

## 15. Exposure scenario 15: Formulation or re-packing - Formulation of mixtures for use in biogas production

**Market sector:** Use in fermentation processes and biogas production

**Product category formulated:** PC 0: Other (Fermentation formulation)

Environment contributing scenario(s):		
CS 1	Formulation of mixtures for use in biogas production ES1 STP Discharge	ERC 2
CS 2	Formulation of mixtures for use in biogas production ES2 Direct Discharge	ERC 2
CS 3	Formulation of mixtures for use in biogas production ES3 Marine Discharge	ERC 2
Worker contributing scenario(s):		
CS 4	Raw material handling	PROC 26
CS 5	Formulation of solutions	PROC 3
CS 6	Production of solid formulations	PROC 3
CS 7	Filling of solutions containing <1 % of cobalt carbonate	PROC 8b
CS 8	Packaging of solid formulations containing <1 % of cobalt carbonate	PROC 26
CS 9	Cleaning & Maintenance	PROC 28

### Explanation on the approach taken for the ES

Please refer to IUCLID Section 13 for a detailed description of the specific methodology applied for the occupational exposure assessment.

### 15.1. Env CS 1: Formulation of mixtures for use in biogas production ES1 STP Discharge (ERC 2)

#### 15.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
<ul style="list-style-type: none"> <li>Daily use at site: <math>\leq 0.069</math> tonnes/day <i>The tonnage and further exposure is always expressed in cobalt.</i></li> </ul>
<ul style="list-style-type: none"> <li>Annual use at a site: <math>\leq 25</math> tonnes/year <i>For the generic exposure scenario a tonnage covering 100% of the sector tonnages was selected.</i></li> </ul>
<ul style="list-style-type: none"> <li>Number of release days per year: <math>\geq 360</math> days/year <i>The selected number of production days per year is the median value based on data from 3 companies.</i></li> </ul>
Technical and organisational conditions and measures
<ul style="list-style-type: none"> <li>Risk management measures: One or more of the following measures should be present to reduce emissions to water: Chemical precipitation, Sedimentation, Filtration, Electrolysis, Reverse osmosis or Ion exchange.</li> </ul>
<ul style="list-style-type: none"> <li>Risk management measures: One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones, but as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.</li> </ul>
Conditions and measures related to sewage treatment plant
<ul style="list-style-type: none"> <li>Municipal STP: Yes</li> </ul>
<ul style="list-style-type: none"> <li>Discharge rate of STP: <math>\geq 2E3</math> m<sup>3</sup>/d</li> </ul>
<ul style="list-style-type: none"> <li>Application of the STP sludge on agricultural soil: Yes</li> </ul>

Conditions and measures related to treatment of waste (including article waste)
<p>• Particular considerations on the waste treatment operations: No (low amount) (Particular risks from waste treatment unlikely due to small fraction of used substance entering into the waste stage. Waste disposal according to national/local legislation is sufficient.)  <i>Wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately or/and with other cobalt compounds waste to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the cobalt content of the waste is elevated enough, internal or external recovery/recycling might be considered. Appropriate waste codes: 01 03 07*, 02 01 10*, 06 05 02*, 06 03 13*, 06 03 15*, 06 04 05*, 10 08 04, 10 10 03, 10 10 05*, 10 10 07*, 10 10 10, 10 10 11*, 11 02 07*, 12 01 03*, 12 01 04, 15 01 04*, 15 01 10*, 16 01 04*, 16 01 06*, 16 01 18*, 16 03 03*, 16 06 02*, 16 06 05, 16 08 02*, 16 08 03, 16 10 01*, 17 04 07*, 17 04 09*, 17 09 04*, 19 10 02*, 19 12 03*,... Suitable disposal: Keep separate and dispose of to either - Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006. - Hazardous landfill operated under Directive 1999/31/EC. A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)</i></p>
Other conditions affecting environmental exposure
• Discharge rate of effluent: $\geq 2E3$ m <sup>3</sup> /d
• Receiving surface water flow rate: $\geq 9.98E5$ m <sup>3</sup> /d
• Final dilution factor: $\geq 500$

### 15.1.2. Releases

The local releases to the environment are reported in the following table.

