Case study:
Mixture exposure scenario for a coating product
Overview

• Introduction
• Case study: Mixture exposure scenario for a coating product
• Pros and cons for the case study
• General challenges and future improvements
• Sum up
Introduction

Communication with own manufacturing sites

Registrant

Manufacturer / Importer

Substance

Downstream user

Supplier

Raw material

Downstream user

Formulator

Product

Downstream user

End user

Introduction

Communication of safe use to the customer

Registrand → Downstream user

Manufacturer / Importer → Supplier

Substance → Raw material

Downstream user → Formulator

Product → End user

Exposure scenario for a mixture

REACH Article 31 (7), § 2
Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

ECHA Guidance for downstream users 2.1
If you place dangerous preparations on the market (formulator) you will still have to provide safety data sheets to your customers. In some cases, this may require you to consolidate or develop exposure scenarios covering uses of substances in your preparations further down the supply chain and to attach them to the safety data sheet (article 31 of REACH).
How to provide exposure scenario information to customers?

Options:

- Integrate information into the relevant sections of the SDS
- Develop exposure scenarios for your mixtures
- Attach the relevant exposure scenarios for the individual substances
Case study:
Mixture exposure scenario for a coating product

A typical protective coating product

- Contains 30 substances from 15 raw materials
- 50% of the substances are classified
- Classified substances often at concentrations <1%
- 5-10 substances contribute to the classification of the mixture
Basic assumptions

- Relevant exposure scenarios for all critical substances are received
- Our use is covered for all critical substances

Critical substances: substances that determine the risk for one or more adverse effects via one or more exposure pathways
Main goal

To provide a mixture exposure scenario which communicate information on safe use

How:
1. Identify critical substances
2. Evaluate and extract information from the substance exposure scenario
3. Adapt information to the mixture exposure scenario
4. Communication to end user
5. Use the mixture exposure scenario for similar products
1. Identify critical substances

DPD+ methodology
- Method to identify critical substances in a mixture (based on the Dangerous Preparations Directive)
- Taking vapour pressure into account
- For different exposure pathways (e.g. dermal, inhalation and the environment)
- Some substances need to be specifically addressed (e.g. CMRs, sensitizers and corrosive substances)

Link to DPD+ guide:
1. Identify critical substances

Seven substances contribute to the classification of the product.
Take all seven into account?

Two of seven substances are identified as critical substances using DPD+ methodology

Assumption: the two substances represent the dominant risks for the mixture
2. Evaluate and extract information from the substance exposure scenarios

Control of worker exposure – professional use, indoor

<table>
<thead>
<tr>
<th>Activity</th>
<th>RMM: Critical substance 1</th>
<th>RMM: Critical substance 2</th>
<th>Consolidated RMM: Critical substance 1 + 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preparation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventilation:</td>
<td>10-15 ACH</td>
<td>3-5 ACH</td>
<td>10-15 ACH, 15 mins - 1 hour</td>
</tr>
<tr>
<td>Duration:</td>
<td>15 mins - 1 hour</td>
<td>15 mins - 1 hours</td>
<td></td>
</tr>
<tr>
<td>RPE:</td>
<td>RPE (EN136)</td>
<td>RPE (EN136)</td>
<td></td>
</tr>
<tr>
<td><strong>Roller application</strong></td>
<td>10-15 ACH</td>
<td>RPE (EN140)</td>
<td>10-15 ACH, RPE (EN140)</td>
</tr>
<tr>
<td>Ventilation:</td>
<td>LEV</td>
<td>Partial enclosure + LEV</td>
<td></td>
</tr>
<tr>
<td>RPE:</td>
<td>RPE (EN136)</td>
<td>RPE (EN136)</td>
<td></td>
</tr>
<tr>
<td>Duration:</td>
<td>RPE (EN136)</td>
<td>1 - 4 hours</td>
<td></td>
</tr>
<tr>
<td><strong>Spray application</strong></td>
<td>LEV</td>
<td>Partial enclosure + LEV</td>
<td></td>
</tr>
<tr>
<td>Ventilation:</td>
<td>LEV</td>
<td>LEV (EN136)</td>
<td></td>
</tr>
<tr>
<td>RPE:</td>
<td>RPE (EN136)</td>
<td>RPE (EN136)</td>
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<tr>
<td>Duration:</td>
<td>RPE (EN136)</td>
<td>1 - 4 hours</td>
<td></td>
</tr>
</tbody>
</table>

RMM = Risk Management Measures
ACH = Air Changes per Hour
RPE = Respiratory Protective Equipment
LEV = Local Exhaust Ventilation
3. Adapt information to the mixture exposure scenario

Control of worker exposure – professional use, indoor

<table>
<thead>
<tr>
<th>Activity</th>
<th>Consolidated RMM: Critical substance 1+2</th>
<th>Product specific RMM in ES</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preparation</strong></td>
<td>10-15 ACH</td>
<td>10-15 ACH</td>
<td>RPE (EN140): 90 % exposure reduction 8 hours -&gt; 1 hour: 80% exposure reduction</td>
</tr>
<tr>
<td>Ventilation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration:</td>
<td>15 mins - 1 hour</td>
<td>15 mins - 1 hour <strong>or</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>RPE (EN140)</td>
<td></td>
</tr>
<tr>
<td><strong>Roller application</strong></td>
<td>10-15 ACH</td>
<td>10-15 ACH</td>
<td></td>
</tr>
<tr>
<td>Ventilation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Spray application</strong></td>
<td>Partial enclosure + LEV</td>
<td>Partial enclosure + LEV</td>
<td>Conc. of substance 1 in product &lt; 25% -&gt; Remove 1- 4 hours</td>
</tr>
<tr>
<td>Ventilation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration:</td>
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<td></td>
<td></td>
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RMM = Risk Management Measures
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4. Communication to end user

