

# Session 1

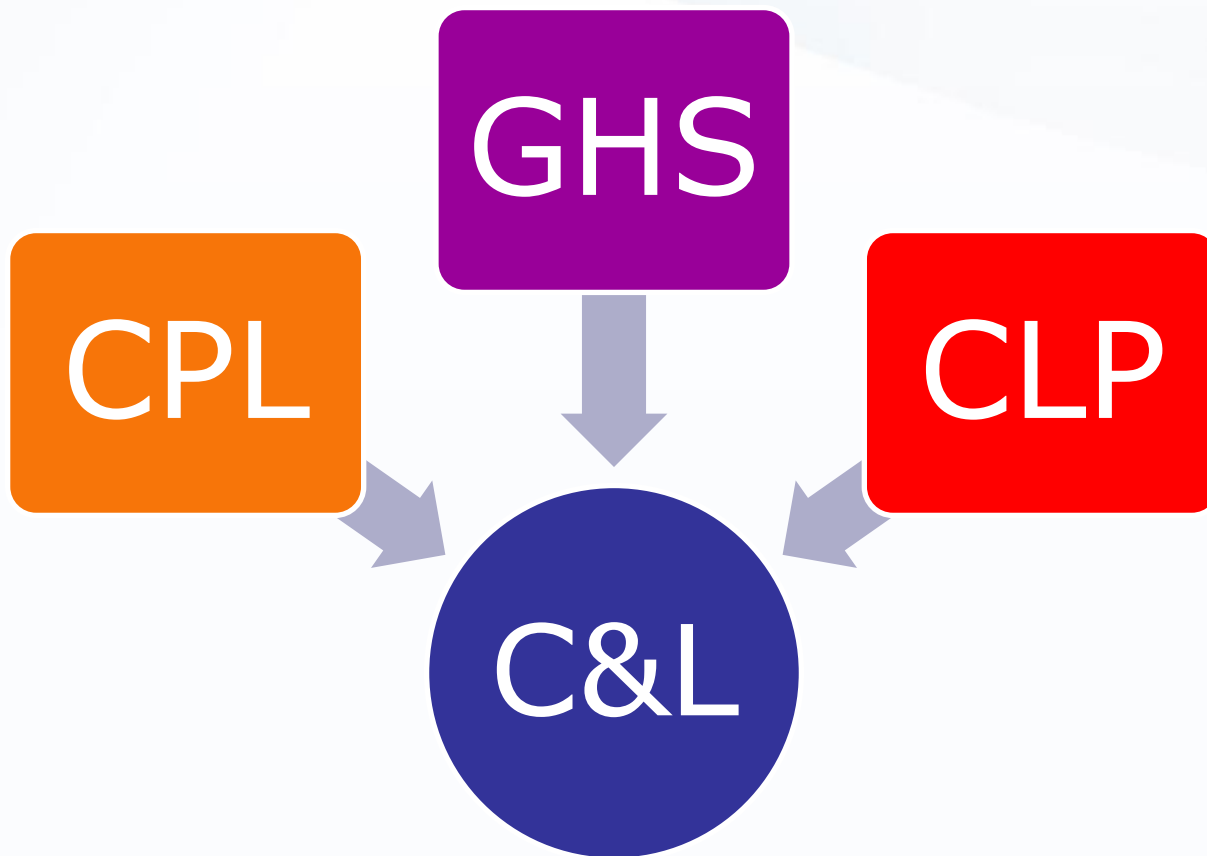
## Labelling & Packaging Requirements

Caroline Walsh





# Acroynms



# Key Topics



- CLP Regulation: WHY? HOW? WHO? WHEN?
- Labelling & **P**ackaging rules
- Guidance & Help



