Image: Search for legal entities to be assigned to the user Note: Only official entities (LEO) that have been created on and downloaded from the IUCLID Download web site can be assigned to a user Legal entity name Company8 Town
only Legal entity name Company8 Country Show only active values Search ROP Name E-mail Address
Legal entity name CompanyB Town d les Country Country Showonly active values Search emi ROP Name E-mail Address
ed le Country Show only active values Search
ed les Country Show only active values Search
Country Show only active values Search
IROP Name E-mail Address
IROP Name E-mail Address
Company R (Halainki, nama @Company R av. Relayertment 1, 133456, Ha
GG- GK- Companys / Heisinki name@Companys.eu Bakerstreet 1, 125456, He
Number of results: 1/1
Assign <u>Close</u>

• Right click on the Legal entity you want to assign. If the tick box for "Active trade partner" is not checked, click on "active trade partner" to activate it. Then press "Assign".

	🚺 Query						
Jnassigned 事	Search for legal enti Note: Only official en can be assigned to a	ties to be assig ntities (LEO) the 1 user	ned to the user at have been created on a	and downloaded from 1	the IUCLID Download web	site	
-uii access Read-only							
	Legal entity name CompanyB						
	Town						
ssigned le	Country						
2	Country						
ф ф					Show only active va	lues Search	
🏥 Chemi							
EUROP	Name CompanyB / H	lelsinki hami	E-mail e@CompanyBeu	Address akerstreet 1 123456	He		
📕 HÄGG-			邊 <u>P</u> rint table				
			☐ <u>C</u> opy table	Ctrl-C			
			Active trade	e partner			
		Number of rec	ults: 1/1				
		rumber of rest					
		Number of res					
					Assign	Close	

• Press the "Save" button to save the changes. This change will only be active the next time you log in, so you may need to re-initialise IUCLID 5.

🚰 IUCLID 5 - Warning	
Warning	1
Changes will become active after th	e next login (USR2020)
	<u></u> K

- The next time you log in IUCLID 5 as that user, the new Legal entity will be assigned to your user account.
- Where you have assigned more than one official Legal entity to the same user, you may switch between them by clicking on the name of the Legal entities at the bottom of the main screen. The substances and dossiers created will, by default, be associated to the Entity selected in this box.



<u>Creating a Legal entity for customers to be listed in a PPORD</u> <u>notification</u>

The Legal entity of the PPORD customers can be created directly from IUCLID 5 as non-official Legal entity. For further information, please consult the IUCLID 5 End User manual available on the IUCLID 5 web site.

However, it is recommended instead to get from the customers or create on their behalf on the IUCLID web site official Legal entities for a better management of the contact details. To create and/or import the official Legal entity of the PPORD customer, follow the procedure described above. Note that you do not need to assign the official Legal entity of the PPORD customers to your user account.

2. REFERENCE SUBSTANCES

To correctly identify the substance in a PPORD notification dossier, it is important to understand the concept of substance, Substance dataset and Reference substance in IUCLID 5.

The PPORD notification dossier is prepared for a **substance** as defined under REACH (Article 3(1)).

In IUCLID 5, the information related to that substance (such as the identity of the substance, its composition, classification and labelling, tonnage, etc) should be specified in the **Substance dataset** created for that substance.

To insert information on the identity of your substance and its constituents in the Substance dataset, you will need to use the concept of "**Reference substance**". A "Reference substance" is nothing more than a link to the identity of a chemical. The concept of a "Reference substance" enables you to store identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc), identity codes (e.g. EC number, CAS number), molecular and structural information in a central place, so that the information can be re-used in other datasets without having the need to retyping the data. The "Reference substance" inventory is directly maintained by you, in your local installation.

To extend the number of entries in your Reference substance inventory, we recommend you to download the ca. 70.000 pre-filled Reference substances from the IUCLID 5 web site and import them to your local installation (unless already done so during the IUCLID 5 installation). These pre-defined Reference substances have been prepared to improve data quality and minimise data entry.

In addition, you should also download an EC inventory from the IUCLID 5 web site (unless already done during the IUCLID 5 installation). This inventory consists of a list of substance identities which is based on a combination of the following EU inventories: EINECS, ELINCS and NLP-list. When creating a new Reference substance with an EC number, you can minimise the data entry and ensure data quality by extracting the data from the EC inventory.

In this section of the manual, you will find the procedure to be followed for searching, updating and creating the Reference substances to be assigned to your substance directly from the main task panel. Note that it is also possible to create Reference substance directly from the Substance dataset (see point 4).

Querying / updating Reference substances in your inventory

• Click on "Update" under "Reference substance" on the main task panel.



 If during the installation of IUCLID 5 you have chosen to download and install the Reference substance inventory, you will have approximately 70.000 Reference substances stored in your computer. A warning will appear, indicating that the query panel can only show 500 items. If you answer "Yes", this warning will not appear in the future. If you answer "No", you will have the same warning every time you go to the Reference substance inventory. Either way, you will be redirected to the Reference substances screen.



• Press the "Query" button.

Eile Edit Go Window Help Plugins C O 🟫 🔜 🖶 🗹 🔃 🍲 🗇	8 6 0 A 1 6 9 1 6
💐 Navigation 🗖 🗖	12
Query results Query	Please open a document

• A dialog box will appear. Select "Find Reference substances" from the "Select query" pick list.



• Type the search criteria for the substance you are looking for and press "Search". You can use the asterisk (*) as a wild card. For example, to get all the substances starting by "phenol" you would type "phenol*". To get all the substances ending in "amine" you would type "*amine" (note that only 2.000 results will be shown).

1	🖁 Query 🛛 🔀				
1	Select query result type: 😻 Reference substance 🔹 👻				
	Select query: Find reference substances 🔷 👻				
	Query specific fields				
	Reference substance name eth#				
	CAS number (EC Inventory)				
	EC name				
	EC number				
	CAS number				
	CAS name				
	IUPAC name				
	Synonyms				
	SMILES notation				
	Molecular formula				
	InChi				
	Search Cancel				

• Double click on the Reference substance to display the related data

NUCLID 5					
<u>F</u> ile <u>E</u> dit <u>Go W</u> indow <u>H</u> elp <u>P</u> lugins					
G D 🏫 H H Z @ B 4 1	3 🖆 🖉 🕲 🖉 🕲	n P			
💐 Navigation 🖓 🗖	2				- 0
Query results	Please open a decum	ant			
Query	riease open a docume	ent			
*					
🗊 ethacridine / 7-ethoxyacridine-3.9-diami 🔺					
thacridine lactate / 2-bydroxypronanoic					
t ethambutol / 2.2'-(ethane-1.2-dividiiming					
🕱 ethane / ethane / 74-84-0					
😰 ethane-1,2-diol / ethylene glycol / 107-2					
🐮 ethane-1,2-disulphonic acid, compound v					
😰 ethane-1,2-disulphonic acid, compound v					
🕸 ethane-1,2-dithiol / ethane-1,2-dithiol / :					
🗊 ethane-1,2-diyl palmitate / ethane-1,2-di					
🗱 ethane-1,2-diylbis[dichloromethylsilane]					
💱 ethanesulphonic acid / ethanesulfonic aci					
💱 ethanesulphonyl chloride / ethanesulfony					
T ethanethiol (ethanethiol (75-08-1					
🗱 ethanol / ethanol / 64-17-5					
1 thaverine / 1-(3,4-diethoxybenzyl)-6,7-					
🐺 ethaverine hydrochloride / 1-(3,4-dietho:					
🐺 ethenzamide / 2-ethoxybenzamide / 938-					
🐺 ethiazide / 6-chloro-3-ethyl-3,4-dihydro					
🕸 ethinamate / 1-ethynylcyclohexyl carbam					
ethinylestradiol / 17-ethynylestra-1,3,5(1					
thion / 0,0,0',0'-tetraethyl S,S'-methyle					
ethionamide / 2-ethylpyridine-4-carboth					
thisterone / 17-hydroxypregn-4-en-20					
etnoate-methyl / S-[2-(ethylamino)-2-ox					
etnoneptazine / etnyl 1-methyl-4-phenyla					
sthosuvinide (B-athyl-B-mathyleverolide					
Construction of the second sec					
	Information				8 8
📑 start 🔰 🕼 🔄 🗹 🖾 🖸 🍳	🛅 2 Win 👻 🕎 2 Mic 👻	🚳 C:\WI 🥻 🚺 IUCLID 5	谢 untitle	EN 🕄 🚆	10:25

• Check the data on the Reference substance. To update/add any information on the Reference substance, press the "Edit item" button (☑) in the toolbar on the top of the screen, edit the information on the Reference substance, and save the changes.

