

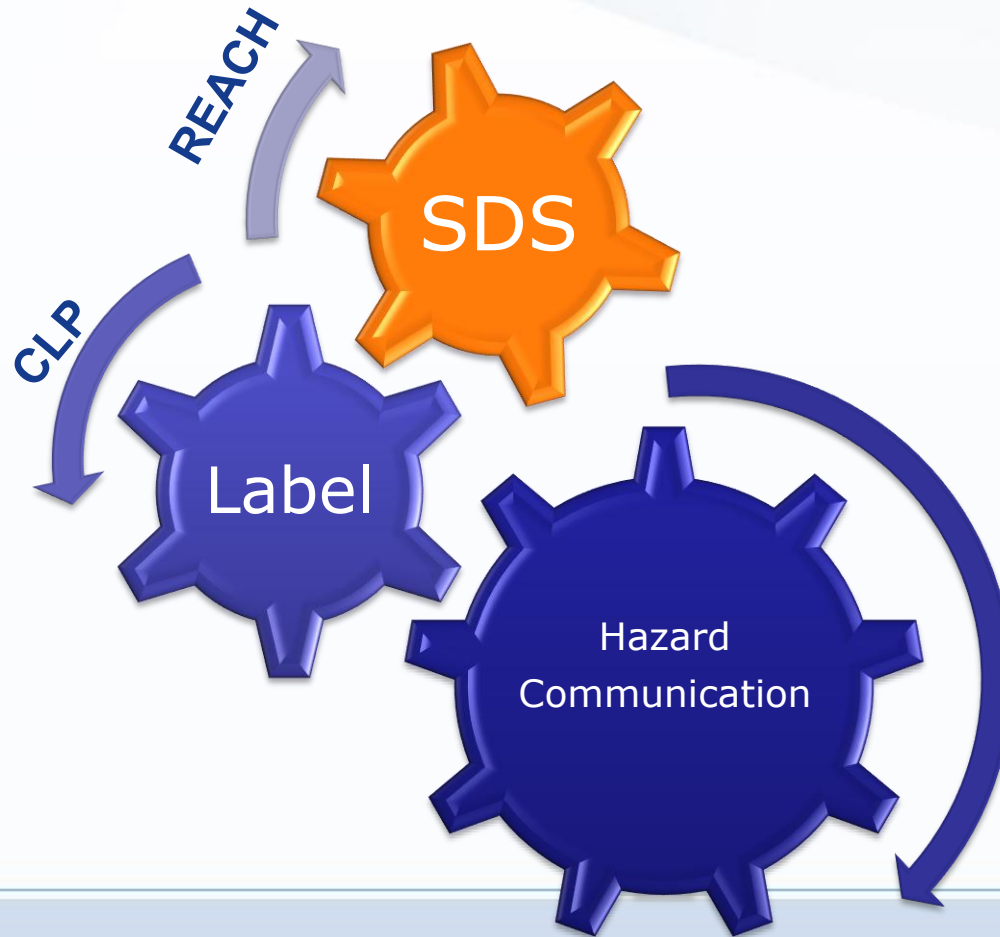
Hazard Communication:

A practical approach to the new requirements of CLP Regulation and Safety Data Sheets (SDSs) under the REACH Regulation





Opening Remarks



CLP and the Classification & Labelling Inventory

Sinead McMickan



Overview



- Introduction to CLP
- Obligations under CLP
- Identification of role under CLP
- Classification duties
- Notification duties to the C&L Inventory



Introduction to CLP



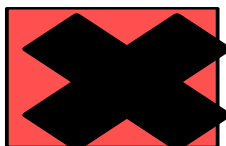
- Different hazard classification and labelling schemes were developed globally over the past 40 years
- The result.....



Inconsistency

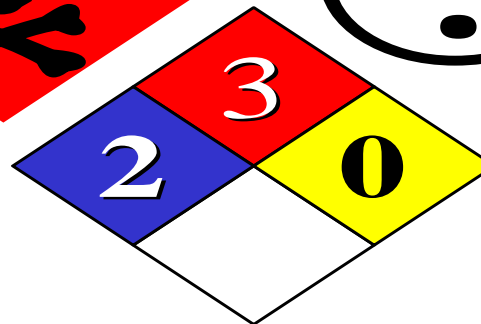
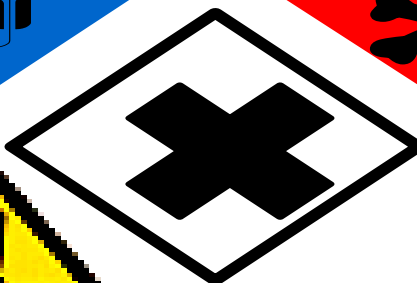
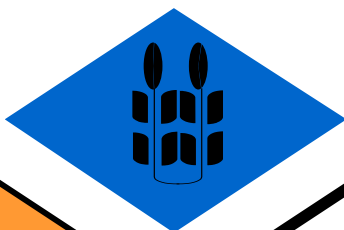


HARMFUL IF SWALLOWED



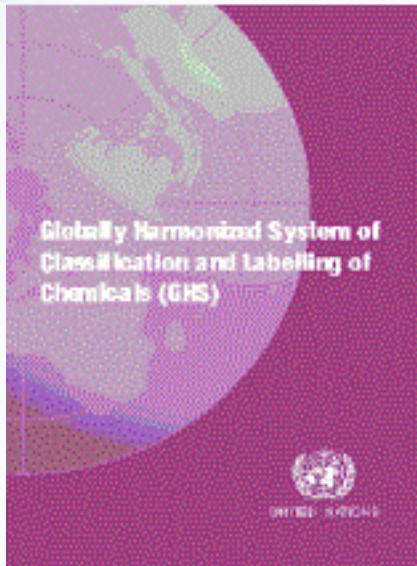
警告

WARNING!





The Solution: GHS



HARMFUL IF SWALLOWED



Warning

International
Convention



CLP Regulation





- CLP Regulation (EC) No. 1272/2008: EIF 20th Jan 2009
- Amends CPL EU Directives – transposed as:
 - S.I. No. 116 of 2003 and S.I. No. 62 of 2004
- Replaces from 2015
- Applies general principles of GHS
- Uses “Building Block Approach”
- Consistency with transport needs



Changes in Terminology

CLP
Classification,
Labelling &
Packaging

Existing	New
CPL Directives 67/548/EEC & 1999/45/EC	CLP Regulation (EC) No 1272/2009
Annex I	Annex VI
Dangerous	Hazardous
Preparations	Mixtures
Symbols 	Pictograms 
Indication of Danger: Irritant Xi	Signal Word: Warning
Risk Phrases: R38	Hazard Statements: H315
Safety Phrases: S2	Precautionary Statements: P102



CLP Regulation: Objectives



- Protection human health & environment by:
 - Determining which properties of substances & mixtures lead to classification as hazardous
 - Correctly identifying hazards
 - Communicating hazards

Scope of CLP



- Obligations:
- **Classify**
- **Label**
- **Package**
- **Notify** to C&L inventory



Roles & Obligations



	Classify	Label	Package	Notify	Keep info 10 yrs
Manufacturer	✓	✓	✓	✓	✓
Importer	✓	✓	✓	✓	✓
Downstream User	✓ *	✓	✓	x	✓
Distributor	x **	✓	✓	x	✓

*If DU changes composition, must classify. If not, use classification other actor

