

Registration Procedure:

Exposure Scenarios (ES) and Chemical Safety Assessment (CSA)



<i>Exposure Scenario Format (1) addressing uses carried out by workers</i>
1. Title
2. OCs and RMMs
2.1 Control of workers exposure
2.2 Control of environmental exposure
3. Exposure estimation and reference to its source
4. Guidance to DU to check own conditions
Additional good practice advise beyond CSA

REACH : où en est-on ?
Chambre de Commerce à Luxembourg
15 décembre 2009



PD Dr. Dirk Bunke, Öko-Institut e.V., Institute for Applied Ecology

15 décembre 2009

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1. Registration procedure – Chemical Safety Assessment – Chemical Safety Report* – Exposure scenarios*: Why? When?



2. Exposure Scenarios*

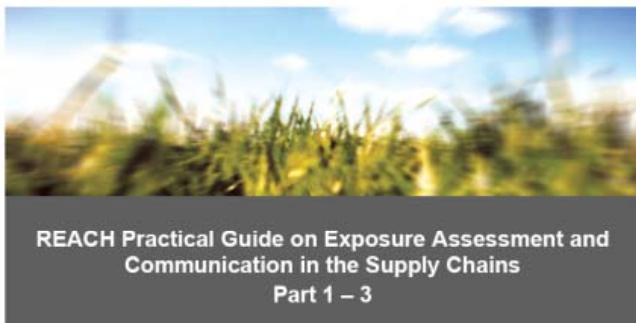


3. Relevance for downstream user*



***: examples available.....more information available....
REACH Practical Guide.....**

<http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm>



May 2009


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VERBAND DER CHEMISCHEN INDUSTRIE e.V. 

**REACH Praxisführer
zur Expositionsbewertung und zur
Kommunikation in den Lieferketten**

Materialband

**M 2: Stoffsicherheitsbericht
Kaliumtertiärbutylat**
Dieses Beispiel veranschaulicht die Stoffsicherheitsbeurteilung eines Stoffes, zu dem nur begrenzte Daten öffentlich verfügbar sind.

Kontaktperson für dieses Beispiel:
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Projektgruppe CSA/CSReSDB des VCI
Autoren des REACH Praxisführers:
Öko-Institut, PD Dr. Dirk Bunke, Rita Groß,
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**M 5: Erweitertes Sicherheitsdatenblatt
für die Zubereitung Lederplex 900**
Dieses Beispiel zeigt ein erweitertes Sicherheitsdatenblatt für eine Zubereitung, das als Anhang ein Expositionsszenario enthält.

Kontaktperson für dieses Beispiel:
PD Dr. Dirk Bunke, Öko-Institut e.V.
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**1. Registration procedure – Chemical Safety
Assessment – Chemical Safety Report* –
Exposure scenarios*: Why? When?
- Software tools -**



- 1. Registration procedure → Registration dossier*
 - Safe use of chemicals? → Chemical Safety Assessment** (CSA)
 - Heart of the whole process: → Exposure Scenarios*** (ES)
 - Documentation: → Chemical Safety Report** (CSR)
→ ECHA (as part of registration dossier)
-

Communication of results into supply chains:

→ extended Safety Data Sheet (eSDS)

