

The Implications of REACH Regulations on LSC Cocktails

Triskem Users Group Meeting
Webb Library of Jesus college in
Cambridge
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Content:

- Chemical Regulations – REACH
- Implications for our products
- Implications for Industry

Chemical Regulations - REACH



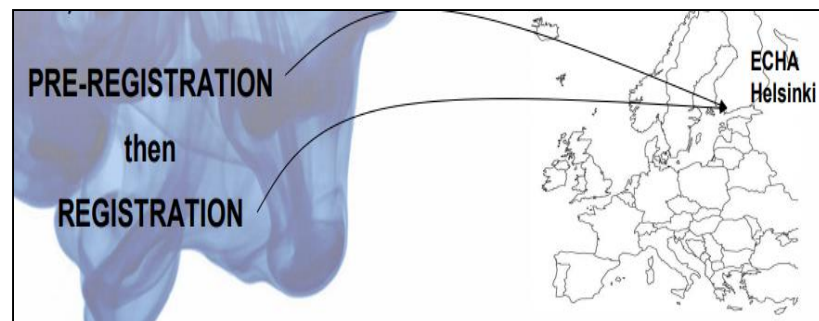
- Regulation No.1907/2006 which came into force in 2007.
- Law about chemicals and their lifecycle.
- European Chemicals Agency (ECHA) are the administrative body.
- Major impact on industry, affecting all stages of the supply chain.
- Originated in the UK (HSE / Defra).

Aims:

- Improve protection of human health and the environment.
- 'One substance, one registration'.
- Reduce tests on vertebrates & costs through collaboration.
- Force a change to safer alternative chemicals or technologies.

Registration

- If your company introduces to the EU a substance by manufacture or importation at ≥ 1 tonne per year then it needs to have REACH Registration in place.
- No Registration = No Market
- **Registration dossier** contains information on:
 - The properties and uses of the substance
 - Assessment on the hazards and potential risks
 - Submitted to ECHA
- Substance registration is very costly



- ECHA and the Member States evaluate the information provided in the registration dossiers.
- They review three aspects: dossier, substance & testing proposals.
- Request additional information if they identify data gaps.
- **Does the substance need to be controlled more?**
- Additional measures required to reduce the risk may include;
 - Listing on the **Community Rolling Action Plan (CoRAP)**
 - Listing on **Candidate List for Authorisation**
 - Putting a **Restriction** in place specifying when and how it is used
 - Harmonisation of classification and labelling
- Substances that cause cancer, genetic mutations, or birth defects (CMRs), as well as substances that are persistent, bioaccumulative and toxic are classified as **Substances of Very High Concern (SVHC) and subject to authorisation.**

- Substances of Very High Concern (SVHC) are subject to **Authorisation** meaning that **they cannot be used in the EU without authorised permission or an exemption in place.**
- SVHC are on the Candidate List for Authorisation; Annex XIV REACH Regulations.
- Companies have to apply for an authorisation to be granted which allows the continued use of the substance.
- Authorisation is a costly process and only granted for an interim period whilst an alternative substance is sought.
- If an alternative substance is available authorisation will **not be granted**
- **No Authorisation = SUBSTANCE BAN IN EU** after sunset date.
- Unless there is an exemption in place.

Restrictions

- Substances that pose an “unacceptable risk” are subject to **Restrictions**.
- These are detailed in Annex XVII of the REACH Regulations.
- The list details the restricted substance and specifies which uses are restricted or even banned.

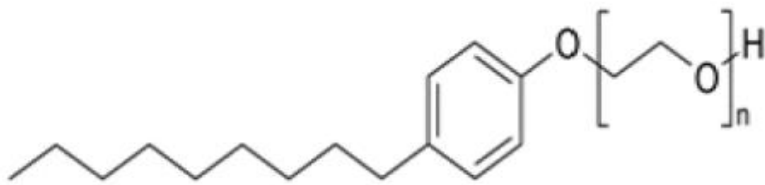
“ A substance shall not be manufactured, placed on the market or used unless it complies with the conditions of the restriction”.

REACH Implications on LSC Cocktails

- LSC cocktails contain 3 main components; Solvent, Surfactants and Fluor
- 2 of these components are adversely affected by REACH;

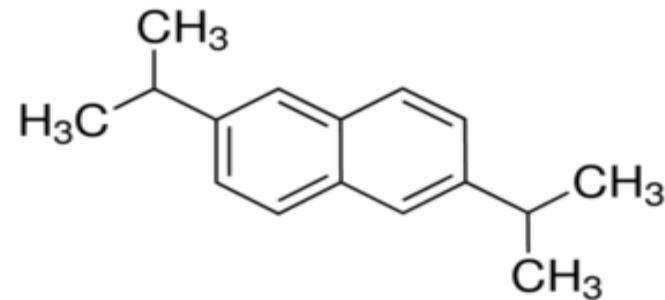
Surfactant

4 Nonyl Phenol Ethoxylates



Solvent

Di-isopropylnaphthalene



4 Nonyl Phenol Ethoxylates (NPE's)

- Non-ionic surfactants
- Used in many products leading to widespread release into the environment.
- Toxic to aquatic organisms because they convert male fish to female fish
- Added to **Candidate List and classified as SVHC in July 2017.**

Implications

After January 2021 we cannot use NPE's within the EU unless authorisation granted or exemption applies.

