Occupational exposure scenarios

Diamminedichloropalladium

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9.0 Introduction

The current document includes all relevant exposure scenarios (ES) for the manufacture and use of diamminedichloropalladium (DDP) as required under the REACH Regulation (Regulation (EC) No 1907/2006). For the development of the ES the Regulation and the relevant REACH Guidance have been considered. For the description of the covered uses and processes, the "R.12 – Use descriptor system" guidance (Version: 2, March 2010, ECHA-2010-G-05-EN), for the description and implementation of risk management measures (RMM) the "R.13 – Risk management measures" guidance (Version: 1.2, October 2012, ECHA-12-G-19-EN) and for the actual exposure assessment the "R.14 – Occupational Exposure Assessment" (Version: 2.1, November 2012, ECHA-2010-G-09-EN) and "R.16 – Environmental Exposure Estimation" (Version: 2.1, October 2012, ECHA-10-G-06-EN) were used (Source: European Chemicals Agency, http://echa.europa.eu/).

9.0.1 Methodology – occupational exposure

According to REACH, an ES has to describe which operational conditions (OC) and risk management measures (RMM) ensure safe use of the substance. Safe use has to be demonstrated by an exposure assessment in which the estimated exposure level has to be below the respective derived no-effect level (DNEL), expressed by a risk characterisation ratio (RCR) of below 1. For inhalation exposure, the RCR is based on the DNEL (long-term, systemic effects) for diamminedichloropalladium (DDP) of 42 µg DDP/m³. For the dermal route, the RCR is based on the DNEL (long-term, systemic effects) of 0.83 mg DDP/day. Acute DNELs or DNELs for local effects were not derived. Please refer to the DNEL report attached to the IUCLID file for further information. It has to be noted that the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use.

Kommentar [EBRC1]: To be confirmed. DNEL to be specified.

Kommentar [EBRC2]: Still in consideration of 100 % dermal absorption. DNEL to be specified.

Kommentar [EBRC3]: To be confirmed since exposure-based waiving is not possible.

According to the REACH Guidance R.14, an occupational exposure assessment may be conducted at specific tiers. Preference should be given to monitoring data obtained under the same OC and with the same RMM implemented as described in the ES. If such monitoring data are not available, analogous exposure data can be used given that OC and RMM under which these analogous data were obtained, are comparable to an extent which justifies such read-across. If monitoring data are not available at all, occupational exposure can be assessed by the aid of exposure assessment tools.

As a first step in the development of any exposure scenarios it is therefore important to obtain and summarise information on OC and RMM prevailing at actual workplaces. Thus, for the development of ES for palladium substances, an occupational exposure questionnaire was sent to the consortium members. To facilitate the generation of ES which are generic to the entire sector, grouping of workplaces, tasks and activities conducted by workers is inevitable. As a reflection of the need for further aggregation of reported data, so-called activity classes (ACs) were developed that are used to describe similar tasks that are conducted under specific operational conditions (e.g. closed processes compared to open processes). Companies were then asked to provide information on further OC and RMM associated with individual ACs.

As a further benefit of these ACs, existing monitoring data could easily be linked with the required contextual information by simply assigning the data to the ACs. As a consequence, a task-specific exposure assessment can be conducted.

Draft activity classes were developed by screening available literature on processes and tasks conducted by workers as well as by qualitatively assessing the emission potential of such activities. The resulting draft activity classes were subsequently circulated to an industry expert group for review and amendment. As a final plausibility check, a site visit in a palladium producing site was conducted and the observations were compared with the proposed list of ACs. The final list of ACs

is given in the table below. It is noted that the list was developed for several palladium substances which have to be registered either in 2013 or 2018 so that some ACs are potentially not relevant for DDP.

Table 1: Developed activity classes (ACs) and use of ACs in the occupational exposure scenario for DDP

Activity class (AC)	Title	Covered tasks	ACs relevant for the assessment of exposure to DDP
AC1	Automated handling (non-direct contact) of dusty materials at ambient temperature	Transferring, mixing/blending, solution/suspension preparation, weighing, sampling, sieving, furnace loading/unloading	
AC2	Manual handling of dusty materials at ambient temperature	Transferring, solution/suspension preparation, weighing, sampling, furnace loading/unloading, emptying of filter bags	X
AC3	Handling of non-/very low dusty materials at ambient temperature	Non-abrasive tasks: e.g. transferring, mixing/blending, weighing, sampling, separation, filtration, furnace loading/unloading, solution/suspension preparation	X
AC4	Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry)	Transferring, drying, filtration, mixing/blending, sampling, separation	X
AC5	Wet chemistry in closed systems/vessels (including chemical reactions, mixing)	Supervision, control walks, maintenance (routine work)	X
AC6	Operations at furnaces, smelters, ovens in open process at substantially elevated temperatures (e.g. furnace in operation)	Furnace loading/unloading, casting, sintering, calcination, conversion, smelting	
AC7	Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting)	Supervision, control walks, maintenance (routine work)	X
AC8	Mechanical operations in open or semi-closed processes	Abrasive tasks: e.g. crushing, milling, mixing/blending	
AC9	Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance)	Supervision, control walks, maintenance (routine work)	X
AC10	Non-routine work	Irregular cleaning, maintenance, repairing, sampling, tests/improvement experiments	X

On the basis of these ACs, inhalation monitoring data as submitted by industry were pooled over various individual data submitters still maintaining the required contextual information in terms of OC and RMM. In addition to already existing exposure data, a sampling campaign was initiated and measurements were taken according to suggestions made in the report to the site visit mentioned above.

Since at specific manufacturing sites, multiple palladium substances are often produced or handled in parallel, any measured exposure levels do always represent combined exposure to these substances. Since the sampled dust is commonly analysed for palladium only, it is not possible to assess the contribution of DDP to overall exposure to palladium (ions). Therefore, combined exposure to different sources of palladium is already inherently included in the exposure assessment for DDP in a conservative approach when measured data are concerned.

Based on results of dustiness tests performed with the involved palladium substances, it is considered that the substance-intrinsic emission potential of the handled palladium substances is very similar. Since the activity classes were developed on the basis of similar process intrinsic emission potential, it is therefore considered justified to also use measured inhalation exposure

data that were submitted for other palladium substances than DDP in the assessment of exposure to DDP below given that the quality and extent of the corresponding contextual information is sufficient.

Generally, the manufacturing process of DDP is characterised by either wet chemical processes or handling activities with damp filter cakes or wetted powders. The considerable moisture content (XXX %) of these materials justifies the assumption of a low to very low potential. The assumption of a very low emission potential is also supported by the observation of handling of only very small amounts of the substance during a shift. This very low emission potential is particularly relevant in cases in which the exposure assessment was based on modelling and for setting the applicability boundaries of the ES below.

The only exception from the wet or damp use conditions may occur during loading/unloading of furnaces when furnaces are in operation (i.e. heated). According to a survey among manufacturers of DDP, operations at furnaces, smelters and ovens in open process at substantially elevated temperatures (please refer to activity class 6 below), are however not relevant for DDP since furnaces are exclusively loaded when cooled down. Due to the closed nature of the furnaces and due to the fact that DDP is transformed into another substance (palladium metal) at approx. 320°C, exposure to DDP is expected to be very low during furnace operations. It is also noted that such furnace operations do always represent the last step in the life-cycle of the substance.