* : For substances with a production volume of 1 t/year (M/I) and more

** : For substances with a production volume of 10 t/year (M/I) and more

***: For dangerous substances / PBT- , vPvB- substances

Tool Nr. 1

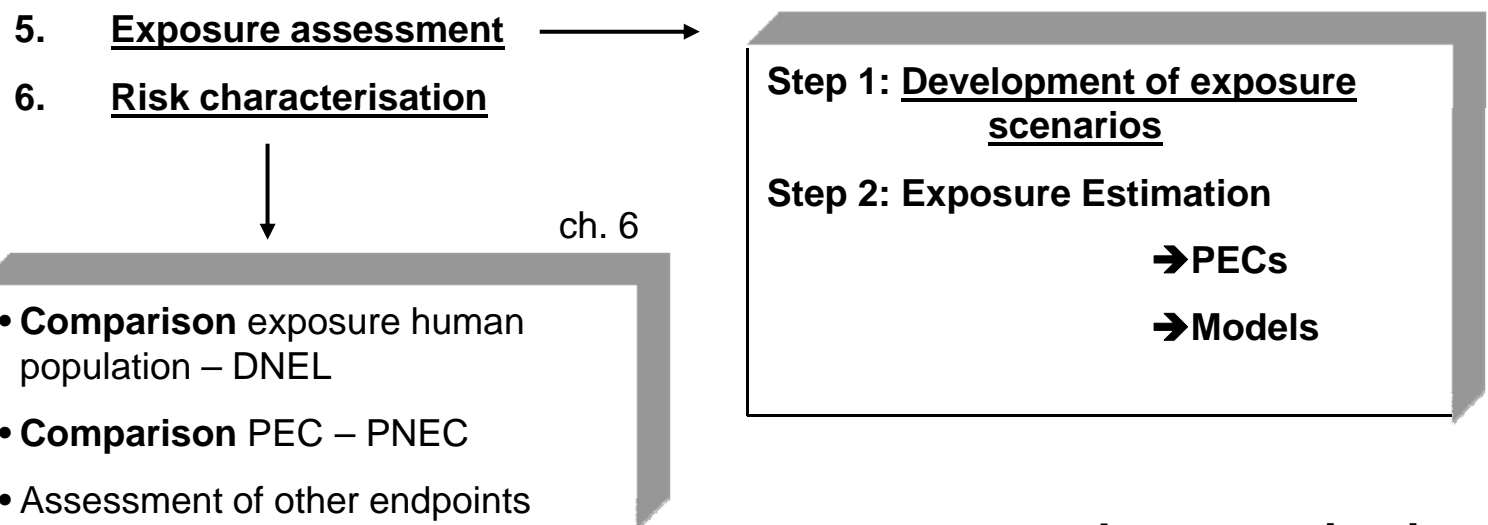
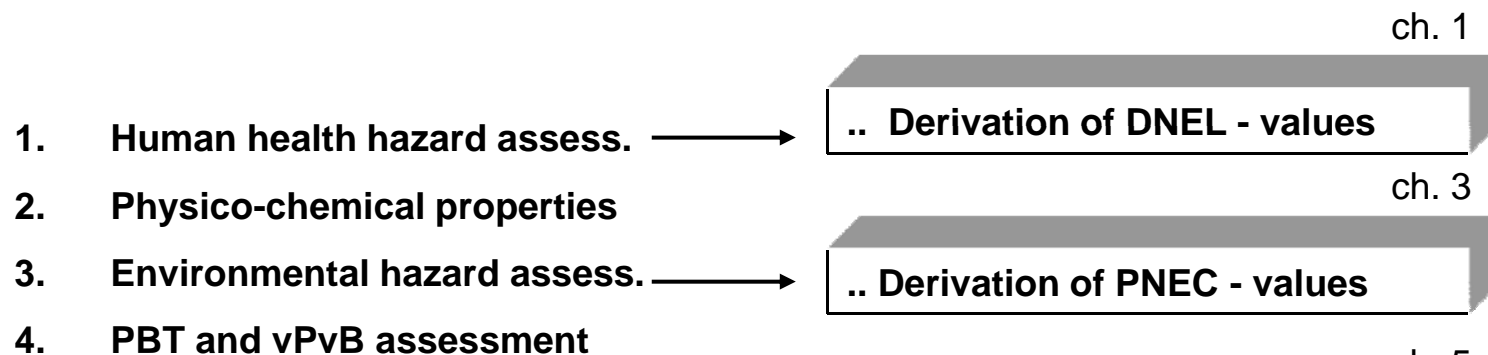
Chemical Safety Assessment

Assessment under which conditions substances can be used safely

Necessary:

**Assessment of substance properties (hazard assessment)
+ conditions of use (exposure assessment and risk
Characterisation)**





...and communication

1. Substance properties

Molecular weight, vapor pressure

—————→ **Knowledge of registrant**

2. Characteristics of processes and products

Type of activity

Duration / Frequency of use

Process category (e.g. closed system),

Degree of fixation

Properties of product (mixture, article) / concentration of ingredients

Amount used daily

Risik management measures and efficiency of measures

—————→ **Knowledge of downstream user**

3. Properties of the surrounding environment

Room volume, capacity of the receiving water volume

—————→ **Knowledge of downstream user**



Tool Nr. 2

Chemical Safety Report (CSR)

The chemical safety report documents the results of the chemical safety assessment.



Example: **—————>** **Chemical Safety Report Acetonitrile**

Example: CSR Acetonitril....

Tools for exposure assessment and risk characterisation:

EUSES

ECETOC TRA Version 2

ConsExpo

EMKG

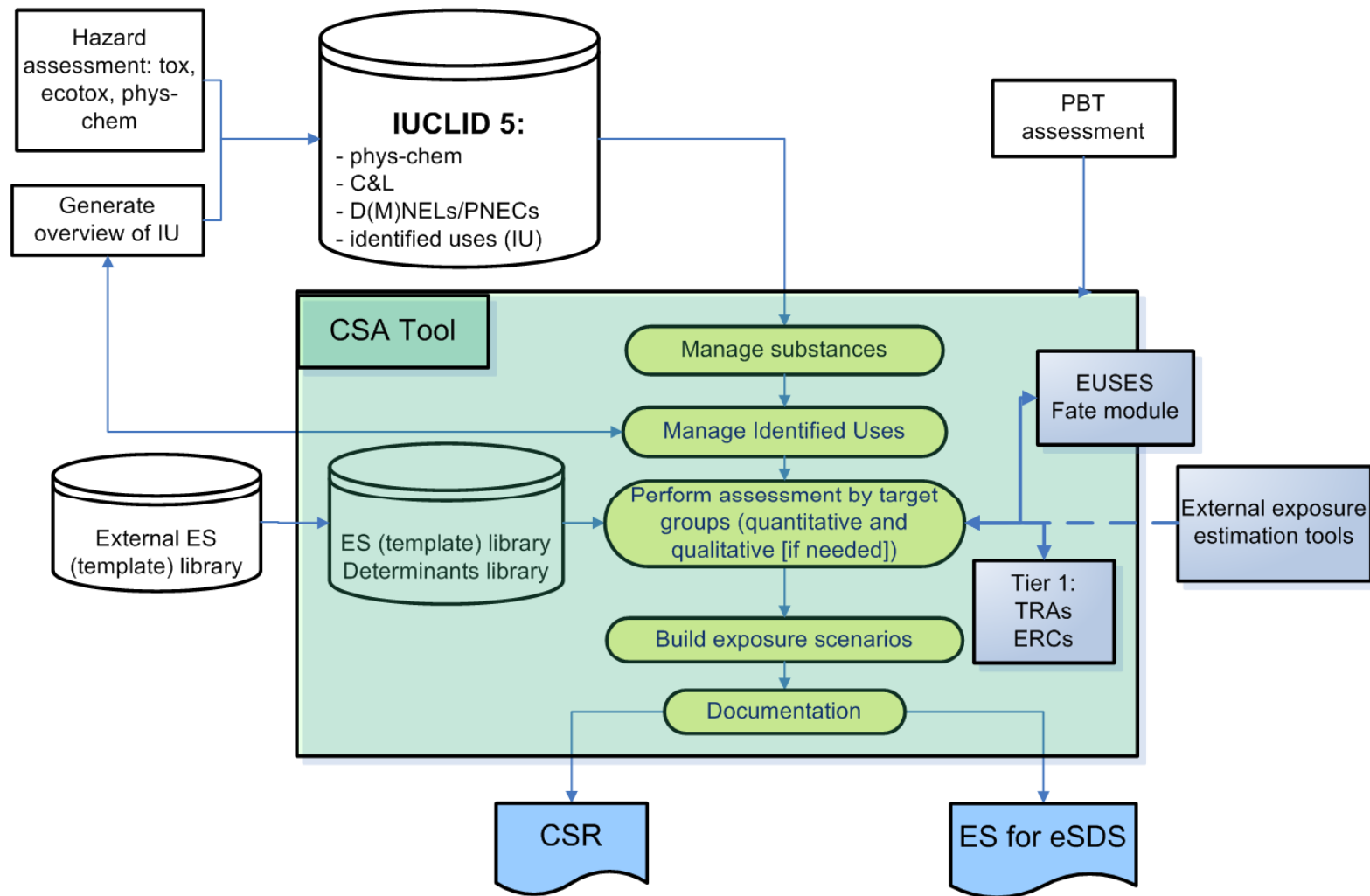
Iterative 3 step approach for exposure assessment