Authorisation

- Is costly (£250K)
- Only granted for few years whilst an alternative found

Exemption

- SR&D exemption for substances used in R&D only.
- Only small volumes < 1 tonne/ annum

Manufacturers are stopping production NOW

- Dramatically limiting availability of LSC Cocktail components
- 57 LSC cocktails could be reduced down to **ONLY 9 by 2021**

DIN (Di-isopropylnaphthalene)

- DIN is a solvent, used in carbonless copy papers and as a transformer fluid.
- Listed on **Community Rolling Action Plan (CoRAP)** in 2013 because;
 - Suspected PBT/vPvB (Persistent, Bioaccumulating and Toxic)
 - High (aggregated) tonnage & wide dispersive use
- PBT chemicals resist degradation and persist in the environment
- Member State carrying out evaluation - **Swedish Chemicals Agency**.
- Initial study was incomplete and extra study needed to make a full assessment.
- DIN has been shown to be toxic to Daphnia (water fleas).
- Looks like it fulfils **B & T** criteria but insufficient data to conclude on Persistence.
- Current Status “Under Evaluation”

Implications

- If DIN moves to Candidate List – it will require authorisation to continue use or an exemption sought.
- Substances on Candidate list aim to be phased out within 3-5 years.
- Dramatically limiting availability of LSC Cocktails.

REACH Implications for Industry

- Stringent REACH Regulations are prohibiting the use of key raw materials in LSC cocktails.
- Thus, reducing the number of LSC cocktails that will be available in the very near future.
- Dramatically effecting all industries that carry out radioactivity testing.
- Ultimately removal of certain LSC cocktails will mean that no testing can occur.

**BE PROACTIVE – SWITCH TO REACH
COMPLIANT LSC COCKTAILS NOW**

Where do we go from here?

REACH Forwards or Backwards!

Which LSC cocktails contain NPE's ?

LSC cocktails containing NPE's

Meridian	Perkin Elmer	Zinsser	National Diagnostics
Gold Star	Ultima Gold	Aquasafe 300 Plus	Ecoscint A
Gold Star Quanta	Ultima Gold XR	Aquasafe 500 Plus	Ecoscint XR
Gold Star LT2	Ultima Gold MV	Quicksafe A	Ecoscint Ultra
Opti-PXE	Ultima Gold AB	Quicksafe 400	Ecoscint H
Gold Flow	Ultima Gold LLT	Irgasafe Plus	Ecoscint Flow
Star Gel	Ultima Gold uLLT	Quickszint Flow 302	Uniscint BD
TritiumCount	OptiPhase Hi-Safe 3	Quickszint 212	Ecoscint Original
	Insta-Gel Plus	Unisafe 1	Hydrofluor
	Hionic-Fluor	Oxysolve-T	Liquiscint
	OptiFluor	Quickszint 1	Fluorodyne
	Emulsifier Safe	Supersolve-X	Ultrafluor
	Ultima-Flo M		Bioscint
	Ultima-Flo F		Soluscint XR
	Ultima-Flo AP		Monoflow 1
	Flo-Scint A		Monoflow 2
	Flo-Scint II		Monoflow 3
	Flo-Scint III		Monoflow 4
	Monophase S		Monoflow 5
	Microscint-20		Oxosol-3H
	Microscint-40		

NPE-free LSC cocktails

Meridian	Perkin Elmer	Zinsser	National Diagnostics
ProSafe+	Pico-Fluor Plus*	Quicksafe Flow 2	
ProSafe HC+	Bio-Fluor Plus*		
ProSafe FC+	* Based on Pseudocumene		
ProSafe TS+			
ProFlow G+			
ProFlow P+			

- 57 LSC cocktails could be reduced down to **ONLY 9 by 2021**.
- Meridian have formulated alternative LSC Cocktails that are NPE-free.

What cocktails can these replace????

	Possible alternative	Availability
Gold Star	ProSafe HC+	In stock
Gold Star Quanta	None	-----
Gold Star LT ²	ProSafe LT ² +	In development
Opti-PXE	None	-----
Gold Flow	ProFlow G+	In stock
Ultima Gold	ProSafe+	In stock
Ultima Gold XR	ProSafe HC+	In stock
Ultima Gold AB	ProSafe LT ² +	In development
Ultima Gold LLT	ProSafe LT ² +	In development
Ultima Gold uLLT	ProSafe LT ² +	In development
Insta-Gel Plus	None	-----
Ultima-Flo M	ProFlow G+	In stock
Aquasafe 300 Plus	ProSafe+	In stock
Aquasafe 500 Plus	ProSafe HC+	In stock
Quicksafe 400	ProSafe LT ² +	In development

Which LSC cocktails contain DIN?