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   - Product name
   - Product code
   - Product description
   - Product type
   - Other means of identification

1.2 Relevant identified uses of the substance or mixture and uses advised against

<table>
<thead>
<tr>
<th>Identified uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses in Coatings - Industrial use</td>
</tr>
<tr>
<td>Uses in Coatings - Professional use</td>
</tr>
</tbody>
</table>

See Annex to the Safety data sheet for additional information in the Exposure Scenario(s).
4. Communication to end user

**Exposure Scenario:** Uses in Coatings - Professional use

<table>
<thead>
<tr>
<th>Sector of Use</th>
<th>Professional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Category</td>
<td>PROC05 PROC08a PROC10 PROC11</td>
</tr>
<tr>
<td>Environmental Release Categories</td>
<td>ERC8a ERC8d</td>
</tr>
</tbody>
</table>

Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including product transfer and preparation, application by brush, spray by hand or similar methods) and equipment cleaning.

**Operational conditions and risk management measures**

**Control of worker exposure**

<table>
<thead>
<tr>
<th>Frequency and duration of use</th>
<th>Covers daily exposures up to 8 hours (unless stated differently).</th>
</tr>
</thead>
<tbody>
<tr>
<td>General - Operational conditions</td>
<td>Assumes use at not more than 20°C above ambient temperature (unless stated differently). Assumes a good basic standard of occupational hygiene is implemented.</td>
</tr>
<tr>
<td>General - Risk Management Measures</td>
<td>Wear chemical-resistant gloves (tested to EN374) in combination with ‘basic’ employee training. Wear suitable coveralls to prevent exposure to the skin. Use suitable eye protection. See Section 8 for information on appropriate personal protective equipment.</td>
</tr>
</tbody>
</table>
### Risk Management Measures

<table>
<thead>
<tr>
<th>Type of activity or process</th>
<th>Risk Management Measures</th>
</tr>
</thead>
</table>
| Preparation of material for application - Indoor. | Provide a good standard of controlled ventilation (10 to 15 air changes per hour). Avoid carrying out activities involving exposure for more than 1 hour.  
or  
Provide a good standard of controlled ventilation (10 to 15 air changes per hour). Wear a respirator conforming to EN140 with Type A/P2 filter or better. |
| Preparation of material for application - Outdoor. | Ensure operation is undertaken outdoors. Avoid carrying out activities involving exposure for more than 1 hour.  
or  
Ensure operation is undertaken outdoors. Wear a respirator conforming to EN140 with Type A/P2 filter or better. |
| Roller, spreader, flow application - Indoor. | Provide a good standard of controlled ventilation (10 to 15 air changes per hour). Wear a respirator conforming to EN140 with Type A/P2 filter or better. |
| Roller, spreader, flow application - Outdoor. | Ensure operation is undertaken outdoors. Wear a full-face respirator conforming to EN136 with Type A/P2 filter or better. |
| Spraying - Manual - Indoor. | Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings. Wear a full-face respirator conforming to EN136 with Type A/P2 filter or better. |
| Spraying - Manual - Outdoor. | Ensure operation is undertaken outdoors. Wear a full-face respirator conforming to EN136 with Type A/P2 filter or better. |

### Control of environmental exposure

| Organisational measures to prevent/limit release from site | Prevent environmental discharge consistent with regulatory requirements. |
| Conditions and measures related to external treatment of waste for disposal | External treatment and disposal of waste should comply with applicable local and/or national regulations. See Section 13 for additional waste treatment information. |
| Conditions and measures related to external recovery of waste | External recovery and recycling of waste should comply with applicable local and/or national regulations. |

### Additional information

The exposure scenario for the mixture is based on the following substances:

REACH #: [Redacted]
REACH #: [Redacted]
5. Use the mixture exposure scenario for similar products

- Products with same critical substances at similar concentration range
- Same use descriptors (PROCs)
- The previous case study can be populated for ca. 30 products
- Many mixtures have only one critical substance
Pros and cons for the case study

Pros
• User friendly solution, one-page which communicates information on safe use of the mixture
• Verifiable, reference to substance
• Use existing software solution

Cons
• DPD+ is a hazard based approach
• Whole mixture not assessed
• Time-consuming and manual approach (grouping of formulation recipes makes it manageable)
General challenges and future improvements

Challenges
- Large variation in quality of substance exposure scenario
  -> improvement with Chesar and 2013 registration?
- Exposure levels are often not made available in eSDS
  -> not possible to derive risk characterisation ratios
- Technical challenges

Future improvements
- Anticipate that the DPD+ methodology can be substituted by “CLP+”
- More automated, less time-consuming approach
Sum up

• It is possible to develop a legal, user friendly, exposure scenario for a mixture

• Downstream users need to make the best out of the information they get from their suppliers (not in theory, but in real life)

• Focus on the main goal -> what information is needed for safe handling of the mixture
Thank you for your attention!