Tool for preparation of chemical safety reports, exposure scenarios and extended safety data sheets:

ECHA CHESAR

CHESAR: ECHA CSA / CSR IT Tool (based on IUCLID 5)



Tool Nr. 3

Exposure scenarios



Exposure scenarios describe how substances (as such or in mixtures) can be used safely.

Exposure scenarios are built as part of the chemical safety assessment. They become part of the chemical safety report .

Example: →

extended SDS Lederplex

Several types...
Different wording.....
Changes in terminology...

December 2009:

1. Two types:

 broad generic exposure scenarios („GES“)

 specific exposure scenarios („SES“)

2. ECHA: 4 Standard formats for exposure scenarios

 Link exposure scenarios in the chemical safety reports and exposure scenarios for communication in the supply chains.

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

2. Operational conditions and risk management measures

2.1 Control of workers exposure

2.2 Control of environmental exposure

2.3 Control of consumer exposure

3. Exposure estimation and reference to its source

4. Guidance to DU to check own conditions

Additional good practice advice beyond the REACH CSA

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

2. OCs and RMMs

2.1 Control of workers exposure

2.2 Control of environmental exposure

Max. amount: 240 kg/day

2.3 Control of consumers exposure

3. Exposure estimation and reference to its source

4. Guidance to DU to check own conditions

Additional good practice advise beyond the REACH CSA



Exposure scenarios, Standard format

<i>Exposure Scenario Format (1) addressing uses carried out by workers</i>	
1. Title	
Free short title	<i>Industrial Cleaner I</i>
Systematic title based on use descriptor	<i>SU3 (Industrial Manufacturing),, PROC4, PROC8 , PROC9, PROC10 ERC4</i>
Processes, tasks activities covered	<i>Metal cleaner (degreaser, descaler, etch); Manual process, Semi-Automatic process, Automatic process (according to A.I.S.E.)</i>
Assessment Method*	<i>ECETOC TRA, DPD +</i>
2. Operational conditions and risk management measures	
<i>Brief description of overall operational conditions referring to process categories (PROC) and environmental release categories (ERC)</i>	
<i>Number of sites using the substance supplied by the registrant (potentially required to demonstrate strictly controlled conditions, in order to justify waiving of information according to Annex XI of REACH) *</i>	
2.1 Control of workers exposure	
Product characteristic	
Amounts used	
Frequency and duration of use/exposure	
Human factors not influenced by risk management	
Other given operational conditions affecting workers exposure	
Technical conditions and measures at process level (source) to prevent release	
Technical conditions and measures to control dispersion from source towards the worker	
Organisational measures to prevent /limit releases, dispersion and exposure	
Conditions and measures related to personal protection, hygiene and health evaluation	

Tool Nr. 4

Extended Safety Data Sheet

It remains the most important communication tool between manufacturers of substances and mixtures and their customers



Example: → Safety Data Sheet Lederplex

Registrants: IUCLID 5 (technical dossiers), ECETOC TRA, EUSES, CHESAR

Downstream users:

-Formulators - EUSES, ECETOC TRA

-End user - easy-to-use tools.....

COMMON LANGUAGE

- Use Descriptor System**
- Mapping of uses**



Structured communication of uses and conditions of use

= determinants of exposure!



Use Descriptor System inclusive Environmental Release Categories (ERCs) and specific Environmental Release Categories (SPERCs)

→ ECHA Guidance IR & CSA, Part R12

Indication: Which uses are covered by the exposure scenario?