**Dist may use classification of another actor

Classification



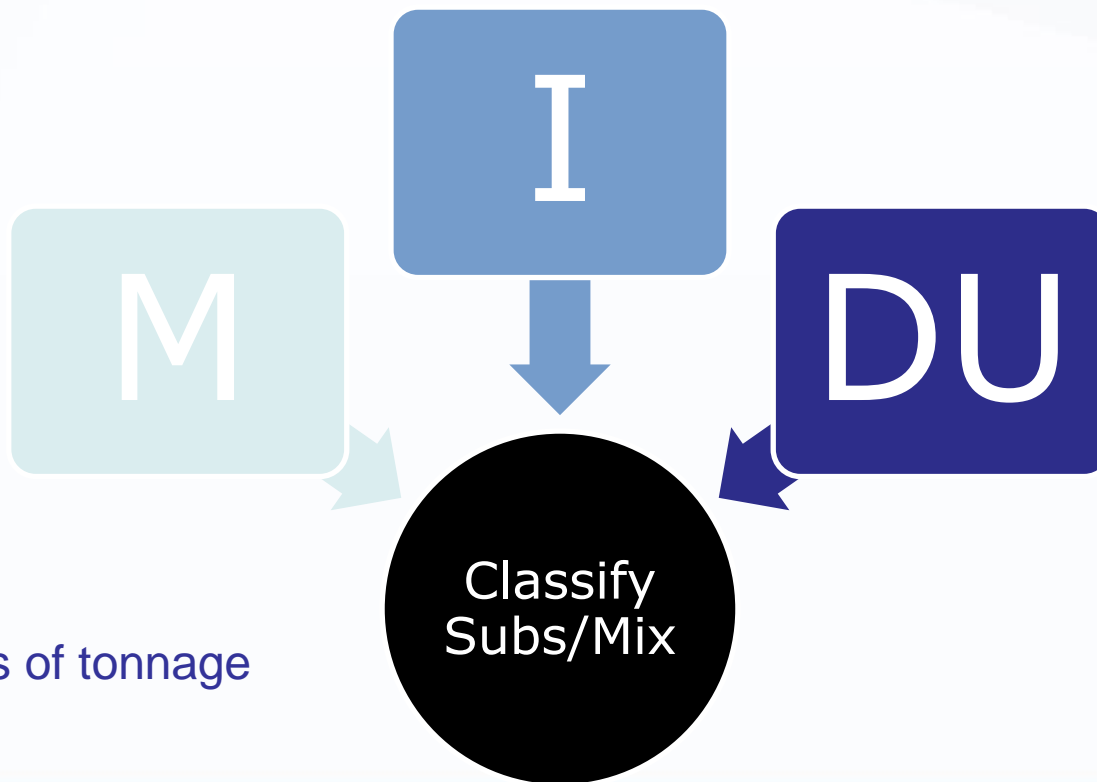
Pictograms for labelling



Placing substances/mixtures on market?



Classification triggered by CLP Regulation:



Regardless of tonnage



Exemptions from CLP



- Radioactive substances
- Subject to customs supervision
- Non-isolated intermediates
- R&D not placed on market
- Waste
- Substance/Mixture used in defence
- Substance/Mixture in finished state for final user:
 - Medicinal/Veterinary products
 - Cosmetics
 - Medical devices
 - Food/Feeding stuffs



What to Classify



- Substance or Mixture meeting hazard criteria in parts 2-5 of Annex I

• Physical:



• Human Health:



• Environment:





Classification Steps



- There are 4 main steps to classifying:
 - 1. Gather** available information
 - Test data, non-test data, human data, other
 - 2. Examine** data
 - Expert judgement; adequate, reliable data
 - 3. Evaluate** & review the information
 - Apply criteria; Weight of evidence
 - 4. Decide on Classification**
 - If substance/mixture meets criteria assign classification
 - Hazard class and category



Classification: Substances



- Classification of substances assigned by:
 - Using **Harmonised classification:**
 - 8000 substances in Annex VI Table 3.1
 - **Self-classification:**
 - Apply in absence of harmonised C&L or where harmonised C&L available for some endpoints only
 - Using **Translation Table:**
 - Annex VII



Classification: Mixtures



- Classification of Mixtures assigned by:
 - **Self Classification**
 - Data available for mixture
 - Application bridging principles (health & env)
 - Calculation: Use known data individual ingredients to classify
 - Using Harmonised classification, Translation Tables



Classification



- Harmonised classification:
- Annex I of DSD now Table 3.2 of Annex VI CLP
- Use mandatory for substances
- Applied by all suppliers of same substance
- Under DSD all endpoints harmonised
- Under CLP CMRs, respiratory sensitisers, others case-by-case



Annex VII



- Use of Translation table optional
- Only used to translate existing classification if:
 - Substance/mixture classified according DSD/DPD before Dec 2010/June 2015 **and**
 - No data available for hazard class
- If data available, DO NOT use Annex VII

Translation between classification in accordance with Directive 67/548/EEC and this Regulation

Classification under Directive 67/548/EEC	Physical state of the substance when relevant	Classification under this Regulation		Note
		Hazard Class-and-Category	Hazard statement	
E; R2		No direct translation possible.		
E; R3		No direct translation possible.		
O; R7		Org. Perox. CD	H242	
		Org. Perox. EF	H242	
O; R8	gas	Ox. Gas 1	H270	
O; R8	liquid, solid	No direct translation possible.		
O; R9	liquid	Ox. Liq. 1	H271	
O; R9	solid	Ox. Sol. 1	H271	
R10	liquid	No direct translation possible. Correct translation of R10, liquid is: <ul style="list-style-type: none"> — Flam. Liq. 1, H224 if flashpoint < 23 °C and initial boiling point ≤ 35 °C — Flam. Liq. 2, H225 if flashpoint < 23 °C and initial boiling point > 35 °C — Flam. Liq. 3, H226 if flashpoint ≥ 23 °C 		
F; R11	liquid	No direct translation possible. Correct translation of F; R11, liquid is: <ul style="list-style-type: none"> — Flam. Liq. 1, H224 if initial boiling point ≤ 35 °C — Flam. Liq. 2, H225 if initial boiling point > 35 °C 		
F; R11	solid	No direct translation possible.		
F+; R12	gas	No direct translation possible.		

How to prepare for Classification duties



How to prepare



- Identify your role(s) and obligations
- Create an inventory of all substances/mixtures
- Ensure expertise
- Check all substances identities
- Gather all information
- Examine, evaluate
- Classify

Classification & Labelling Inventory



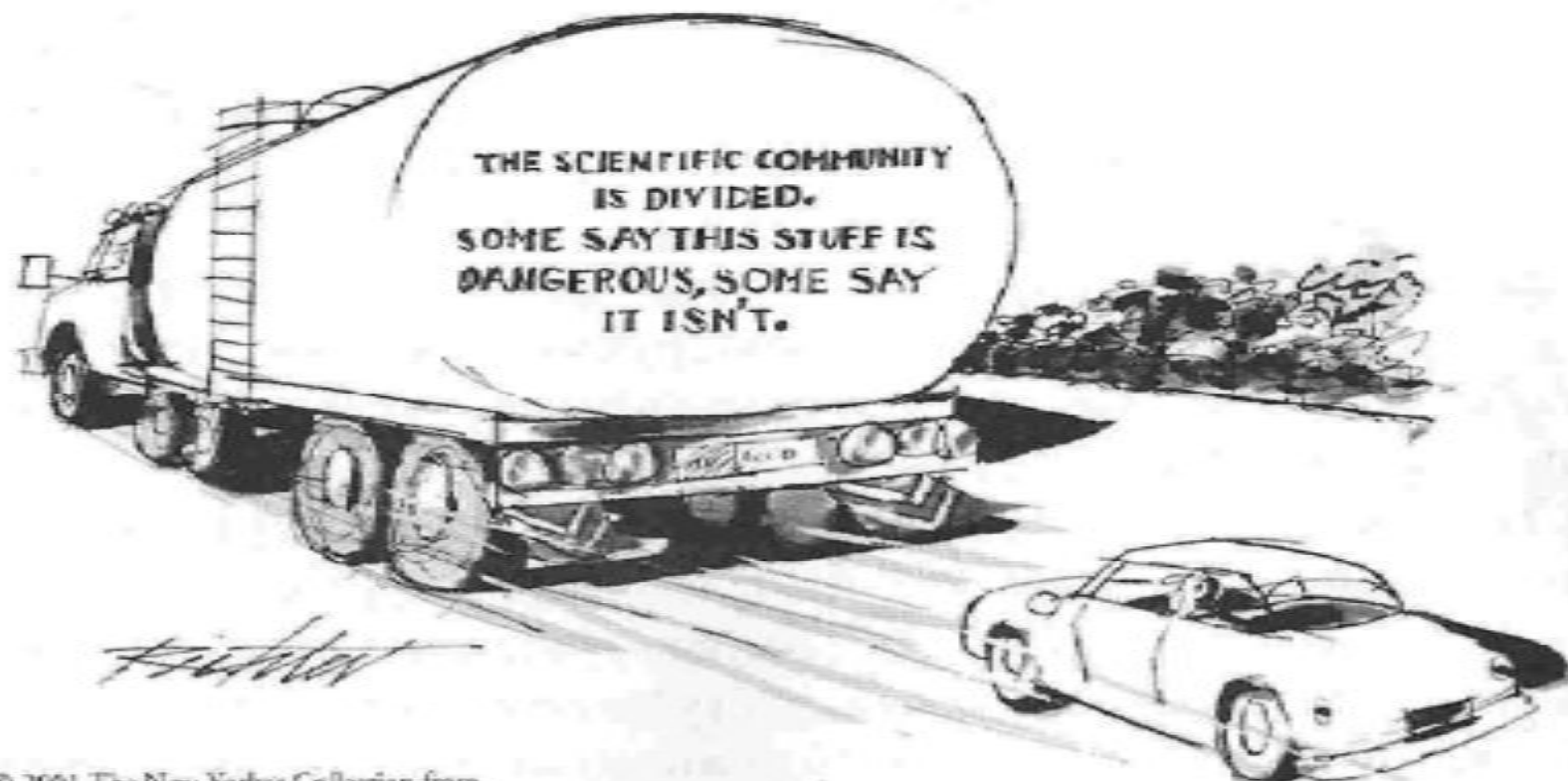
What is the Inventory?