# WHY? 'The problem'

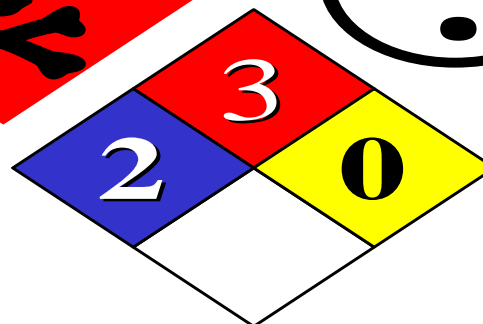
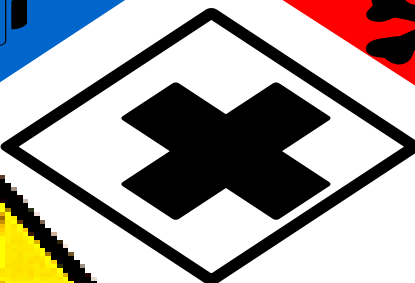
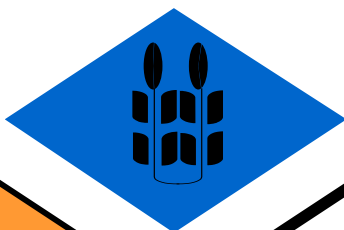


## HARMFUL IF SWALLOWED



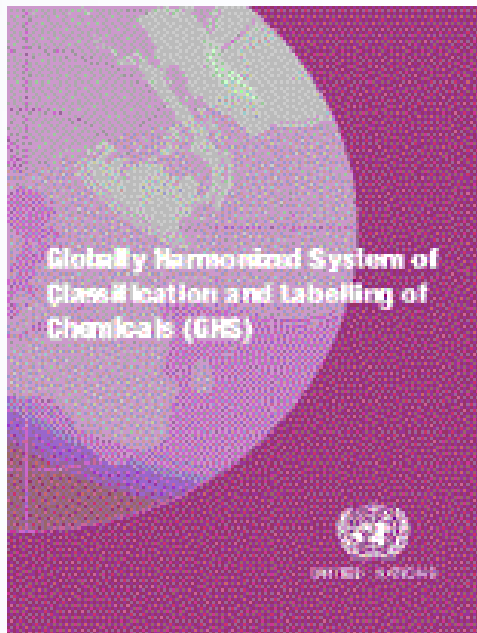
警告

WARNING!





# WHY? 'The Solution'



*Pictograms for labelling*

UNGHS International Convention



# HOW? 'The legal bit'



- CLP Regulation. 'Direct Acting' **in EU**
- (EC) No. 1272/2008
- 1<sup>st</sup> ATP ( EC) No 790/2008
- 2<sup>nd</sup> ATP (EC) No XX/2011 ( pending)
  
- Chemicals (Amendment ), Bill No 47 of 2010 (pending) for admin/enforcement **in Ireland**



# WHEN?



- CLP Regulation 1272/2008 entered force on **20<sup>th</sup> Jan 2009**
- From 1<sup>st</sup> Dec 2010 applies to substances placed on the market derogation to 1<sup>st</sup> December 2012 if already 'on the shelf'.
- From 1<sup>st</sup> June 2015 applies to substances placed on the market with a derogation to 1<sup>st</sup> June 2017 if already 'on the shelf'



