Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

dibutyl phthalate use: Industrial use in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors.

ECHA/RAC/SEAC: AFA-O-0000006676-63-02/F

Consolidated version

Date: 10/07/2018

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Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name:	**dibutyl phthalate**
EC No.:	**201-557-4**
CAS No.:	**84-74-2**

for the following use:

Industrial use in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors.

Intrinsic property referred to in Annex XIV:

Article 57 (c) of the REACH Regulation

Applicant:

AVX Limited

Reference number:

11-2120754104-63-0001

Rapporteur, appointed by the RAC:	**Urs SCHLÜTER**
Co-rapporteur, appointed by the RAC:	**Marian RUCKI**
Rapporteur, appointed by the SEAC:	**Andreas LÜDEKE**
Co-rapporteur, appointed by the SEAC:	**Martien JANSSEN**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 11/12/2017 **AVX Limited** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **29/01/2018** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **14/02/2018**. Interested parties were invited to submit comments and contributions by **11/04/2018**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

The draft opinions of RAC and SEAC take into account the responses of the applicant to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **09/07/2018**.

On **10/07/2018** the applicant informed ECHA that they did not wish to comment on the opinions. The draft opinions of RAC and SEAC were therefore considered as final on **10/07/2018**

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **8/06/2018**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **10/07/2018.**

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **14/06/2018**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **10/07/2018.**

THE OPINION OF RAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC has formulated its opinion on: the risks arising from the use applied for, the appropriateness and effectiveness of the risk management measures described, the assessment of the risks related to the alternatives as documented in the application, the information submitted by interested third parties, as well as other available information.

RAC confirmed that it was possible to determine a DNEL for the Toxic for reproduction (Article 57c) properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that there appears not to be any suitable alternatives that further reduce the risk.

RAC confirmed that the risk assessment in the application demonstrates adequate control of risks from the use applied for, provided that the risk management measures and operational conditions as described in the application are adhered to. The suggested conditions and monitoring arrangements are expected to address RAC's moderate concerns.

THE OPINION OF SEAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC has formulated its opinion on: the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application, the information submitted by interested third parties, as well as other available information.

SEAC took note of RAC's confirmation that it is possible to determine a DNEL for the Toxic for reproduction (Article 57c) properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC took note of RAC's confirmation that the risk(s) to human health from the use of the substance is demonstrated to be adequately controlled.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

The following conditions and monitoring arrangements are recommended in case the authorisation is granted:

- Additional engineering controls shall be implemented to reduce worker exposure, particularly for those activities where manual handling of DPB still occurs as described in the CSR (e.g. WCS 3, WCS 4, WCS 11). Where possible, open handling shall be replaced by closed systems.
- Exposure monitoring
    - The applicant shall establish and implement a regular (at least annual) programme of occupational exposure measurements for all activities with potential for worker exposure.
    - Monitoring programmes shall be based on relevant standard methodologies or protocols and be representative of the range of tasks undertaken in the WCSs and resulting in potential for exposure and of the total number of workers potentially exposed. Where appropriate, biomonitoring shall also be used as a complementary methodology to assess workers exposure.
    - The information gathered in the monitoring programmes shall be used by the applicant to review the appropriateness and effectiveness of the risk management measures (RMMs) and operational conditions (OCs) to limit workers' exposure to DBP. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented.
    - The results of the monitoring and of the review of the OCs and RMMs must be maintained, made available to national enforcement authorities and be included in any subsequent authorisation review report submitted.

Description of monitoring arrangements for review reports:

- Exposure modelling
    - In case that exposure modelling is still necessary for the review report, e.g. in the case that dermal exposure cannot be monitored by biomonitoring satisfyingly, the application holder shall take into account the uncertainties identified (selection of PROCs, high level of exposure reduction capacity claimed for dermal assessment).
- In the review report the improvement of operational conditions and risk management measures shall be documented.
- The applicant shall measure the actual releases of DBP to the environment (air) with a view to verifying the release factor used for the assessment of indirect exposure to human via the environment. Measurement(s) shall be based on relevant standard methodologies with detection limits allowing meaningful analysis of releases.
  The results of the measurement shall be made available to national enforcement authorities and included in any subsequent authorisation review report submitted.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received in public consultation on the broad information on use the duration of the review period for the use is recommended to be **7 (seven) years**.

JUSTIFICATIONS

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property/properties:

- ☐ Carcinogenic (Article 57(a))
- ☐ Mutagenic (Article 57(b))
- ☒ Toxic to reproduction (Article 57(c))
- ☐ Persistent, bioaccumulative and toxic (Article 57(d))
- ☐ Very persistent and very bioaccumulative (Article 57(e))
- ☐ Other properties in accordance with Article 57(f) [please specify]:

2. Is the substance a threshold substance?

- ☒ YES
- ☐ NO

Justification:

For the reproductive toxicity of DBP, RAC considers DBP to be a threshold substance and has established the reference Derived No Effect Levels (DNELs; RAC/24/2013/09 rev. 2; Helsinki, 12 April 2013).

3. Hazard assessment. Are appropriate reference values used?

Justification:

RAC established reference DNELs for the reproductive toxicity of DBP. The reference DNELs for workers are:

- Inhalation: DNEL of 0.13 mg/m³ (8h-TWA)
- Dermal: DNEL of 0.19 mg/kg/d (external values)

The reference DNELs for general population are:

- Inhalation: DNEL of 0.02 mg/m³
- Dermal: DNEL of 0.07 mg/kg/d
- Oral: DNEL of 0.007 mg/kg/d

For the purpose of their risk assessment for DBP, the applicant applied the RAC reference DNELs.

4. Exposure assessment. To what extent is the exposure from the use described?

Description:

Short description of the use

The use of dibutyl phthalate (DBP) as a process plasticiser takes place at a single manufacturing site in Coleraine, Northern Ireland, UK. The plant manufactures multilayer ceramic capacitors (MLCCs) from the Thin Tape Process (TTP) production line, and its market are primarily the automotive and aerospace sectors. The plasticiser DBP is used to provide flexibility to the cast ceramic sheet to enable rolling and unrolling numerous times, during processing.

In their CSR submitted, the applicant provided one environmental contributing scenario (ECS) and eleven worker contributing scenarios (WCSs). On RAC's request the applicant reconsidered some of the information presented, especially:

- the assignment of use descriptors (ERC/PROC) in order to achieve a better allignement with the relevant ECHA guidance (R12)[1]
- any changes in the process that were introduced since submission.

Table 1 presents the contributing scenarios as described following RAC's request. More details on the changes made are available in Annex 1.

Table 1: Contributing Scenarios presented in the Use

Scenario	ERC/PROC	Name of the Scenario
ECS 1	ERC 4	Use at industrial sites
WCS 2	PROC 8a	Transfer of DBP from IBC to binder solution
WCS 3	PROC 8a	Transfer of binder solution to ceramic slurry
WCS 4	PROC 8a	Transfer of ceramic slip to a small tank for transport and use in production
WCS 5	PROC 14	Casting operation: transfer of the ceramic slip from the closed tank on to Mylar tape via a slot die head
WCS 6	PROC 14	Printing operation
WCS 7	PROC 14	Stacking Operation
WCS 8	PROC 21	Lamination Operation
WCS 9	PROC 21	Dicing operation
WCS 10	PROC 3	Burn-out process
WCS 10a	PROC 21	Spreading of capacitors before loading in oven for burnout process
WCS 11	PROC 28	Maintenance and cleaning of machinery

The updated use description is considered by RAC to better account for steps in the process where exposure to DBP could occur and therefore allows a more realistic exposure assessment to be developed, compared to the description contained in the CSR originally submitted. The following evaluation is based on the updated information.

[1] The applicant based his assessment on modelled data and therefore the descriptors assigned and used have an impact on the modelling result.

Workers exposure

The use of DBP can be divided into two main stages:

In the first stage (material manufacturing) manual handling of DBP or mixtures including DBP during several mixing and loading activities occur:

- **WCS 2**: DBP is stored in an Intermediate Bulk Container (IBC) which is connected directly via piping to the materials' room, where the mixing takes place. At the end of the pipe is a dispensing tap located over the weighing station. An empty steel binder solution pot is placed on top of the weighing scales into which the required quantity of DBP is pumped. The solvents and binder powders are added afterwards to a final concentration of DBP of 2.6 % w/w. Charging of DBP lasts approximately 2 minutes and the operation is carried out twice per shift at most, for a total duration of 4 minutes.
- **WCS 3**): transfer of the binder solution to the ceramic slurry vessel, for mixing into the finished ceramic slip[2] (at this stage DBP makes up 1 – 5 % of the total solution). This transfer process takes less than 15 minutes. The operators make 1 – 2 ceramic slips per shift.
- **WCS 4**: transfer of the ceramic slip into the small tank for transport and use in the manufacturing process. One batch of slip fills 2.5 tanks, which takes 18 minutes. This process takes place 1 -3 times per shift.