- Database with:
 - C&L information on notified & registered substances received from manufacturers & importers
 - list of harmonised classifications (Table 3.1 of Annex VI to CLP)
- Established and maintained by ECHA
- Made public in 2011



Why have an Inventory?



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HEALTH AND SAFETY
AUTHORITY

REACH

REGISTRATION, EVALUATION AND
AUTHORISATION OF CHEMICALS

Who must notify to Inventory?



- Manufacturers.....
- Importers.....
- or group of manufacturers or importers ...
- who place on the market a hazardous substance on its own or in hazardous mixtures...*
- ...must notify to the Agency (ECHA)

***regardless of tonnage**



What must be notified?



- **Substances** subject to registration under REACH and placed on the market
- **Substances** classified as hazardous and placed on the market on their own or
- Hazardous substances present in a mixture above concentration limit resulting in mixture being classified as hazardous



Exemptions?



- No notification is required, if the same information has already been submitted as part of a registration dossier*

*in accordance with CLP



Information to be notified



Article 40:

- Identity and contact details of the notifier
- Identity of the substance
- Classification of the substance **according to CLP**
- The reason for “no classification” for endpoints
- SCLs or M-factors and justification
- Label elements (hazard pictograms, signal words, hazard statements, supplemental statements)

Health hazards		
	Hazard statement	Reason for no classification
Acute toxicity - oral	<input type="text"/>	<input type="text"/>
Acute toxicity - dermal	<input type="text"/>	<input type="text"/>
Acute toxicity - inhalation	<input type="text"/>	<input type="text"/>
Skin corrosion/irritation	<input type="text"/>	<input type="text"/>
Serious damage/eye irritation	<input type="text"/>	<input type="text"/>
Respiratory sensitization	<input type="text"/>	<input type="text"/>
Skin sensitization	<input type="text"/>	<input type="text"/>
Aspiration hazard	<input type="text"/>	<input type="text"/>
Germ cell mutagenicity		
<input type="text"/>		
Carcinogenicity		
<input type="text"/>		
	Hazard statement	Reason for no classification
Reproductive toxicity	<input type="text"/>	<input type="text"/>
Specific effect	<input type="text"/>	<input type="text"/>
Route of exposure	<input type="text"/>	<input type="text"/>
Effects on or via lactation	<input type="text"/>	<input type="text"/>



When must information be notified?



- Within 1 month after placing substance on market on or after 1st December 2010
- First deadline: 3rd January 2011
- May be notified prior to this date



How is info notified?



- C&L notifications shall be submitted electronically via REACH-IT

ECHA

Home

Welcome Sandrine Lef.

You have 7 unread message(s) in your message box.

Classification and Labelling

- Notify a C&L online
- Notify a C&L using IUCLID
- Notify bulk C&L
- Manage groups of Manufacturer(s) / Importer(s)
- View my submitted C&L notifications
- Consult the public C&L inventory

- Request for alternative name under CLP art. 24

- Proposal for Harmonised C&L under CLP art. 37

Add a new item in the menu

With the following sub-menu

To be added later

How to prepare for notification to C&L Inventory duties



How to prepare



- List substances/mixtures manufactured or imported
- Any exempted from CLP?
- Any subject to REACH registration?
- Collect information on substance identity and composition
- Name all substances in line with the guidance on Substance Identity
- Check if substances are listed in Annex VI to CLP



How to prepare (contd.)



- Gather all available & reliable info on hazardous properties of substance (if C&L not harmonised)
- Classify substances
- Prepare a scientific justification if M-factor specified or set specific concentration limit (SCL)
- Decide to establish or join a group of manufacturers and/or importers
- Create C&L notification in the appropriate format
- Create REACH-IT account & submit notification



In summary:



- Identify your role(s) under CLP
- Understand your obligations
- Have you duty to Classify?
 - Prepare by gathering data, examining, evaluating and deciding on classification
- Have you duty to notify classification and labelling to the C&L Inventory?
 - Create C&L notification in the appropriate format
 - Create REACH-IT account & submit notification



Don't wait 'til last minute....





Hazard Labelling and Packaging requirements

Caroline Walsh



Overview



- Who is responsible for Labelling & Packaging (L&P)
- What are the labelling elements
- Precautionary(P) statement assignment
- General labelling rules
- Labelling & Article 33 explained
- Exemptions & Derogations from L&P
- When to update the label
- What are the packaging rules
- Timelines and Conclusions

Scope of CLP



- Obligations:
- Classify
- Label
- Package
- Notify to C&L inventory



Scope of L & P



	Classify	Label	Package	Notify	Keep info 10 yrs
Manufacturer	✓	✓	✓	✓	✓
Importer	✓	✓	✓	✓	✓
Downstream User	✓ *	✓	✓	✗	✓
Distributor	✗ **	✓	✓	✗	✓

*If DU changes composition, must classify. If not, use classification other actor

**Dist may use classification of another actor



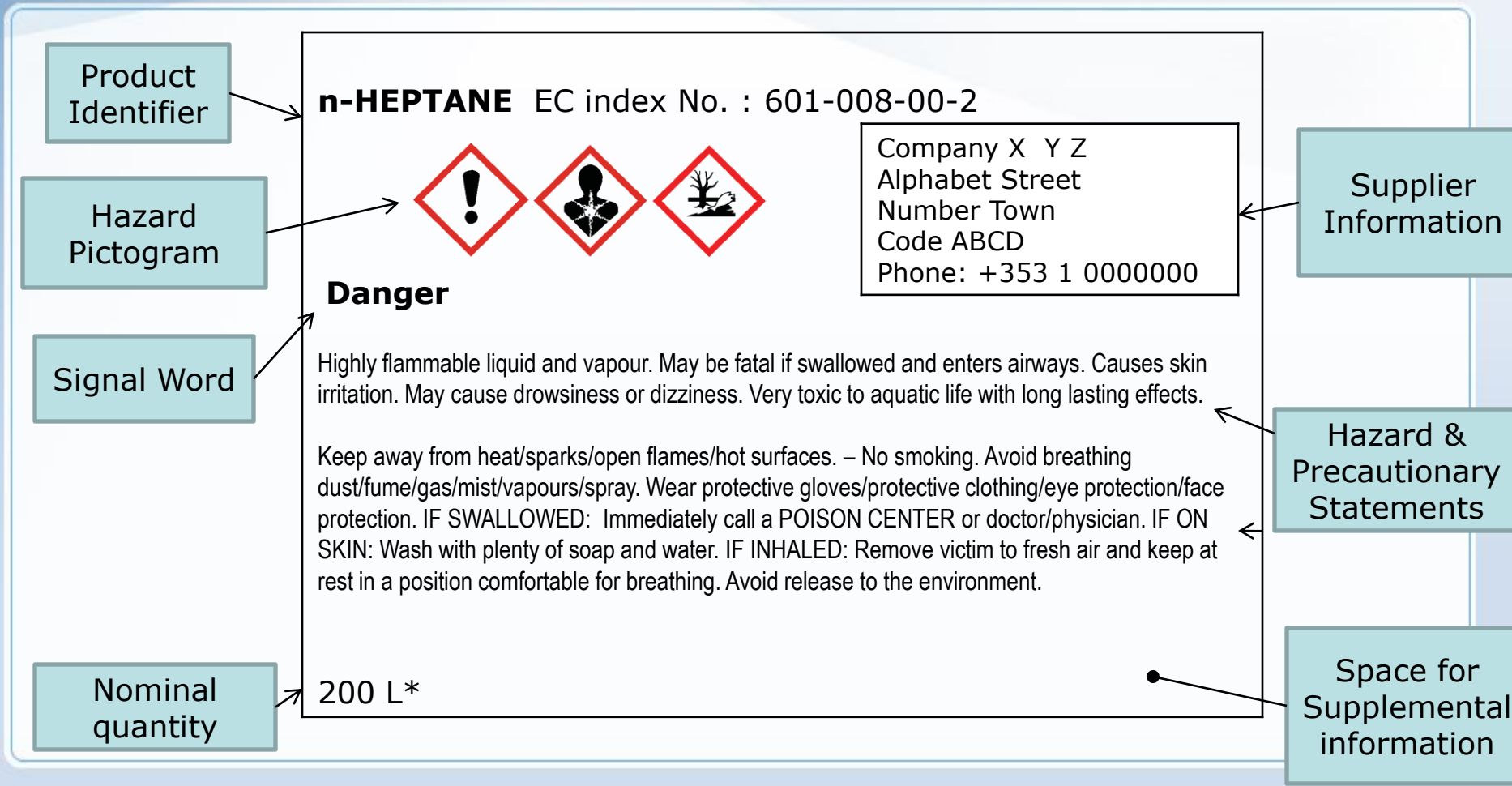
Label elements



- Name, address & telephone number of supplier
- Nominal quantity
- Product identifier
- Hazard Pictogram(s)
- Signal word
- Hazard (H) Statements
- Precautionary (P) Statements
- Supplemental information
- Official language