**Table 9.141. Local releases to the environment**

Release	Release factor estimation method	Explanation / Justification
<b>Water</b>	Release factor (SpERC for formulation of metal compounds)	<b>Initial release factor:</b> 0.5% <b>Final release factor:</b> 0.5% <b>Local release rate:</b> 0.347 kg/day <b>Explanation / Justification:</b> Eurométaux, 2012, version 2.1 The reported release factor for water is based on emissions before treatment. Reported risk management measures for wastewater is on-site WWTP (removal efficiency >75%). The release factor to water after treatment for this specific use is thus 0.5% (i.e. 5000 g/T)
<b>Air</b>	Release factor (SpERC for formulation of metal compounds)	<b>Initial release factor:</b> 0.01% <b>Final release factor:</b> 0.01% <b>Local release rate:</b> 0.007 kg/day <b>Explanation / Justification:</b> Eurométaux, 2012, version 2.1
<b>Soil</b>	Release factor	<b>Final release factor:</b> 0% <b>Explanation / Justification:</b> No direct release to soil.

#### Releases to waste

**Release factor to external waste:** 0.1 %

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

### 15.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.142. Exposure concentrations and risks for the environment and man via the**

**environment**

Protection target	Exposure concentration	Risk characterisation
Freshwater	<b>Local PEC:</b> 0.23 µg/l	0.38
Sediment (freshwater)	<b>Local PEC:</b> 9.32 mg/kg dw	0.98
Sewage treatment plant	<b>Local PEC:</b> 0.10 mg/l	0.28
Air	<b>Local PEC:</b> 1.9 ng/m <sup>3</sup>	No environmental hazard
Agricultural soil	<b>Local PEC:</b> 3.28 mg/kg dw	0.30
Man via Environment - Inhalation	<b>Local PEC:</b> 1.9 ng/m <sup>3</sup>	< 0.01
Man via Environment - Oral	<b>Exposure via food consumption:</b> 0.324 µg/kg/d	< 0.01

**Conclusion on risk characterisation****MAN VIA ENVIRONMENT:**

The use of EUSES to predict the concentration in food is difficult to apply for metals and associated with much higher uncertainties than using measured data. Therefore, deviations from the TGD food basket approach for the exposure route “ingestion of food”, have been applied as shortly described in section 9.0.3.6..

Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species. The oral exposure concentration in µg/kg bw/day has been derived by taking 2L of drinking water (PEC freshwater taken from the local environmental exposure assessment) + the worst case exposure of 19 µg Co/d from food (97.5th percentile from the 1994 UK total diet study (please refer to section 9.0.3.6) and a default body weight of 60kg into account.

For the risk characterisation the following DNELs based on cobalt were used:

DNEL inhalation, local, long-term of 6.3 µg Co/m<sup>3</sup>

DNEL oral, systemic, long-term of 8.6 mg Co/kg bw/day

As such a combined RCR cannot be provided (local and systemic effects).

## **15.2. Env CS 2: Formulation of mixtures for use in biogas production ES2 Direct Discharge (ERC 2)**

### **15.2.1. Conditions of use**

<b>Amount used, frequency and duration of use (or from service life)</b>
<ul style="list-style-type: none"> <li>Daily use at site: &lt;= 0.069 tonnes/day <i>The tonnage and further exposure is always expressed in cobalt.</i></li> </ul>
<ul style="list-style-type: none"> <li>Annual use at a site: &lt;= 25 tonnes/year <i>For the generic exposure scenario a tonnage covering 100% of the sector tonnages was selected.</i></li> </ul>
<ul style="list-style-type: none"> <li>Number of release days per year: &gt;= 360 days/year <i>The selected number of production days per year is the median value based on data from 3 companies.</i></li> </ul>
<b>Technical and organisational conditions and measures</b>
<ul style="list-style-type: none"> <li>Risk management measures: One or more of the following measures should be present to reduce emissions to water: Chemical precipitation, Sedimentation, Filtration, Electrolysis, Reverse osmosis or Ion exchange.</li> </ul>
<ul style="list-style-type: none"> <li>Risk management measures: One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones, but as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.</li> </ul>
<b>Conditions and measures related to sewage treatment plant</b>
<ul style="list-style-type: none"> <li>Municipal STP: No [Effectiveness Water: 0%]</li> </ul>
<b>Conditions and measures related to treatment of waste (including article waste)</b>
<ul style="list-style-type: none"> <li>Particular considerations on the waste treatment operations: No (low amount) (Particular risks from</li> </ul>

waste treatment unlikely due to small fraction of used substance entering into the waste stage. Waste disposal according to national/local legislation is sufficient.)

*Wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately or/and with other cobalt compounds waste to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the cobalt content of the waste is elevated enough, internal or external recovery/recycling might be considered. Appropriate waste codes: 01 03 07\*, 02 01 10\*, 06 05 02\*, 06 03 13\*, 06 03 15\*, 06 04 05\*, 10 08 04, 10 10 03, 10 10 05\*, 10 10 07\*, 10 10 10, 10 10 11\*, 11 02 07\*, 12 01 03\*, 12 01 04, 15 01 04\*, 15 01 10\*, 16 01 04\*, 16 01 06\*, 16 01 18\*, 16 03 03\*, 16 06 02\*, 16 06 05, 16 08 02\*, 16 08 03, 16 10 01\*, 17 04 07\*, 17 04 09\*, 17 09 04\*, 19 10 02\*, 19 12 03\*,... Suitable disposal: Keep separate and dispose of to either - Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006. - Hazardous landfill operated under Directive 1999/31/EC. A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)*

#### Other conditions affecting environmental exposure

- Discharge rate of effluent:  $\geq 2E3$  m<sup>3</sup>/d
- Receiving surface water flow rate:  $\geq 1.998E6$  m<sup>3</sup>/d
- Final dilution factor:  $\geq 1E3$

## 15.2.2. Releases

The local releases to the environment are reported in the following table.

**Table 9.143. Local releases to the environment**

Release	Release factor estimation method	Explanation / Justification
Water	Release factor (SpERC for formulation of metal compounds)	<b>Initial release factor:</b> 0.5% <b>Final release factor:</b> 0.5% <b>Local release rate:</b> 0.347 kg/day <b>Explanation / Justification:</b> Eurométaux, 2012, version 2.1 The reported release factor for water is based on emissions before treatment. Reported risk management measures for wastewater is on-site WWTP (removal efficiency >75%). The release factor to water after treatment for this specific use is thus 0.5% (i.e. 5000 g/T)
Air	Release factor (SpERC for formulation of metal compounds)	<b>Initial release factor:</b> 0.01% <b>Final release factor:</b> 0.01% <b>Local release rate:</b> 0.007 kg/day <b>Explanation / Justification:</b> Eurométaux, 2012, version 2.1
Soil	Release factor	<b>Final release factor:</b> 0% <b>Explanation / Justification:</b> No direct release to soil.

### Releases to waste

**Release factor to external waste:** 0.1 %

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

## 15.2.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.144. Exposure concentrations and risks for the environment and man via the environment**

Protection target	Exposure concentration	Risk characterisation
-------------------	------------------------	-----------------------

Protection target	Exposure concentration	Risk characterisation
Freshwater	Local PEC: 0.21 µg/l	0.35
Sediment (freshwater)	Local PEC: 8.48 mg/kg dw	0.89
Air	Local PEC: 1.9 ng/m <sup>3</sup>	No environmental hazard
Agricultural soil	Local PEC: 0.01 mg/kg dw	< 0.01
Man via Environment - Inhalation	Local PEC: 1.9 ng/m <sup>3</sup>	< 0.01
Man via Environment - Oral	Exposure via food consumption: 0.324 µg/kg/d	< 0.01

### **Conclusion on risk characterisation**

#### **MAN VIA ENVIRONMENT:**

The use of EUSES to predict the concentration in food is difficult to apply for metals and associated with much higher uncertainties than using measured data. Therefore, deviations from the TGD food basket approach for the exposure route “ingestion of food”, have been applied as shortly described in section 9.0.3.6..

Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species. The oral exposure concentration in µg/kg bw/day has been derived by taking 2L of drinking water (PEC freshwater taken from the local environmental exposure assessment) + the worst case exposure of 19 µg Co/d from food (97.5th percentile from the 1994 UK total diet study (please refer to section 9.0.3.6) and a default body weight of 60kg into account.

For the risk characterisation the following DNELs based on cobalt were used:

DNEL inhalation, local, long-term of 6.3 µg Co/m<sup>3</sup>

DNEL oral, systemic, long-term of 8.6 mg Co/kg bw/day

As such a combined RCR cannot be provided (local and systemic effects).

