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REGISTRATION OF CHEMICAL SUBSTANCES



B&B

A Segore

REGISTRATION

A technical registration dossier has to be sent to the European Chemicals Agency (ECHA) for each substance manufactured or imported to the EU in more than 1 ton/year.

The information requirements for the registration dossier, on the hazards, use conditions and exposure for chemicals, depends on the manufacture/import volume band (Annex VII to X of REACH)

The hazard information of a chemical substance must be shared among all registering companies in so-called SIEFs (Substance Information Exchange Forums).

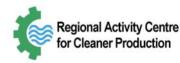
If a company uses information owned by another company, the information owner is entitled to compensation.





REGISTRATION

- Manufacturers of substances and manufacturers of transported isolated intermediates in quantities of 1 tonne or more per year need to submit a registration dossier if they are not exempted.
- Manufacturers of substances that are not intermediate, need to present a registration dossier including all the information required in base of the tonnage band.
- Manufacturers of intermediates requiring registration can provide reduced registration information, if they can demonstrate the very high strictly conditions in all the cycle life of the intermediate.

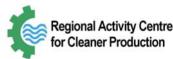




Reduced required information INTERMEDIATES

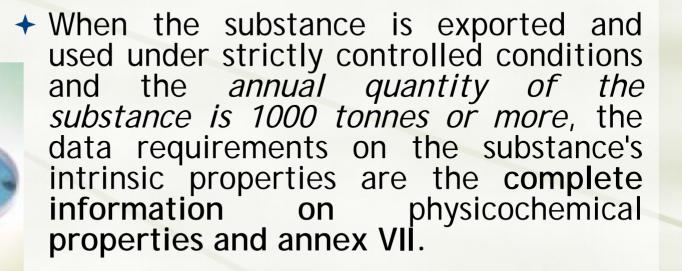
- The identity of the OR (representing the manufacturer)
- The identity and classification of the intermediate
- Any available existing information on the physicochemical, human health or environmental properties of the intermediate.
- A brief general description of the use
- Information high strictly conditions and on risk management measures

Note: To apply the reduced registration the intermediate manufacturer of non EU Company has to assure that he has received confirmation from the user (inside or outside the EU) that the manufacturing and use takes place on other sites under strictly controlled conditions.





✦ If the annual export volume of the substance is *less than 1000 tonnes*, the information requirements relative to the substance's intrinsic properties (physicochemical, human health and environment properties) are reduced to available data





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If the exporter sells the substance not exclusively for the use as an intermediate, or if the transport and use(s) of the intermediate can not be descripted as under strictly controlled conditions, the exporter (non EU company) needs to submit a "standard" registration dossier (full information based on the tonnage band)

★ If only part of the tonnage exported is for use as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirements of the full registration dossier. Nevertheless, use as an intermediate should be documented in the registration dossier, including the volume manufactured or imported for that purpose



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If the intermediate is exported and used under strictly controlled conditions during its whole lifecycle (since it is introduced in Europe), the registrant should evaluate and demonstrate whether the following conditions are met:

- The substance is rigorously contained by technical means during its whole lifecycle (transport, storage, sampling, analysis, loading and unloading of equipment or vessels, waste disposal....;
- Procedural and control technologies shall be used that <u>minimise</u> emission and any resulting exposure;
- Only properly trained and authorised personnel handle the substance;
- In the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- In cases of accident and where waste is generated, procedural and/or control technologies are used to.



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IUCLID: International Uniform Chemical Information Database



IUCLID5 is a software with the official format for the registration dossier.

IUCLID5 also allows users to develop pre-registrations, notification on uses, authorizations request, notification on classification and labelling, etc.

Free for download: www.iuclid.eu





FECHA



IUCLID 5 plays a central role in the IT environments of all organisations that have to cope with data submission requirements of REACH and other programmes (OECD HPV, EU Biocides and others). Industry stakeholders, EU Member States, the European CHemicals Agency (ECHA), and any other interested party obtain the IUCLID installation kit from this web site; once installed, the local IUCLIDs are the essential tool to canture & store, submit.

News

[18.07.2007] Clarifications concerning License Agreement

The IUCLID 5 Service Support Team has received numerous questions concerning the IUCLID 5 End User License Agreement. This news article provides a number of important clarifications.

[19.06.2007] The IUCLID Format (XML) is available

The XML format used to generate export files for data exchange (with worldwide regulatory bodies or between users) is now available and can be downloaded from the web site.

