

# Regulatory Compliance for Chemicals on the Global Markets

Sabine Hausmann Head of Global EH&S, FUCHS Petrolub SE

www.atiel.org

### Overview

- (1) Welcome and Introduction
- (2) From Substance to Lubricant
- (3) The Regulatory Landscape



- (4) Regulatory Compliance of Existing and New Chemicals
- (5) Communication in the Supply Chain vs. Protection of CBI
- (6) Outlook and Next Steps

## **Welcome & Introduction**

- The volume of the lubricant market in 2018 reached nearly 30 Mio. Tons globally
- The Automotive Industry is the most important customer
- Global availability of the products is mandatory
- Global Regulatory Compliance is of vital importance



## **Welcome & Introduction**

- Chemical Products are subject to numerous Regulatory Requirements
- The Regulatory Landscape for Chemicals is rapidly changing
- To ensure Global Regulatory Compliance for Chemicals Products has become quite complex
- Communication of regulatory information within the supply chain has become very important



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## **Welcome & Introduction**

We would like to improve the communication in our supply chain and the mutual understanding of the different requirements.

Therefore we would like to invite you to an open discussion on

- what needs to be improved and
- how can we achieve it



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# **From Substance to Lubricant**





- A finished lubricant is a formulation of various additive packages in a base fluid
  - Mineral Oil
  - Synthetic Oil
- Typical Additives are:
  - Antioxidants
  - Viscosity Modifiers
  - Pourpoint Depressants
  - Detergents / Dispersants
  - Antiwear and Extreme Pressure Additives
  - Friction Modifiers
  - Corrosion Inhibitors
- It can easily contain >3 different additives and >15 substances



- Chemical Inventories and Registration Schemes for Chemicals are Substance related
- In general, the Manufacturer of a Substance registers the substance in the relevant inventories
- To protect companies Intellectual Property, the complete composition of an Additive is typically <u>not disclosed</u> to the Formulator of a Lubricant
- In general, Lubricant Manufacturers collect regulatory information on Additive Level, in exceptional cases on substance level

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# **The Regulatory Landscape**



#### **Important Regulatory Requirements**





#### The Global Harmonized System (GHS)

- In 1992 the UN Conference on Environment and Development (UNCED) agreed upon the Agenda 21
- Chapter 19 is dealing with the Management of Toxic Chemicals and contains 6 Program Areas:
  - (a) Expanding and accelerating international assessment of chemical risks;
  - (b) Harmonization of classification and labelling of chemicals;
  - (c) Information exchange on toxic chemicals and chemical risks;
  - (d) Establishment of risk reduction programs;
  - (e) Strengthening of national capabilities and capacities for management of chemicals;
  - (f) Prevention of illegal international traffic in toxic and dangerous products
- This was the political mandate for the development of GHS



#### The Global Harmonized System (GHS)

- The GHS only is a recommendation
- Needs to be adopted into the national or regional legislation
- When adopting GHS, countries also often establish a Chemical Inventory
- Or existing Chemical Inventories are being revised
- That is the reason, why we see so many new Inventories and new legal requirements coming up



#### **GHS and Inventories – current Status**



# **Regulatory Compliance of Existing and New Chemicals**

## **Chemical Inventories**

- The different Inventories were established at different times – some were established > 40 years ago
- The requirements / definitions of the different inventories are quite different
- It is possible that the same substance has been registered under different names / identifiers in the different inventories

ENCS (Japan)	established in 1973
TSCA (USA)	established in 1976
EINECS (EU)	established in 1981
ELINCS (EU)	established in 1981
NLP (EU)	established in 1993
NICNAS (Australia)	established in 1990
DSL / NDSL (Canada)	established in 1991
KECI (Korea)	established in 1991
PICCS (Philippines)	established in 1998
NZIoC (New Zealand)	established in 2001
IECSC (China)	established in 2012
TSCI (Taiwan)	established in 2014



#### **Same Substance – different Identifiers**

- Under EU REACH many substances were registered under new identifiers
- In other Inventories the old CAS-No is still in use:

C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2- 25%)	927-344-2	$\rightarrow$	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy
C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2- 25%)	919-164-8	$\rightarrow$	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy
C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C8-12, n-alkanes, isoalkanes, cyclics, aromatics (2- 25%)	928-136-4	$\rightarrow$	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy; Low boiling point hydrogen treated naphtha
C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2- 25%)	919-446-0	$\rightarrow$	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy
			→	64742-88-7	Solvent naphtha (petroleum), medium aliphatic

#### Same Substance – different Identifiers Example: Lithium 12-Hydroxystearate (Grease Thickener)

- Greases are oils, contained in a "chemical sponge"
- The "chemical sponge" is formed by a metal soap of fatty acid which acts as a dispersant (Grease Thickener)
- The Thickener is typically manufactured in-situ during the manufacturing process





#### Same Substance – different Identifiers Example: Lithium 12-Hydroxystearate (Grease Thickener)

**Starting Materials of the reaction:** 





Li-Hydroxide

#### Hydrogenated Castor Oil (HCO; CAS: 8001-78-3)

Triglyceride – Ester of Glycerol with the saturated, hydroxylated 12-hydroxy, 9-octadecanoic acid, known as 12-Hydroxystearic acid

OR

12-Hydroxystearic acid (12-HSA; CAS: 106-14-9)



## Same Substance – different Identifiers Example: Lithium 12-Hydroxystearate (Grease Thickener)

Saponification Reaction:

 $3 \times \text{LiOH} + 1 \times \text{HCO} = 3 \times \text{Lithium} - 12 - \text{HS} + \text{Glycerol}$ 

 $1 \times \text{LiOH} + 1 \times 12 \text{-HSA} = 1 \times \text{Lithium} - 12 \text{-HS} + H_2O$ 

Water and Glycerol evaporate, due to high temperatures. De described as: rate (CAS: 7620-77-1)

The Reaction Product can be described as:

- Lithium 12-Hydroxystearate (CAS: 7620-77-1)
- Castor Oil, hydrogenated, lithium salt (CAS: 64754-95-6)
- Fatty acids, castor-oil, hydrogenated, lithium salts (CAS: 68604-46-6)

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## **New Substance Notifications**

- Definitions of "New Substance" can be different from Inventory to Inventory
- Multiple ways to be compliant, beyond inventory listing
- Substance definitions are quite different; under EU REACH we know:
  - Mono-Constituent Substances
  - Multi-Constituent Substances
  - UVCB Substance
  - Polymers
- Multi-Constituents and UVCB Substances in some Inventories not defined
- Polymer requirements can vary



## **New Substance Notification – Example China**



#### **Differences in**

- Notification Requirements
- Notification Thresholds
- Data Requirements
- Testing requirements

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## **New Substance Notifications**

- In China and Japan a new substance is listed 5 year after notification
- During this time only the notifier is allowed to manufacture or import
- This right cannot be transferred in the supply chain

If the additive manufacturer holds a New Substance Notification, then

every importing legal entity needs to submit a secondary notification for the same substance!

# Communication in the Supply Chain vs. Protection of CBI



## **Communication in the Supply Chain**

- Communication within the supply chain is very important
- What is really needed, what is nice to have?
- Maintaining Confidential Business information (CBI) through-out the supply chain.



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# **Outlook and Next Steps**

## **Outlook and Next Steps**

- This was just a short overview of the most important topics
- The following presentations will provide more details on the impacts
- Let's discuss how we can get the regulatory "Monster" under control
- And have globally compliant products on the market!