(1) Sector of use (SU) e.g. construction products

(2) Product category (PC) e.g. adhesive

(3) Process category (PROC) e.g. industrial spraying

(4) Article category (AC) e.g. batteries

(5) Environmental Release Categories (ERCs)

+ sector-specific environmental Release Categories („spERCs“)

**ECHA Guidance Information requirements and CSA, Part D, Chap. 4.3.1,
p. 25, + chapter R12.**



DUCC



Downstream Users of Chemicals Co-ordination group

UseR: Use Reporting

This document provides a common DUCC format for reporting uses under REACH:

Uses are mapped using the Use Descriptor System and additional information is provided to allow exposure assessment at screening level (using ECETOC TRA). Each Downstream User Association is responsible for filling and updating the use information for its sector, following the format provided in this document.

Explanations:

Page 1	Mapping of uses
Page 2	Use descriptors with operations Conditions (OC)

Examples:

Page 3	Mapping of uses
Page 4	Use descriptors with operations Conditions

Blank:

Page 5	Mapping of uses
Page 6	Use descriptors with operations Conditions

UseR: Use Reporting

Common template for downstream users to report their uses (Mapping of uses)

1. Registration procedure – Chemical Safety Assessment – Chemical Safety Report – Exposure scenarios*: Why? When?



2. Exposure Scenarios



3. Relevance for downstream user

To be (covered) or not to be

Downstream User ES Compliance Check

Scaling*

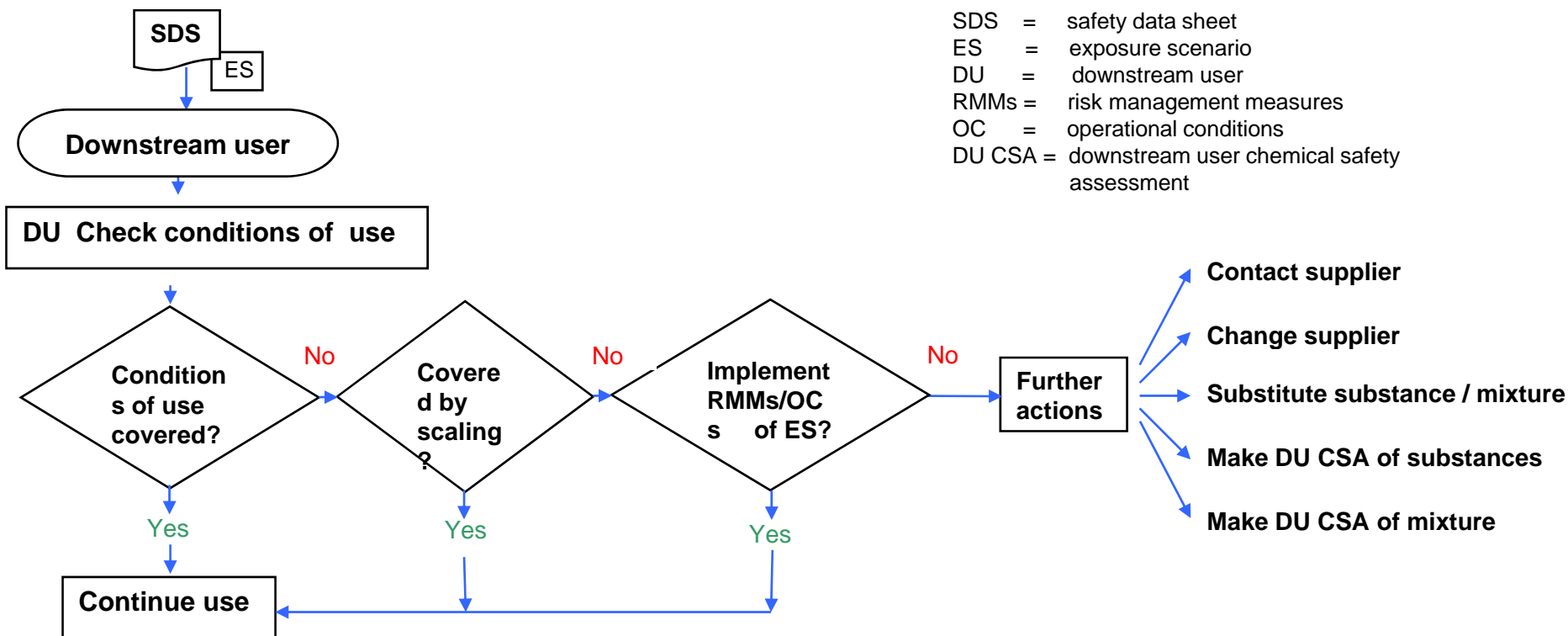
DU Chemical Safety Assessment



DU Check ES : Steps and possibilities to act / Overview

Registration → CSR incl. ES → Registration dossier → ECHA

↓
 Extended Safety Data Sheet



SDS = safety data sheet
 ES = exposure scenario
 DU = downstream user
 RMMs = risk management measures
 OC = operational conditions
 DU CSA = downstream user chemical safety assessment

What to do? Identify information and compare....

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Technical conditions and measures to control dispersion from source towards the worker	
Organisational measures to prevent /limit releases, dispersion and exposure	
Conditions and measures related to personal protection, hygiene and health evaluation	

← Deviation from title?
 If yes, no direct consequences!

← Deviation from operational conditions and risk management measures?
 If yes, direct consequences!