Label elements





Product Identifier



- Product Identifier for substance or mixture on the **label** must be the same as that used on the **SDS**
- Product Identifier for **substance** must be either
 - **Identification Number: Annex VI, Part 3 or**
 - **Name & Identification Number: C&L inventory or**
 - **CAS number & IUPAC name or another international chemical name or**
 - **IUPAC or another international chemical name**
 - **If IUPAC >100 characters use trade/other name***



Product Identifier



- Product Identifier for a **mixture** consists of Trade name or designation of the mixture
- The identity of the substances contribute to the classification of mixture if:
 - Acute toxicity, skin corrosion, serious eye damage, CMR's, STOT, skin or respiratory sensitisation, aspiration Hazards
- Max of 4 names required unless more needed to reflect severity of hazards



Hazard Pictograms



Principles of precedence

		Only applies if for skin or eye irritant
		Only applies if GHS 08 for respiratory sensitisation then GHS 07 not to appear for skin sensitisation or skin & eye irritant



Signal Word



DANGER or **WARNING**

- Use will depend on the classification of the substance or mixture
- If Danger is used Warning shall not appear on the label
- Clear and simple language to indicate the degree of hazard



H Statements



Hazard	Code	Example	Text
Physical	H200-299	H241	Heating may cause fire or explosion
Health	H300-399	H311	Toxic in contact with skin
Environment	H400-499	H412	Harmful to aquatic life with long lasting effects.



P Statements



Code	Purpose	Example	Text
100	General	P102	Keep out of reach of children
200	Prevention	P201	Obtain special instructions before use
300	Response	P310	Call a poison centre
400	Storage	P410	Store in a well ventilated place
500	Disposal	P501	Dispose of container...



Supplemental Information



CLP
Classification,
Labelling &
Packaging

- New concept introduced with CLP
- To incorporate labelling 'EU leftovers'
- Allowed because of UNGHS 'Building Block Approach'
- New Codes to distinguish from H statements e.g. EUH001
- Obligatory & Non-Obligatory
- Applicable in EU & EEA countries only



Supplemental Information



• **Obligatory**

- From CPL- substances e.g. EUH001, EUH059
- From CPL- preparations e.g. EUH201
- From other Community laws e.g. EUH401 (PPP)
- **Shall** be placed alongside other label elements





Supplemental Information



CLP code	CPL R phrase	Text
EUH001	R1	'Explosive when dry'
EUH066	R66	'Repeated exposure may cause skin dryness or cracking'
EUH059*	R59	'Hazardous to ozone layer'





Supplemental information



CLP Code	CPL Special Provisions
EUH201/201A	Contains lead. Should not be used on surfaces liable to be chewed or sucked by children . Warning contains lead.
EUH202	Cyanoacrylate. Danger. Bonds eyes and skin in seconds. Keep out of reach of children.
EUH204	Contains Isocyanates. May produce an allergic reaction
EUH210	Safety data sheets available on request.



Supplemental information



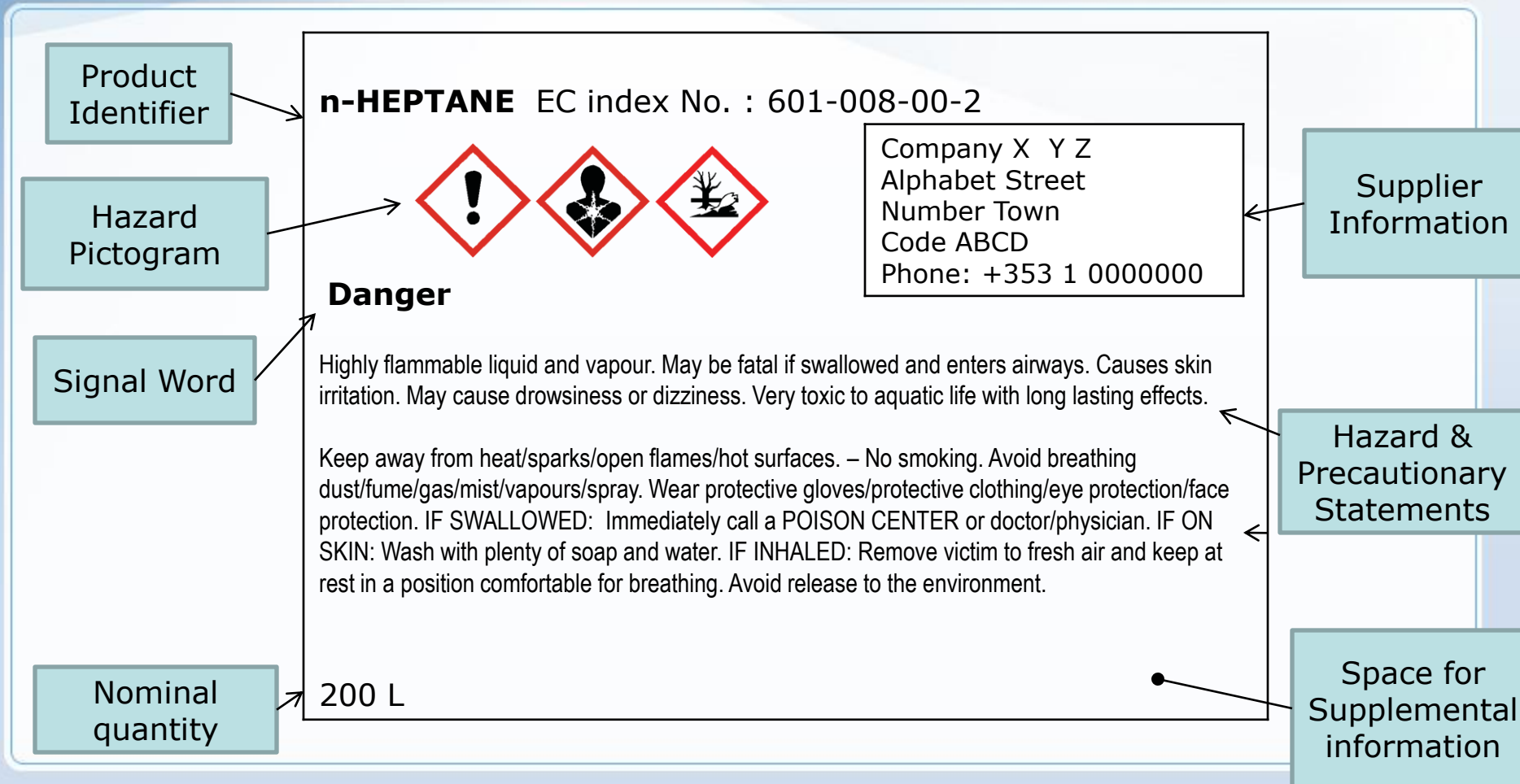
• **Non-Obligatory**

- Content up to the supplier, e.g. specific product information or instructions for use.
- **May** be placed alongside other label elements
- **Not distract from nor contradict obligatory labelling elements.**





Label elements





P Statement Assignment



- **Double amount** of P Statements to S Phrases
- Very limited 'conditions of use', **none obligatory**
- P Statement assignment a new challenge
- Omit only if clearly redundant/unnecessary
- P Statement on disposal required for general public
- **No more than 6** P Statements on label



P Statement Assignment



- ECHA Guidance being developed using S Phrase 'conditions of use' to assist in P Statement selection
- Will include a 'traffic light' system
 - Highly Recommended
 - Recommended
 - Optional
- Available by December 2010





General label rules



- Label firmly affixed to immediate packaging unless on packaging itself
- Label is readable horizontally when set down
- Hazard pictogram stands out clearly & text easy to read



General Label rules



- Label 'dimension' requirements brought over from CPL 74mm X 105mm >3litres<50Litres
- Pictograms must be set in a point, have a red frame , black symbol and be at least 1/15th of surface of harmonised label > 1cm²



Label content: → increase



NEW CLP



DANGER

- H301 Toxic if swallowed
- H330 Fatal if inhaled
- H314 C causes severe skin burns and eye damage
- H317 May cause an allergic skin reaction
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H400 Very toxic to aquatic life

P statements: selection from ca 30

EXISTING CPL



Toxic

Dangerous to the environment

- R23/25 Toxic by inhalation and if swallowed
- R34 Causes burns
- R42/43 May cause sensitisation by inhalation and by skin contact
- R50 Very toxic to aquatic organisms

S phrases: (1/2-)26-36/37/39-45-61



Labelling & Article 33



- Specific Rules for labelling outer, inner & single packaging
- Don't use both the CLP & Transport pictogram for same hazard on outer packaging
- Outer packaging does not need label if label on inner package can be seen clearly.