Kommentar [EBRC4]: Value to be taken from dustiness tests.

Kommentar [EBRC5]: We are waiting for the results of the additional dustiness tests.

9.0.1.1 Measured data

9.0.1.1.1 Dermal exposure data

No dermal exposure data representing actual workplace measurements were provided.

9.0.1.1.2 Inhalation exposure data

A detailed description of the quality criteria applied to the measured inhalation exposure data can be found in several risk assessment (RA) reports as conducted under 793/93/EEC (e.g. the RA of diantimony trioxide). For the sake of brevity, only the most important qualifiers are listed below:

- In general, only personal measurements of inhalation exposure data have been used.
- Depending on the exposure duration, these values have to be either full-shift-representative (at minimum of 120 minutes measurement duration) or must have been obtained during the entire task duration. If the latter is the case and, in addition, it could be shown that exposure is negligible for the remaining shift, values have been weighted accordingly to obtain time weighted averages (TWA). If applicable, the corresponding task durations can be found under Section 2.1, “Frequency and duration of use/exposure”. Because of the combined exposure settings observed for DDP, the zero background concentration was not considered being applicable so that TWAs were consequently not calculated.
- The measured fraction must be “inhalable” according to EN 481.
- All measurements have to be assigned to a specific workplace, process, task or class of processes/tasks/activities.
- The measurement date has to be reported.
- Additional information such as sampling equipment and method of analysis has to be provided for individual data sets.

In addition, measured data were only used for the purpose of REACH ES if the operational conditions (including AC) and risk management measures which prevail during the measurements are reported.

9.0.1.1.3 Assessment of data quality and percentiles to be used

Whenever measured data are used in the ESs below they have been checked for their quality by applying the quality criteria as outlined above. According to R.14 of the REACH guidance, the percentile reflecting the exposure level for workers has to be determined according to the specificity of the data to the ES of interest and the variability of the data (Table R.14-2) as reflected by the geometric standard deviation (GSD). Additionally, the guidance requires a minimum number of measurements based on the GSD. For that purpose, the table below summarises the relevant information for all data which was used (including supportive data) for the exposure assessment in the ES below.

Table 2: Quality assessment of measured data of personal inhalation exposure

Activity class (AC)	Exposure route	Counts	Quality/Specificity of data	GSD	Use in exposure assessment
9.1 - Manufacture of diamminedichloropalladium					
AC2	inhalation	21	high (Data originate from the workplace/activity under scrutiny.)	3.5	90th percentile
AC3	inhalation	5	low (Count of measurements is below the indicative number for required measurements.)	2.3	supportive information
AC4	inhalation	2	low (Count of measurements is below the indicative number for required measurements.)	4.5	supportive information
AC5	inhalation	1	low (Count of measurements is below the indicative number for required measurements.)	n.a.	supportive information
AC10	inhalation	6	high (Data originate from the workplace/activity under scrutiny. Due to the low number of measurements, it was decided to use a higher percentile for the exposure assessment.)	5.9	95th percentile
Job rotation	inhalation	9	high (Manufacture of DDP is in large part characterised by wet chemistry in closed systems with low emissions. Personal inhalation exposure measurements from job rotation during all tasks that are performed during the manufacture of DDP therefore reflect exposure during all tasks relevant for AC5 (e.g. supervision, control walks, maintenance during wet chemical reactions in closed systems/vessels). Due to the low number of measurements, it was decided to use a higher percentile for the exposure assessment.)	3.7	95th percentile
Job rotation, elevated emission potential (EP)	inhalation	22	high (Only a low number of exposure situations with elevated emission potential (EP) exist (see AC2 and AC10) during the manufacture of DDP. Personal inhalation exposure measurements from job rotation during these tasks are therefore reflective of exposure situations as relevant for AC2 and AC10. These measurements are used as supportive data for these ACs.)	2.3	supportive information
Job rotation, elevated EP	inhalation	1	not applicable This single value was considered as being a sampling artefact and was therefore not used in the exposure assessment.	n.a.	n.a.

9.0.1.1.4 Analysis of air monitoring data

The exposure estimates below are calculated from measured palladium levels by taking into account the molecular weight (by multiplication with a factor of 1.986) to reflect exposure to DDP[1].
It is noted that the analysed data below were measured outside any respiratory protective equipment. Such equipment is taken into account by dividing the calculated exposure level by the so-called assigned protection factor (APF) as reported in the exposure scenarios below. These APFs have been set according to BS EN 529:2005 and can also be looked up in the glossary of MEASE. It is additionally noted that the estimated exposure levels represent full-shift exposure levels and do not represent time weighted averages as outlined in Section 9.0.1.1.2.
The analysis of the data is provided in the table below:

Table 3: Analysis of personal air monitoring data [µg DDP/m³] used for exposure estimation

Activity class (AC)	Counts	GSD	Minimum	Median	75th percentile	90th percentile	95th percentile	Maximum
9.1 - Manufacture of diamminedichloropalladium								
AC2	21	3.5	2.0	47.7	90.1	146.0	151.0	262.2
AC10	6	5.9	0.3	0.8	1.7	20.9	30.3	39.7
Job rotation	9	3.7	0.1	1.0	2.7	3.7	3.9	4.1

Shaded cells indicate the selected percentile.

The table below summarises personal air monitoring data considered as supportive information in exposure assessment (e.g. in cases in which the required number of observations does not comply with R.14 of the REACH (Table 14-2), see also Table 2).

Table 4: Analysis of personal air monitoring data [µg DDP/m³] used as supportive information

Activity class (AC)	Counts	GSD	Minimum	Median	75th percentile	90th percentile	95th percentile	Maximum	supportive for
9.1 - Manufacture of diamminedichloropalladium									
AC3	5	2.3	2.0	2.0	4.0	9.5	11.3	13.1	supporting MEASE assessment for AC3*
AC4	2	4.5	1.2	5.6	7.7	9.1	9.5	9.9	supporting MEASE assessment for AC4**
AC5	1	n.a.	4.5	4.5	n.a.	n.a.	n.a.	4.5	supporting all tasks (job rotation)
Job rotation, elevated EP	22	2.3	4.0	27.3	45.5	55.1	95.2	170.0	supporting AC2 and AC10/cleaning tasks
Job rotation, elevated EP	1	n.a.	723.0	723.0	n.a.	n.a.	n.a.	723.0	n.a.***

*In contrast to the MEASE assessment conducted for the ES below, the initial MEASE assessment was conducted without considering the use of LEV. This assessment resulted in an exposure estimate of 50 µg/m³. Measured data obtained from workplaces without such LEV, clearly support the worst case nature of this MEASE estimate. However, as an effort to demonstrate safe use of DDP, an LEV has to be considered in the MEASE assessment and is therefore pre-scribed in the exposure scenario below.
**The measurements for AC4 support the corresponding MEASE estimate for this activity class/exposure setting and its conservative nature.
***This single value was considered as being a sampling artefact and was not used in the exposure assessment.

[1] Please note the pre-cautionary nature of this approach as combined exposure from multiple palladium substances is exclusively attributed to DDP as already explained in Section 9.0.1.