How to do?

*Exposure Scenario Format (1) addressing uses carried out by **workers***

1. Title

2. OCs and RMMs

2.1 Control of workers exposure

2.2 Control of environmental exposure

Max. amount: 240 kg/day

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4. Guidance to DU to check own conditions



How to do?

2.2 Control of environmental exposure

Max. amount: 240 kg/day



1. Information from ES :

240 kg/day

2. Information from plant :

100 kg/day

3. Compare

4. Judgement: Effect on exposure?

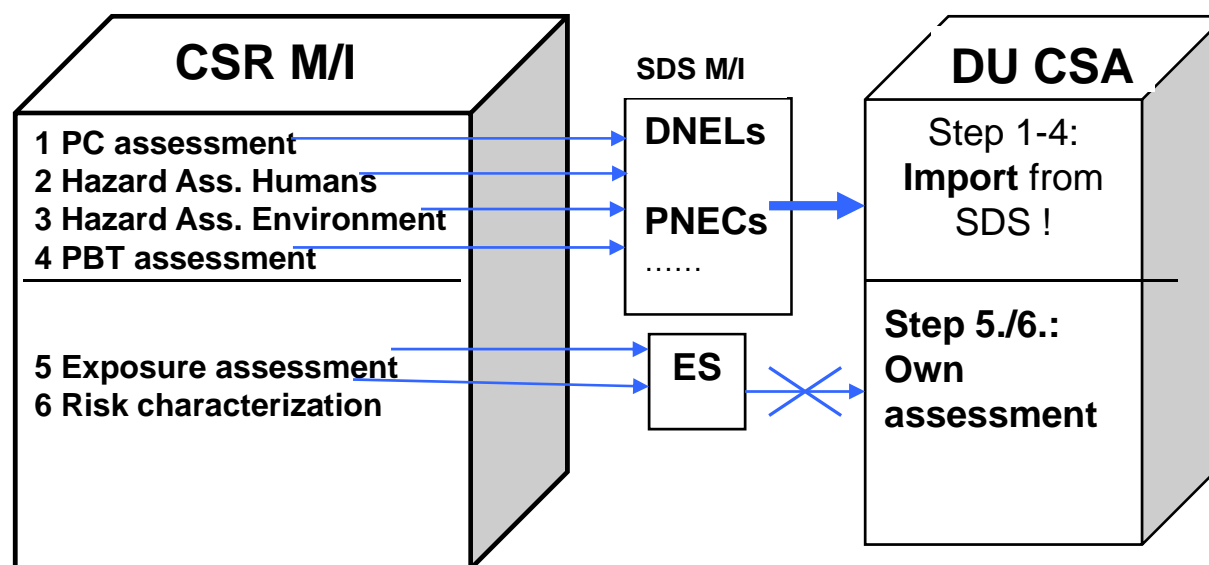
Lower exposure

Higher exposure

Go to next parameter

In depth analysis,
scaling

Preferred option: compliance by scaling!



* Example Oven cleaner

„In principle, the downstream user should comply with the conditions of use indicated in the exposure scenario of his supplier.

However, if he has another combination of operational conditions and risk management measures which allow him to achieve the same level of safety, he can use scaling to demonstrate that he is in compliance.“
(ECHA DU Guidance, p.46)



**„Scaling in this context means the use of simple equations in the exposure scenario by which the downstream user can demonstrate that he operates within the conditions of the exposure scenario provided by the registrant.“
(ECHA Guidance on IR / CSA, Part G, p. 18.)**

Use of simple mathematics.....

Example formula

$$M_{\text{safe}}_{\text{actual}} = M_{\text{safe}}_{\text{ES}} \times \frac{C_{\text{ES}}}{C_{\text{actual}}} \times \frac{f_{\text{water, ES}}}{f_{\text{water, actual}}} \times \frac{(1 - f_{\text{abatement, ES}})}{(1 - f_{\text{abatement, actual}})}$$

Abbreviations:

- M_{safe} = amount of product for which safe use has been shown
- actual = situation of downstream user
- ES = exposure scenario
- C = concentration of substance in product
- F_{water} = fraction of product released to waste water
- F_{abatement} = efficiency of abatement measure

Experience: many risks to make mistakes.....



Electronic tools

ES modifier

SciDeEx („Scaling of inhalative and dermale Exposure“)

REACH Scale



ES Modifier (CEPE / FDLF / DHI , summer 2009)



Target groups: manufacturers / formulators

Helpful tool



Summer 2010

Scaling/1 : ES Modifier as starting point / CEPE / FDLF / DHI

MANUFACTURE

FORMULATION

END USE

SERVICE LIFE

CAS NUMBER

USE SECTOR

PRODUCT CATEGORY

PROCESS CATEGORY

ARTICLE CATEGORY

HOME

LOAD STUDY

SAVE STUDY

SUBSTANCE DATA
PHYS.-CHEM. DATA

HAZARD DATA

MIXTURE DATA

MODEL DATA

USE DATA

RCR DETAILS

RESULTS - PRODUCT LEVEL

REPORT

RCR

Inhalation	
Dermal	
Oral	
Water	
Soil	
STP	
Air	

Welcome to ES-modifier

On this sheet you get a very brief introduction to ES-modifier. Do you need more information? You can find a more detailed manual via the menu point MANUAL.

With the menu point: LOAD STUDY, you can open studies which are filled in before. The menu point SAVE STUDY enables you to save your work.