In the second stage (TTP, finishing and burnout), mostly closed or semi-closed systems and automated processes with advanced extraction and relatively limited opportunities for direct contact and exposure occur:

- **WCS 5**: transfer of the ceramic slip, via a slot die / nozzle, onto the Mylar tape during the casting operation. This is a full shift task.
- **WCS 6**: an electrode pattern is screen printed onto the solid ceramic tape. This is a highly automated process with only monitoring activities for the operators. Each printer has its own extraction ventilation system. Loading and unloading takes approximately 1 hour per shift.
- **WCS 7**: printed sheets are cut and stacked in layers (typically 200 – 300 per pad) to form a pad. This is a highly automated process with only monitoring activities for the operators. Loading and unloading takes approximately 1 hour per shift.
- **WCS 8**: the pad is vacuum hermetically sealed and placed into a water reservoir to compress the layers into a solid block.
- **WCS 9**: the pad is cut into individual capacitors in wet process and there are no vapours associated with this process. The dicing equipment is fully enclosed with no exposure to the operator. The only manual intervention is the loading of the pads and the removal of the cut capacitors. Dicing takes place throughout the shift, but loading and unloading is usually less than 1 hour per shift.
- **WCS 10**: the parts are placed onto an alumina tile and are loaded into a closed oven and the DBP is thermally degraded.
- **WCS 10a**: This is a manual operation however as the MLCC's are easily damaged at this stage, handling is minimised. This operation is carried out in a well ventilated work area.

[2] The ceramic slip is the mixture of DBP, solvents and binder that is used in the TTP production line.

After the thermal process stage (WCS 10) no DBP remains in the product.

WCS 11: Cleaning and maintenance is carried out by the Technician group and contract cleaners. This includes cleaning of floors around machinery, removal of splashes and removal of filters and flushing through of equipment with denatured alcohol. This removes all traces of DBP prior to any maintenance activities.

On RAC's request the applicant described in detail the different cleaning and maintenance activities that are necessary in the different production areas.

Exposure estimation methodology

The applicant relies almost entirely on exposure modelling for inhalation and dermal exposure. The model used is ECETOC TRA (worker version 3), frequently used for applications for authorisation. The input parameters for the models are described in the CSR. Model outputs (printouts, result sheets), were made available on RAC's request by the applicant.

On the request of RAC the applicant submitted a monitoring report of workplace air measurements from March 2018 that was not available at the time of submission of the application. Additionally, some qualitative information was presented about biomonitoring for Toluene (handled together with DBP in mixtures).

The applicant states that in future, air monitoring and biomonitoring – so far carried out specifically for toluene in the materials manufacturing and the casting areas – is intended to be extended to include DBP.

Risk management measures (RMMs) applied

The applicant describes comprehensively (in the CSR and in the succinct summary of RMMs) which RMMs are applied for each WCS. During the application process the applicant decided to introduce process modifications in order to eliminate multiple steps in charging of DBP into the binder solution and minimise manual intervention as a means to reduce potential exposure to DBP (WCSs in the materials manufacturing area).

The RMMs applied and taken into consideration in exposure assessment include

- Containment solution for some WCS
- Enhanced ventilation / forced ventilation for all WCS:
  - 3 – 5 air exchanges per hour (ACH) in WCS 2 – WCS 4 materials manufacturing area
  - 5 – 10 ACH in WCS 5 – WCS 10 casting area
- Local exhaust ventilation (LEV) at the source of exposure for WCS 2, 3, 4, 5, 6, 10, 10a
- PPE for most WCS
  - Chemically resistant gloves conforming to EN374 (with specific activity training) and appropriate dermal protection (Tyvek chemical suits comply with EN ISO 13982 an EN13034)
  - Operators in the materials area wear respirator face masks: Sunstorm SR 100, 2 filters are used with these masks; SR510 P3 Particulate filter and SR 299 -2 filter for organic compounds. Filters are changed regularly these are logged and checked. APF for this mask is 20, as described by the manufacturer.

Some more details on RMMs for each of the WCS and how they are taken into account for exposure assessment are provided in table 2.

Table 2: Operational Conditions and Risk Management Measures

Contributing scenario	Duration, frequency of exposure	Concentration of the substance	LEV used + effectiveness	RPE used + effectiveness	Skin protection + effectiveness	Other RMMs
WCS 2 + PROC 8a	4 min., 1 – 2 times per 24 h	100	lip extraction at weighing station, 90%	95%	95%	3 – 5 ACH, automatically controlled flow rate to avoid splashes and aerosolisation, taps equipped with drip pots
WCS 3 + PROC 8a	10 min., 1 – 2 times per 12 h	1 – 5% w/w	elephant trunking, 90 %	95%	95%	3 – 5 ACH
WCS 4 + PROC 8a	15 – 20 min., 2 – 3 times per 12 h	1 – 5% w/w	elephant trunking, 90 %	95%	95%	3 – 5 ACH
WCS 5 + PROC 14	full shift, Mylar tape changing 2 – 3 times per 12 h	< 2% w/w	LEV, 90%	No	95%	5 – 10 ACH
WCS 6 + PROC 14	≤ 2 h per shift	≤ 2% w/w	integral extraction, 90%	No	95%	5 – 10 ACH
WCS 7 + PROC 14	≤ 2 h per shift	≤ 2% w/w	No	No	95%	Automated, fully enclosed process, 5 – 10 ACH
WCS 8 + PROC 21	≤ 2 h per shift	≤ 2% w/w	No	No	95%	3 – 5 ACH
WCS 9 + PROC 21	≤ 2 h per shift	≤ 2% w/w	No	No	95%	Enclosed, wet process, 3 – 5 ACH
WCS 10 + PROC 3	≤ 1 h per shift	≤ 2% w/w	integrated decoupled	No	95%	Completely closed, 3 – 5 ACH

			extraction, 90%			
WCS 10a + PROC 21	3 – 4 h per shift	≤ 2% w/w	LEV, 90%	No	95%	3 – 5 ACH
WCS 11 + PROC 28	< 1 h per shift	1 – 5% w/w	No	No	95%	5 – 10 ACH

For the effectiveness of LEV the applicant considers a 90 % reduction of exposure for both the inhalation and the dermal exposure pathway. This is considered for all WCS except WCS 7, 8, 9 and 10a where the effectiveness is only claimed for inhalation. The applicant justifies the chosen effectiveness qualitatively based on the type of LEV available and the achievable ACH. It is questionable whether a LEV has this level of exposure reduction capacity for dermal exposure. Therefore the dermal exposure assessment is uncertain to some extent.

Values for effectiveness for LEV and general ventilation are considered to be conservative by the applicant because usually ACH for LEV are measured to be 15 – 20 ACH and general ventilation is higher than the standard band of 3 – 5 or 5 – 10 as foreseen in CHESAR/ECETOC TRA version 3.

During the public consultation for this application a company submitted a proposal for a closed system that could reduce the level of exposure during the transfer activities. This comment was submitted based on the CSR presented by the applicant.

RAC acknowledges that in the meantime, the applicant has improved the RMM in place for the transfer operation with the highest potential for worker exposure. This is also highlighted in the answer of the applicant to the public comment submitter.

However, RAC notes that the current WCS 3 and 4 still contain transfer activities where exposure levels could be reduced with appropriate containment measures.

Other Risk management measures used to control exposure:

The applicant describes comprehensively in the CSR a number of RMMs that are relevant for each of the WCS but are not taken into account quantitatively for exposure assessment. These other RMMs include:

- Workplace risk assessments according to occupational safety and health regulations are reviewed every 3 years or when there is a change in the process.
- The materials' manufacturing area is designated an ex rated production area under the DSEAR (Dangerous Substances and Explosive Atmospheres) regulations and access to the area is restricted, with a swipe card access system in place.
- The casting area also has integral room extraction and local extraction. Air handlers force air into the printing and stacking areas for ventilation purposes.
- All extraction systems are tested 6 monthly.
- Employee training (including face fit testing for respirators) is carried out annually. Additionally, all employees are assessed every 2 years through questions and observations to ensure compliance with and competency in work and safety procedures.
- An advanced PPE management system (training, supply, replacement every shift for suits and at each stage of the process for gloves, logging and checking for respirators) is in place.

- All employees receive annual health surveillance, which includes an assessment of general health, breathing test and advice on how to work safely with chemicals and the importance of dermal protection.

Discussion of the exposure information:

The **exposure description** is comprehensive and clear regarding the presentation in writing. However, some of the use descriptor assignments were not in line with the guidance document R12 in the CSR submitted for this application. On RAC's request the applicant revisited the PROC assignment for all WCS and chose a more conservative approach. The applicant also provided supportive air monitoring data.

According to the applicant, the model used tends to overestimate the worker exposure. The applicant also explains that due to the nature of their processes, they had difficulties selecting a representative PROC for each worker contributing scenario. Therefore, they state that the modelling results for inhalation and dermal exposure may not be representative of the actual process.

The exposure assessment (deriving of exposure values and levels) is almost purely based on **modelling**. For inhalation and dermal exposure the ECETOC TRA Worker version 3 model – a tier 1 model – is used.