[18.06.2007] More than 1000 copies of IUCLID 5 downloaded!

Today, the threshold of 1000 downloads of the IUCLID 5 software has been exceeded

[14.06.2007] eChemPortal, the Global Portal to Information on Chemical Substances has been launched!

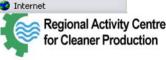
eChemPortal, the Global Portal to Information on Chemical Substances is now available for public access. To search multiple international databases simultaneously, visit the website http://www.oecd.org/ehs/echemportal.

[12.06.2007] IUCLID 5 is now available!

IUCLID 5 can now be obtained free of charge in the "Get IUCLID 5" section. Both the standalone and the distributed versions are available for download.

[01.06.2007] IUCLID 5 coming soon!

_IUCLID 5. the main tool for the Chemical Industry to fulfill their REACH legal obligations, will be 🛛 💌



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Tasks



Legal entity Create and update company /organisation related information



Create and update substance related information New, Update



Template Create and update template related information New, Update

New, Update

Substance



Dossier View dossier data View, Compare

Inventories



Inventory View EC inventory related information



Reference substance Create and update reference substance related information

Tools and administration

View, Import

New, Update



Manage users, roles, preferences, etc.



Import Import data from other IUCLID 5 systems

Plugins

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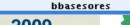
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User preferences, Set password, User management, Role management Import, Bulk import

Legal entity site

New, Update

New, Update

New, Update

Literature reference

View

Category

Mixture

Create and update legal entity sites

Create and update mixture related information

Create and update category related information

View literature reference inventory related information

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Information		



REACH- Description of Uses (I)

1) Industry Category:

Information from the industrial economic sector in which the substance is used.



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	nent 1: Descriptor for industry categories
Code 2007	NACE 2007
A	AGRICULTURE, FORESTRY AND FISHING
В	MINING AND QUARRYING
С	MANUFACTURING
10	Manufacture of food products
13	Manufacture of textiles
14	Industry for clothing and fur
15	Manufacture of leather and related products
16	Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
17	Manufacture of paper and paper products
18	Printing and reproduction of recorded media
19	Manufacture of coke and refined petroleum products
20	Manufacture of chemicals and chemical products
20.1	Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
20.2	Manufacture of pesticides and other agrochemical products
20.3	Manufacture of paints, varnishes and similar coatings, printing ink and mastics
20.4	Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations
20.5	Manufacture of other chemical products
21	Manufacture of basic pharmaceutical products and pharmaceutical preparations
20.60	Manufacture of man-made fibres
22	Manufacture of rubber and plastic products
22.1	Manufacture of rubber products
22.2	Manufacture of plastics products



Description of Uses (II)

2) Use category:

Information on the technical functionality of the use of a substance.



Attachment 2: Descriptor for technical f preparations	unction of substances and end use
Technical function of substance	
Dust binding agent	Metal surface treatment products, including galvanic and electroplating products,
Electrolyte	Non-metal-surface treatment products
Emulsifier	Heat Transfer Fluids
Emulsion-inhibiting agents	Hydraulic Fluids
Etchant and acids	Ink and Toners
Extraction agents	^a Inorganic / organic substances and preparations used as ph-regulators, flocculants, precipitants, neutralization agents and comparable unspecific uses
Filler	Laboratory Chemicals
Fixing agent Flame retardant or fire preventing agent	Lawn and Garden Preparations, including fertilizers Leather tanning, dye, finishing, impregnation and care products
Flavouring agent	Lubricants, Greases and Release Products
Flocullant	Metal Working Fluids
Flotation agent	Paper and Board dye, finishing and impregnation products
Flow modifier	Perfumes, Fragrances
Flux agent	Pharmaceuticals
Foaming or blowing agent	Photochemicals
Food and fodder additive	Polishes and Wax Blends
Friction agent	Polymer Preparations and Compounds



Description of Uses (II)

3. Application Type

technique / process in which the substance is applied.