## **15.3. Env CS 3: Formulation of mixtures for use in biogas production ES3 Marine Discharge (ERC 2)**

### **15.3.1. Conditions of use**

<b>Amount used, frequency and duration of use (or from service life)</b>
<ul style="list-style-type: none"> <li>Daily use at site: &lt;= 0.069 tonnes/day <i>The tonnage and further exposure is always expressed in cobalt.</i></li> </ul>
<ul style="list-style-type: none"> <li>Annual use at a site: &lt;= 25 tonnes/year <i>For the generic exposure scenario a tonnage covering 100% of the sector tonnages was selected.</i></li> </ul>
<ul style="list-style-type: none"> <li>Number of release days per year: &gt;= 360 days/year <i>The selected number of production days per year is the median value based on data from 3 companies.</i></li> </ul>
<b>Technical and organisational conditions and measures</b>
<ul style="list-style-type: none"> <li>Risk management measures: One or more of the following measures should be present to reduce emissions to water: Chemical precipitation, Sedimentation, Filtration, Electrolysis, Reverse osmosis or Ion exchange.</li> </ul>
<ul style="list-style-type: none"> <li>Risk management measures: One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones, but as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.</li> </ul>
<b>Conditions and measures related to sewage treatment plant</b>
<ul style="list-style-type: none"> <li>Municipal STP: No [Effectiveness Water: 0%]</li> </ul>
<b>Conditions and measures related to treatment of waste (including article waste)</b>
<ul style="list-style-type: none"> <li>Particular considerations on the waste treatment operations: No (low amount) (Particular risks from waste treatment unlikely due to small fraction of used substance entering into the waste stage. Waste disposal according to national/local legislation is sufficient.) <i>Wastes from onsite risk management measures and solid or liquid wastes from production, use and</i></li> </ul>

cleaning processes should be disposed of separately or/and with other cobalt compounds waste to hazardous waste incineration plants or hazardous waste landfills as hazardous waste. Releases to the floor, water and soil are to be prevented. If the cobalt content of the waste is elevated enough, internal or external recovery/recycling might be considered. Appropriate waste codes: 01 03 07\*, 02 01 10\*, 06 05 02\*, 06 03 13\*, 06 03 15\*, 06 04 05\*, 10 08 04, 10 10 03, 10 10 05\*, 10 10 07\*, 10 10 10, 10 10 11\*, 11 02 07\*, 12 01 03\*, 12 01 04, 15 01 04\*, 15 01 10\*, 16 01 04\*, 16 01 06\*, 16 01 18\*, 16 03 03\*, 16 06 02\*, 16 06 05, 16 08 02\*, 16 08 03, 16 10 01\*, 17 04 07\*, 17 04 09\*, 17 09 04\*, 19 10 02\*, 19 12 03\*,... Suitable disposal: Keep separate and dispose of to either - Hazardous waste incineration operated according to Council Directive 2008/98/EC on waste, Directive 2000/76/EC on the incineration of waste and the Reference Document on the Best Available Techniques for Waste Incineration of August 2006. - Hazardous landfill operated under Directive 1999/31/EC. A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

#### Other conditions affecting environmental exposure

- Discharge rate of effluent:  $\geq 2E3$  m<sup>3</sup>/d
- Receiving surface water flow rate:  $\geq 1.598E6$  m<sup>3</sup>/d
- Final dilution factor:  $\geq 800$

### 15.3.2. Releases

The local releases to the environment are reported in the following table.

**Table 9.145. Local releases to the environment**

Release	Release factor estimation method	Explanation / Justification
Water	Release factor (SpERC for formulation of metal compounds)	<b>Initial release factor:</b> 0.5% <b>Final release factor:</b> 0.5% <b>Local release rate:</b> 0.347 kg/day <b>Explanation / Justification:</b> Eurométaux, 2012, version 2.1 The reported release factor for water is based on emissions before treatment. Reported risk management measures for wastewater is on-site WWTP (removal efficiency >75%). The release factor to water after treatment for this specific use is thus 0.5% (i.e. 5000 g/T)
Air	Release factor (SpERC for formulation of metal compounds)	<b>Initial release factor:</b> 0.01% <b>Final release factor:</b> 0.01% <b>Local release rate:</b> 0.007 kg/day <b>Explanation / Justification:</b> Eurométaux, 2012, version 2.1
Soil	Release factor	<b>Final release factor:</b> 0% <b>Explanation / Justification:</b> No direct release to soil.