The results of modelling are supplemented by **personal and static air monitoring data**. Seven personal and eight static samples were taken in total, representing exposures of WCSs 2 to 10. No need for more samples was identified at the time by the applicant, because the operators carrying out the tasks are following strict procedures.

Sampling duration ranged from 240 to 272 minutes, with a sampling volume of approximately 1 m^3 per hour. The tasks carried out during that period by each operator tested are considered by the applicant to be representative for the whole shift. Sampling was carried out over two days in March 2018. The tasks for which samples were taken are as below:

- Weighing, mixing & transferring of DBP, in the materials area (WCS 2-4)
- Casting, in the TPP clean room (WCS 5)
- Printing, in the TPP clean room (WCS 6)
- Stacking, in the TPP clean room (WCS 7)
- Lamination, in the TPP manufacturing area, outside of the clean room (WCS 8)
- Dicing, in the TPP manufacturing area, outside of the clean room (WCS 9)
- General kiln work, including spreading of capacitors and loading of setter plates with capacitors in the burnout oven (WCS 10/10a)

It is important to understand that the **monitoring values** as presented in table 3 **do not take into account RPE**. The modelled data however take into account the exposure reduction capacity of PPE.

The values for dermal and inhalation exposure are summarised in table 3. It has to be considered that the measurements presented are only single values per WCS.

Table 3: Exposure – dermal and inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value
WCS 2; PROC 8a; Transfer from IBC	Inhalation	ECETOC TRA	0.0004 mg/m^3
		Air monitoring, personal*	0.0006 mg/m^3
		Air monitoring, static**	0.0004 & 0.01 mg/m^3
	Dermal	ECETOC TRA	0.069 mg/kg bw/day
WCS 3; PROC 8a; Transfer of binder to slurry	Inhalation	ECETOC TRA	0.0002 mg/m^3
		Air monitoring, personal*	0.0006 mg/m³
		Air monitoring, static**	0.0004 & 0.01 mg/m^3
	Dermal	ECETOC TRA	0.014 mg/kg bw/day
WCS 4; PROC 8a; Transfer of ceramic slip	Inhalation	ECETOC TRA	0.0002 mg/m^3
		Air monitoring, personal*	0.0006 mg/m^3
		Air monitoring, static**	0.0004 & 0.01 mg/m^3
	Dermal	ECETOC TRA	0.014 mg/kg bw/day
WCS 5; PROC 14; Casting	Inhalation	ECETOC TRA	0.007 mg/m^3
		Air monitoring, personal*	0.004 mg/m^3
		Air monitoring, static**	0.012 mg/m^3
	Dermal	ECETOC TRA	0.0034 mg/kg bw/day
WCS 6; PROC 14; Printing	Inhalation	ECETOC TRA	0.0042 mg/m^3
		Air monitoring, personal*	0.033 mg/m^3
		Air monitoring, static**	0.229 mg/m^3***
	Dermal	ECETOC TRA	0.0034 mg/kg bw/day
WCS 7; PROC 14; Stacking	Inhalation	ECETOC TRA	0.042 mg/m^3
		Air monitoring, personal*	0.011 mg/m^3
		Air monitoring, static**	0.016 mg/m^3
	Dermal	ECETOC TRA	0.034 mg/kg bw/day
WCS 8; PROC 21; Lamination	Inhalation	ECETOC TRA	0.084 mg/m^3
		Air monitoring, personal*	0.034 mg/m^3
		Air monitoring, static**	0.027 mg/m^3
	Dermal	ECETOC TRA	0.017 mg/kg bw/day
WCS 9; PROC 21; Dicing	Inhalation	ECETOC TRA	0.084 mg/m^3
		Air monitoring, personal*	0.058 mg/m^3
		Air monitoring, static**	0.020 mg/m^3
	Dermal	ECETOC TRA	0.017 mg/kg bw/day
WCS 10; PROC 3; Spreading and burnout	Inhalation	ECETOC TRA	0.0097 mg/m^3
		Air monitoring, personal*	0.011 mg/m^3
		Air monitoring, static**	0.003 mg/m^3
	Dermal	ECETOC TRA	0.0007 mg/kg bw/day
WCS 10a; PROC 21; Spreading of capacitors	Inhalation	ECETOC TRA	0.014 mg/m^3
		Air monitoring, personal*	0.011 mg/m^3
		Air monitoring, static**	0.003 mg/m^3
	Dermal	ECETOC TRA	0.028 mg/kg bw/day
WCS 11;**** PROC 28 → 9; Cleaning and maintenance	Inhalation	ECETOC TRA	0.014 mg/m^3
		Air monitoring, personal*	Not available
		Air monitoring, static**	Not available
	Dermal	ECETOC TRA	0.069 mg/kg bw/day

* The personal air monitoring measurements are recalculated from the original measurement value (representing a shorter measurement period) to an 11h TWA which is representative for the workplaces in question.

** The static air monitoring values represent the measurement value in air without recalculation to an 11 h TWA. But it is reasonable to assume that due to the prolonged sample time (> 4 hours) the value will not change dramatically.

*** Evaluation by the applicant: Inhalation exposure calculated by the model for WCS 6 is lower than that measured in the static monitoring exercise, during the operator's shift. This is in contrast to the results in the other WCS. Upon review of the location of the sampler, it was thought that it was placed incorrectly on the control box at the back of the printer. The operator spends all of their time at the front of the machine, and the data from the personal monitoring was more accurate, in terms of exposure. This static measurement is planned to be repeated, with the position of the sampler close to the where the operator works at the printer.
**** PROC 28 is a PROC specifically for cleaning and maintenance activities, but it is not included in ECETOC TRA or Chesar. Therefore, PROC 9 was used instead due to the similar exposure pattern. This considered to be a conservative approach by the applicant.

Additionally to the above exposure assessment the applicant explained – on RAC's request – that they carry out **biomonitoring** for toluene that is handled together with DBP in the same mixture but in a much higher volume. Toluene has also a much higher vapour pressure. The biomonitoring was carried out on a worst case scenario basis at the end of a three shift cycle, which is the longest exposure time for operators and the applicant explains that results were within UK guidance limits. RAC considers that this information gives some confidence in the conservativeness of the above exposure assessment.

RAC acknowledges that for workers exposure the applicant provided measured data and that these data support the modelling outcome. However, due to the very limited data sample, only the modelling outcome will be considered for the further part of this opinion. RAC notes that the applicant has provided the calculations (combined exposure and RCRs) with the measured data as well and that there is no significant difference to be seen in the outcome of the assessment.

Combined exposure

There is no use of other phthalates within the production process at AVX in Coleraine therefore this type of combined exposure was not considered. The use of DBP as a plasticiser has been divided into 11 WCSs. The areas operate on a shift basis. There are 4 individual shifts covering these areas. Between 5 and 25 employees are working in the different WCS.

According to the applicant the following combinations of WCS can occur during a shift:

- WCS 2 + WCS 3 + WCS 4, all materials manufacturing
- WCS 5 + WCS 6, Casting and Printing
- WCS 6 + WCS 7, Printing and stacking
- WCS 5 + WCS 6 + WCS 7, Casting, Printing and Stacking
- WCS 10 + WCS 10a, Spreading and burnout oven

Only the following combinations will be considered for further assessment, as the other combinations are also represented:

- WCS 2 + WCS 3 + WCS 4, all materials manufacturing
- WCS 5 + WCS 6 + WCS 7, Casting, Printing and Stacking
- WCS 10 + WCS 10a, Spreading and burnout oven

Table 4: Combined exposure

Materials Manufacturing

Contributing scenario	Route	Exposure value corrected for PPE
WCS 2	Inhalation	0.0004 mg/m³
	Dermal	0.069 mg/kg bw/day
WCS 3	Inhalation	0.0002 mg/m³
	Dermal	0.014 mg/kg bw/day
WCS 4	Inhalation	0.0002 mg/m³
	Dermal	0.014 mg/kg bw/day
Total exposure for 11 hours	Inhalation	**0.0008 mg/m³**
	Dermal	**0.097 mg/kg bw/day**

Casting Printing and Stacking

Contributing scenario	Route	Exposure value corrected for PPE
WCS 5	Inhalation	0.007 mg/m³
	Dermal	0.0034 mg/kg bw/day
WCS 6	Inhalation	0.0042 mg/m³
	Dermal	0.0034 mg/kg bw/day
WCS 7	Inhalation	0.0042 mg/m³
	Dermal	0.0034 mg/kg bw/day
Total exposure for 11 hours	Inhalation	**0.0154 mg/m³**
	Dermal	**0.0102 mg/kg bw/day**

Spreading and burnout oven

Contributing scenario	Route	Exposure value corrected for PPE
WCS 10	Inhalation	0.0097 mg/m³
	Dermal	0.0007 mg/kg bw/day
WCS 10a	Inhalation	0.014 mg/m³
	Dermal	0.028 mg/kg bw/day
Total exposure for 11 hours	Inhalation	**0.0237 mg/m³**
	Dermal	**0.0287 mg/kg bw/day**

Uncertainties related to the exposure assessment:

Related to RMMs some minor discrepancies about the values for RMM effectiveness are identified, e.g.

