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UVCB substances and SID



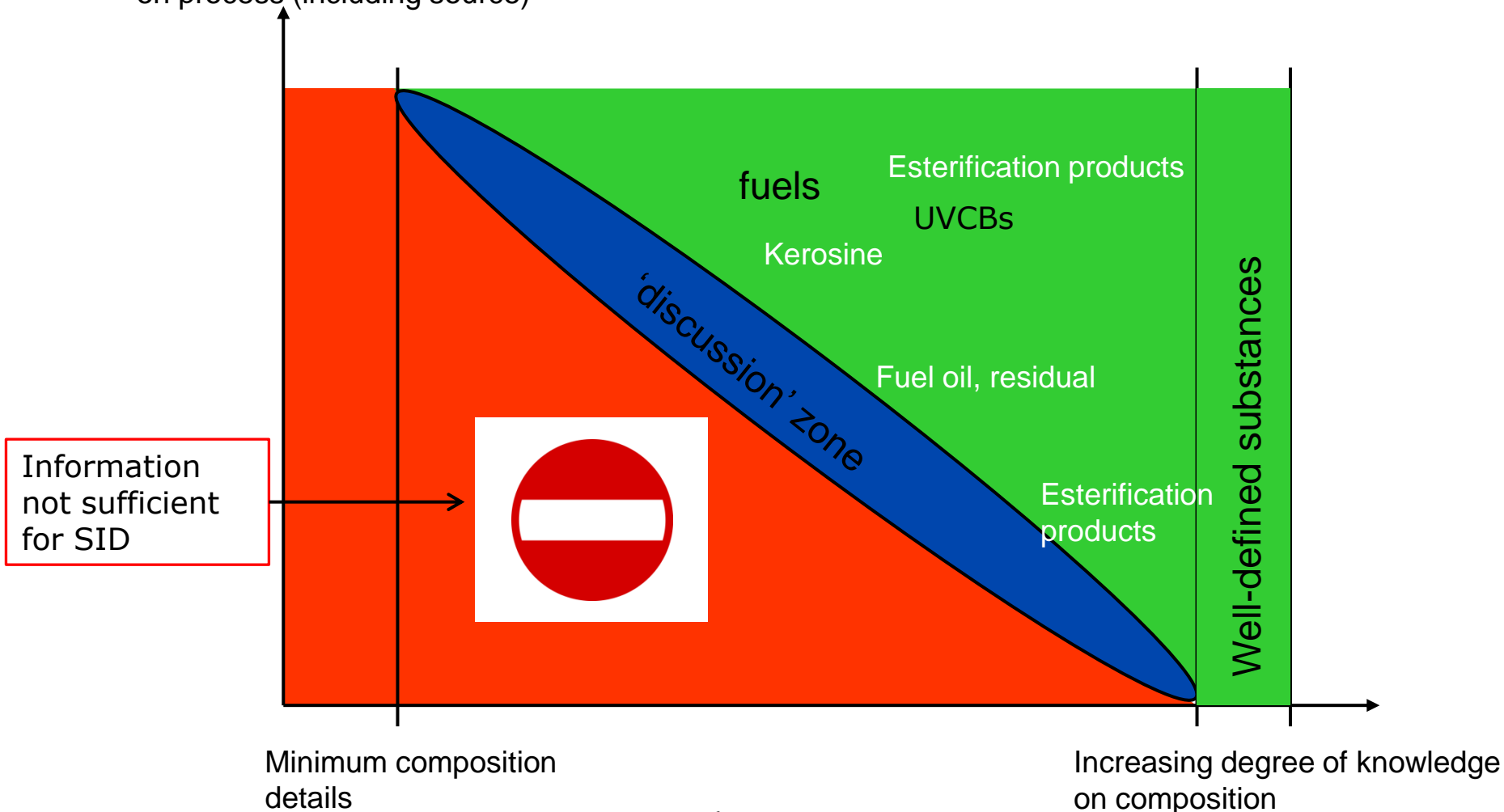
UVCB substances

- Main identifiers for various types of UVCB substances are related to:
 - Source of the substance and
 - Process used for obtaining the substance (e.g. reaction type).
- Significant change of source or process would lead to a different substance.
- The requirements for substance identification as described in Annex VI (2) to REACH apply also to UVCB substances. Analytical information has to be provided.

