Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion on an Application for Authorisation for

Dibutyl phthalate (DBP)

used as an absorption solvent in a closed system in the manufacture of maleic anhydride

ECHA/RAC/SEAC: AFA-O-0000004250-87-15/D

Consolidated version

Date: 28 November 2014

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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(s):	**Dibutyl phthalate (DBP)**
EC No.:	**201-557-4**
CAS No.:	**84-74-2**

for the following use:

Use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride.

Intrinsic property referred to in Annex XIV:

Toxic to reproduction (Article 57 (c) of the REACH Regulation)

Applicant

DEZA a.s.

Reference number

11-0000000329-74-0000

Rapporteur, appointed by RAC: **Safia KORATI**
Co-rapporteur, appointed by RAC: **Jose L. TADEO**

Rapporteur, appointed by SEAC: **Catheline DANTINNE**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On **13 August 2013 DEZA a.s.** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **6 November 2013**, ECHA received the required fee in accordance with the Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **13 November 2013**. Interested parties were invited to submit comments and contributions by **8 January 2014**.

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 and those of third parties to the requests that SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

Due to the need to ensure the efficient use of resources, and in order to synchronise the public consultation with the plenary meetings of the Committees, the time limit set in Article 64(1) for the sending of the draft opinions to the applicant was extended until 17 September 2014.

The draft opinions of RAC and SEAC were sent to the applicant on **17 September 2014**.

On 23 October 2014 the applicant informed ECHA that they did not wish to comment on the opinions with regard to this use. However, the applicant submitted comments to ECHA with regard to other use applied for on 14 November 2014. After assessing the submitted comments the draft opinions of RAC and SEAC with regard to all the uses applied for were adopted on **28 November 2014**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or 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 **14 March 2014**.

The draft opinion of RAC was adopted by consensus.

The opinion of RAC

Based on the aforementioned draft opinion, the opinion of RAC was adopted as final on **28 November 2014**.

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 March 2014.**

The draft opinion of SEAC was adopted by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion, the opinion of SEAC was adopted as final on **28 November 2014**.

THE OPINION OF RAC

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

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

RAC confirmed that it was possible to determine a DNEL for the reprotoxic properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that the exposure assessment in the application demonstrated 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 duration for the review period has been suggested below.

THE OPINION OF SEAC

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 and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH

Regulation that is relevant to the Committee's remit.

SEAC took note of RAC's confirmation that it is possible to determine a DNEL for the reprotoxic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC took note of RAC's confirmation that the risk 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.

The duration for the review period has been suggested below.

USE

The authorisation is considered for the following use:

Use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

- No additional conditions to those described in the application are proposed.

Monitoring arrangements

- No additional monitoring arrangements to those described in the application are proposed.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **12 years**.

JUSTIFICATIONS

Substance name:	Dibutyl phthalate (DBP)
Name of applicant(s):	DEZA a.s.
Use name:	Use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride.
Reference number:	11-0000000329-74-0000

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 previously established reference Derived No Effect Levels (DNELs; RAC/24/2013/09 rev. 2; Helsinki, 12 April 2013) and considered DBP to be a threshold substance.

3. Hazard assessment. Are the DNEL(s) appropriate?

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)

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

4. Exposure assessment. Is the exposure from the use adequately described?

☒ YES

☐ NO

Justification:

The applicant described one exposure scenario:

"Use as an absorption solvent in a closed system in the manufacture of maleic anhydrite (MA)."

This scenario covered all industrial activities of the applicant's downstream users associated with the use of DBP as a solvent in a closed system in the manufacture of MA.

The applicant described the following steps for this exposure scenario:

ES1-WCS1: **Closed system (minimal contact during routine operations)**

ES1-WCS2: **Material transfer**

ES1-WCS3: **Laboratory use**

The operational conditions in which DBP is used (in closed, continuous process with occasional controlled exposure and operated via a central control room) may be characterized as a well-controlled workplace. DBP is recovered and recycled for reuse. The amount of DBP used in the manufacture of MA is less than 1000 tonnes per year.

For the purpose of this risk assessment, RAC used the following exposure values based on modelling as these represent the highest exposure to workers for this use of DBP:

Inhalation exposure:

0.002 + 0.004 = **0.006 mg/m³** (for respectively WCS1 and WCS2)

Dermal exposure:

0.002 + 0.013 = **0.015 mg/kg/day** (for respectively WCS1 and WCS2)

This is based on the information that the only possibility for exposure from more than one process during a single shift is the combination of activity WCS1 with the activities described in WCS2.