With the current version of ES-modifier, you can work on substance level. However, you have the possibility to enter substance data for up to 30 substances via the menu point SUBSTANCE DATA. You can do this either manually or by importing data. You should then select the substance to be used in the calculations via the drop-down list on the upper left corner.

Besides substance data, you also need to specify:

- "Life cycle stages (LCS)" -by clicking on one of the icons on the upper banner. For the LCS "End-use" and "Service life" you also need to specify the user group: industry, professional or consumer. The selected LCS and user group are then marked as white icons.
- "Descriptors of Use" (DoU): Sector of Use (SU), Product Category (PC), Process Category (PROC), Article Category (AC). For more details on these categories, contact the manual.
- More detailed use data – you do this via the menu point USE DATA.

As a default, ES-modifier applies the ECETOC model for the human exposure calculations and EUSES for the environmental exposure calculations. Do you want to apply another model? Please go to the menu point MODEL DATA. If you want to adjust some of the default settings, you can do this via the menu point USE DATA.

Calculation results are specified on 3 levels:

- RCR-thermometer shown on the lower left corner. The RCR is the "Risk Characterization Ratio". If the RCR is below 1 then safe use can be assumed.
- Details of the RCR can be found via the menu point RCR DETAILS
- A report showing detailed input and output data

LCS - Use categories - Select substance - Substance phys.-chem. data - Substance tox data - Model data - Use data - Calculation

CSA prepared by M / I using exposure estimation tools

(tier 1 or higher tiers)



REACH Scale



Scaling for subsequent downstream users of mixtures

- Scaling tool (excel-based) Environment
- Scaling tool (excel-based) Inhalative Exposure
- Scaling tool (excel-based) Dermal Exposure

Reference: CSA M/I, several exposure estimation tools

REACH: Scale

Product: Lederplex 900

Environment

Water

1. Your receiving water volume (after STP)?

200.000 m3/day

Assumption: 200.000 m3 /day

! Maximum value: 2 Mio m3/day!



2. Your "In house" - emission reduction (RMM)?

99 %

Assumption: Precipitation with Fe(OH)3, 99% Reduction

0,01

0,01



How much I can use per day under the conditions described (see 1,2,3,4)?

570 kg / day

Amount emitted to surface water

0,57 kg / day

How much I can use less than 12 times/year?

5.700 kg / day

In specific cases it may be possible for you to change also the following parameters:

3. Degree of fixation

90 %

0,10

Assumption: 90%

0,10

4. Emission reduction by municipal sewage treatment plant

0 %

0,00

Assumption: 0 %

0,00

The following parameters are fixed and can not be changed:

PNEC water, local

2 microgram/l

PEC/ PNEC maximum

1

Amount used per day under default conditions:

570 kg/day

3 conditions:

Options and limitations of scaling are to be communicated by the supplier.

Scaling rules have to be described in the exposure scenario.

If instruments are recommended, input parameters should be given.

-
- The domain of applicability has to be checked from the registrant within his chemical safety assessment.

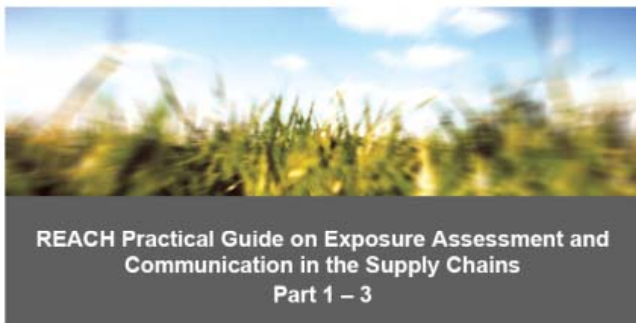


More information.....