Creating a Reference substance

If you do not find in your Reference substance inventory the Reference substance you need, you can create it following this procedure:

• In the main screen, go to inventories and click on "New" under "Reference substance".



• Type the name of the Reference substance in the "Reference substance assistant" pop-up window. The box "Active Reference substance" should be checked, as only Reference substances marked as "active" can be used during the creation of a substance dataset.

Reference substance ass	istant 🔀
Create a new reference substan	ce
Reference substance name Re	etinoline ۹
	< <u>B</u> ack Next > <u>Finish</u> <u>C</u> ancel

• Select the "Finish" button; the Reference Substance is created and an empty Reference substance section appears. Click on the "Edit item" button.

👣 Reference substanc	re: Retinoline 📼	٥
General inform	ation	
Reference substance r	name Retinoline	
EC inventory —		
EC number	CAS number	
EC name [1000
Molecular formula	٩	
Description		
No EC Informat	Ion available	
Justific	cation	
Reference subs	tance information	
۳		
CAS information	·	
CAS nu	imber 🔍	
CAS	name	

- If the Reference substance is listed in the EC-inventory:
 - Assign that entry by pressing the *inventory* button. The query dialog appears in which EC inventory entries can be searched.
 - Search using any of the criteria listed, such as the EC name of the substance. Again, you can use "*" as a wild card.

🚰 Query					
Find information	n in the EC inv	rentory			
EC v	umber				
<u>د د ا</u>					
. E [,]	C name ret*				
CASI	number				
EC molecular f	ormula				
Desc	Description				
					Search
State	EC number	EC name	CAS number	Molecular f	Descriptic
*	200-683-7	retinol	68-26-8	C20H30O	
*	201-228-5	retinyl palm	79-81-2	C36H60O2	
n 🚖	204-135-8	retinaldehy	116-31-4	C20H28O	
*	204-844-2	retinyl acet	127-47-9	C22H32O2	200
*	230-363-2	retinyl prop	7069-42-3	C23H34O2	
*	243-876-1	retinyl pival	20559-05-1	C25H38O2	
*	289-433-6	retinyl hept	88641-44-5	C27H42O2	-
•		333333			
	Numb	per of results: :	11		
	Assign <u>C</u> lose				<u>C</u> lose

- Highlight from the list the entry that matches your Reference substance.
- Click the "Assign" button. The information for this Reference substance will be included in your new Reference substance.
- If your Reference substance is not in the EC inventory, select a justification from the pick list proposed under the "No EC information available" section.

No EC information a	available
Justification	۹. 🗹

• Complete as far as possible the remaining fields of the Reference substance.

When completing the information for your Reference substance, the following information should be submitted for all the known constituents and impurities:

- EC number and EC name (when available)
- CAS number and CAS name (when available)
- IUPAC name

- Molecular formula
- Molecular weight
- SMILES notation
- Structural formula

VI IUCLID 5		
<u>Eile Edit Go Window H</u> elp <u>P</u> lugins		
00 🝙 🔒 😸 🔯 💩 🔶		
💐 Navigation 🖳 🗖	💖 Reference substance: Retinoline	-
Query results	General information	
Query	Reference substance name Retinoline	۹ 🎾
	EC inventory	
	EC number 200-683-7	× Ø 🔀
	EC name retinol	
	Molecular formula C20H30O	9,
	Description	
	No EC information available	
	Justification	
	Reference substance information	
	P	
	CAS information	
	CAS number 68-26-8	
	CAS name	
	IUPAC name	
	Decoviation	
	Description	1

For the structural formula, go to "Structural formula", under "Molecular and structural information" and press the "Add" button. You can then upload an image file with the structural formula.

۴	E Open	
Molecular formula	Look jn: Desktop	- E 🖨 🛱 🗄
Molecular weight range 🛛 👻	w u07102	image preview
SMILES notation	My Network Places My Network Places My Network Places Shortcut to general on 's-echa-vpsv-04Data' (W)	
InChi		
Structural formula		
Eoad	File Name:	
Remarks	Files of Type: Images (*.gif;*.jpg;*.jpeg;*.png)	

3. CREATING A SUBSTANCE DATASET

To create a PPORD notification dossier in IUCLID 5, you need first to create a Substance dataset. A Substance dataset is the repository of data, which is used as a basis to create the dossier to be submitted to the ECHA.

• On the IUCLID 5 Task Panel, under Tasks, select "New" from Substance.



• Type the name of your substance for which you are conducting PPORD activities on. The name can be anything, but it is logical to use an identifier that you are familiar with such as a trade name or chemical name, a CAS number, etc.

Substance assi	stant	
Create a new substar	nce	5
Chemical name PP	ORD-Reaction mass	٩
E-2 Set name	Sack Next > Einish	Cancel

• Click the "Next" button. Select the Legal entity to be assigned to the Substance dataset. This Legal entity must be the PPORD notifier.

🐖 Substance assistant	
Create a new substance	5
Legal entity 🏾 🏦 CompanyB / Helsinki / Fin 🔻	
2 < <u>Back</u> Einish Set legal entity	<u>C</u> ancel

Remark: if the Legal entity to be linked to the Substance dataset is not available from the pick up list, a new Legal entity can be assigned to the user. For this purpose, please refer to the instruction provided in the "Creating an official Legal entity" and "Downloading an official Legal entity and importing it into IUCLID 5" sections above.

- Click the "Finish" button. You have now created a Substance dataset.
- The section tree of your Substance dataset is displayed in the navigation part of the screen (to see the complete tree view press and select "expand all" from the pop up menu).

Query results Section tree	Substance identification Chemical name ppORD- Reaction mass			
<u></u>	Legal entity flags			
🕀 🎓 0 Related Information	Refresh			
🕀 🥦 1 General Information	🖪 Expand all Ctrl-Plu	5		
2 Classification and Labelling	📃 Collapse all			
 S Manufacture, use and exposure 4 Physical and chemical properties 	Update references			
 For the second se	Show endpoint study records only Show endpoint summaries only			
8 Analytical methods	Show endpoint study records and summaries			
12 Literature search	Copy contents to clipboard	ily representative		
🔤 🌪 13 Assessment Reports	Reference substance			
	Type of substance Composition Origin Trade names	4 7 4 4 7 4		

 IUCLID 5 also offers the possibility of highlighting sections that are suggested for completion to assist in the preparation of a PPORD dossier. Click on the button and select "REACH PPORD" from the pick list.

Jery results 🛛 😻 Section tree	Substance identification	
CH PPORD	E List	
	Select an item	
🛓 0 Related Information 📃 🔺		
🤀 0.1 Templates		
😳 🐻 0.3 Mixtures		
L General Information	REACH PPORD	A .
1.1 Identification	REACH Registration 1 - 10 tonnes, physicochemical requirements	
1.2 Composition	REACH Registration 1 - 10 tonnes, standard requirements	
1.3 Identifiers	REACH Registration 10 - 100 tonnes	
	REACH Registration 100 - 1000 tonnes	
1.8 Recipients	REACH Registration above 1000 tonnes	Downstream user
	REACH Registration member of a joint submission - general case	
2 Classification and Labelling	REACH Registration member of a joint submission - intermediates	
2.1 GHS	OK Can	el
2.2 DSD - DPD		
3 Manufacture, use and exposure	Type of substance	
4 Physical and chemical properties	Composition	9
4 1 Appearance (physical state (colo		
4 2 Melting point /freezing point	Origin 🔍 📉	9
4 3 Boiling point		11
4.4 Density	Trade names	
	Trade names flag 🏾 🏴	
🔶 4.6 Vapour pressure		
🔶 4.7 Partition coefficient		Name
🛛 🌪 4.8 Water solubility		

• In the section tree, the sections IUCLID 5 suggests as necessary for a PPORD dossier will appear marked in red (* or -). The ones that IUCLID 5 consider optional for a PPORD dossier are marked green. It is important to note that this is just for guidance. You should refer to the legal text of the REACH regulation to understand fully your requirements.

4. ENTERING INFORMATION IN THE SUBSTANCE DATASET

Once you have created a Substance dataset for your substance that has been assigned to the Legal entity of the PPORD notifier, you can enter data on the substance in this dataset. The information requirement to be included in the Substance dataset is described in the REACH regulation (Article 9(2)) and the associated PPORD guidance available on the ECHA website (http://reach.jrc.it/guidance_en.htm).

