

# *Hazard and Exposure Screening Methods for HPV Categories: Amine Oxides a Case Study*

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On behalf of the Soap and Detergent Association (SDA)



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The Home of the Cleaning Products and Oleochemical Industries

# Acknowledgments

- ◆ SDA HPV task force
- ◆ SDA Amine Oxides Consortia
  - ❖ Presented at Organization for Economic Co-operation and Development (OECD) Spring 2006 – sponsored by the USEPA
- ◆ Sister organizations:
  - ❖ International Council of Chemical Associations (ICCA)
  - ❖ The Cosmetic, Toiletry, and Fragrance Association (CTFA)
  - ❖ The European Cosmetic, Toiletry and Perfumery Association (COLIPA)
  - ❖ Consumer Specialty Products Association (CSPA)
  - ❖ Japanese Soap and Detergent Association (JSDA)
  - ❖ European Chemical Industry Council (CEFIC)
  - ❖ European Oleochemicals and Allied Products Group (APAG)
  - ❖ Comite Europeen des agents de Surface et de leurs Intermediaires Organiques (CESIO)
  - ❖ Japan Cosmetic Industry Association (JCIA)

## SDA Background

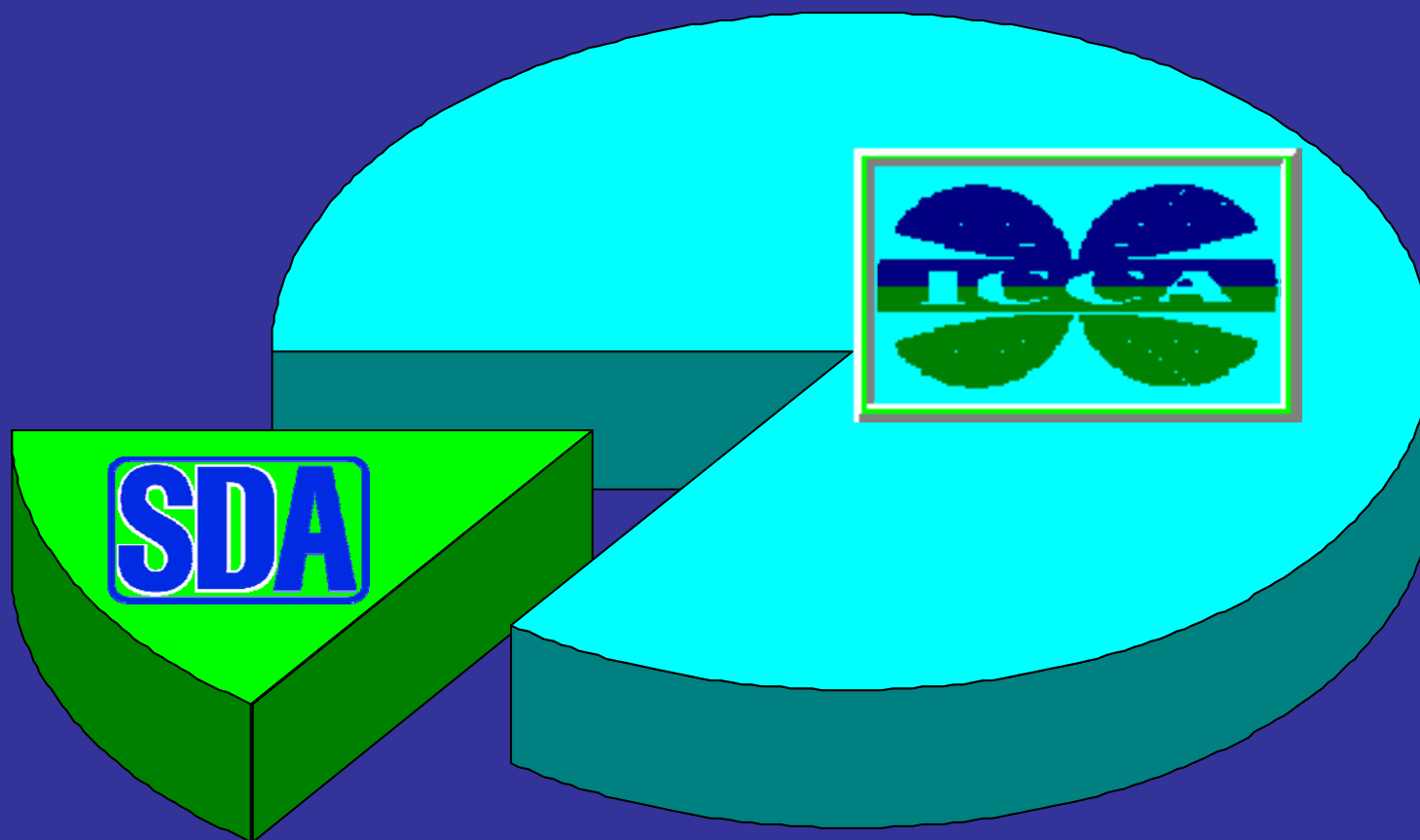
- ◆ Founded 1926
- ◆ >100 member companies
- ◆ Produce >90% of residential, industrial, institutional cleaning products sold in US
  - ❖ Cleaning Product Formulators
  - ❖ Chemical Suppliers
  - ❖ Finished Packaging Suppliers
- ◆ > 40 years of human and environmental safety research and assessment