# WHO?



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

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

\*\*Dist may use classification of another actor





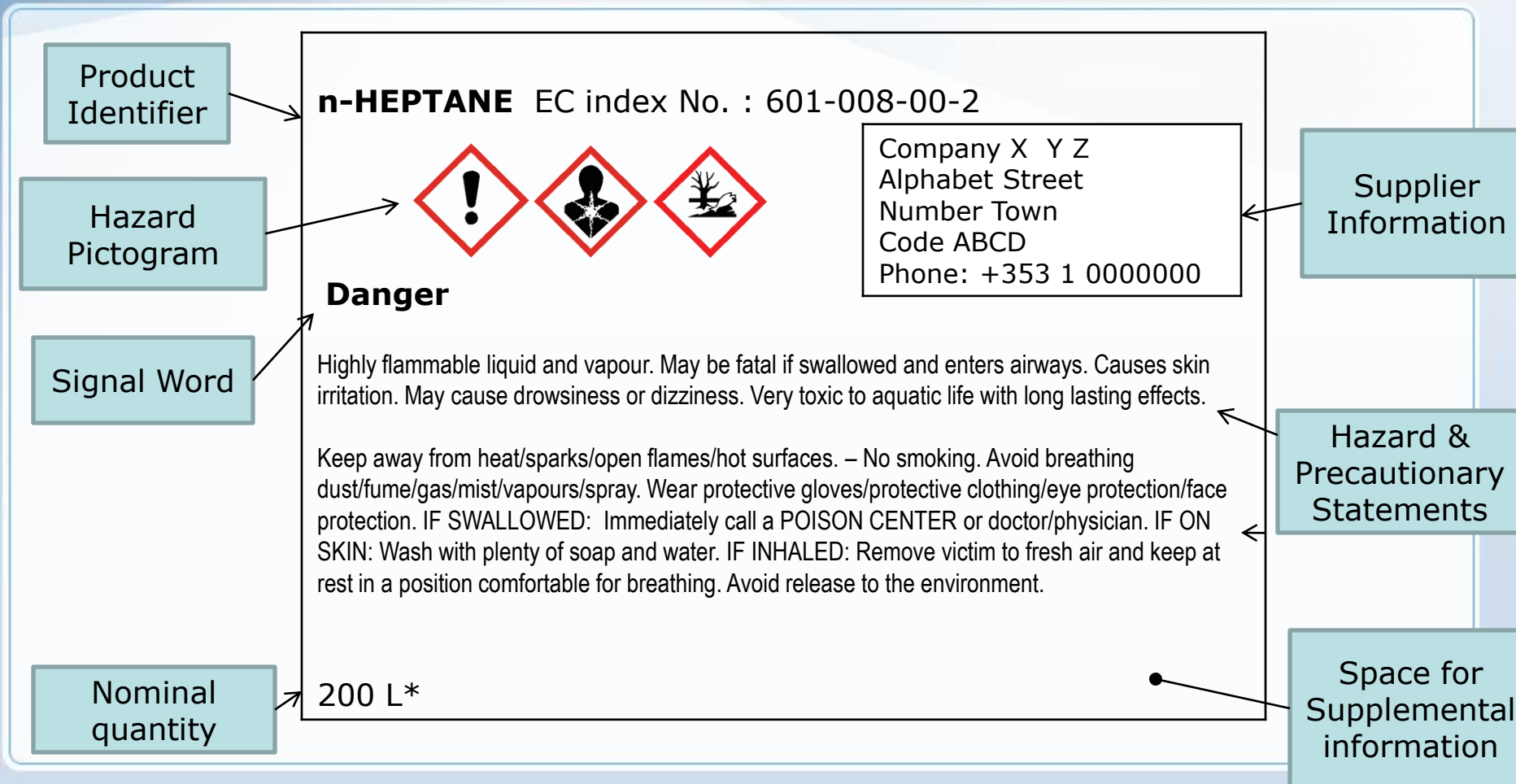
# Label elements



- 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

- 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

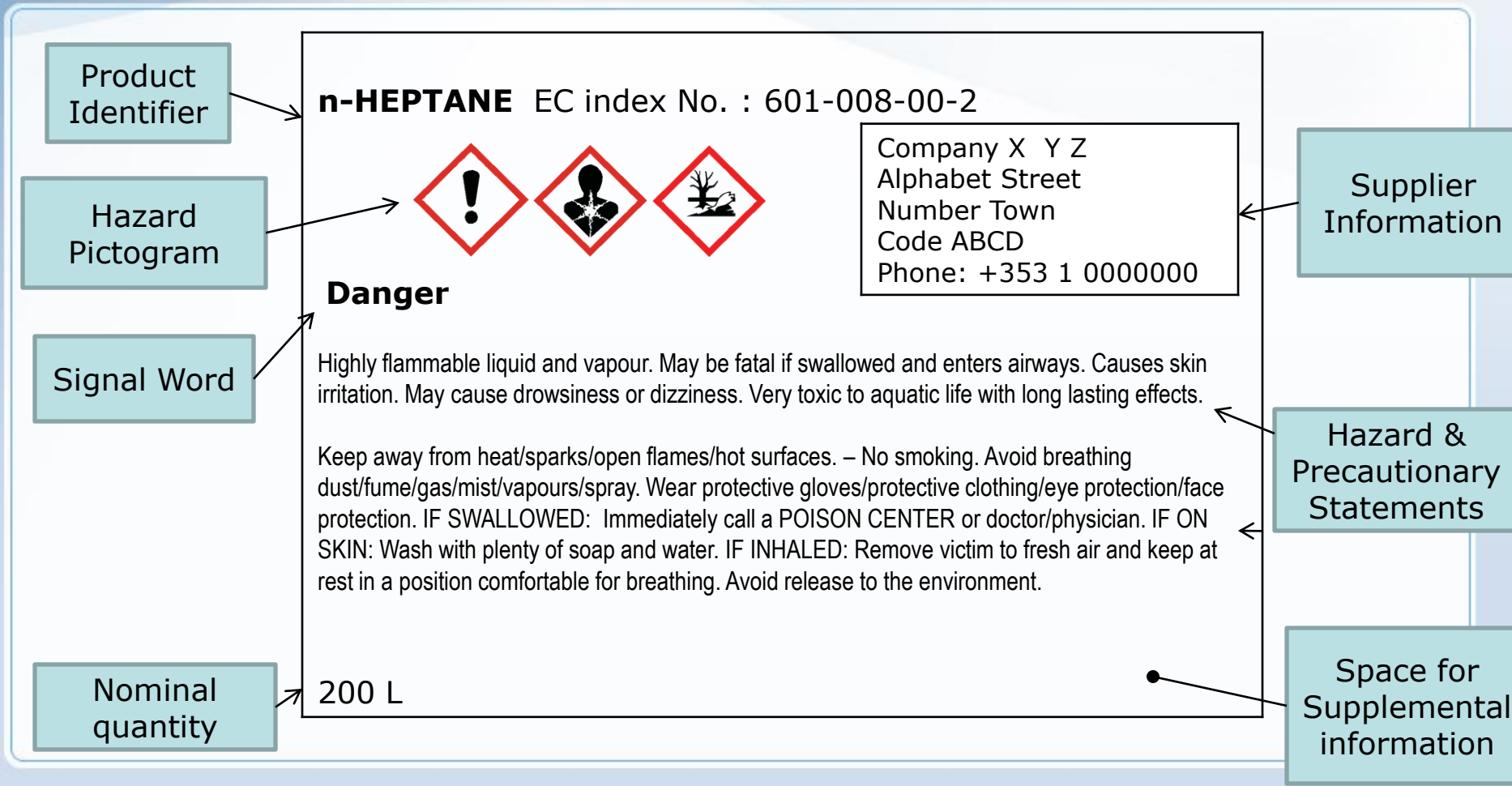


## • Non-Obligatory

- 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 Spring 2011 ([draft](#))





# General label rules



- Firmly affixed to immediate packaging unless on packaging itself
- Readable horizontally when set down
- Hazard pictogram stands out clearly & text easy to read
- Label 'dimension' e.g. 74mm X 105mm >3litres<50Litres
- Pictograms at least 1/15th of surface of label > 1cm<sup>2</sup>