To retrieve the substance dataset you have already created, press "Update" under "Substance" in the main task panel, and select your substance from the list by double clicking on it.



Then, open the section tree and proceed to complete the necessary sections. Double click in each section to open it, and press the "Edit item" button in the upper part of the screen to complete the fields.



Section 1: General information

1.1: Identification

Name of the substance

• In "Reference substance" click on the 🖉 button to assign a "Reference substance" to your substance.

Reference substance	\frown
	S 2 2 2

• A query dialog appears. Search for your "Reference substance" as described in point 2 of this manual.

Third party	Sterv Cuerv	
in the supply chain	Find the reference substance	
Role flags		EE
Role: Manufacturer 🔲 Importer 📄 Only representativ	e Do	
ranca cubstanca	Defense and the second proper by the second	
Tence substance	Reference substance name PPORD Reference substance	
	CAS number (EC Inventory)	
of substance	EC name	
omposition 🔍 💌	EC number	
Origin 🔍 👻	CAS number	
	CAS name	ī
e names	IUPAC name	
	Supervine	
	Synonyms	
	SMILES NOTATION	
	Molecular formula	
	InChi	
Add Edit Delete		the values
act person		
erson flags 🛛 🥦		
roanisation	9	
	New Ass	gn <u>C</u> lose

• Highlight the Reference substance from the results and click "Assign".

na me reference substance				hili
Reference substance name	PPORD Refer	ence substance		
CAS number (EC Inventory)				
EC name				
EC number				
CAS number				
CAS name				
IUPAC name				
Synonyms				
SMILES notation				
Molecular formula				
InChi				
	E] Show only active	e values	Search
Name		UUID 🔻	Rema	arks Las
FPORD Reference su	bstance /	IUC5-5b3b1bf5	·0	200

Note: It is possible that the Reference substance exists but you have not set it as "Active". In this case, untick the "Show only active values" tick box to display both the Reference substances marked as active and inactive. Right click on the non activated substance you want to assign. Click on "active trade partner" to activate it. Then press "Assign".

- If you cannot find your Reference substance because it has not been created yet:
 - Click on "New" to create a new Reference substance.

na the reference substa	nce			hth
Reference substance na	ame PPORD ref	erence		
CAS number (EC Invento	ory)			
EC na	ame			
EC num	ber			
CAS num	ber			
CAS na	ame			
IUPAC na	am e			
Synony	/m s			
SMILES nota	tion			
Molecular form	iula			
In	Chi			
		5	Show only active values	Search
Name	UUID 🔻	Remarks	Last modification	
	Number of	results:		
				100000000000000000000000000000000000000

- You will be redirected to the "Reference substance assistant" (see previous section of the manual).
- Type the name of the Reference substance you need to create.

igs P	
ole: 🗌 Manufactu	rer 🗌 Importer 🔲 Only representative 📄 Downstream user
substance —	Reference substance assistant
	Create a new reference substance
bstance —	
ion	
gin	Reference substance name PPORD reference substance
es	Active reference substance
lag 🏴	
	< <u>Back</u> Next> Einish Cancel

• To specify the information on the new Reference substance, press the blue arrow button.

PPORD reference substance	
number EC name	

- You will be redirected to the screen for the new Reference substance. Fill in all the possible fields as shown in point 3 of this manual.
- Press the "Save" button.
- Press G button to go back to the Substance (save when requested).
- Fill manually all the other boxes (again, you should complete as many as possible).
- The buttons The boxes "Composition" and "Origin" allow you to choose from pick lists.
- The button "Add" (Add.) allows you to create boxes to add trade names.

Contact person

Although the contact details of your company are specified in the "Legal entity", you can also indicate the information details of the contact person for that specific substance. Complete as many of the fields as possible.

Contact perso	on	
Person flags	h	
Organisation	CompanyB 🔍	
Department	Regulatory affairs	
Title	Mr 🔍	
First name	First Name	
Last name	Last Name 🔍	
Phone	+1234567890	
Mobile	+0501234567890	
Fax	+1209876543	
E-mail	name.surname@CompnayB.eu 🔍	
Address	Bakerstreet 1	
Address	٩,	
Postal code	123456	
Town	Helsinki	
Region / State	٩	
Country	Finland 🔍 🔽	۹,
Remarks	<u>ا</u> ۹	

1.2: Composition

- Click on section 1.2 (Composition) and press the "Edit item" button.
- Click the "Add" button
- Write the name and a brief description of your substance.

Reaction mass of i	odocyclopentane and cyclopentane-1,2,3,4-tetracarboxylic acid	*	4	4	• (×
Name	Reaction mass of iodocyclopentane and cyclopentane-1,2,3,4-tetracarboxylic acid				Q	4
Brief description	Multiconsituent substance for PPORD				Q	

• Complete the "Degree of purity" section. The degree of purity to be specified should correspond to the purity of the main constituent(s) of the substance. The arrow buttons allow you to pick symbols or units from a pick list, and the boxes allow you to type numbers. In this part you can give the normal range of purity for the substance. For instance, a substance with purity between 95-98% (w/w) will be given as shown in the picture.

1	

- Open the Constituents repeatable block (by pressing the "Add" button 中).
- Assign a "Reference substance" to the newly created Constituent by pressing the *button*, as described above. Search for the appropriate Reference substance and add it by selecting it and pressing "Assign". Create the substance you need if it was not created in advance.
- Indicate the typical concentration and the concentration range for every constituent in the same manner as indicated for the substance purity.

		¥ 🛠 (
. 48 % (w/w) A /iodoc	/clopentane / iodocyclopentane / 1556-18-9	🗙 全 冬 争 []
)PP		
Reference substance	🕸 A / iodocyclopentane / iodocyclopentane / 1556-18-9	۵ 🎽 🍂
	EC number EC name	
	216-311-1 🔍 iodocyclopentane	
	CAS number CAS name	
	1556-18-9 🔍 iodocyclopentane	
	IUPAC name	
	iodocyclopentane	
ypical concentration	ca. 🔻 48 56 (w/w) 🔻	
Concentration range	> • 47 < • 49 % (w/w) •	
Remarks		۹,

If you need to specify more than one constituent, click the "Add" button in the relevant section, and more boxes will appear.

a. 48 % (w/w) iodocycl	opentane / iodocyclopentane / 1556-18-9	****
p		
Reference substance	🔯 iodocyclopentane / iodocyclopentane / 1556-18-9	۵ 🗙 🔇
	EC number EC name	
	216-311-1 🔍 iodocyclopentane	
	CAS number CAS name	
	1556-18-9 🦄	
	IUPAC name	
	iodocyclopentane	1
Evnical concentration		
Concentration range	> • 47 < • 49 % (w/w) •	
Remarks		9
	L	× 4 8 4 1
		¥ ÷ 3 ¢
1. 42 % (w/w) cycloper	l ntane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5	¥ 2 3 4 \$ 2 3 4
1. 42 % (w/w) cycloper	ntane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5	¥ ≵ 3 ⊕ ★ 1 3 ⊕
a. 42 % (w/w) cycloper P Reference substance	ntane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5	× + 3 + 1 × + 3 + 1 × + 3 + 1 × >
a. 42 % (w/w) cycloper p Reference substance	tane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5	× • 3 • 1 × • 3 • 1 ~ () × 8
a. 42 % (w/w) cycloper p Reference substance	tane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5	× 2 3 4 1
a. 42 % (w/w) cycloper p Reference substance	Itane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid Image: cyclopentane-1,2,3,4-tetracarboxylic acid CAS number CAS name	 ★ ★ 3 ↓ 1 ★ ★ 3 ↓ 1 <!--</td-->
a. 42 % (w/w) cycloper p Reference substance	Itane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid Image: c	× + 3 + 1
a. 42 % (w/w) cycloped p Reference substance	Itane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid CAS number CAS number Image: cyclopentane-1,2,3,4-tetracarboxylic acid Image: cyclopentane-1,2,3,4-tetracarboxylic acid CAS number CAS number Image: cyclopentane-1,2,3,4-tetracarboxylic acid Image: cyclop	× • 3 • 1
a. 42 % (w/w) cycloper	Itane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid / cyclopentane-1,2,3,4-tetracarboxylic acid / 3724-52-5 Image: cyclopentane-1,2,3,4-tetracarboxylic acid Conumber EC name Image: cyclopentane-1,2,3,4-tetracarboxylic acid Conumber EC name Image: cyclopentane-1,2,3,4-tetracarboxylic acid Conumber CAs number Image: cyclopentane-1,2,3,4-tetracarboxylic acid Image: cyclopentane-1,2,3,4-tetracarboxylic acid	

		¥
		🗙 🕆 3 🍨
P		
Reference substance		۹ > X
Typical concentration		
Concentration range		
Remarks		
ditives		
ditives		¥ :
ditives		¥ : \$ 2 3 \$
ditives		×: \$ ÷ 3 ∳
ditives		¥ : ★ ÷ 3 ∳
ditives		× : ♦ € € \$ €
ditives	<u>مامار</u>	× • • • • • ۹ الا (
ditives		¥ : • • • • ۹)گارا
ditives		× * * * * * *
ditives		۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲ ۲
ditives		ي ي مر]
ditives		پ ۹ ۹ ۹ ۹ ۱۹ ۹

• Follow the same procedure to complete the impurities and additives fields.

