

INTCF (Instituto Nacional de Toxicología y Ciencias Forenses) Servicio de Información Toxicológica

GesFicCom

USER GUIDE: software tool to prepare toxicological files USER MANUAL (abridged)

GesFicCom 'November 2017'



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Introduction

This abridged user manual provides instructions for the GesFicCom application, devised to generate the toxicological files for product notification to the INTCF (Spanish PC), in compliance with current regulations (Ley 8/2010, de 31 de marzo and Orden JUS/909/2017 of September 25th, regulating the notification procedure of toxicological files to the INTCF).

The information closely respects the structure displayed on the main screen. However, 'Management of company/enterprise data' and 'Management of ingredients data' sections precede the description of 'Management of toxicological files' (it is advisable to complete the former sections prior to the submission procedure), and chapter 'Generate an EXPORT File' has been added.

The main screen contains a text menu bar and action icons

🔏 GestionF	ichas	Table 2011 Server of the	and in the local division of	-		-				
Archivo	Gestión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Ver Ventar	as Ayuda				
1 🖬 🖌	🗙 i 🗟 🛝 i 🎯									
Archi	ivo Gestión de Ficha	as Toxicológicas	 Gestión de En 	npresas	Gestión o	e Ingredien	tes Herramientas	Ver	Ventanas	Ayuda

Toolbar menu options:

- File (Archivo)
- Management of toxicological files (Gestión de Fichas Toxicológicas)
- Management of company/enterprise data (Gestión de Empresas)
- Management of ingredients data (Gestión de Ingredientes)
- Tools (Herramientas)
- View (Ver)
- Windows (Ventanas)
- Help (Ayuda)

Bar action icons:

Save (Guardar): Saves the file you are working with, but should not be used if you intend to validate and generate the definite Export file for product notification to the INTCF.

Accept (Aceptar):

Validates/checks the information of the file you are working with, so that you complete the mandatory fields (incomplete fields are shown in red). When done, the application automatically asks if you wish to save the file (automatic saving option). This action is absolutely necessary to generate the export file for notification to the INTCF.

Cancel (Cancelar):

Cancels the on-going activity and closes the file.

Print (Imprimir):

- Manages Export file production for notification/submission to the INTCF. - Prints or saves edited files in pdf format.



Preview (Vista Previa de Impresión):

To visualize the active/open file in pdf format. It does not allow printing.

3 Help (Ayuda):



Provides tutorial in Spanish: "Instructions for Installing the GesFicCom application" (Manual de Instalación y Uso de la Aplicación Informática para la Elaboración de Fichas Toxicológicas, Manual de Administrador-Usuario Versión 2.0.0.17). FILE (Archivo)

GestionFichas	1. Save (Guardar)
Archivo Gestión de Fichas Toxicológicas Gestión de Empresas Gestión de Ingredientes Herramientas Ver Ventanas Ayuda Guardar Ctrl+S Guardar como	2. Save as (Guardar como) 3. Print (Imprimir)
Imprimir Ctrl+P Vista previa de impresión Salir	 4. Print Preview (Vista previ de impresión) 5. Exit (Salir)

1. Save (Guardar)

Changes are saved if you click this option; it will display a warning message:

	×1
ATENCIÓN: Si desea guardar la ficha para su tramitación en el INTCF, debe "clickear" el icono 🖋 Aceptar	

BEWARE

If you want to save this file for future notification/submission to the INTCF: Click icon 2 "Accept" (Aceptar)

IMPORTANT: Thus, this option <u>must not be used</u> to generate the toxicological file for submission to the INTCF.

However, if you have selected this option to merely save the changes, the following message is displayed:



2. Save as (Guardar como) Name a file and store the saved file



IMPORTANT:
This option must not be used
to generate the toxicological
file for submission to the
INTCE

3. Print (Imprimir)

	FICHA	DE INFORMACIÓN DE JCTO PARA EL INTCF	*
		DATOS GENERALES	
	Bescepcion	Value	
	Sondra	Propino amar	
	Revisión	1	
	facha de presiden	OWESOERS	1
	Typ:producto	PCID Examilação Cesmilição cuidado de la piel C1 Productos para ta fesperar de la per	-
	Apicaciones	coundica	
	Geolescie segar Oredina EC 100045	Serviciantes	
	Chertexado ungát CLP	Acute Tax. 1 (Freedow) 14220	
	Amontecian	Salas	
	Feche ecuse derectio	2662085	
	Patra sendata par	Aresoria Munica	
User guide:	limprote responsable de la puedla en el mercado	NY AMARE, Multinacional Hoangang colo pagano, 14 MICITETHIO MICITETHIO MICITETHIO Providence and antipologic management (Anticles and Partie and Developed Developed	ïles
Second Second	höpmaçılırı tiskanala por	HOMENE Lanarative Calle del Dede, 24 07760441	
GesFicCom		nergetiğenersez juticie os Morceder Cenccian	-

Displays and/or prints the Product information file/report (FICHA DE INFORMACION DE PRODUCTO PARA EL INTCF) of an open or saved <u>.xml file</u>.



4. Print Preview (Vista previa de impresión)

FICHA	DE INFORMACIÓN DE JCTO PARA EL INTCF					
Description Votor						
Norders	Provincialitar					
Mevtalin	1					
Fecha de creación	04/03/2015					
Tipo producto	PC99 Cosmetticos Cosmetticos cuidado de la piel C1 Finaluctos premia linguieza-de la piel					
Aplicaciones	coordica					
Clashicación segun Directiva EC 1998/46	Sensitilizanteo					
Clashicactin según CLP	Acute Tex. 1 (Inhubition) F030					
Prezentacion	Sileta					
Fecha acuse de recibo	26402/0016					
Ficha renilida por	Asesoriatécrica					
Empresa responsable de la puesta en el mercado	NOMERE: Multivecional Roskigog celle alrgano, 14 983373145					

To view active/open files. Printing is not enabled.

5. Exit (Salir)



MANAGEMENT OF COMPANY/ENTERPRISE DATA

(Gestion de Empresas)

Manages all information related with company/enterprise.

Gestion	Fichas								_ 8 ×
Archivo	Gestión de Eichas Toxicológicas	Gestión de <u>H</u> ojas de Ingredientes	Gestión de Empresas	Gestión de Ingredientes	Herramientas	⊻er	<u>V</u> entanas	Ayuda	
1 🖬 🛛 🖋	🗙 i 🧟 🖾 i 🎯		•	,					

Inforr	nació	in de las Empresas							×
		Nombre	Cif	Dirección	Teléfono	Fax	E-Mail	Persona de	
•		Lejias Merce 2	1234356/	C/ Alcala					
		Multinacional Rodrigog	09328782g	calle pinguino, 14	983273145	983273145	mercedes.gallego	Rodrigo G	
		Lenonvov	78887474P	Calle del Deste, 24	977888481		mergart@empres	Mercedes	
*									
₹								Þ	5
,							-		<u></u>

It displays screen 'Company Information' (Información de las Empresas)

The table will contain the company data, to be included in the following fields:

- Name (Nombre): name of the company
- CIF/VAT (Cif): ID number of the company.
 - * This field is mandatory when generating the toxicological file
- Address (Dirección): full company address
- Telephone number (Teléfono)
- Fax number (Fax)
- Email (E-mail): Email of contact person for inquiries from the INTCF
- Contact person (Persona de contacto): name of contact person for inquiries from the INTCF
- Position (Cargo): position of the contact person in the company
- Logo: company logo

*Click the column titles to re-arrange the table order

This screen provides the following action icons:

- Add (agregar) icon : adds extra companies
- Eliminate (eliminar) icon si deletes company data (checking box in the first column)
- Save (guardar) icon¹: saves changes
- Use Selections (usar seleccionados) icon 🖉: Transfers information to the active/open file

IMPORTANT:

This icon is <u>'active'</u> when completing 'Marketing company' (*Empresa Responsable de la Puesta en Mercado*) and 'Information elaborated by' (*Información Elaborada por*) fields, during the process of generating a toxicological file ('Management of Toxicological Files' function).

- Cancel (cancelar) icon Set closes this window



ADD/INTRODUCE NEW COMPANY DATA

Archivo Gestión de Fichas Toxicológicas Gestión de Empresas Gestión de Ingredientes Herramientas Ver Ventanas Ayuda	
Información de las Empresas Nortige Of Devición Teléfons Fax • <t< th=""><th>Click icon 'Add' (agregar) Complete all fields in the table</th></t<>	Click icon 'Add' (agregar) Complete all fields in the table
Artenite is in the second Artenite is in the second in the seco	'Active' cell is displayed in blue (e.g.:'Company name' Nombre)
To include the LOGO, locate the logo file. A search window oper Select the file by click	, click icon 🔍 'Select' <i>(seleccionar)</i> to ns king 'Open' <i>(Abrir)</i>
Sectoration de las forgeneses	The search window closes, and the logo 'moves' to the Company Information table (Informacion de las Empresas). Click icon : (save' (guardar) to include the data in your DB, or click icon 'cancel' (cancelar) to discard changes.

