CHEMICAL SAFETY REPORT

SECTIONS 9 & 10

CHESAR

Stearic acid, cobalt salt

Final Report

8 November 2018

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9. EXPOSURE ASSESSMENT (and related risk characterisation)

The sections 9 and 10 of this CSR have been generated with Chesar 3.3.

9.0. Introduction

9.0.1. Overview on uses

See the description of the various uses in section 2 of the CSR.

9.0.2. Assessment entity groups

Not applicable.

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

Not applicable.

9.0.3.2. Scope and type of assessment for the environment

The scope of exposure assessment and type of risk characterisation required for the environment are described in the following table based on the hazard conclusions presented in section 7.

Table 9.2. Type of risk characterisation required for the environment

Protection target	Risk characterisation type	Hazard conclusion (see section 7)
Fresh water	Quantitative	PNEC aqua (freshwater) = 0.62 µg/L
Sediment (freshwater)	Quantitative	PNEC sediment (freshwater) = 53.8 mg/kg sediment dw
Marine water	Quantitative	PNEC aqua (marine water) = 2.36 µg/L
Sediment (marine water)	Quantitative	PNEC sediment (marine water) = 69.8 mg/kg sediment dw
Sewage Treatment Plant	Quantitative	PNEC STP = 0.37 mg/L
Air	Undefined	
Agricultural soil	Quantitative	PNEC soil = 10.9 mg/kg soil dw
Predator's prey (freshwater)	Not needed	No potential for bioaccumulation
Predator's prey (marine water)	Not needed	No potential for bioaccumulation
Top predator's prey (marine water)	Not needed	No potential for bioaccumulation
Predator's prey (terrestrial)	Not needed	No potential for bioaccumulation

9.0.3.3. Fate and distribution parameters

Physicochemical properties used for exposure estimation

The following substance properties are used in the fate estimation done by EUSES. They correspond to the "value used for CSA" reported in sections 1 and 4.

Table 9.3. Substance key phys-chem and fate properties

Substance property	Value
Molecular weight	
Molecular weight used for the assessment	625.9
Vapour pressure	1E-12 Pa at 20 °C
Water solubility	92.6 mg/L at 20 °C
Biodegradation in water: screening tests	under test conditions no biodegradation observed
Log Kp (solids-water in soil)	3.47
Log Kp (solids water in sediment)	2.94
Log Kp (solids-water in suspended matter)	4.59

Fate (release percentage) in the modelled biological sewage treatment plant

In a standard (modelled) biological STP, the emissions are distributed in the following way:

Release to water	60%
Release to air	0%
Release to sludge	40%
Release degraded	0%

The fractions reported in the above table have been set by the assessor .
Explanation: Based on measured release rates.

9.0.3.4. Comments on assessment approach for the environment

The regional concentrations are reported in section 10.2.1.1. The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional concentrations (PEC regional).

ADDED RISK APPROACH
Guidance on the how to deal with natural background issues is provided in the Appendix R.7.12-2 guidance document on the 'Environmental risk for metals and metal compounds' (ECHA, 2008). In order to deal with the presence of a natural background, various concepts have been developed, such as the Added Risk approach (Added RA) and the Total Risk approach (Total RA) concepts. In essence the Added RA assumes that species are fully adapted to the natural background concentration and therefore that only the anthropogenic added fraction should be regulated or controlled. The Total RA assumes that "exposure" and "effects" should be compared on the combination of the natural background and the added anthropogenic concentrations.

According to the FOREGS database, natural background concentrations in the different environmental compartments are very close or even below their respective PNEC values. Indeed, the median background concentration in the EU surface waters (i.e. 0.44 µg/l) is very close to the realistic worst case PNECtotal of 0.70 µg/l; the median background concentration in the EU soils (i.e. 16.1 mg/kg) is above the PNECtotal of 10.1 mg/kg. In those situations where it is expected that background metals concentrations are a significant portion of the derived PNEC, the Added Risk Approach should be applied, therefore the added risk approach was selected in this CSR. Although the median background concentration in the EU freshwater sediment (i.e. 16.5 mg/kg) is below the PNECtotal of 69.8 mg/kg, the Added Risk Approach is also applied for consistency reasons.

In the present environmental exposure assessment, the use of the added risk approach implies that the PECadd values have been calculated from cobalt emissions due to anthropogenic activities. Thus, the PECadd is the anthropogenic part of the cobalt concentration in the environment. The predicted cobalt concentrations in the environment with EUSES, which is based on the anthropogenic emissions, therefore reflect the "added" part of the cobalt concentration in the environment. Measured cobalt concentrations could also serve as the basis for the derivation of added environmental exposure concentrations. However, it is known from literature that the natural background concentrations of metals may substantially vary seasonally over different geographic regions, therefore hampering the establishment of a "default background concentration" and therefore also the "added risk approach".

In the environmental effects assessment, the use of the added risk approach implies that the PNECadd has been derived from toxicity data that are based on the added cobalt concentration in the tests.
Finally, in the environmental risk characterisation, the use of the added risk approach implies the evaluation of the PECadd / PNECadd ratios.

9.0.3.5. Scope and type of assessment for man via environment

The scope of exposure assessment and type of risk characterisation required for man via the environment are described in the following table based on the hazard conclusions presented in section 5.11.

Table 9.4. Type of risk characterisation required for man via the environment

Route of exposure and type of effects	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation: Long term, local*	Quantitative	DNEL (Derived No Effect Level) = 66.9 µg/m³ DNEL (Derived No Effect Level) = 6.3 µg Co/m³ **
Oral: Long term, Systemic	Quantitative	DNEL (Derived No Effect Level) = 49.9 µg/kg bw/day DNEL (Derived No Effect Level) = 4.7 µg Co/kg bw/day**

* The DNEL for long-term inhalation exposure, systemic effects was not derived, because systemic impacts in long-term rodent inhalation studies are considered to be secondary to local pulmonary toxicity. It is assumed that the low long-term inhalation DNEL for local effects will prevent significant systemic exposure. No combined risk characterisation will be provided.

** The exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt will be used.

9.0.3.6. Comments on assessment approach for man via the environment

For a detailed description of the methodology used for the indirect exposure assessment for men via the environment and the evaluation of data, please refer to the document attached in IUCLID section 13. A brief description is given below:
The sources of human exposure to cobalt handled under indirect exposure via the environment are food, water and air. The assessment has been based on cobalt, since this is the toxic species.
Cobalt is released to the environment through air effluents and wastewater from manufacture, formulation, processing, use and disposal of cobalt containing products.
Cobalt is also a naturally occurring element. Therefore, its presence in the environment, and thereby also indirect in water, food and beverages produced from agricultural goods, may also be attributed to natural sources. Furthermore, cobalt constitutes 4% by weight of vitamin B12, an essential human nutrient.
Regarding the ingestion of food, the conventional partitioning-based TGD methodology for determining air-to-soil and soil-to-plant factors in the assessment of human uptake pathways may be considered as mostly inapplicable to metals. Therefore, the HERAG FACT Sheet on indirect exposure via the environment has been considered as guidance.
The concentrations in environmental compartments and intake media which are used to derive the daily intake are preferably based on monitored data, since the alternative route by modelling of environmental concentrations is associated with much higher uncertainties and also difficult to apply for metals. In deviation from the TGD food basket approach for the exposure route “ingestion of food”, an assessment of measured and publicly available data on cobalt in the diet was performed and the following study designs have been considered: duplicate meal studies, total diet studies and market basket studies.
In duplicate meal studies, duplicate samples of meals, snacks and beverages are collected and analysed. In total diet studies, food items are processed for consumption and are analysed individually or in food groups. Cobalt intake is calculated as the product of the cobalt level in the food and the corresponding amount consumed. In market basket studies, individual food items are sampled from retail outlets (according to typical daily market basket determined from national databases) and subsequently analysed. Based on these cobalt levels and on estimated consumption, total cobalt intake is calculated.

EXPOSURE FROM FOOD
All available published dietary intake studies are based on cobalt levels in food and consumption patterns. As duplicate meal studies were only available for special subpopulations the exposure assessment of cobalt via the diet for adults has been based on the UK total diet study from 1994.
- typical exposure: the median value, i.e. 12 µg Co/day
- worst-case: the 97.5th percentile, i.e 19 µg Co/day
EXPOSURE VIA DRINKING WATER
The concentrations in drinking water are normally taken from regional and local environmental exposure assessment. However, these values refer to surface waters, which are normally not used directly for human consumption.
Therefore, cobalt concentrations in drinking water in Europe (regional) are based on measured data which are more precise. An assessment of publicly available data on cobalt in drinking water was performed. The most recent and very comprehensive data source is from Reimann & Birke 2010. In a wide geographical distribution of water sources across 40 European countries, the bottled mineral, drinking and tap waters are characterized. The median (0.023 µg/L) derived in this dataset has been used as a typical cobalt concentration in drinking water in Europe.
EXPOSURE VIA AIR
Cobalt concentrations in air were taken from (a) calculated industrial site emission data (local) and (b) ambient monitoring data (regional), which were taken from the environmental risk assessment.

9.0.4. Introduction to the assessment for workers

9.0.4.1. Scope and type of assessment for workers

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 9.5. Type of risk characterisation required for workers

Route	Type of effect	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation	Systemic effects - long term	Not needed	No hazard identified
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Quantitative	DNEL (Derived No Effect Level) = 424.8 µg/m³
	Local effects - acute	Not needed	No hazard identified
Dermal	Systemic effects - long term	Not needed	No hazard identified
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	Qualitative	Medium hazard (no threshold derived)
Eye	Local effects	Not needed	No hazard identified

9.0.4.2. Comments on assessment approach for workers

Assessment approach related to toxicological hazard:

QUANTITATIVE EXPOSURE ASSESSMENT
Please refer to IUCLID Section 13 for a detailed description of the specific methodologies used for the worker contributing scenarios below.
QUALITATIVE RISK CHARACTERISATION FOR LOCAL EFFECTS ON THE SKIN
In addition to the quantitative risk characterisation, demonstrating that prescribed operational conditions and risk management measures effectively control exposure well below the respective chronic DNELs,

residual exposure concentrations may theoretically still cause local effects. As a precautionary measure, it is therefore prescribed to use personal protective equipment in situations in which such residual exposure concentrations cannot be excluded. The risk of local effects is therefore adequately controlled.

Assessment approach related to physicochemical hazard:

No physicochemical hazards identified.