***<http://www.sdahq.org>***

# SDA HPVC Program

- ◆ Ten SDA-managed Consortia (3 US and 7 OECD) addressing >240 chemicals
  - ❖ >40 companies
- ◆ HPV commitment: Fill hazard data needs
- ◆ Extended commitment: Assessment reports to include global use/exposure information

# SDA-managed Consortia Commitments Related to International Council Chemical Associations (ICCA) total commitment



## SDA HPV Vision

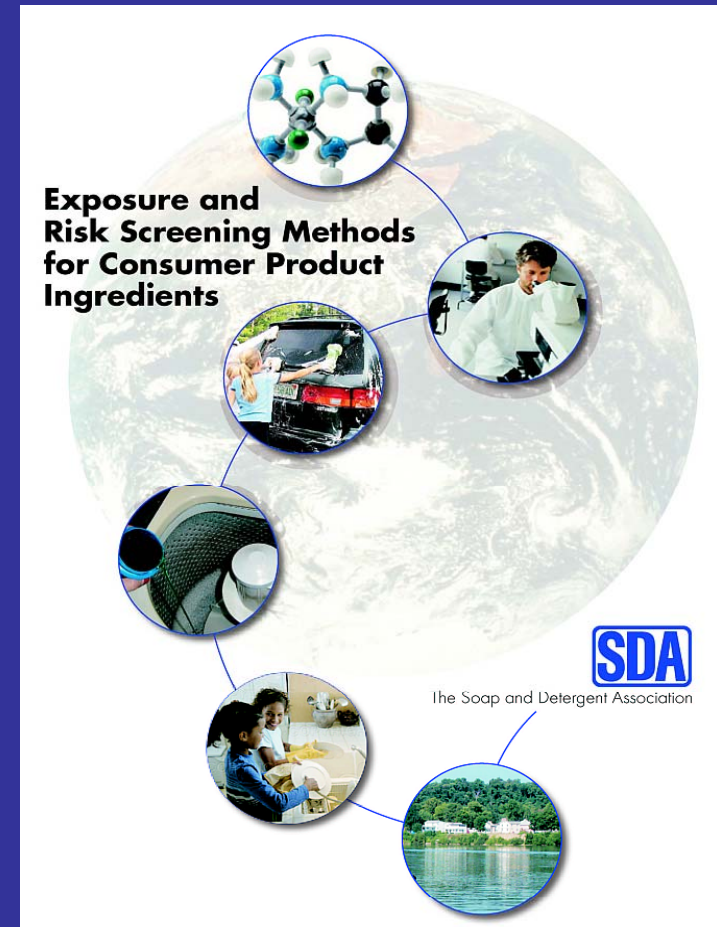
- ◆ Support key ingredients made and used by members in the US/ICCA HPV Programs
- ◆ Go beyond hazard — compile information sufficient to characterize uses, exposures and risks associated with committed HPV's
- ◆ Develop screening level assessments with:
  - ❖ Hazard data
  - ❖ Use / exposure information
  - ❖ Exposure / risk characterization

