Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion on an Application for Authorisation for

Bis(2-ethylhexyl) phthalate (DEHP)

used in the processing of a stop-off formulation during the diffusion bonding and manufacture of aero engine fan blades.

ECHA/RAC/Opinion N° AFA/RAC-001-2013 Final
ECHA/SEAC/Opinion N° AFA/SEAC-001-2013 Final

Consolidated version

Date: 20 December 2013

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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):	**Bis(2-ethylhexyl) phthalate (DEHP)**
EC No.:	**204-211-04**
CAS No.:	**117-81-7**

for the following use:

The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.

Intrinsic property referred to in Annex XIV:

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

Applicant

Rolls-Royce plc

Reference number

11-0000000298-71-0000

Rapporteur, appointed by RAC: **Urs SCHLÜTER**
Co-rapporteur, appointed by RAC: **Norbert RUPPRICH**

Rapporteur, appointed by SEAC: **Jean Marc BRIGNON**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

Rolls-Royce plc submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **13 August 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 **14 August 2013**. Interested parties were invited to submit comments and contributions by **10 October 2013**.

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.

The draft opinions of RAC and SEAC were sent to the applicant on **13 December 2013**.

On **20 December 2013,** the applicant informed that it did not wish to comment on the opinions and the draft opinions of RAC and SEAC were therefore considered as the final on **20 December 2013.**

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 **5 December 2013**.

The draft opinion of RAC was adopted 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 **20 December 2013**.

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 **12 December 2013**.

The draft opinion of SEAC was adopted 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 **20 December 2013**.

THE OPINION OF RAC

RAC has formulated its opinion on the risks arising from the use applied for and the appropriateness and effectiveness of the described risk management measures, and on 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 confirms that it is possible to determine a DNEL for the reprotoxic properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirms that the exposure assessment in the application demonstrate 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 applicant included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

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

SEAC confirms 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:

The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.

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 **seven years**.

JUSTIFICATIONS

Substance name: Bis(2-ethylhexyl) phthalate (DEHP)

Name of applicant(s): Rolls-Royce plc

Use name: Use 1: The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.

Reference number: 11-0000000298-71-0000

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 DEHP, RAC has previously established reference Derived No Effect Levels (DNELs; RAC/24/2013/08 rev. 2; Helsinki, 12 April 2013) and considers DEHP to be a threshold substance.

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

Justification:

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

Inhalation: DNEL of 0.88 mg/m³ (8h-TWA)

Dermal: DNEL of 1.882 mg/kg/d (external values)

For the purpose of their risk assessment for DEHP the applicant referred to and applied the DNELs proposed by RAC.

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

☒ YES

☐ NO

Justification:

The applicant describes one exposure scenario:

"The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades."

For the manufacture process of fan blades the applicant describes the following steps:

ES1-W1: **Preparation**

ES1-W2: **Transfer and sampling**

ES1-W3: **Application of stop-off formulation to define the internal structure of fan blades**

ES1-W4: **Diffusion bonding, superplastic forming**

The situation described in which DEHP is used may be characterized as a well controlled workplace with clean room conditions. DEHP is used for one specific reason only and in a very low quantity.

For the purpose of this risk assessment, RAC used the following exposure values:

Inhalation exposure:

10 µg/m³

Dermal exposure:

48 µg DEHP per shift resulting in **0,857 µg/kg/d**

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

☒ YES

☐ NO

Justification:

For the purposes of this risk assessment consumer exposure and indirect exposure via the environment can be considered to be negligible. Based on the use-specific DEHP exposure information and the available DNELs a quantitative health risk assessment for workers was performed.

RAC calculated a Risk Characterisation Ratio of 0.01 for exposure by inhalation and a RCR of 0.0005 for dermal contact. The combined RCR for workers is 0.01.

The risk from this specific use of DEHP is considered to be even lower than calculated because the estimated exposure levels used for risk assessment were based on measurements in the working environment which were below the specific limits of detection.

RAC concludes that for this specific use the DEHP health risk to workers (specifically developmental 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 is currently still evaluating the technical feasibility of alternatives (ethanol, glycerol). So far the applicant did not perform a detailed hazard, exposure and risk assessment for these alternatives. The applicant so far referred only to some general information on classification and occupational exposure levels. Due to this it is not possible for RAC to compare the risks caused by DEHP 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 for the applicant?

☐ YES

☒ NO

Justification:

The applicant has investigated a number of alternatives since 1997, initially motivated by a desire to reduce the use of Volatile Organic Compounds. The research was focused on Yttrium based bonding stop-off agents, since it is the view of the applicant that using agents other than Yttrium would require changing the whole fan blade and engine technology.