9.0.5. Introduction to the assessment for consumers

9.0.5.1. Scope and type of assessment for consumers

The scope of exposure assessment and type of risk characterisation required for consumers are described in the following table based on the hazard conclusions reported and justified in section 5.11.

Table 9.6. Type of risk characterisation required for consumers

Route	Type of effect	Risk characterisation type	Hazard conclusion (see section 5.11)
Inhalation	Systemic effects - long term	Not needed	No hazard identified
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Quantitative	DNEL (Derived No Effect Level) = 66.9 µg/m³
	Local effects - acute	Not needed	No hazard identified
Dermal	Systemic effects - long term	Not needed	No hazard identified
	Systemic effects - acute	Not needed	No hazard identified
	Local effects - long term	Qualitative	Medium hazard (no threshold derived)
	Local effects - acute	Qualitative	Medium hazard (no threshold derived)
Oral	Systemic effects - long term	Quantitative	DNEL (Derived No Effect Level) = 50 µg/kg bw/day
Eye	Local effects	Not needed	No hazard identified

9.0.5.2. Comments on assessment approach for consumers

Further information on assessment approach for consumers:

According to the REACH-guidance (REF R.15) different methodologies may be used for consumer exposure assessment.
In general measured data are preferred over modelled data provided they are reliable and representative for the situation that needs to be assessed. For most consumer exposure scenarios, measurements of the actual exposure of consumers will not be available. However, measured data may be used in combination with modelling tools to predict exposure.
USED DATA
To assess exposure associated with the use of recycled rubber in consumer applications, particularly playgrounds and athletic fields a published study (OEHHA 2007 and RIVM 2016) were used. Furthermore, the parameters for the exposure scenario used were taken from the Annex XV report (ECHA, 2017).
REFERENCE

•ECHA 2017: Annex XV report - AN EVALUATION OF THE POSSIBLE HEALTH RISKS OF RECYCLED RUBBER GRANULES USED AS INFILL IN SYNTHETIC TURF SPORTS FIELDS

•OEHHA 2007: Evaluation of Health Effects of Recycled Waste Tires in Playground and Track Products. Integrated Waste Management Board: Sacramento, CA.

•RIVM 2016: Beoordeling gezondheidsrisico's door sporten op kunstgrasvelden met rubbergranulaat.

9.1. Exposure scenario 1: Manufacture - Manufacture of stearic acid, cobalt salt

Environment contributing scenario(s):		
CS 1	Manufacture of stearic acid, cobalt salt	ERC 1
Worker contributing scenario(s):		
CS 2	Raw material handling	PROC 26, PROC 8b
CS 3	Reaction	PROC 4, PROC 1; PROC 3
CS 4	Packaging of low and/or medium dusty materials	PROC 26, PROC 8b; PROC 9
CS 5	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.
It is noted that exposure from process steps with feed materials other than the substance is merely reported for the sake of completeness. Please refer to information on safe use for the handling of the individual raw materials for process steps preceding the chemical transformation step.

9.1.1. Env CS 1: Manufacture of stearic acid, cobalt salt (ERC 1)

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 1.8 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 250.0 tonnes/year *For the generic exposure scenario a tonnage covering 100% of the sector tonnages was selected.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *The majority of the sites do not have emissions to air, the process is enclosed and the manufacture is in a liquid medium. In case emissions to water are still applicable, one or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*
• Risk management measures to limit releases to water: *The majority of the sites do not have emissions to water, liquid waste resulting from the manufacture of cobalt carboxylates is collected and disposed of to a specialized treatment company. In case emissions to water are still applicable, 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.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Site specific [Effectiveness Water: 40%] *Applicable if releases to water.*
• Discharge rate of STP: >= 40000 m3/day
• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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 for cobalt carboxylates: 01 03 07, 06 05 02*, 06 03 13*, 06 03 15*, 06 04 05*, 06 05 02*, 08 01 11*, 08 01 13*, 08 01 21*, 08 03 12*, 15 01 10*, 15 02 02*, 16 03 03*, 16 03 05*, 16 07 09*, 16 10 01*, 19 01 13*, 19 01 17*, 19 02 04*, 19 02 08*, 19 02 09*, 19 08 13*,… 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
• Dilution factor to freshwater: <= 10.0

Fate (release percentage) in the biological sewage treatment plant

The biological STP is site specific and the releases to the various compartments have been set by the assessor They are distributed in the following way:

Release to water	60%
Release to air	0%
Release to sludge	40%
Release degraded	0%

Explanation:
Based on measured removal rates.

9.1.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.7. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 5.6E-3% **Release factor after on site RMM:** 5.6E-3% **Local release rate:** 0.101 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment but before treatment in a municipal STP. Note that most sites do not have emissions to water.
Air	Estimated release factor	**Release factor before on site RMM:** 7E-4% **Release factor after on site RMM:** 7E-4% **Local release rate:** 0.013 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. These emissions are related to cobalt carboxylates in solid form. Note that most sites do not have emissions to air.
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.1.1.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.8. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 1.95E-4 mg/L	RCR = 0.315
Sediment (freshwater)	**Local PEC:** 7.99 mg/kg dw (Clocal: 3.73 mg/kg dw estimated by PEC sediment calculation method for metals (local PEC = Clocal,sed + PECreg,sed))	RCR = 0.149
Sewage Treatment Plant	**Local PEC:** 1.51E-3 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.282 mg/kg dw	RCR = 0.026
Man via environment - Inhalation	**Concentration in air:** 1.33E-6 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.068
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.1.2. Worker CS 2: Raw material handling (PROC 26, PROC 8b)

Task(s) covered with this contributing scenario: Raw material handling, reactor loading, immediate removal of wet splashes.

9.1.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, powder / dust	Monitoring data
• Additional physical form of substance: Solution	Monitoring data
• Maximum emission potential of the substance: High *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.*	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Monitoring data

	Method
Technical and organisational conditions and measures	
• Process temperature: Ambient	Monitoring data
• Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] *High efficiency*	Monitoring data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.*	Monitoring data
• General good occupational hygiene practices *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.*	Monitoring data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.1.2.2. Exposure and risks for workers

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

Table 9.9. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	218.2 µg/m³ (Measured data: Monitoring data)	RCR = 0.514

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: 26 ; GSD: 4.23

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.
Additional remarks on risk characterisation:
It is noted that exposure from process steps with feed materials other than the substance is merely reported for the sake of completeness and for precautionary reasons. Any derived exposure estimate and risk characterisation ratio are only applicable if exposure to the substance occurs. Please refer to the specific exposure scenarios for the raw materials used as a downstream use of these substances if the substance is not concerned.

9.1.3. Worker CS 3: Reaction (PROC 4, PROC 1; PROC 3)

Task(s) covered with this contributing scenario: Wet process, dry process, mixing, dissolving, precipitation, separation, filtration, pumping, cleaning, unloading, reaction, stripping, extraction, formulation.

9.1.3.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solution	Analogous data
• Maximum emission potential of the substance: Very low *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.*	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Maximum process temperature: 180.0 °C	Analogous data
• Level of containment: Closed process *Closed transfer systems, closed reactor and vacuum scrubbing system*	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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,*	

	Method
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.	
• General good occupational hygiene practices *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.*	Analogous data
• Certified safety clothing and shoes *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.*	

9.1.3.2. Exposure and risks for workers

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

Table 9.10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	5 µg/m³ (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: 94 ; GSD: 2.65

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.1.4. Worker CS 4: Packaging of low and/or medium dusty materials (PROC 26, PROC 8b; PROC 9)

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

9.1.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, pellet / pastille	Analogous data
• Maximum emission potential of the substance: Medium *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.*	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Level of automation: Semi-automated process	Analogous data
• Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] *High efficiency*	Analogous data
• Process temperature: Ambient	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.*	Analogous data
• General good occupational hygiene practices *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.*	Analogous data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.1.4.2. Exposure and risks for workers

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

Table 9.11. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	178.1 µg/m³ (Measured data: Analogous data)	RCR = 0.419

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: 132 ; GSD: 4.62

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.1.5. Worker CS 5: 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.

9.1.5.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, powder / dust	Analogous data
• Maximum emission potential of the substance: High *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.*	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Process temperature: Ambient	Analogous data
• Process pressure: Ambient	Analogous data
• 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.	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *APF = assigned protection factor according to EN 529. At minimum any*	Analogous data

	Method
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.	
• General good occupational hygiene practices *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.*	Analogous data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.1.5.2. Exposure and risks for workers

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

Table 9.12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	87.1 µg/m³ (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: 4.23

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.2. Exposure scenario 2: Use at industrial sites - Use as an intermediate in chemical manufacturing

Market sector: Manufacture of other cobalt substances (intermediate use)
Sector of use: SU 8: Manufacture of bulk, large scale chemicals (including petroleum products); SU 9: Manufacture of fine chemicals

Environment contributing scenario(s):		
CS 1	Use as an intermediate in chemical manufacturing ES1 STP Discharge	ERC 6a
CS 2	Use as an intermediate in chemical manufacturing ES2 Direct Discharge	ERC 6a
CS 3	Use as an intermediate in chemical manufacturing ES3 Marine Discharge	ERC 6a
Worker contributing scenario(s):		
CS 4	Raw material handling	PROC 26, PROC 8b; PROC 9
CS 5	Mixing/Reaction in vessel/bath	PROC 5, PROC 1; PROC 2; PROC 3; PROC 4
CS 6	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.
It is noted that this exposure scenario focusses on exposure to the registered substance. Please refer to information on safe use for the handling of the individual manufactured substances for process steps commencing the chemical transformation step.