## SDA HPV Commitments

- ◆ 1998 commitment to providing additional information, including use/exposure, to support risk communication in HPVC assessment efforts
- ◆ Initiation of Use/Exposure Information and Risk Methodologies Data Collection Project
  - ❖ Global input from interested producers and downstream users – CTFA, CSPA, JSDA, CEFIC, APAG, CESIO, JCIA
- ◆ Emphasis on expanding scientific understanding of risk characterization process through dialogue with variety of stakeholders
  - ❖ Input sought from academia, governments, NGOs

# SDA Exposure and Risk Screening Methodologies

- ◆ Initiated December 2000
  - ❖ >40 companies participated
  - ❖ CTFA, COLIPA, CSPA, JSDA
- ◆ Create database of product related information and summarize exposure assessment methodologies for human and environmental safety
  - ❖ Models, calculations, assumptions, habits
  - ❖ International Peer-Review





# SDA Exposure and Risk Screening Methodology Project

## ◆ Scope

- ❖ Consumer products (i.e., cleaning, beauty care, baby care, personal care)
- ❖ North America and Europe

## ◆ Goal

- ❖ To develop and make publicly available the exposure scenarios, exposure equations, and appropriate parameters (habits & practices data).

## ◆ Process

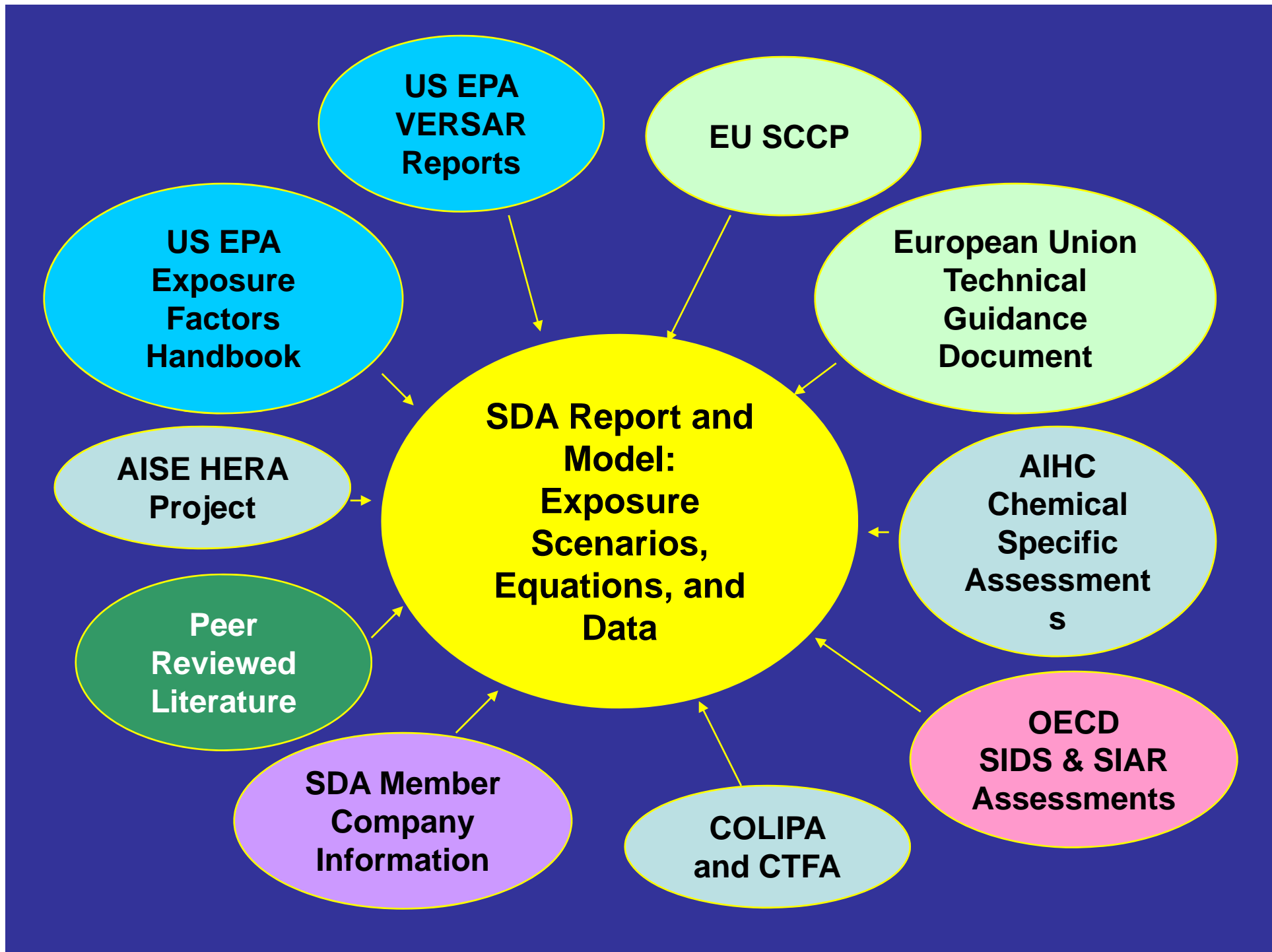
- ❖ Gather current publicly available scenarios, equation, and recommended parameter values
- ❖ Supplement with company specific data

