



International Association for Soaps,
Detergents and Maintenance Products

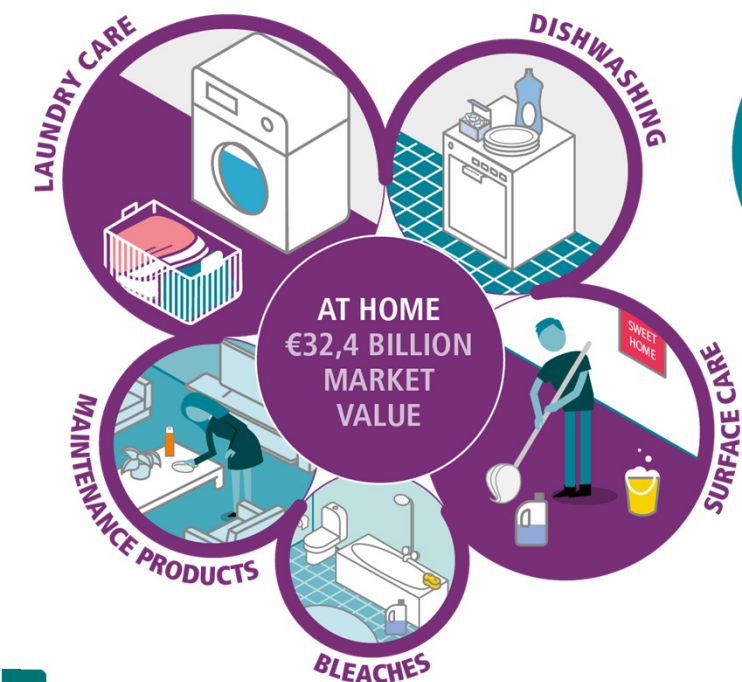
IMPACTS OF A MAF – CASE STUDY FROM THE DETERGENTS SECTOR (A.I.S.E.)



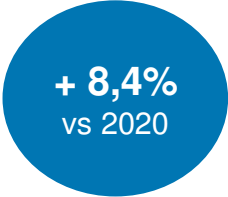
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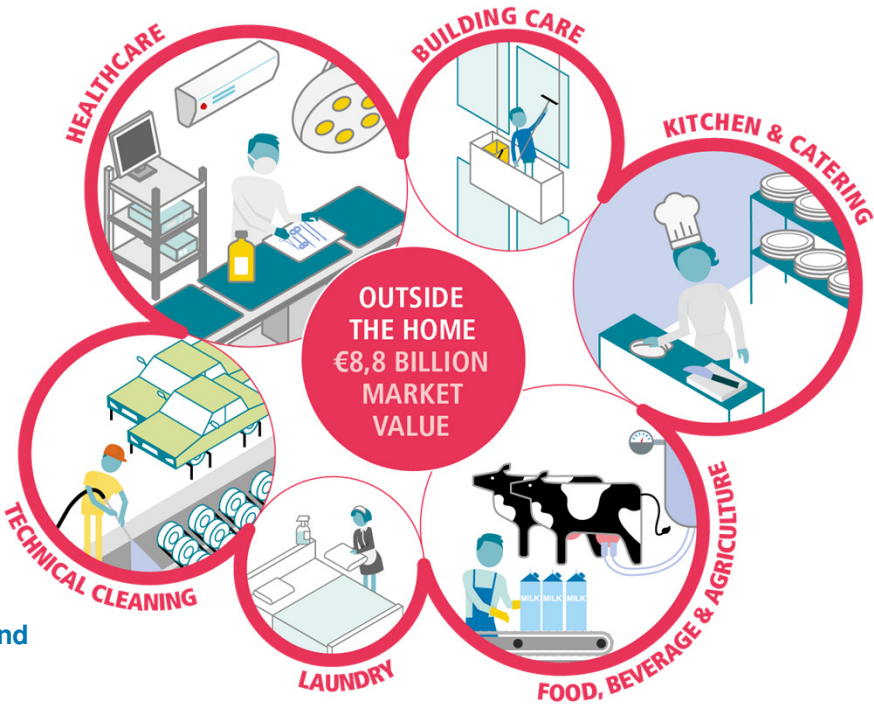
HOUSEHOLD & PROFESSIONAL/I&I DETERGENT AND MAINTENANCE PRODUCTS



HOUSEHOLD



Including **disinfectants/hand disinfectants** (Biocides)
= Key against COVID-19



PROFESSIONAL

WHAT IS OUR OVERALL AIM?

