

Compilation of the **Chemical Safety Report**

Product Safety

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The Chemical Company

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Objectives of the CSR

- Principle of REACH:
responsibility of manufacturers/importers/downstream users to ensure that the substances handled by them do not harm human health or the environment (Art. 1, 3.)
 - Fulfilment of these duties will be documented / controlled via registrations
 - Registrations include a Chemical Safety Assessment
 - Chemical Safety Assessment is documented by a
 - technical dossier and a
 - Chemical Safety Report (CSR)
- ➔ **CSR = Core of the safety assessment:
Facilitates and documents the
comparison of key data and conclusions on safety**

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The CSR in the REACH text

- Article 10 Information to be submitted for general registration purposes
- Article 14 Chemical Safety Report and duty to apply and recommend risk reduction measures
- Article 36 Downstream user chemical safety assessment and duty to identify, apply and recommend risk reduction measures
- Article 37 Obligations for downstream users to report information
- Annex I General provisions for assessing substances and preparing a CSR

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Obligations

Manufacturer/Importer:

- Register substance
- Assess safety of identified uses
- Implement & Communicate risk reduction measures (via MSDS)

Downstream User:

- Check whether own use is covered by uses described in MSDS
- Implement recommended risk reduction measures
- If own use not covered:
 - make use known to supplier or
 - own safety assessment
 - report to agency

➔ **3 types of documents:
technical dossier, CSR, MSDS**

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Information to be submitted for registration

Technical dossier:

- Manufacturer / importer
- Substance
- Identified uses
- Classification & labelling
- Guidance on safe use
- Study summaries of studies as defined by annexes VII-XI (phys-chem, tox, ecotox)
- Qualification of assessor
- Testing proposals ...

Chemical safety report

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When is a CSR required?

- For substances > 10 tpa being subject to registration (Art. 14)
- For substances in preparations only
 - if exceeding C&L concentration limits
 - if PBT or vPvB and >0,1% in preparation
- **Who has to file it?**
 - Registrant or
 - Downstream User

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Safety Assessment



Gather & validate & generate relevant information



Technical dossier
Identity etc.
Study summaries



CSR
Summarize/assess data in

1. Human Health hazard assessment
2. Physicochemical hazard assessment
3. Environmental hazard assessment
4. PBT / vPvB assessment

CSR
5. Exposure assessment & estimation
6. Risk characterisation

YES

dangerous substance according to C&L criteria? PBT / vPvB?

NO

MSDS
Recommend risk reduction measures

Submit documents to agency

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CSR format

■ Annex I

7. CHEMICAL SAFETY REPORT FORMAT

The Chemical Safety Report shall include the following headings:

CHEMICAL SAFETY REPORT FORMAT	
PART A	
1.	SUMMARY OF RISK MANAGEMENT MEASURES
2.	DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED
3.	DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED
PART B	
1.	IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES
2.	MANUFACTURE AND USES
2.1.	Manufacture
2.2.	Identified uses
2.3.	Uses advised against
3.	CLASSIFICATION AND LABELLING
4.	ENVIRONMENTAL FATE PROPERTIES
4.1.	Degradation
4.2.	Environmental distribution
4.3.	Bioaccumulation
4.4.	Secondary Poisoning
5.	HUMAN HEALTH HAZARD ASSESSMENT
5.1.	Toxicokinetics (absorption, metabolism, distribution and elimination)

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CSR content

Part A:

- Summary of risk reduction measures (RRM)*
- Declarations that RRM are implemented and communicated

Part B:

- Identity and phys-chem properties*
- Manufacture, identified uses, uses advised against*
- Classification and labelling*
- Environmental fate
- Human health hazards
- Human health hazards of phys-chem properties
- Environmental hazards
- PBT / vPvB assessment
- Exposure assessment
- Risk characterisation

Risk Characterisation ES 1	
Human Health	<i>Worker</i>
	<i>Consumer</i>
	<i>Via environment</i>
Environment	<i>Aquatic</i>
	<i>terrestrial</i>
	<i>atmospheric</i>
	<i>STP microorg.</i>

Risk Characterisation ES 2	
Human Health	<i>Worker</i>
	<i>Consumer</i>
	<i>Via environment</i>
Environment	<i>Aquatic</i>
	<i>terrestrial</i>
	<i>atmospheric</i>
	<i>STP microorg.</i>

Exposure scenario 1
Exposure scenario 2
Exposure scenario 3
...