An **oral** intake of **0.016 mg/kg/day** was calculated by RAC based on the 90th percentile of exposure estimates from urinary biomonitoring data of the applicant's workers.

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

☒ YES

☐ NO

Justification:

For the purposes of this risk assessment indirect exposure of the general population via the environment was considered to be negligible and was not considered further in the assessment of adequate control. Based on the use-specific DBP exposure information and the available DNELs a quantitative health risk assessment for workers was performed.

Based on modelling, the applicant calculated a Risk Characterisation Ratio (RCR) of 0.05 for combined (i.e., for WCS1 and WCS2) exposure by inhalation and an RCR of 0.08 for combined dermal contact. The combined RCR for workers from both routes is 0.13. On the other hand, RAC calculated an RCR for workers using biomonitoring data of 0.83.

RAC concluded that for this specific use of DBP, the health risk to workers (specifically reproductive toxicity) is **adequately controlled**.

6. If adequate control is not demonstrated, is the remaining risk reduced to as low a level as is technically and practically possible?

Justification and concluding on the remaining risk:

Not applicable.

7. Justification of the suitability and availability of alternatives

7.1 Would the alternatives lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

7.1.1 Are the risks of alternatives adequately described and compared with the Annex XIV substance?

☐ YES

☒ NO

☐ NOT APPLICABLE

Justification:

The applicant provided detailed analysis of the suitability of the other two commercially proven technologies for the manufacture of MA: solvent-based (ALMA) technology (using diisobutyl hexahydrophthalate (DIBE)) and a water-based technology for the recovery of MA (using a combination of water and xylene). The assessment of the suitability of these alternatives is presented in the Analysis of alternatives (AoA) from the perspective of the downstream user that would benefit from the authorisation. The applicant cannot currently manufacture or supply either of the two commercially proven alternatives.

The risks of the alternatives are discussed as follows:

a) DIBE-based technology

The applicant presented information that indicates that DIBE has more benign hazard profile than DBP. This was corroborated by information received during the public consultations and published on ECHA's website. The applicant indicated that during the course of the transition to the DIBE higher CO_2 emissions would occur due to increased fuel consumption.

b) Water and xylene based technology

The applicant did not provide a comparison of the hazards of DBP to those of o-xylene as the use of xylene is only a minor component in the water-based recovery technology and o-xylene cannot be considered to constitute a direct replacement for DBP. However, the applicant provided argumentation that the water-based recovery is environmentally more burdensome than the Huntsman technology in terms of energy consumption and wastewater generation which result in increased CO_2 emissions.

The applicant did not perform a detailed exposure and risk assessment of the alternatives. Thus, it was not possible for RAC to compare the risks caused by DBP to those caused by possible alternatives and to assess whether the alternatives would lead to an overall reduction of risk.

7.2 Are the alternatives technically and economically feasible?

☐ YES

☒ NO

Justification:

The technical and economic feasibility of the alternatives for the use applied for was evaluated. As the applicant (a manufacturer of DBP) is applying for authorisation on behalf of the downstream user of DBP (a manufacturer using DBP as a solvent in the manufacture of MA), the feasibility of the alternatives for the downstream user is assessed. The feasibility of the alternatives for the applicant is taken into account in

the assessment of the socio-economic implications of no authorisation for the purpose of the setting of the review period.

The applicant presented the suitability analysis first from the perspective of the downstream user and second, from their perspective.

Technical feasibility

DIBE-based (ALMA) technology

The applicant evaluated DIBE against the technical comparison criteria and found the potential alternative to have lower boiling point, inferior dissolution of fumaric acid (FAc) and small difference between its density and that of water. Overall, the applicant argued that the DBP-based technology has technical advantages over the ALMA technology, although these statements were disputed in public comments published on ECHA's website for other applications for authorisation.

Water-based recovery technology

The applicant presented arguments indicating the technical advantages of the DBP-based technology over the water-based technology: the greater recovery efficiency for the manufactured MA; the lower energy consumption (lower steam consumption); the lower generation of wastewater; the lower incidence and implications of fouling; and more desirable for some downstream users quality of the final MA product. However, this latter statement was not supported by public sources[1]. No comments were received during the public consultation. The downstream user who is to benefit from the potential authorisation evaluated the merits of this alternative technology over the DBP-based technology prior to the decision to convert their plant from a water-based to a DBP-based technology in 1999.