Protection of health and environment

- Place safe products on the market
- Drive resources of EU industry towards achieving the objectives on the green deal
- Proportionality on animal testing
- Potential “elevated mixture risks” (KEMI report 2021)



A.I.S.E. COMMENTS ON THE MAF

Case Studies:

- Surfactant Example - LAS 
- Enzymes
- Preservatives
- NaOH

*What are the chances of ending up in an unintended mixture?
Can they contribute to unintended mixture toxicity (Env & HH)?
What would the impact of a blanket MAF be?*

- Alternatives to a blanket MAF

CASE STUDY LINEAR ALKYL BENZENE SULPHONATE (LAS, CAS NO. 68411-30-3)

- *Surfactants*: key ingredients in detergent and maintenance products.
 - Change the surface tension of water to assist cleansing, wetting surfaces, foaming, and emulsifying, to remove particles of dirt and soil.
- LAS is an anionic surfactant. Introduced in 1964 as the readily biodegradable replacement for highly branched alkylbenzene sulphonates (ABS).
 - Most widely used surfactant in laundry detergents and cleaning products worldwide because of its excellent cleaning properties.



LAS - LITERATURE - ENVIRONMENT

- Detergent Regulation (EC) 648/2004 biodegradability requirements: surfactants do not lend themselves to combined exposures following release into the environment
 - *Very low chance of ending up in unintended mixture*
- LAS has a nonspecific mode of action described as “narcosis toxicity” (Roberts 1991; Fendinger *et al.*, 1994) and does not dominate mixture toxicity.



LAS - LITERATURE – HUMAN HEALTH

- Potential health hazards of LAS have been well characterized to include systemic endpoints such as; oral, inhalation and dermal endpoints (ECHA, 2021 (Registration Dossier - ECHA (europa.eu)).
- ECHA, 2021 derived a Derived No Effect-Level (DNEL) value of 0.425 mg/kg bw/day for LAS based on a repeated dose sub-chronic oral toxicity study
- Considering this substance will not be used in products where oral exposure is anticipated (via ingestion), there are no combined exposure effects anticipated where LAS products are concerned (ECHA, 2021).



Conclusion

No indication that LAS can contribute to the problem of unintended mixture toxicity: MAF is not scientifically reasonable for this substance.

What if a blanket MAF was applied anyway?



IMPACTS OF A BLANKET APPROACH ON LAS

Used the most recent Chemical Safety Assessment from the LAS suppliers

Applied a MAF of 10

CSR for LAS RCRs >0.1 for many uses for workers, consumers and environment

$$RCR > 0.1 \quad \times 10 = \quad RCR > 1$$



IMPACTS OF A BLANKET APPROACH ON LAS

Result ?

- Calculated unacceptable risk for the environment for several uses of LAS in professional products
- Calculated unacceptable risk for consumer safety for many consumer uses



IMPACTS OF A BLANKET APPROACH ON LAS

Can the MAF of 10 be mitigated?