A message is displayed: it requests to confirm that you want to save the changes.

	Nombre	CH	Dirección	Teléfono	Fax	E-Mail	Persona de	
C	Lejas Merce 2	12343567	C/ Alcela					
	Multinacional Rochigog	09328782g	calle pinguino, 14	983273145	983273145	mercedes.gallego	Rodrigo G	
		78887474P						1
								_
			Acaptar				•	

You can delete all data from a company by selecting the check box in that row

and clicking icon 'Delete' (Eliminar)

*If you forget to check, the application displays a reminder message. Click 'Accept' (*Aceptar*) and check the box.



MODIFY COMPANY DATA



saved

Accept

Aceptar



MANAGEMENT OF INGREDIENTS DATA

(Gestión de Ingredientes)

This option is available from:

- a) The bar menu
- b) The 'composition' tab of an active/open file (in order to add selected ingredients)

It opens the Ingredients Information table (Información de los Ingredientes), which includes the following fields:



AUTOMATIC LOADING OF INGREDIENTS DATA

*ECHA registered substances (ECHA, http://echa.europa.eu) and substances included in Annex VI of CLP Regulation are pre-loaded in the the GesFicCom application. This enables to automatically recover the information of a substance by introducing the CAS or EC number.

CAS / EC

To search for an inventoried substance, click cell in column CAS/EC

It will open a 'pop-up' window to introduce the CAS or EC numbers.

*The CAS number field accepts up to 12 digits separated by hyphens (xxxxxx-xx-x), and the EC number field accepts 7 digits with format (xxx-xxx-x).

Informació	n CAS / EC	×
• CAS		
C EC		<i></i>
CAS/EC Ir	formation wind	ow





The system **automatically up-loads the data** of the corresponding **CAS** (from Annex VI of CLP) or **EC** (from ECHA registered substances) numbers.

Example of pre-loaded data recovered by introducing CAS or EC numbers

You must select a substance in table 'Substance Information' (CAS or EC) (Informacion de las

Sustancias) (CAS/EC) by checking the box (on the left) and clicking icon \swarrow ; the information will then be automatically up-loaded to the 'Ingredients Information' table (*Informacion de los Ingredientes*).

The following Data will be automatically up-loaded when you launch search by introducing:

a) CAS number: Type of ingredient (*Tipo de Ingrediente*) CAS/EC Chemical name (*Denominación*) CLP classification (*Clasificación CLP*)

b) EC number: CAS/EC Chemical name (Denominación)

The remaining fields must be completed manually.

In both cases (search by CAS or EC number), <u>additional information</u> must be introduced manually.

IMPORTANT:

• If the ingredient is <u>included in Annex VI</u> of the CLP Regulation, preferentially introduce the CAS number, so that all related information will be automatically uploaded.

• If the ingredient is <u>not included in Annex VI</u> of CLP Regulation, introduce the EC number; in this case, the hazard data must be introduced manually.

• If the ingredient is <u>not included in neither Annex VI nor ECHA</u>, all data must be introduced manually.

MANUAL INTRODUCTION OF INGREDIENTS DATA

If the ingredient is not included in any of the pre-loaded databases (Annex VI or ECHA), all data must be introduced manually (this is not a recommended procedure).

Gestio	mFichas				
Archivo	Gestión de Fichas Toxi	cológicas Gestión de	Empresas Gestión de Ingredientes Herramientas Ve	r Ventanas Ayuda	
🖬 🗸	X 🗟 🛕 🚳 👘				
Informaci	ón de los Ingredientes	5			×
	Tipo Ingrediente	CAS / EC	Denominación	Clasificación CLP	Información Adi Buscador
		-			
			Información CAS / EC	3	
			← CAS 68439-46-3_		
				2 🕙	
•					2
,					
			Carga de Sustancias(CAS/EC)	x	
			No se han encontrado Sustancias con ese	códgo.	💷 🐷 🙍
				Aceptar	
Estado					,ii
Mess	age: 'Su l	bstance	not found'		

(e.g.: CAS 68439-46-3, Alcohols, C9-11, ethoxylated)



We advise to manually **introduce the data in the following sequence**, to achieve the automatic up loading of most of the information:

1) CAS/EC:

Tipo Ingrediente		CAS / EC	Denominación	Clasificación CLP	Información Ad	Buscad
SU3-Telf. 24h	-					
Peligrosidad 1	-					_
SU3-Telf. 24h	-		dfd			
No Clasificado	-		no tiene peligro			
Peligrosidad 2	-	120307-06-4	tetrabutylammonium butyltriphenylborate	Skin Sens. 1 H317 H400		
	•	3343	CAS 3343 EC	Cerrar		
			m		۰. ۲	

Click the cell and include the CAS number.

It will be transferred to the CAS/EC cell of the table

CAS/EC information (Detail)

2) Chemical name (Denominación):

· ·	
Denominación	corres
Butypareben	
"Chemical name" (Denominación)	ar

Introduce the chemical name in the corresponding cell

*Names must comply with the policy reported in article 18 of EC Regulation 1272/2008 (CLP).

3) CLP classification (Clasificación CLP):

Report the mixture classification according to the CLP Regulation.



Clicking cell (*Clasificación CLP*) will open a drop-down list with choice options

Check the adequate options and save by clicking icon ; the values will be transferred and included in the corresponding cell.

To cancel selections click icon 送.

*When the CLP classification field is uploaded *via* introduction of a CAS number, it is non-editable.

'CLP classification' field (Clasificación CLP) (Drop-down list)

4. Type of ingredient (Tipo Ingrediente)

Click cell 'Tipo de ingrediente' and use button 🔽 to display the drop-down list with the following options:

- **Type 1 Hazard** (*Peligrosidad 1*): substance included among one of the following hazard categories (according to the CLP classification):

Acute Toxicity (by oral, dermal or inhalation route) categories 1, 2 or 3 Specific target organ toxicity - Single exposure: (STOT SE) Category 1 or 2 Specific target organ toxicity - Repeated exposure: (STOT RE) Category 1 or 2 Skin corrosion, category 1A, 1B or 1C



Serious eye damage, Category 1

MINISTERIO DE JUSTICIA

- Type 2 Hazard (*Peligrosidad* 2): substance, which, according to the CLP classification, is not included among the hazard categories mentioned above (see Type I hazard categories).

- Non-classified (*No Clasificado*): substance not classified as hazardous according to the CLP (EC Regulation 1272/2008).

- Mixture (Mezcla):

a) Mixture previously notified to the INTCF by a supplier/manufacturer, and which has been assigned an INTCF Reference number.

In this case, you must <u>exclusively complete the Additional Information field</u> (*Informacion Adicional*), by including:

- The INTCF Reference number of the mixture (DRP...)
- The manufacturer/supplier company name between brackets
 - e.g.: DRP15-0000111 (Martinez, Ltd.)

Leave the remaining fields empty.

b) Mixture not previously notified to the INTCF or DRP reference number is unknown, will depend on the hazardousness of the mixture and its concentration in the final mixture (Safety Data Sheet of the mixture (MiM) can be attached (*Others*) in the xml file).

- U3-Tel. 24h (SU3-Telf. 24h): Ingredient for industrial use <u>only</u>: when the final user is exclusively industrial ('SU3'), and the product is unavailable for consumer or professional use.

In this case, you must <u>exclusively complete Additional Information field</u> (Informacion Adicional) (although all fields are active): Include the 24h telephone number.

* This option is restricted to companies that have previously established a formal agreement with the INTCF in order to benefit from a special notification procedure (reduced composition data, and the guarantee to provide complete formula composition in Spanish in less than 15 minutes).

* Only <u>a single 'SU3-Tel. 24h type' ingredient</u> may be included in the composition of a mixture.

5. Additional Information (Información adicional):

Relevant extra information about the ingredient may be included in this field. Similarly, this field must be completed following the requirements mentioned above, when you have selected "Mezcla" or "SU3-Tel. 24h" Ingredient type .

Información Adicional
DRP15-0000111 (MARTINEZ, S.L.)
Example of reference number (DRP)

TINEZ, S.L.) 91132132 number (DRP...) Example of

SEARCH SYSTEM

_	Tipo ingrediente	_	CAS / EC	Denominación	Información Adicional	Buscado
	SU3-Telf. 24h					
	Pelgroeidad 1					(
	SU3-Telf. 24h			dfd		0
۵	No Clasificado			no tiene peligro		
	Pelgrosidad 2	•	120307-06-4	tetrabutylammonium butyltiphenylborate		
			3343			

Información Adicional 911321321 Example of 24h telephone number

Click the search button (Buscador), select the appropriate field, and introduce your number/term to locate an ingredient in your list.

