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**COMMISSION IMPLEMENTING DECISION**

**of 21.3.2019**

**granting an authorisation for a use of dibutyl phthalate under Regulation (EC) No  
1907/2006 of the European Parliament and of the Council (AVX Limited)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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**granting an authorisation for a use of dibutyl phthalate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (AVX Limited)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) Dibutyl phthalate (DBP) is listed in Annex XIV to Regulation (EC) No 1907/2006 and is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 11 December 2017, AVX Limited ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of DBP in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors.
- (3) On 19 July 2018, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency<sup>2</sup> on the application pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its opinion, RAC confirmed that it is possible to determine a derived no-effect level (DNEL) for the toxicity to reproduction of DBP in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that, therefore, DBP is a threshold substance.
- (5) RAC concluded that the risk to human health from the use of DBP applied for is adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006, provided that the risk management measures and operational conditions described in the application and in the chemical safety report, as updated by the applicant in reply to clarifications requested by RAC<sup>3</sup>, are fully applied. However, due

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> <https://echa.europa.eu/documents/10162/74eb441f-a58d-077f-ec6f-d88f7ecb515c>

<sup>3</sup> <https://ec.europa.eu/docsroom/documents/31667>

to certain tasks involving manual, open handling of DBP and due to the lack of measurement of the releases of DBP to the environment, RAC recommended additional conditions for the authorisation, as well as monitoring arrangements.

- (6) Therefore, in accordance with Article 60(2) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of DBP applied for, provided that the risk management measures and operational conditions described in the application and, in particular, in the chemical safety report, as well as the conditions set out in this Decision, are fully applied.
- (7) Commission Implementing Decision (EU) No 2017/1210<sup>4</sup> identifies DPB as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) No 1907/2006 due to its endocrine disrupting properties for human health. Since those intrinsic properties are not yet included in Annex XIV to that Regulation, this authorisation does not take them into account.
- (8) In its opinion, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years. The Commission concurs with that recommendation, taking into account the relevant elements from the RAC's and the SEAC's assessments and, in particular, RAC's conclusion that the risk to human health arising from the use of the substance is demonstrated to be adequately controlled, the significant socioeconomic benefits of continued use, the lack of suitable alternatives despite the applicant's research and development activities, the time needed by the applicant for transitioning to the most promising alternative, and the fact that the situation in terms of risk and benefits of continued use is unlikely to change during the time foreseen for this transition.
- (9) In view of RAC's and SEAC's opinions, the Commission considers it appropriate that as regards the use of DBP applied for the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 be set at seven years as from the adoption of this Decision.
- (10) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.
- (11) This Decision does not affect the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect either the obligation of the authorisation holder to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible pursuant to Article 60(10) of Regulation (EC) No 1907/2006 or the obligation of the employer to eliminate or reduce to a minimum the risks to the health and safety of workers at work involving hazardous chemical agents pursuant to Article 5(2) of Council Directive

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<sup>4</sup> Commission Implementing Decision (EU) 2017/1210 of 4 July 2017 on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OJ EU OJ L 173, 6.7.2017, p. 35).

98/24/EC<sup>5</sup>. In addition, this Decision is without prejudice to the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC<sup>6</sup> and 98/24/EC<sup>7</sup>, Directive 2004/37/EC of the European Parliament and of the Council<sup>8</sup>, and Council Directives 92/85/EEC<sup>9</sup> and 94/33/EC<sup>10</sup>.

- (12) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directives 2010/75/EU<sup>11</sup> and 2008/50/EC<sup>12</sup> of the European Parliament and of the Council, as well as with emission limit values set to achieve compliance with the environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council<sup>13</sup> and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council<sup>14</sup>. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.
- (13) On 29 March 2017, the United Kingdom submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. The Treaties will cease to apply to the United Kingdom from the date of entry into force of a withdrawal agreement or failing that, two years after that notification, unless the European Council, in agreement with the United Kingdom, unanimously decides to extend that period. This Decision is addressed to a legal entity established in the United Kingdom. Unless otherwise provided for in a withdrawal agreement, this Decision can therefore only apply until the Treaties cease to apply to and in the United Kingdom notwithstanding the end of the validity laid down in this Decision.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

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<sup>5</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)(OJ L 131, 5.5.1998, p. 11).

<sup>6</sup> Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

<sup>7</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

<sup>8</sup> Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004).

<sup>9</sup> Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

<sup>10</sup> Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

<sup>11</sup> Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)(OJ L 334, 17.12.2010, p. 17).

<sup>12</sup> Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

<sup>13</sup> Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

<sup>14</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

HAS ADOPTED THIS DECISION:

*Article 1*

An authorisation is granted in accordance with Article 60(2) of Regulation (EC) No 1907/2006 for the following use of dibutyl phthalate (DBP) (EC No 201-557-4, CAS No 84-74-2), provided that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, as well as the conditions set out in this Decision are fully applied:

Authorisation number	Authorised use
REACH/19/15/0	Industrial use of dibutyl phthalate in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors

*Article 2*

The authorisation referred to in Article 1 shall be subject to the following conditions:

- Without undue delay, the authorisation holder shall implement additional engineering controls to reduce worker exposure, particularly for those activities where manual handling of DBP still occurs as described in the chemical safety report (e.g. in workers contributing scenarios 3, 4 and 11) referred to in Article 1.
- The authorisation holder shall replace open handling by closed systems, where possible. Where this is not possible, reasons for it shall be documented and submitted, upon request, to the competent authority of the Member State where the authorised use takes place.

*Article 3*

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 March 2026.
2. The authorisation shall cease to be valid 21 March 2026 in case a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 21 September 2024, unless a decision to withdraw the authorisation is adopted earlier.

*Article 4*

The following monitoring arrangements shall apply:

- (a) the authorisation holder shall conduct regular occupational exposure measurements of DBP related to the use described in Article 1 for all activities with potential for worker exposure. Those measurements shall:
  - (i) take place at least annually;
  - (ii) be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit;
  - (iii) be representative of the range of tasks with possible exposure to DBP and of the total number of workers that are potentially exposed;

- (iv) include contextual information about the tasks with possible exposure to DBP;
- (b) where possible, the authorisation holder shall use biomonitoring as complementary methodology to the measurements referred to in point (a);
- (c) the authorisation holder shall measure the actual emissions of DBP into the air related to the use referred to in Article 1. Those measurements shall:
  - (i) be undertaken according to standard sampling and analytical methods;
  - (ii) ensure a sufficiently low detection limit;
- (d) the authorisation holder shall use the information gathered by performing the measurements referred to in points (a), (b) and (c) to regularly review the effectiveness of the risk management measures and operational conditions, and to take action, as appropriate, in order to further reduce workers' exposure to DBP and its emissions into the air;
- (e) the authorisation holder shall use the information gathered by performing the measurements referred to in point (c) to verify the release factor used for the assessment of indirect exposure to human via the environment;
- (f) the results of the measurements referred to in points (a), (b) and (c), as well as the outcome and conclusions of the review and any actions taken in accordance with points (d) and (e) shall be documented, maintained and submitted upon request to the competent authority of the Member State where the authorised use takes place, and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

#### *Article 5*

The authorisation holder shall submit, upon request, to the competent authority of the Member State where the authorised use takes place a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report in an official language of that Member State.

*Article 6*

This Decision is addressed to AVX Limited, Prospect House, 6 Archipelago Lyon Way, GU16 7ER, Frimley, Surrey, United Kingdom.

Done at Brussels, 21.3.2019

*For the Commission*  
*Elżbieta BIEŃKOWSKA*  
*Member of the Commission*