- The applicant considered an exposure reduction of 90% for dermal exposure for some activities. It is questionable whether a LEV has this capacity for dermal exposure reduction. Therefore the dermal exposure assessment is uncertain to some extent.
- It is questionable whether the excessive use of PPE – especially RPE – for the materials manufacturing area is justified given the level of exposure. The applicant acknowledges this. They consider this a "belt and braces" approach. However, RAC notes that the applicant stated they will continue developing and improving engineering controls in line with the hierarchy of controls principles.

Regarding the exposure estimation methodology a number of uncertainties are identified with different effects on the estimated exposure level:

- Due to the nature of the applicant's processes, it was not easy for the applicant to select representative PROCs. Therefore, modelling results for inhalation and dermal exposure may not be representative of the actual process.
- Almost only modelling was used for inhalation exposure estimation at the workplaces, in most cases this will result in conservative exposure values compared to measurements. However for single WCS the modelled values are comparable to the supplementing personal monitoring data.
- Only one personal and one static sample were taken for each WCS 3 to 10, with WCSs 2-4 are represented by 1 personal and 2 static samples. The applicant explain they did not identify the need for additional samples because of the strict procedures followed by operators. However RAC considers that additional measurement would increase the reliability of the measured data and improve the robustness of the exposure assessment.
- For dermal exposure assessment only modelling is available. For some of the WCS it is questionable whether the modelled value is valid (high level of exposure reduction capacity claimed).

Environmental releases / Indirect exposure to humans via the environment

RMMs applied

The applicant explains that the following risk management measures are in place to prevent releases to the environment:

- Air: there are no filters for air releases to the environment from the process. During the burnout step, DBP contained in the capacitors is thermally degraded and therefore not released to the environment. The burnout oven extracts are de-coupled so degradation products condensate and are collected to be sent for disposal as hazardous waste.
- Water, soil: the process is a contained batch process with no releases to water. All liquid and solid wastes are controlled and consolidated in fully bunded specific site locations, hence preventing accidental releases. All waste is processed by a licensed waste treatment facility, located approximately 50 miles from the manufacturing plant.

Releases and exposure estimation methodology

According to the applicant, there are no releases of DBP to water or soil. The emissions sources to air are:

a) exhaust air from LEV systems, during mixing and pouring
b) exhaust air from LEV during casting

The applicant did not measure the emissions of DBP to air. However, LEV extractive testing was conducted in November 2017. The results, indicates Volatile Organic Compound (VOC) as total carbon of 18 mg/Nm^3. The applicant explains that as the mixture contains highly volatile organic solvents (ethanol and toluene), it can be assumed that these are the major contributors.

The applicant explained that they used the Chesar in-built EUSES exposure dataset to estimate the DBP releases. The applicant first presented the results of the modelling considering a release factor of 0.1 % and an amount used of 3.1 tonnes. The choice of the release factor was not justified transparently considering the absence of quantification of the releases. Reference made to the OECD Emission Scenario Document on Plastic Additives was not fully appropriate due to absence of measures to control the releases of DBP to the environment. In addition, the oral route was missing from the assessment.

At RAC request, the applicant corrected the Environmental Release Category (ERC) assigned to their use and revisited their assessment.

A more detailed stepwise assessment was presented. The applicant noted that by using the default worst-case release factor to air (100 % for ERC 4), adequate control could be shown for the inhalation route but not for the oral route. The applicant explained that due to the low vapour pressure of DBP, the high speed and relative low temperature of the casting process and the fact that at the burnout stage the DBP contained in the capacitors is degraded, it is unrealistic to expect that 100 % of the DBP used would be released to the air. The applicant also showed that the area within 1 km of the plant is mostly commercial and residential, with little agricultural activity and concluded that the oral exposure of man via the environment at local scale is considered to be an overestimation.

The applicant also presented a summary of the risk characterisation ratios (inhalation and oral) for different emission factors based on different assumptions made in the OECD Emission Scenario Document on Plastic Additives. A sensitivity analysis was also conducted and the applicant explains that the maximum acceptable emission factor for their process is approximately 3.69 %.

RAC notes that the additional information provided by the applicant brings further transparency to the assessment and diminishes the uncertainties related to the release factor chosen.

Table 5: Summary of environmental emissions

Release route	Release rate	Release estimation method and details
Water	0 %	not applicable
Air	0.1 % (3.1 kg/year)	Based on vapour pressure of DBP and temperature of involved processes
Soil	0 %	not applicable

Table 6: Summary of indirect exposure to humans via the environment

Local exposure

Protection target	**Exposure estimate and details (i.e. methodology and relevant spatial scale)**
Man via Environment - Inhalation	$2.36x10^{-6}$ mg/m^3 (EUSES 2.1.2, RCR < 0.01)
Man via Environment - Oral	1.9x10-4 mg/kg bw/day (EUSES 2.1.2, RCR < 0.027)
Man via Environment - Combined	RCR < 0.027

Regional exposure

Protection target	**Exposure estimate and details (i.e. methodology and relevant spatial scale)**
Man via Environment - Inhalation	$1.39x10^{-4}$ mg/m^3 (EUSES 2.1.2, RCR < 0.01)
Man via Environment - Oral	$1.16x10^{-8}$ mg/kg bw/day (EUSES 2.1.2, RCR < 0.01)
Man via Environment - Combined	RCR < 0.01

Uncertainties related to the exposure assessment:

The lack of actual quantification of the releases of DBP to the environment (air) is the main source of uncertainty in the assessment of indirect exposure to humans via the environment. RAC considers that measurement of the releases of DBP would allow to verify the release factor used and improve the robustness of the exposure assessment.

Conclusion

RAC considers that:

DBP is used as a process plasticiser for multilayer ceramic capacitors (MLCC's) at a single manufacturing site with number of manual, open tasks. However the applicant has already made some improvements to the process, described them in the application and will focus to continue developing and improving engineering controls in line with the hierarchy of control principles.

There is no subsequent exposure of professionals or consumers (burnout of DBP in final product).

There are currently no RMMs to prevent releases of DBP to air from tasks not performed under closed systems and these releases have not been measured.

5. If considered a threshold substance, has adequate control been demonstrated?

☒ YES

☐ NO

☐ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

ECETOC TRA Worker version 3 has been used to provide exposure estimates for inhalation and dermal exposure assessment. In addition, for the inhalation route, the modelling results are supported by a small number of static and personal.

Based on the use-specific DBP exposure information and the available DNELs, a quantitative health risk assessment for workers was performed.

Table 7: Combined exposure

Combination of WCS	**RCR***			**Combined RCR****	**Combined RCR*****
WCS 2 + WCS 3 +WCS 4 Materials Manufacturing	0.364	0.073	0.073	**0.510**	**0.519**
WCS 5 +WCS 6+WCS 7 Casting Printing and Stacking	0.072	0.050	0.502	**0.624**	**0.586**
WCS 10 +WCS 10a Lamination and Dicing	0.029	0.255		**0.284**	**0.232**

For three WCS a combination of exposure is not foreseen by the applicant. Therefore also a combined risk assessment is not warranted.

WCS	**RCR***	**RCR*****
WCS 8 Lamination	**0.736**	**0.351**
WCS 9 Dicing	**0.736**	**0.535**
WCS 11 Cleaning & Maintenance	**0.468**	**Not available**

* Combined routes (dermal, inhalation), systemic, long-term
** Combination for different WCS, based on modelling only
*** Combination for different WCS, based on personal measurements for inhalation and modelling for dermal exposure

RAC notes that the duration of the working shift at the applicant site is 12 hours (including 1 hour break) with an average of 42 hours per week. This differs slightly from the basis on which the DNELs for workers are derived (8 hours TWA, 40 hours week). RAC also notes that the modelling results are also based on an 8 hours TWA, 40 hours week.

However, the applicant provided the calculations (combined exposure and RCRs) with the measured data (personal sampling) for which a recalculation to an 11 hours TWA was done. This information is presented in table 3 and table 7.

RAC acknowledges that no significant difference can be seen between the different approaches and that the RCRs for the individual and combined scenarios stay below 1.

However, RAC has noticed that not all possible engineering controls are currently implemented (see also contribution in the public consultations[3]). The principles of hierarchy of controls are not followed in the selection and implementation of risk management measures. RAC points out that it is likely that additional engineering controls minimising the potential for dermal exposure, for example eliminate manual transfers and manual handling, would result in lower overall levels of exposure.

6. If adequate control is not demonstrated, are the operational conditions and risk management measures described in the application appropriate and effective in limiting the risk?

☐ YES

☐ NO

☒ NOT RELEVANT, adequate control has been demonstrated

7. Justification of the suitability and availability of alternatives

It is worth noting here that the applicant (a downstream user of DEZA a.s.) currently benefits from the authorisation delivered in April 2016 to DEZA a.s. for the industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements. The review period for the DEZA's authorisation expires on 21 February 2019.

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Description:

Summary of the analysis of alternatives undertaken by the applicant

General introduction

The applicant uses DBP as a plasticiser within the Thin Tape Process (TTP) for the production of multilayer ceramic capacitors (MLCCs). These capacitors are primarily supplied to customers in 'high reliability' sectors, predominantly automotive and aerospace.