You may cancel the search option by clicking the 'Buscador' tab.



CONCLUDE MANAGEMENT OF INGREDIENTS LIST

Save your task by clicking icon

*This option is exclusively available when the ingredient list is managed with an active/open file.

	Tipo Ingrediente		CAS / EC	Denominación	Información Adicional	Busci
1	SU3-Tell. 24h	-				
E	Pelgrosidad 1					
1	SU3-Telf. 24h			dfd		
1	No Clasificado	-		no tiene peligro		
8	Pelgrosidad 2	•	120307-06-4	tetrabutylammonium butyltriphenylborate		
1	1	-	3343			
*						

When elaborating a toxicological file, select the composition ingredients by marking the corresponding check boxes, and then click icon



MANAGEMENT OF TOXICOLOGICAL FILES

(Gestión de Fichas Toxicológicas)

This function manages the information of the toxicological files; it is found in the toolbar menu, and comprises the following options:

📑 Gestion	Fichas				
Archivo	Gestión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Add new file (Añadir)
i 🔛 🖋	Añadir				Add new me (Anddir)
	Modificar				Modification (Modificar)
	Modificar No Esencial				Non-critical Modification (Modificar No Econcial)
	Modificar F Papel				Non-critical modification (modifical no esencial)
	Copiar				Modify paper F (Modificar F Papel)
	Dar de Baja				Conv (Conier)
	Editar				copy (copiar)
					Withdrawal (Dar de baja)
					Edit (Editar)
0.11		. Charles Inc.	Acres 1 Cills of the l		

Options: 'Management of toxicological files' tab

ADD A NEW TOXICOLOGICAL FILE (NEW ENTRY)

This option enables to generate a new toxicological file.

R ² Ficha 0		
Principal Composición Adjuntos		
Nombre		Click option 'Add' (Añadir)
	UFI	
Persona que Elabora la Ficha	Fecha de Creación 12/03/2015	
Tipo de Usuario Final		
Tipo de Producto	Aplicaciones	A screen (Ficha 0) with 3 tab
Clasificación según Directiva EC 1999/45	Clasificación según CLP	is displayed.
Indicaciones de Peligto en Etiqueta	Indicaciones.de. Precaución en Elsueta	- Main (Principal)
Pictogramas en Etiqueta	Sección 11 de la FDS	- Composition (Composición
Presentación	• Color	- Attachments (Adjuntos)
	Envase	

New toxicological file

MAIN DATA TAB

The Main (*Principal*) tab provides the following fields: *NOTE: all multi-line fields are expanded into larger windows by double-clicking.

Name (Nombre):

It is a mandatory field.

Check the help message bubble in "Nombre" for related instructions:

"Provide the full trade name (CAPITAL LETTERS) as displayed on the product label (avoid abbreviations), to enable non-ambiguous identification of a product, and in particular, in case of variants with the same generic trade name. When possible, indicate the Register numbers displayed on the label".

Use a new file for each product with different trade name (**<u>BEWARE</u>**: products with the same composition/formula but different trade names cannot be notified in the same file).

However, <u>variants of a mixture with a common trade name</u> may be notified together in a single file, but only when fulfilling the following criteria:

- a) They exclusively differ in colour or perfume
- **b)** The ingredients of all variants are included in the same concentration ranges
- c) Concentration of hazardous ingredients remains constant
 - (<u>Applies to ingredients classified as</u>: Acute Toxicity by oral, dermal or inhalation route categories 1, 2 or 3; Specific target organ toxicity Single exposure STOT SE Category 1 or 2; Specific target organ toxicity Repeated exposure STOT RE, Category 1 or 2; Skin corrosion, category 1, 1A, 1B or 1C and Serious eye damage, Category 1).

In this case, all variant names must be provided together with the common trade name. Additionally, labels for all variants must be supplied as attached objects.

When the label of a product marketed in Spain includes translations into other national languages (e.g.: basque, catalan, etc), indicate all these names in the same file.

UFI (Unique Formula Identifier):

It is a <u>mandatory field.</u>

For the moment (and until the actual UFI is agreed), it is the company reference number/code identifying the formula; therefore, it will change when the mixture undergoes composition modifications.

Person elaborating the file (Persona que Elabora la Ficha):

Provide the full name of the person elaborating the file.

Date of file production (Fecha de Creación):



Fecha de Creación 25/02/2015

The date is automatically provided whenever a file is generated (follow format *dd/mm/yyyy*).

Please ensure your pc has the same date format.

Type of Final User (Tipo de Usuario Final):

It is a mandatory field. Indicate the final user/s of the mixture.

Ti	po de Usuario Final	×
	Consumider	
	Profesional	

Click on 'active legend' (<u>Tipo de Usuario Final</u>); it opens a pull down list displaying the following options: Consumer (*Consumidor*), Industrial (*Industrial*) and Professional (*Profesional*).

You may select one or several options, and save by clicking icon \swarrow , or click icon \circledast to cancel.

Final user field



Product Type/Category (Tipo de Producto): It is a mandatory field.

> You must select the product type among the pull down menu options. The mixture must be precisely typified: choose all necessary options (product with several types of final users).



Select the corresponding check boxes and save by clicking icon \swarrow , or click icon \bigotimes to cancel. IMPORTANT:

the options are contained in a tree structure; therefore display sub-options by successively clicking the "+" box and select all appropriate check boxes.

Product Type window



Then save your choices by clicking icon \swarrow , or click icon 🤒 to cancel.

Tree structure of the "Product Type" roll-down menu

Product Uses (Aplicaciones):

It is a mandatory field. Briefly describe the intended application of the mixture

Classification according to EC Directive 1999/45 (Clasificación según Directiva EC 1999/45):

Indicate the hazard classification of the mixture according to this Directive.

Clasificación según Click active legend Directiva EC1999/45; it displays the classification options.

Clasificación Según Directiva EC 1999/45	×
Monitationada Construction Magninos Magninos Magninos Nociose Simulationiste Simulationiste Tofanose Tofanose Tofanose Tofanose Simulationiste Tofanose Tofanose	
	<i></i>

Click on the appropriate check boxes.

Save your choices by clicking icon \swarrow or icon \circledast to cancel.

> *Select 'Non-classified' (No Clasificado) option if the mixture is considered as non-hazardous (according to EC Directive 1999/45)

Classification (EC Directive 1999/45)



Classification according to CLP (Clasificación según CLP):

Indicate the hazard classification of the mixture according to the EC Regulation 1272/2008 (CLP Regulation).

Click active legend; it displays the classification options.

Then select by clicking on the appropriate check boxes, and save your choices by clicking icon \swarrow , or click icon \gtrless to cancel.

Hazard statements on the label (Indicaciones de Peligro en Etiqueta):

Report the most relevant hazard statements regarding mixture handling, as displayed on the label.



Click the active legend a roll-down menu.	Indicaciones de Peligro en Eliqueta ; it opens
Select the hazard state check boxes, and click icon 🧭 to cancel.	ment with the appropriate the icon 📂 to save, or

Precautionary statements on the label (Indicaciones de Precaución en la Etiqueta):

Indicate the most relevant precautionary statements regarding the mixture handling, as displayed on the label.

Indicaciones de Precaución	×
P101 Si se necesita consejo médico, tener a mano el envase o la et	
P102 Mantener fuera del alcance de los niños.	
P201 Pedir instrucciones especiales antes del uso.	
P202 No manipular la sustancia antes de haber leído y comprendido	
P210 Mantener alejado de tuentes de calor, chispas, llama abierta o P211 No pulverizar sobre una llama abierta u otra fuente de ignición	
P220 Mantener o almacenar alejado de la ropa//materiales combu	
P221 Tomar todas las precauciones necesar las para no mezclar co	
P222 No dejal que entre en contacto con el ane. P223 Mantener alejado de cualquier posible contacto con el agua, (
P230 Mantener humedecido con	
P231 Manipular en gas inerte. P231 + P232 Manipular en gas inerte. P231 + P232 Manipular en gas inerte.	
P232 Proteger de la humedad.	
P233 Mantener el recipiente herméticamente cerrado.	
P234 Conserval unicalience en el recipience original. P235 Mantener en lugar fresco.	
N 19 🖉 🧕	

Precautionary statements window



Select the precautionary statements by marking the appropriate check box, and click the icon to save or the sicon to cancel.

Pictograms on the label (Pictogramas en Etiqueta):

Report the most relevant hazard pictograms regarding mixture handling (as displayed on the label).



Click legend <u>en Etiqueta</u>; it opens a multi-choice window (roll-down menu).