SEAC noted that the technical feasibility of both the ALMA and water-based technologies has been demonstrated over several decades on the market. Thus, SEAC further assessed the suitability of the alternatives on the basis of their economic feasibility for the use applied for.

Economic feasibility

DIBE-based (ALMA) technology

The applicant identified that the following costs would be incurred by the downstream user to transition to the alternative:

[1] RIVM, Final report, December 2013: Analysis of alternatives for a group of phthalates, AMEC Environment and Infrastructure UK Limited
http://www.rivm.nl/dsresource?objectid=rivmp:235700&type=org&disposition=inline&ns_nc=1

a. costs arising from the increased price of the absorption solvent;
b. costs arising from increased absorption solvent consumption;
c. costs arising from the modifications to the downstream user's plant in order to convert from the DBP-technology to the ALMA technology;
d. costs arising from increased fouling of the production line and associated maintenance requirements associated with the reduced solubility of fumaric acid in DIBE (not quantified);
e. cost of a new licence to operate under the ALMA technology;
f. costs of changes in steam generation and consumption.

Comments published on ECHA's website for other applications for authorisation stated that these costs are overestimated. However, no detailed information was provided to SEAC.

Taking into account the qualitative argumentation of the applicant and publicly available information, SEAC concluded that at a minimum the following net costs would likely be incurred by the downstream user in the event it is required to transition to the alternative: loss of profit during plant conversion, additional borrowing costs, increased absorption solvent price, changes in steam generation and consumption, and licensing fee for the ALMA technology. SEAC found these net costs plausible.

Thus, SEAC concluded that, at present, the ALMA technology could not be considered as economically feasible for the use applied for.

Water-based recovery technology

The applicant identified that the following costs would be incurred by the downstream user in order to transition to this alternative:

a. costs arising from converting the downstream user's plant from the DBP-based technology back to water-based recovery of MA;
b. costs arising from lower process efficiency of the MA recovery;
c. costs arising from greater steam consumption and lower export;
d. costs arising from increase in wastewater generation;
e. costs arising from increased fouling of the production line and associated maintenance requirements; and
f. costs associated with the loss of customer base due to adverse effects on the quality of the MA product (xylene impurities).

Based on the qualitative argumentation by the applicant, SEAC concluded that the transition to the water-based technology would likely lead to net costs to the downstream user. These net costs would likely be of the character described in bullets b) to e) above. With respect to the plant conversion costs (referred to in a) above), SEAC concluded that at a minimum the downstream user would likely incur net costs related to equipment addition and conversion, loss of profit during plant conversion, as well as additional borrowing costs. Thus, SEAC found these net costs plausible. SEAC concluded that, at present, the water-based technology could not be considered

as economically feasible for the use applied for.

Overall, SEAC considered that, at present, the alternatives cannot be considered economically feasible for the use applied for.

7.2.1 Are the technical and economic feasibility of alternatives adequately described and compared with the Annex XIV substance?

☒ YES

☐ NO

Justification:

SEAC concluded that the applicant demonstrated sufficient research into possible alternatives: The applicant outlined "technical comparison criteria" to guide the assessment of alternative substances and technologies. The applicant provided information on extensive screening for possible alternatives without identifying suitable alternatives to DBP: more than 13,000 substances were examined for close marches of key physical properties and screened for economic and technical feasibility, including alternative solvents for which there are patents. Indicative list of the screened alternatives solvents was provided in table 3.2 of the AoA. Nine potential alternatives, still in the R&D stage but not in commercialisation stage, were assessed against the technical comparison criteria in table 3.3 of the AoA. A cost comparison was performed to seven of these alternatives in table 3.4 of the AoA. The analysis showed that the technical suitability of these solvents has not been proven and the examination of their key physico-chemical properties suggested that they could not be feasibly used as substitutes for DBP in DBP-based MA technology, at least with current knowledge and expertise.

