



Concawe's approach to classification of petroleum UVCB substances

Enforcement Forum Open session
29 October 2020, teleconference

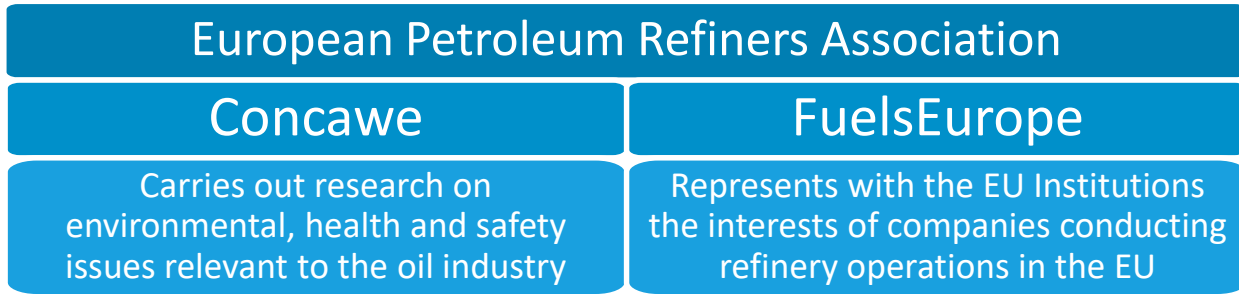
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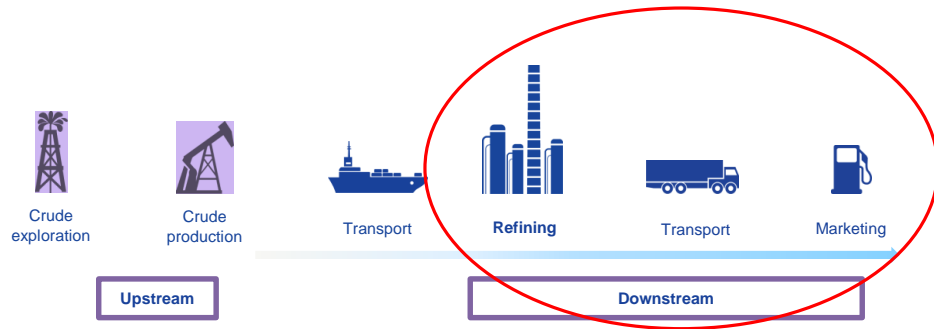
Agenda

- 1 Introduction - who are we?
- 2 Petroleum substances are UVCBs - challenging to regulate
- 3 Concawe's approach to classification of petroleum UVCB substances
- 4 Example 1 (conservative application of bridging principle): Heavy Fuel Oil
- 5 Example 2 (use of marker molecules): Gasoline
- 6 Example 3 (conditional classification, application of classification notes): Base Oils
- 7 Key messages

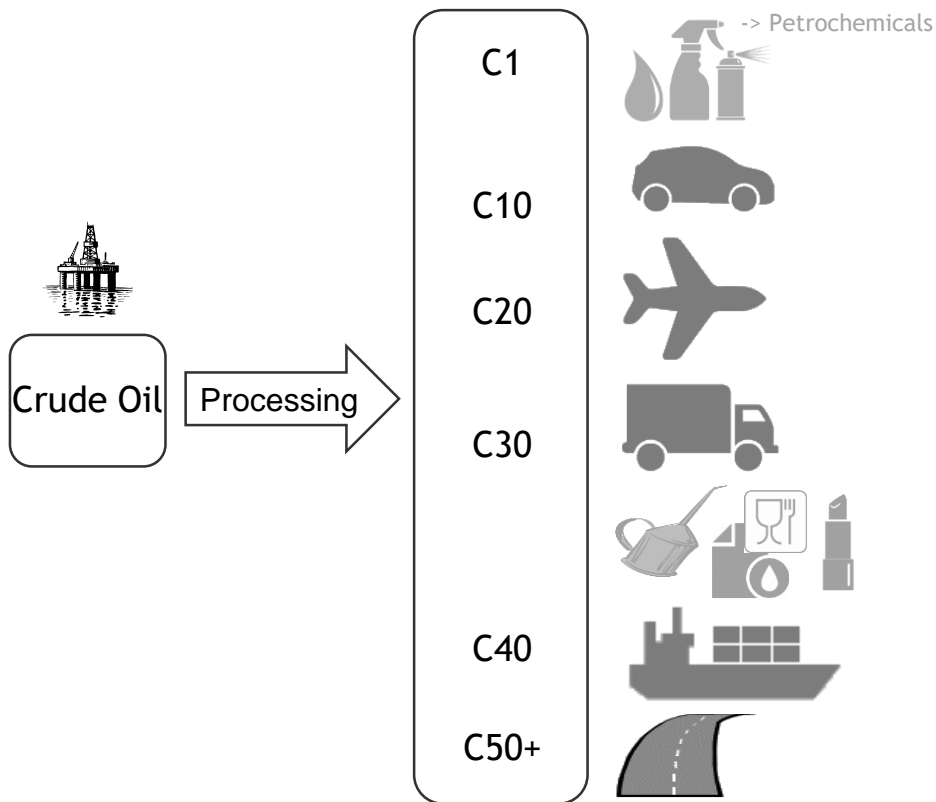
1. Introduction – who are we?