9.2.1. Env CS 1: Use as an intermediate in chemical manufacturing ES1 STP Discharge (ERC 6a)

9.2.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 1.1 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 400.0 tonnes/year *For the generic exposure scenario a tonnage covering 50% of the sector tonnages was selected.*
• Number of release days per year: >= 360.0 days/year *The selected number of production days per year is the median value based on data from 9 companies.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*
• Risk management measures to limit releases to water: *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.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 40%]
• Discharge rate of STP: >= 2000 m3/day

• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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
• Dilution factor to freshwater: <= 1000
• Discharge to: Freshwater only

9.2.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.13. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 7.5E-3% **Release factor after on site RMM:** 7.5E-3% **Local release rate:** 0.083 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. The selected value is the 50th percentile of 9 companies.
Air	Estimated release factor	**Release factor before on site RMM:** 4.52E-3% **Release factor after on site RMM:** 4.52E-3% **Local release rate:** 0.05 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. The selected value is the 50th percentile of 6 companies.
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.2.1.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.14. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 1.16E-4 mg/L	RCR = 0.187
Sediment (freshwater)	**Local PEC:** 4.87 mg/kg dw (Clocal: 0.61 mg/kg dw estimated by PEC sediment calculation method for metals local PEC = Clocal,sed + PECreg,sed))	RCR = 0.091
Sewage Treatment Plant	**Local PEC:** 0.025 mg/L	RCR = 0.068
Agricultural soil	**Local PEC:** 0.946 mg/kg dw	RCR = 0.087
Man via environment - Inhalation	**Concentration in air:** 1.38E-5 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.067
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.2.2. Env CS 2: Use as an intermediate in chemical manufacturing ES2 Direct Discharge (ERC 6a)

9.2.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 1.1 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 400.0 tonnes/year *For the generic exposure scenario a tonnage covering 50% of the sector tonnages was selected.*
• Number of release days per year: >= 360.0 days/year *The selected number of production days per year is the median value based on data from 9 companies.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*
• Risk management measures to limit releases to water: *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.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low amount) *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: >= 2000 m3/day
• Dilution factor to freshwater: <= 1000
• Discharge to: Freshwater only

9.2.2.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.15. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 7.5E-3% **Release factor after on site RMM:** 7.5E-3% **Local release rate:** 0.083 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. The selected value is the 50th percentile of 9 companies.
Air	Estimated release factor	**Release factor before on site RMM:** 4.52E-3% **Release factor after on site RMM:** 4.52E-3% **Local release rate:** 0.05 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. The selected value is the 50th percentile of 6 companies.
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.2.2.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.16. Exposure concentrations and risks for the environment and man via the

environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 1.26E-4 mg/L	RCR = 0.204
Sediment (freshwater)	**Local PEC:** 5.28 mg/kg dw (Clocal: 1.02 mg/kg dw estimated by PEC sediment calculation method for metals local PEC = Clocal,sed + PECreg,sed))	RCR = 0.098
Agricultural soil	**Local PEC:** 0.245 mg/kg dw	RCR = 0.022
Man via environment - Inhalation	**Concentration in air:** 1.38E-5 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.067
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.2.3. Env CS 3: Use as an intermediate in chemical manufacturing ES3 Marine Discharge (ERC 6a)

9.2.3.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 1.1 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 400.0 tonnes/year *For the generic exposure scenario a tonnage covering 50% of the sector tonnages was selected.*
• Number of release days per year: >= 360.0 days/year *The selected number of production days per year is the median value based on data from 9 companies.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*
• Risk management measures to limit releases to water: *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.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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: >= 2000 m3/day
• Discharge to: Marine water only
• Dilution factor to marine water: <= 100.0

9.2.3.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.17. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 7.5E-3% **Release factor after on site RMM:** 7.5E-3% **Local release rate:** 0.083 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. The selected value is the 50th percentile of 9 companies.
Air	Estimated release factor	**Release factor before on site RMM:** 4.52E-3% **Release factor after on site RMM:** 4.52E-3% **Local release rate:** 0.05 kg/day **Explanation:** This release factor is based on reported emissions after on-site treatment. The selected value is the 50th percentile of 6 companies.
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.2.3.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.18. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Marine water	**Local PEC:** 0.195 µg/L (Clocal: 0.18 µg/L estimated by Clocal calculation with Kp susp. matter marine (logKp = 4.94))	RCR = 0.083
Sediment (marine water)	**Local PEC:** 30.43 mg/kg dw (Clocal: 15.73 mg/kg dw estimated by PEC sediment calculation method for metals local PEC = Clocal,sed + PECreg,sed))	RCR = 0.436
Agricultural soil	**Local PEC:** 0.245 mg/kg dw	RCR = 0.022
Man via environment - Inhalation	**Concentration in air:** 1.38E-5 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.067
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.2.4. Worker CS 4: Raw material handling (PROC 26, PROC 8b; PROC 9)

Task(s) covered with this contributing scenario: Loading/unloading, weighing, immediate removal of wet splashes.

9.2.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid	Analogous data
• Additional physical form of substance: Solution	Analogous data
• Maximum emission potential of the substance: Medium *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.*	Analogous data
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Level of automation: Semi-automated process	Analogous data
• Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] *High efficiency*	Analogous data

	Method
• Process temperature: Ambient	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• Respiratory protective equipment (RPE): RPE with minimum APF = 10 [Effectiveness Inhalation: 90%] *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.*	Analogous data
• General good occupational hygiene practices *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.*	Analogous data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.2.4.2. Exposure and risks for workers

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

Table 9.19. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	178.1 µg/m³ (Measured data: Analogous data)	RCR = 0.419

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: 132 ; GSD: 4.62

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.2.5. Worker CS 5: Mixing/Reaction in vessel/bath (PROC 5, PROC 1; PROC 2; PROC 3; PROC 4)

Task(s) covered with this contributing scenario: Mixing, blending, reaction, formulation, electro-winning, immediate removal of wet splashes.
It is noted that the substance is used as an intermediate so that the substance has been chemically transformed into another substance.

9.2.5.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solution	MEASE 1.02.01
• Maximum emission potential: Very low *Only the highest emission potential (EP) of the substance in this process is reported. Lower EPs (e.g. if materials of lower dustiness are being handled in parallel or if the actual process temperature or the level of abrasion is lower) are thus automatically covered in this assessment.*	MEASE 1.02.01
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1.02.01
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	MEASE 1.02.01
Technical and organisational conditions and measures	
• Process temperature: Elevated	MEASE 1.02.01
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• General good occupational hygiene practices *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*	MEASE 1.02.01

	Method
splashes) with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.	
• Certified safety clothing and shoes *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.*	

9.2.5.2. Exposure and risks for workers

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

Table 9.20. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	10 µg/m³ (MEASE 1.02.01)	RCR = 0.024

Remarks on exposure data from external estimation tools:

MEASE 1.02.01:
Explanation: Inhalation, local, long term
PROC3 was assessed as emission potential is driven by the containment of the process rather than by the conducted activities (i.e. mixing system is fully contained)

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.2.6. Worker CS 6: 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.

9.2.6.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, powder / dust	Analogous data
• Maximum emission potential of the substance: High *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.*	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Process temperature: Ambient	Analogous data
• Process pressure: Ambient	Analogous data
• 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.	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required	

	Method
Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.	
• Respiratory protective equipment (RPE): RPE with minimum APF = 40 [Effectiveness Inhalation: 97.5%] *APF = assigned protection factor according to EN 529. At minimum combination of particle filter class P3 with face piece according to EN 136, EN 12941 or EN 12942 or any RPE providing higher APFs according to EN 529 is required.*	Analogous data
• General good occupational hygiene practices *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.*	Analogous data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.2.6.2. Exposure and risks for workers

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

Table 9.21. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	214.5 µg/m³ (Measured data: Analogous data)	RCR = 0.505

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: 85 ; GSD: 5.86

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.3. Exposure scenario 3: Use at industrial sites - Production and use as rubber adhesion agent

Market sector: Rubber adhesion agent
Product category used: PC 1: Adhesives, Sealants; PC 32: Polymer Preparations and Compounds
Sector of use: SU 11: Manufacture of rubber products

Environment contributing scenario(s):		
CS 1	Production and use as rubber adhesion agent ES1 STP Discharge	ERC 5
CS 2	Production and use as rubber adhesion agent ES2 Direct Discharge	ERC 5
CS 3	Production and use as rubber adhesion agent ES3 Marine Discharge	ERC 5
Worker contributing scenario(s):		
CS 4	Raw material handling	PROC 9, PROC 5; PROC 8b
CS 5	Kneading (mixing)	PROC 5, PROC 2; PROC 3
CS 6	Shaping	PROC 21, PROC 14; PROC 6
CS 7	Finishing and shipping	PROC 21
CS 8	Cleaning & Maintenance	PROC 28

Subsequent service life exposure scenario(s):
ES4: Service life (worker at industrial site) - Handling of tyres in industrial settings
ES5: Service life (professional worker) - Handling of tyres in professional settings
ES6: Service life (consumers) - Service life of tyres/shredded tyres

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.
It is noted that the substance is chemically transformed into another substance during this use. Consequently, exposure can no longer occur to the registered substance. Please refer to information on safe use for the handling of the individual manufactured substances for process steps commencing the chemical transformation step.

9.3.1. Env CS 1: Production and use as rubber adhesion agent ES1 STP Discharge (ERC 5)

9.3.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.14 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 50.0 tonnes/year *For the generic exposure scenario a tonnage demonstrating safe use was selected.*
• Number of release days per year: >= 346.0 days/year *The selected number of production days per year is based on the median value from the sector.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*

• Risk management measures to limit releases to water: *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.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 40%]
• Discharge rate of STP: >= 2000 m3/day
• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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 to: Freshwater only
• Dilution factor to freshwater: <= 10.0

9.3.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.22. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (SpERC from ETRMA)	**Release factor before on site RMM:** 1.56E-3% **Release factor after on site RMM:** 1.56E-3% **Local release rate:** 2.26E-3 kg/day **Explanation:** ETRMA provided emission data from representative sites to be used for formulation and industrial use in the tyre and general rubber goods industry (ETRMA, 2018)
Air	Estimated release factor (SpERC from ETRMA)	**Release factor before on site RMM:** 1.08E-3% **Release factor after on site RMM:** 1.08E-3% **Local release rate:** 1.57E-3 kg/day **Explanation:** ETRMA provided data from representative sites to be used for formulation and industrial use in the tyre and general rubber goods industry (ETRMA, 2018)
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.3.1.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.23. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 1.43E-4 mg/L	RCR = 0.23
Sediment (freshwater)	**Local PEC:** 5.9 mg/kg dw (Clocal: 1.64 mg/kg dw estimated by PEC sediment calculation method for metals local PEC = Clocal,sed + PECreg,sed))	RCR = 0.11
Sewage Treatment Plant	**Local PEC:** 6.79E-4 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.258 mg/kg dw	RCR = 0.024
Man via environment - Inhalation	**Concentration in air:** 4.11E-7 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.067
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.3.2. Env CS 2: Production and use as rubber adhesion agent ES2 Direct Discharge (ERC 5)

9.3.2.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.14 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 50.0 tonnes/year *For the generic exposure scenario a tonnage demonstrating safe use was selected.*
• Number of release days per year: >= 346.0 days/year *The selected number of production days per year is based on the median value from the sector.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*

• Risk management measures to limit releases to water: *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.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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 to: Freshwater only
• Dilution factor to freshwater: <= 10.0
• Discharge rate of effluent: >= 2000 m3/day