Select the appropriate check box, and click \swarrow icon to save, or \triangleleft icon to cancel.

Pictograms window



Section 11 of the SDS (Sección 11 de la FDS):

Include the toxicological information described in section 11 of the SDS (health effects), and when available, extra data on toxicokinetics, metabolism and distribution.

Physicochemical state of the mixture (Presentación):

It is a <u>mandatory field</u> .							
	Presentación	l	\ -				
		Gas					
		Líquido					
		Sólido					

Click icon 📕 to select one of the options: Gas, Liquid or Solid.

'Physicochemical state of the mixture'

Colour (Color):

Indicate the precise colour of the mixture (not the	ne packaging).
Preferentially use basic colour names (e.g.: green	n, red, white, etc)
Color	

Package (Envase):

- Describe the type of packaging (e.g: bottle, bag, sack, can, etc).
- If the product has a double packaging, describe both.

- Report all package size/s and types of packaging in the same product file (normally in g, Kg, ml, etc).

- If the package contains individual units, precise the number of blocks, tabs, towels, etc.

- Provide more detailed information for final user 'consumer'.

Envase	

Package window

рН (*pH*)

It is a mandatory field.

- For liquids:

Indicate pH value of undiluted product, or provide the solution percentage (e.g.: 10%) in window *"en Solución al"* when measuring the diluted product.

- For solids:

Indicate pH value of the diluted product and provide the solution percentage in window *"en Solución al"* when measuring the diluted product.

рН	en Solución al		
pΠ	en solucion al	1	

*Field "en solución al" is not mandatory.

***NOTE:** when pH values cannot be measured (e.g.: organic solvents), report as 'NA' (non applicable).



COMPOSITION TAB



QUANTITATIVE COMPOSITION OF THE MIXTURE (Composicion cuantitativa):

The table must contain at least one ingredient.

For the moment, and until the European harmonisation process for product notification is achieved, the following requirements must be fulfilled:

All ingredients in the mixture must be notified, albeit their toxicity, in decreasing order of concentration.

The exception to this requirement applies to ingredients below 1% in the final mixture, and non-classified as hazardous (according to CLP Regulation).

IDENTIFICATION OF INGREDIENTS:

Chemical names must comply with the nomenclature in Annex VI, part 3 of the European Regulation 1272/2008 (CLP), IUPAC or other internationally accepted chemical names, together with the CAS or EC numbers.

GENERIC TERMS:

- Such as perfume or fragrance, may be used only below 5% in final mixture.
- Terms such as pigment, dye or colouring agent, may be used only below 25% in final mixture if Not-Classified as hazardous, according to CLP Regulation.

Introduce these terms in the Additional Information (Informacion Adicional) field.

HAZARD CLASSIFICATION:

According to the European Regulation 1272/2008 (CLP).

TYPE OF INGREDIENT:

Select among the 5 options (following the criteria previously described):

- Type 1 Hazard (Peligrosidad 1)
- Type 2 Hazard (Peligrosidad 2)
- Non-classified (No clasificado)
- Mixture (Mezcla)
- SU3-Tel. 24h (SU3-Telf. 24h)

This parameter is mandatory for file validation.

CONCENTRATION:

Indicate the concentration (percentage) of each ingredient:

a) Selecting pre-established default concentration ranges (Porcentaje)

b) Providing exact concentration (% Propio)



c) Providing your own concentration range (% Propio), in agreement with the following requirements:

- 1. For <u>all ingredients classified</u>, <u>according to Directive 1999/45/EC</u> as: T+, T or C
 - Or according to CLP Regulation (1272/2008) as:
 - -Acute Toxicity (by oral, dermal or inhalation routes) categories 1, 2 or 3 -Specific target organ toxicity-Single exposure (STOT SE) Category 1 or 2 -Specific target organ toxicity-Repeated exposure (STOT RE), Category 1 or 2 -Skin corrosion category 1, 1A, 1B or 1C
 - -Serious eye damage Category 1

The concentration range intervals must comply with the requirements depicted in TABLE I.

(%) EXACT CONCENTRATION INCLUDED IN:	MAXIMUM CONCENTRATION WIDTH (units):
25-100%	5
10-25%	3
1-10%	1
0,1-1%	0,3
0-0,1%	0,1

TABLE I

Example:

32% is the exact concentration of a hazardous ingredient (one of the hazard classification categories mentioned above).

If you choose to provide **your own concentration range** (on basis of: confidentiality, reduce re-notifications, etc.), **32%** exact concentration is comprised in range **25-100%**, so that **5** units maximum concentration width is applicable. Thus, the following ranges comply with the requirements: 27-32%, 28-33%, and 29-34%.

Moreover $\underline{30-33\%}$ is an accepted option, because you have chosen the 3-unit interval (below the maximum concentration width).

- 2. For the remaining ingredients:
 - Substances with hazard classification not included in (1.)
 - Non-classified substances above 1%
 - Mixtures pre-notified to the INTCF

The concentration range limits must comply with the requirements depicted in <u>TABLE II.</u>

TABLE II

(%) EXACT CONCENTRATION INCLUDED IN:	MAXIMUM CONCENTRATION WIDTH (units):
25-100%	20
10-25%	10
1-10%	3
0-1%	1



MIXTURE (Mezcla):

a) <u>Mixture previously notified to the INTCF by a supplier/manufacturer, and which</u> <u>has been assigned an INTCF Reference number (DRP number).</u>

A company (the marketing company, as displayed on the label) selling a mixture/product (100% or as a component in the final mixture, MIM) bought from another company (supplier/manufacturer) may notify according to the following procedure:

- 1. Select option "Mezcla" in the 'Type of Ingredient' (*Tipo Ingrediente*) field
- 2. Include Trade name in Chemical name (*Denominación*)
- **3.** Select CLP Classification (*Clasificación CLP*)
- **4.** Provide INTCF reference number assigned to the supplier (e.g. DRP17-1234567) and the supplier's name (in brackets) in the 'Additional Information' (*Informacion Adicional*) field
- **5.** Indicate the concentration (percentage) of each ingredient.

The commitment of the supplier to inform the marketing company in case of formula modification (so that the marketing company notifies the "Modification" to the INTCF)

- b) <u>Mixture not previously notified to the INTCF or DRP reference number unknown,</u> will depend on the hazardousness of the mixture and its concentration in the final mixture (Safety Data Sheet of the mixture (MiM) can be attached (*Others*) in the xml file). It will be notified as follows:
 - 1. If a "Mixture" ingredient is classified as hazardous (according to CLP Regulation) and below 5% in the final mixture:

COMPOSITION:

Type of Ingredient (*Tipo Ingrediente*): Mixture (*Mezcla*) Chemical name (*Denominación*): Trade name CLP Classification (*Clasificación CLP*): To be included Additional Information (*Información adicional*): the name of mixture "SDS pdf file" that must be attached in the xml file (Attachment "*Adjuntos*", Other: "*Otros*"). Indicate the concentration (percentage) of each ingredient.

2. If a "Mixture" ingredient is Non-classified as hazardous (according to CLP Regulation) and below 20% in the final mixture:

COMPOSITION:

Type of Ingredient (*Tipo Ingrediente*): Mixture (*Mezcla*) Chemical name (*Denominación*): Trade name CLP Classification (*Clasificación CLP*): Non-classified (*No clasificado*) Additional Information (*Información adicional*): the name of mixture "SDS pdf file" that must be attached in the xml file (Attachment "*Adjuntos*", Other: "*Otros*"). Indicate the concentration (percentage) of each ingredient.



MINISTERIO DE JUSTICIA

COMPOSITION DATA, A SUMMARY OF THE PROCEDURE:

QUALITATIVE COMPOSITION:

Data is recovered from the Management of Ingredients inventory/table: Type of Ingredient (*Tipo Ingrediente*) CAS/EC Chemical name (*Denominación*) CLP Classification (*Clasificación CLP*) Additional Information (*Información adicional*)

QUANTITATIVE COMPOSITION:

Non-default concentration (% propio): introduce manually. Default concentration range (Porcentaje): select from roll-down menu.

In the open file, go to the 'Composition' tab (*Composición*) and click icon 🖄 to access the Ingredients data (*Información de Ingredientes*). Ingredients data may have been previously stored using the 'Management of ingredients' (*Gestion de Ingredientes*) function (see Management of Ingredients).

Check the boxes to select the ingredients (the selected rows turn pink), and click icon transfer the selected ingredients to 'Quantitative Composition' (*Composición Cuantitativa*) window.



Introduce the actual concentration of each ingredient in 'Non-default concentration' (%Propio) or 'Default concentration' (Porcentaje) columns (see Composition).

It is mandatory to fill-in one of these field options.