#### Releases to waste

**Release factor to external waste:** 0.1 %

A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

### 15.3.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.146. Exposure concentrations and risks for the environment and man via the environment**

Protection target	Exposure concentration	Risk characterisation
Marine water	<b>Local PEC:</b> 0.11 µg/l	0.35
Sediment (marine water)	<b>Local PEC:</b> 8.75 mg/kg dw	0.92

Protection target	Exposure concentration	Risk characterisation
Air	Local PEC: 1.9 ng/m <sup>3</sup>	No environmental hazard
Agricultural soil	Local PEC: 0.01 mg/kg dw	< 0.01
Man via Environment - Inhalation	Local PEC: 1.9 ng/m <sup>3</sup>	< 0.01
Man via Environment - Oral	Exposure via food consumption: 0.317 µg/kg/d	< 0.01

#### Conclusion on risk characterisation

##### MAN VIA ENVIRONMENT:

The use of EUSES to predict the concentration in food is difficult to apply for metals and associated with much higher uncertainties than using measured data. Therefore, deviations from the TGD food basket approach for the exposure route "ingestion of food", have been applied as shortly described in section 9.0.3.6..

Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species. The oral exposure concentration in µg/kg bw/day has been derived by taking 2L of drinking water (PEC freshwater taken from the local environmental exposure assessment) + the worst case exposure of 19 µg Co/d from food (97.5th percentile from the 1994 UK total diet study (please refer to section 9.0.3.6) and a default body weight of 60kg into account.

For the risk characterisation the following DNELs based on cobalt were used:

DNEL inhalation, local, long-term of 6.3 µg Co/m<sup>3</sup>

DNEL oral, systemic, long-term of 8.6 mg Co/kg bw/day

As such a combined RCR cannot be provided (local and systemic effects).

## 15.4. Worker CS 4: Raw material handling (PROC 26)

Task(s) covered with this contributing scenario: Opening of containers / dosing, immediate removal of wet splashes.

### 15.4.1. Conditions of use

	Method
Product (Article) characteristics	
<ul style="list-style-type: none"> <li>Maximum emission potential of the substance: Medium <i>Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]</li> </ul>	
<ul style="list-style-type: none"> <li>Physical form of substance: Solid, powder / dust</li> </ul>	
<ul style="list-style-type: none"> <li>Additional physical form of substance: Aqueous solution</li> </ul>	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> <li>Duration per shift: = 480.0 min</li> </ul>	
<ul style="list-style-type: none"> <li>Shifts per year: = 24.0 Shifts/year <i>Typical number of shifts per year during which this task is conducted considering a single worker. This value has been taken into account in the calculation of excess cancer risk.</i></li> </ul>	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> <li>Process temperature: Ambient</li> </ul>	
<ul style="list-style-type: none"> <li>Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] <i>High efficiency</i></li> </ul>	
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
<ul style="list-style-type: none"> <li>• General good occupational hygiene practices <i>Required good occupational hygiene practices to ensure a safe handling of the substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required <i>Due to the skin sensitizing effect of the substance, protective gloves according to EN 374 have to be worn at all workplaces unless any exposure to the substance can be excluded when taking into account the nature of the conducted process, applied exposure prevention measures and physical appearance of the substance of concern in the specific type of application (e.g. protecting from splashes by containment of emission source). Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. Additionally, face protection is required to be worn as appropriate. This level of protection is to be achieved by continuous supervision and training of workers wearing gloves.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Certified safety clothing and shoes <i>Certified safety clothing including coveralls and safety shoes are to be worn as appropriate. Face protection may be worn if the type of process is associated with the risk of face injuries due to thermal or mechanical stress.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Chemical protective suit according to EN 13982 <i>In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.</i></li> </ul>	

#### 15.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.147. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	1 µg/m <sup>3</sup> (Measured data: Monitoring data)	RCR = 0.012

#### Remarks on measured exposure:

##### **Monitoring data**

Identity of the substance used: Exposure reported as substance

Inhalation exposure, long term concentration: Number of measured data points: 6; GSD: 1

##### Risk characterisation

Qualitative risk characterisation:

The risk characterisation for local dermal effects is given in Section 9.0.4.2.