# Exposure and Risk Assessment Methodology

- ◆ Compilation of methods
  - ❖ Models, first principle equations, exposure factors (habits and practices), default assumptions
  - ❖ Tiered approaches — use of conservative defaults, refine as necessary with more realistic data
  - ❖ Approach to address chemical categories

# Product Exposure Data Sources

- ◆ Extracted from a large variety of sources
- ◆ Priority was given to:
  - ❖ Government documents (i.e., US EPA's exposure factor handbook, European Union Technical Guidance Document (TGD))
  - ❖ Documents submitted to regulatory authorities
  - ❖ SDA member company data
  - ❖ Survey data from associations (CTFA, COLIPA)
  - ❖ Open literature
  - ❖ Consideration for recent data



## Results – Scenarios

- ◆ 46 different products/exposure route combinations:
  - ❖ 37 Dermal
  - ❖ 4 Oral
  - ❖ 5 Inhalation

## Results – Product Use Categories:

- Laundry detergents
- Fabric conditioners
- Dishwashing detergents
- Hard surface cleaners
- Shampoos and conditioners
- Hair rinses, gels, sprays
- Toothpaste, mouthwash
- Hand, face and body soaps/cleansers
- Antiperspirants/Deodorants
- Lotions, creams, moisturizers
- Cosmetics, face/eye/lip makeup
- Fine fragrances, after shave

## Results - Product Category Exposure Factors (‘Habits and Practices’ Info)

- ◆ Use frequency
- ◆ Task duration
- ◆ Amount used
- ◆ Concentration in use
- ◆ Transfer amount/residual
- ◆ Contact area
- ◆ Fraction ingested, inhaled/dermal penetration
- ◆ Other – body weight and surface area, breathing rates, use category specific factors (e.g. room volume)

## SDA Peer Review Panel

- ◆ Advise SDA on document concerning methodologies to assess exposure and risk for HPVs
- ◆ Panel membership:
  - ❖ Recognized experts in human and environmental exposure and risk assessment; non-profit groups, academia
  - ❖ Individuals with experience that enables SDA to obtain broader understanding of stakeholders perspective (NGOs, government, etc.)
  - ❖ Represent broad cross section of interests (Europe, Japan, North America)



## SDA Peer Review - Panel Charge

- ◆ Is approach adequately described?
- ◆ Is the method adequate to assess exposure at a screening level?
- ◆ Are there omissions that would significantly impact assessment results?
- ◆ Are there refinements that would improve the efficiency of the methodology? Suggestions for refinements.
- ◆ Are there omissions that would significantly impact assessment results?
- ◆ Work product of Panel: Report addressing above questions. Input was used to revise the document.