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

- 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

#### Dangerous to the environment

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





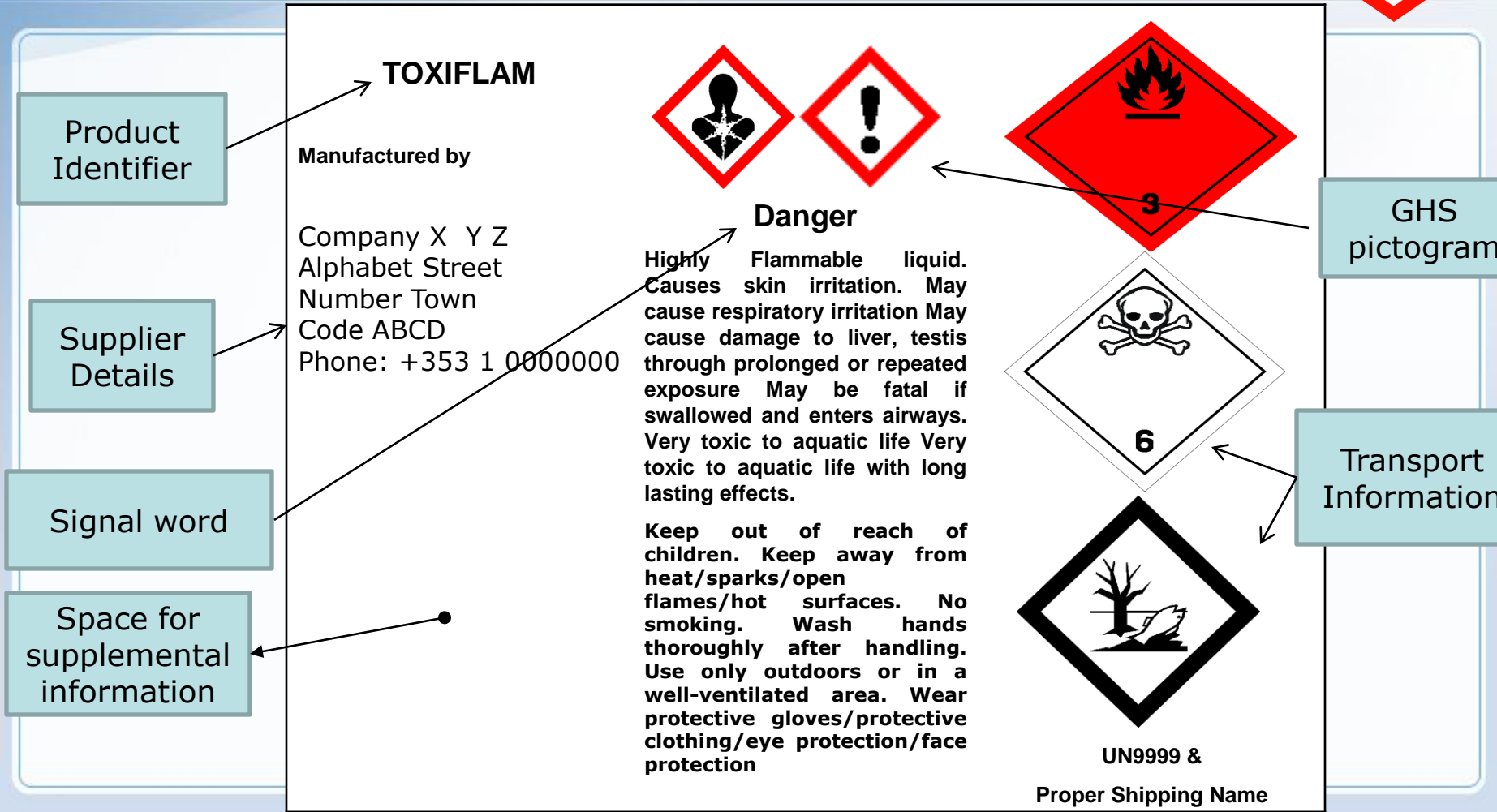
# Labelling & Article 33



- 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.