1.3 Identifiers

In this section you can add identifiers for other regulatory programmes or IT systems.

In particular, if the research activities for which the PPORD notification dossier is prepared correspond to a PORD notification expiring on 1st June 2008, it is recommended that you report the corresponding PORD notification number as follows:

• Open the section 1.3 of the IUCLID 5 substance dataset by doubleclicking on "1.3 Identifiers" and press the "Edit item" button.

Query results 🛛 😪 Section tree	Identifiers			
Complete 🔍 👻	identifiers			
*	Regulatory programme iden	tifiers		
E 😵 0 Related Information	Flags	Regulatory programme	ID	Remarks
🚊 🍖 1 General Information				
1.1 Identification				
1.3 Identifiers				
1.4 Analytical Internation	Add III Edit	Delete		
1.6 Sponsors		an benere		
1.7 Suppliers	Other IT system identifiers			
	Flags	IT system	ID	Remarks
1.9 Product and process oriented rese				
🗄 🜪 5 Environmental fate and pathways				
🖶 🜪 6 Ecotoxicological Information				
7 Toxicological information	Add Edit	Delete		
O Analytical methods 9 Residues in food and feedingstuffs				
B 10 Effectiveness against target organisms				
🕫 🐤 11 Guidance on safe use				
13 Assessment Reports				
	information			
	Information Modification k	istony	schwants Annotations in Validation	
	Mudification r	istory access of consumation State	Armotations 🔀 Validation	-

• In the "Regulatory programme identifiers", select "Add" to edit the list of identifiers. A new window entitled "Regulatory programme identifier" appears on the screen.

Query results 🛛 🙀 Section tree	Identifiars	
Complete 🔍 🗸 🔽		
₩ ▼	Regulatory programme identifiers	
T O Deleted lefermation	Flags Regulatory programme ID	Remarks
1.1 Identification		
- 1.3 Identifiers		
1.4 Analytical information	Regulatory programme identifier	
1.5 joint submission	Md a resultion programme identifier	
1.0 sponsors	Other in victor identifiars	
1.8 Recipients		
1.9 Product and process oriented rese	15	
🕀 🌪 2 Classification and Labelling	L	
B S Manufacture, use and exposure		
	Regulatory programme	a, 🕶 a,
6 Ecotoxicological Information		
🗈 🤹 7 Toxicological information	R Add R Edit R Delete	
🗕 🜪 8 Analytical methods	Remarks	٩
9 Residues in food and feedingstuffs		
The section of t	ля 	QK <u>C</u> ancel
12 Literature search		
🕞 😨 13 Assessment Reports		
	information	- 8
	🔯 Information 🛯 😵 Modification history 🛛 👶 Access 📝 💋 Consultation 🛸 Attachments 👘 Annotations 👘 🙀 Validat	ion
•		:

- In the new "Regulatory programme identifier", complete the fields as follows:
 - "Other" should first be selected as regulatory programme.
 - "PORD" should then be specified as the regulatory program in the subsequent field, to clarify that the identifier to be provided corresponds to a PORD notification number.
 - The number or identifier of the PORD notification corresponding to the PPORD to be notified to the ECHA should be specified in the "ID" field. This number should be a unique identifier of the PORD that was provided by the MS CA.
 - Finally, the country where the PORD notification was made should be indicated in the "Remarks" field. It is recommended that the name of the country is given in English language (i.e. Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Germany, Denmark, Estonia, Finland, France, United Kingdom, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Poland, Portugal, Romania, Spain, Sweden, Slovenia, or Slovakia).

For instance, a PORD notification made in Germany which was attributed the number "4567/07" by the German MS CA should be reported as follows:

🚰 Regulatory program	me identifier	
Edit the regulatory progra	umme identifier	
P		
Regulatory programme	other:	PORD
ID	4567/07	۹,
Remarks	Germany	٩
		<u>OK</u> <u>C</u> ancel

• By pressing OK in the "Regulatory programme identifier" window, the PORD notification number will appear in the list of regulatory identifiers.

Query results 🛛 📦 Section tree	ldentifiers				
Complete 🔍	Pagulatory programme identifiers				
⇒ 1	Regulatory programme identifie	irs			
😥 🜪 0 Related Information	Flags	Regulatory programme	ID	Remarks	
🖶 🌪 1 General Information		otherPORD	4567/07	Germany	
1.1 Identification					
1.2 Composition					
1.3 Identifiers					
1.5 Joint submission	Add Edit	Delete			
1.6 Sponsors					
1.7 Suppliers	Other IT system identifiers				
1.0 Recipients	Flags	IT system	ID	Remarks	
Classification and Labelling					
🗄 🍖 3 Manufacture, use and exposure					
🛓 🍖 4 Physical and chemical properties					
🖶 🐤 5 Environmental fate and pathways					
🐵 🜪 6 Ecotoxicological Information					
7 Toxicological information	🙀 Add 🔛 Edit 🙀	Delete			
8 Analytical methods					
9 Residues in food and feedingstuffs					
10 Effectiveness against target organisms					
12 Literature search					
13 Assessment Reports					
	Information			- 8	
	👔 Information 🛛 😢 Modification history	y 👌 Access 💋 Consultation 📎 Atta	chments 📃 Annotations 🗌 📩 Validation		
				:	

• Where a PORD application has been accepted in more than one EU country the notifier of the corresponding PPORD should indicate each PORD identifier/number and country.

1.4: Analytical information

- Double click on 1.4 "Analytical information" and press the "Edit item" button.
- Under the "Analytical method" field, describe the analytical methods used to characterise your substance, and where appropriate, the impurities and additives. You can also attach such information by pressing the Substance (note that you can only attach one file in each field).
- Under the "Optical activity" field, provide information on the optical activity and typical ratio of (stereo) isomers, whenever applicable and appropriate.

Analytical info	ormation
۳	
Analytical methods and spectral data	UV/VIS spectra, IR spectra, NMR spectra
	0 B
Ontirel activity	
Optical activity	See attached file

 Provide the analytical results used to characterise the substance, such as spectral data (UV, IR, NMR, MS, etc.), chromatographical data, etc. For each analysis, press the "Add" button and enter the analysis type, the tested substance, the method used and any remark you consider relevant. For every analysis you can also attach one file by pressing the S button.

Results of analy	vsis
,	× × 🕈
HPLC chromatogra	phy 😞 👳 🕸 🖡 🙀
Analysis type Tested substance Method used	HPLC chromatography
Remarks	

1.8: Recipients

This section can be used to indicate the identity of all the customers involved in the PPORD activity, including their names and addresses.

- If you have not already imported the Legal entities of your customers or created them in IUCLID 5, please refer to the point 1 of this manual.
- In the section tree of your Substance dataset, double click on section "1.8. Recipients".
- Press the "Edit item" button (²).
- Press the "Add" button. A new box where you can enter the identity of your customer will appear.

Recipients	
	¥ ☆ 🌵
	🗶 🕆 🐺 🛔 🖊
4	
Name	۵ 🗶 🆉
Remarks	

• Press the button, and the dialog to look for the Legal entities will appear. Search your customer or enter an asterisk in one of the boxes and press enter to see all the available Legal entities.

Query		
Legal entity name PPORD* Town Country Official legal entity ;		
Name	E-mail	Address
Number c	f results: 1/1	
	New	Assign <u>C</u> lose

 Select the Legal entity of your customer from the list and press "Assign". Note that you will not be able to do so if you did not check the box "Active trade partner" during the creation of the Legal entity where you stored the information of your customer. You may also provide additional information in the "Remarks" field.