The applicant provided detailed analysis of the suitability of the other two commercially proven technologies for the use applied for: solvent-based (ALMA) technology (using diisobutyl hexahydrophthalate (DIBE)) and a water-based technology for the recovery of MA (using a combination of water and xylene). Their technical and economic feasibility is discussed in detail in sections 4.1 and 4.2 of the AoA. No other alternatives were identified by third parties during the public consultation on this use.

The applicant showed extensive literature and database research and supplier consultations to identify possible alternatives, including possible alternative solvents.

In addition to discussing alternatives for the use applied for, the applicant discussed their ability to manufacture and supply these alternatives to the downstream user. In sections 4.1 and 4.2 of the AoA, the applicant argued that they could not manufacture or supply either of the two commercially proven alternatives. This was partially challenged for DIBE in a comment published on ECHA's website for a public consultation on the same use. The technical and economic feasibility for the applicant

to supply the possible alternatives was taken into account in the assessment of the socio-economic implications of no authorisation for the purpose of the setting of the review period for the use applier for.

The applicant provided satisfactory written answers to SEAC questions of whether they assessed selected other alternatives discussed in the public domain as possible alternatives in the recovery of MA. The applicant also addressed in writing the non-confidential public consultation comments.

7.3 If alternatives are suitable, are they available to the applicant?

☐ YES

☐ NO

☒ NO SUITABLE ALTERNATIVES EXIST

Justification:

As SEAC concluded that no suitable alternatives exist at present for the use applied for, further investigation of the availability of the alternatives was not performed.

8. For non-threshold substances, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

9. Do you propose additional conditions or monitoring arrangements

☐ YES

☒ NO

Detailed description for additional conditions and monitoring arrangements:

No additional conditions and monitoring arrangements

Justification for additional conditions and monitoring arrangements:
The conditions (risk management measures (RMMs) and operating conditions (OCs)) described in the Chemical Safety Report of the applicant need to be observed strictly to ensure adequate control for this use of DBP. Adhering to these RMMs and OCs is a necessary condition for the authorisation. Therefore, no additional conditions and monitoring arrangements were proposed by the Committees.

10. Proposed review period:

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. _years)

☐ Other:

Justification for the suggested review period:

RAC's conclusions on risks arising from the use of DBP in the manufacture of MA are that the only possible exposure to DBP is for workers (around 50 employees) and this exposure is adequately controlled. Within its own remit, RAC saw no reason to recommend a short review period.

As the application demonstrates adequate control, a conclusion on whether the benefits of continued use exceed the risks to human health and the environment was deemed unnecessary. SEAC assessed the information provided by the applicant in the Analysis of Alternatives and the Socio-economic analysis report for the purpose of determining the length of the review period.

Taking into account RAC's conclusion on adequate control, SEAC considered the risks of continued use as minimal and impacting a small population of workers whose safety, health and welfare are assumed to be taken into account in the reference DNEL set by RAC and used by the applicant as the basis of their application for authorisation.

In the event of no authorisation, SEAC concluded that there would likely be considerable socio-economic implications for the applicant and its supply chain. These implications would likely be considerably in excess of the avoided risks in the event of

no authorisation (already stated to be minimal due to adequate control).

SEAC considered plausible that the immediate transition after the sunset date to the ALMA or water-based recovery technologies would place substantial financial burden on the applicant's supply chain.

Thus, SEAC also considered plausible that a suitable course of action is to identify an alternative absorption solvent for the DBP-based MA recovery technology. The applicant provided information on the timelines and activities required by members of its supply chain to identify an alternative (a minimum of 13 years) and test its commercial viability prior to making it available for the replacement of DBP in commercial operations. Subsequently, further five years would be required for plant conversion. Although not able to evaluate the R&D program to be undertaken, SEAC considered that the technological and economic environment would likely substantially change over a period of 18 years. Therefore, SEAC recommended that the merit of continued use of DBP in the manufacture of MA is re-evaluated no further than within 12 years.

A further argument for a long review period is the long investment cycle of the MA manufacturing sector (i.e., the production is capital intensive) – in excess of 20 years according to the applicant – which makes it technically and economically meaningful to substitute only when a major investment or refurbishment takes place.

Thus SEAC recommended a review period of **12 years** based on the following three arguments supporting long review period:

- socio-economic implications for the applicant and its supply chain would likely be considerably in excess of the avoided risks in the event of no authorisation;
- long time period would be required to transition to a suitable alternative; and
- the industry's investment cycle is demonstrably long.