European Petroleum Refiners Association represents 40 Member Companies ≈ 100% of EU Refining



2. Petroleum substances are UVCBs - Challenging to regulate 1(3)



- Around 175 registered petroleum substances across 20 categories
 - About 4,500 registrations
- **Thousands to millions of molecules (isomers) per petroleum substance**
- **UVCB**
 - Unknown or
 - Variable composition,
 - Complex reaction products,
 - Biological materials
- Yearly cycle of comprehensive dossier updates

2. Petroleum substances are UVCBs - Challenging to regulate 2(3)

Petroleum substances are UVCBs

• UVCB

- Unknown or
- Variable composition,
- Complex reaction products,
- Biological materials

- The chemical composition of petroleum UVCBs can never be fully characterized analytically

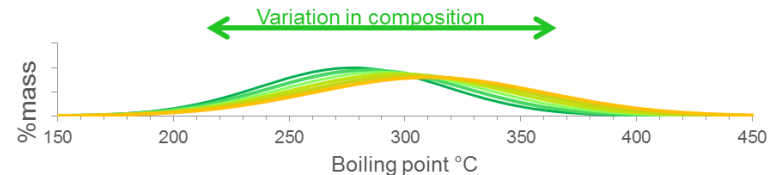
C number	Boiling point (n-alkanes) (°C)	Number of isomers (alkanes only!)
3	-42	1
4	-1	2
5	36	3
6	69	5
7	98	9
8	126	18
10	174	75
15	269	4 347
20	343	366 231
25	402	36 777 419
30	450	4 108 221 447
35	490	493 054 243 760
40	525	62 353 826 654 563

Petroleum substances are UVCBs

• UVCB

- Unknown or
- Variable composition,
- Complex reaction products,
- Biological materials

- Variability is limited to meet product specification

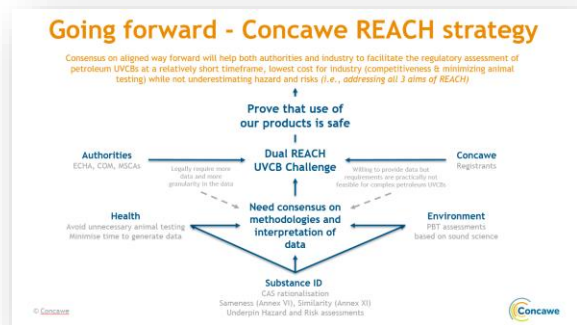


Petroleum substances are UVCBs - Challenging to regulate 3(3)

Follow up from Concawe presentation during last year's Enforcement Forum

- It was concluded that there is a need for consensus on an aligned approach to help both authorities and industry move forward with the regulatory assessment of UVCBs
- Status one year later: data generated, dossiers updated further
 - *some areas (e.g., environment) remain challenging*
 - *progress made in other areas (e.g., analytical, human health assessment), where extensive data has been and is being generated*
- As new data become available, the next step is to update the registration dossier, including review of classification and labelling (C&L)
- Process is not straightforward: again, there are specific challenges to C&L application for UVCBs, which Concawe has addressed in their C&L approach
 - *as published in their recommendations report (next slide)*

Slide taken from last year's Concawe presentation:



3. Concawe's classification and labelling recommendations report

Hazard classification and labelling of petroleum substances in the European Economic Area - 2017 report



CONCAWE report no. 13/17

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4. Example 1: Heavy Fuel Oil Components (HFO)

Worst case classification applied to entire category (bridging principle)

6.11. HEAVY FUEL OIL COMPONENTS (HFO)

Definition / Domain: The domain of this category is defined as streams obtained as either distillates or residues from distillation and cracking processes and containing saturated, aromatic and olefinic hydrocarbons, with carbon numbers >C₈ and boiling point range of 150 to >750°C.