### 15.5. Worker CS 5: Formulation of solutions (PROC 3)

Task(s) covered with this contributing scenario: Dissolution.

#### 15.5.1. Conditions of use

	Method
Product (Article) characteristics	
<ul style="list-style-type: none"> <li>Maximum emission potential of the substance: Very low <i>Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]</li> </ul>	
<ul style="list-style-type: none"> <li>Physical form of substance: Aqueous solution</li> </ul>	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> <li>Duration per shift: = 480.0 min</li> </ul>	
<ul style="list-style-type: none"> <li>Shifts per year: = 24.0 Shifts/year <i>Typical number of shifts per year during which this task is conducted considering a single worker. This value has been taken into account in the calculation of excess cancer risk.</i></li> </ul>	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> <li>Process temperature: Ambient</li> </ul>	
<ul style="list-style-type: none"> <li>Level of containment: Closed process <i>Closed pipe system, closed reaction vessels</i></li> </ul>	
<ul style="list-style-type: none"> <li>Level of automation: Semi-automated process</li> </ul>	
<ul style="list-style-type: none"> <li>Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] <i>High efficiency Vapour extraction units in the tank</i></li> </ul>	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> <li>General good occupational hygiene practices <i>Required good occupational hygiene practices to ensure a safe handling of the substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required <i>Due to the skin sensitizing effect of the substance, protective gloves according to EN 374 have to be worn at all workplaces unless any exposure to the substance can be excluded when taking into account the nature of the conducted process, applied exposure prevention measures and physical appearance of the substance of concern in the specific type of application (e.g. protecting from splashes by containment of emission source). Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. Additionally, face protection is required to be worn as appropriate. This level of protection is to be achieved by continuous supervision and training of workers wearing gloves.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Certified safety clothing and shoes <i>Certified safety clothing including coveralls and safety shoes are to be worn as appropriate. Face protection may be worn if the type of process is associated</i></li> </ul>	

	Method
<i>with the risk of face injuries due to thermal or mechanical stress.</i>	

### 15.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.148. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	5 µg/m <sup>3</sup> (Measured data: Analogous data)	RCR = 0.062

#### Remarks on measured exposure:

#### **Analogous data**

Identity of the substance used: Exposure reported as substance

Inhalation exposure, long term concentration: Number of measured data points: 94; GSD: 2.7

#### Risk characterisation

Qualitative risk characterisation:

The risk characterisation for local dermal effects is given in Section 9.0.4.2.

## 15.6. Worker CS 6: Production of solid formulations (PROC 3)

Task(s) covered with this contributing scenario: Mixing, milling, sieving, blending.

### 15.6.1. Conditions of use

	Method
Product (Article) characteristics	
<ul style="list-style-type: none"> <li>Maximum emission potential of the substance: Medium <i>Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]</li> </ul>	
<ul style="list-style-type: none"> <li>Physical form of substance: Solid</li> </ul>	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> <li>Duration per shift: = 480.0 min</li> </ul>	
<ul style="list-style-type: none"> <li>Shifts per year: = 24.0 Shifts/year <i>Typical number of shifts per year during which this task is conducted considering a single worker. This value has been taken into account in the calculation of excess cancer risk.</i></li> </ul>	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> <li>Process temperature: Ambient</li> </ul>	
<ul style="list-style-type: none"> <li>Level of containment: Closed process <i>Closed pipe system, closed reaction vessels</i></li> </ul>	
<ul style="list-style-type: none"> <li>Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] <i>High efficiency</i></li> </ul>	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> <li>General good occupational hygiene practices <i>Required good occupational hygiene practices to ensure a safe handling of the</i></li> </ul>	

	Method
<p>substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.</p>	
<ul style="list-style-type: none"> <li>Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required  <i>Due to the skin sensitizing effect of the substance, protective gloves according to EN 374 have to be worn at all workplaces unless any exposure to the substance can be excluded when taking into account the nature of the conducted process, applied exposure prevention measures and physical appearance of the substance of concern in the specific type of application (e.g. protecting from splashes by containment of emission source). Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. Additionally, face protection is required to be worn as appropriate. This level of protection is to be achieved by continuous supervision and training of workers wearing gloves.</i> </li> </ul>	
<ul style="list-style-type: none"> <li>Certified safety clothing and shoes  <i>Certified safety clothing including coveralls and safety shoes are to be worn as appropriate. Face protection may be worn if the type of process is associated with the risk of face injuries due to thermal or mechanical stress.</i> </li> </ul>	