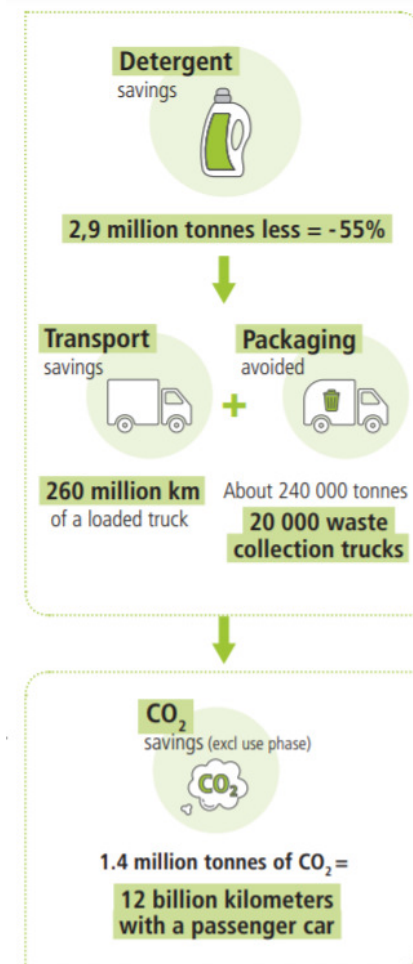
- Performing an assessment with a different (higher tier) modelling tool would not lead to a different outcome
 - *A.I.S.E. Use Maps already contribute to most realistic worst-case assessment*
- Introducing additional risk management measures (RMM) not possible in practice.
- Lowering concentration would impact product effectiveness and sustainability



IMPACTS OF A BLANKET APPROACH ON LAS

Removing products containing LAS from the market

- LAS is a crucial ingredient in formulation for other benefits like water saving, heat/energy saving → **compaction** (i.e. concentrated products that use less water and packaging)
- Negative effects on sustainability in other case studies as well, e.g. enzymes (washing at lower temperatures)
- Similar results expected for many other substances used in our industry sector



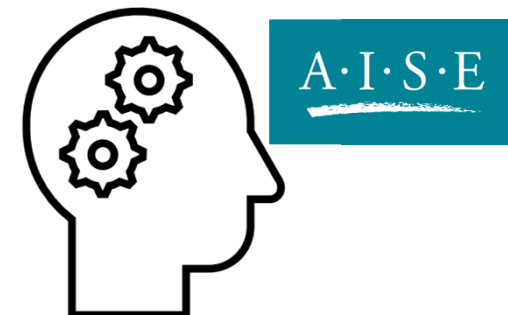
ALTERNATIVES TO A BLANKET VALUE

The A.I.S.E. exercise presented some learnings

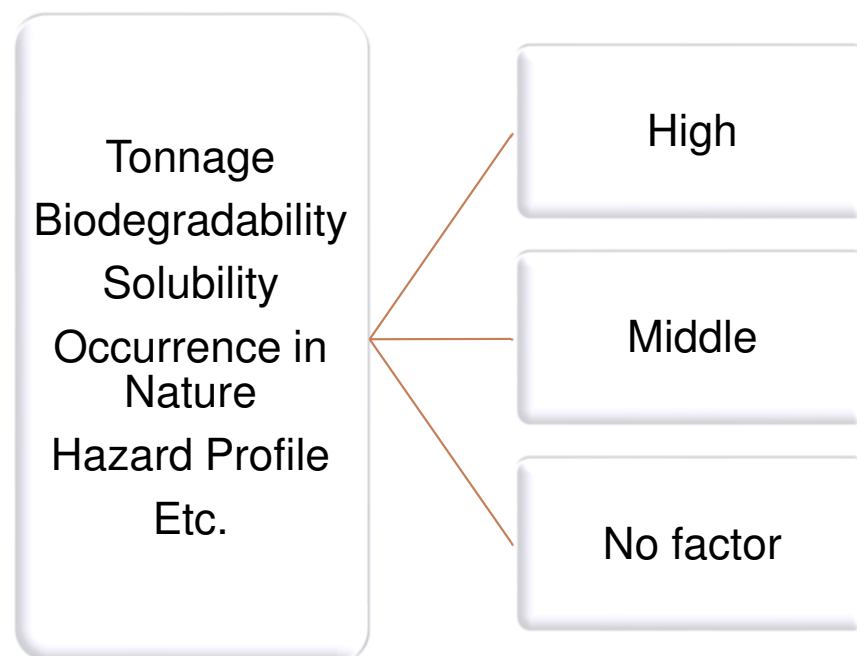
- Blanket MAF can have big, disproportionate negative impacts
- A.I.S.E. paper presents some alternatives
 - *Example of decision tree logic*



ALTERNATIVES TO A BLANKET VALUE



Consider criteria to identify specific substances where an additional assessment to consider combined exposure may be considered. **This should consider also criteria for exclusion.**