MLCCs consist of many layers of dielectric ceramic material and electrode. The microscopic structure of an MLCC is the factor that will determine its effectiveness. The ideal structure consists of a high number of thin layers that increase the capacitance for a constant electrode area. Generally, the thickness of the dielectric layer is between 10 and 30 µm.

[3] See ECHA website, consultation number 0126-01; https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/18903/del/200/col/synonymDynamicField_302/type/asc/pre/2/view

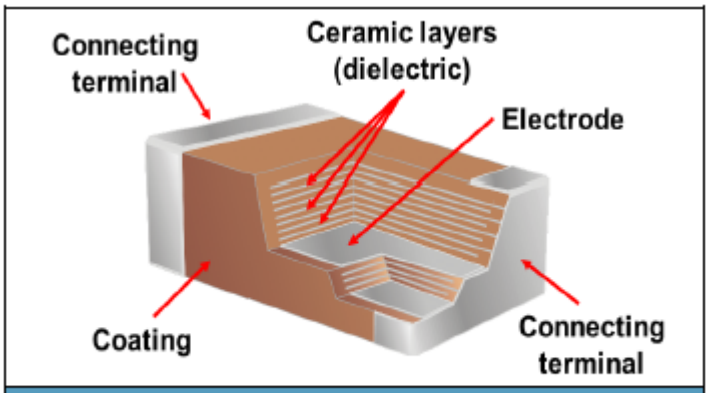

Figure 3-5: A diagram of MLCC construction
Source: Elcap (2012)

The applicant highlights that the overall MLCC manufacturing process is a complex and highly technical one, which has evolved taking into account decades of technical progress. The applicant shifted from the CMAP technology (based on a flat plate system and therefore not requiring a plasticiser) to the TTP technology years back. This was part of a technology transfer from Kyocera Corp (AVX belongs to the Kyocera Group), who had developed the TTP in order to manufacture the next generation capacitors. These capacitors require thinner dielectric layer thicknesses than what the CMAP technology was able to produce. The thinner layers allow for more layering and higher capacitance in the same space. The applicant also presents a performance comparison between the different types of capacitors where it is clear that the MLCCs rank overall the highest. During the production process, the ceramic sheets are rolled and unrolled several times. DBP is used to provide flexibility to the cast ceramic sheet to withstand these rolling and unrolling steps otherwise it would crack and the resultant quality of the capacitors would be unacceptable.

Process alternatives

The applicant discusses briefly the option of potential process alternatives without the use of plasticiser. These alternatives can be divided in two categories:

a. The CMAP or other casting technology
b. Other electrode material within the TTP

The applicant moved from CMAP technology to TTP in order to produce thinner dielectric layer thicknesses than what the CMAP technology was able to produce. According to the applicant, moving back to CMAP is not considered a realistic option to move away from the use of DBP as it would not allow AVX to continue manufacturing the range of advanced products it does and to continue supplying the 'high reliability' automotive and space sectors of the market. On requests by SEAC the applicant answered they knew no other processes than TTP that could produce the required product range.

According to the applicant, the use of an alternative electrode material with a higher oxidising temperature than nickel could in theory make a broader range of substances suitable as alternatives. The silver-palladium electrodes that were utilised in MLCCs became economically infeasible in the late 1990's after the price of palladium rocketed by almost 1000%. Furthermore, the applicant indicate in the Economic impact chapter that the palladium MLCCs are significantly larger than their nickel equivalents meeting the same specifications, resulting in cost implications in terms of weight and size of the component

in which they are used. The applicant provide a cost estimation for applying these palladium MLLCs in the space sector due to the increased weight and the very high launch costs. These higher costs would amount as much as €1.5 million on an annual basis and €23 million over the period 2019 to 2025 assuming a 20% annual increase in sales. The applicant also evaluated copper as a potential electrode material but was unsuccessful in its implementation. According to the applicant, the technical feasibility of this option is doubtful and its economic infeasibility is certain due to the high investment that would be required.

Substance alternatives

Technical feasibility criteria

The applicant provides a description of the technical feasibility criteria which an alternative plasticiser must meet and which are based on DBPs characteristics. These criteria are:

Criterion 1 – Solubility in organic solvents (allow complete dissolution and prevent quality issues at subsequent steps of the production process);

Criterion 2 – To provide flexibility in cast tape (allowing rolling and unrolling without cracking);

Criterion 3 – Low volatility (avoid evaporation of plasticiser during the first phase of the production process);

Criterion 4 – Clean removal at temperatures below 250 °C in air (prevent quality issues at subsequent steps of the production process);

Besides these criteria, a number of indicators/process steps are described to perform initial material tests and to evaluate the material performance within the manufacturing process, such as rheological analysis, thermogravimetric analysis test and air burnout and quality check after high temperature firing.

The applicant states that at the time DEZA a.s. applied for authorisation in 2013, they were already attempting to substitute DBP with a separately identified potential alternative, recommended by the producer of the binder material. The applicant believed that the alternative was a feasible substitute and focussed resources on its implementation. The applicant describes the R&D efforts undertaken between early 2013 and 2016 with the support of different actors. Using the alternative, the applicant successfully manufactured samples of small case size capacitors with thinner dielectric thickness. However, after burnout and sintering, delaminations were evident in 30% of the jobs and quality assurance testing showed a high percentage of failures. These tests showed that a proper burnout process to thermally degrade the organics in the capacitors, such as DBP, is essential. Although this substitution effort was ultimately unsuccessful, the applicant explains that it helped them gain a better understanding of the process, which is useful for further substitution activities.

The applicant continued their search for an alternative. They explain that since they did not have access to the full confidential documentation that was submitted by DEZA a.s. in 2013, they relied partly on their own R&D efforts for the identification of potential alternatives.

The applicant followed a two-step screening approach.

1. Initial identification of list of potential alternatives: the applicant approached its suppliers and performed a search in the literature. This resulted in twelve candidate alternative substances.
2. Refinement based on expert assessment and preliminary hazard screening: the applicant screened the alternatives on technical feasibility and then to identify and prioritise a single substance for more detailed review. The refinement resulted in three potential alternatives that met the technical feasibility criteria. The main factors used to review and rank the potential alternatives were the substance boiling point and vapour pressures. Furthermore, the hazard characteristics of the substances were reviewed by consulting the ECHA PACT tool, CoRAP, ECHA's Registry of Intentions, Harmonised classification and Annex XVII restriction list and ongoing proposals.

The applicant reviewed seven potential alternatives from the original application for authorisation submitted by DEZA that the applicant considered to be technically feasible and five alternatives recommended by the applicant's suppliers of material other than DBP. In response to SEAC's question the applicant indicated that they provided more weight to the suggestions by their suppliers as they would have considered the applicant's particular situation and technical feasibility parameters. The shortlist was further assessed with a refinement based on expert assessment and preliminary hazard screening, resulting in three potential alternatives. Based on the learnings gained during the R&D efforts undertaken between early 2013 and 2016, the technical characteristics and the hazard characteristics of the substances one potential alternative was selected for further analysis and testing. The applicant also explains that the supplier of the selected substance had provided them with a technical report containing encouraging data on the performance of the substance.

The other two substances may still be available for further testing in case the selected one prove to be unsuccessful. One of these potential alternatives has been set aside by the applicant on basis of the potential hazard. However, recently RAC decided on the non-classification of this substance.

The applicant concluded that the process alternatives are not feasible and that the selected substance is most suitable and likely to succeed as a substitute.

Technical feasibility

To assess the technical feasibility of the selected substance the applicant compares it against the four technical feasibility criteria identified and describes the steps required for the implementation of the substitution.

The selection of potential alternatives was initially based on three criteria. The selected alternatives were ranked against a range for feasible boiling points and vapour pressures based on earlier experiences of the applicant. DEZA did not apply such a range in their selection. The applicant does not provide an explanation for a ranking based on boiling point and vapour pressure, but probably these criteria are most critical and can be applied in advance of generating experimental data (in contrast to the criterion of flexibility). Of the 12 alternatives identified, three substances met the three criteria. The applicant investigated the advantages and disadvantages of these three alternatives and continued further process steps, such as material tests, performance tests and implementation, with the most promising substance. The tests are described quite extensively and comprised the fourth criterion: flexibility in cast tape allowing roll-up without cracking. This process is still

ongoing, time scale was provided in the application. There was already some experience with the selected alternative that the applicant got through recommendations of one of their suppliers. Of the other two substances only theoretical data of the physical parameters were available. Technical feasibility has to prove itself during testing and the pilot production of the MLCCs with the alternative substance. Thus, SEAC is not able to judge the availability of a feasible alternative for this specific application currently on basis of its technical feasibility.