Non-default concentration range (%Propio)

In this case, you must <u>exclusively complete the Additional Information field</u> (*Informacion Adicional*), by including:

- The INTCF Reference number of the mixture (DRP...)

- The manufacturer/supplier company name between brackets e.g.: DRP15-0000111 (Martinez, Ltd.)

Leave the remaining fields empty.

SU3-Telf. 24h



If you check 'SU3-Telf. 24h' Type of Ingredient option (Tipo Ingrediente) from the

"Informacion de Ingredientes" table, click 'Use selected' (Usar Seleccionados) icon



The following pop-up message is displayed:



Composition management The 24h telephone number is valid for mixtures with industrial final use. You must contact the INTCF in order to benefit from this notification procedure with 24h phone assistance.

Accept

Contact INTCF for notification procedure '24h telephone'

ATTACHMENTS TAB



Open the last 'page' to be completed with the 'Attachments' tab (Adjuntos)

'Attachments' (Adjuntos) tab

The following fields are found in this page:

FILE SUBMITTED BY (Ficha remitida por): person elaborating the notification file, and providing the data.

Ficha Remitida por	
	Asesoría técnica Fabricante del producto Otros Besponsable de la puesta en el mercado
"File submitted	bv" field

- Technical consultant (Asesoría técnica)
- Manufacturer (Fabricante del producto)
- Others (Otros)
 - Marketing company (Responsable de la puesta en mercado) (Company responsible for placing the product on the market)



MARKETING COMPANY (Empresa responsable de la Puesta en el Mercado): Company responsible for placing the product on the market.

It is a mandatory field.

The marketing company is absolutely required for product notification to the INTCF. This company is responsible of communicating the new entries, modifications and withdrawals of the products to the INTCF; however, other companies (manufacturers, technical consultants, etc) may perform the notifications on their behalf.

In agreement with current regulations the marketing company must be identified and displayed on the label.



Click the active legend Empresa Responsable de la Puesta en el Mercado (Marketing company).

It opens window 'Responsible of placing the product on the market' (Responsable de la puesta en el Mercado)

Window: "Marketing company" (Responsable de la puesta en el Mercado)

The marketing company must provide the following data:

- Name (Nombre): name of the company or social site
- CIF or VAT identification number of the marketing company (Cif)
- Address (Dirección): dirección completa de la empresa
- Telephone number (Teléfono)
- Fax (Fax)
- Email (E-mail): contact person Email address for INTCF inquiries
- Name of contact person (Persona de contacto): for INTCF inquiries
- Position (Cargo): contact person's position in the marketing company
- *Logo (Logo): the marketing company's logo



Click icon to locate the logo file in your computer, select it, and upload it with button Open (Abrir)



Locate and include the logo (details)

A message is displayed:

sponsa	ple de la puesta en el mercado								
	Nombre	Teléfono	Fax	E-Mail	Persona de Contacto	Cargo	Logo		
Г	Cosmética Merui	677854778	677854778	mercedes.gallego	Mercedes Gallego	Dirección	10 miles (1)		
*			2	Sestión de Empres 2 Desea G Si	ns 🔀 Jardar los cambios? No		× (),	.	<u>Management of company</u> <u>data</u> Do you want to save the changes? Yes (Si) No (No)"
							= 📂		
ess	age: 'Do you wan	t to save th	e chan	ges?'					

Press 'Yes' (Si) to accept, or (No) to discard the changes. Empresa Responsable de la Puesta en el Mercado window of the actual open file, To transfer the information to the select the check box and click icon \min; to cancel, click icon

To delete a company ID data, click the corresponding checkbox and press icon

The data included in this table enables to complete both fields: a) Company elaborating the file Información Elaborada por ... Émpresa Responsable de la

b) Marketing company Puesta en el Mercado

DATA ELABORATED/PROVIDED BY (Información elaborada por)

This is a mandatory field.

Provide the following information to identify the company and person elaborating the file:

- Company name (Nombre)
- CIF/VAT ID number (Cif)
- Full company address (Dirección)
- Telephone number (Teléfono)
- Fax number (Fax)
- Email address (E-mail): contact person Email address for INTCF inquiries
- Name of contact person (Persona de contacto): for INTCF inquiries
- Position (Cargo): contact person's position in the company
- Logo (Logo): company's logo

)rn	ació	in elaborada por							
_	1	Nombre	Teléfono	Fax	E-Mail	Persona de Contacto	Cargo	Logo	7
Þ		Lejias Merce 2						× 🕺	1
		Multinacional Rodrigog	983273145	983273145	mercedes.galego	Rodrigo G	Directivo	1 (Como)	1
								× 😣	
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ī									
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Ĵ	4.	alaborated/a	rouidod b		daw (In	formación a	Ichoroda		

Click legend Información Elaborada por ...

It displays window 'Data elaborated/provided by' (Información elaborada por).

Provide data and proceed as described in previous section ('Marketing company').

Data elaborated/provided by' window (Información elaborada por)



ATTACHMENTS (Documentos adjuntos)

Mandatory attachments:

- Product label
- SDS

<u>Optional documents:</u> technical files, ingredients data sheets, certificates, ADR documents, etc.



incipal Composición Adjuntoc Ficha Remitida por	Asecoría técnica 💌		
mpresa Responsable de la Puesto en el Mercodo	VDMBRE Multinacional Rockigog zale propuento, 14 382227145 982227145 Recting G Rockigo G Deschiro Deschiro		
Vintemo Información Elaborada por Clade au Olem, 24 97/80491 regard/exeressa juntica es Mecedes Dirección		CIF/AAT Number [780074749	
File Constant Constan	réa Puta de Acceso via de seguridad (PDS) iva de ingredientes		2

Include the information in the red-boxed area.

Press button <u>Type of</u> <u>Attachment</u> (*Tipo de Adjunto*) to display the roll-down options menu:



- Others

Attachments (Adjuntos) tab (field is shown boxed in red)

Product label (Etiqueta)

Attach the label actually displayed on the product to be marketed in Spain. Only <u>one label required</u> if the product is supplied in different volumes or sizes. <u>Notification of variants (colour, fragance, etc): all variant labels required.</u> Labels must be provided in **pdf** format.

NOTE: If the mixture is marketed without label, you must attach a document (pdf format) clarifying the 'lack of label', and including the product trade name, marketing company name and hazard pictograms.

SDS (Ficha de datos de seguridad (FDS)

It is <u>mandatory</u> to provide the SDS for hazard-classified mixtures (according to CLP Regulation 1272/2008)



VERY IMPORTANT:
To save the completed file for submission to the INTCF, click icon $\stackrel{\scriptstyle \mbox{\scriptsize scale}}{=}$ "Accept" (Aceptar) in the tool bar menu.
IMPORTANT: do not modify the name of the up-loaded files

VALIDATE AND SAVE THE FILE

Subsequently, the system will check the file, and if mandatory fields are incomplete, alert messages will be displayed to amend the mistake.



inciael		
Composicion Adjuntos		
Nombre		
	UFI	
Persona que Elabora la Ficha	Fecha de Creación 12/03/2015	
Tipo de Usuario Final		
		The inc
Tipo de Producto	Aplicaciones	fieldes
		netus
Clasificación según	Clasificación según	
Directiva EC 1999/45		
Indicaciones de Peligro	Indicaciones de	
en caqueta	en Etiqueta	
Pictogramas	Sección 11 de la	
STI LINUSIA	PDS	
Presentación	- Color	
	Envase	
	pH en Solución al	

The incomplete mandatory fields will be shown in red.

Incomplete mandatory fields shown in red (example)



Once validated, the application requires saving the file.



Select the folder* and name the file (currently, the product trade name)

*Path established when installing GesFicCom application or default installing path

"Save file" window

Once saved, a message is displayed informing that the file has been successfully saved for notification/submission to the INTCF.

If the system 'spots' a file with the same name, it will display a message asking whether you intend to replace the previous file.

If unwilling to do so, click <u>"No"</u> and change the file name.

IMPORTANT: the file has been saved for subsequent Export under 'New' (Nueva) status.



MODIFY A TOXICOLOGICAL FILE

General concepts:

The marketing company (company responsible of placing the product in the market) is responsible for updating the information of the mixtures placed in the market. Thus, it must submit all information regarding modifications of the notified products, which includes withdrawal from the market.

CRITICAL MODIFICATION (Modificar)

Re-submission <u>is mandatory</u> when **the composition of a** previously notified **mixture is modified.**

The following criteria imply composition changes:

- Add or exclude any of the ingredients
- Change the concentration range of any ingredient
- Change the pH value or the dilution for pH measurement

📑 GestionF	ichas						
Archivo	Gestión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Ver	Ventanas	Ayuda
i 🖬 i 🗹 :	Añadir						
	Modificar						
	Modificar No Esencial						
	Modificar F Papel						
	Copiar						
	Dar de Baja						
	Editar						

Go to the main toolbar menu, open Management of toxicological files (Gestion de Fichas Toxicológicas) tab and select Modify (Modificar) option.