HFO substances are produced using various refinery distillation and cracking processes. The most common components are:

- Long residue: the residue from the atmospheric distillation of crude oil.
- Short residue: the residue from the vacuum distillation of crude oil.
- Thermal cracker or visbreaker residue: the residue from thermal cracking processes.
- Cat cracker slurry oil (clarified oil): a heavy fraction from a catalytic cracking.
- Thermally cracked or visbreaker gas oil: a middle distillate fraction from thermal cracker or visbreaker units.
- Vacuum gas oil: a heavy gas oil fraction (vacuum distillate) from the vacuum column.
- Cat cracker cycle oil: a middle distillate fraction from the catalytic cracking unit.
- Gas oil: a heavier middle distillate fraction from the atmospheric column.

Appendix 1 lists only those HFO substances with active registrations at the time of issuing this report.

Part 1 – Classification Endpoint Rationale / Data Summary

Part 2 – Summary of Classification and Labelling Recommendations

The information below represents the 'worst-case' C&L recommendation and must be used in the absence of information on certain relevant substance characteristics (C&L drivers). Appendix 6 lists all alternative C&L recommendations (C&L permutations).

Classification and labelling according to CLP / GHS

Hazard class	Hazard category	Hazard statement
Acute toxicity - inhalation:	Acute Tox. 4	H332: Harmful if inhaled.
Aspiration hazard:	Asp. Tox. 1	H304: May be fatal if swallowed and enters airways.
Reproductive Toxicity:	Repr. 2 Specific effect: Unborn child	H361d: Suspected of damaging the unborn child.
Carcinogenicity:	Carc. 1B	H350: May cause cancer.
Specific target organ toxicity - repeated exposure:	STOT Rep. Exp. 2 Affected organs: Blood, thymus, liver	H373: May cause damage to blood, thymus and liver through prolonged or repeated exposure.
Hazards to the aquatic environment (acute/short-term):	Aquatic Acute 1	H400: Very toxic to aquatic life (M-Factor =1).
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects (M-Factor =1).

5. Example 2: Low Boiling Point Naphthas (GASOLINES)1(3)

Classification is driven by marker molecules (not intrinsic hazard of full UVCB substance)

Gasoline; EC# 289-220-8

Harmonised C&L (Carc. 1B H350; Muta. 1B H340; Asp. Tox. 1 H304) & Note P (Annex VI CLP)

C&L drivers				Classification	
Benzene ≥ 0.1%w/w	Toluene ≥ 3% w/w	n-hexane ≥ 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility and unborn child H361fd; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility and unborn child H361fd; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility and unborn child H361fd; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
Toluene ≥ 3% w/w	n-hexane < 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: unborn child H361d; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
				Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: unborn child H361d; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: unborn child H361d; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
Toluene < 3% w/w	n-hexane ≥ 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility H361f; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
			Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility H361f; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
			Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility H361f; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
Toluene < 3% w/w	n-hexane < 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
			Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
			Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Muta. 1B H340; Carc. 1B H350; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	

5. Example 2: Low Boiling Point Naphthas (GASOLINES) 2(3)

Classification is driven by marker molecules (not intrinsic hazard of full UVCB substance)

Gasoline; EC# 289-220-8

Harmonised C&L (Carc. 1B H350; Muta. 1B H340; Asp. Tox. 1 H304) & Note P (Annex VI CLP)

C&L drivers				Classification	
Benzene < 0.1%w/w	Toluene ≥ 3% w/w	n-hexane ≥ 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility and unborn child H361fd; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility and unborn child H361fd; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
			Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility and unborn child H361fd; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
	Toluene ≥ 3% w/w	n-hexane < 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: unborn child H361d; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: unborn child H361d; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
			Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: unborn child H361d; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
	Toluene < 3% w/w	n-hexane ≥ 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility H361f; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility H361f; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
			Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; Repr. 2 Specific effect: Fertility H361f; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	
	Toluene < 3% w/w	n-hexane < 3% w/w	Flash point < 23°C	Initial boiling point ≤ 35°C	Flam. Liquid 1 H224; Skin Irrit. 2 H315; Asp. Tox. 1 H304; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
				Initial boiling point > 35°C	Flam. Liquid 2 H225; Skin Irrit. 2 H315; Asp. Tox. 1 H304; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.
			Flash point ≥ 23°C and ≤ 60°C	Flam. Liquid 3 H226; Skin Irrit. 2 H315; Asp. Tox. 1 H304; STOT Single Exp. 3 Affected organs: Central nervous system; Route of exposure: Inhalation H336; Aquatic Chronic 2 H411.	