Economic feasibility

In the selection of the alternative substance to proceed with, economic considerations were also taken into account. For the two other alternatives, the applicant either does not know whether commercial quantities are available on the market or foresees that a restriction may limit its availability in the future. The applicant does not foresee any issues with implementing the selected substance in terms of economic feasibility provided that the alternative is technically feasible. The applicant also foresees supply of the alternative in sufficient quantity. Economic feasibility is not further discussed in the analysis of alternatives. The applicant states that due to the fact that all of the other alternatives show significant technical failures, no quantitative analysis of the economic feasibility was performed. Because no quantitative data are provided it is not possible for SEAC to scrutinise this part.

Conclusion

The applicant describes the different stages of their search for an alternative over the last years in detail. Both process and substance alternatives have been considered.

For the process alternatives, although the arguments provided by the applicant for the economic infeasibility seem plausible, no detailed quantification was provided. However, the section on economic impact contains some considerations on the cost implications of using alternative electrode material.

The applicant started their search for substance substitutes with a screening of the technical characteristics of potential substitutes, based on experiences with an initial substitute in 2013, based on a literature search and contact with suppliers. This approach is described quite extensively. On request the applicant indicated that the literature search was carried out Google search, Science direct and Google books using relevant entries and that an additional search was carried out by their consultant.

The infeasibility of the 2013 alternative is also described extensively and facilitates understanding the technical feasibility of potential alternatives. The description of the selection of the three newly selected alternatives could be clearer and presented more comprehensively although argumentation for selecting the preferred alternative is provided. Limited information on economic feasibility was provided and confined to the one alternative selected. The applicant does not foresee problems with availability of the preferred alternative. Certification requirements are mentioned in the dossier and described more extensively in annex 1.

SEAC concludes that the approach by the applicant followed a logic line of reasoning. Firstly, physical chemical characteristics of a set of alternatives were compared to that of DBP. Subsequently, R&D for performance and possible implementation is applied on the most

preferred alternative out of three selected, which sounds plausible to SEAC considering cost aspects and logistics related to experimental work. These tests are still ongoing. Technical feasibility still has to prove itself during testing and the pilot production of MLCCs with the alternative substance. According to SEAC experiences with a previous potential alternative concerning flexibility of the casts and proper burnout and reflecting the practical endeavours have been convincingly described by the applicant.

7.2 Are the alternatives technically and economically feasible before the sunset date[4]?

☐ YES

☐ NO

Applicant's assessment/evaluation of the technical feasibility of the alternatives shortlisted

Process alternatives

The applicant is, besides the information provided in the analysis of alternatives, not aware of any alternative process to the TTP which could produce the required product range of MLCCs. Transfer to an alternative electrode material is not considered to be a realistic option because of technical or economic feasibility.

Substance alternatives

The applicant provided background of the tests carried out on a possible alternative in the period between 2013 and 2016 and provided a description of the selection and a time schedule concerning technical feasibility of 12 potential alternatives they started in 2017. After selection of 12 potential alternatives on the basis of technical feasibility criteria, initial material tests evaluation of the material performance, performance of the production line and implementation initiation phase have been scheduled.

The applicant explains in detail the different tests, performance evaluation and quality check steps required to complete the initial phase of implementation. A detailed timeframe for this is provided. According to the applicant, this could be completed by the end of Q3 2019 under a 'realistic best case'.

After this initial phase requalification of the capacitors and implementation is needed. The applicant presents the requalification processes for the automotive grade and the space grade MLCC as well as the timelines involved. According to the applicant, this requires approximately 30 months for the automotive and approximately 4 years for the aerospace sector. Q3 of 2023 is scheduled to have the full requalification for the relevant MLLCs.

The applicant indicates to need an additional 2.5 years for final implementation and contingency phase. The applicant provided two lines of justification for that. Firstly, the applicant indicates that preparing a review report for re-application in parallel with implementation of the alternative would be highly burdensome as indicated in 'Setting the review period when RAC and SEAC give opinions on an application for authorisation'. Secondly, it provides the applicant with some flexibility in case the implementation of the alternative substance would be unsuccessful in its early stages of the R&D. It provides the

[4] The sunset date for DBP was 21/02/2015. The applicant benefits from their supplier's authorisation until 21 February 2019. For this reason, this section will consider if there are alternatives technically and economically feasible before 21 February 2019.

applicant with some additional time to implement the other potential alternatives. The time frame provided by the applicant thus ends Q1 of 2025.

Applicant's conclusion on technical feasibility of the alternatives shortlisted

The applicant presents a short overview of the key advantages and disadvantages of all three potential alternative substances identified but only discusses the technical feasibility of the selected one.

The applicant explains that testing and analysis started in 2017 to ascertain the technical feasibility of the selected substance. These results are expected in the last quarter of 2018. It is therefore difficult to definitely conclude on the technical feasibility of the selected alternative substance.

The applicant selected three alternative substances for DBP. On the basis of their characteristics, further testing was carried out with the most promising one. Although testing with this substance has started, its technical feasibility will become clear after these tests have been fully performed at the end of 2018. Of the other substances, the identity of which is claimed confidential, physical parameters fulfilled the criteria. However, as experiments with these alternatives were not carried out, technical feasibility could not be provided.

Applicant's conclusion on economic feasibility of the alternatives shortlisted

The applicant does not expect any issues with implementing the selected substance in terms of economic feasibility in case technical feasibility shows to be sufficient. It is anticipated that the substance will be fully economically feasible and available in the required quantities.

SEAC's conclusion on technical and economic feasibility of the alternatives shortlisted

The current authorization of DBP applied for by DEZA for this applicant's use expires in February 2019.

R&D of the applicant fully focusses on the development of one alternative substance. Process alternatives are set aside mainly for economic reasons, for reasons of timing and technical feasibility and these potential alternatives are not (extensively) discussed by the applicant. Based on the limited available information, SEAC is unable to evaluate the validity of the provided conclusion. Although it may be plausible that substantial investments are required to shift to an alternative electrode material, SEAC has no further information to check this statement. However, SEAC believes this does not change the opinion considering the availability of alternatives before the expiration date of the supplier's authorisation.

SEAC notes that the applicant selected only one alternative for further R&D. This alternative still needs to prove itself in terms of technical feasibility. In the applicant's response to SEACs questions, the applicant indicates that in case the selected alternative is unsuccessful, there still is a fall-back option that may be realised within the indicated time frame, as the potential implementation of a second identified potential alternative which will be further explored.

In the most optimistic scenario, the applicant knows around the expiry date of the current authorisation whether the potential substitute is technically feasible or not, but still needs sufficient time for performing requalification requirements for automotive and space applications and final implementation. These processes will only be completed far beyond the expiry date of the current authorisation. The ECHA-EASA document "(a)n elaboration of key aspects of the authorisation process in the context of aviation industry" (ECHA 2014) indicates that it will generally take several years to pass through the approval process and be ready for adoption after a suitable alternative within the aviation industry has been found. The applicant provided an extensive argumentation of the time frame needed for testing and implementation. Thus, the indicated time frames by the applicant seem plausible to SEAC.

As described under conclusions in 7.1 the applicant is currently testing a potential alternative for DBP in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors. **Based on the available information in the application and information supplied in the responses to SEAC's questions, SEAC concludes that currently, it appears there are no suitable alternatives for the application of DBP in the production of multilayer ceramic capacitors and that further R&D is required for the development of alternatives.**

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Description:

The applicant proposes twelve potential alternatives. For three of the 12 listed alternatives, ECHA PACT tool, CoRAP, ECHA's Registry of Intentions, Harmonised classification and Annex XVII restriction list and ongoing proposals were consulted to evaluate potential risks of these alternative substances. The other nine (of the 12) substances were set aside by the applicant because of technical feasibility reasons.

With respect to the selected most relevant possible alternative substance for further analysis, the applicant has checked the ECHA C&L Inventory using the EC number for the substance. The inventory includes one entry for the substance with the indication that it is not classified. The applicant's supplier has stated that the alternative is "Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008". The applicant states that, based on initial discussions with the substance supplier, the substitute is considered to fulfil the requirement of leading to overall reduced risks, when used as an alternative for DBP. No further remarks on risks are provided in the application.

RAC notes that based on the available information, it is difficult to conclude upon the potential risks of the selected alternative compared to DBP.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☐ YES

☒ NO

☐ NOT APPLICABLE

Justification:

The fact that the substance has not been classified by the single notifier may indicate that the substance is not hazardous, but it may also indicate a lack of information on potential hazard characteristics of the substance, especially when considering that the substance has not been registered.

Conclusion

RAC cannot finally conclude on a reduction of the risk by the proposed substitution of DBP. There is an entry for the potential substitute proposed in the dossier in the C&L inventory with one notifier, but the substance is not classified. See remark under 7.3.

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available before the sunset date?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

There are no technically and economically feasible alternatives available before the end of the applicable review period. See description under 7.1 to 7.4.

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☐ YES

☐ NO

☒ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

Summary of the applicant's assessment

RAC has supported the conclusion of the applicant's assessment that all exposures associated with the current use of DBP are below the DNEL. Therefore, the application can proceed under the 'adequate control' route. On this basis, the costs of continued use are effectively zero. SEAC agrees with this conclusion.