Attach	Attachment 3: Descriptors for application techniques (operation units)					
	Operation unit	Examples or explanation				
13.*	Drying	Tray drying over, spray drying				
14.	Storage	General and open bulk storage				
15.1*	Passive release of substances from articles in service life: long-life, large surface, outdoor ¹²	E.g. construction material				
15.2*	Passive release of substances from articles in service life. Abrasive use processes	Tyres, brake pads, road surface, shoe soles				
15.3*	Passive release of substances from articles in service life: indoor with permanent or repeated skin and/or mouth contact	E.g. dyes in textiles				
15.4*	Passive release of substances from articles in service life: other indoor	Floor coatings and coverings;				
16.*	Burning of fuels including waste incineration; limited exposure to the fuel in its unburned form.	Heat and power generation, incineration of waste, pyrolysis				
17.1	Biological, chemical or physical treatment of waste in open tanks, bunkers or basins	Neutralization, reducing, oxidizing, oil/water separation				
17.2	Mechanical crushing and/or sorting of waste (manually or semi-automated)					
17.3	Landfilling of substances in waste					



Description of Uses (II)

4. Article category in which a substance has been used::

Unintended release-

Deliberate release-



TRA Category	Pick-list for article types	TARIC category	
	Rubber products: footwear	Section XII Chapter 64	
	Rubber products: toys	Section XX Chapter 95	
C17	Wood and wood furniture: flooring	Section IX Chapter 44	
	Wood and wood furniture: furniture	Section XX Chapter 94	
	Wood and wood furniture: toys	Section XX Chapter 95	
C18	Other ¹³ :		
C19.1	Constructional articles and building material for indoor use ¹⁴ : wall construction material ceramic, metal, plastic and wood construction material, insulating material.	Glass, ceramic, cement: 6806, 6810, 6815,	
C19.2	Constructional articles and building material for outdoor use ¹⁵ : wall construction material, road surface material, ceramic, metal, plastic and wood construction material, insulating material.	6901, 6902,7016, 7018,7019,7308 Wood: 4407- 4413,4418	
C20	Commercial and consumer plastic products like disposable dinner ware, food storage, food packaging, baby bottles	Section VII Chapter 39 Code 3923, 3924	
	Plastic products: Flooring	Section VII Code 3918	
	Plastic products: Toys	Section XX Chapter 95	

and the second second	tachment 4b: Substances in articles with intended release
De	escriptor based on an indicative list of examples
	Scented articles
	Clothes
	Eraser
	Candle
	Tays
	Paper articles
	CD
	Other scented articles; please specify
	Articles for printing and writing
	Crayon
	Type writer ribbon
	Printer cartridge
	Pons
	Correction rollers and pans
	Other articles for printing and writing
	Articles releasing polishes and cleaners
	Polishing textiles
	Cleaning wipes
	Cleaning sponge
	Shoe polishing sponge
	Other articles; please specify
	Articles releasing grease and/or corrosion inhibitors
	Packaging material for metal parts
	Other articles; please specify
	Hygiene products and medical articles releasing scent, lotions and other agents, no notified as medicinal product, cosmetic product and/or biocide product
	Diapers with scents or lotion
	Wet wipes with scents or lotion

Plasters releasing substances.

Other articles; please specify

Functional containers from which substances or preparations are released

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RISK INFORMATION ALONG THE SUPPLY CHAIN

The downstream user in the use chain must receive manufacturer information on how to handle a product with hazardous substances

	Risk	=	Danę	ger	•	Exposure
ealth	Risk =	Toxic	city •	Ехро	sure	

<u>This user</u> must communicate to the next actor the use and exposure of the products containing hazardous substances to the humans and the environment.

The Safety Data Sheet will serve as an information platform in the use chain, extended with:

- The identified uses and
- Measures for a safe handling during their use.





What uses cover?

Strategic decision of the Operating Unit

What Markets / Customers / Applications should be covered?

This decision should be based on economics reasons and also it should be taking into account: :

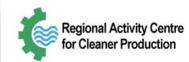
How is cover the product value chain?
The number of applications covered (uses)



What applications cover?

Preparation of the information

- For each intended application:
 - Prioritization according to economic criteria
 - Determination of the quantities of substances commercialized
 - Identify those customers with typical applications that are willing to provide exposure data.
 - + If possible, identification of the use type
 - + intermediate, monomer
 - + Industrial use, professional use, final consumer
 - Uses development and exposure scenarios
 - It must be developed during the process of preparing the registration dossier
- → Dialogue between manufacturer ← → Customer

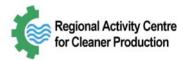


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Why the applications are important?

Companies that register shall describe how to control the exposure to humans and the environment for all the uses of the substance.