# SDA Risk Screening Methodology document content

- ◆ Assessment methods
  - ❖ Environmental
    - ◆ Overall approach
    - ◆ Assessment methods and regional models
  - ❖ Human -Consumer
    - ◆ Overall approach
    - ◆ Key scenarios/exposure factors
      - ; by product category; route; and geography
- ◆ Case Studies
  - ❖ Linear alkylbenzene sulfonate (LAS)
  - ❖ Hydrotropes
  - ❖ Triclocarban

## Summary

- ◆ One of the largest, broadest, most recent compilation of consumer exposure information with references
- ◆ Model iterative; employs conservative default assumptions at early stages
- ◆ Enables efficient use of resources by focusing on greatest exposures
- ◆ Considers aggregate exposures from multiple products
- ◆ Model/approach received independent peer review
- ◆ Can be applied to other categories when hazard and practices information available

## Potential Uses of SDA Document

- ◆ HPV and other public assessments
- ◆ Incorporation in regulatory programs
  - ❖ Priority setting
  - ❖ Providing screening level consumer exposure assessment
- Internal company safety assessment

## Case Study Amine Oxides (AO) Category\*

- ◆  $R_3N=O$  (alkyl chain length 8-20 (12-14 predominant))
- ◆ 16 CAS numbers
- ◆ US Tonnage: 26,000 Tonnes
- ◆ Amphoteric surfactants used in personal care and cleaning products (conditioning and foam stabilizers, etc)
- ◆ Here only focus on: Screening level human health – conservative default assumptions → likely overestimate exposure and risk

# Product Ingredient AO Concentration\*

Dishwashing detergents (liquid)	0.1 – 10 %
Hard surface cleaners (liquid spray)	0.05 – 5 %
Hard surface cleaners (liquid)	0.5 – 5 %
Laundry detergents (liquid)	1 – 5 %
Hand/face soaps (bar)	0.1 – 5 %
Shampoos	0.09 – 5 %
Hair conditioners	0.6 – 0.7 %
Hair styling tonic/gel	0.1 – 2 %
Cleansing products	0.04 – 9 %
Skin creams/moisturizers	0.2 – 0.6 %
Aftershaves	0.5 – 1 %
Home dry cleaning products	0.1 – 0.5 %
Douches	1 – 2 %
Face/eye foundations (liquid)	< 0.1 %
Hair coloring preparations	< 0.1 %
Permanent waves preparations	1 – 2 %

\* Source: Company and Association surveys

# Estimated Highest Product Category Dermal\* Exposures (mg AO/kg BW/day) Minimum to Maximum

Body Moisturizer	1.1 to 3.2
Hair Care	1.1E-2 to 2.4E-1
Aftershave	7.0E-2 to 1.4E-1
Laundry Detergent – liquid	3.0E-3 to 1.5E-2
Bar Soap	4.1E-4 to 2.0E-2
Cleansing Products	2.3E-4 to 5.1E-2
Dish Detergent – liquid	1.2E-5 to 1.2E-3
Hard Surface Cleaner – liquid	1.1E-4 to 5.5E-3

\*These are leave on products, with minimal inhalation and oral exposures (highest other for spray cleaner exposure is inhalation: 1.6 E-6 to 8.2 E-5)

# Conservative calculation

- ◆ Lowest No Observed Adverse Effect Level (NOAEL) = 80 mg AO/kg BW/day (non cancer endpoint need to indicate type of study e.g. 90-day?)
- ◆ Maximum product exposure (PE): Dermal, body moisturizers = 3.2 mg AO/kg BW/day
- ◆ Maximum product ingredient concentration (IC) = 0.6%
- ◆  $MOE = NOAEL/PE \times IC \rightarrow$   
 $MOE = 80/3.2 \times 0.6 = \underline{41}$