Main toolbar menu: Management of toxicological files - Critical modification option (Modificar)

0 N

Abrir							고즈
Buscar en	🗋 🗀 Ficha	5		•	🔆 🦻 🖻	• 📰 و	
Documentos recientes	Bajas merce.: Pinguin Pinguin Total.x	xml merce 2.xml oAffair2.xml oAffair.xml ml					
Escritorio Mis documentos							
MiPC							
Mis sitios de red	Nombre:	T otal.xml				•	Abrir
	Tipo:	Archivos d	le texto (*.xml)			Ŧ	Cancelar

It opens a window to locate the original file to be modified.

Select and 'open' (*Abrir*) the appropriate file.

Locate file for modification

You must complete the file following the procedure described for NEW ENTRY.

However, in this case:

- 'Product name' (Nombre) and 'Marketing company' (Empresa responsable de la puesta en el mercado) fields are blocked.
- "Revision" box is checked
- "N^o Ref" field is available

IMPORTANT:
+ Update the UFI (it must change with formula modifications)
+ Include the 'old' INTCF Reference number in field "Nº Ref" (INTCF reference
number assigned to the previously notified product that has been modified)

	MINISTERIO DE JUSTICIA	User Manual	Servicio de Información Toxicológica	
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Once validated, the file will be saved for subsequent Export under 'Modification' status (*Modificación*).

E.	I\Archivos de programa\Gesf	icCom\/Ficheros\/Fichas\/Total.aml			10×
	hinoipal Composición Adjuntos				
	Nombre	MerTotal			
	Revision Nt Ref		- 18		
	Persona que Elabora	, [Fecha de Creación	02/03/2015	
	Tipo de Usuario Final	Consumidor	-		
	Tipo de Producto	PC27 Fitosanitarios uso agricola. Acericida	Aplicaciones	todes	
	Clasificación según Directiva EC 1999/46	No Clasificado	Clasificación según CLP	No Clasificado	
	Indicaciones de Peligro en Etiqueto	EUH 201/201A Contiene plomo. No utilizer en objetos que los niños louaden mesticer o chuper.	Indicaciones de Precaución en Etiqueta	P101 Si se necesita consejo médico, tener a mano el envase o la atousta	
	Eiclogromos en Etiqueto	Bomba explotando	Sección 11 de la FDS		
	Presentación	Solido	Color	,	
			Envase		
			pH 5	en Sciución el	

Introduce the changes in the composition table (to be found in *(Composición)* tab of the open file), <u>following the procedure described for NEW ENTRY</u>.

Once finished, click Accept icon (Aceptar) to save the modified file.

A security copy of the 'old' file is generated and saved in directory: GesFicCom\Ficheros\ Fichas\Bajas".

🗁 Bajas			
Archivo Edición Ver Favorito	os Herramientas Ayuda		
🔇 Atrás 🔹 🕥 🖌 🏂 🔎	Búsqueda 💫 Carpetas 🛄 🕇 🔞 Si	cronización de carpetas	
Dirección 🛅 C:\Archivos de progra	ma\GesFicCom\Ficheros\Fichas\Bajas		💌 🏓 Ir
Tareas de archivo y carpeta Crear nueva carpeta Publicar esta carpeta en We Compartir esta carpeta	Merce el bueno.xml Documento XML 4 K8	Todekani Documento XML 3 HS	
Otros sitios	*		
Eichas Mis documentos MIPC MIPC			
Detalles	*		

Security copy of the 'old' file saved in directory C: \Program Files\GesFicCom\Ficheros\ Fichas\Bajas"

NON-CRITICAL MODIFICATION (Modificar No Esencial)

Considered as substantial changes in the appearance of the previously notified mixture:

- Significant changes in packaging (size and type)
- Relevant changes in label design
- Colour of the mixture changed
- Updated pictograms in label
- SDS updates (new versions)

However, it will not comply with a non-critical modification if changes affect:

- The product name
- The composition



- The pH value or dilution for measurement

🛃 Gestion	Fichas						
Archivo	Gestión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Ver	Ventanas	Ayuda
i 🕍 i 🛷 i	Añadir 📄						
	Modificar						
	Modificar No Esencial						
	Modificar F Papel						
	Copiar						
	Dar de Baja						
	Editar						

Go to the main toolbar menu Open 'Management of toxicological files' (*Gestion de Fichas Toxicológicas*) tab, and select 'Non-critical Modification' (*Modificar No Esencial*)



It displays a window to locate the original file to be modified.

Select and 'open' (Abrir) the appropriate file.

You must complete the file following the procedure described for NEW ENTRY.

However, in this case:

- 'Product name' (*Nombre*), 'UFI', 'pH and dilution', 'Composition' and 'Marketing company' fields <u>are blocked</u>.

- "Revision" box is checked, and "Nº Ref" field is available

IMPORTANT: Include the 'old' INTCF Reference number in field "N° Ref" (INTCF reference number assigned to the previously notified product).

rogram Files (x80)/GesFicCo	m\Ficheros\Fichas\Gabi nuevo gesficom 2	7 feb.xml				
al Composición Adjuntos						
Nombre	Gabi					
Revisión Nº Ref			UFI	13343		
Persona que Elabora la Ficha		Fecha o	de Creación	05/03/2015		
Tipo de Usuario Final	ConsumidorIndustrialProfesional					
Tipo de Producto	PC39 Cosméticos Cosméticos cuidado de la piel	A	plicaciones	aplicaciones		
Clasificación según Directiva EC 1999/45	Extremadamente inflamables Irritantes Muy tóxicos	<u>Clasifica</u>	ación según <u>CLP</u>	Acute Tox. 1 (Si Acute Tox. 2 (In Acute Tox. 2 (O	kin) H310 halation) H330 rai) H300	
Indicaciones de Peligro <u>en Etiqueta</u>	EUH 401 A fin de evitar riesgos para las personas y el medio ambiente, siga las instrucciones de	Indic	aciones de Precaución en Etiqueta	P202 No manip antes de haber todas las instru	oular la sustancia leído y comprendido cciones de	
Pictogramas en Etiqueta	Corrosión Llama sobre círculo Signo de exclamación	Secci	ión 11 de la FDS	seccion 11		
Presentación	Gas 👻	Color	rojo a333			
		Envase	vacio			
		pН	4	en Soluci	ón al ea	

'Active' and 'blocked' fields (example)

Introduce the changes in the open file.

<u>Example:</u> Change in label design

DE ESPANA MINISTERIO	User Manual	Servicio de Información Toxicológica
DE INFORMACIÓN DE INSTITUTA	GesFicCom	INTCF
Colored protocol (Articles / house /	Open Atta	achment " <i>Adjunto</i> s" tab

There are two ways to include new attachments:

- a) Change the path by clicking icon 🖳 to locate and upload the new file
- **b)** Use check box, select the file and delete with icon subsequently, attach the new file by clicking icon .

Once finished, click Accept icon $\leq (Aceptar)$ in the main toolbar menu to save the modified file.

Once validated, the file will be saved for subsequent Export under Non-critical Modification status (*Modificación no esencial*).

In this case, the file name cannot be changed.

MODIFICATION PAPER F (Modificación F Papel)

This option generates new electronic files of mixtures previously notified to the INTCF in the 'expired' paper format. These products have an assigned INTCF reference number.

Go to the main toolbar menu, open Management of toxicological files (Gestion de Fichas Toxicológicas) tab and select the Modification Paper F (Modificar F Papel) option.

It will directly open a blank file to be completed (see <u>NEW ENTRY</u> section); however, it will display the 2 checked fields: *"Revisión" and "N^o Ref"*.

Basically, follow the procedure described for notification of <u>NEW ENTRY</u>, and include the INTCF reference number of the previously notified 'Paper F' product in "N° Ref".

Once finished, click Accept icon $\leq (Aceptar)$ in the main toolbar menu to save the file. Mandatory fields will be checked and file validated (as described for notification of <u>NEW</u> <u>ENTRY</u> procedure).

Once validated, the file must be saved and named (as described for notification of $\underline{\text{NEW}}$ $\underline{\text{ENTRY}}$ procedure).

Finally, the saved file will be stored for subsequent Export under 'Modification' status (Modificado)



COPY A TOXICOLOGICAL FILE (Copiar)

This option enables to copy a similar completed file, and change the fields of our concern; it saves work.

📑 Gestion	icha	5						
Archivo	Ge	stión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Ver	Ventanas	Ayuda
1		Añadir						
		Modificar						
		Modificar No Esencial						
		Modificar F Papel						
		Copiar						
		Dar de Baja						
		Editar						
	-							

Go to the main toolbar menu, open Management of toxicological files (Gestion de Fichas Toxicológicas) tab, and select the 'Copy' (Copiar) option.