# Example- single packaging





# 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](http://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



- Comes from existing CPL ( not in GHS)
- Aligned with most transport packaging requirements
- Includes EU provisions for
  - Child resistant fastening\*
  - Tactile warnings of danger\*

*Applies with EU/EEA only \**





# Which ONE to use?





# Preparation tips



- Confirm substance/mixture identity/name
- Apply the classification from M/I\* only
- Do any labelling exemptions apply?
- Include supplier details, including phone No.
- Decide on the pictogram(s), Signal word,
- H & P Statements & supplemental information
- Check label dimensions/presentation
- Ensure information consistent with SDS



# Helpdesk & Guidance



## HSA

- Helpdesk Ph. 1890 289 389
- CLP Helpdesk: email [clp@hsa.ie](mailto:clp@hsa.ie)
- CLP Webpage: [www.hsa.ie/clp](http://www.hsa.ie/clp)
- CLP [Posters](#) A1 & A4 formats
- CLP [Brochure](#)

## ECHA

- CLP FAQ [Version 1.2](#) (24/11/10)
- Introduction to CLP [1](#)
- Labelling & Packaging [3](#) (18/11/10)( draft!!)

# Session 2

## New Requirements for Safety Data Sheets

Sinead McMickan



# Key Topics



- Why do we need new Legislation
- Changes to SDS
- Timelines for implementing
- Updates to SDSs
- Guidance & Help



# Legislation



- Reg. (EC) No. 453/2010 amends Annex II of REACH & adapts it:
  - to the criteria for classification as given in CLP Reg
  - to take account of SDS rules as set out in GHS



# When?



- Came into force on 20 June 2010
- From 1<sup>st</sup> Dec 2010 Annex I of 453 replaces Annex II (1907/2006)
- From 1<sup>st</sup> June 2015 Annex II of 453 replaces Annex I of 453





# Format (as per Art 31)



## SDS Required Headings

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







# Changes....



- Regulation changes text of Annex II from  
*“a guide to the compilation of safety data sheets”*  
to  
*“requirements for the compilation of safety data sheets” ...*



# Major Changes





# Section 1



- Product identifier
- Registration no.
- Uses advised against
- Details of Supplier of SDS now includes OR
  - Details of non-EU manufacturer/formulator may be provided also (where OR appointed)



# Section 2



- For substances:
- Existing CPL (DSD) & new CLP classifications must appear in parallel from 1<sup>st</sup> Dec 2010 to 1<sup>st</sup> June 2015 in section 2.1
- Label elements must appear in section 2.2 (Label must be to CLP)



# SDS for Substances



## 2. Hazard Identification

### 2.1 Classification of the substance

Classification according to Regulation (EC) No. 1272/2008 (CLP):  
Flam. Liq 2; H225  
Acute Tox 3; H301

Classification according to Directive 67/548/EEC:  
F; R11  
T; R25

### 2.2 Label elements

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

Hazard Pictograms:



Signal Word: Danger

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 1<sup>st</sup> Dec 2010  
to 1<sup>st</sup> Jun 2015



**CLP & DSD**



**CLP Only  
(as on Label)**



# Label Example (Substance):



**SUBSTANCE X**

CAS No. 123-45-6



Name: XYZ Company  
Address: Z Street,  
Town XY99 9YZ  
Tel. 012-345678

**Danger**

Highly Flammable  
Toxic if swallowed

Keep out of reach of children. Keep away from heat/sparks/open flames/hot surfaces. – No smoking. Store in a well-ventilated place. Keep container tightly closed. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Avoid release to the environment. Collect spillage.