9.3.2.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.24. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (SpERC from ETRMA)	**Release factor before on site RMM:** 1.56E-3% **Release factor after on site RMM:** 1.56E-3% **Local release rate:** 2.26E-3 kg/day **Explanation:** ETRMA provided emission data from representative sites to be used for formulation and industrial use in the tyre and general rubber goods industry (ETRMA, 2018)
Air	Estimated release factor (SpERC from ETRMA)	**Release factor before on site RMM:** 1.08E-3% **Release factor after on site RMM:** 1.08E-3% **Local release rate:** 1.57E-3 kg/day **Explanation:** ETRMA provided data from representative sites to be used for formulation and industrial use in the tyre and general rubber goods industry (ETRMA, 2018)
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.3.2.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.25. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Fresh water	**Local PEC:** 1.71E-4 mg/L	RCR = 0.277
Sediment (freshwater)	**Local PEC:** 7 mg/kg dw (Clocal: 2.74 mg/kg dw estimated by PEC sediment calculation method for metals local PEC = Clocal,sed + PECreg,sed))	RCR = 0.13
Agricultural soil	**Local PEC:** 0.239 mg/kg dw	RCR = 0.022
Man via environment - Inhalation	**Concentration in air:** 4.11E-7 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.067
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.3.3. Env CS 3: Production and use as rubber adhesion agent ES3 Marine Discharge (ERC 5)

9.3.3.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 0.14 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 50.0 tonnes/year *For the generic exposure scenario a tonnage demonstrating safe use was selected.*
• Number of release days per year: >= 346.0 days/year *The selected number of production days per year is based on the median value from the sector.*
Technical and organisational conditions and measures
• Risk management measures to limit releases to air: *One or more of the following measures should be present to reduce emissions to air: Electrostatic precipitators, Wet electrostatic precipitators, Cyclones as primary collector, Fabric or bag filters, Ceramic/Metal mesh filters or Wet scrubbers.*
• Risk management measures to limit releases to water: *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.*

Conditions and measures related to biological sewage treatment plant
• Biological STP: None [Effectiveness Water: 0%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low amount) *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 to: Marine water only
• Discharge rate of effluent: >= 2000 m3/day
• Dilution factor to marine water: <= 100.0

9.3.3.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.26. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor (SpERC from ETRMA)	**Release factor before on site RMM:** 1.56E-3% **Release factor after on site RMM:** 1.56E-3% **Local release rate:** 2.26E-3 kg/day **Explanation:** ETRMA provided emission data from representative sites to be used for formulation and industrial use in the tyre and general rubber goods industry (ETRMA, 2018)
Air	Estimated release factor (SpERC from ETRMA)	**Release factor before on site RMM:** 1.08E-3% **Release factor after on site RMM:** 1.08E-3% **Local release rate:** 1.57E-3 kg/day **Explanation:** ETRMA provided data from representative sites to be used for formulation and industrial use in the tyre and general rubber goods industry (ETRMA, 2018)
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** 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)

9.3.3.3. 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. The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 9.27. Exposure concentrations and risks for the environment and man via the environment

Protection target	Exposure concentration	Risk quantification
Marine water	**Local PEC:** 0.02 µg/L (Clocal: 5E-3 µg/L estimated by Clocal calculation with Kp susp. matter marine (logKp = 4.94))	RCR < 0.01
Sediment (marine water)	**Local PEC:** 15.12 mg/kg dw (Clocal: 0.42 mg/kg dw estimated by PEC sediment calculation method for metals local PEC = Clocal,sed + PECreg,sed))	RCR = 0.217
Agricultural soil	**Local PEC:** 0.239 mg/kg dw	RCR = 0.022
Man via environment - Inhalation	**Concentration in air:** 4.11E-7 mg/m³	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.317 µg/kg/d	RCR = 0.067
Man via environment - combined routes		Not required (local and systemic effects)

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 the introductory section 9.0..
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 from food (see introductory section 9.0.) and a default body weight of 60kg into account.
Furthermore, the exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

9.3.4. Worker CS 4: Raw material handling (PROC 9, PROC 5; PROC 8b)

Task(s) covered with this contributing scenario: Storage, unloading, weighing, mixing, immediate removal of wet splashes.

9.3.4.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, powder / dust	Monitoring data
• Additional physical form of substance: Solid, pellet / pastille *Paste*	Monitoring data
• Additional physical form of substance: Solution	Monitoring data
• Maximum emission potential of the substance: Medium *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.*	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness	Monitoring data

	Method
Inhalation: 0%, Dermal: 0%]	
Technical and organisational conditions and measures	
• Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] *High efficiency*	Monitoring data
• Process temperature: Ambient	Monitoring data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• General good occupational hygiene practices *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.*	Monitoring data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.3.4.2. Exposure and risks for workers

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

Table 9.28. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	21.2 µg/m³ (Measured data: Monitoring data)	RCR = 0.05

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: 33 ; GSD: 11.1

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.3.5. Worker CS 5: Kneading (mixing) (PROC 5, PROC 2; PROC 3)

Task(s) covered with this contributing scenario: Kneading (mechanical mixing in huge mill between large metal rollers under pressure and temperature).

9.3.5.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, powder / dust *Paste*	Monitoring data
• Additional physical form of substance: Solution	Monitoring data
• Maximum emission potential of the substance: Medium *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.*	Monitoring data
• Content in preparation: Not restricted [Effectiveness Inhalation: 0%, Dermal: 0%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• Maximum process temperature: 180.0 °C	Monitoring data
• Level of containment: Closed process	Monitoring data
• Integrated local exhaust ventilation: Upper confidence limit (industrial use) [Effectiveness Inhalation: 90%] *High efficiency*	Monitoring data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• General good occupational hygiene practices *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*	Monitoring data

	Method
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.	
• Certified safety clothing and shoes *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.*	

9.3.5.2. Exposure and risks for workers

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

Table 9.29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	24.9 µg/m³ (Measured data: Monitoring data)	RCR = 0.059

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: 36 ; GSD: 7.11

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.3.6. Worker CS 6: Shaping (PROC 21, PROC 14; PROC 6)

Task(s) covered with this contributing scenario: Milling, building, precuring, curing, calendaring, final treatment.

9.3.6.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Massive object	Monitoring data
• Maximum emission potential of the substance: Very low *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.*	Monitoring data
• Content in preparation: 1 - 5 % [Effectiveness Inhalation: 80%, Dermal: 80%]	Monitoring data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Monitoring data
Technical and organisational conditions and measures	
• Maximum process temperature: 135.0 °C *During shaping*	Monitoring data
• Maximum process temperature: 205.0 °C *During curing of tyres*	Monitoring data
• Generic local exhaust ventilation: Lower confidence limit (industrial use) [Effectiveness Inhalation: 78%] *Standard efficiency*	Monitoring data

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required *Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.*	
• General good occupational hygiene practices *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.*	Monitoring data
• Certified safety clothing and shoes *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.*	

9.3.6.2. Exposure and risks for workers

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

Table 9.30. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	0.9 µg/m³ (Measured data: Monitoring data)	RCR < 0.01

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: 38 ; GSD: 4.51

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.3.7. Worker CS 7: Finishing and shipping (PROC 21)

Task(s) covered with this contributing scenario: Quality control, enhancement, packaging.

9.3.7.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Bound in article *Covered by tyre rubber*	Monitoring data
• Maximum emission potential of the substance: Very low *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.*	Monitoring data

9.3.7.2. Exposure and risks for workers

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

Table 9.31. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	0.6 µg/m³ (Measured data: Monitoring data)	RCR < 0.01

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: 4 ; GSD: 1.14

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.3.8. Worker CS 8: 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.

9.3.8.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Solid, powder / dust	Analogous data
• Maximum emission potential of the substance: High *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.*	Analogous data
Amount used (or contained in articles), frequency and duration of use/exposure	
• Maximum duration of exposure: > 240 min (not restricted) [Effectiveness Inhalation: 0%, Dermal: 0%]	Analogous data
Technical and organisational conditions and measures	
• Process temperature: Ambient	Analogous data
• Process pressure: Ambient	Analogous data
• 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.	Analogous data
Conditions and measures related to personal protection, hygiene and health evaluation	
• Gloves: Gloves protecting from sensitizing properties to skin, continuous supervision of workers required	

	Method
Gloves protecting from sensitizing properties to skin, continuous supervision of workers required (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.	
• Respiratory protective equipment (RPE): RPE with minimum APF = 40 [Effectiveness Inhalation: 97.5%] *APF = assigned protection factor according to EN 529. At minimum combination of particle filter class P3 with face piece according to EN 136, EN 12941 or EN 12942 or any RPE providing higher APFs according to EN 529 is required.*	Analogous data
• General good occupational hygiene practices *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.*	Analogous data
• Certified safety clothing and shoes *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.*	
• Chemical protective suit according to EN 13982 *In cases where direct contact with the substance cannot be avoided, a protective suit conforming to EN 13982 should be worn.*	

9.3.8.2. Exposure and risks for workers

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

Table 9.32. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	214.5 µg/m³ (Measured data: Analogous data)	RCR = 0.505

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: 85 ; GSD: 5.86

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.4. Exposure scenario 4: Service life (worker at industrial site) - Handling of tyres in industrial settings

Market sector: Rubber adhesion agent
Article categories: AC 10: Rubber articles

Environment contributing scenario(s):		
CS 1	Use of tyres in industrial settings	ERC 12a
Worker contributing scenario(s):		
CS 2	Handling of tyres (stearic acid, cobalt salt completely enclosed with rubber)	PROC 21

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES3: Use at industrial sites - Production and use as rubber adhesion agent

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.
It is noted that the substance is used as raw material in the production of rubber articles. During the production, the substance is completely transformed into another substance. Consequently, exposure can no longer occur to the registered substance.