Select and 'open' (*Abrir*) the file you want to copy.

The system opens a window to select the fields you wish to copy.

ección Datos a Copiar		×
✓ Nombre	🔽 Señales de Peligro	Composición Cuantitativa
E Revisión	Señales de Precaución	
🗖 N ¹ Ref	Pictogramas	Remitente
E UR	🔽 Información Toxicologica	Empresa Responsable de la
🔽 Persona que Elabora la Ficha	Presentación	Puesta en el Mercado
Tipo de Usuario Final	Color	Información Elaborada por
Tipo de Producto	F Envase	Adjuntos
Aplicaciones	₽ Ph	
Clasificación según Directiva EC 1999/45	En Solución al	
Clasificación según CLP	🔲 Fecha Acuse de Recibo	🔔 急

We can uncheck all fields by clicking "uncheck

all" (*desmarcar todos*) icon <u>s</u> and then select only the fields we want to copy.

This action displays ""check all" icon <u>\$</u> (*marcar todos*), so that all available fields may be selected again.

Once selected fields are checked, click icon

'Accept' (*Aceptar*) to open the file, and then fill in the missing data to generate the **new file**.

Example:

We want to copy all data except the "Name" (Nombre) and "Attachments" (Adjuntos); therefore, these two fields have been unchecked.

When the new data is included, click icon 'Accept' (Aceptar) in the main toolbar menu.

Composición Cuantitativa Nombre 🔽 Señales de Peligro 🔽 Señales de Precaución Remitente □ Nº Ref Pictogramas 🔽 Información Toxicologia Empresa Responsable de la Puesta en el Mercado 🔽 Persona que Elabora la Fichi Presentación 🔽 Información Elaborada p 🔽 Tipo de Usuario Final Color Adjunto: 🔽 Tipo de Producto 🔽 Envase Aplicacione: 🔽 Ph 🔽 Clasificación según Directiva EC 1999/45 🛛 🖾 En Solución al <u>é</u> 🔽 Clasificación según CLP ΠE



lección Datos a Copi



GOBIERNO DE ESPANA	MINISTERIO DE JUSTICIA	User Manual GesFicCom	Servicio de Informac INTC	ión Toxicológica F	
Empty fields in the open fi					
Create Market and Create	T Guadar T Cancelar	Finally name and say clicking icon 'Save' (G	ve the file by <i>uardar)</i>		
Saving the file The following message	e is displayed:				
G	estión de Fichas Toxicológic	as 🗴 " <u>Management o</u> ctamente. File has bee	of toxicological files on properly saved		

Aceptar

Message: confirms file is saved correctly

WITHDRAWAL OF A TOXICOLOGICAL FILE (Dar de Baja)

This option is meant for the notification of product withdrawal from the market of mixtures previously registered at the INTCF.

Archivo	Ges	tión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Ver	Ventanas	Ayuda
i 🖬 🗹 🕯		Añadir						
		Modificar						
		Modificar No Esencial						
		Modificar F Papel						
		Copiar						
		Dar de Baja						
		Editar						
	_		-					

Go to the main toolbar menu, open 'Management of toxicological files' (*Gestion de Fichas Toxicológicas*) tab, and select the 'Withdrawal' (*Dar de Baja*) option.

<u>Accept</u>"

It opens a window to locate the original file of the product to be withdrawn.

Select and open (Abrir) the appropriate file.

All fields are blocked (shown in grey).

wn in grey).	Indextained as the high sector set of the sector
	Click Accept icon description (Aceptar) in the main toolbar menu, and a message is displayed:

.______



EDIT A TOXICOLOGICAL FILE (Editar)

This option opens a completed file; it is useful went you want to modify data before the notification process, or if you want to introduce the INTCF reference number assigned ($N^{\circ} Ref$) to the notified product.

This option does not change the file status (e.g.: if already processed or notified as a New Entry, this status is preserved); therefore, it enables to modify data without altering its "fate" for future export and notification to the INTCF.

Thus, if you want to modify the data in a file, but not sure yet about the final goal, do select this option.



If the product has been previously notified to the INTCF, it cannot be re-submitted with the new



PRINT OPTION / EXPORT AN OPEN FILE

The "Print" icon (*Imprimir*) (in the tool bar menu) <u>prints or stores</u> '<u>open' files</u> in pdf or Excel formats.

FICHA	DE INFORMACIÓN DE
DDODI	
PRODU	JCTO PARA EL INTCF
	DATOS GENERALES
	The second s
Description	
Nontre	Pinguno affer
URI	123456
recha de creación	2/02/2015
Tipo producto	PC39 Cosméticos
	Costreticos cuaterio de la pel
Aplicaciones	cosmética
Clasificación según Directiva EC 1999/45	Sensibilizantes
Clasificación según CLP	Acute Tax. 1 (Inhelation) H330
Presentacion	Sélete
Fecha acuse de recibo	26/02/2015
Fiche rentide por	Asezoria técnica
Franzos repronsable de la maesta	N/MERF M disarianal Bartriana
en el mercado	calle pinguino, 14
	903273145
	mercedes aslegotBerroreses justicia es
	Rodrigo G
	Directivo
nformacion elaborada por	Cole del Center 24
	977000401
	merganigenpresas juitos es
	Dirección
РН	5 ·
CENAT Number FREM	093287828
CENAT Number notificationa	78587474P
Señal de Peligro	EUH 205 Contiene componentes eposidicos. Puede provocar
and the second se	una reaución altrigica.
Senal de Precaución	comprendido todas las instrucciones de seguridad.
Pictogramas	Signo de excheneción
These dis Line statis Filment	Concerning .

Open Attachment "Adjuntos" tab

When clicked, it displays this window.

It provides a tool bar menu with several options:

print, zoom, export page in pdf or Excel format, change page, refresh, save, search, etc.



GENERATE AN EXPORT FILE

This function generates the final Export file from <u>previously elaborated and stored files</u> in .xml format (see "Management of toxicological files" options).

VERY IMPORTANT:

This is the option devised to generate the correct Export file for submission to the INTCF.

en	ndientes Histórico							
	Path N	ombre	UFI	N [∎] Ref.	Fecha	Usuario	Estado	
	C:\Archivos de programa\GesFicCom Pro	ducto Merce	1343		25/02/2015	Merce	Nuevo	
	D Pir	iguino affair	123456		26/02/2015		Nuevo	
	D Pir	iguino affair	123456		26/02/2015		Nuevo	
	E Pir	iguino affair	123456		26/02/2015		Nuevo	
	C:\Archivos de programa\GesFicCom., Pir	iguino affair	123456		26/02/2015		Nuevo	6
	C:\Archivos de programa\GesFicCom Me	rTotal	123456		27/02/2015		Nuevo	

Click icon "Print" 🔚 (in tool bar menu).

The system displays the 'Impresión' window

Select the files for submission.

The main function of this window is TO GENERATE EXPORT FILES

The 'Impresion' window has 2 main tabs:

- + 'Pending' (Pendientes): stored .XML files for future submission to the INTCF
- + 'Historical' (Histórico): stored .XML files already submitted to the INTCF.

Filter by Date:

Select the lag period (date) in which files were elaborated. Thus, in order to filter by date, use cells "date from" (*Fecha desde*) "to" (*hasta*). 'Active' calendars are also available.

Filter by "Status" (Estado):

The "Status" (*Estado*) roll-down window further narrows the search option.



Open Status *(Estado)* roll-down list (use button 💌) and select your option:

'Filter by Status' window

- Pending for submission (Pendientes de remitir (Altas): To notify New submissions (New entries) - Status (Estado) = <u>Nuevo</u>
- Withdrawals (Bajas): To notify product withdrawals- Status (Estado) = <u>Baja</u>
- Modifications (Modificaciones): To notify Critical (Modificación) and Paper format (Modificar F papel) Modifications - Status (Estado)= <u>Modificación</u>
- Non-critical Modifications: To notify Non-critical Modifications - Status (*Estado*)= <u>Modificación</u>



Make sure that the encryption Certificate has been installed

The following message will be displayed (compliance with current regulations):



Product Export
Is the company responsible of
providing full and accurate
information, in agreement with
Article 15 of Orden JUS/836/2013 of
7 May?
<u>Yes (Si) No (No)</u>

If you click Si (Yes), the next message is displayed (Export file path /stored in Export folder):

Exportac	ión de Productos 🛛 🔀
į)	Estos ficheros se han almacenado en el directorio:
	Aceptar

<u>Product Export</u> These files have been stored in directory: C:\Archivos de programa \GesFicCom\Export\20150302_121656 <u>Accept</u>

The Export file name format is: yyyymmdd_hhmmss (e.g.: 20150302_121656)

If we accept, the next message is displayed:

Gestión d	e Productos 🔀	
į	Base de Datos de Productos Pendientes Guardados Correctamente.	
	Aceptar	

<u>Product Management</u> Database of pending products correctly saved <u>Accept</u>

If we accept, the next message is displayed:



<u>Product Management</u> Database of submitted products correctly saved <u>Accept</u>



For example, if we generate an Export file to notify a 'New entry' (Alta) of products, this file will be stored in the Export folder.