- I ECHA Guidances**
- II CEFIC Guidances**
- III REACH Practical Guide**

Spring 2010: Special REACH and mixtures

<http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm>



May 2009


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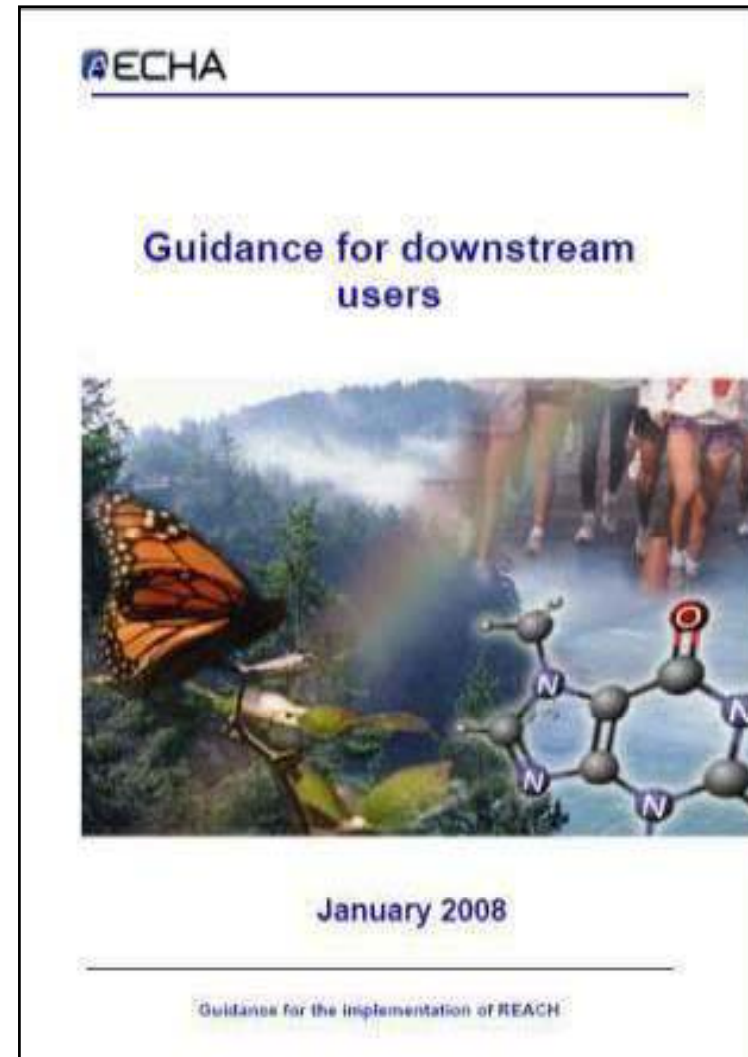
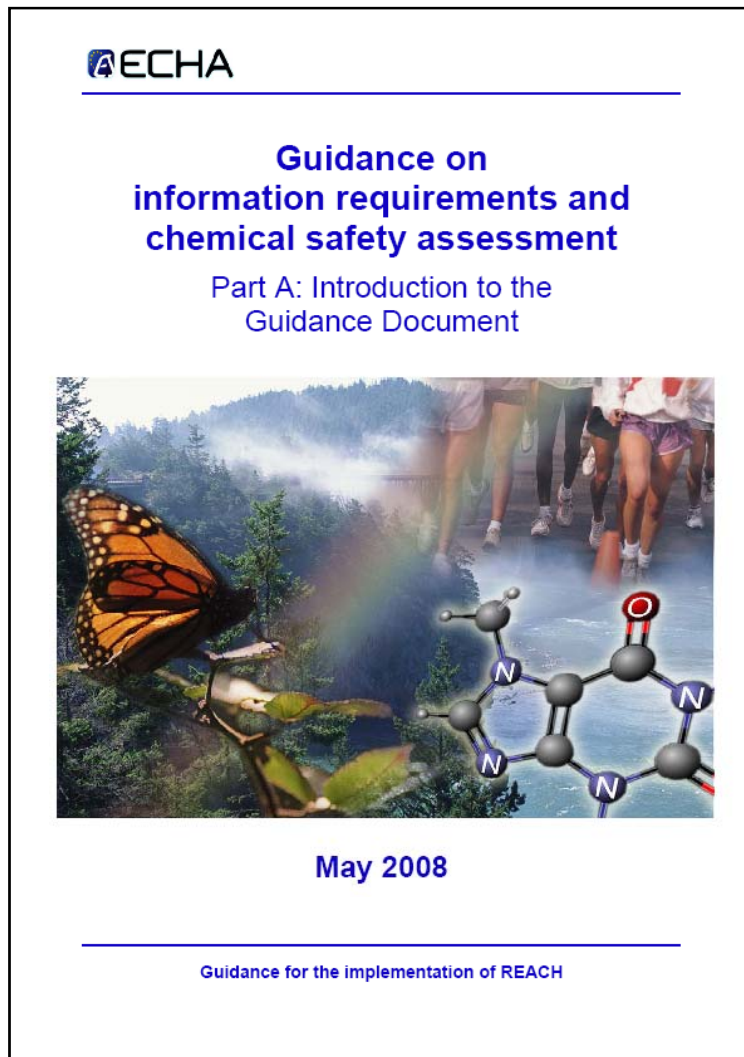
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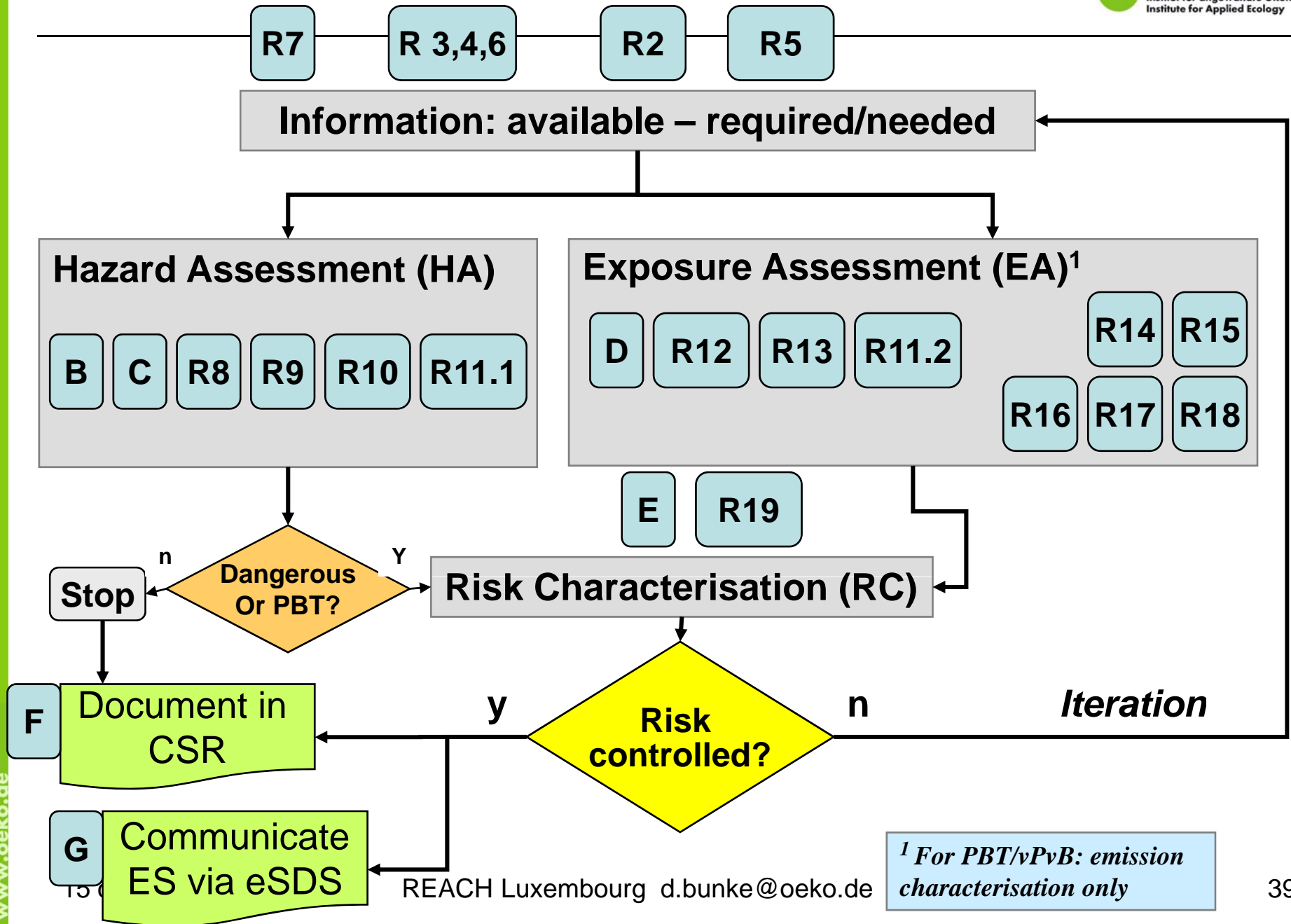
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What is a Generic Exposure Scenario?