 Downstream users are not authorized to use a substance in their products if the user exposure scenarios are not defined for that substance



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	Risk evaluatio	n		
POR Asesores	1 20 à i -1	Who uses the product? • Consumer •Professional •Industrial		
WHO		Closed or open system?		
WHERE		Inside or outside?		
HOW	indoor outdoor	Application type? Directly or not Type of equipment used		
AMOUNT		Amount of product used? <1Kg		
FREQUENCY		Frequency of use? <once a="" td="" year<=""></once>		
DURATION		Duration of use?		
Preventive Measures		Preventive Measures		
		Waste Management		
Waste Management	STP	Facilitate the recycling,,Proper handling		
25 REA	ACH Seminar – Ankara, November 1	•Plant treatment or authorized manager		

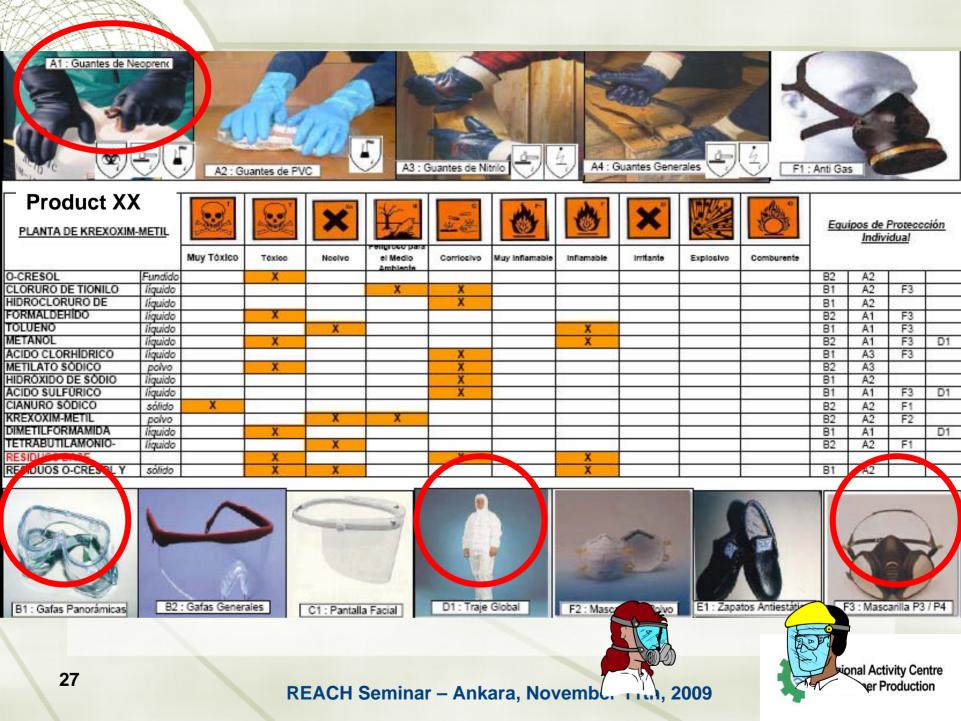


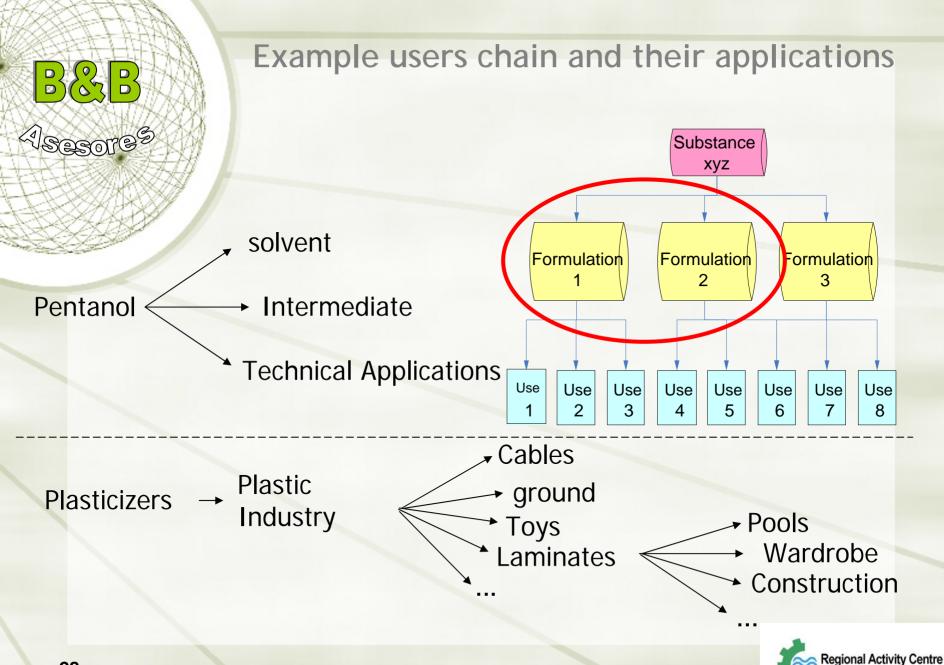
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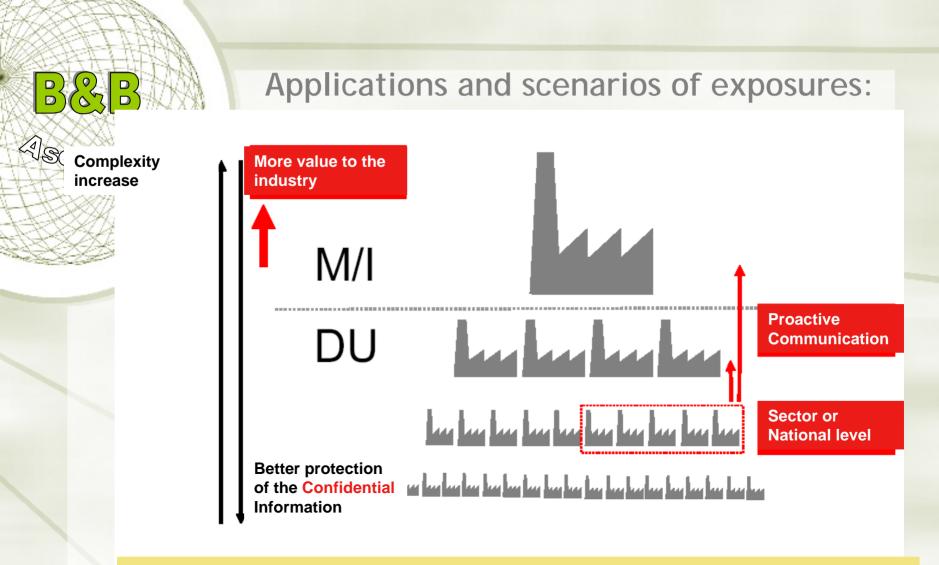
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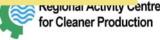
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for Cleaner Production



• The registration information should be elaborated the more upstream possible in the use chain.

•It is important that the downstream user participate actively in defining the standard uses.



RB	REA	ACH-IT	
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Pre-registration	You have 0 unread message(s) in your message box.	The clock is ticking - Form your SIEF now 16/06/2009	
Pre-SIEF		If you have pre-registered a substance with a	2010
Online dossiers		registration deadline and you are not yet activ	
Phase-in Informatio	n	your SIEF, you need to act now. If you are a L Registrant please inform ECHA about your ele	