### 15.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.149. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	1 µg/m <sup>3</sup> (Measured data: Analogous data)	RCR = 0.012

#### Remarks on measured exposure:

##### **Analogous data**

Identity of the substance used: Exposure reported as substance

Inhalation exposure, long term concentration: Number of measured data points: 6; GSD: 1

##### **Risk characterisation**

Qualitative risk characterisation:

The risk characterisation for local dermal effects is given in Section 9.0.4.2.

## 15.7. Worker CS 7: Filling of solutions containing <1 % of cobalt carbonate (PROC 8b)

Task(s) covered with this contributing scenario: Filling of formulated solutions, immediate removal of wet splashes.

### 15.7.1. Conditions of use

	Method
Product (Article) characteristics	

	Method
<ul style="list-style-type: none"> <li>Maximum emission potential of the substance: Very low <i>Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Content in preparation: &lt; 1 % [Effectiveness Inhalation: 90%, Dermal: 90%]</li> </ul>	
<ul style="list-style-type: none"> <li>Physical form of substance: Aqueous solution</li> </ul>	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> <li>Duration per shift: = 480.0 min</li> </ul>	
<ul style="list-style-type: none"> <li>Shifts per year: = 24.0 Shifts/year <i>Typical number of shifts per year during which this task is conducted considering a single worker. This value has been taken into account in the calculation of excess cancer risk.</i></li> </ul>	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> <li>Process temperature: Ambient</li> </ul>	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> <li>General good occupational hygiene practices <i>Required good occupational hygiene practices to ensure a safe handling of the substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required <i>Due to the skin sensitizing effect of the substance, protective gloves according to EN 374 have to be worn at all workplaces unless any exposure to the substance can be excluded when taking into account the nature of the conducted process, applied exposure prevention measures and physical appearance of the substance of concern in the specific type of application (e.g. protecting from splashes by containment of emission source). Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. Additionally, face protection is required to be worn as appropriate. This level of protection is to be achieved by continuous supervision and training of workers wearing gloves.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Certified safety clothing and shoes <i>Certified safety clothing including coveralls and safety shoes are to be worn as appropriate. Face protection may be worn if the type of process is associated with the risk of face injuries due to thermal or mechanical stress.</i></li> </ul>	

### 15.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.150. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
---------------------------------------	------------------------	---------------------

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	1 µg/m <sup>3</sup> (Measured data: Analogous data)	RCR = 0.012

**Remarks on measured exposure:****Analogous data**

Identity of the substance used: Exposure reported as substance

Inhalation exposure, long term concentration: Number of measured data points: 6; GSD: 1

**Risk characterisation**

Qualitative risk characterisation:

The risk characterisation for local dermal effects is given in Section 9.0.4.2.

## 15.8. Worker CS 8: Packaging of solid formulations containing <1 % of cobalt carbonate (PROC 26)

Task(s) covered with this contributing scenario: Packaging of powders, granules or other solid formulations.

**15.8.1. Conditions of use**

	Method
Product (Article) characteristics	
<ul style="list-style-type: none"> <li>Maximum emission potential of the substance: Medium <i>Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Content in preparation: &lt; 1 % [Effectiveness Inhalation: 90%, Dermal: 90%]</li> </ul>	
<ul style="list-style-type: none"> <li>Physical form of substance: Solid, powder / dust</li> </ul>	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> <li>Duration per shift: = 480.0 min</li> </ul>	
<ul style="list-style-type: none"> <li>Shifts per year: = 24.0 Shifts/year <i>Typical number of shifts per year during which this task is conducted considering a single worker. This value has been taken into account in the calculation of excess cancer risk.</i></li> </ul>	
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> <li>Process temperature: Ambient</li> </ul>	
<ul style="list-style-type: none"> <li>Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] <i>High efficiency</i></li> </ul>	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> <li>General good occupational hygiene practices <i>Required good occupational hygiene practices to ensure a safe handling of the substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.</i></li> </ul>	