# AO margin of Exposures relative to different product types

<u>Product Type</u>	<u>Minimum</u>	<u>Maximum</u>
Body Moisturizer	41.6	363
Aftershave	570	1,109
Hair Care	332	7,268
Laundry Detergent – liquid	5,329	26,650
Bar Soap	3,997	195,005
Cleansing Products	1,567	347,617
Hard Surface Cleaner – liquid	14,537	726,836
Dish Detergent – liquid	66,626	6,662,666

For moisturizers and aftershave exposure defaults should be refined with measured or modelled data of e.g. absorption.

# SDA science portal

- ◆ New portal; transparency about how SDA ensure sustainability through sound science
- ◆ Search functionality
  - ❖ Ingredient
  - ❖ Product type
  - ❖ Categories
- ◆ Increase availability of data to all stake-holders



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**FEATURES**

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### INGREDIENT INFORMATION

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### INGREDIENTS BY PRODUCT

DATA MANAGEMENT

Laundry Detergent

PRODUCT INFORMATION

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Home > Ingredient Information > Ingredients by Product > Laundry Detergent

ENVIRONMENTAL HEALTH

## LAUNDRY DETERGENT

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[Hydrotropes](#)

[Donec Auctor](#)

[Mauris Lorem](#)

[Donec Gravida](#)

[Nunc Egestas](#)

[Quisque](#)

[Praesent](#)

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Home > Ingredient Information > Ingredients by Product > Laundry Detergent > Hydrotropes

HYDROTROPES

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Sponsored CAS Numbers

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SIAM 21, 18-20 October 2005

AUS/ICCA

**SIDS INITIAL ASSESSMENT PROFILE**

**CAS Nos.  
and  
Chemical names**

(1300-72-7 and 827-21-4) Xylenesulfonic acid, sodium salt

(12068-03-0) Toluenesulfonic acid, sodium salt

(26447-10-9) Xylenesulfonic acid, ammonium salt

(28348-53-0 and 32073-22-6) Cumenesulfonic acid, sodium salt

(37475-88-0) Cumenesulfonic acid, ammonium salt

(28088-63-3) Xylenesulfonic acid, calcium salt

(30346-73-7) Xylenesulfonic acid, potassium salt

(16106-44-8) Toluenesulfonic acid, potassium salt

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# HERA Human and Environmental Risk Assessment on ingredients of household cleaning products

## Welcome to HERA

A voluntary industry programme to carry out Human and Environmental Risk Assessments on ingredients of household cleaning products

A unique European partnership established in 1999 between the makers of household cleaning products (A.I.S.E) and the chemical industry (Cefic) who supplies the raw materials.



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## Risk Assessments

"The following risk assessments have been conducted according to the principles of the [HERA methodology document](#) (pdf document)."

### Substance group: Linear Alkylbenzene Sulphonate

CAS numbers: [1322-98-1](#) [25155-30-0](#) [68411-30-3](#) [85117-50-6](#) [90194-45-9](#)

Risk Assessment	Status	Publish Date R.A.
<a href="#">Full (PDF)</a> 805 Kb	New Updated Edition	31/07/2002

### HERA Comments

This updated version 2.0 of the HERA Risk Assessment takes account of comments from the External advisory Panel on Environmental and Human Risk Assessment parts.

Version 1.0 of this Risk Assessment can be requested by using the Contact Form on this site.

### External Comments

Comments ERASM statement on sediment rationale- see attached.	
<a href="#">ERASMstatement18Oct02.doc</a> 24 kb Comments ERASM statement on sediment rationale- see attached.	16/06/2003





**Human and Environmental Risk Assessment**

**LAS**

**Linear Alkylbenzene Sulphonate**

(CAS No. 68411-30-3)

**Version 2.0**

**May, 2004**

"This updated version 2.0 of the HERA Risk Assessment takes account of comments from the External Advisory Panel on Environmental and Human Risk Assessment parts"

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