Registration /	View registration /	On the other hand, if you do not intend to reg	ister
notification	notification	by 1 December 2010 you need to change you status in REACH-IT.	ll.
Joint submission	Submit	status in REACHEL.	
Message box	registration / notification	REACH-IT closed for holiday and maintenance	<u>e</u>
User account		16/06/2009 REACH-IT will be closed on Thursday 18 June	ant
Invoices	Claim Notified Substance	19:00 EET.	, at
Search		Normal service will resume on Monday 22 Jun	e at
Search		10:00 EET. ECHA apologizes for any inconvenience cause	ed.
		Data Submission Manual 5 has been updated 19/05/2009	1
		Data Submission Manual 5: How to complete a	
		technical dossier for registrations and PPORE notifications has been updated. This manual)
		outlines the IUCLID 5 sections/fields to be fille	
		order to prepare a complete dossier accordin Article 20(2) of REACH. The changes made in	
(******		version 2.0 are listed on page 2 of this manual	
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REACH - IT Submit Dossier Introduction

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Eavoritos

Registration / notification submission

🔁 GPF-GHS-JUNIO09

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).

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MORE INFORMATION

The REACH section on the website of the European Chemicals Agency (ECHA) gives an overview of the Regulation.

The website also provides:

- A Navigator tool which will assist importers and Only Representatives to find out their obligations and how to fulfil them
- Extensive guidance on REACH provisions
- IT tools for REACH uses and how to operate them

Please see the ECHA website : <u>http://echa.europa.eu</u>



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Thank you

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