

Compilation of the **Chemical Safety Report**

Product Safety


The Chemical Company

Dr. H.M. Hollnagel

GD / BfR REACH –Symposium

Berlin, 12 Oct 2006

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**

Product Safety

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

Product Safety

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**

Product Safety

 **BASF**
The Chemical Company

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

Product Safety

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

Product Safety

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

Product Safety

BASF
The Chemical Company

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) |

Product Safety

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



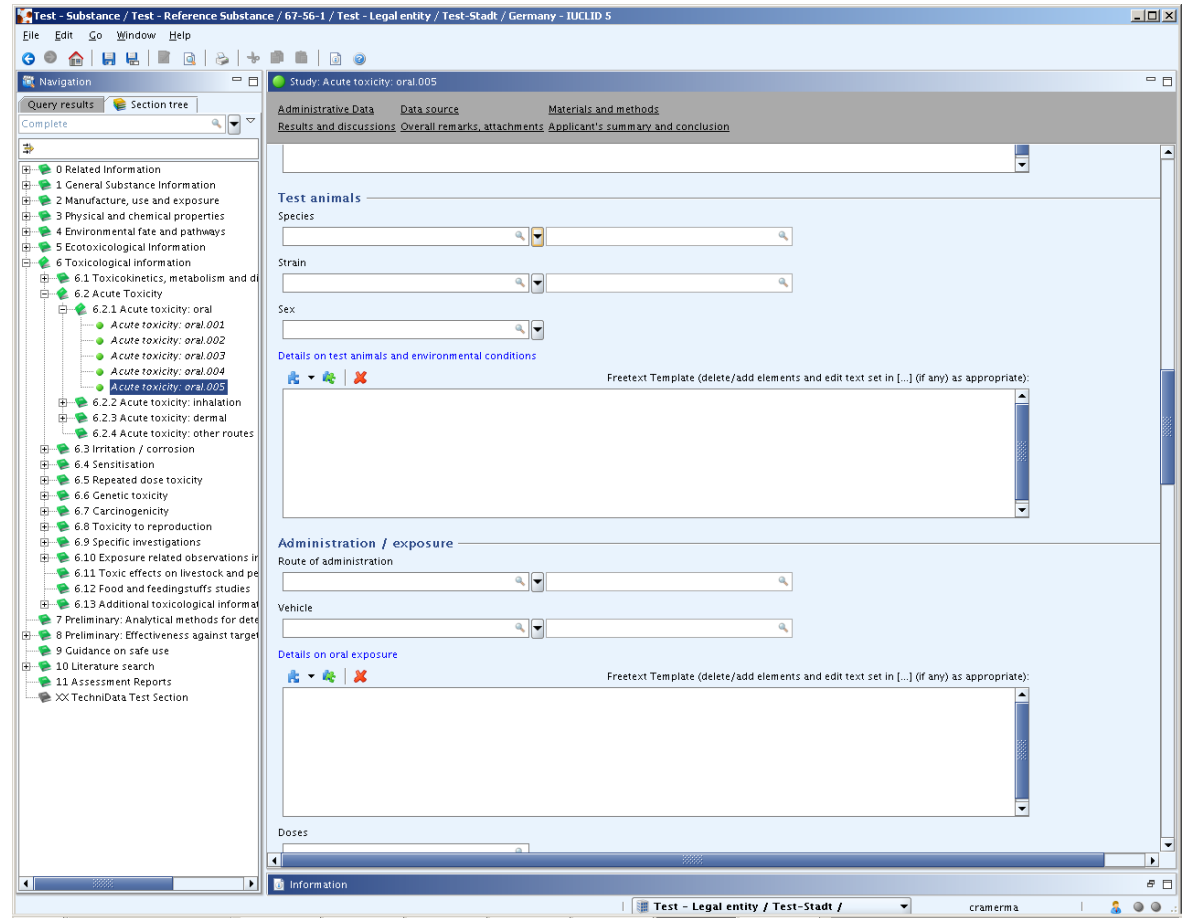
- Uses to be assessed:
 - All identified uses
 - Use as substance on its own, in preparations and articles
 - Exception: human health risk from use in cosmetics or food contact



- 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

Product Safety

 **BASF**
The Chemical Company

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

Product Safety