9.4.1. Env CS 1: Use of tyres in industrial settings (ERC 12a)

9.4.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use amount at site: <= 25.0 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
• Annual use amount at site: <= 500.0 tonnes/year
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 40%]
• Discharge rate of STP: >= 2000 m3/day
• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) *Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010)* *Appropriate waste codes:* *20 01 34, 20 01 40, 20 03 01, 20 03 07, …* *Suitable Disposal:* *Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.* *Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).* *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)*

9.4.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.33. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 0% **Release factor after on site RMM:** 0% **Local release rate:** 0 kg/day **Explanation:** There are no intended cobalt releases due to service life of cobalt containing tyres, the non-intended releases are negligible and pose no threat to the environment.
Air	Estimated release factor	**Release factor before on site RMM:** 0% **Release factor after on site RMM:** 0% **Local release rate:** 0 kg/day **Explanation:** Not relevant
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** Not relevant

Releases to waste

Release factor to external waste: 60 %
Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010).
Note that the 60% does not specifically apply to this use but applies to all professional, consumer or service life uses from cobalt.
A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

9.4.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) for the service life are negligible and pose no threat to the environment.
Emission data from municipal STPs have been collected for Belgium (via VMM) and The Netherlands (WATSON database). For Belgium 6 data points are available between 2011 and 2013. Only one data point is above the DL, the effluent concentration of the STP above the DL is 3 µg Co/L. For the Netherlands 272 data points are available between 2005 and 2012. Only 69 data points are above the DL, the median effluent concentration is below the DL and the 90th percentile is 2.69 µg Co/L. These concentrations are a factor 100 below the PNEC for STP of 370 µg Co/L.

9.4.2. Worker CS 2: Handling of tyres (stearic acid, cobalt salt completely enclosed with rubber) (PROC 21)

Task(s) covered with this contributing scenario: Handling and transfer operations.

9.4.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Bound in article *Covered by tyre rubber*	Qualitative assessment
• Maximum emission potential of the substance: Very low *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.*	Qualitative assessment

9.4.2.2. Exposure and risks for workers

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

Table 9.34. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	1E-3 µg/m³ (Qualitative assessment .)	RCR < 0.01

Remarks on exposure data from external estimation tools:

Qualitative assessment .:
Explanation: Inhalation, local, long term
The substance is used as rubber adhesion agent in steel radial tyres to permanently bind the rubber on the steel belting. Thus, the substance is covered by the tyre rubber and cannot lead to exposure under intended and foreseeable use conditions.

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.5. Exposure scenario 5: Service life (professional worker) - Handling of tyres in professional settings

Market sector: Rubber adhesion agent
Article categories: AC 10: Rubber articles

Environment contributing scenario(s):		
CS 1	Use of tyres in professional settings	ERC 10a, ERC 11a
Worker contributing scenario(s):		
CS 2	Handling of tyres (stearic acid, cobalt salt completely enclosed with rubber)	PROC 21

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES3: Use at industrial sites - Production and use as rubber adhesion agent

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.
It is noted that the substance is used as raw material in the production of rubber articles. During the production, the substance is completely transformed into another substance. Consequently, exposure can no longer occur to the registered substance.

9.5.1. Env CS 1: Use of tyres in professional settings (ERC 10a)

9.5.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily local widespread use amount: <= 0.00027 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
Conditions and measures related to biological sewage treatment plant
• Biological STP: Standard [Effectiveness Water: 40%]
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) *Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010)* *Appropriate waste codes:* *20 01 34, 20 01 40, 20 03 01, 20 03 07, …* *Suitable Disposal:* *Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.* *Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).* *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)*

9.5.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.35. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 0% **Release factor after on site RMM:** 0%

Release	Release estimation method	Explanations
		Local release rate: 0 kg/day **Explanation:** There are no intended cobalt releases due to service life of cobalt containing tyres, the non-intended releases are negligible and pose no threat to the environment.
Air	Estimated release factor	**Release factor before on site RMM:** 0% **Release factor after on site RMM:** 0% **Explanation:** Not relevant
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** Not relevant

Releases to waste

Release factor to external waste: 60 %
Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010).
Note that the 60% does not specifically apply to this use but applies to all professional, consumer or service life uses from cobalt.
A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

9.5.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) for the service life are negligible and pose no threat to the environment.
Emission data from municipal STPs have been collected for Belgium (via VMM) and The Netherlands (WATSON database). For Belgium 6 data points are available between 2011 and 2013. Only one data point is above the DL, the effluent concentration of the STP above the DL is 3 µg Co/L. For the Netherlands 272 data points are available between 2005 and 2012. Only 69 data points are above the DL, the median effluent concentration is below the DL and the 90th percentile is 2.69 µg Co/L. These concentrations are a factor 100 below the PNEC for STP of 370 µg Co/L.

9.5.2. Worker CS 2: Handling of tyres (stearic acid, cobalt salt completely enclosed with rubber) (PROC 21)

Task(s) covered with this contributing scenario: Handling and transfer operations.

9.5.2.1. Conditions of use

	Method
Product (Article) characteristics	
• Physical form of substance: Bound in article *Covered by tyre rubber*	Qualitative assessment
• Maximum emission potential of the substance: Very low *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.*	Qualitative assessment

9.5.2.2. Exposure and risks for workers

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

Table 9.36. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	1E-3 µg/m³ (Qualitative assessment .)	RCR < 0.01

Remarks on exposure data from external estimation tools:

Qualitative assessment .:
Explanation: Inhalation, local, long term
The substance is used as rubber adhesion agent in steel radial tyres to permanently bind the rubber on the steel belting. Thus, the substance is covered by the tyre rubber and cannot lead to exposure under intended and foreseeable use conditions.

Risk characterisation

Qualitative risk characterisation:
Further information on the risk characterisation for local effects on the skin is given in Section 9.0.4.2.

9.6. Exposure scenario 6: Service life (consumers) - Service life of tyres/shredded tyres

Market sector: Rubber adhesion agent

Environment contributing scenario(s):		
CS 1	Service life of tyres/shredded tyres	ERC 10a, ERC 11a
Consumer contributing scenario(s):		
CS 2	Use of recycled rubber granules on recreational areas	AC 10

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):
ES3: Use at industrial sites - Production and use as rubber adhesion agent

Further description of the use:

HUMAN HEALTH:
Exposure during the normal use of steel radial tyres has not been assessed. Exposure to the cobalt compound in steel radial tyres is not possible due to the fact that the rubber adhesive is in the internal part of the tyre and not in the treat.
However, recycled tires are used as ground rubber for a variety of uses including: rubber modified asphalt, athletic surfaces such as fields and tracks, reuse in tires/automotive products, construction, landscaping, and playgrounds.
For the use of recycled rubber granuels on recreational areas (e.g. playgrounds or sport fields) the following exposure routes were addressed:

1. Ingestion of small ground rubber particles by children
2. Dermal contact
3. Inhalation of dust generated due to wear
4. Oral exposure via hand to mouth activity was not assessed as the amount of cobalt released to the skin due to contact with the playground was negligible and as such also oral exposure due to hand-to-mouth contact will be negligible.

Explanation on the approach taken for the ES:

HUMAN HEALTH
To assess exposure associated with the use of recycled rubber in consumer applications, particularly playgrounds and athletic fields a published study (OEHHA 2007) was used. Furthermore, the parameters for the exposure scenario used were taken from the Annex XV report (ECHA, 2017).
ORAL EXPOSURE
It cannot be ruled out that users sometimes accidentally swallow rubber granulate. This will be especially relevant for children.
According to the RIVM (2016) report, it was estimated that children would swallow 0.2 g rubber granules in one event and adults 0.05 g granules. However, it is difficult to imagine, that an amount of 0.2g would be swallowed regularly. According to ECHA 2017 a more realistic amount of 0.05 g for children has been used.
An OEHHA gastric digestion simulation study has been performed to estimate the kind and amount of chemicals that could potentially be extracted in a child´s gastrointestinal tract. The parameters are: 21 hour incubation at 37°C in a solution that mimicked the gastric environment. The derived release rate was 0.25 µg Co/g shredded tyres (OEHHA, 2007). Furthermore, a release rate of 2 µg Co/g recycled rubber granules were derived by RIVM (2016).
DERMAL EXPOSUE:
Substances in rubber granules may come into contact with the skin when playing on synthetic turf. Both rubber granules and airborne rubber dust contributes to the skin exposure. The dermal exposure may happen as contact to the rubber granules occurs e.g. touching granules with hands, sitting or laying on the turf or sliding on the turf. Deposition of airborne dust, which include substances on the skin may also contribute to the dermal exposure.
An OEHHA wipe sampling of playground surfaces was performed to measure the chemicals that might be transferred to a child´s hand through contact with unitary playground surface made of recycled tyres. The wiping was performed using distilled water. Samples were taken in duplicate from two playgrounds. Cobalt was not detected.

The exposure estimation through the dermal route, was estimated in analogy to the approach reported in RIVM (2016) was used. The dermal exposure level was estimated by using the migration factor into the artificial sweat. The content of the substance was multiplied with the migration factor to estimate the total external amount on the skin.
The migration of cobalt from rubber to artificial sweat has been taken from (RIVM 2016).
INHALATION EXPOSURE:
Humans may be exposed to substances in rubber granules through inhalation. Substances that can be inhaled are those that are volatile (or semi volatile) or those that are bound to airborne dust. However, the concentration of metals is in general low and at the same level as ambient air.
References:

• OEHHA 2007: Evaluation of Health Effects of Recycled Waste Tires in Playground and Track Products. Integrated Waste Management Board: Sacramento, CA.

• RIVM 2016: Beoordeling gezondheidsrisico's door sporten op kunstgrasvelden met rubbergranulaat. RIVM.

• ECHA 2017: Annex XV report - AN EVALUATION OF THE POSSIBLE HEALTH RISKS OF RECYCLED RUBBER GRANULES USED AS INFILL IN SYNTHETIC TURF SPORTS FIELDS

9.6.1. Env CS 1: Service life of tyres/shredded tyres (ERC 10a)

9.6.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily local widespread use amount: <= 0.00027 tonnes/day *The tonnage and further exposure is always expressed in cobalt.*
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) *Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010)* *Appropriate waste codes:* *20 01 34, 20 01 40, 20 03 01, 20 03 07, …* *Suitable Disposal:* *Waste from end-of-life articles can be disposed of as municipal waste, except when they are separately regulated, like electronic devices, batteries, vehicles, etc.* *Disposal of wastes is possible via incineration (operated according to Directive 2000/76/EC on the incineration of waste) or landfilling (operated according to Reference Document on the Best available Techniques for Waste Industries of August 2006 and Council Directive 1999/31/EC and Council Decision 19 December 2002).* *A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)*
Other conditions affecting environmental exposure
• Biological STP: Standard [Effectiveness Water: 40%]

9.6.1.2. Releases

The local releases to the environment are reported in the following table. Note that the releases reported do not account for the removal in the modelled biological STP.