It is noted that the analysed data above represent personal exposure levels outside any respiratory protective equipment (RPE). If applicable, such equipment was taken into account by dividing the calculated exposure level by the so-called assigned protection factor (APF) as reported in the exposure scenarios below. These APFs have been set according to BS EN 529:2005 and can also be consulted in the glossary of MEASE.

In addition to personal measurements, also static measurements have been provided that are also used as supportive information in the occupational exposure scenario as suggested by the guidance.

Table 5: Analysis of static air monitoring measurements [µg DDP/m³] used as supportive information

Activity class (AC)	Counts	GSD	Minimum	Median	75th percentile	90th percentile	95th percentile	Maximum	supportive for
9.1 - Manufacture of diamminedichloropalladium									
Job rotation	22	5.8	0.01	0.1	0.6	1.0	3.6	8.8	supporting all tasks (job rotation) and AC5

As can be seen in Table 4 and Table 5 above, all supportive personal full-shift inhalation monitoring data show measurements that are below or in the range of the values as used for exposure assessment in the exposure scenarios below (with one exception in which LEV was additionally used in MEASE assessment, see first table note of Table 4). In addition, the 95th percentile value of 22 static air monitoring values (3.6 µg/m³) supports the exposure estimate derived for AC5 (4.5 µg/m³) and the 95th percentile value of 9 personal air monitoring measurements obtained during job rotation (3.9 µg/m³). Since handling of DDP is in large parts characterised by wet chemistry in closed systems, it is therefore considered appropriate to use the 95th percentile value of the personal measurements obtained during job rotation for AC5.

9.0.1.2 Analogous data

For workplaces for which no measured data were available, analogous data have been used to estimate exposure. The table below summarises for which workplace this was the case, from which sources the analogous data were taken, the specific justification for such a read-across and the used extrapolation methodology.

Table 6: Use of analogous data in the occupational exposure scenario for DDP

Exposure scenario - workplace	Exposure route	Data source	Justification for read-across	Mode of extrapolation
9.1 – AC5	inhalation	**9.1 – Job rotation**	All relevant tasks during the manufacture of DDP were performed during job rotation. In general, the manufacturing process of DDP is characterised by wet chemical processes, where only supervision and control walks are required. Since these tasks are relevant for AC5, measured data from job rotation are considered to adequately reflect exposure during these tasks.	DDP and other palladium containing substances were handled when exposure was measured during relevant activities for AC5. Exposure was measured in Pd and calculated for DDP by taking the molecular weight of DDP into account. Therefore, provided exposure levels are reflective of personal exposure to DDP and other Pd containing substances.
9.1 – AC10	inhalation	**9.1 – AC2**	Since immediate cleaning is required during activities that involve overspill to avoid drying of damp powders or splashes, it is assumed that the handling of low dusty solids adequately reflects tasks that are performed during non-routine work as grouped under AC10.	DDP and other palladium containing substances were handled when exposure was measured during relevant activities for AC2. Exposure was measured in Pd and calculated for DDP by taking the molecular weight of DDP into account in a simple read-across. However, since local exhaust ventilation (LEV) cannot be assumed during cleaning in general, the standard efficiency of such LEV of 78 % was used to eliminate the impact of LEV on the 90th percentile value (RWC) of AC2 (RWC/(1-0.78)).
9.2 – Raw material handling	inhalation	**9.1 – AC2**	The handling of low dusty solids at manufacturing sites and at industrial downstream user sites is assumed to be similar since it is assumed that the same operational conditions and risk management measures apply.	DDP and other palladium containing substances were handled when exposure was measured during relevant activities for AC2. Exposure was measured in Pd and calculated for DDP by taking the molecular weight of DDP into account and simple read across was conducted to reflect exposure in downstream uses.
9.2 – Cleaning & maintenance	inhalation	**9.1 – AC10, 9.1 – AC2**	The exposure potential during cleaning and maintenance at industrial downstream user sites is assumed to be similar compared to manufacturing sites since it is assumed that the same operational conditions and risk management measures apply.	DDP and other palladium containing substances were handled when exposure was measured during relevant activities for AC10 and AC2. Exposure was measured in Pd and calculated for DDP by taking the molecular weight of DDP into account and simple read-across was conducted from tasks grouped under AC10 during manufacture. Local exhaust ventilation (LEV) cannot be assumed during cleaning (AC2) in general, the standard efficiency of such LEV of 78 % was used to eliminate the impact of LEV on the 90th percentile value (RWC) of AC2 (RWC/(1-0.78)).

Exposure scenario - workplace	Exposure route	Data source	Justification for read-across	Mode of extrapolation
9.3 – Raw material handling of solids	inhalation	**9.1 – AC2**	The handling of low dusty solids at manufacturing sites and at industrial downstream user sites is assumed to be similar since it is assumed that the same operational conditions and risk management measures apply.	DDP and other palladium containing substances were handled when exposure was measured during relevant activities for AC2. Exposure was measured in Pd and calculated for DDP by taking the molecular weight of DDP into account and simple read across was conducted to reflect exposure in downstream uses.
9.3 – Cleaning & maintenance	inhalation	**9.1 – AC10, 9.1 – AC2**	The exposure potential during cleaning and maintenance at industrial downstream user sites is assumed to be similar compared to manufacturing sites since it is assumed that the same operational conditions and risk management measures apply.	DDP and other palladium containing substances were handled when exposure was measured during relevant activities for AC10 and AC2. Exposure was measured in Pd and calculated for DDP by taking the molecular weight of DDP into account and simple read-across was conducted from tasks grouped under AC10 during manufacture. Local exhaust ventilation (LEV) cannot be assumed during cleaning (AC2) in general, the standard efficiency of such LEV of 78 % was used to eliminate the impact of LEV on the 90th percentile value (RWC) of AC2 (RWC/(1-0.78)).

9.0.1.3 Modelled exposure

When neither measured data nor analogous data were available occupational exposure was assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool (http://www.ebrc.de/mease.html) was used. All parameters needed to run the tool are provided in the ESs below.

As can be seen in Table 4 above, all supportive personal full-shift inhalation monitoring data are below or in the range of the values as used for exposure assessment of relevant workplaces with MEASE (without consideration of reduced exposure duration in MEASE assessments) in the exposure scenarios below. It has to be noted that operational conditions during supportive measurements for AC3 were different at different data submitters and the maximum value of 13.1 µg/m³ was taken from a company not having a local exhaust ventilation in place during the measurement. This fact and the measurements for AC4 also support the conservativeness of the exposure assessment based on the MEASE tool.

9.0.1.4 Scope and type of exposure assessment

In consideration of the classification of DDP and available DNELs, the scope and type of exposure assessment is summarised as follows:

Table 7: Scope and type of exposure assessment for DDP

Route	Type of effect	Type of risk characterisation	Hazard conclusion
Inhalation	systemic effect / long-term	quantitative	DNEL = 42 µg/m³
	systemic effect / acute	To be amended…	To be amended…
	local effect / long-term	not required	no hazard identified
	local effect / acute	To be amended…	To be amended…
Dermal	systemic effect / long-term	quantitative	DNEL = 0.0119 mg/kg bw/d
	systemic effect / acute	not required	no hazard identified
	local effect / long-term	not required	no hazard identified
	local effect / acute	not required	no hazard identified
Eyes	local effect	qualitative	low hazard

Kommentar [EBRC6]: To be confirmed. DNEL to be specified.