Risk Characterisation overall exposure	
Human Health	
Environment	

Comprehensiveness of the safety assessment



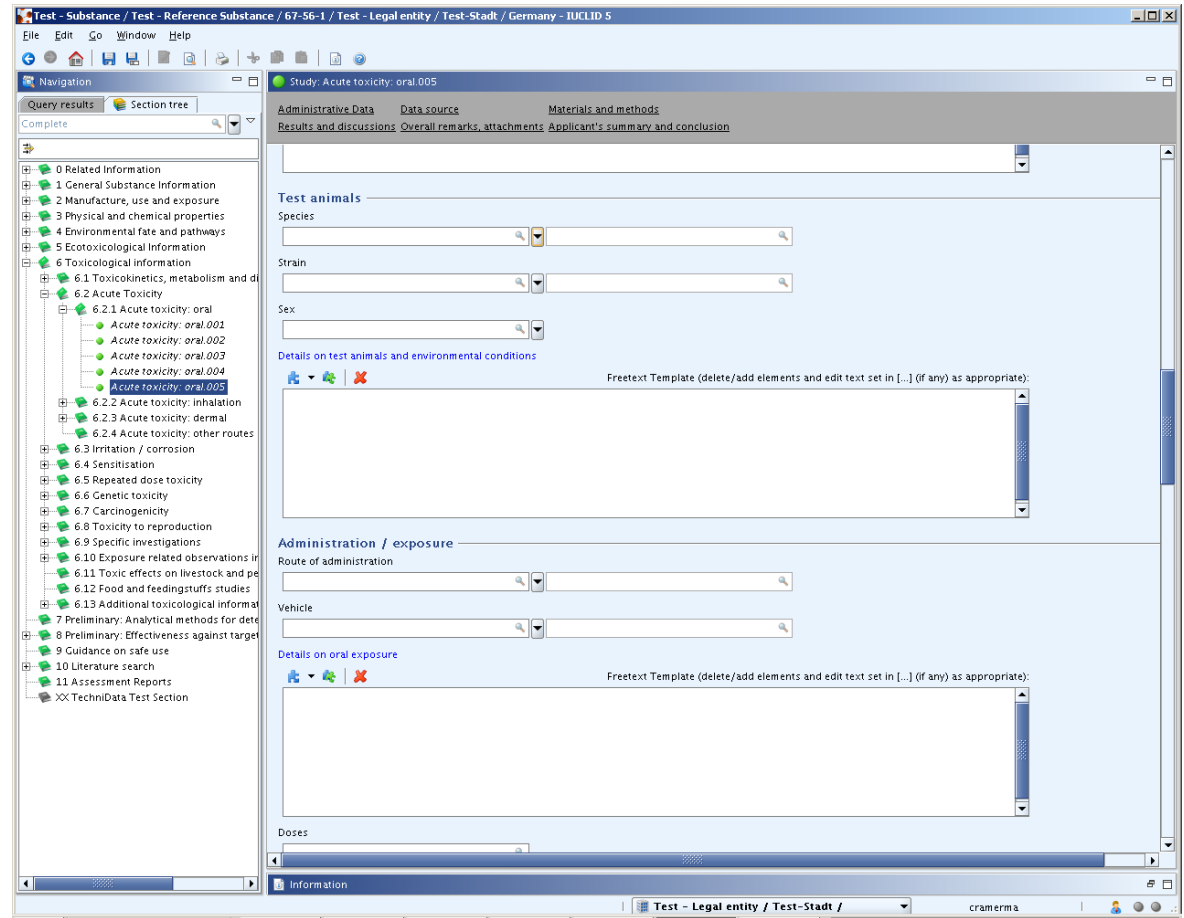
- Uses to be assessed:
 - All identified uses
 - Use as substance on its own, in preparations and articles
 - Exception: human health risk from use in cosmetics or food contact



- Exposures to be addressed:
 - Known and reasonably foreseeable exposures
 - With account to implemented and recommended risk management measures and operational conditions



IT-Tools?



- Data format for submission of technical dossier (Art. 110):
IUCLID
(International Uniform Chemical Information Database)
- Planned:
Software to generate parts of the CSR from information in
IUCLID

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Challenges

- Workload to fill IUCLID and prepare CSRs
- Need of trained personnel
- Laboratory capacities
- Estimate exposures
 - prerequisite:
detailed information from customers about
uses & operational conditions
 - calculation model EUSES extremely over-predictive
- Comprehensive communication of assessment via MSDS

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