Table 9.37. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor before on site RMM:** 0% **Release factor after on site RMM:** 0% **Local release rate:** 0 kg/day **Explanation:** There are no intended cobalt releases due to service life of cobalt containing tyres, the non-intended releases are negligible and pose no threat to the environment.
Air	Estimated release factor	**Release factor before on site RMM:** 0%

Release	Release estimation method	Explanations
		Release factor after on site RMM: 0% **Explanation:** Not relevant
Non agricultural soil	Estimated release factor	**Release factor after on site RMM:** 0% **Explanation:** Not relevant

Releases to waste

Release factor to external waste: 60 %
Fraction of daily/annual use expected in waste: 60% of all articles, 40% is recycled. (EC, 2010).
Note that the 60% does not specifically apply to this use but applies to all professional, consumer or service life uses from cobalt.
A detailed assessment has been performed and is reported in the Waste report (ARCHE, 2011)

9.6.1.3. Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) for the service life are negligible and pose no threat to the environment.
Emission data from municipal STPs have been collected for Belgium (via VMM) and The Netherlands (WATSON database). For Belgium 6 data points are available between 2011 and 2013. Only one data point is above the DL, the effluent concentration of the STP above the DL is 3 µg Co/L. For the Netherlands 272 data points are available between 2005 and 2012. Only 69 data points are above the DL, the median effluent concentration is below the DL and the 90th percentile is 2.69 µg Co/L. These concentrations are a factor 100 below the PNEC for STP of 370 µg Co/L.

9.6.2. Cons CS 2: Use of recycled rubber granules on recreational areas (AC 10)

9.6.2.1. Conditions of use

	Method
Product (article) characteristics	
• Percentage (w/w) of substance in mixture/article: <= 0.027 % *cobalt was found in recycled rubber granules with varying concentrations (3.5 - 268 mg/kg) (ECHA, 2017)*	analogy to Annex XV report, ECHA 2017
• Fraction released due to ingestion : 2.0 µg/g *2µg Co/g of rubber granules acc to RIVM 2016* *0.25 µg Co/g of shredded tyres (Highest amount released per g of tire (from among three shredded tire samples subjected to "gastric digestion")* *Reference: OEHHA 2007*	analogy to Annex XV report, ECHA 2017
• Exposure via inhalation route: Inhalation exposure is considered to be not relevant *Since the playgrounds of consideration are outdoors, fine particles becoming re-suspended would enter the atmosphere and quickly disperse, precluding the inhalation of significant amounts by children. Thus, inhalation exposure is not a significant route of exposure.* *According to ECHA (2017) the concentrations of metals is in general low, and at the same level as ambient air.*	Qualitative assessment .
• Exposure via dermal route: Dermal exposure assumed to be negligible *An OEHHA wipe sampling of playground surfaces was performed to measure the chemicals that might be transferred to a child´s hand through contact with unitary playground surface made of recycled tyres. The wiping was performed using distilled water. Samples were taken in duplicate from two playgrounds. Cobalt was not detected.(OEHHA, 2007)* *A release of 0.048% of Cobalt from shredded tyres into artificial sweet solution*	analogy to Annex XV report, ECHA 2017

	Method
has been reported by RIVM (2016).	
• Exposure via oral route: Yes *It cannot be ruled out that users sometimes accidentally swallow rubber granulate. This will be especially relevant for children.*	analogy to Annex XV report, ECHA 2017
Amount used (or contained in articles), frequency and duration of use/exposure	
• Amount used : 0.05 g *Ingestion rate for children:* *value taken from ECHA (2017)*	analogy to Annex XV report, ECHA 2017
• Time of contact: = 1.0 hr *1h/event acc. to ECHA (2017)*	
• Amount available for ingestion: 0.05 g *Ingestion rate for children:* *value taken from ECHA (2017)*	analogy to Annex XV report, ECHA 2017
Other conditions affecting consumers exposure	
• Population exposed: child *Body weight: 15.7 kg (3-6 years, acc. to ES1, ECHA 2017)* *Exposure to nickel due to hand-to-mouth contact after handling of coinage, tools and other nickel containing surfaces can occur for each category of the general population (children and adults). However, among the general population, children are the most at risk individuals, especially children below 36 months (RIVM (2008)). Indeed, the frequency of their mouthing activities and hand-to-mouth behaviours is higher than the ones of older children and adults.*	analogy to Annex XV report, ECHA 2017
• Amount available for dermal contact: 1.0 g *acc to ES1 in ECHA (2017)*	analogy to Annex XV report, ECHA 2017
• Surface area: 1260 cm² *1/4 leg + 1/2 arms and hands (acc. to ES1 in ECHA (2017)*	analogy to Annex XV report, ECHA 2017
• Conversion factor: = 10.6 *cobalt -> stearic acid, cobalt salt taking a cobalt mass fraction of 9.4% into account*	analogy to Annex XV report, ECHA 2017

9.6.2.2. Exposure and risks for consumers

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

Table 9.38. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk quantification
Inhalation, local, long term	0 µg/m³ (Qualitative assessment .)	RCR < 0.01
Dermal, local, long term	1.03 ng/cm² (analogy to Annex XV report, ECHA 2017) **Supportive exposure (not used for RC):** 0 µg/cm² (Measured data: OEHHA 2007)	
Dermal, local, acute	1.03 ng/cm² (analogy to Annex XV report, ECHA 2017) **Supportive exposure (not used for RC):** 0 µg/cm² (Measured data: OEHHA 2007)	
Oral, systemic, long term	0.021 µg/kg bw/day (analogy to Annex XV report, ECHA 2017)	RCR < 0.01
Combined routes, systemic,		

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

Remarks on exposure data from external estimation tools:

analogy to Annex XV report, ECHA 2017:
Explanation: DERMAL, local, based on cobalt
dermal local = (A * C * R)/ S
R = release into artificial sweat = 0.048%
C = concentration in granules
A = amount available for dermal contact
S = surface area
ORAL
oral exposure = amount ingested * fraction released * conversion factor / body weight

Remarks on measured exposure:

OEHHA 2007:
Identity of the substance used: cobalt
Dermal exposure, local concentration on skin: Number of measured data points: 4
Explanation: Dermal, local:
In a wipe sampling test of playground surfaces performed by OEHHA no cobalt could be detected. To measure the chemicals that might be transferred to a child's hand through contact with a unitary playground surface made of recycled waste tires, the following wipe sampling study was performed by OEHHA. The protocol is modified from the US EPA (2003a) protocol used to wipe sample arsenic from CCA-treated wood. Polyester wipes (catalogue #TX1009) were purchased from ITW Texwipe (Upper Saddle River, New Jersey). These wipes are 9 inches by 9 inches and weigh approximately 8.3 grams. Prior to sampling, each wipe was put into a clean glass jar with 23 mls of distilled water. The area wiped was 3021 cm2. Two pour-in-place playground surfaces with bottom layers of recycled tires and top layers of EPDM were wipe tested. Playground surfaces were sampled in duplicate. The analytical method used was EPA 6020.

Risk characterisation

Qualitative risk characterisation:
DERMAL:
Based on the data provided on the release of cobalt from recycled rubber granules into artificial sweat, as reported by RIVM 2016 and the parameters for the exposure estimation given in ECHA 2017, dermal exposure from recycled rubber granules can be regarded as negligible. This is also confirmed by a wipe sampling test of playground surfaces performed by OEHHA, where no cobalt could be detected.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

This chapter describes why a separate risk characterisation related to combined exposure is not required and why any risks from potentially combined exposure sources are adequately controlled within the conditions of use prescribed in the exposure scenarios above. Combined exposure may result from any of the following scenarios:

1. Multiple cobalt substances handled in parallel at the same workplace.
2. Inhalation and dermal exposure route contributing to systemic effects at the same time.
3. More than just a single contributing occupational exposure scenario relevant for an individual worker.
4. Workers that are also exposed to cobalt in their free time (e.g. as member of the general population or as consumer).

These scenarios are considered below:

1. Multiple cobalt substances handled in parallel at the same workplace:

Inhalation exposure monitoring data were obtained from several workplaces where cobalt and/or cobalt substances are manufactured or handled in parallel. Sampled dust is subsequently analysed for its cobalt content but further chemical speciation is normally not done. Thus, measured cobalt levels as reported above, are in most cases already reflective of parallel exposure to a variety of cobalt substances and not only relevant for a single cobalt substance. Exposure estimates are reported in µg Co/m³ and are back-calculated to other cobalt substances by considering the molecular weight of the specific substance for which exposure needs to be assessed and without further modification. Thus, in the assessment for this specific cobalt substance, contribution to cobalt exposure from other cobalt substances handled in parallel is intrinsically included. The approach therefore intrinsically represents a combined exposure assessment for workers so that further summation of RCRs for different cobalt substances is not appropriate.

2. Inhalation and dermal exposure route contributing to systemic effects at the same time:

Since systemic effects are not relevant for the assessed cobalt substances, a summation of RCRs for the dermal and inhalation route is not required.

3. More than just a single contributing occupational exposure scenario relevant for an individual worker:

For aggregated exposure resulting from the applicability of more than just a single contributing worker scenario in a single work shift, it is noted that all exposure levels were derived for a full-shift exposure time and a safe use was demonstrated for each of these contributing scenarios. Thus, by demonstrating a safe use for individual contributing scenarios it is assured that a combination of activities within a single shift, could not exceed the highest calculated RCR for any of the individual activities in that shift.

4. Workers that are also exposed to cobalt in their free time (e.g. as member of the general population or as consumer):

For workers who are members of other populations to be protected in this chemical safety assessment (i.e. general population), a specific combined exposure assessment is not required as workers represent a less vulnerable population in comparison to subpopulations (e.g. children) which may be considered in assessments for the general population. Any RCR from these subpopulations could safely be assumed to be in fact significantly lower if re-calculated for workers. In a combined assessment of exposure, one would also avoid adding the worst case RCR for workers with the worst case RCR of another population as this would lead to an unrealistic scenario. Instead typical RCRs would be taken which would in combination lead to a low combined RCR. It can be easily seen, that RCRs for workers

based on worst case occupational exposure levels would exceed such realistic RCRs for combined exposure. The latter is therefore considered to be already intrinsically included in the worker's RCRs reported in the occupational exposure scenarios above.

10.1.2. Consumer

According to REACH Annex I, the registrant should consider risks from combined/(aggregated) exposure across different uses (products) relevant for his substance. Some general advice are given in Reach guidance document R 15, v.3.0., chapter R.15.6 and in Reach guidance document Part E, v.3.0, chapter 3.5 and 3.5.1.
Combined exposure may result from any of the following scenarios:

1. Combined exposure across the three routes (inhalation, oral and/or dermal) per contributing scenario
2. Aggregated exposure resulting from simultaneous use of different products/articles
3. In addition to direct exposure resulting from the use of products/articles, the general population may be exposed to the substance indirectly via the environment.