Kommentar [EBRC7]: Still in consideration of 100 % dermal absorption. DNEL to be specified.

9.0.2 Methodology – environmental exposure

To be included

9.0.3 Methodology – indirect exposure via the environment

To be included

Table 8: Overview on exposure scenarios and coverage of substance life cycle

ES #	Exposure scenario title	Volume (tonnes)	Identified uses				Resulting life cycle stage		Manufacture (M)/Formulation/ Identified Use (IU)/Service Life (SL) number in IUCLID/CSR	Sector of use category (SU)	Chemical product category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Manufacture	Formulation	End use	Consumer use	Service life (for articles)	Waste stage						
9.1	Manufacture of diamminedichloropalladium		X							3		1, 2, 3, 4, 5, 8a, 8b, 9, 21, 26		
9.2	Industrial use of diamminedichloropalladium as intermediate in the manufacture of other substances			X	X					3, 8, 9, 10, 15, 24	19, 20, 21	1, 3, 4, 8a, 8b, 9, 15, 26		
9.3	Industrial use of diamminedichloropalladium for electroplating of massive objects			X	X					3, 15, 16	14, 19	4, 5, 8a, 8b, 9, 13, 21, 24, 26	2, 7	

9.1 Manufacture of diamminedichloropalladium

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Manufacture of diamminedichloropalladium (DDP)			
Systematic title based on use descriptor	appropriate PROCs and ERCs are given in Section 2 below			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of occupational exposure in this scenario is based on the following assessment methods: (i) measured data, (ii) analogous data and/or (iii) modelled data. For each reported occupational exposure estimate it is reported which method was used in Section 3 of this exposure scenario. A detailed description of the methodology can be found in Section 9.0.1 of the exposure scenario addendum of the chemical safety report.			
2. Operational conditions and risk management measures				
Description of activity class (AC) and AC number	**Involved tasks**	**Involved PROCs**	**ERC**	**REACH description**
Manual handling of dusty materials at ambient temperature (AC2)	Transferring, solution/suspension preparation, weighing, sampling, furnace loading/unloading, emptying of filter bags	4, 8b, 9, 26		
Handling of non-/very low dusty materials at ambient temperature (AC3)	Non-abrasive tasks: e.g. transferring, mixing/blending, weighing, sampling, separation, filtration, furnace loading/unloading, solution/suspension preparation	4, 21		
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	Transferring, drying, filtration, mixing/blending, sampling, separation	4, 5, 8b, 9		
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	Supervision, control walks, maintenance (routine work)	1, 2, 3		
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)*	Supervision, control walks, maintenance (routine work)	1		
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)	Supervision, control walks, maintenance (routine work)	1, 2, 3		
Non-routine work (AC10)	Irregular cleaning, maintenance, repairing, sampling, tests/improvement experiments	8a, 26		
*It is noted that DDP has a decomposition temperature of 323°C. It is therefore chemically transformed into another substance at higher temperatures during this process step. However, exposure to DDP is assessed for this process step for pre-cautionary reasons.				

2.1 Control of workers exposure

Product characteristics

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Further information can be found in the glossary of the MEASE tool (www.ebrc.de/mease.html).

Description of activity class (AC) and AC number	Use in preparation	Content in preparation	Physical form	Emission potential
Manual handling of dusty materials at ambient temperature (AC2)	not restricted		solid	low
Handling of non-/very low dusty materials at ambient temperature (AC3)	not restricted		solid	very low
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	not restricted		aqueous solution	very low
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	not restricted		aqueous solution	very low
			solid	low
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)	not restricted		solid	high (temperature based)*
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)	not restricted		solid	low
Non-routine work (AC10)	not restricted		wet splashes, dried splashes or solid residuals dust in filter bags	very low (splashes) low (dusty residuals) high (dust in filter bags)

*It is noted that DDP has a decomposition temperature of 323°C. It is therefore chemically transformed into another substance at higher temperatures during this process step. However, exposure to DDP is assessed for this process step for pre-cautionary reasons.

Amounts used

The actual tonnage handled per shift is not considered influencing the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROCs and technical conditions) is the main determinant of the process-intrinsic emission potential.

Kommentar [EBRC8]: To be supported by additional dustiness tests.

Frequency and duration of use/exposure	
Description of activity class (AC) and AC number	**Duration of exposure (per shift/day)**
Manual handling of dusty materials at ambient temperature (AC2)	<240 minutes
Handling of non-/very low dusty materials at ambient temperature (AC3)	<240 minutes
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	<240 minutes
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	not restricted (480 minutes)
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)	not restricted (480 minutes)
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)	<240 minutes
Non-routine work (AC10)	<240 minutes (general activities) <15 minutes (emptying of filter bags)
Human factors not influenced by risk management	
The shift breathing volume during all process steps is assumed to be 10 m^3/shift (8 hours).	

Other given operational conditions affecting workers exposure				
Description of activity class (AC) and AC number	**Process temperature**	**Room volume**	**Indoor or outdoor use**	**Process pressure**
Manual handling of dusty materials at ambient temperature (AC2)	ambient	Operational conditions such as room volume and process pressure are not considered relevant for occupational exposure assessment of the conducted processes.		
Handling of non-/very low dusty materials at ambient temperature (AC3)	ambient			
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	up to 50℃			
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	up to 130℃			
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)	elevated (up to 700℃)			
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC 9)	ambient			
Non-routine work (AC10)	ambient			

Technical conditions and measures at process level (source) to prevent release		
Description of activity class (AC) and AC number	**Level of containment**	**Level of segregation**
Manual handling of dusty materials at ambient temperature (AC2)	not required	not required
Handling of non-/very low dusty materials at ambient temperature (AC3)	partly enclosed process	not required
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	not required	not required
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	fully enclosed process	not required
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)	fully enclosed process	not required
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)	fully enclosed process	not required
Non-routine work (AC10)	not required	not required

Technical conditions and measures to control dispersion from source towards the worker				
Description of activity class (AC) and AC number	**Level of separation**	**Localised controls (LC)**	**Efficiency of LC (according to MEASE)**	**Further information**
Manual handling of dusty materials at ambient temperature (AC2)	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation or rim ventilation as relevant for the scale of operation standard efficacy	78 %	Immediate removal of splashes/overspill is required to avoid drying of damp powders or splashes and potential resulting formation of dusty materials. Please note that measures to prevent formation of explosive gas mixtures have to be taken into account (e.g. wet chemical reduction under nitrogen atmosphere).
Handling of non-/very low dusty materials at ambient temperature (AC3)		generic local exhaust ventilation	78 %	
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)		not implemented	na	
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)		not implemented	na	
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)		not implemented	na	
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)		generic local exhaust ventilation	78 %	
Non-routine work (AC10)		not implemented	na	
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good occupational hygiene practices (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. Unless otherwise stated below, wear standard working clothes and shoes. Do not wear contaminated clothing at home. Do not blow dust (e.g. from dried splashes) off with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.				