5. Example 2: Low Boiling Point Naphthas (GASOLINES) 3(3)

Classification is driven by marker molecules (not intrinsic hazard of full UVCB substance)

- Example for permutation 1 (out of 20 possible for EC# 289-220-8)

CLP 01. Naphtha (Benzene \geq 0.1% w/w; Toluene \geq 3% w/w; n-hexane \geq 3% w/w; Flashpoint $<$ 23°C and Initial boiling point \leq 35°C)

Classification and labelling according to CLP / GHS

Hazard class	Hazard category	Hazard statement
Flammable liquids:	Flam. Liquid 1	H224: Extremely flammable liquid and vapour.
Skin corrosion / irritation:	Skin Irrit. 2	H315: Causes skin irritation.
Aspiration hazard:	Asp. Tox. 1	H304: May be fatal if swallowed and enters airways.
Reproductive Toxicity:	Repr. 2 Specific effect: Fertility and unborn child	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Germ cell mutagenicity:	Muta. 1B	H340: May cause genetic defects.
Carcinogenicity:	Carc. 1B	H350: May cause cancer.
Specific target organ toxicity - single exposure:	STOT Single Exp. 3 Affected organs: Central nervous system Route of exposure: Inhalation	H336: May cause drowsiness or dizziness.
Hazards to the aquatic environment (chronic/long-term):	Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.

6. Example 3: Other Lubricant Base Oils (LBO)

Classification is conditional, with the application of CLP / oil industry notes

CLP 4. LBO (IP 346 < 3% w/w; Viscosity > 20.5 mm²/s at 40°C)

The following Oil Industry Note (OIN) has been applied:

- OIN 8 - The classifications as a reproductive toxicant category 2; H361d (Suspected of damaging the unborn child) and specific target organ toxicant category 1; H372 (Causes damage to organs through prolonged or repeated exposure) need not apply if the substance is not classified as carcinogenic.

The following Note has been applied:

- Note L - The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346 "Determination of polycyclic aromatics in unused lubricating base oils and asphaltene free petroleum fractions - Dimethyl sulphoxide extraction refractive index method", Institute of Petroleum, London. This note applies only to certain complex oil-derived substances in Part 3.

Example for Distillates (petroleum), solvent- refined heavy paraffinic; EC# 265-090-8
Harmonised C&L (Carc. 1B H350) & Note L (Annex VI CLP)

C&L drivers		Classification
IP 346 ≥ 3% w/w	Viscosity ≤ 20.5 mm ² /s at 40 °C	Asp. Tox. 1 H304; Repr. 2 Specific effect: Unborn child; Route of exposure: Dermal H361d; Carc. 1B H350; STOT Rep. Exp. 1; Affected organs: Adrenals, bone marrow, liver, lymph nodes, kidney, stomach, thymus; Route of exposure: Dermal H372.
	Viscosity > 20.5 mm ² /s at 40 °C	Repr. 2 Specific effect: Unborn child; Route of exposure: Dermal H361d; Carc. 1B H350; STOT Rep. Exp. 1; Affected organs: Adrenals, bone marrow, liver, lymph nodes, kidney, stomach, thymus; Route of exposure: Dermal H372.
IP 346 < 3% w/w	Viscosity ≤ 20.5 mm ² /s at 40 °C	Asp. Tox. 1 H304;
	Viscosity > 20.5 mm ² /s at 40 °C	Not classified

Key messages

UVCB petroleum substances...

- Have 4500 actively maintained REACH registrations for 170 substances and 20 categories since 2010 and are widely used in consumer, professional and industrial products
- Face specific regulatory challenges in testing and assessment as current legislation is generally made for simple, well defined chemicals
- Are being tested and assessed by Concawe
 - *to increase understanding of their chemical composition and potential effects on human health and environment;*
 - *data are being published, shared with authorities and submitted in registration dossier updates.*
- Are classified and kept up to date based on data available in their registration dossiers
 - *published in [Concawe's classification and labelling recommendations report](#) (2017 version, 2020 version pending for publication).*
- Could aid in overcoming more general issues with the testing, assessment and C&L of complex (UVCB) substances

Hazard classification and labelling of petroleum substances in the European Economic Area - 2017. Concawe report no. 13/17.
https://www.concawe.eu/wp-content/uploads/2017/11/Rpt_17-13.pdf



www.concawe.eu

**Thank you for
your attention**

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