🗁 Export					_ @ ×
Archivo Edición Ver Favoritos Her	ramientas Ayuda				A
🌀 Atrás 🔹 🌍 🔹 🏂 🔎 Búsqu	eda 🜔 Carpetas 🛛 🔢 🛛 🔞 Sini	cronización de carpetas			
Dirección 🛅 C:\Archivos de programa\Gest	FicCom\Export				💌 🄁 Ir
Tarces de archivo y carpeta * Image: Carbier nontine a esta carpeta Mover esta carpeta Image: Carbier esta carpeta esta carpeta Publicar esta carpeta est velo Image: Carpetar esta carpeta estrónico los archivos Ensinger carpeta esta carpeta Image: Carpetar esta carpeta Ensinger carpeta acestrónico los archivos Image: Esta esta carpeta Ensinger esta carpeta	20150225_094846 25/02/2015 9+48	20150225_095244 25/02/2015 9/52	20150302_121656 02/03/2015 12:31	20150303_00F732 03002015 9:59	

The following items are stored inside the Export file folder (e.g: 20150302_121656):

- 1. Product submission list in pdf format (Pendientes de Remitir (Altas).PDF)
- 2. Attachments (ADJUNTOS) folder (containing encrypted pdf files of SDS, labels, etc)
- 3. Product data XML files (encrypted:.xml.enc) (Producto 1 Pruebas.xml.enc)



IMPORTANT Export restrictions:

- Maximum of 50 .XML files per Export file
- A single marketing company per Export file

VERY IMPORTANT:

- + Do not modify the default name of the EXPORT folders
- + Do not submit 'open' EXPORT folders



TOOLS (Herramientas)

The following options are found in the Tools (Herramientas) tab from the main menu bar:

🛃 Gestion	Fichas							
Archivo	Gestión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramienta	s Ver	Ventanas	Ayuda	Configurat
: 🚮 🍼	× 🖻 🕰 🧒			Validar	Datos	- h		Validate D
				Copia o	de Segurio	dad 🔸		Security co

Configuration (Configuracion) Validate Data (Validar Datos) Security copy (Copia de Seguridad)

CONFIGURATION (Configuracion)



Working Directory (Directorio de trabajo):

Storage location of the GesFicCOm application (files, tables, etc)

Buscar carpeta	
Image: Secretaria ▲ Image: Secretaria Image: Secretaria Image: Secretaria Image: Secr	Click 'Select directory' (seleccionar directoricon to select your working directory. It displays a current directory selection.
Cancelar	Select and press Accept (Aceptar).

Company name (*Nombre de la Empresa*) of the company where the application has been installed.

Provide your company name so that it is displayed in the application.

Company Logo (LOGO) of the company where the application has been installed.

Buscar en:	Mi PC		Y () 1 P	· 🗄	
Documentos recientes Escritorio	Disco los Dotos (f Unidad I Unidad I Unidad I Unidad I	cal (C:) 5:) DVD (E:) DVD-RAM (F:) Integrated Webcam				
e documentos						
is documentos	Nombre:				× [Abri





SIT Public Certificate (Clave Pública SIT) file: for data encryption.





VALIDATE DATA (Validación de Datos)

To validate data and structure of the XML files generated by this application.

Validación de Datos 외	Click icon to choose option. e.g.: Companies (Empresas)
Fichero	
2	Click icon Select file" (Seleccionar fichero)

Field "Type of file" (Tipo de Fichero) provides the following options for validation:



- Toxicological files (Fichas)
- Pages (Hojas)
- Ingredients (Ingredientes)
- Lists (Listados)



It opens a search window to select a file. Press 'Open' (*Abrir*)

IMPORTANT: the file has been saved for subsequent Export under 'New' (Nueva) Status.



Validacio	in de Datos	
8	Resultado de la Validación: Fallo (Error de Validación: The 'COMPONENTES' element is not declared.) Aceptar	<u>Data</u> Valid The ' decla

<u>Data validation</u> Validation result: Failure (Validation error: The 'COMPONENTES' element is not declared) <u>Accept</u>

SECURITY COPY (Copia de Seguridad)

To generate new security copies of the main directories of the application, and to restore previous security copies.

GENERATE SECURITY COPIES (Crear copia de seguridad)

s GestionFichas Archivo Gestión de Fichas Toxicológicas Gestión de Empre ﷺ। ≪ X । ≝ ्रि, । आ	sas Gestión de Ingredientes Herramientas Ver Ventanas Ayuda Configuración Validar Datos Copia de Seguridad → Crear Copia Restaurar Copia	It displays a window with the following folder options:
Copia de Seguridad (CREAR) 2 Image: Tablas Auxiliares Image: Tricheros de Datos Image: Ficheros de Ayuda Contextual Image: Tricheros Auxiliares Image: Ficheros Auxiliares Image: Listados de Productos Image: Exportaciones Image: Listados de Datos	Tablas auxiliares = AuxTables Ficheros de Datos = Ficheros Ficheros de Ayuda Contextual = Help Ficheros Auxiliares = ListView [Companies (Empresas) & Ingredients (Ingredientes)] Listados de Productos = Print Exportaciones = Export	Check selection/s and Click icon 'Accept' (Aceptar) to generate the security copy of the selected elements





shown:

A window is displayed to store the saved copy in a specific location.



RESTORE SECURITY COPIES (*Restaurar copia de seguridad*)



If correctly performed, the following message is displayed:





VIEW (Ver)

To display or hide the tool bar (Barra de Herramientas) or Status bar (Barra de Estado).

Ver	Herramientas	Ventanas
~	Barra de herrami	entas
~	Barra de estado	



"Tool bar"	(Barra de Herramien)	tas), displays the
tool bar icor	is on the top left ha	nd side.

at the sector	a domentation of the process interest	2010	alu
Principe Composición Adjunio	•		
Nombre	Producto Merce		
Descara and Elaborat		UR	
la Ficto	Merce	Fecha de Creazión (04/03/2015	
Tipo de Usuario Fina	Consumidor@industria@Profesional	-	
Tipo de Producto	PC29 Medicementos	Aplicaciones aplicacones	
	C Aperato Cardiovascular D Terapia Dermatológica		
Clasificación segú Directiva E/C 1928/4	Explosivos	Classificación según Acute Tox 2 (Intelation) H330	
LINCING CO. 19154	Mutegánicos	Acute Tox 3 (Inteletion) H331 Acute Tox 3 (One) H331	
Indicaciones de Pelign en Etiquet	EUH207 yAtención/ Contiene	Indicaciones de P202 No manipular la sustancia Precaución antes de bahar laiño y compressión	
	desprenden vepores peligrosos.	en Exquette todes les instrucciones de	
Pictograma: en.Etiqueti	Uama. Uama sobre circulo	Sección 11 de la sección FDS	
	Peligro para la salud		
Presentació	n Ges	Color scul	
		Envese vecio	

'Status bar' *(Barra de Estado)*, displays the status bar at the bottom of the window.



WINDOWS (Ventanas)

Organizes the window display view (several open windows).

Ven	itanas	Ayuda			
	Casca	da			
	Mosaico vertical				
	Mosai	co horizontal			
	Cerra	r todo			
	Organ	izar iconos			
~	1 C:\/	Archivos de programa\GesFicCom\Ficheros\Fichas\nueva merce 2.xml			

Select option from Window menu (Ventanas):

- Cascade Vertical Mosaic
- Horizontal Mosaic
- Close all
- Organize icons







Cascade window display (Cascada)

Vertical Mosaic window display (Mosaico vertical)

Horizontal Mosaic window display (Mosaico horizontal)



HELP (Ayuda)

l	Gestion	Fichas									
	Archivo	Gestión de Fichas Toxicológicas	Gestión de Empresas	Gestión de Ingredientes	Herramientas	Ver	Ventanas	Ayu	ıda		_
	🕍 🗹	🗙 😹 🖾 🚳						3	Índice	F1	
								Q	Buscar		
I								0	Acerca de		
I											

By selecting "Index" *(Indice)* option, you may view or download the 'Application Installing and User Manual' *(Manual de Instalación y Uso de la Aplicación Informática para la Elaboración de Fichas Toxicológicas, Manual de Administrador-Usuario, Versión 2.0.0.17)*