Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

SCEDs
Specific Consumer Exposure Determinants

Namali Corea – SC Johnson / A.I.S.E.
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SCEDs

- Overview of the SCEDs
- Purpose & development of the SCEDs
- The SCEDs within ECETOC TRA
- Case study

SCEDs – General overview

- Sets of **habits and practices data** (e.g. in REACH terminology Operational Conditions for consumers)
  - Cover a range of **consumer products**
  - Documented in factsheets
- Provide **more realistic exposure estimates** (compared with default estimates from the ECETOC TRA).
- **Harmonised source** consumer exposure information for communication.
- Are intended to be **used directly in ECETOC TRA and CHESAR** for refined exposure estimation (similar to SPERCs).

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Why SCEDs?

- Tier 1 consumer estimates in ECETOC TRA v2 and v3
  - **very conservative** which limits its usefulness.
- Consumer exposure estimates for specific subcategories in ECETOC TRA v3 are new
  - Allow for **more flexibility** via refined assessment.
  - Flexibility may reduce **harmonization**
- SCEDs provide harmonised sets of parameters for ECETOC TRA v3 refined assessments
  - Support harmonised communication of consumer exposure data

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SCEDs- Expected benefits/improvements

- Better consumer exposure scenarios for downstream users
  - Benefits both registrants and DUs by **avoiding any unnecessary communication of RMM or OC** within affected supply chains.
- More certainty on safe use
  - By using the SCEDs it is also more likely that safe use can be demonstrated, i.e. RCR<1.
- Easiness of Chemical Safety Assessment
  - Refined exposure estimates without having to use more complex, higher tier models.
- Standardisation and harmonisation of communication in the supply chain
  - The SCEDs will also serve to standardise and harmonise such communications, resulting in efficiency gains in supplier/DU dialogue.

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SCEDs – How were they developed?

- Joint activity by several sectors – coordinated by **DUCC** with the participation of **CONCAWE**.

DUCC = platform for associations whose member companies use chemicals to formulate mixtures as finished products for end users (including consumers and professional users).

DUCC focuses on DU needs, rights, duties and specificities under REACH and CLP.

Downstream Users of Chemicals Co-ordination group

Activity of DUCC members

A.I.S.E./FEA, FEICA and CEPE created SCEDs. EFCC is evaluating whether additional SCEDs are needed for other families of products used in construction.

✓**A.I.S.E./FEA** uses HERA tables of habits and practices as a basis, plus information from published literature and higher Tier exposure models.

✓**CEPE** has used the draft indoor air/paint emissions standard prEN 16402 and the RIVM Paint Products Fact Sheet as sources for its determinants.

✓For **FEICA**, modified values have also been taken from RIVM Fact Sheets.

One common format for displaying key exposure determinants.

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The A.I.S.E. SCEDs – An Overview

AISE Category	SCEDs
LAUNDRY PRODUCTS	Laundry products (regular & compact)
	Fabric conditioners (regular & compact)
	Laundry additives, e.g. Bleach (specific)
	Water softener (specific)
	Laundry aids, e.g. Ironing aids (specific)
CLEANERS	All-purpose cleaners (non spray)
	All-purpose cleaners (spray)
	Hand dishwash
	Autodishwash
AIR FRESHENERS	Air fresheners
POLISHES & WAXES	Polishes and waxes

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23 August 2012 – Version 1

A.I.S.E. Specific Consumer Exposure Determinants ("SCEDS")

Blue text denotes refinements beyond the capabilities of ECETOC TRA version3 "Add Subcategories tab". These data can be used manually in the TRA[1] or in higher tier tools.

Exposure Descriptor or Determinant	Value	Justification
Use description	**Surface cleaner – non-spray application**	
Product/Article Use Category	PC35 – Washing and cleaning products	**A.I.S.E. use mapping table:** C7: SURFACE CLEANERS (powder, liquid, gel net) for consumer use – Not including spray
PC/AC Subcategory	2 subcategories	Powder (solid) Liquid, gel (non spray application)
Product Ingredient Fraction (by weight) – This is substance specific information and should be adjusted on a case by case basis	Powder (including tablet) : 0.9g/g Liquid:0.1g/g	Default generic maximum concentration of any ingredient (substance) in a surface cleaner product. Source: www.cleanright.eu This is a default generic value to be used only in absence of specific substance and product data
Frequency of Use (events/day , and for an infrequently used product also provide days/year)	1 time per day	A.I.S.E. H&P[2]: 2 events/week Unchanged from TRA default value
Relevant Route(s) of Exposure	Dermal Inhalation (optional). Can be considered for solvents and perfumes)	Oral exposure is not considered relevant because its contribution to total exposure will be minimal (based on REACT & HERA[3]) Inhalation exposure is expected to be minimal when compared to dermal exposure estimated by ECETOC TRA (given the exaggerated assumptions used). If desired, for solvents and perfumes estimation of inhalation exposure can be done using higher tier models such as ConsExpo.