You have now assigned one customer to the Substance dataset.

• To report more than one customer for the PPORD, reiterate the procedure described above as many times as needed.

1.9: Product and process oriented research and development

- In the Substance dataset section tree, double click on 1.9: "Product and process oriented research and development". Then press the "Edit item" button .
- By pressing the 👎 button you can now include the following information:
 - a name for the PPORD activities for which the notification is prepared.
 - the estimated quantity of your substance. You must report the estimated quantity of the substance to be manufactured, imported or used in the production of an article for the purpose of PPORD for the calendar year of the notification. This estimation, to be documented in section 1.9 of the IUCLID 5 Substance dataset, can be provided as an exact or approximate tonnage, or as a tonnage range. It is however important to provide as specific tonnage as possible.

You can also add, in the "remarks" field, additional information, you consider relevant for the PPORD notification dossier, such as the Research and Development programme. This information can be provided as an attachment document, using the button (here you can only attach one file: if you wish to attach several files, please use the procedure described in this manual under "Attach several files as additional information", in point 7 "Updating a dossier").

	¥ & 4
Reaction mass - PPORD	★ ÷ 3 ⊕ ¥
P	
Name Reaction mass - PPORD	
Medicinal product for human or veterinary use	
Substance not placed on the market	
Estimated quantity > V 5 Metric tonnes V	
Remarks R&D program is in attached file	
Document	
bocument	

Section 2: Classification and Labelling

The available information on the classification and labelling (C&L) for your substance should be reported in Section 2.2 (DSD-DPS) of the IUCLID 5 Section tree, in accordance with Directive 67/548/EEC.

Note however that from the 1st December 2010, the C&L will have to be reported in Section 2.1 (GSH) of the IUCLID 5 Section tree in accordance with the Global Harmonised System.

2.1. Global Harmonised System

- Double click on 2.1. "GHS".
- Press the "Edit item" button and then the "Add" button to display the fields where the information on the C&L can be specified.

Query results 🛛 😪 Section tree	l p					
REACH PPORD						
⇒ ▽	General information					
	Name					
Harman Ceneral Information						
2 Classification and Labelling	Not classified					
2.1 GHS	Implementation	Implementation				
2.2 DSD - DPD	Remarks					
🕀 🥐 3 Manufacture, use and exposure						
🕀 🐢 4 Physical and chemical properties						
🖶 🤹 5 Environmental fate and pathways						
🖹 📲 5.1 Stability	Classification					
5.1.1 Phototransformation in air	Physical hazards					
5.1.2 Hydrolysis			Hazard statement	Reason for no classification		
	Explosives	۹ 🔫	9	۹ 🗸		
🕀 🤏 5.2 Biodegradation	-					
🕀 🌪 5.3 Bioaccumulation	Flammable gases			<u> </u>		
🕀 🍖 5.4 Transport and distribution	Flammable aerosols	۹. 🔫	۹ 🔻	a		
🕀 🥐 5.5 Environmental data	Ovidiaina assas			a 🖢		
5.6 Additional information on environ	Oxidizing gases			10		
	Gases under pressure	۹ 🔻	۹ 💌	۹. 💌		
Arialytical methods	Flammable liquids		٩. 🗣 🛛	٩ 🗸		
🜪 11 Guidance on safe use						
🛶 🗭 12 Literature search	Flammable solids	× 🔟	Sec. 2 ≤ 1	۹ 🚬		
13 Assessment Reports	Self-reactive substances and mixtures	٩ 🖬 [٩ 🖬 [٩ 🕶		
	Pyrophoric liquids	۹. 🛨	۹. 💌	۹. 🔻		
	Pyrophoric solids	۹ 🗖	۹ 🗖	۹ 🔻		
	Self heating substances and mixtures	٩ -	۹ 🗖 📘	۹ 🗸		
	Substances and mixtures which in contact with water emits flammable gases	٩.	٩.	٩		
	Oxidising liquids	۹. 🗖	۹ 🗖	۹ 🔻		
	Oxidising solids	۹. 🗖	۹ 🗖	۹ 🔻		
	Organic peroxides	۹ 🗖	۹ 🗖	۹ 🖣		
	Substance and mixtures corrosive to metals	٩.	٩ 🖬 [۹ 🗸		
	Health hazards					
	Hazard statement Reason for no classification					
	Acute toxicity - oral	٩.	٩	٩ 🗸	-	
	Para a					

• For each hazardous property, you will find three different pick up menus:

Lassification	Pick list	
hysical hazards —		cation
Explosives	a 🚽 🛛	٩
Flammable gases	unst.expl.	٩
Flammable aerosols	a 🗨 expl. div. 1.2	Q
Oxidizing gases	expl. div. 1.3	9
Gases under pressure	expl. div. 1.5	٩
Flammable liquids	expl. div. 1.6	9
Flammable solids		2K <u>C</u> ancel
Self-reactive substances	Q . Q .	
and mixtures		0

 \circ $\;$ The first one allows you to enter the classification:

 \circ $\,$ The second one allows you to enter a hazard statement

sification			Dick list
cal hazards —			
	Haza	ard statement	3
Explosives	۹.		Lastable evaluation
Flammable gases	٩ 🖬		explosive; mass explosion hazard
Flammable aerosols	94	٩.	explosive; severe projection hazard
Oxidizing gases	٩. 🗸	٩.	explosive; fire, blast or projection hazard fire or projection hazard
Gases under pressure	8	٩	may explode in fire
Flammable liquids	۹ .	٩.	
Flammable solids	٩ 🗸	٩	<u>Q</u> K <u>C</u> ancel
e			

• The third one allows you to explain the reason why the substance has not been classified in accordance with the proposed classification and hazard statement.

hysical hazards ———			
	н	azard statement	Reason for no classification
Explosives	۹. 🚽	۹ 🕶	
Flammable gases	٩.	٩. 🗖	Pick list
Flammable aerosols	۹. 🚽	٩	李1
Oxidizing gases	۹.	۹. 🕶	data lacking
Gases under pressure	۹. 🛫	٩	inconclusive
Flammable liquids	۹ 🖌	٩. 🕶	conclusive but not sufficient for classification
Flammable solids	۹ 🖉	۹. 🚽	
Self-reactive substances and mixtures	٩.	٩.	
Pyrophoric liquids	۹. 🕙 [٩	OK Cancel
Pyrophoric solids	٩.	٩ 🕶	
12 (18) (1) (1) (1) (1) (1)			

- Once completed, press 📕 to save the changes.
- For the fields of "Carcinogenicity", "Germ cell mutagenicity", "Specific organ target toxicity-single" and "Specific organ target toxicity-repeated" you will need to press the
 button in order to display the boxes you need to complete.

erm cell mutagenicity			
muta. cat. 1A			🗶 알 주 🚇 🐂
		Hazard statement	Reason for no classification
Germ cell mutagenicity	muta. cat. 1A 🛛 🔍 🔽	may cause genetic 🔍 🔽	inconclusive 🔍
Route of exposure			Q
arcinogenicity —			
			**
carc. cat. 2			× 7 7 4 1
		Hazard statement	Reason for no classification
Carcinogenicity	carc. cat. 2 🔍 💌	suspected of causi 🔍 🍸	conclusive but not sufficient for class
Route of exposure			G
		Hazard statement	Peacon for no classification
Reproductive toxici	tv renr cat 1A		data lacking
a in a	, repried. Dr		our area and a
specific effe	α		
Route of exposu	re		
Effects on via lactatio	or 🔍	•	•
pecific target organ to	xicity - single		
			**
STOT single exp. cat 2			* + 3 4
		Hazard statement	Peacon for no classification
Specific target organ	STOT single exp. c .		
toxicity - single	stor single exp. e. e		L
Affected organs			3
Route of exposure			9
pecific target organ to	oxicity - repeated		(

		Hazard statement	Reason for no classification

• For "Labelling" you will find a pick list where you can state the "Signal word" in your labelling.

lazard statements	Pick list
	danger
Additional precautionary statements	warning
	no signal word
Additional labelling requirements	

• Press the button next to "Hazard statements", "Additional precautionary statements", "Additional labelling requirements", "Specific concentration limits" and "Notes" to access the pick up lists from which you can select the labelling

zard statements	
	* 1 *
	🎗 🛊 🕀 😫 🕽 🎽
Hazard statements user = 1 - 2 - 11 - 1	
H3UI Taxic II Swallowed.	
Additional text	Q.
ditional precautionary statements	
	* * *
	A 4 3 8 1
	× • • • • •
Precautionary statement P102 Keep out of reach of children.	۵. 🔻
4 ditional text	
Additione text	· · · · · ·
ditional labelling requirements	(
	× × 4
	🗶 🛊 🕸 🛊 🛛 🥻
	<u> </u>
Additional text	9
ecific concentration limits	
	* * *
	A A A A I
	× I V T A
Concentration range (S)	
llazard categories	
	× × +
tor	
100	
	* 1
lote C	🎗 🕆 🕀 🛛 🦹
Note L 📉 📉 📉	

2.2 DSD – DPD

- Double click on 2.2. "DSD-PDP".
- Press the "Edit item" button and then the "Add" button to display the fields to be filled for C&L.