- Describes the integrated Risk Management Measures (RMMs) and Operating Conditions (OCs) relevant to the safe use (S, H & E) of a substance or group of similar substances (or preparation/mixture) for an area of operation in industry
 - A development from similar concepts already existing in some Member States e.g. COSHH Essentials
- Describes the RMMs appropriate for different ‘risk bands’ i.e. may equally be relevant for similar substances or different substances presenting comparable risks
 - A particular use may have a number of GESs which cover the different risks that the use of any substance may present e.g. low volatility/low hazard versus moderate volatility/high hazard, etc.
 - And where the limitations of application are clearly described
- Developed in a manner consistent with the REACH TGD based upon an initial mapping of use within the supply chain
 - And ideally in partnership between DUs and M/Is





REACH Navigator - The Guidance on Information Requirements and Chemical Safety Assessment - Windows Internet Explorer

http://reach.jrc.it/docs/guidance_document/information_requirements_en.htm#F

Figure 3: Reference between the process steps and the guidance elements

RIP 3.2 structure

Part A - Introduction to the Guidance Document
[[download PDF version - PART A](#)] [[download ZIP version - PART A](#)]

Part B - Hazard Assessment
[[download PDF version - PART B](#)] [[download ZIP version - PART B](#)]

Part C - PBT Assessment
[[download PDF version - PART C](#)] [[download ZIP version - PART C](#)]

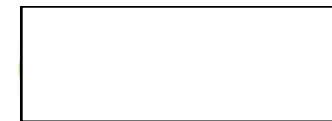
Part D - Exposure Scenario Building
[[download PDF version - PART D](#)] [[download ZIP version - PART D](#)]

Part E - Risk Characterisation
[[download PDF version - PART E](#)] [[download ZIP version - PART E](#)]

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CEFIC tools & documents / libraries



REACH Implementation: Libraries - Windows Internet Explorer

http://www.cefic.org/Templates/shwStory.asp?NID=494&HID=645&PHID=643

REACH Implementation: Libraries

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REACH Implementation

Libraries

Standardised approach is also needed for the preparation of Exposure Scenarios (ES) and Chemical Safety Reports (CSR), in order to make communications up and down the supply chain more efficient.

- Risk Management (RM) Library as part of the Technical Guidance Document for preparing the Chemical Safety Assessment to be published by the European Chemicals Agency.
- April 2008, "Preparation for Pre-registration"
- June 2008, "Guidance on SIEF Formation"

In this Section

- ▶ Tools
- ▶ Libraries
- ▶ Workshops
- ▶ Links

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CEFIC Guidance Supply Chain Communication and ES



http://cefic.org/files/Downloads/Guidance_Use_and_ES_dvlpt_and_SCCm.doc

Nr.	Ingredient		%	Classification & Labelling
1	Water		91,50	
2	Sodium hydroxide 33%		2,50	C - R 35
3	Sodiummethylhexyl- sulfate	(43 % in Water) Anion. Tensid	4,00	Xi-R 38,41
4	Lithium Sodium Magnesium Silicate		1,90	non hazardous
5	Xanthan Gum		0,10	non hazardous

Non hazardous ingredients can modify the emission properties

REACH Practical Guide

→ Spring 2010: Supplement „Mixtures under REACH“

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