Conditions and measures related to personal protection, hygiene and health evaluation				
Description of activity class (AC) and AC number	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
Manual handling of dusty materials at ambient temperature (AC2)	FFP2 half mask	APF = 10	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	Due to the eye irritating properties of DDP, avoid direct eye contact with the substance, also via contaminated hands. Suitable eye protection equipment (e.g. safety goggles or visors) must be worn, unless contact with the eye can be excluded by the emission potential of DDP resulting from the nature of the process, applied exposure prevention measures and physical appearance of DDP in the specific type of application (e.g. protecting from splashes by containment of emission source). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
Handling of non-/very low dusty materials at ambient temperature (AC3)	not required	na		
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	not required	na	not required	
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	not required	na	not required	
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)	not required	na	not required	
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)	not required	na	not required	
Non-routine work (AC10)	not required for cleaning of very low dusty residuals (e.g wet splashes), FFP3 full mask required for dusty residuals, including dried splashes and dust in filter bags	na APF = 40	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	

The use of personal protective equipment should always be seen as a last resort after operational conditions and further risk management measures have been improved.
If RPE as defined above is required, this shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.
If gloves are required, it is noted that the workers should receive a specific activity training (e.g. procedure for less removal and disposal) for the associated tasks according to ECETOC TRA, version 3 (2012).

2.2 Control of environmental exposure
Product characteristics
Amounts used
Frequency and duration of use
Monitored Emissions
Annual measured tonnage emitted to air/water
Environment factors not influenced by risk management
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Conditions and measures related to municipal sewage treatment plant
Conditions and measures related to external treatment of waste for disposal
Conditions and measures related to external recovery of waste

3. Exposure estimation and reference to its source

Occupational exposure

The risk characterisation ratio (RCR) is the quotient of the exposure estimates and the DNELs (derived no-effect levels) and the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use. For inhalation exposure, the RCR is based on a DNEL (long-term, systemic effects) for DDP of 42 µg/m³. For dermal exposure, the RCR is based on a DNEL (long-term, systemic effects) for DDP of 0.83 mg/day.

Description of activity class (AC) and AC number	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Manual handling of dusty materials at ambient temperature (AC2)	measured data	14.6 µg/m³ (0.35)	MEASE (PROC 26, NDM)*	0.297 mg/d (0.36)
Handling of non-/very low dusty materials at ambient temperature (AC3)	MEASE (PROC 4)	7 µg/m³ (0.17)	MEASE (PROC 21, NDM)*	0.594 mg/d (0.72)
Manipulation of solutions/suspensions in open or semi-closed processes (wet-chemistry) (AC4)	MEASE (PROC 5)	30 µg/m³ (0.71)	MEASE (PROC 5, NNM)*	0.144 mg/d (0.17)
Wet chemistry in closed systems/vessels (including chemical reactions, mixing) (AC5)	analogous data	3.9 µg/m³ (0.09)	MEASE (PROC 2, NNN)*	0.24 mg/d (0.29)
Closed processes at elevated temperatures (including sintering, calcination, conversion, smelting, casting) (AC7)**	MEASE (PROC 1)	10 µg/m³ (0.24)	MEASE (PROC 1, NNN)*	0.12 mg/d (0.14)
Operations in closed processes at ambient temperature (including mechanical manipulation of handled substance) (AC9)	MEASE (PROC 3)	13 µg/m³ (0.31)	MEASE (PROC 2, NNN)*	0.144 mg/d (0.17)
Non-routine work (AC10)	measured data analogous data MEASE (PROC 26)	30 µg/m³ (0.72) 16.6 µg/m³ (0.4) 25 µg/m³ (0.6)	MEASE (PROC 8a, NDM* MEASE (PROC 26, NDM)* MEASE (PROC 26, NDM)*	0.072 mg/d (0.087) 0.297 mg/d (0.36) 0.05 mg/d (0.06)

*The letters in brackets have to be interpreted as follows:
1st letter reflects the "pattern of use": W=wide dispersive use, N=non-dispersive use, I=inclusion into matrix, C=closed system without breaches
2nd letter reflects the "pattern of exposure control": D=direct handling, N=non-direct handling
3rd letter reflects the "contact level": E=extensive, M=intermittent, I=incidental, N=none.

**It is noted that DDP has a decomposition temperature of 323°C. It is therefore chemically transforme d into another substance at higher temperatures during this process step. However, exposure to DDP is assessed for this process step for pre-cautionary reasons.

Environmental emissions

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The downstream user (DU) works inside the boundaries set by the ES if the proposed operational conditions (OCs) and risk management measures (RMMs) as described in the exposure scenario (ES) are met (including substance/product characteristics). If the DU's conditions slightly deviate (slight deviations are specified below) from the conditions as described in the ES, the DU may either inform the supplier of the substance to reflect the DU's conditions in a modified exposure scenario or has to ensure his slightly modified OCs and implemented RMMs are adequate. Depending on the basis for the exposure assessment (EA) conducted for the ES, this needs to be done in different ways:

Use of measured data as basis for assessment: If the EA in the ES is based on measured data, the same approach can be used at DU level. Please note that 6 measurements per workplace are required for an EA as a minimum. Depending on the variability of the data sets (expressed as the geometric standard deviation) and the level of the resulting risk characterisation ratio (RCR), additional measurements may be required. Only measurements of personal exposure to the inhalable fraction (according to EN 481) of airborne dust should be used. The exposure data shall either be applicable to the length of a specific task to be assessed or to a full-shift (i.e. sampled over a duration of at least 120 min) if the task to be assessed is conducted for a significant portion of the work shift. From the exposure data set the 90th percentile is to be used as a reasonable worst case (RWC) estimate for comparison with the relevant DNEL. RPE may be taken into account by applying the assigned protection factor applicable to the equipment used as given in EN 529:2005.

It is noted that deviations from the ES are only allowed for the efficacy of installed RMMs, exposure duration and used personal protective equipment.

Use of exposure models: If the EA in the ES is based on modelled data, the same model can be used to justify specific slight deviations from the conditions as described. All parameters needed to run the exposure estimation tool MEASE (available on www.ebrc.de/mease.html) can be found in the ES. It is noted that the installation of the described RMMs is mandatory and that exclusively the modification of the used PPE is allowed as deviation. The only parameters which may therefore be modified in the MEASE-calculation are consequently exposure duration, efficacy of the installed RMMs and PPE.

Generic to both assessment bases, safe use is demonstrated, if the calculated exposure levels are below the relevant DNELs (RCR <1). Since systemic DNELs for two different routes of exposure are available, it has to be noted that the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use. It is noted also that smaller RCRs provide additional margin of safety and should therefore be envisaged.

$DNEL_{inhalation}$: 42 µg/m³ (as diamminedichloropalladium)

$DNEL_{dermal}$: 0.83 mg/day (as diamminedichloropalladium)

Environmental emissions

9.2 Industrial use of diamminedichloropalladium as intermediate in the manufacture of other substances

Exposure Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	Industrial use of diamminedichloropalladium (DDP) as intermediate in the manufacture of other substances
Systematic title based on use descriptor	SU3 (Industrial uses), SU8, SU9, SU10, SU15, SU24 PC19, PC20, PC21 (appropriate PROCs and ERCs are given in Section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of occupational exposure in this scenario is based on the following assessment methods: (i) measured data, (ii) analogous data and/or (iii) modelled data. For each reported occupational exposure estimate it is reported which method was used in Section 3 of this exposure scenario. A detailed description of the methodology can be found in Section 9.0.1 of the exposure scenario addendum of the chemical safety report.