[1] In this document TRA is referring to ECETOC TRA version 3 available under http://www.ecetoc.org/tra
[2] A.I.S.E. habits and practices tables available under http://www.aise.eu/reach/?page=exposureass_sub3
[3] Van de Plassche et al. (1998). Moret Ernst & Young Management Consultants, Second Draft, Rep.No. 601503 013, Nov. 1998 1-64.

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A.I.S.E. SCEDs – What do they look like?

23 August 2012 – Version 1

Dermal Specific Parameters		
Skin Contact Area	857.5cm²: hands	Unchanged from TRA default value
Skin Transfer Factor	1	Unchanged from TRA default value
Inhalation Specific Parameters		
Amount of Product used per application (g)	110	Taken as maximum level from AISE Habits and Practices table developed by AISE within the HERA project (2002) – updated 2009
Exposure Time (hr)	0.3	Unchanged from ECETOC TRA
Room Volume (m³)	20	Unchanged from TRA default value
Is product used outdoors only?	No	/
Ventilation specified or likely due to properties (i.e., odour, etc.)- if so what type – (open window, fan)	0.6 ACH	Unchanged from TRA default value
Oral Specific Parameters		
Volume Ingested (cm3)	n/a	Oral route is not considered relevant for this use
Oral Transfer Factor	n/a	Oral route is not considered relevant for this use
Sector/organisation with responsibility for the sheet	A.I.S.E.	Jay Ingram (Unilever), Sophie Mathieu (sophie.mathieu@aise.eu)

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How to use the SCEDs in ECETOC TRA v3

- Not to change the underlying **algorithms** in the TRA v3.
- The SCEDS **provide data** (exposure parameters) that can be used for consumer exposure assessment.
- ECETOC TRA v3 allows more **effective iteration of the exposure assessment**.
- The SCEDs values can be inserted into the **"Add subcategory" tab** in the TRA v3.

The data from the SCEDs can be used beyond ECETOC TRA, i.e. in other higher Tier exposure estimation tools.

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ECETOC TRA – Add subcategories (1/2)

CLICK TO ADD BLANK ROWS (Added rows cannot be deleted but		Only for PC		ROUTES OF EXPOSURE c = child, a = adult LEAVE BLANK if exposure pathway not relevant			ALL Enter value <1	DERMAL		ADULT	CHILD
Select from drop down	Free Text	Default is non-spray	Default is non-solid								
Descriptor	Product Subcategory	Product is a spray	Product is a solid	Dermal	Oral	Inh	Product Ingredient Fraction by Weight	Default = 1 (100%) TF dermal	Select body part exposed	Skin Contact Area (cm^2)	Skin Contact Area (cm^2)
PC35: Washing and cleaning products (including solvent based products)	C7: SURFACE CLEANERS - Liquid cleaning product for manual application	No	No	a	a		0,1		3: hands	857,5	
PC35: Washing and cleaning products (including solvent based products)	C7: SURFACE CLEANERS - Abrasive product for manual surface application	No	Yes	a	a		0,05		3: hands	857,5	
PC35: Washing and cleaning products (including solvent based products)	C7: SURFACE CLEANERS - Abrasive product for manual surface application	No	No	a	a		0,05		3: hands	857,5	
PC35: Washing and cleaning products (including solvent based products)	C7: SURFACE CLEANERS - Carpet cleaners	No	No	a	a		0,3		3: hands	857,5	

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ECETOC TRA – Add subcategories (2/2)

ORAL				DERMAL/ORAL	INHALATION			
		ADULT	CHILD					
Default = 1 (100%) TF oral	Select surface area mouthed	Contact Area (cm^2)	Contact Area (cm^2)	FreQ of Use (events/day)	Amount Product used per Application (g/event)	Exposure Time (hr)	FreQ of Use (events/day)	COMMENTS (Enter your ju
				1	110	0,3	1	
				1	110	0,3	1	
				1	110	0,3	1	
				1	110	0,3	1	

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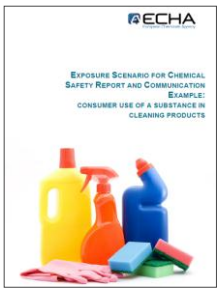
A.I.S.E. case study – Use of SCEDs

- Based on example jointly developed with ECHA for a widely used alcohol as a component in cleaning products (PC35): http://echa.europa.eu/documents/10162/13564/es_for_consumer_20110829_en.pdf



- In their document, ECHA made use of ConsExpo for all surface cleaners as ECETOC TRAv2 estimations were too conservative.
- Hazard data for the substance and the exposure scenario from the ECHA document were used in the following exercise.