Costs of continued use (HH)

The authorisation holder has provided a break-even analysis, as an uncertainty analysis, in order to compare the potential human health effects to the benefits of continued use for the authorisation holder and its supply chain, in the event adequate control is not confirmed by RAC. For valuation of the health impacts of infertility and developmental toxicity effects,

the applicant has applied costs per case of male infertility, cryptorchidism and hypospadias adapted from the Annex XV Restriction Report - Four Phthalates. For calculation of societal benefits of continued use the profit losses, quantified losses to downstream users and social costs of unemployment were used. The calculated break-even numbers for male infertility, cryptorchidism and hypospadias are considered by the authorisation holder as highly unrealistic (i.e., in comparison to the estimated male births of female employees at AVX over 7 years; exact figures claimed confidential).

Benefits of continued use (cost of non-use scenario)

At the Coleraine site, in addition to the TTP process, AVX runs a low volume production process (European Manufacture of Advanced Products (EMAP)) for capacitors used as legacy parts for the space sector. This process is not using DBP.

Non-use scenario

In selecting the non-use scenario, the applicant presents the options they could have if the authorisation for the continued use of DBP was not granted. These include:

- NUS 1: Substitution of DBP by an alternative substance within AVX's manufacturing process;
- NUS 2: Cessation of production while substituting DBP by an alternative technology;
- NUS 3: Relocation of MLCC manufacturing activities to separate AVX Corporation facility;
- NUS 4: Closure of the TTP at Coleraine with continuation of EMAP;
- NUS 5: Site closure at Coleraine.

In their analysis of the different scenarios, the applicant identifies and describes the relevant elements having an impact in each scenario and explains their consequences to the activities at the Coleraine site and for AVX Ltd in wider terms. Some of the key elements considered include:

- Absence of alternative substances or technologies
- Loss of AVX´s market share to competitors and reputational losses
- CMPA technology not supporting the type of advanced capacitors requested by the market sectors currently served
- Time needed and costs for relocation of production capacities
- Relative low profitability of EMAP production process.

The applicant concludes that out of the 5 potential scenarios presented, "stop of the TTP production and closure of the site" is the most realistic.

Economic and social impacts of the non-use scenario

The applicant provides quantitative and qualitative information for the valuation of economic impacts of the non-use scenario owing to AVX at Coleraine site, connected business units of AVX Ltd and AVX's customers.

The costs of the closure of the AVX facilities were calculated by the applicant based on the expected profit losses of the Thin Tape Process using DBP, and of the EMAP capacitor production technology for legacy spare parts in space sector. However, this EMAP process contributes only marginally to the total profits of the AVX site. The profit losses are estimated to be in the order between 10 to 100m€ over the requested review period of 7 years (exact figures claimed confidential).

According to the applicant these profit losses represent a welfare loss for society since the competitors would not be able to close the supply gap quickly. Also, in case of a fast response, the profits would be permanently lost to EEA since the main competitors in automotive sector are located outside EEA.

The applicant describes qualitatively further economic impacts of the closure of the AVX site for the connected business units of the AVX cooperation located in one EU site and one non-EU site, which are involved in finishing, packaging and distribution of the capacitors. Revenue and profit losses are expected, and also jobs involved in finishing activities in the EU site may be are at risk. Moreover, the impacts of the closure of the AVX site for the downstream users of multi-layer ceramic capacitors (MLCC) which produce electronic components for automotive and space industry are described qualitatively and also partly quantitatively. Possible knock-on effects of production stops at automotive producers are also mentioned.

As social costs, the applicant has included job losses of staff made redundant at AVX´s facility in case of closure of the site (<500 persons; exact figure claimed confidential). The calculation of social impacts follows the approach outlined in the SEAC paper on the Social Cost of Unemployment (ECHA 2016). Social costs of unemployment are calculated to be in the range between 10 and 100m€ (exact figure claimed confidential).

Furthermore, a qualitative description of the reduction in the level of competition in the market for multi-layer ceramic capacitors in case the applicant leaves the market is provided. This is relevant for the claims the applicant makes regarding the impacts of closure of the site.

Applicant's conclusion on benefits and costs of continued use:

The applicant states that the risks of continued use are adequately controlled for the use applied for, and therefore the human health impacts are considered to be zero. Nevertheless, a break-even analysis has been prepared taking into account the number of workers exposed. According to the applicant, unrealistically high numbers of future cases of male infertility, cryptorchidism or hypospadias would be required for break-even between risks and benefits. The benefits of continued use are estimated to be larger than **100M€** over 2019-2025 (exact figures claimed confidential). **Therefore, the applicant concludes that the benefits of continued use clearly outweigh the risks to human health.**

SEAC's conclusion on benefits and costs of continued use:

Risks of continued use:

For assessing the risks of continued use, a break-even analysis was performed. The assumptions used for calculation of the average costs per case of male infertility, cryptorchidism and hypospadias are based on Willingness to pay reference values (SEAC 2016) and the analysis is in line with the recent SEAC opinion on the restriction proposal on four phthalates. SEAC recognizes that the Willingness to pay reference values applied are not the most conservative ones. Application of the corresponding higher values would result in lower break-even values, but without having an impact on the Applicant´s conclusion.

For comparison of derived break-even values the estimated number of male birth of AVX female workers employed at Coleraine site was used (exact figure claimed confidential).

The estimation of male births is based on reliable data sources (e.g. Eurostat). It has to be recognized that the number of children having developmental effects would be much lower. In response to a SEAC question, the applicant provided information on the current age structure of female workers, with the vast majority being in the 40-49 and 50+ age groups.

Overall, SEAC considers the assumptions used in the Break-even analysis plausible. But, SEAC cannot finally conclude on the applicant's conclusion that the required break-even statistical cases are unrealistically high in comparison to the estimated number of male children of female workers at the production site, because the identified uncertainties regarding the quantified economic and social impacts may result in some overestimation of these impacts.

Benefits of continued use (cost of non-use scenario):

As adequate control of risk has been confirmed by RAC, the costs of continued use are effectively zero. Nevertheless, the applicant has assessed the costs of the non-use scenario and this is useful in deciding on the recommendation for the review period.

Non-use scenario:

Selecting complete closure of the production site (NUS 5) as the non-use scenario is considered by SEAC as a plausible starting point for the assessment of the economic impacts of non-use.

The arguments provided by the applicant to dismiss the non-use scenario of substitution of DBP (NUS 1) and relocation (NUS 3) seem plausible to SEAC. In both cases AVX would suffer a reputational loss as a reliable supplier because of non-availability of AVX's products for its customers during the time needed for implementing substitution of DBP or relocation. SEAC considers plausible that recovering the customer base which would likely be lost to competitors during this time would be difficult.

In case of substitution of TTP production technology (NUS 2) by shifting back to the CMAP production technology (CMAP was replaced by TTP) the applicant would erode its competitive advantage of producing capacitors of high reliability and capacity, and would be competing with suppliers having lower production costs. Rejecting this economically disadvantageous option is plausible to SEAC.

Some uncertainty remains for SEAC regarding whether complete closure of the site is the most likely option since the second production process (EMAP), although having a comparatively low profit margin, is in principle economically viable (NUS 4). However, only a small share of the overall production volume and profits of the Coleraine production site arise from the production of the EMAP process. Therefore, SEAC considers plausible the applicant's claim that production of the EMAP process alone would not be profitable enough to justify maintaining the site.

Benefits of continued use:

It is plausible for SEAC that shut-down of production and possible production delays in automotive and space sector (AVX´s direct customers) will transfer to some degree into welfare losses. However, the quantification of these welfare losses by profit losses, and costs of the production delays of AVX's customers is considered uncertain due to missing

information on production capacities and market strategies of the competitors. On SEAC's request, the applicant provided further information on timescales for delivery of necessary production equipment for TTP (6 – 24 months; exact numbers claimed confidential). This information cannot be scrutinized in detail, but indicates that a fast ramping up of capacities by AVX´s competitors is considered unlikely, such that at least for a short time period a supply shortage in MLCC cannot be excluded. SEAC recognises that, in an any case, since the main competitors are located outside EEA, the transfer of AVX´s profit to its Non-EEA competitors would represent a loss for EEA.

The quantification of costs of production delay due to market shortage in supply of MLCC for downstream users in automotive industry and space sector was not further scrutinized in detail by SEAC. Due to missing information on production capacities of competitors and MLCC stocks at distributers and downstream customers the occurrence of production delays is considered uncertain. However, in response to a SEAC's question, the applicant provided information on the level of MLCC stocks held by AVX' distributors showing a decreasing trend over the last 35 months. Furthermore, AVX reports examples for costs of production delays raised by their customers: 200,000€ per day for a 4-day production delay, 50,000 to 100,000€ charged to AVX in case of delayed delivery and 43,000€ for 2-day delay for a customer outside EEA. SEAC considers plausible and recognizes that non-availability of AVX production volume may increase the risk of market shortages and that production disruptions may cause significant costs at AVX´s customers at least over a short period of time.