EU limit for this product is (cat.A/d): 300 g/l.  
This product contains max 300 g/l VOC



**1L**



# Section 2



- For mixtures:
- Existing CPL (DPD) classification must appear in section 2.1 from 1<sup>st</sup> Dec 2010 to 1<sup>st</sup> June 2015
- Label elements must appear in section 2.2 (Label must be to DPD)





# SDS for Mixtures



## 2. Hazard Identification

### 2.1 Classification of the mixture

Classification according to Directive 1999/45/EC:  
Xi; R36/38

### 2.2 Label elements:

Labelling according to Directive 1999/45/EC:

Symbol:



Indication of Danger:  
Irritant

### Risk Phrases:

R36/38 Irritating to eyes and skin

### Safety Phrases:

S(2) Keep out of the reach of children

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37 Wear suitable gloves

From 1<sup>st</sup> Dec 2010  
to 1<sup>st</sup> Jun 2015:

**DPD**

**DPD**  
(as on Label)





# Label Example (Mixture):



## MIXTURE X CLEAN IT



Name: XYZ Company  
Address: Z Street,  
Town XY99 9YZ  
Tel. 012-345678

### Irritant

Irritating to eyes and skin

Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves.

Contains: Substance x and substance y

1L

EXAMPLE

## Section 2



- Also.... if substance is subject to authorisation, auth no. must be included in 2.2 (label elements)
- Under 2.3 Other hazards:
- State if PBT or vPvB



# Section 3



- Appropriate & available safety info on surface chemistry indicated (Nano ref)
- Provide info on **substance** in 3.1:
  - Product identifier (or other id)
  - Chemical id of any classified impurity, stabilising additive etc. contributing to classification of substance including:
    - Product identifier (or other)
- Info on Multi-constituent substances

# Section 3



- Provide info on Mixtures in 3.2:
- Product identifier for all substances listed in s3
- Conc. of subs as:
  - exact % in descending order by mass or volume or
  - ranges of % in descending order by mass or vol (if technically possible)



# Section 3



- For substances listed provide classification according to CPL (DSD):
  - Indication of danger, symbol letter, R phrases
- If CLP classification made available by supplier for substance in mixture, then give:
  - Hazard class, Category code, Hazard statements
- Provide registration number for substances listed where available



# Sections 4, 5 & 6



- More detail is required for example:
- S.4: advice to be provided on whether PPE required for first aider
- S.5: specific advice for fire fighters
- S.6: Methods and Material for containment and cleaning up
- Subsections





# Section 7



- More specifics required under subsections of:
  - Precautions for safe handling
  - Conditions for safe storage, including any incompatibilities
  - Specific end uses



# Section 8



- National OELVs and national biological limits for MS where SDS being provided
- Info on control banding approach
- More specifics required eg. Thermal hazards



# Section 9



- Reference to Nanotechnology under 9.1:
  - *Appearance: physical state (solid (incl. appropriate & available safety info on granulometry & specific surface area))*
- And under 9.2:
  - *Appropriate & available safety info on redox potential, radical formation potential and photocatalytic properties*



# Section 9



- New in 453:
  - Odour threshold
  - Melting point/freezing point
  - Upper & lower Flammability or Explosive limits
  - Auto-ignition temperature
  - Decomposition temperature
  - Solubility(ies): merging solubility & water solubility
- If property doesn't apply, state why.

# Section 10



- Again more detailed under specific subsections:
  - Reactivity
  - Chemical stability
  - Possibility of hazardous reactions
  - Conditions to avoid
  - Incompatible materials
  - Hazardous decomposition products



# Section 11



- From 1 Dec 2010 for substances & 1 June 2015 for mixtures: info on STOT SE & RE
- Info on all hazard classes (no data, tech impossibility, inconclusive or insufficient for classification)
- Brief summaries & ref. to test methods
- Summarised evaluation of CMR properties



# Sections 12, 13 & 14



- Again more detailed:
- S.12: Results of PBT **and** vPvB assessment
- S.13: Waste treatment methods to be described
- S.14: Special precautions for user; transport in bulk info