2. Operational conditions and risk management measures

Workplace	Involved tasks	Involved PROCs	ERC	REACH description
Raw material handling	loading, unloading, weighing, sampling	8b, 9, 15, 26		
Wet chemical reaction*	mixing, formulation, reduction, reaction	3, 4		
Calcination*	calcination in closed furnace	1		
Cleaning & maintenance	manual cleaning, repair and maintenance operations, removal of residuals from e.g. filters/overspill or as waste	8a, 26		

*It is noted that DDP is used as an intermediate and has been chemically transformed into another substance during these process steps. Further process steps and uses are therefore out of the scope of this exposure scenario.

2.1 Control of workers exposure

Product characteristics

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Further information can be found in the glossary of the MEASE tool (www.ebrc.de/mease.html).

Workplace	Use in preparation	Content in preparation	Physical form	Emission potential
Raw material handling	not restricted		solid	low
Wet chemical reaction	not restricted		aqueous solution	very low
Calcination	not restricted		solid	high (temperature based)*
Cleaning & maintenance	not restricted		wet splashes, dried splashes or solid residuals dust in filter bags	very low (splashes) low (dusty residuals) high (dust in filter bags)

*It is noted that DDP has a decomposition temperature of 323°C. It is therefore chemically transformed into another substance at higher temperatures during this process step.

Amounts used

The actual tonnage handled per shift is not considered influencing the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROCs and technical conditions) is the main determinant of the process-intrinsic emission potential.

Kommentar [EBRC9]: To be supported by additional dustiness tests.

Frequency and duration of use/exposure	
Workplace	**Duration of exposure (per shift/day)**
Raw material handling	<240 minutes
Wet chemical reaction	<240 minutes
Calcination	not restricted (480 minutes)
Cleaning & maintenance	<240 minutes (general activities) <15 minutes (emptying of filter bags)

Human factors not influenced by risk management
The shift breathing volume during all process steps is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure				
Workplace	**Process temperature**	**Room volume**	**Indoor or outdoor use**	**Process pressure**
Raw material handling	ambient	Operational conditions such as room volume and process pressure are not considered relevant for occupational exposure assessment of the conducted processes.		
Wet chemical reaction	ambient, up to 50°C			
Calcination	elevated (up to 700°C)			
Cleaning & maintenance	ambient			

Technical conditions and measures at process level (source) to prevent release		
Workplace	**Level of containment**	**Level of segregation**
Raw material handling	not required	not required
Wet chemical reaction	closed reactor	not required
Calcination	fully enclosed furnace	not required
Cleaning & maintenance	not required	not required

Technical conditions and measures to control dispersion from source towards the worker				
Workplace	**Level of separation**	**Localised controls (LC)**	**Efficiency of LC (according to MEASE)**	**Further information**
Raw material handling	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation or rim ventilation as relevant for the scale of operation standard efficacy	78 %	Immediate removal of splashes/overspill is required to avoid drying of damp powders or splashes and potential resulting formation of dusty materials. Please note that measures to prevent formation of explosive gas mixtures have to be taken into account (e.g. wet chemical reduction under nitrogen atmosphere).
Wet chemical reaction		not implemented	na	
Calcination		not implemented	na	
Cleaning & maintenance		not implemented	na	

Organisational measures to prevent /limit releases, dispersion and exposure
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good occupational hygiene practices (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. Unless otherwise stated below, wear standard working clothes and shoes. Do not wear contaminated clothing at home. Do not blow dust (e.g. from dried splashes) off with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.

Conditions and measures related to personal protection, hygiene and health evaluation				
Workplace	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
Raw material handling	FFP2 half mask	APF = 10	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	Due to the eye irritating properties of DDP, avoid direct eye contact with the substance, also via contaminated hands. Suitable eye protection equipment (e.g. safety goggles or visors) must be worn, unless contact with the eye can be excluded by the emission potential of DDP resulting from the nature of the process, applied exposure prevention measures and physical appearance of DDP in the specific type of application (e.g. protecting from splashes by containment of emission source). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
Wet chemical reaction	not required	na	not required	
Calcination	not required	na	not required	
Cleaning & maintenance	not required for cleaning of very low dusty residuals (e.g wet splashes), FFP3 full mask required for dusty residuals, including dried splashes and dust in filter bags	na APF = 40	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	

The use of personal protective equipment should always be seen as a last resort after operational conditions and further risk management measures have been improved.
If RPE as defined above is required, this shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.
If gloves are required, it is noted that the workers should receive a specific activity training (e.g. procedure for less removal and disposal) for the associated tasks according to ECETOC TRA, version 3 (2012).

2.2 Control of environmental exposure

Product characteristics

Amounts used

Frequency and duration of use

Monitored Emissions

Annual measured tonnage emitted to air/water

Environment factors not influenced by risk management

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Conditions and measures related to municipal sewage treatment plant

Conditions and measures related to external treatment of waste for disposal

Conditions and measures related to external recovery of waste

3. Exposure estimation and reference to its source

Occupational exposure

The risk characterisation ratio (RCR) is the quotient of the exposure estimates and the DNELs (derived no-effect levels) and the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use. For inhalation exposure, the RCR is based on a DNEL (long-term, systemic effects) for DDP of 42 µg/m³. For dermal exposure, the RCR is based on a DNEL (long-term, systemic effects) for DDP of 0.83 mg/day.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Raw material handling	analogous data	14.6 µg/m³ (0.35)	MEASE (PROC 26, NDM)*	0.297 mg/d (0.36)
Wet chemical reaction**	MEASE (PROC 4)	30 µg/m³ (0.71)	MEASE (PROC 4, NNM)*	0.144 mg/d (0.17)
Calcination*	MEASE (PROC 1)	10 µg/m³ (0.24)	MEASE (PROC 1, NNN)*	0.12 mg/d (0.14)
Cleaning & maintenance	analogous data analogous data MEASE (PROC 26)	30 µg/m³ (0.72) 16.6 µg/m³ (0.4) 25 µg/m³ (0.6)	MEASE (PROC 8a, NDM* MEASE (PROC 26, NDM)* MEASE (PROC 26, NDM)*	0.072 mg/d (0.087) 0.297 mg/d (0.36) 0.05 mg/d (0.06)

*The letters in brackets have to be interpreted as follows:
1st letter reflects the "pattern of use": W=wide dispersive use, N=non-dispersive use, I=inclusion into matrix, C=closed system without breaches
2nd letter reflects the "pattern of exposure control": D=direct handling, N=non-direct handling
3rd letter reflects the "contact level": E=extensive, M=intermittent, I=incidental, N=none.

**It is noted that DDP is used as an intermediate and has been chemically transformed into another substance during these process steps. Further process steps and uses are therefore out of the scope of this exposure scenario.