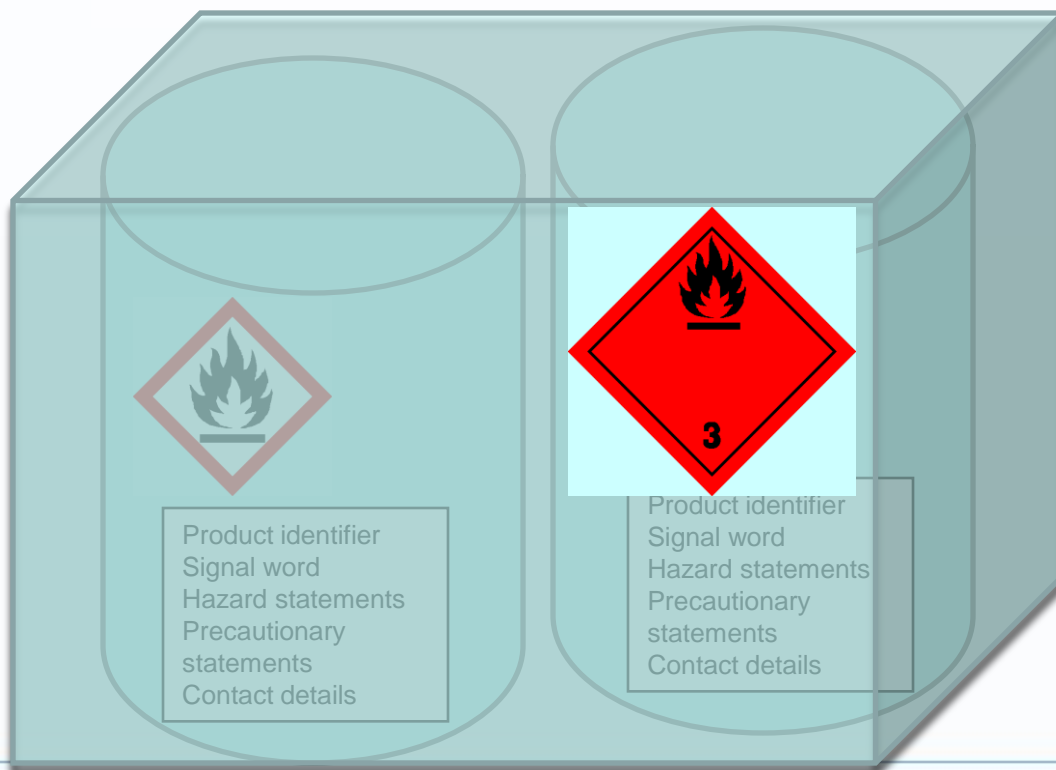


Labelling & Article 33 (1)



Classified for
transport &
supply

Outer & Inner packaging



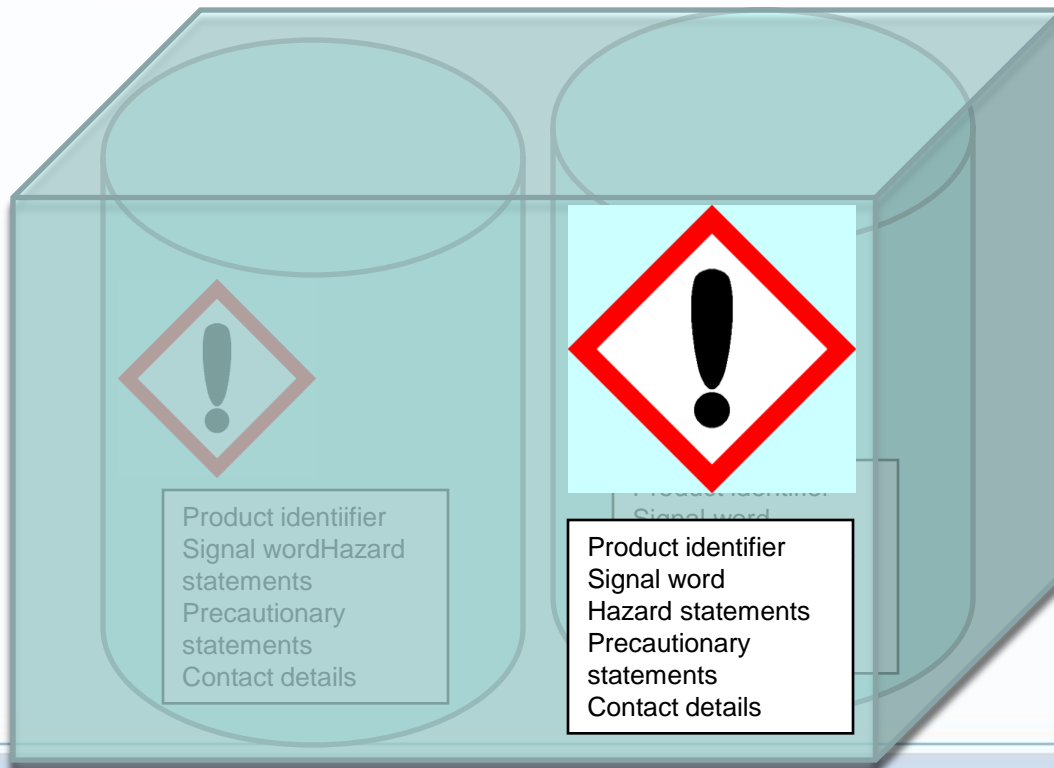


Labelling & Article 33 (2)



Classified
for **supply**
only

Outer & Inner packaging





Labelling & Article 33 (3)