	Method
<ul style="list-style-type: none"> <li>Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required <i>Due to the skin sensitizing effect of the substance, protective gloves according to EN 374 have to be worn at all workplaces unless any exposure to the substance can be excluded when taking into account the nature of the conducted process, applied exposure prevention measures and physical appearance of the substance of concern in the specific type of application (e.g. protecting from splashes by containment of emission source). Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. Additionally, face protection is required to be worn as appropriate. This level of protection is to be achieved by continuous supervision and training of workers wearing gloves.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Certified safety clothing and shoes <i>Certified safety clothing including coveralls and safety shoes are to be worn as appropriate. Face protection may be worn if the type of process is associated with the risk of face injuries due to thermal or mechanical stress.</i></li> </ul>	

### 15.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.151. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	1 µg/m <sup>3</sup> (Measured data: Analogous data)	RCR = 0.012

#### Remarks on measured exposure:

#### **Analogous data**

Identity of the substance used: Exposure reported as substance

Inhalation exposure, long term concentration: Number of measured data points: 6; GSD: 1

#### Risk characterisation

Qualitative risk characterisation:

The risk characterisation for local dermal effects is given in Section 9.0.4.2.

## 15.9. Worker CS 9: Cleaning & Maintenance (PROC 28)

Task(s) covered with this contributing scenario: Manual cleaning, repair and maintenance operations, removal of residuals from e.g. filters/overspill or as waste.

### 15.9.1. Conditions of use

	Method
Product (Article) characteristics	
<ul style="list-style-type: none"> <li>Maximum emission potential of the substance: High <i>Only the highest emission potential (EP) is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel) are thus automatically covered in this assessment.</i></li> </ul>	
<ul style="list-style-type: none"> <li>Physical form of substance: Solid, powder / dust</li> </ul>	
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> <li>Duration per shift: = 480.0 min</li> </ul>	
<ul style="list-style-type: none"> <li>Shifts per year: = 24.0 Shifts/year <i>Typical number of shifts per year during which this task is conducted</i></li> </ul>	

	Method
<i>considering a single worker. This value has been taken into account in the calculation of excess cancer risk.</i>	
Technical and organisational conditions and measures	
• Process temperature: Ambient	
• Process pressure: Ambient	
• Additional operational conditions for cleaning and maintenance: Maintenance and repair work only at machinery/systems which are not in operation. Minor cleaning tasks may be conducted under operation.	
Conditions and measures related to personal protection, hygiene and health evaluation	
<ul style="list-style-type: none"> <li>• General good occupational hygiene practices <i>Required good occupational hygiene practices to ensure a safe handling of the substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required <i>Due to the skin sensitizing effect of the substance, protective gloves according to EN 374 have to be worn at all workplaces unless any exposure to the substance can be excluded when taking into account the nature of the conducted process, applied exposure prevention measures and physical appearance of the substance of concern in the specific type of application (e.g. protecting from splashes by containment of emission source). Gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier. Additionally, face protection is required to be worn as appropriate. This level of protection is to be achieved by continuous supervision and training of workers wearing gloves.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Certified safety clothing and shoes <i>Certified safety clothing including coveralls and safety shoes are to be worn as appropriate. Face protection may be worn if the type of process is associated with the risk of face injuries due to thermal or mechanical stress.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Chemical protective suit according to EN 13982 <i>In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.</i></li> </ul>	
<ul style="list-style-type: none"> <li>• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] <i>APF = assigned protection factor according to EN 529. At minimum any combination of particle filter class P2 with mask according to EN 140, EN 1827 or EN 136 or filtering half mask (FF P2) according to EN 149 or combination of P1 filter with face piece according EN 12942 or any RPE providing higher APFs according to EN 529 is required.</i></li> </ul>	

### 15.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

**Table 9.152. Exposure concentrations and risks for workers**

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	16.5 µg/m <sup>3</sup> (Measured data: Analogous data)	RCR = 0.205

**Remarks on measured exposure:****Analogous data**

Identity of the substance used: Exposure reported as substance

Inhalation exposure, long term concentration: Number of measured data points: 106; GSD: 4.2

**Risk characterisation**

Qualitative risk characterisation:

The risk characterisation for local dermal effects is given in Section 9.0.4.2.