# Section 15



- No more label info!!!
- Regulatory info:
  - Not included elsewhere:
    - POPs, Ex/Im, Seveso category
  - Authorisation/restriction info
  - CSA





# Section 16



- As before:
  - Revision details, references, training details, list R phrases, H statements
- New:
  - Details of methods of evaluating info for mixtures (Art 9 CLP)
  - If mix supplier chooses to identify & inform of CLP classification w/o labelling, include classification here



# Timelines



- Came into force on 20 June 2010
- From 1<sup>st</sup> Dec 2010 Annex I of 453 replaces Annex II (1907/2006)
- From 1<sup>st</sup> June 2015 Annex II of 453 replaces Annex I of 453



# A few Musts...



- From 1<sup>st</sup> Dec 2010, ALL suppliers of substances & mixtures **MUST** provide SDS according to Annex I (453)
- From 1<sup>st</sup> June 2015, ALL suppliers **MUST** provide SDSs according to Annex II (453)

# And a few Don't need to yets....



- Substances on market before 1<sup>st</sup> Dec 2010  
→ SDS to Annex I (& CLP) by 1<sup>st</sup> Dec 2012
- Mixtures on market before 1<sup>st</sup> June 2015  
→ SDS Annex II (& CLP) by 1<sup>st</sup> June 2017
- Mixture SDS provided to customer before 1<sup>st</sup> Dec 2010 → SDS to Annex I by 30<sup>th</sup> Nov 2012



## However.....



- Suppliers of Mixtures can apply Annex II to 453/2010 (& CLP) before 1<sup>st</sup> June 2015 ....but
- MUST provide classification of mixture in s.2.1 according to CPL **AND** CLP .....AND
- Label MUST be to CLP
- MUST provide classification of substances in mixture in s.3.2 according to **CPL & CLP**



Or.....



- Between 1<sup>st</sup> Dec 2010 & 1<sup>st</sup> June 2015:
- Mixture suppliers **may choose** to identify CLP classification only by adding CLP classification to section 16 only



**UPDATE!**



# When to Update



- For substances & mixtures placed on the market from 1<sup>st</sup> Dec 2010: update SDS according to Annex I of 453/2010 NOW
- Derogations in place for those already on market but don't apply if update required by Art 31(9)



# Art 31(9) of REACH



*Suppliers shall update the safety data sheet without delay on the following occasions:*

- (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;*
- (b) once an authorisation has been granted or refused;*
- (c) once a restriction has been imposed.*

**UPDATE!**



# When to Update



- For substances already on the market:
- If SDS needs updating at any time after 30 Nov 2010 according to Art 31(9): needs to be aligned with new Annex (even before 1 Dec 2012)
- For mixtures:
- If SDS needs updating according to Art 31(9): needs to be aligned with relevant version of 453/2010 (even before 1 June 2015)



# Remember



- CLP derogations apply
- If the label is CLP → CLP classification in Section 2 of SDS

Don't  
**FORGET!**



## Remember:

- Consistency between sections
- Consistency with ES/CSRs/registration dossier
- All sections mandatory. No blanks!
- No generic statements



# Summary



- For **substances** – CLP info in SDS (also on labels) from **1 Dec 2010**, with possible **transition to 1 Dec 2012**
- For **mixtures** - CLP info in SDS (also on labels) from **1 June 2015**, with possible **transition to 1 June 2017**
- **No transition for substances or mixtures with** respect to SDS **if any conditions in Art 31(9) apply requiring update**
- Early implementation allowed under certain conditions for mixtures



# Guidance & Help



- Information Sheet on Safety Data Sheets Publications page on [www.hsa.ie](http://www.hsa.ie)
- 2<sup>nd</sup> draft of Guidance on compilation of SDSs (Oct 2010) for commenting- due in Spring 2011 on ECHA website
- REACH HelpDesk: [reachright@hsa.ie](mailto:reachright@hsa.ie) or LoCall 1890 289 389



# THANK YOU