With the information made available to SEAC, it was evident that the applicant had carried out a broad and long-lasting research programme for alternatives, that narrowed down, on technical grounds, to two candidates :

- Stop-flo No2 (Alternative 3) has passed only initial tests but appears as a potential candidate. However the applicant indicated that significantly more testing will be required to confirm its technical feasibility.
- Stopyt-62G (Alternative 4) has a composition similar to the current stop-off agent (except that DEHP is replaced by glycerol) and is considered by the applicant as the most credible alternative, after completion of nearly half of the planned testing program. In the most optimistic scenario, the applicant expects to finalise the planned testing program in mid-2016 if no problems occur.

During the Public Consultation, one contribution suggested that an alternative based on boron nitride had been used in similar industrial situations (stop-off agent in the diffusion bonding process for the manufacture of titanium blades). However further discussion with submitters of the comment and with applicant in the Trialogue indicated that this alternative is not an option for aerospace engine fan blades manufactured by the applicant. The applicant indicated that although boron nitride can be used on the external side of the blades, it has been found to potentially produce micro-cracks on the internal face of the blades.

Since the applicant did not carry out tests with boron nitride, and since the stakeholder suggesting boron nitride was unable to provide more detail, SEAC was unable to further assess boron nitride as a potential alternative. However, SEAC considers that, even if boron nitride were a potential alternative this would not change the outcome of this assessment because testing, validation and certification would still be necessary for a boron nitride-based alternative.
Overall, SEAC considers that alternatives cannot be considered as technically feasible at present.

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

☒ YES

☐ NO

Justification:

The applicant describes the technical and economic features of four selected alternatives. These four were selected after a broader search for alternatives as described by the applicant.
For each of them, an assessment of the technical performance has been carried out or is underway. For the alternatives that have been already rejected on technical grounds (Alternatives 1 and 2), there is a description of the technical failures (in terms of the gap between performance of the current formulation containing the Annex XIV substance and the alternative).

Since alternatives are first assessed in technical terms, economic feasibility is also addressed but to a lesser extent by the applicant. However, SEAC considers that economic feasibility is adequately described given the current state of the substitution process.

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

☐ YES

☐ NO

☒ NO SUITABLE ALTERNATIVES EXIST

Justification:

SEAC considers that no suitable alternatives exist at present, but that potentially suitable alternatives do exist. If remaining testing by the applicant is successful, Alternative 4 could be considered suitable at the earliest by mid-2016. If not, then further testing on Alternative 3 would similarly determine if it is actually suitable.

Despite the above, the application contains information on availability. In particular, the applicant clearly states that Alternatives 3 and 4 have been confirmed to be available with the two suppliers, one of them being the same as the supplier of the current stop-off agent. SEAC therefore anticipates no availability issue.

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:

Justification for additional conditions and monitoring arrangements:

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years

☐ Short (…. _years)

☐ Other:

Justification for the suggested review period:

For the specific 'use applied for' RAC calculated the rather low overall RCR of ~ 0.01. Therefore, SEAC in its rationale first took into account that the risk is adequately controlled for workers and that the duration of the review period can be set only with other considerations than risk.

The applicant did not fully clarify the time required to confirm the technical feasibility and implement the two foreseen alternatives. Between 5 to 10 years is mentioned in some parts of the dossier, and up to 12 years in Appendix A of the Analysis of Alternatives.

Based on available information, SEAC considers that 12 years would only be needed in a worst-case scenario, in which :
1°) Alternative 4, which has already passed successfully the first tests and is very similar to the current formulation, would fail,
2°) For Alternative 3 testing and certification could only be started after Alternative 4 testing has been finished (concerns regarding the availability of testing facilities availability and testing costs were raised by the applicant),
3°) Alternative 3 tests and certification tasks would be run sequentially without apparent time optimisation.

Moreover, boron nitride based mixtures which SEAC was unable to assess as a potential alternative, have unfortunately not been included by the applicant in their analysis of alternatives.

Given the low RCRs for workers and the particular context of high safety and extensive testing requirements in the aerospace industry, SEAC considers that a short review period of e.g. four years would not be justified in this case.

In case of a new submission by the applicant, a review period of seven years would allow SEAC to assess the advancement of Alternative 3 and to assess whether the possible situation in which Alternative 3 fails tests has been anticipated by the applicant.

Given that the applicant provided consistent information that the alternative would be implemented in a period between five and 10 years, SEAC recommends a "normal" review period of **seven years**.