	1			
Query results 🛛 🙀 Section tree	Classification and Label	ling according 67/	548/EEC (DSD)	
REACH PPORD		3 3 /-		×
4				***
				🗶 🕁 🖓 🙀 📕 🖊
0.3 Mixtures				
🗄 🦿 1 General Information	P			
1.1 Identification				
1.2 Composition	General information -			
1.4 tradution information	Name		9	
1.4 Analytical Information				
1 9 Product and process oriented r	Not classifie	d		
2 Classification and Labelling	Status	9.	- Q	
		بال		
2.2 DSD - DPD	Index number		4	
B & 3 Manuractore, use and exposure	ATPinserted		Q.	
3.3 Sites				
🖶 🥷 4 Physical and chemical properties	ATP last update		٩	
4.1 Appearance/physical state/col	Burnada -			
🛛 🎭 4.2 Melting point/freezing point	Remarks			
🛜 4.3 Boiling point	C1 10 11			
🚗 😪 4.4 Density	Classification			
		Classification	Reason for	
🛶 🗣 4.6 Vapour pressure			no crassification	
	Explosiveness	•	× •	
🛁 🏶 4.8 Water solubility	Ovidising properties	•	٩. 🗸	
	extensing properties		·	
🌪 4.10 Surface tension	Flammability	•	۹. 🛨	
	The sum of starts like	-		
	i nermai stability	•	`	
	Acute toxicity	•	٩, 🗸	
4.14 Explosiveness	territe territeiter immersensible			
4.15 Oxidising properties	damage after single exposure	•	٩ 🗉	
4.16 Oxidation reduction potential		-		
 4.17 Stability in organic solvents at 4.40 Generative and billion of the solvents at 	Repeated dose toxicity	•	•	
4.10 Storage stability and reactivity	Irritation / Corrosion	•	۹ 🗸	
4.19 Stability: thermal, sunlight, me				
4.20 pm	Sensitisation	× 1	× •	
4.22 Dissociation constant	Carcinogenicity	Q 🖵	٩. 🗸	
4.22 viscosky	carenogenety		· · · · ·	
E 4 5 Environmental fate and nativeavs	Mutagenicity - Genetic Toxicity	۹, 🕶	۹. 🔻	
a 🔶 5.1 Stability	Toxicity to reproduction -			
5.1.1 Phototransformation in a	fertility	× •	۹. T	
5.1.2 Hydrolysis	Toxicity to reproduction -			
5.1.3 Phototransformation in w	development	<u> </u>	¥	
5.1.4 Phototransformation in se	Toxicity to reproduction -			
🖃 🔮 5.2 Biodegradation	breastfed babies			

- For every hazardous property, there are two boxes with pick lists:
 - The first one allows you to choose the classification (in the pick list that opens when you press a button, there are several options for classification):

ATP last update		Select picklist values
Remarks Classification ———		Select a value for: "Explosiveness"
Explosivenes Oxidising properties		E; R2 Explosive; Risk of explosion by shock, friction, fire or other sources of ignition.
Flammability Thermal stability	• •	IR1 Explosive when dry. R16 Explosive when mixed with oxidising substances. R18 In use, may form flammable/explosive vapour-air mixture.
Acute toxicity Acute toxicity - irreversible	•	R19 May form explosive peroxides. R4 Forms very sensitive explosive metallic compounds.
damage after single exposure Repeated dose toxicity	•	R44 Risk of explosion if heated under confinement.
Irritation / Corrosion	•	<u>Q</u> K <u>Cancel</u>

• The second box of each property allows you to explain the reason why the substance is not classified, even where data is available.

Classification —		Reason for	Pick list
	Classification	no classification	Select a value for:
Explosiveness	-		"Explosiveness"
Oxidising properties	•	٩ 🖬	
Flammability	-	9	₽
Thermal stability	▼	٩	data lacking
Acute toxicity	·	٩ 💽	inconclusive
Acute toxicity - irreversible damage after single exposure	•	٩	conclusive but not sufficient for classification
Repeated dose toxicity	-	٩. 🗸	
Irritation / Corrosion	-	٩	
Sensitisation	٩. 🖬	٩.	<u>OK</u> ancel
Carcinogenicity	٩. 🗸	ચા ન	

• Press the 🔂 button next to "Hazard statements", "Additional precautionary statements", "Additional labelling requirements", "Specific concentration limits" and "Notes" to access the pick lists from which you can select the labelling.

labelling	
Indication of danger	\frown
	* * *
T - toxic	x + + + + X
T - toxic 🔍 🔽	
Risk phrases	
	× 6 4
R21/22 - harmful in contact with skin and if swallowed	★ ☆ 주 ⊕ ¥
R21/22 - harmful in contact with skin	
F	
Safety phrases	\sim
	¥ 🛠 🜩
S1/2 - keep locked up and out of reach of children	× + 3 +
Code S1/2 - keep locked up and out of reac 🔍 👻	
Additional text	
Specific concentration limits	\frown
	* * *
	🗶 🕆 🕸 🙀
Concentration range (%) 👻 🔍	
Indication of danger (symbols)	
	¥ & +
<u>.</u>	
Notes	<u>^</u>
	¥ & 🔹
Note C	2 4 3 A
Note C R	

Section 3: Manufacture, use and exposure

3.3. Sites

You can use this section to indicate the sites where the PPORD activity of the notifier takes place. First, you should create those sites in the relevant section of the main task panel.

Creating a site

- On the main task panel click on "New" under "Sites".
- The Site assistant will appear. Type the name of your site.

🚰 Site ass	istant	
Create a nev	w site	
Site name	PPORD use site	ď
E-2 Set name	<pre></pre>	Cancel

• Assign the Legal entity of the notifier to the site and press Finish.

🚰 Site assistant	
Create a new site	
Legal entity owner [📕 CompanyB / Helsinki / Fin 🔻
Image: Set legal entity	< <u>Back</u> Next > Einish Cancel

• The Legal entity screen will appear. Indicate the address of your site, as well as the contact details and other IT identifiers.

	Flags	IT system	ID
Add	Edit Delete		
ntact addr	ess		
Address flags	P		
Address	PPORD site address	٩	
Address		9	
Postal code	9		
Town	PPORD site town	9	
Dealer / Caste		9	
Region / State			
Country		d 🖌 d	
Phone	+0987654321	٩	
Fax		94	
E-mail	ppordusesite@companyname.n	net a	
			-

• Press "Save" You have now created a site for the PPORD notifier Legal entity.

Assigning a site

- In the section tree of the substance dataset, double click on "3.3 Sites" and press the "Edit item" button
- Press the 🕂 button to display the fields for your production or use site
- Press the left button and a pop up window with all the sites assigned to your Legal entity will appear. Select the site and press "ok".

	*:
	🗴 🕆 🕹
e	< > ×
Production site	
Use site	Select a site reference
	Select a site from Company® / Helsinki / Finland
	· · · · · · · · · · · · · · · · · · ·
	🥩 PPORD use site

- Tick the box below the "Site" field to indicate if it is a production or use site.
- If you need to indicate more production or use sites, press the 🖶 button and repeat the procedure described above.

Sections 4 to 13

Although not compulsory, in sections 4 to 13 of IUCLID 5 it is possible to provide additional information about a substance in a PPORD dossier, such as information on physico-chemical, toxicological or ecotoxicological properties and guidance on safe use. The procedure on how to provide this information is thoroughly described in the IUCLID 5 guidance documents available at http://iuclid.eu.

5. CREATING A PPORD DOSSIER

On the IUCLID 5 Task Panel, select "Update" from Substance.

- All available Substances are displayed; select the substance for which you want to create the PPORD dossier.
- Right-click on a Substance in the query results list. From the pop-up menu select "Create Dossier".