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A.I.S.E. case study

Results of assessment using "product subcategory" of ECETOC TRA v3:

Laundry and dish washing products	Detergent liquids ; laundry products; Hand dishwashing liquids; Machine dishwashing products ; rinse aids	✓ Use assessed as safe
Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners)	All-purpose cleaners; Abrasive liquids; Floor cleaners; Carpet cleaners; Glass cleaners	X Use assessed as unsafe
Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)	All-purpose cleaners- sprays, Glass cleaners - sprays	✓ Use assessed as safe

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Results of the calculations with and without SCEDs

Summary of Results for Consumer Product Exposure (By Product Subcategory)

	Descriptor	Product Subcategory	Dermal Exposure Estimate (mg/kg/day)	Dermal Risk Characterisation Ratio	Oral Exposure Estimate (mg/kg/day)	Oral Risk Characterisation Ratio	Inhalation Exposure Estimate (mg/kg/day)	Inhalation Exposure Estimate (mg/m³)	Inhalation Risk Characterisation Ratio	Worst-case Exposure Scenario	Combined Risk Characterisation Ratio
	PC35: Washing and cleaning products (including solvent based products)	Laundry and dish washing products	2,14E+01	1,04E-01			5,35E+00	2,34E+02	2,47E-01	Adult	3,51E-01
		Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners)	4,29E+01	2,08E-01			2,36E+01	3,13E+03	3,29E+00	Adult	3,50E+00
		Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)	2,14E+01	1,04E-01			7,06E+00	7,72E+01	8,13E-02	Adult	1,85E-01
	NEW SUBCATEGORIES									NOT APPLICABLE	
1											
2	PC35: Washing and cleaning products	C7: SURFACE CLEANERS - Liquid cleaning product for man	1,43E+01	6,94E-02			3,19E+00	4,66E+02	4,91E-01		5,60E-01
3	PC35: Washing and cleaning products	C7: SURFACE CLEANERS - Abrasive product for manual sur	7,15E-01	3,47E-03			1,60E+00	2,33E+02	2,45E-01		2,49E-01
4	PC35: Washing and cleaning products	C7: SURFACE CLEANERS - Abrasive product for manual sur	7,15E+00	3,47E-02			1,60E+00	2,33E+02	2,45E-01		2,80E-01
5	PC35: Washing and cleaning products	C7: SURFACE CLEANERS - Carpet cleaners	4,29E+01	2,08E-01			9,58E+00	1,40E+03	1,47E+00		1,68E+00

SCEDs

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Results of the calculations -Summary table

Product Subcategory	Dermal Exposure Estimate (mg/kg/day)	Dermal Risk Characterisation Ratio	Inhalation Exposure Estimate (mg/m^3)	Inhalation Risk Characterisation Ratio	Combined Risk Characterisation Ratio
Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners)	4,29E+01	2,08E-01	3,13E+03	3,29E+00	3,50E+00
C7: SURFACE CLEANERS - Liquid cleaning product for manual application	1,43E+01	6,94E-02	4,66E+02	4,91E-01	5,60E-01
C7: SURFACE CLEANERS - Abrasive product for manual surface application	7,15E-01	3,47E-03	2,33E+02	2,45E-01	2,49E-01
C7: SURFACE CLEANERS - Abrasive product for manual surface application	7,15E+00	3,47E-02	2,33E+02	2,45E-01	2,80E-01
C7: SURFACE CLEANERS - Carpet cleaners	4,29E+01	2,08E-01	1,40E+03	1,47E+00	1,68E+00

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Comparison of Risk Characterisation Ratios across exposure tools.

Product Subcategory	Combined Risk Characterisation Ratio using ECETOC TRA v3 WITHOUT SCEDs	Combined Risk Characterisation Ratio using ECETOC TRA v3 WITH SCEDs	Risk Characterisation Ratio using ConsExpo (as calculated by ECHA in context of the example)
Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners)	3,5		
C7: SURFACE CLEANERS - Liquid cleaning product for manual application		0,56 (÷ 6)	0,073 (÷ 8)
C7: SURFACE CLEANERS - Abrasive product for manual surface application		0,25 (÷ 14)	0,023 (÷ 11)
C7: SURFACE CLEANERS - Abrasive product for manual surface application		0,28 (÷ 13)	0,023 (÷ 12)
C7: SURFACE CLEANERS - Carpet cleaners		1,68 (÷ 2)	0,221 (÷ 8)

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Conclusion

- Refinement can be provided with the tab "**Add subcategory" tab of ECETOC TRA v3**.
- The SCEDs allow to populate this tab in a harmonised way providing **more consistency**.
- **User friendly** compared to higher tier assessment tool.
- The **parameters** in the SCEDs and their **sources** have been documented and **justified**.
- **ECETOC TRA v3 + SCEDs**:
  - Identifies specific subcategories that pose acceptable risk.
  - Target specific subcategories for higher tier assessment.
  - Remains conservative (in this example, SCEDs exposure are ≈ 10 fold higher than ConsExpo).

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Timeline

- Some Sectors involved in the project have finalised their SCEDs; others will finalise their SCEDs by the end of 2012.
- **Document** to support the concept is being developed.
- ECHA and some Member State Competent Authorities are aware of this project.
- To follow: **dialogue** with authorities is essential for acceptance.
- SCEDs to be made available on **sector associations websites**, easily accessible to risk assessors for 2013 registrations.

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