Combined exposure across the three routes per contributing scenario:
The risks from combined exposure across the three routes (i.e. inhalation, dermal and oral) is not possible, since systemic effects are only relevant for the oral route for the assessed cobalt substance.
Combined/(aggregated) exposure from simultaneous use of different products/articles:
No combined exposure assessment is needed since only one exposure estimate was provided.
Combined exposure indirectly via the environment and from consumer products/articles:
The focus of this section will be on the oral and inhalation pathway. However, it is no possible to provide a combined RCR over both routes as one DNEL is based on local effects whereas the other is based on systemic effects.
The RCR for systemic toxicity (oral) from the service life scenario "Use of shredded tyres on recreational facilities" is < 0.01. Adding the contributing RCR, with the highest RCR from a local indirect assessment will not change the RCR of the later.
No RCR (local effects) for the inhalation route has been derived from service life scenario, thus the outcome of the indirect assessment via inhalation will not be changed.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the table below. This is the sum of the releases to the environments from all exposure scenarios addressed.
Where there is more than one contributing scenario for the environment for a given exposure scenario, the highest release per route across all the contributing scenarios within the use has been taken into account as the release for the use (both for the regional and the exposure due to all the widespread uses). This may lead to overestimation of the PEC.

Table 10.1. Total releases to the environment per year from all life cycle stages

Release route	Total releases per year
Water	138.8 kg/year
Air	57.6 kg/year
Soil	0 kg/year

10.2.2. Regional assessment

The regional predicted environmental concentration (PEC regional) and the related risk characterisation ratios when a PNEC is available are presented in the table below. The exposure to man via the environment from regional exposure and the related risk characterisation ratios are also provided (when relevant). The exposure concentration for human via inhalation is equal to the PEC air.

The exposure estimates have been obtained with EUSES 2.1.2 unless stated otherwise.

Table 10.2. Predicted regional exposure concentrations (Regional PEC) and risks for the environment

Protection target	Regional PEC	Risk characterisation
Fresh water	**Regional PEC:** 0.1 µg/L (See below)	RCR = 0.161
Sediment (freshwater)	**Regional PEC:** 4.26 mg/kg dw (See below)	RCR = 0.079
Marine water	**Regional PEC:** 0.015 µg/L (See below)	RCR < 0.01
Sediment (marine water)	**Regional PEC:** 14.7 mg/kg dw (See below)	RCR = 0.211
Agricultural soil	**Regional PEC:** 0.239 mg/kg dw (See below)	RCR = 0.022
Man via environment - Inhalation	**Concentration in air:** 1.56E-7 ng/m³ (See below)	RCR < 0.01
Man via environment - Oral	**Exposure via food consumption:** 0.2 µg/kg bw/day (Measured data: Measured data)	RCR = 0.04
Man via environment - combined routes		Not required (local and systemic effects)

EUSES 2.0 is used for calculating the regional PECadd values for each environmental compartment. The Co inputs for the regional assessment are the anthropogenic point and diffuse emissions to air, wastewater, surface water, agricultural soil and industrial/urban soil.
More information available in the CSR in section “Diffuse source analysis and modeled PEC (EUSES)”.

Man via environment - Inhalation
Calculated regional air background concentration (EUSES model)

Man via environment - Oral
2L of drinking water (0.023 µg Co/L: median value from the “Geochemistry of European Bottled Water”) + the typical exposure from food (12 µg/d: median value from the 1994 UK total diet study) and the default body weight of 60kg have been taken into account.

Remarks on risk characterisation for regional concentrations:
Conclusion: The risk characterisation ratios (PECadd/PNECadd) for the different compartments are all below 1. Hence no regional risks for the different environmental compartments are predicted on the basis of modelled (EUSES) data.

MAN VIA ENVIRONMENT
The exposure assessment is based on the cobalt ion, as this is the toxic species, as such for the risk characterisation the DNELs based on cobalt were used.

Diffuse source analysis and modelled PEC (EUSES)

An extended analysis of the diffuse sources for cobalt has recently been initiated (CDI, 2010). Emission of cobalt to the different compartments (air, soil, surface water) for the selected region is presented in Table 1 A regional emission of 1477.2 kg Co/year to the air compartment, 778.5 kg Co/year to the surface water and 16474.2 to the soil compartment were noted.

Table 1: Regional emission of cobalt (kg Co/year) to the different environmental compartments

Emission source	Air (kg Co/year)	Surface water (kg Co/year)	Soil (kg Co/year)	Total
Industry	528.66	485.00	/	1013.66
Traffic				
- Combustion of LPG by road traffic	709.50	/	/	709,50
Agriculture				
- Use of fertilisers manure and sewage sludge on agricultural land	/	/	16468.00	16468.00
- Soil erosion	/	/	/	0
Households				
- Fossil fuel burning				0
* Coal	91.20	/	/	91.20
* LPG	28.80	/	/	28.80
- Use of compost	/	/	/	0
- Tobacco smoke	/	/	/	0
Waste management				
- Incineration	/	44.00	/	/
- Incineration	119.00	43.00	/	/
- STP	/	194.00	/	/
- Domestic wastewater discharge	/	12.51	6.21	18.72
TOTAL	1477.16	778.51	16474.21	18329.88

A continental emission of 316771.5 kg Co/year to the air compartment, 90895.9 kg Co/year to the surface water and 345273 kg Co/year to the soil compartment were noted (Table 2).

Table 2: Continental (EU-27 + Norway) emission of cobalt (kg Co/year) to the different environmental compartments

Emission source	Air (kg Co/year)	Surface water (kg Co/year)	Soil (kg Co/year)	Total
Industry	3427.00	3144.00	/	6571.00
Traffic				
- Combustion of LPG by road traffic	8982.30	/	/	8982.30
Agriculture				
- Use of fertilisers manure and sewage sludge on agricultural land	/	/	330650.00	330650.00
- Soil erosion	0	2.45	0	2.45
Households				
- Fossil fuel burning				
* Coal	198220.80	/	/	198220.80
* LPG	104955.00	/	/	104955.00
- Use of compost	/	/	6928.00	6928.00
- Tobacco smoke	0.83	/	66.99	67.82
Waste management				
- Incineration	1185.54	430.57	/	0
- Landfilling	/	1233.90	/	0
- STP	/	70598.00	/	0
- Domestic wastewater discharge	/	15487.00	7628.00	23115.00
TOTAL	316771.47	90895.92	345272.99	679492.37

EUSES 2.0 is used for calculating the regional PEC values for each environmental compartment. The Co inputs for the regional assessment are the anthropogenic point and diffuse emissions to air, wastewater, surface water, agricultural soil and industrial/urban soil (as presented in Table 3).
The input of chemicals is regarded in the model as continuous and equivalent to continuous diffuse emission. For metals, all individual compounds are assumed to transform into the ionic species. The results from the models are steady-state concentrations, which can be regarded as estimates of long-term average exposure levels.
In the continental model, it is assumed that all anthropogenic Co emissions enter into the continental environment. It is also assumed that no inflow of air and water across the boundaries of the continent occurs. Continental exposure concentrations are calculated based on the combined anthropogenic Co emissions from all EU countries (extrapolated) and on the natural/pristine ambient background of Co.
An overview of the added regional exposure concentrations for the different compartments is summarised in Table 3.

Table 3: Calculated PECadd regional for the different environmental compartments

Compartment	Regional PECadd	
surface water (total)	0.151	µg/L
sea water (total)	0.0174	µg/L
surface water (dissolved)	0.10	µg/L
sea water (dissolved)	0.015	µg/L
air	1.56E-13	mg/m3
agricultural soil (total)	0.239	mg/kg dw
porewater agricultural soil	1.99E-03	mg/L
natural soil	1.23E-02	mg/kg dw
industrial soil	0.0128	mg/kg dw
sediment	4.26	mg/kg dw
marine sediment	0.65	mg/kg ww

Measured background concentrations

Freshwater

The baseline background concentrations of cobalt in freshwaters generated from the FOREGS monitoring program are summarised in Table 4.

Table 4: Baseline cobalt concentrations (in µg/L) in European surface water (data from FOREGS Geochemical Baseline Program)

Country	50th percentile (µg/L)	90th percentile (µg/L)
Austria	0.11	0.25
Belgium	0.20	0.54
Czech republic	0.17	0.38
Denmark	0.80	1.77
Estonia	0.15	0.21
Finland	0.20	0.93
France	0.16	0.38
Germany	0.15	0.61
Greece	0.09	0.14
Hungary	0.22	0.46
Ireland	0.23	0.45
Italy	0.15	0.87
Latvia	0.16	0.21
Lithuania	0.21	0.31
Norway	0.05	0.22
Poland	0.28	0.58
Portugal	0.14	0.51
Slovakia	0.23	0.43
Slovenia	Mean: 0.12	/
Spain	0.13	0.55
Sweden	0.10	0.82
The Netherlands	0.30	0.39
United Kingdom	0.18	0.76
Albania	Mean: 0.07	/
Croatia	0.19	0.39
Switzerland	0.14	0.34
Median for Europe: 0.44		
Median for EU-27 + Norway: 0.45		

Dissolved cobalt levels ranged between 0.01 and 19.5 µg Co/L. The median value of the calculated, country-specific 50th percentiles is considered as a reliable value for a “typical” Co-baseline level in EU surface waters. Taking all European countries into account, this value is 0.45 µg/L. Discarding the data for Albania, Croatia and Switzerland, a value of 0.44 µg/L is derived for the EU (incl. Norway). Taking into account the high quality of the data set, the median value of 0.44 µg/L can be accepted as a typical background concentration for cobalt in European surface waters (Europe-regional scale).

Freshwater sediment

The baseline background concentrations of cobalt in freshwater sediments generated from the FOREGS monitoring program are summarised in Table 5.