Environmental emissions

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The downstream user (DU) works inside the boundaries set by the ES if the proposed operational conditions (OCs) and risk management measures (RMMs) as described in the exposure scenario (ES) are met (including substance/product characteristics). If the DU's conditions slightly deviate (slight deviations are specified below) from the conditions as described in the ES, the DU may either inform the supplier of the substance to reflect the DU's conditions in a modified exposure scenario or has to ensure his slightly modified OCs and implemented RMMs are adequate. Depending on the basis for the exposure assessment (EA) conducted for the ES, this needs to be done in different ways:

Use of measured data as basis for assessment: If the EA in the ES is based on measured data, the same approach can be used at DU level. Please note that 6 measurements per workplace are required for an EA as a minimum. Depending on the variability of the data sets (expressed as the geometric standard deviation) and the level of the resulting risk characterisation ratio (RCR), additional measurements may be required. Only measurements of personal exposure to the inhalable fraction (according to EN 481) of airborne dust should be used. The exposure data shall either be applicable to the length of a specific task to be assessed or to a full-shift (i.e. sampled over a duration of at least 120 min) if the task to be assessed is conducted for a significant portion of the work shift. From the exposure data set the 90th percentile is to be used as a reasonable worst case (RWC) estimate for comparison with the relevant DNEL. RPE may be taken into account by applying the assigned protection factor applicable to the equipment used as given in EN 529:2005.

It is noted that deviations from the ES are only allowed for the efficacy of installed RMMs, exposure duration and used personal protective equipment.

Use of exposure models: If the EA in the ES is based on modelled data, the same model can be used to justify specific slight deviations from the conditions as described. All parameters needed to run the exposure estimation tool MEASE (available on www.ebrc.de/mease.html) can be found in the ES. It is noted that the installation of the described RMMs is mandatory and that exclusively the modification of the used PPE is allowed as deviation. The only parameters which may therefore be modified in the MEASE-calculation are consequently exposure duration, efficacy of the installed RMMs and PPE.

Generic to both assessment bases, safe use is demonstrated, if the calculated exposure levels are below the relevant DNELs (RCR <1). Since systemic DNELs for two different routes of exposure are available, it has to be noted that the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use. It is noted also that smaller RCRs provide additional margin of safety and should therefore be envisaged.

$DNEL_{inhalation}$: 42 µg/m³ (as diamminedichloropalladium)

$DNEL_{dermal}$: 0.83 mg/day (as diamminedichloropalladium)

Environmental emissions

9.3 Industrial use of diamminedichloropalladium for electroplating of massive objects

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Industrial use of diamminedichloropalladium (DDP) for electroplating of massive objects			
Systematic title based on use descriptor	SU3 (Industrial uses), SU15, SU16 PC14, PC19 AC2, AC7 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of occupational exposure in this scenario is based on the following assessment methods: (i) measured data, (ii) analogous data and/or (iii) modelled data. For each reported occupational exposure estimate it is reported which method was used in Section 3 of this exposure scenario. A detailed description of the methodology can be found in Section 9.0.1 of the exposure scenario addendum of the chemical safety report.			
2. Operational conditions and risk management measures				
Workplace	**Involved tasks**	**Involved PROCs**	**ERC**	**REACH description**
Raw material handling of solids	loading/unloading, weighing, mixing	8b, 9, 26		
Raw material handling of aqueous solutions	filling, mixing	8b, 9		
Wet processes	dissolution, formulation, electroplating, anodising or chemical processing, drying, mixing, transfer	4, 5, 8b, 9		
Plating/Application in conveyor system	plating in open vessels, roller application or brushing (conveyor system)	13		
Mechanical processing of plated objects*	mechanical processing, abrasive processes	24		
Handling of plated objects*	non-abrasive handling, packaging	21		
Cleaning & maintenance	manual cleaning, repair and maintenance operations, removal of residuals from e.g. filters/overspill or as waste	8a, 26		
*It is noted that DDP is chemically transformed to palladium metal during plating. Exposure to palladium metal is assessed for these process steps for pre-cautionary reasons.				

2.1 Control of workers exposure

Product characteristics

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Further information can be found in the glossary of the MEASE tool (www.ebrc.de/mease.html).

Workplace	Use in preparation	Content in preparation	Physical form	Emission potential
Raw material handling of solids	not restricted		solid	low
Raw material handling of aqueous solutions	not restricted		aqueous solution	very low
Wet processes	not restricted		aqueous solution	very low
Plating/Application in conveyor system	not restricted		aqueous solution	very low
Mechanical processing of plated objects	DDP is no longer present on the surface of treated objects. Exposure assessment conducted for the sake of completeness, assuming 100 % palladium metal on the surface. Risk assessment not conducted as palladium metal is not classified for human health.		massive	high
Handling of plated objects	DDP is no longer present on the surface of treated objects. Exposure assessment conducted for the sake of completeness, assuming 100 % palladium metal on the surface. Risk assessment not conducted as palladium metal is not classified for human health.		massive	very low (only swarf-formation possible, no dust-formation)
Cleaning & maintenance	not restricted		wet splashes, dried splashes or solid residuals dust in filter bags	very low (splashes) low (dusty residuals) high (dust in filter bags)

Kommentar [EBRC10]: To be supported by additional dustiness tests.

Amounts used

The actual tonnage handled per shift is not considered influencing the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROCs and technical conditions) is the main determinant of the process-intrinsic emission potential.

Frequency and duration of use/exposure

Workplace	Duration of exposure (per shift/day)
Raw material handling of solids	<240 minutes
Raw material handling of aqueous solutions	not restricted (480 minutes)
Wet processes	<240 minutes
Plating/Application in conveyor system	not restricted (480 minutes)
Mechanical processing of plated objects	not restricted (480 minutes)
Handling of plated objects	not restricted (480 minutes)
Cleaning & maintenance	<240 minutes (general activities) <15 minutes (emptying of filter bags)

Human factors not influenced by risk management

The shift breathing volume during all process steps is assumed to be 10 m^3/shift (8 hours).

Other given operational conditions affecting workers exposure				
Workplace	**Process temperature**	**Room volume**	**Indoor or outdoor use**	**Process pressure**
Raw material handling of solids	ambient	Operational conditions such as room volume and process pressure are not considered relevant for occupational exposure assessment of the conducted processes.		
Raw material handling of aqueous solutions	ambient			
Wet processes	ambient			
Plating/Application in conveyor system	ambient			
Mechanical processing of plated objects	ambient			
Handling of plated objects	ambient			
Cleaning & maintenance	ambient			

Technical conditions and measures at process level (source) to prevent release		
Workplace	**Level of containment**	**Level of segregation**
Raw material handling of solids	not required	not required
Raw material handling of aqueous solutions	not required	not required
Wet processes	closed reactor	not required
Plating/Application in conveyor system	not required	not required
Mechanical processing of plated objects	not required	not required
Handling of plated objects	not required	not required
Cleaning & maintenance	not required	not required

Technical conditions and measures to control dispersion from source towards the worker				
Workplace	**Level of separation**	**Localised controls (LC)**	**Efficiency of LC (according to MEASE)**	**Further information**
Raw material handling of solids	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation or rim ventilation as relevant for the scale of operation standard efficacy	78 %	Immediate removal of splashes/overspill is required to avoid drying of damp powders or splashes and potential resulting formation of dusty materials. Please note that measures to prevent formation of explosive gas mixtures have to be taken into account (e.g. wet chemical reduction under nitrogen atmosphere).
Raw material handling of aqueous solutions		not implemented	na	
Wet processes		not implemented	na	
Plating/Application in conveyor system		not implemented	na	
Mechanical processing of plated objects		not implemented	na	
Handling of plated objects		not implemented	na	
Cleaning & maintenance		not implemented	na	

Organisational measures to prevent /limit releases, dispersion and exposure
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good occupational hygiene practices (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. Unless otherwise stated below, wear standard working clothes and shoes. Do not wear contaminated clothing at home. Do not blow dust (e.g. from dried splashes) off with compressed air. Regular training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.