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Why is manufacturing process important?

Increasing degree of knowledge
on process (including source)



Common SID challenges for UVCBs – manufacturing process

- Manufacturing process needs to include information on:
 - starting materials and their ratios
 - reaction type(s) (e.g. esterification, alkylation...)
 - processing steps (e.g. reaction, extraction, distillation...),
 - processing parameters (e.g. temperature and pressure)
- If EINECS includes a description of the substance ensure that the provided process description/information on constituents is in line with this information

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Common SID challenges for UVCBs - composition

- Not enough to describe the composition as "100% my substance"
- Composition needs to include
 - known constituents irrespective of their concentration
 - constituents/groups of constituents in line with the chemical species in the substance identified as far as possible; generic groups of constituents can be reported (e.g. linear alkanes C7-C12, mono-aromatic hydrocarbons)
 - typical concentrations and realistic concentration ranges specific for your substance
- If several grades are covered, it is recommended to report the grades as different composition blocks instead of one generic composition

Common SID challenges for UVCBs – analytical information

- General REACH requirements of Annex VI(2) for analytical information apply also to UVCB substances – if something is not included justification needs to be added
- Included analytical information needs to be sufficient to identify and quantify the constituents included in section 1.2
 - Any additional information that is necessary to demonstrate this is recommended to be included (e.g. other analytical methods, reaction mechanisms, theoretical calculations...)

UVCB examples – manufacturing process

1. An aqueous solution (...%) of A is acidified by addition of acid X in a 1:1 molar ratio to form B at temperature T_1 .
2. This solution is then reacted with C, which is dissolved in solvent Y, in a 1:2 molar ratio.
3. This 2-phase reaction forms the substance D, dissolved in solvent Y.
4. The aqueous layer is separated and disposed of.
5. The substance D is purified by distillation at pressure p_1 and temperature range T_2 - T_3 .

UVCB examples – composition

- A hydrocarbon-based UVCB substance has been analysed and contains > 50 constituents of which none are > 10 % in the chromatogram. The company has generically presented the composition as follows:
 - Linear alkanes (C20-C32) 60-80 % w/w
 - Branched alkanes (C20-C25) 20-35 w/w
 - Cyclic alkanes (C20-C25) 0-5 % w/w

UVCB examples – waiving of spectral data

- A company produces a crystalline inorganic UVCB substance.
- The company considers that the list of spectral data in Annex VI 2.3.5 is not the best way to identify the substance but instead applies elemental analysis (XRF) as well as XRD and IR spectral analyses.
- These analyses characterise the substance.
- In addition the company waives NMR and UV spectral analysis based on the substance structure and the fact that more appropriate techniques have been applied instead.

Tools and further resources

- IUCLID tools
 - Technical completeness check plug-in
 - Dossier quality assistant: TCC plug-in 5.4.3 containing the Dossier Quality Assistant was released on 11/02/2013 – addresses shortcomings in SID
 - Recommended to be used to identify SID deficiencies before ECHA carries out automatic screening (end of 2013)
- Resources on the ECHA webpages
 - Guidance documents
 - Q&A documents
 - Data submission manuals
 - Webinars on SID
 - List available at the end of the presentation

Key messages

- Correct substance identification is the first step in all REACH processes
- Ensure that the information in your dossier is
 - Specific for your substance
 - Complete regarding the information requirements
 - Sufficient to identify your substance
 - Clear and consistent
- Check your dossier in advance with the available tools
- Visit the ECHA webpages for more information