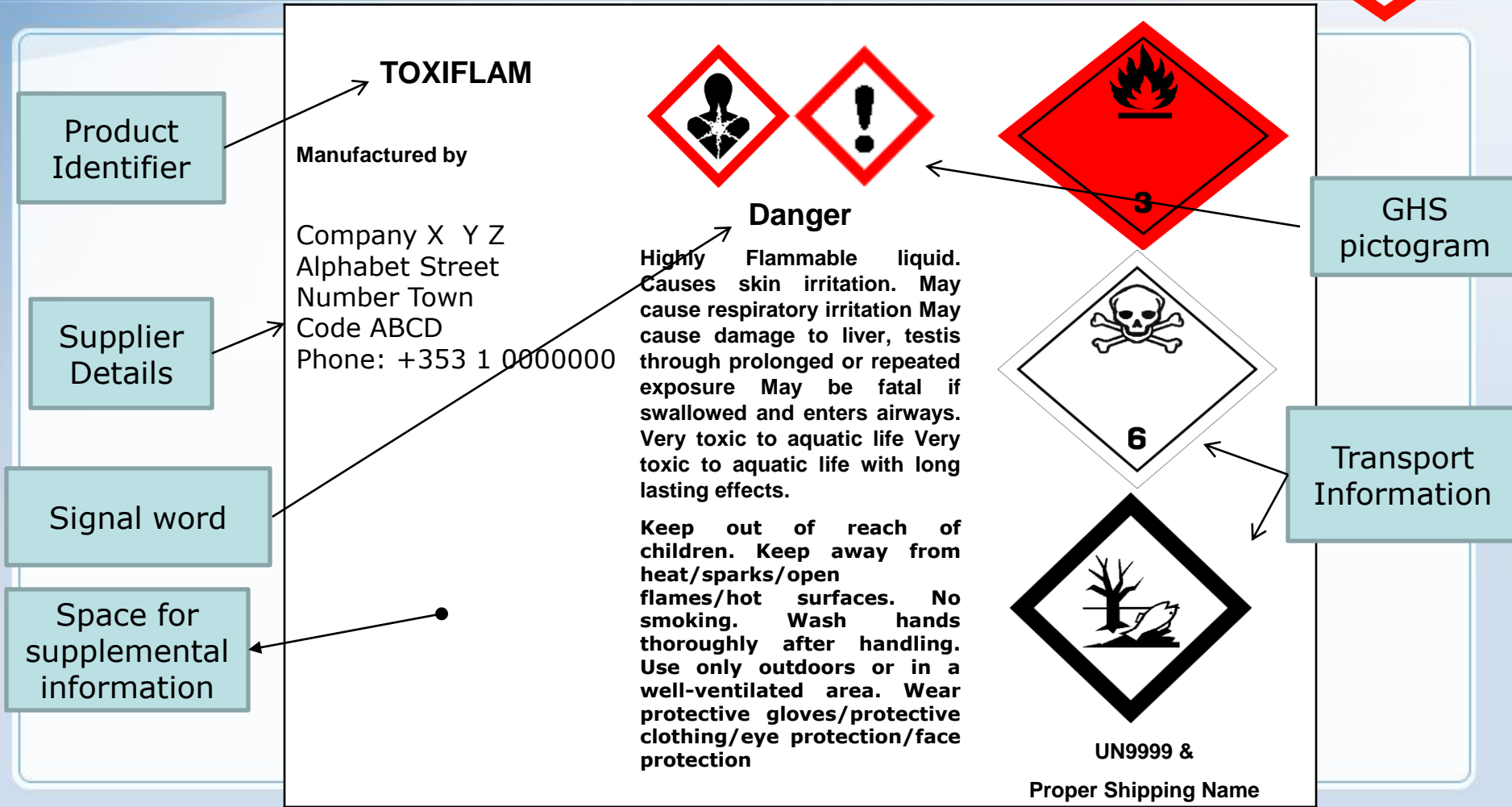
Single packaging

Classified
for **supply &
transport**





Example- single packaging





Example- inner packaging



Product Identifier

TOXIFLAM



Manufactured by

Company X Y Z
Alphabet Street
Number Town
Code ABCD
Phone: +353 1 0000000

Supplier Details

Danger

Highly Flammable liquid.
Causes skin irritation. May cause respiratory irritation May cause damage to liver, testis through prolonged or repeated exposure May be fatal if swallowed and enters airways. Very toxic to aquatic life Very toxic to aquatic life with long lasting effects.

GHS pictograms

Signal word

Space for supplemental information

Keep out of reach of children. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection

UN9999 &
Proper Shipping Name



Exemptions from L&P



- If '*such a shape or form*' or is '*so small*' that impossible to meet labelling rules'
- Allows for new fold-out label; or on tie-on tags; or on outer packaging.
- Packaging <125ml; similar to existing CPL scheme



Example: Small label



Hazard Pictograms

Signal Word, Hazard & Precautionary Statements

199999925

K12345678 808
Lot

125 g

min. shelf life: 31.12.08

Sodium dichromate dihydrate
GR for analysis



Danger. May cause cancer. May cause genetic defects. May damage fertility or the unborn child. Fatal if inhaled. Toxic if swallowed. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes damage to organs through prolonged or repeated exposure. Obtain special instructions before use. IF exposed: Immediately call a POISON CENTER or doctor/physician. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Wear protective gloves/protective clothing/eye protection/face protection.

Index-No: 024-004-01-4

Fa. Muster KG, Musterdorf,
Germany, www.mcwustermann.de
Tel. +49(0)1234 56-7890

Product identifier & supplier information



Exemptions from L&P



• New Provisions

- Labelling of *soluble packaging* for single use (excludes PPP/Biocides)
- Label to accompany delivery of '*Ready mix cement & concrete in wet state*' to general public *without packaging*





Derogations from Labelling



- Derogations : Article 23 & Annex 1.3
 - Transportable gas cylinders
 - Gas containers for propane, butane & LPG
 - Aerosols with fitted seal spray
 - Metals in massive form, alloys, polymer mixtures
 - Explosives – for pyrotechnic effect



Updating Label



- New requirement under CLP
 - Supplier to ensure label is updated without undue delay if a more severe C&L required
 - Other changes within 18 months
 - PPP and Biocides label update in accordance with their Directives.



Packaging



- Provisions come from existing CPL legislation
- Designed so its contents don't damage it or react with contents & fastening remain intact during normal use
- Designed not to arouse curiosity of children/mislead consumers or have similar presentation or design that looks like food.



Packaging-issues!



Packaging



- Aligned with most transport packaging requirements
- Includes EU provisions for
 - Child resistant fastening
 - Tactile warnings of danger
- Applies with EU/EEA only



Conclusions



- Basic principles of labelling remain the same
- CPL labelling rules encompassed in CLP
- Maintain current level of protection
- Global label: new pictograms & terminology
- More flexibility: small packaging
- Increase in labelling content anticipated
- Selecting precautionary statements- a challenge
- New rules for supply & transport labels
- New requirement to update label
- If you apply new CLP label do not use existing CPL

THANK YOU



Tea / Coffee Break & Reach IT account Set up



REACH-IT @ ECHA



ECHA Website - Company Sign-up - Microsoft Internet Explorer provided by Health & Safety Authority

http://echa.europa.eu/reachit/createaccount-it_en.asp

File Edit View Favorites Tools Help

ECHA Website - Company Sign-up

English



European Chemicals Agency

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REACH

CONSULTATIONS

ECHA CHEM

REACH-IT

Portal

News

FAQ's

Sign-up

Notification to the C&L

Company Sign-up

Each company and party must sign-up, online, and create an account in REACH-IT. The identification of the companies (legal entity name, contact details and billing information) must be done online via the REACH-IT portal.

There are two accepted methods for creating an official Legal Entity Object (LEO), and consequently for the creation of a REACH-IT user account:

- via the official IUCLID 5 website (but not from your IUCLID 5 stand-alone application);
- created directly in REACH-IT.

The clock is ticking

Internet 100%



User Account



Company sign-up User account

User account

Company Information

Billing information

Contacts

Validation

You need to specify a REACH-IT administrator for your company account. This administrator will be granted special rights (creation of additional REACH-IT users for your company, modification of company information, etc). Please provide the requested information here below.

Fields marked with an asterisk (*) are mandatory. Hovering over a (?) sign displays help information.

User information - General

* First Name:

* Last Name:

* E-mail:



* User ID:



ID may consist of up to 20 letters [A-Z a-z], digits [0-9] or underscores

* Password:

The password must have at least 8 letters and contain three of the following character types: uppercase letter, lowercase letter, number and non-alphabetical



HEALTH AND SAFETY
AUTHORITY



REGISTRATION, EVALUATION AND
AUTHORISATION OF CHEMICALS



Company Information



Reach-IT

Company sign-up > Company Information

User account

Company Information

Billing information

Contacts

Validation

Please import your IUCLID LEOX into REACH-IT. If you do not have any LEOX or do not intend to get one, you may [encode your information](#) into REACH-IT. REACH-IT will then attribute to your company a Universal Unique Identifier (UUID).

If you already have a company definition file in the IUCLID format (also known as the LEOX file format), and if you want to have the same UUID for your REACH-IT company definition as for your IUCLID LEOX, you should imperatively import your LEOX, and not enter your company information directly into REACH-IT.

Please load the file in which your company information has been saved.

Fields marked with an asterisk (*) are mandatory.

* File name:

Browse...

Load file



Company Information



Reach-IT

Company sign-up > Company Information

User account

Company Information

Billing information

Contacts

Validation

Please provide your company information below

Fields marked with an asterisk (*) are mandatory. Hovering over a (?) sign displays help information.

General information

* Company name:

Company UUID:

ECHA-361e81a8-8b4e-4960-ab67-6c123e7a6b9b

D-U-N-S number:



Example: 12-3456-789

VAT number:



Format: Country code + Number; e.g. BE-111-222-333

D-U-N-S Number is a unique nine-digit identification sequence for a business entity. It links together the different legal entities in a cooperation.



Billing Information



Company sign-up > Billing information

User account

Company Information

Billing information

Contacts

Validation

Please provide your company billing information

Fields marked with an asterisk (*) are mandatory. Hovering over a (?) sign displays help information.

Billing information

Billing organisation name:

Fax:

Billing address

[Same as Company](#)

* Street:

13 Bally craggan

Street 2:

* Postal code:



Contacts



Reach-IT

Company sign-up > Contacts

User account

Company Information

Billing information

Contacts

Validation

You can specify here contact persons for your company.
Please note that additional contact persons can be specified during the pre-registration process.

This step is optional, you can skip it by going directly to the [[Validation](#)] page.

[Add new contact](#)

Select	First Name	Last Name	Phone	Fax	Email
<i>No Records Found</i>					
<< Previous			Next >>		



Validation



Reach-IT

Company sign-up > Validation

User account

Company Information

Billing information

Contacts

Validation

Please verify the company and user data you have entered. You may go back to modify the information by clicking the relevant link here below.