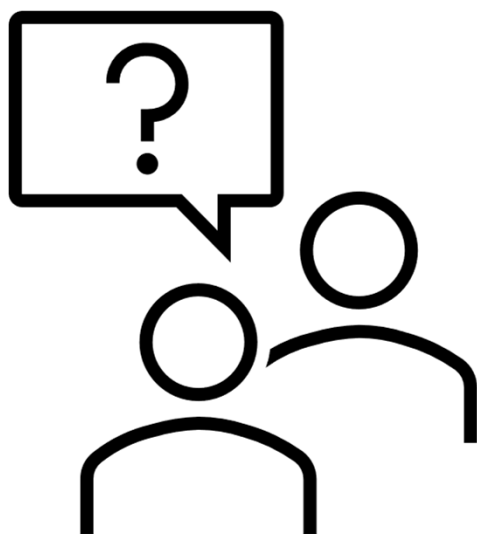


KEY MESSAGES

1. The introduction of a blanket MAF will bring significant impacts on products being placed on the market, while case studies suggest that this introduction is not proportional for many substances.
2. A blanket MAF can have a negative impact from sustainability perspective
3. These impacts can rarely be mitigated by Downstream Users
4. Ask for resources to be targeted towards what matters and driven to the objectives of the green deal.
5. Focus MAF only on those substances that actually contribute to the potential issue of combined exposure to unintended mixtures



QUESTIONS



REFERENCES

- KEMI, Swedish Chemicals Agency. Improving the regulatory assessment of combination effects: steps towards implementing the mixture assessment factor (MAF) in chemical regulation. <https://www.kemi.se/download/18.663e01517a129aa97f5cd/1624266627992/PM%208-21-Improving-the%20regulatory-assessment-of-combination-effects-steps-towards-implementing-the-mixture-assessment-factor-MAF-in-chemical-regulation.pdf>
- Roberts D. 1991. QSAR issues in aquatic toxicity of surfactants. *Sci Total Environ* 109/110: 557-568.
- Fendinger NJ, Versteeg DJ, Weeg E, Dyer SD, Rapaport RA. 1994. Environmental behavior and Fate of anionic surfactants. In: Baker LA (ed), *Environmental Chemistry of Lakes and Reservoirs*, ACS Advances in Chemistry Series No. 237. American Chemical Society, Washington, DC, p 528.
- McDonough K, Casteel K, Itrich N, Menzies J, Belanger S, Wehmeyer K, Federle T. 2016. Evaluation of anionic surfactant concentrations in US effluents and probabilistic determination of their combined ecological risk in mixing zones. *Sci Total Environ* 572:434–441.
- Holmes CM, Maltby L, Sweeney P, Thorbek P, Otte JC, Marshall, S. 2021a. Increasing Ecological Relevance of Chemical Risk Assessments using Geospatial Approaches: Results from Two Case Studies. SETAC Europe Meeting 2021, Platform presentation 4.05.10; abstract available: <https://www.ecetoc.org/taskforce/geospatial-approaches-increasing-ecological-relevance-chemical-risk-assessments/>
- Holmes CM, Marshall, S., Otte JC, Sweeney P, Thorbek P. 2021b. Surfactant case study: Increasing the ecological relevance of chemical risk assessments using geospatial approaches. SETAC Europe 31st Annual Meeting, Poster presentation 4.05.09; abstract available: <https://www.ecetoc.org/taskforce/geospatial-approaches-increasing-ecological-relevance-chemical-risk-assessments/>
- ECHA LAS registration dossier: <https://echa.europa.eu/registration-dossier/-/registered-dossier/15879/7/6/2>
- EFSA Scientific Committee, More, SJ, Bampidis, et. al. C, 2019. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. *EFSA Journal* 2019;17(3):5634, 77 pp. <https://doi.org/10.2903/j.efsa.2019.5634>
- Tralau, T., Oelgeschläger, M, Kugler, J., et al. A prospective whole-mixture approach to assess risk of the food and chemical exposome. *Nature Food* Vol 2, 463-468 (2021)