LSC cocktails containing DIN

Perkin Elmer	Zinsser	National Diagnostics
Ultima Gold,	Aquasafe 300+	Ecoscint XR
Ultima Gold XR	Aquasafe 500+	Ecoscint A
Ultima Gold AB	Aquasafe 800	Ecoscint H
Ultima Gold LLT	Quicksafe A	Ecoscint Flow
Ultima Gold uLLT	Quicksafe 400	Ecoscint Ultra
Ultima Gold MV	Quicksafe N	Ecoscint BD
Ultima Gold F	Filtersafe	Ecoscint Bioscint
Optiphase Hisafe 2		
Optiphase Hisafe 3		
Optiphase Hi-Load		
Optiphase Supermix		

DIN-free LSC cocktails based on Pseudocumene























Meridian	Perkin Elmer	Zinsser	National Diagnostics
MicroFlow G	Insta-Gel Plus	Quickszint 1	Oxosol 306
CarbonCount	Hionic-Fluor	Quickszint 212	Oxosol C-14
TritiumCount	Flo-Scints	Quickszint 501	Hydrofluor
	Filter-Count	Quickszint 2000	Liquiscint
	Monophase-S	Oxysolve-T	Betafluor
	Permafluor E+	Oxysolve C400	Monofluor
			Filtron-X
			Monoflow 1
			Monoflow 2
			Monoflow 3
			Monoflow 4
			Monoflow 5
			Soluscint XR



DIN free LSC cocktails based on PXE , LAB or PXE/LAB

Perkin Elmer	Meridian	Zinsser	National Diagnostics
Emulsifier Safe	Opti-PXE	IrgaSafe Plus	Ecoscint XR
Opti-Fluor			Ecoscint A
Ultima-Flo M			Ecoscint H
Ultima-Flo AF			Ecoscint Flow
Ultima-Flo AP			Ecoscint Ultra
StarScint,			Ecoscint BD
Lumasafe Plus			Ecoscint Bioscint
Irgasafe Plus			Ecoscint Original

Solvents used in Liquid Scintillation Counting

	Time frame	Flash point	Hazards	Warning
Benzene	1954-60	-11°C	  	Capable of causing cancer
1-4 Dioxan	1960-65	12°C	  	Suspected of causing cancer
Toluene	1964-70	4°C	  	Suspected of damaging the unborn child
Xylene	1965-70	25°C	 	Possibly carcinogenic to humans (ethylbenzene)
Pseudocumene	1970-2018	48°C	  	Toxic to aquatic life with long lasting effects
Dodecyl benzene	1984-2018	109°C	 	Very toxic to aquatic life with long lasting effects
Phenylxylyl ethane	1985-2018	140°C	  	Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment
Di-isopropylnaphthalene	1985-2018	140°C	  	Very toxic to aquatic life with long lasting effects

Implications

- Use of safer DIN based cocktails will need to be replaced by more hazardous alternative formulations – Backward step.
- Reduction in the number of LSC cocktails available - Dramatic effect on all industries that use radioactivity.
- Removal of certain LSC cocktails = NO RADIOACTIVE TESTING POSSIBLE.



The Way Forward

Use of safer DIN based cocktails will need to be replaced by more hazardous alternative formulations – Backward safety step and these will also eventually be restricted

Reduction in the number of LSC cocktails available - Dramatic effect on all industries that use radioactivity.

Removal of certain LSC cocktails = NO RADIOACTIVE TESTING POSSIBLE.

1. Nuclear Power Stations would quickly have to shut down.
 - Reduction in electricity supply.
 - Decommissioning of “closed” Nuclear Power Station not possible (20-40 years to complete).
2. No new drugs from Pharmaceutical Industry.
3. Radiotherapy wards in hospitals.
4. Defence – no new nuclear powered submarines.

Which business sectors are most at risk???

Power Generation	Electricity
Pharmaceuticals	New drug development
Hospitals	Radiotherapy
Universities	Research
Defence	Nuclear-powered ships & submarines

Who is at risk????

Europe	Country	Number of Reactors	% of Electricity
	France	59	72%
	Belgium	7	51%
	Sweden	12	40%
	UK	15	26%
Rest of World	Country	Number of Reactors	% of Electricity
	South Korea	25	30%
	Japan	43	28%
	USA	99	20%
	Canada	19	18%
	Russia	36	12%
	China	36	5%

Who is at risk????

FRANCE

72% of electricity from 59 nuclear reactors

Stringent testing in place to ensure

- Safe reactor operation

- Safety of workers

- No environmental contamination

UK

15% of electricity from 15 nuclear reactors

Similar stringent testing in place.

Hinckley Point 'C' cost is now at £37bn!!!!!!

Where do we go from here?

REACH Forwards or Backwards!

REACH Forwards or Backwards



Corrosive



Warning



Env. Hazard

P264 Wash thoroughly after handling

P273 Avoid release to the environment

P280 Wear protective gloves/protective clothing/eye protection/face protection

P305+351+338

IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing

P310 Immediately call a POISON CENTER or doctor/physician

H315 Causes skin irritation

H318 Causes serious eye damage

H412 Harmful to aquatic life with long lasting effects

What does this refer to???

REACH Forwards or Backwards



Corrosive



Warning



Env. Hazard



The pen in your pocket!!!!!!