General information

Company name: Mert Co Ltd

Company UUID: ECHA-361e81a8-8b4e-4960-ab67-6c123e7a6b9b

General contact information

Phone: 067 24593

Fax:

Mobile phone:

E-mail: marphymurphy@mertco.ie

Company web site: http://



HEALTH AND SAFETY
AUTHORITY

REACH

REGISTRATION, EVALUATION AND
AUTHORISATION OF CHEMICALS



REACH-IT signup page



- http://echa.europa.eu/reachit/create-account-it_en.asp
- Essential Guides:
 - Industry User Manual - Part 1: [Getting started with REACH-IT](#)
 - Industry User Manual - Part 2: [Sign-up and account management](#)

Safety Data Sheets Practicalities

Roseleen Murphy
Inspector



Overview



- Introduction
- Regulatory Requirements
 - Format & Content
- SDS and CLP
- Annex II changes
- Suppliers Duties
- Recipients Duties
- Summary and Guidance



Introduction



- **Safety Data Sheets (SDS)**
- Professional end users
- Familiar tool for hazard communication
- Suppliers of hazardous or classified substances/mixtures(preparations) must provide
- Function to provide appropriate information on safe use of chemicals
- Required under the REACH Regulation



REACH and SDS



REACH Regulation

'shall ensure a high level of protection of human health and the environment'



Regulatory Requirements



- Dictated by REACH Title IV ' Information in the Supply Chain'
 - applies to all actors in the supply chain
 - Article 31, Requirements for SDS
 - Annex II, Guide to the compilation of SDS
- C&L elements encompassed in SDS
- Echoes repealed SDS Directive



General Requirements



- SDS must:
 - be prepared by a competent person & include email address
 - be clear and understandable
 - take account of the specific needs and knowledge of user
 - include registration number after registration (where appropriate)



General Requirements



- Enable users to take necessary measures to
 - protect human health & worker safety
 - protect the environment
- by providing appropriate information on handling, storage, transport and disposal of substances and mixtures



SDS Format



- 16 sections with many subsections
- In an official language where substance/mixture is placed on the market
- Paper or electronically
- Consistent with the registration dossier
- No fixed length
- Should include page number (page x of y)
- Should include a date and revision status
- Exposure Scenario may be attached



Annex II SDS Format



SDS Required Headings

- | | |
|--|--|
| 1. Identification of the substance/mixture and of the company/undertaking | 9. Physical and Chemical Properties |
| 2. Hazard Identification | 10. Stability and Reactivity |
| 3. Composition/Information on Ingredients | 11. Toxicological Information |
| 4. First Aid Measures | 12. Ecological Information |
| 5. Fire-Fighting Measures | 13. Disposal Considerations |
| 6. Accidental Release Measures | 14. Transport Information |
| 7. Handling and Storage | 15. Regulatory Information |
| 8. Exposure Controls/Personal Protection | 16. Other Information |



Exposure Scenarios



- Applies to hazardous substances M/I > 10t/yr
- Describes the conditions of use of a substance & mixtures
- Sets out operational conditions & details risk management measures for a specific use
- Part of the registration requirements
- May be seen from 2011



Exposure Scenario elements



- Short title of ES
- Description of activities/process
- Operational conditions
- Physical form of the product
- Risk Management Measures
 - Occupational & environmental
 - Predication of exposure



SDS & CLP Transition



- C&L elements in section 2 of SDS must be consistent with the label
- Transitional arrangements for CLP apply to SDS
- Existing (CPL) and new (CLP) classifications must appear in parallel from 1st Dec 2010 to 1st June 2015



SDS & CLP Transition



2. Hazard Identification

2.1 Classification of the substance

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP)

Flam. Liq. 2, H225

Acute Tox. 3 H301

2.1.2 Classification according to Directive 67/548 EEC

F; R11

T; R23/24/25

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Hazard Pictograms



Hazard Statements:

H225 Highly Flammable

H301 Toxic if swallowed

Precautionary Statements:

P210 : Keep away from heat/sparks/open flames/hot surfaces. -No smoking

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTRE or

Doctor/Physician

From 1st Dec 2010
to 1st Jun 2015

CLP & DSD

CLP Only





Annex II Revision



- To facilitate new CLP requirements and GHS global SDS Format;
- Annex II of REACH being amended and replaced to two phases;
 - Annex II (I) effective from 1st December 2010 applies to substances to 1st June 2015
 - Annex II (II) effective from 1st June 2015 applies to substances and mixtures



Annex II Revision



- Allows for CLP Transitional period
- 16 headings as before but 48 sub-sections
- All are mandatory (exception section 3)
- No subsections are to be left blank!



Annex II Revision & CLP



Today

1st Dec 2010

1st Jun 2015

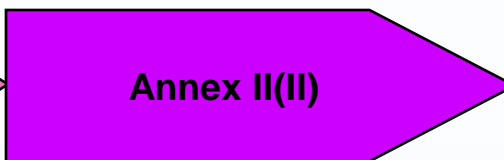
CPL Binding CLP Optional

CLP Binding for substances optional for mixtures

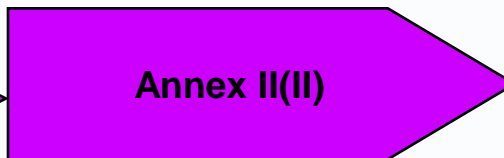
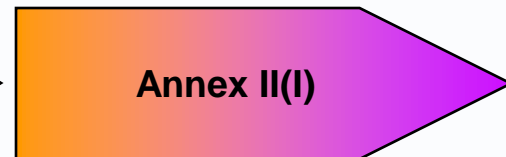
CLP Binding for substances & mixtures

Double classification

Substances



Mixtures



Existing CPL



New CLP

Derogation for already placed on the market :
- substances until 1/12/2012
- mixtures until 1/06/2017



Suppliers Duties



- Supplier evaluate the requirements for SDS
- Supplier required to provide a SDS in accordance with article 31 and Annex II;
 - substance or mixture is classified as hazardous
 - meets the criteria of persistent, bio accumulative and toxic (PBT)
 - included in the Candidate list of Substances of Very High Concern for reasons other than those listed above



Provision on request



- Supplier must provide SDS at **recipients request** where mixture not hazardous but contains a substance which:
 - poses human health or environmental hazard ($\geq 1\%$ w/w non-gaseous/ $\geq 0.2\%$ w/v gaseous mixtures); or
 - is a PBT or vPvB ($\geq 0.1\%$ w/w) or
 - is on Candidate List of SVHC ($\geq 0.1\%$ w/w) or
 - has an occupational exposure limit (OELV)





Provision not necessary



- Substances or mixtures not classified
- Substances or mixtures offered to general public provided sufficient safety information is provided
- Radioactive substances
- Subject to customs supervision
- Non-isolated intermediates
- R&D not placed on market
- Waste
- Substance/Mixture used in defence



Provision not necessary



- Substance/Mixture in finished state for final user:
 - Medicinal/Veterinary products
 - Cosmetics
 - Medical devices
 - Food/Feeding stuffs



When to Update



- Existing SDS may require an update when:
 - a substance or mixture has been classified, labelled and packaged according to CLP
 - new knowledge on hazards available
 - an exposure scenario becomes available
- Suppliers must update without delay
- Must alert customers of update within preceding 12 months of supply
- Updates shall include the registration number (If applicable)



SDS Recipients Duties



- Downstream User right to 'make uses of substances known'
- Many 'identified uses' in practice

Identify apply and recommend appropriate measures to adequately control risks identified in the SDS



DU receives an SDS



- ✓ SDS intended for professional end users or Downstream Users (DU)
- ✓ substance or mixture Classified
- ✓ Correct language
- ✓ your use is covered or not advised against
- ✓ 16 mandatory headings and subheadings are complete
- ✓ consistency between classification and product identifiers and label



DU receives an SDS



- ✓ Appropriateness of Risk Management Measures
- ✓ Exposure Scenario is attached
- x If no to any of the above: contact your supplier
 - Evaluate risks to workers
 - Make available to workers
 - Keep records for 10 years



What if my use is not covered?



- Contact your supplier with the aim to include identified use
- Find an alternative supplier who has covered your use
- Find an alternative substance
- Prepare your own Chemical Safety Assessment



Summary



- What will new SDS look like?
 - Main body not be very different from current
 - More detailed structure with more sub-sections
 - Increased content: longer SDS likely
 - More targeted information & ES
 - SDS may be updated regularly to reflect new information
 - Dual Classifications until 2015
 - New Annex II from Dec 2010



Summary



What are the Benefits of SDS?