- The Dossier creation wizard is displayed.
 - Step 1: Select the Dossier template "REACH PPORD"



Note: the dossier template selection helps to determine which IUCLID 5 section and endpoint studies will be part of your dossier.

- Step 2: Define the filters. Every item that matches these filters will be taken into account for the Dossier. The "Select all" buttons allow you to select all possible items at once.
- Step 3: See the state (full, partial...) of all documents taken into account for the Dossier creation. At this stage, please be sure that all the necessary sections for your PPORD notification appear ticked, as only these documents will appear in your dossier. The relevant sections suggested by IUCLID 5 for the creation of a PPORD dossier appear checked by default.

ossier template: REACH PPORD	priate	
🧉 Substance		
Select the parts which should be included:		
1.2 Composition		
1.3 Identifiers		
1.4 Analytical information		
🗌 🗋 1.5 Joint submission		
🔲 🗋 1.6 Sponsors		
1.7 Suppliers		
1.8 Recipients		
🕑 📄 1.9 Product and process oriented research and deve	lopment	
🔽 📄 2.1 GHS		
💌 📄 2.2 DSD - DPD		
🔲 🗋 3.1 Technological process		
🗌 🗋 3.2 Estimated quantities		
🕑 🗋 3.3 Sites		
📃 🗋 3.4 Form in the supply chain		
3.5 Identified uses and exposure scenarios		
📃 🗋 3.6 Uses advised against		
3.7 Waste from production and use		
🔲 🗋 3.8 Exposure estimates		
🔲 🗋 3.9 Biocidal information		
3.10 Application for authorisation of uses		
📄 Required 📋 Optional 📄 Not required		

• Step 4: Select the level of detail for your endpoint study records.



- Step 5: check all related objects to ensure they will be part of your dossier (Legal entity, Reference substance(s) and endpoints).
- Step 6: If necessary, enter additional administrative information concerning your dossier (in case you are submitting an update of the dossier, please see "Updating a dossier", in section 7 of this manual).

				10
Name (given by user) Dossier submission remark				Q.
Type of submission Submission update —	s the submission an update?			
Last submission number				9
Reason for updating —				
	Further to a request/decision from regulatory body	172532		
		*	*	4
[_ spontaneous update	¥	\$	4

• A window informs about the success of the import. When pressing the "View dossier" button, the dossier will be displayed.

Possier creation wizard	
Dossier creation successfully completed	
You can nowview the dossier or close th	nis wizard
View d <u>o</u> ssier	<u>C</u> lose wizard

6. EXPORTING A PPORD DOSSIER

The PPORD dossier needs to be exported in order to be sent to the ECHA via REACH IT.

• In the main screen click in the dossier icon, or in "view".



• Select your PPORD dossier, right click on it and select "Export".



•

• The assistant will ask you if you wish to include your annotations in the dossier. Normally, select "Export without annotations" (unless you have included relevant information as annotations in your dossier) and press next.



• In the next screen press the disk icon, enter the name of your dossier and specify the location where you want to store it.

o <u>W</u> indow <u>H</u> e	🚼 Export assistant 🔀
	Select the folder and specify the name of the export file As appropriate, select the checkbox for Copy-protect and/or Seal
Query 8 Substance: 1,1'-in	Note: the finish button is enabled when a file name has been entered and all dossier information has been collected in the background Depending on the dossier and your system this may take some time Specify the export file:
z Substance: 2-(2- 4	Remarks:
Select the	destination for the export file
s Look In:	Data (D:)
File <u>N</u> ame:	Test PPORD dossier
Files of <u>T</u> ype:	IS2 IUCLID 5 data exchange container
c (Substance: 1-ch	OK Cancel
7 "H / Substance: 1, 8	Scanning document dependencies (6): Complete
/ Substance: 1,2,3 8	Image: Second

• Now press "Finish". The dossier has now been exported to the location you specified; a confirmation message will appear.

Export completed		
Export process report		0
 Export of 6 docume 6 document(s) was/ Export successful 	nt(s) and 0 annotation(s) completed were exported successfully, 0 document(s) v	was/were skipped (00:00)
•		
		Close

7. UPDATING A DOSSIER

Updating the information

If you need to submit further information on your PPORD notification, be it as a result of a request for further information or because of the need to update the data sent in your previous application (e.g. to communicate that the number of customers or the tonnage required have changed), you do not need to re-type again all your substance data.

• In the main screen go to Tasks, and press "Update" under "Substance".



• Select from the list the substance for which you wish to submit new information, and double click on it. Now click on the tab "Section tree" and go to the relevant section that you wish to update. Edit the necessary sections by pressing the "Edit item" button (



Attaching files as additional information

• At the bottom of the Substance dataset screen, a window called "Information" is minimised by default. Press the button to maximise it.

Query results 🛛 🐙 Section tree	Product and process oriented research and development	
REACH PPORD		* * *
*		
🕀 🧆 🛈 Related Information		× 2 + 2 A
🚽 🍖 1 General Information		
1.1 Identification	L.F.	
	Name	
	Madicipal product for human an unteringen una	
1.8 Recipients	Substance not placed on the market	
	Estimated quantity	
🖶 🦿 2 Classification and Labelling		
	remarks	
2.2 DSD - DPD		
S Environmental fate and pathways		
6 Ecotoxicological Information		
🕀 🍖 7 Toxicological information	Document Docubs_substance.doc / 522.5 Kb	
📲 🗭 11 Guidance on safe use		¥ ≩ ∛ ⊉ 1 ¥
2 Literature search		
		<u> </u>
	information	
		(

• The information screen will appear. Click on the tab "Attachments".

information	Modification history	Access	2 Consultation	S Attachments	Annotations	B validation
Type	🖕 Substance		9			
	IUC5-9c725e97-d88f-4817-	a29c-5fd7373e	bdd0	9	4	
sier UUID	0			\$	4	
[Sealed Copy protected	Subset of o	riginal			

• To add an attachment, press the "Edit item" button, right click on the white left field and select "Add".

📓 Information			
🔝 Information 🛛 😢 Modification histor	Y 🔐 Access 💋 Consultation	📎 Attachments 🛛 🕓 Annotations 🗍	Validation
🕂 Add		Remarks	
		Last modified	

• The system will ask you to save the working document. Accept, and the browsing box will appear. Select the file to attach and click "Open".

Look in: 🗋	NewFolder	- 🗈 🖾 😁 🗈
	substance.doc	
IUCLID5_s	substance2.doc	
ile Name:	IUCLID5. substance.doc	
ile <u>N</u> ame:	UCLID5_substance.doc	

• Write remarks on the file if you wish, and press "Save"; the attached file will appear.

	Information	Madification history	C. Brener	Consultation	Attachment
	information	Mounication history	Access	2 Consultation	Trachment No.
	UCLID5_subst	ance.doc / 522.5 KB			Remarks
					Last modified
					Size [b]
l					

• Repeat the previous steps to attach more files. The maximum size for all the combined attachments is 20 megabytes.

information						
Information	Modification history	🚭 Access	Consultation	📎 Attachment	s 📃 Annotations	Validatio
UCLID5_substa	ance.doc / 522.5 KB					
📄 IUCLID5_substa	ance2.doc / 522.5 KB			Remarks		
				Last modified	2007-02-05	
				Size (b)	535,040	

Once the necessary attachments have been added to the Substance dataset, press the "Minimise" button
 to go back to the Substance dataset.

Information	
💿 Information 🥂 Modification history 🛛 🚭 Access 🔗 Consultation	📎 Attachments 📃 Annotations 📑 Validation
UCLID5_substance.doc / 522.5 K8 IUCLID5_substance2.doc / 522.5 K8	Remarks
	Last modified 2007-02-05
	Size [b] 535,040

Creating the updated dossier

The procedure is exactly the same as for creating and exporting a new dossier. However, when you arrive at the screen of "Additional administrative information" during the creation of the dossier (see point 5 of this manual, step 6), you must tick the box "Is the dossier an update?"

If the update is made as a result of a request or decision from the ECHA, tick the box "Further to a request/decision from regulatory body", and then press the button under this section. Use the box called "decision number" to indicate the number of the request or the decision.