For calculation of social impacts the applicant has correctly applied the approach outlined in the SEAC paper (ECHA 2016) (based on gross annual earnings in sector "Manufacture of computer, electronic and optical products" in Northern Ireland). For the calculations, a default value for UK is applied which assumes a mean unemployment duration of 14 months. AVX did not provide evidence on e.g. on the qualification structure of their employees, to conclude on the average unemployment duration, but the seasonally adjusted unemployment rate for Northern Ireland is mentioned. This figure is below UK average as shown in the referenced Labour Force Survey of Northern Ireland. In conclusion, SEAC considers it plausible that social costs of unemployment will arise, but some overestimation of the calculated social costs is possible.

SEAC's conclusion

In general, SEAC considers the applicant's approach for assessing the economic and social impacts to be based on a sound methodological foundation, which identifies relevant direct impacts of the applicant, its downstream customers, and social impacts.

Although there are uncertainties regarding the quantified economic and social impacts, economic and social costs are expected to arise in the non-use scenario. **Given the absence of human health impacts associated with the applicant's use of DBP and the costs of the non-use scenario, it can be concluded that the benefits of the continued use exceed the risk of continued use.**

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

The following conditions and monitoring arrangements are recommended in case the authorisation is granted:

- Additional engineering controls shall be implemented to reduce worker exposure, particularly for those activities where manual handling of DPB still occurs as described in the CSR (e.g. WCS 3, WCS 4, WCS 11). Where possible, open handling shall be replaced by closed systems.
- Exposure monitoring
    - The applicant shall establish and implement a regular (at least annual) programme of occupational exposure measurements for all activities with potential for worker exposure.
    - Monitoring programmes shall be based on relevant standard methodologies or protocols and be representative of the range of tasks undertaken in the WCSs and resulting in potential for exposure and of the total number of workers potentially exposed. Where appropriate, biomonitoring shall also be used as a complementary methodology to assess workers exposure.
    - The information gathered in the monitoring programmes shall be used by the applicant to review the appropriateness and effectiveness of the risk management measures (RMMs) and operational conditions (OCs) to limit workers' exposure to DBP. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented.
    - The results of the monitoring and of the review of the OCs and RMMs must be maintained, made available to national enforcement authorities and be included in any subsequent authorisation review report submitted.

AND

Description of monitoring arrangements for review reports:

- Exposure modelling
    - In case that exposure modelling is still necessary for the review report, e.g. in the case that dermal exposure cannot be monitored by biomonitoring satisfyingly, the application holder shall take into account the uncertainties identified (selection of PROCs, high level of exposure reduction capacity claimed for dermal assessment).
- In the review report the improvement of operational conditions and risk management measures shall be documented.
- The applicant shall measure the actual releases of DBP to the environment (air) with a view to verifying the release factor used for the assessment of indirect exposure to human via the environment. Measurement(s) shall be based on relevant standard methodologies with detection limits allowing meaningful analysis of releases.

The results of the measurement shall be made available to national enforcement authorities and included in any subsequent authorisation review report submitted.

Justification:

Although RAC considers the use of DBP as described by the applicant to be adequately controlled, it is clear that exposures are not as low as it is technically possible to achieve, thus leaving room for improvement. For this reason RAC felt it necessary to recommend additional conditions and monitoring arrangements; this is further explained below.

1. RAC is of the opinion that not all possible engineering controls are currently implemented (see also contribution in the public consultations[5]). The principles of hierarchy of controls are not followed in the selection and implementation of risk management measures. RAC points out that it is likely that additional engineering controls minimising the potential for dermal exposure, for example eliminate manual transfers and manual handling, would result in lower overall levels of exposure.
2. Only limited measurements (air monitoring) were provided but the implementation of a monitoring program is foreseen by the applicant for the future.
3. Exposure modelling for dermal and inhalation exposures shows a number of uncertainties (see above). RAC is of the opinion that modelling might be avoidable in the future when sufficient measured data are available.
4. For a meaningful exposure assessment and a validated exposure scenario the documentation regarding the improvement of operational conditions and risk management measures in the next review period is mandatory. The sheer numbers (level of exposure, number of measurements) are required but not sufficient. For a full understanding the description of the tasks, operational conditions, risk management measures and appropriate contextual information are always necessary.
5. The lack of measurement of the releases of DBP to the environment (air) is the main source of uncertainty in the assessment of indirect exposure to human via the environment.

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification:

In identifying the review period SEAC took note of the following considerations:

RAC's advice: RAC gave no advice to SEAC on the length of the review period.

Other socio economic considerations:

In identifying the proposed review period, SEAC took note of the following considerations:

[5] See ECHA website, consultation number 0126-01; https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/18903/del/200/col/synonymDynamicField_302/type/asc/pre/2/view

- RAC confirmed that the exposures are below the DNEL. Consequently, the applicant's use of Dibutyl phthalate (DBP) is confirmed by RAC to be adequately controlled, and hence the human health impact is effectively zero. In contrast, significant socioeconomic benefits of continued use are expected to arise, and this risk/benefit situation is not likely to change in the time required to implement the change to an alternative substance.
- The applicant has not been able to identify an alternative plasticiser or an alternative production technology for the current process that is currently suitable. The promising alternative identified will not become suitable before the expiration of the supplier's authorisation, on which the applicant currently relies.
- Although there is no technically and economically feasible alternative to implement before the expiry of the applicable review period, the applicant has identified an alternative which could replace the use of DBP within a period of seven years from the expiry of the applicable review period. In this respect, AVX has set out a detailed timeline for transition to the alternative plasticiser during the period of seven years and SEAC agrees with the applicant's assessment.

Taking into account these points, SEAC recommends a 7 year review period, as requested by the applicant.

11. Did the Applicant provide comments to the draft final opinion?

☐ YES

☒ NO

11a. Action/s taken resulting from the analysis of the Applicant's comments:

☐ YES

☐ NO

☒ NOT APPLICABLE

ANNEX 1

The table below presents the contributing scenarios as described in the CSR submitted but also as changed on RAC's request. Important changes are highlighted in green and explained further below the table.

Contributing Scenarios presented in the Use

Initial information			**After RAC's request**		
Scenario	**ERC/ PROC**	**Name of the scenario**	**Scenario**	**ERC/ PROC**	**Name of the scenario**
ECS1	ERC-6a	Manufacture of MLCCs	ECS1	ERC 4	Use at industrial sites
WCS 2	PROC 8b	Transfer from Drum to chemical can	WCS 2	PROC 8a	Transfer of DBP from IBC to binder solution
WCS 3	PROC 8a	Transfer from chemical can to steel vessel			
WCS 4	PROC 8b	Transfer of the binder solution to the ceramic slurry	WCS 3	PROC 8a	Transfer of binder solution to ceramic slurry
WCS 5	PROC 9	Transfer to a small tank for transport and use in production	WCS 4	PROC 8a	Transfer of ceramic slip to a small tank for transport and use in production
WCS 6	PROC 3	Casting operation: transfer of the ceramic slip from the closed tank on to Mylar tape via a slot die head	WCS 5	PROC 14	Casting operation: transfer of the ceramic slip from the closed tank on to Mylar tape via a slot die head
WCS 7	PROC 3	Printing operation	WCS 6	PROC 14	Printing operation
WCS 8	PROC 3	Stacking Operation	WCS 7	PROC 14	Stacking Operation
WCS 9	PROC 1	Lamination Operation	WCS 8	PROC 21	Lamination Operation
WCS 10	PROC 1	Dicing operation	WCS 9	PROC 21	Dicing operation
WCS 11	PROC 3	Spreading and Loading for the burn-out process	WCS 10	PROC 3	Burn-out process
			WCS 10a	PROC 21	Spreading of capacitors before loading in oven for burnout process
WCS 12	PROC 9	Cleaning and Maintenance	WCS 11	PROC 28	Maintenance and cleaning of machinery

Further description of the changes

- ECS 1, ERC 6a to ERC 4: the applicant first chose ERC 6a "*Use of intermediate"* to describe the use. After RAC request the applicant changed this to ERC 4 "*Use of non-reactive processing aid at industrial site (no inclusion into or onto article)*" which is the correct descriptor for the use in question.
- WCS 2 and WCS 3 to WCS 2: the process at the applicant site originally contained three different transfer operations. The first transfer (WCS 2, 100 % DBP, from a drum to a can) was conducted manually as an open system, with virtually only PPE as risk

management measures. The applicant informed RAC that they had improved their process for health and safety reasons. DBP is now stored in an IBC container and is now pumped via piping directly to the binder solution pot is done via piping therefore eliminating direct handling of the substance by operators.

- WCS 11 to WCS 10 and 10a: WCS 11 was originally covering both the spreading and loading for the burnout process and PROC 3 "*Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition"* was attributed to the contributing scenario. The applicant created an additional contributing scenario to better account for the manual spreading of capacitors onto trays before the burnout process. PROC 21 "*Low energy manipulation and handling of substances bound in/on materials or articles*" was attributed to this scenario.
- WCS 12 to WCS 11: in addition to the change of PROC assigned, the applicant provided a more detailed description of the corresponding activities.

It is important to note that the applicant based his assessment on modelled data and therefore the descriptors assigned and used have an impact on the modelling result.