Table 5: Baseline cobalt concentrations (in mg/kg) in European freshwater sediments (data from FOREGS Geochemical Baseline Program)

Country	50th percentile (mg/kg dw)	90th percentile (mg/kg dw)
Austria	6.10	24.1
Belgium	12.6	27.7
Czech republic	12.7	23.4
Denmark	Mean: 2.1	/
Estonia	2.27	4.42
Finland	6.88	15.4
France	7.03	16.2
Germany	6.67	14.8
Greece	14.3	26.2
Hungary	4.82	11.9
Ireland	15.0	28.3
Italy	9.16	20.8
Latvia	3.00	9.69
Lithuania	5.04	8.64
Norway	7.99	19.1
Poland	2.04	5.74
Portugal	10.6	19.8
Slovakia	9.86	14.2
Slovenia	8.66	16.7
Spain	7.88	15.4
Sweden	6.93	17.49
The Netherlands	2.38	8.30
United Kingdom	19.9	37.5
Albania	Mean: 21.0	/
Croatia	8.80	13.2
Switzerland	7.04	17.1
Median for Europe 16.5		
Median for EU-27 + Norway 16.7		

The median value of the calculated, country-specific 50th percentiles is considered as a reliable value for a “typical” Co-baseline level in EU surface waters. Taking all European countries into account, this value is 16.5 mg/kg. Discarding the data for Albania, Croatia and Switzerland, a value of 16.7 mg/kg is derived for the EU (incl. Norway). Taking into account the high quality of the data set, the median value of 16.7 mg/kg dw can be accepted as a typical background concentration for cobalt in European freshwater sediment (Europe-regional scale).

Soil

Country-specific measured concentrations are available in natural soils for the countries reported in Table 6. The range of total soil Co concentrations in natural soils varies between 5.4 and 25 mg Co/kg dw.

Table 6: Measured regional PEC values for natural soils in different countries

Country	50th percentile (mg/kg dw)	90th percentile (mg/kg dw)
Austria	9.71	27.1
Belgium	12.7	17.0
Czech republic	7.75	14.8
Denmark	/	/
Estonia	3.32	7.54
Finland	2.62	7.37
France	8.84	18.1
Germany	5.13	18.3
Greece	16.9	34.5
Hungary	6.46	17.9
Ireland	6.85	16.9
Italy	10.9	23.6
Latvia	3.95	12.9
Lithuania	2.70	7.19
Norway	4.23	10.6
Poland	1.70	5.46
Portugal	5.86	16.7
Slovakia	8.76	21.0
Slovenia	17.4	21.3
Spain	8.04	20.0
Sweden	3.14	7.16
The Netherlands	2.04	6.97
United Kingdom	6.48	20.3
Albania	/	/
Croatia	13.4	21.3
Switzerland	8.02	25.0
Median for the EU: 16.1		
Median for the EU + Norway: 15.6		

The median value of the calculated, country-specific 50th percentiles is considered as a reliable value for a “typical” Co-baseline level in EU top soils. Taking all European countries into account, this value is 16.1 mg/kg. Discarding the data for Albania, Croatia and Switzerland, a value of 15.6 mg/kg is derived for the EU (incl. Norway).

Measured ambient PEC values

The following measured PEC regional values were extracted from literature.

Freshwater

For the freshwater compartment, country-specific measured regional PECs (µg dissolved Co/L) were calculated for sites located in the countries reported in Table 7.

Table 7: Measured regional PEC values for the freshwater in different countries.

Country	Regional RWC-ambient - Co PECs (µg/L)		
	Co_{total}	$Co_{dissolved}$	Not specified
Belgium–Flanders	1.78	/	/
Finland	/	1.01	/
The Netherlands	/	0.65	/
Sweden	/	/	0.24
Belgium	/	1.81	/
Sweden	/	0.68	/
France (data for Seine)	/	0.071	/
Spain	/	1.08	/
United Kingdom	/	1.38	/
Regional RWC-ambient PEC:	0.86 µg Co_{diss}./L		

The median ambient regional PEC for Europe; i.e. 0.86 µg dissolved Co/L is used for sites located in other EU countries.

Marine water

For the marine water compartment, specific measured regional PECs (µg dissolved Co/L) were calculated for sites reported in Table 8.

Table 8: Measured regional PEC values for the marine water at different locations

Location	Mean / Median concentration (range, excl. outliers) ng/L	Ambient PEC (ng/L)
Central/Southern North Sea	8.8 (1.6 - 68.9)	35.1
Atlantic Ocean / Azores (open ocean)	2.10 (0.85 - 6.07)	4.4
Mediterranean area	20	/
Aegean Sea (Greece)	16.3 - 16.5 (median)	65.4
Surf zone water, Baja California	16.5 (median) (6.5 - 34.8)	27.8
Coastal zone water 5-45 km offshore Baja California	2.2 (median) (1.3 - 10)	8.4
Ocean	/ (1.8 - 450)	/
Seawater (unspecified)	270 (35 - 4100)	/
Seawater (unspecified)	590	/
Open coastal pacific Ocean	40	/
North Australian waters (coastal, estuarine)	27.0 (5.4 - 67.6)	58.9
Florida, Indian River Lagoon (USA	29.3 (6 - 50)	47.2
	50P: 17.8 ng/L 90P: 57.4 ng/L	open ocean: 4.4 - 8.4 ng/L coastal: 50P of 46.7 ng/L

The range of dissolved Co concentrations in marine waters vary between 0.0044 and 0.0654 ng dissolved Co/L. For local sites discharging to a marine environment the median ambient PEC for coastal waters of 0.047 µg dissolved Co/L is used as a regional background value.

Freshwater sediment

For the freshwater sediments, country-specific measured regional PECs (mg Co/kg dw) for sites located in the countries reported in Table 9.

Table 9: Measured regional PEC values for the freshwater sediments in different countries

Country	Regional RWC-ambient Co-PECs (mg/kg dry wt)
United Kingdom	24.8
Spain	14.2
Finland	18.9-45.1
Belgium	23.6
France	16.4
Sweden	29.4
Range:	14.2 – 45.1
Regional RWC-ambient PEC:	23.8 mg/kg dw

The measured Co sediment concentrations in EU countries vary between 14.2 and 45.1 mg Co/kg dw. The median ambient regional PEC for Europe i.e. 23.8 mg Co/kg dw is used for sites located in other EU countries.

Marine Sediment

For the marine sediments, country-specific measured regional PECs (mg Co/kg dw) for sites located in the countries reported in Table 10.

Table 10: Measured regional PEC values for the marine sediments at different locations

Location	Mean / Median concentration (range, excl. outliers) in mg/kg dw	Ambient PEC (mg/kg dw)
Baltic Sea	3.5 (0.69 - 18.1)	13.1
Gulf of Saronikos (Greece)	9.7 (5.1 - 12.7)	12.1
Gulf of Cadiz (Spain)	8.1 (3.4 - 11.5)	11.5
Red Sea	4.5 (1.6 - 10)	10.4
Black Sea	2.52 (1.3 - 4.6)	/
Black Sea	14.7 -15.8 (7 - 37)	22.5
Black Sea	24 (21-27)	/
Sea of Marmara	2.05 (9 - 30)	/
Mersin Bay	25.5 (11 - 40)	/
Coastal sediment near Stockholm (Sweden)	15.3	/
Atlantic Ocean	19	/
Bristol Channel (United Kingdom)	11.2 (6.4 - 16)	/
Massachusetts (USA): outer harbour	7.0 (3.6 - 9.8)	/
Massachusetts (USA): inner harbour	6.4 (2.6 - 10.5)	/
Massachusetts (USA): control site	4.8 (1.6 - 8.2)	/
Ross Sea, Antarctica	1.9 ± 3.4 (0.1 - 13)	/
Indian River Lagoon, Florida (USA)	1.8 (0.4 - 6.3)	5.0
Gulf of Mexico: coastal areas	27.6	35.5
Beaufort Sea	89 (± 14)	/
Chukchi Sea (Alaska, USA)	3.02 (16.0 - 74.0)	47.5
	50P: 6.99 mg/kg DW 90P: 24.8 mg/kg DW	Average: 19.7 (5.0 – 47.5) Median: 14.7

The range of Co concentrations in marine sediments varies between 5.0 and 47.5 mg Co/kg dw. For sites discharging to a marine environment; the median ambient PEC for Europe of 14.7 mg Co/kg dw is used as a regional background value.

Soil

Country-specific measured concentrations are available in grazing soils for the countries reported in Table 11. The range of total soil Co concentrations in grazing soils varies between 5.2 and 51.6 mg Co/kg dw.

Table 11: Measured regional PEC values for grazing soils in different countries

Country	50th percentile (mg/kg dw)	RWC-ambient PEC (mg/kg dw)
Austria	11.4	17.0
Belgium	7.3	15.0
Bosnia	16.8	24.3
Bulgaria	11.5	16.7
Croatia	18.7	24.3
Cyprus	14.9	21.1
Czech Republic	10.0	17.7
Denmark	1.8	5.2
Estonia	3.	6.3
Finland	3.5	6.7
France	7.8	16.2
Germany	6.4	15.0
Greece	15.6	26.1
Hungary	7.9	13.2
Ireland	7.5	11.6
Italy	13.1	20.6
Latvia	3.6	7.9
Lithuania	3.7	5.8
Macedonia	13.9	17.2
Macedonia	20.2	30.8
the Netherlands	2.6	8.2
Norway	5.0	11.5
Poland	2.6	8.7
Portugal	4.3	16.0
Serbia	14.2	23.4
Slovakia	12.2	17.3
Slovenia	21.5	51.6
Spain	6.6	14.9
Sweden	3.4	10.8
Switzerland	8.2	14.4
Ukraine	5.7	11.7
United Kingdom	8.1	14.6
Median for the EU: 16.9		
Median for the EU + Norway: 14.8		

Country-specific measured concentrations are available in agricultural soils for the countries reported in Table 12. The range of total soil Co concentrations in agricultural soils varies between 5.4 and 42.7 mg Co/kg dw.

Table 12: Measured regional PEC values for agricultural soils in different countries

Country	50th percentile (mg/kg dw)	RWC-ambient PEC (mg/kg dw)
Austria	11.2	15.1
Belgium	8.2	24.9
Bosnia Herzegovina	18.5	26.2
Bulgaria	13.4	20.1
Croatia	13.5	26.1
Cyprus	14.4	21.4
Czech republic	9.7	17.7
Denmark	2.2	6.1
Estonia	3.6	5.4
Finland	4.4	12.7
France	7.4	19.0
Germany	5.4	21.5
Greece	16.9	32.6
Hungary	7.6	16.3
Ireland	8.9	17.0
Italy	12.1	21.1
Latvia	3.9	9.2
Lithuania	3.9	7.4
Macedonia	14.9	27.9
Montenegro	24.1	37.4
The Netherlands	2.3	10.4
Norway	5.7	14.5
Poland	2.6	8.4
Portugal	4.8	16.0
Switzerland	8.8	14.2
Slovakia	12.1	19.5
Slovenia	22.4	42.7
Spain	6.4	14.9
Serbia	15.0	22.7
Sweden	4.7	11.5
Ukraine	4.9	16.1
United Kingdom	8.1	18.1
Median for the EU: 17.3		
Median for the EU + Norway: 16.3		