- Enhanced protection for man & environment
- Improved flow of communication
- Improved quality of information:
 - Appropriate to uses/exposures
 - Tailored to real needs
 - Consistent
- Will help comply with other legislation
- Global dimension



Guidance and Help



• HSA

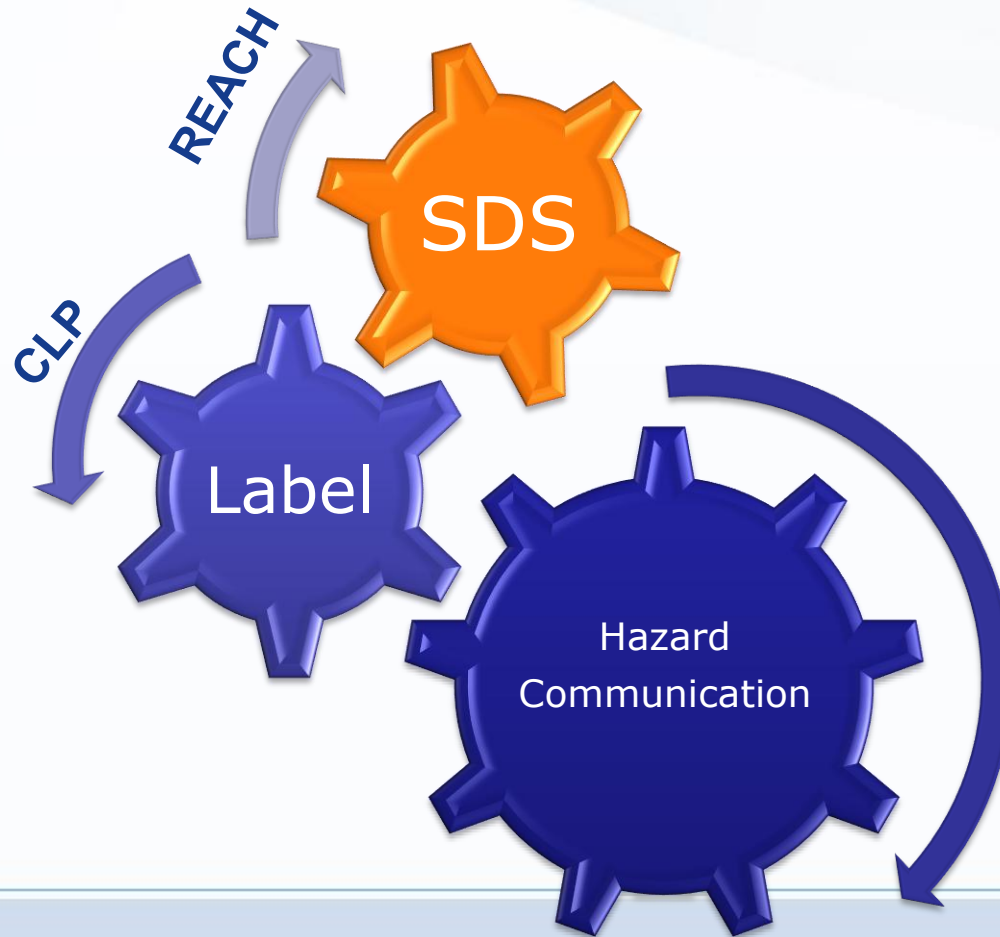
- CLP Helpdesk Ph. 1890 289 389/email clp@hsa.ie
- CLP Webpage Your Industry
[/Chemicals/Classification and Labelling/](#)
- REACH Helpdesk Ph1890 289389/email reachright@hsa.ie
- REACH webpage www.reachright.ie
- REACH & CLP E- Bulletin

• ECHA

- Guidance Document SDS (draft)
- Guidance document for CLP (modules 1 and 2)
- Guidance document for Downstream Users



Closing Remarks





C&L Inventory Notification Tools

Colin Smith and
Marco Valentini



Content



• Four steps:

1. Create a REACH-IT account
2. Create a Notification Group*
3. Prepare your C&L Notification
4. Submit your C&L Notification

*if applicable

1. Create a REACH-IT account

2. Create a Notification Group



Group Creator



a) Online:

- Create the group directly in REACH-IT

b) Offline:

- Use the Group Creator Tool (Excel)

3. Prepare your C&L Notification



REACH-IT online submission



- Intended for SMEs...
 - No need to use IUCLID 5
- C&L notification prepared directly in REACH-IT
- Pragmatic approach:
 - ⇒ Reduced fields
 - ⇒ Default value i.e. "data lacking"
 - ⇒ On-line help
 - ⇒ Compulsory fields identified
 - ⇒ "I agree" concept for Harmonised C&L



REACH IT C&L tool



Substance identity | **Optical information** | **C&L** | **Production site** | **Contact** | **Validation**

Please find below the Harmonised Classification and Labelling related to the substance you want to notify.

Check it and indicate if you want to continue your notification with this C&L or if you want to include further information.

Fields marked with an asterisk (*) are mandatory.

General information

Dossier name: My new dossier name that I gave in the previous screen
Type of notification: Respect harmonised classification
Substance type: Mono-constituent substance

Substance identity

Index number	EC number	CAS number	International Chemical Identification
200-010-010-7	200-010-7	50-10-2	oxyphenonium bromide

Classification

Physical hazards

Physical hazards	Hazard statement
Explosives <input type="text" value="unst.expl."/> ▼	explosive; severe projection hazard ▼
Self-reactive substances and mixtures <input type="text" value="self react. type D"/> ▼	heating may cause a fire or explosion ▼

Health hazards

Health hazards	Hazard statement
Acute toxicity - oral <input type="text" value="acute tox. cat. 3"/> ▼	harmful if swallowed ▼
Acute toxicity - dermal <input type="text" value="acute tox. cat. 2"/> ▼	may be harmful in contact with skin ▼
Acute toxicity - inhalation <input type="text" value="acute tox. cat. 2"/> ▼	fatal if inhaled ▼

To be continued

Labelling

Signal word: ▼

- I want to notify the same classification and labelling as the one Harmonised in Annex VI of the CLP
 I want to notify further classification and labelling information ?

<< Previous

Save and close

Next >>



Bulk xml notification tool





IUCLID 5.2



- Notification created in IUCLID 5
- Template = "CLP notification" in IUCLID 5.2
- Notification submitted via REACH-IT
- Data Submission Manual-Part 12
 - http://echa.europa.eu/doc/reachit/data_submission_manual_12_c&l.pdf
- Practical guides for reporting data
 - http://echa.europa.eu/publications_en.asp

IUCLID 5.2



- Create the legal identity of the notifier
- Create reference substances
- Create the substance dataset
- Enter the C&L information
- Create the C&L notification dossier
- Export the C&L dossier from IUCLID

4. Submit your C&L Notification



(4) REACH-IT



ECHA

Home

Welcome Sandrine L.

You have 0 [unread message\(s\) in your message box.](#)

- Company
- Pre-registration
- Pre-SIEF
- Online dossiers
- Phase-in Information
- Registration / notification
- Joint submission
- Classification and Labelling**
 - Notify a C&L using IUCLID
 - Notify a Bulk C&L
 - Manage the Groups of Manufacturer(s) / Importer(s)
 - Consult the public C&L inventory
- Message box
- User account
- Inventories
- Legal entity change
- Invoices
- Search



(4) REACH-IT



You are connected as [PierreDupont1](#) on behalf of Chemicals and co. - [Preferences](#) - [Log](#)

[Home](#) > [Submit Dossier Intro](#) > [Select group of Manufacturer\(s\)/Importer\(s\)](#)

- Company
- Pre-registration
- Pre-SIEF
- Online dossiers
- Phase-in Information
- Registration / notification
- Joint submission
- Classification and Labelling
- Message box
- User account
- Inventories
- Legal entity change
- Invoices
- Search

Group of Manufacturer(s)/Importer(s)

If the notifier of this C&L notification is a group of Manufacturer(s)/Importer(s), you shall select it from the list below and click on next. If you do not notify this C&L as a group of Manufacturer(s)/Importer(s), click on next.

Please find below the list of group of Manufacturer(s)/Importer(s) that you have already created in REACH-IT and who can notify to ECHA the C&L under the CLP regulation.

If you want to view and/or update the information related to a group (member of the group, member details...), click on the group's name.

You can also [create a new group of Manufacturer\(s\)/Importer\(s\)](#)  if needed.

Select	Group name	Last update
<input type="radio"/>	Group of MI 01	02/03/2010
<input type="radio"/>	Group of MI 02	02/03/2010
<input type="radio"/>	Group of MI 03	02/03/2010
<input type="radio"/>	Group of MI 04	02/03/2010

[Click here to deselect the currently selected group.](#)

Cancel

Next >>





(4) REACH-IT



You are connected as [PierreDupont1](#) on behalf of Chemicals and co. - [Preferences](#) - [Logout](#)

[Home](#) > [Submit Dossier Intro](#) > Select group of Manufacturer(s)/Importer(s) > Submit External Dossier

- Company
- Pre-registration
- Pre-SIEF
- Online dossiers
- Phase-in Information
- Registration / notification
- Joint submission
- Classification and Labelling
- Message box
- User account
- Inventories
- Legal entity change
- Invoices
- Search

Here you can submit a C&L notification dossier.

Classification and Labelling (C&L) notification

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")

* File name:

* Enter the text shown:

Can't read the text below? [Try another](#)



Access code for large files

For the submission of a file larger than 20 MB, please [request a large file access code](#) before submission.

If you have an access code for a large dossier, please, enter it here

Large file access code:





(4) REACH-IT



Successful submission

- Dossier report: Notification number



Submission failure

- Dossier report: reasons for failure





Thank you...



“Don't wait until the last minute”