🚰 Dossier creation wiza	rd	2
Enter additional administrat Dossier template: REACH PP	ive information concerning your dos ORD	sier
e of submission —		
nission update —		
✓ 1	s the submission an update?	
t submission number		٩
on for updating —	urther to a request (decision from re	aulstow kody
		Solatory body
		🎗 🕆 3 🗣 🐰
	Decision number	٩
	Remarks	٩,
	pontaneous update	
		× *
		•

• If it is a spontaneous update, tick the box "Spontaneous update" and then press the 🕩 button under this section. Click the arrow in the "justification" box, and choose the reason for your update from the pick list.

nter additional adm ossier template: RE	inistrative information concernin ACH PPORD	ıg your dossier		<u>}</u>
of submissio ssion update submission numbe i for updating –	n Is the submission an update r Further to a request/decisio	? ? on from regulatory boo	۹. ۲	
	Spontaneous update			
Ill Enter adminis		< ĝack	Change in company identity change in company role in th change in company role in th change in composition of the change of tonnage band new identified uses new uses advised against	e supply chain substance

The rest of the process for creating and exporting the dossier is identical to the procedure described above, under points 5 and 6 of the manual.

8. SUBMITTING A PPORD DOSSSIER TO ECHA

The submission of a PPORD notification dossier prepared using IUCLID 5 should be submitted to the ECHA using REACH-IT by the PPORD notifier. For this purpose, you will need go to the REACH-IT website, sign-up, unless already done, as the notifier of the PPORD, (i.e. the manufacturer or importer or producer of articles for the substance on which the PPORD activity takes place) and submit the PPORD notification dossier. REACH-IT will be available starting 1st June 2008.

Sign-up procedure

If you do not have an account in REACH-IT, follow the instructions in this section.

• Click on "sign-up as a company".

Reach-II
Welcome to REACH-IT
REACH-IT provides an online platform to submit data and dossiers (pre-registration, registration, C&L notification,) on chemicals. It also allows the Agency and Member States authorities to review the dossiers. The Agency will also use REACH-IT to make non-confidential information on chemicals accessible to public on its website.
What can you do?
If you already have an account, you may login to the system. Sign up as a company Sign up as a Data Holder Register as an interested third party Register as a third party representative Need help with REACH-IT or with this site?
REACH-IT Frequently Asked Questions (FAQ) The REACH legal text Contact Information Siter map Search the site
Related links
Eublic REACH information on chemicals Information about REACH on the Europa website

• In the following page, you will be required to accept the terms and conditions in order to proceed with the sign-up procedure. If you agree with the terms and conditions, click on "accept".

Contact | Hole

Contact Help
Reach-II
Company sign-up Terms and conditions
Signing-up as a company is a simple process. You will be guidedthrough the following 5 steps:
 User account - Information for the first user is required Company information - Provide general information on your company Billing information - Provide billing details for your company Contacts (polinal) - Add information about people who may be contact points for SIEFs Validation - Check information you have provided and modify if necessary
At each step prior to the validation you are allowed to go back to any previous step and change the data you already entered.
Before going further in the sign-up process, please read the following terms and conditions:
Terms and conditions
1. A compt Reject
Need help with REACH-IT or with this site?
Specific help on company registration REACH-IT Frequently Asked Questions (FAQ) Legal notice Contact Information

- Follow the sign-up procedure. Signing-up as a company is a simple process. You will be guided through the following 5 steps:
 - User account Create your REACH-IT user account.
 - Company information Provide general information on your company. For consistency, we recommend you to import the LEO created in the IUCLID 5 website, which was linked to the substance for which the IUCLID 5 PPORD notification dossier was made.
 - o Billing information Provide billing details for your company.
 - Contacts In this screen you can select the contact person for the PPORD dossier you intend to submit. You can select among all the users from your Legal entity who have an account in REACH-IT, including yourself.
 - Validation Check the information you have provided and modify if necessary.

Login to REACH-IT

Once you have completed the sign-up procedure you may login to REACH-IT.

• Click on the link "home" to go back to the homepage.



 Login into REACH-IT, using the user ID and password you specified in your user account

RECHA		Re	ach-IT
Login			
Please provide your login information to entr Fields marked with an asterisk (*) are mand	er REACH-IT Iafory.		
* User ID:			
* Password:			
* Enter the text shown:			
Can't read the t	ext below? <u>Try another</u>		
FORK	36		
	Cancel		

Submission of a IUCLID 5 PPORD notification dossier

 To submit a PPORD notification, select on the left side "Registration / notification" > "Submit a registration / notification"



• In the next screen, select the appropriate dossier type "Product and Process Oriented Research and Development (PPORD) notification". In

addition you are required to acknowledge that the substance for which the PPORD dossier is submitted is rightful, in order to proceed further with the submission.

• Click on "Proceed" to continue.

RECH	
	You are connected as David on behalf of ChemicalCompany1 - Preferences - Logou
Company Pre-registration Pre-SIEF Phase-in Information Registration / notification Joint submission Message Box	Registration / notification submission Registration / notification submission Here you can initiate the submission process for registration / notification dossiers (or reports) or their updates. To submit an update you should use the same process as for the first submission of your dossier / report. The updated version should contain all previously submitted valid information and the updated one (please refer to relevant guidance documents). [Select dossier type] Product and ProcessOrientated Research and Development (PPORD) notification [Purchase Order]
User account management Inventories Raw data Invoices	Proceed

- In the following screen and under the "external dossiers" section, select the IUCLID 5 PPORD notification dossier to be submitted. Click on "Browse", select the corresponding PPORD file and click on "submit dossier".
- Note that if your file is exceptionally large (> 20Mbytes), you will need to request an access code from the ECHA that should be reported in this screen before clicking on "submit request".

		Contact Search Hel		
AEC	НА	Reach-II		
		You are connected as David on behalf of ChemicalCompany1 - Preferences - Logo		
	Home > Submit Dossier Intro > Sub	nit External Dossier		
Company	External dossiers Internal doss	iers		
Pre-registration Pre-SIEF	Here you can submit a PPORD noti "Internal dossiers" on this webpage	ication dossier. If you want to create your notification dossier online, please use the "internal dossier" submission tool (click on the tab		
Phase-in Information	Process and Product Oriented I	Research and Development (PPORD) notification submission		
Pagistration /	Please pick here using the "Browse	button the file which contains your dossier (your file should have been created using IUCLID 5 and have the extension "i5z")		
notification	* File name:	C\Documents and Settings\u07069\Desktop\PPORDdossier1.i5z		
Joint submission	Access code for large files			
Message Box	Dossier file cannot exceed the maxi	num size of 20 MBydes		
User account management	If you would like to submit files large	r than this limit, please, request a one-time access code using the following link - <u>request access code</u>		
Inventories	The Agency will check your request and may grant your upload by sending this one-time access code to your personal message box. This process may take up to 24 hours			
Raw data	Please note that in case you submit	a dossier exceeding 20 Mbytes without specifying an access code, your dossier submission will fail.		
Invoices	If you have an access code for a la	ge dossier, please, enter it here		
	Large file access code:			
	Submit dossier			

• Click on "Confirm submission".



• Your dossier has now been submitted. The submission number generated for this submission is specified in the next screen.

🐸 REACH - IT Complete	d Submission - Mozilla Firefox
Elle Edit View History	Boolmarks Iods Help
🔶 - 🎯 📀	🔐 🕒 http://sreach-pslb-04.reach.europa.local/reach/secure/company/dossiers/submits.dossier_confirmation.faces 🔹 🕨 💽 🕞 Google
🀢 Getting Started 🔯 Late	sst Headlines 🥑 PortableApps.com 🔂 PortableApps.com News
	Contact Search He
AEC	
	You are connected as <u>David</u> on behall of Chemical Company1 - <u>Preferences</u> - <u>Logo</u> Home > Submit Dossier Intro > Dossier Submission Successful
Company Pre-registration	Your dossier has been successfully submitted. Please find below the submission number.
Pre-SIEF	Process and Product Oriented Research and Development (PPORD) notification submission
Phase-in Information	Submission number
Registration / notification	Your submission has received the following submission number: WM120515-28 . Please use this number for any subsequent communication concerning this dossier.
Joint submission	Please note that this number is NOT the reference number for your substance (notification or registration number). The reference number will be communicated to you after your dossier has passed the completeness check (this also includes the payment of the fee if appropriate).
Message Box User account management	As the submission process is not instantaneous and some verifications shall be performed, you will be informed at a later time about the status of your dossier by an internal message (please consult your message box).
Inventories Raw data	At any time you can also consult the status of your dossier and the submission report in the menu "Registration/notification \ View registration/notification * and indicating your submission number to retrieve it.
Invoices	

• Subsequent information on the submission will be communicated as an internal message in the message box of the contact person for the dossier. A link to the message box is available on the left.