Conditions and measures related to personal protection, hygiene and health evaluation				
Workplace	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
Raw material handling of solids	FFP2 half mask	APF = 10	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	Due to the eye irritating properties of DDP, avoid direct eye contact with the substance, also via contaminated hands. Suitable eye protection equipment (e.g. safety goggles or visors) must be worn, unless contact with the eye can be excluded by the emission potential of DDP resulting from the nature of the process, applied exposure prevention measures and physical appearance of DDP in the specific type of application (e.g. protecting from splashes by containment of emission source). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
Raw material handling of aqueous solutions	not required	na		
Wet processes	not required	na	not required	
Plating/Application in conveyor system	not required	na	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	
Mechanical processing of plated objects	not required	na	not required	
Handling of plated objects	not required	na	not required	
Cleaning & maintenance	not required for cleaning of very low dusty residuals (e.g wet splashes), FFP3 full mask required for dusty residuals, including dried splashes and dust in filter bags	na APF = 40	protective gloves according to EN 374; gloves have to be changed according to manufacturer's information or when damaged, whatever is the earlier a default efficiency of 95 % as suggested by ECETOC TRA version 3 (2012) was taken into account in the exposure assessment	

The use of personal protective equipment should always be seen as a last resort after operational conditions and further risk management measures have been improved.
If RPE as defined above is required, this shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.
If gloves are required, it is noted that the workers should receive a specific activity training (e.g. procedure for less removal and disposal) for the associated tasks according to ECETOC TRA, version 3 (2012).

2.2 Control of environmental exposure

Product characteristics

Amounts used

Frequency and duration of use

Monitored Emissions

Annual measured tonnage emitted to air/water

Environment factors not influenced by risk management

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Conditions and measures related to municipal sewage treatment plant

Conditions and measures related to external treatment of waste for disposal

Conditions and measures related to external recovery of waste

3. Exposure estimation and reference to its source

Occupational exposure

The risk characterisation ratio (RCR) is the quotient of the exposure estimates and the DNELs (derived no-effect levels) and the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use. For inhalation exposure, the RCR is based on a DNEL (long-term, systemic effects) for DDP of 42 µg/m³. For dermal exposure, the RCR is based on a DNEL (long-term, systemic effects) for DDP of 0.83 mg/day.

Workplace	Method used for inhalation exposure assessment (refer to introduction)	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Raw material handling of solids	analogous data	14.6 µg/m³ (0.35)	MEASE (PROC 26, NDM)*	0.297 mg/d (0.36)
Raw material handling of aqueous solutions	MEASE (PROC 8b)	10 µg/m³ (0.24)	MEASE (PROC 8b, NDM)*	0.12 mg/d (0.14)
Wet processes	MEASE (PROC 5)	30 µg/m³ (0.71)	MEASE (PROC 5, NNM)*	0.144 mg/d (0.17)
Plating/Application in conveyor system	MEASE (PROC 13)	10 µg/m³ (0.24)	MEASE (PROC 13, NDM)*	0.12 mg/d (0.14)
Mechanical processing of plated objects**	MEASE (PROC 24)	2 mg/m³	MEASE (PROC 24, NDM)*	9.9 mg/d
Handling of plated objects**	MEASE (PROC 21)	50 µg/m³	MEASE (PROC 21, NDM)*	9.9 mg/d
Cleaning & maintenance	analogous data analogous data MEASE (PROC 26)	30 µg/m³ (0.72) 16.6 µg/m³ (0.4) 25 µg/m³ (0.6)	MEASE (PROC 8a, NDM* MEASE (PROC 26, NDM)* MEASE (PROC 26, NDM)*	0.072 mg/d (0.087) 0.297 mg/d (0.36) 0.05 mg/d (0.06)

*The letters in brackets have to be interpreted as follows:
1st letter reflects the "pattern of use": W=wide dispersive use, N=non-dispersive use, I=inclusion into matrix, C=closed system without breaches
2nd letter reflects the "pattern of exposure control": D=direct handling, N=non-direct handling
3rd letter reflects the "contact level": E=extensive, M=intermittent, I=incidental, N=none.

**It is noted that DDP is chemically transformed to palladium metal during plating. An exposure assessment is conducted for the sake of completeness, assuming 100 % palladium metal on the surface. A risk assessment is not conducted as palladium metal is not classified for human health.

Environmental emissions

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Occupational exposure

The downstream user (DU) works inside the boundaries set by the ES if the proposed operational conditions (OCs) and risk management measures (RMMs) as described in the exposure scenario (ES) are met (including substance/product characteristics). If the DU's conditions slightly deviate (slight deviations are specified below) from the conditions as described in the ES, the DU may either inform the supplier of the substance to reflect the DU's conditions in a modified exposure scenario or has to ensure his slightly modified OCs and implemented RMMs are adequate. Depending on the basis for the exposure assessment (EA) conducted for the ES, this needs to be done in different ways:

Use of measured data as basis for assessment: If the EA in the ES is based on measured data, the same approach can be used at DU level. Please note that 6 measurements per workplace are required for an EA as a minimum. Depending on the variability of the data sets (expressed as the geometric standard deviation) and the level of the resulting risk characterisation ratio (RCR), additional measurements may be required. Only measurements of personal exposure to the inhalable fraction (according to EN 481) of airborne dust should be used. The exposure data shall either be applicable to the length of a specific task to be assessed or to a full-shift (i.e. sampled over a duration of at least 120 min) if the task to be assessed is conducted for a significant portion of the work shift. From the exposure data set the 90th percentile is to be used as a reasonable worst case (RWC) estimate for comparison with the relevant DNEL. RPE may be taken into account by applying the assigned protection factor applicable to the equipment used as given in EN 529:2005.

It is noted that deviations from the ES are only allowed for the efficacy of installed RMMs, exposure duration and used personal protective equipment.

Use of exposure models: If the EA in the ES is based on modelled data, the same model can be used to justify specific slight deviations from the conditions as described. All parameters needed to run the exposure estimation tool MEASE (available on www.ebrc.de/mease.html) can be found in the ES. It is noted that the installation of the described RMMs is mandatory and that exclusively the modification of the used PPE is allowed as deviation. The only parameters which may therefore be modified in the MEASE-calculation are consequently exposure duration, efficacy of the installed RMMs and PPE.

Generic to both assessment bases, safe use is demonstrated, if the calculated exposure levels are below the relevant DNELs (RCR <1). Since systemic DNELs for two different routes of exposure are available, it has to be noted that the overall RCR (i.e. $RCR_{inhalation,\ systemic\ effects}$ + $RCR_{dermal,\ systemic\ effects}$) has to be below 1 to demonstrate safe use. It is noted also that smaller RCRs provide additional margin of safety and should therefore be envisaged.

$DNEL_{inhalation}$: 42 µg/m³ (as diamminedichloropalladium)

$DNEL_{dermal}$: 0.83 mg/day (as diamminedichloropalladium)

Environmental emissions