Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion on an Application for Authorisation for

Dibutyl phthalate (DBP)

for industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles

ECHA/RAC/SEAC: AFA-O-0000004249-70-12/D

Consolidated version

Date: 25 June 2014

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

for the following use:

Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles.

Intrinsic property referred to in Annex XIV:

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

Applicant

Roxel (UK Rocket Motors) Ltd

Reference number

11-0000000325-82-0001

Rapporteur, appointed by the RAC: **Christine Bjørge**
Co-rapporteur, appointed by the RAC: **Jose L. Tadeo**

Rapporteur, appointed by the SEAC: **Catheline Dantinne**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 12 August 2013 Roxel (UK Rocket Motors) Ltd submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **29 October 2013** 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/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.

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 **17 June 2014**.

On **25 June 2014** 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 **25 June 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 and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **25 June 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 **13 June 2014**.

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 RAC was adopted as final on **25 June 2014**.

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 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 of 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(s) to human health or the environment 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 of the review period has been suggested below.

Use

The authorisation is considered for the following use:

- Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles.

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 4 years.

JUSTIFICATIONS

Substance name:	Dibutyl phthalate (DBP)
Name of applicant(s):	Roxel (UK Rocket Motors) Ltd
Use name:	Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles.
Reference number:	11-0000000325-82-0001

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

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

Justification:

RAC established reference DNELs for 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 referred to and applied the reference DNELs proposed by RAC.

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

☒ YES

☐ NO

Justification:

The applicant describes one exposure scenario:

Use at industrial site – Industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles

The applicant describes the following steps for this exposure scenario:

ES1-WCS1 and WCS2 and WCS13:[1] Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

ES1-WCS3: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)

ES1-WCS4 and WCS7 and WCS14: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

ES1-WCS5 and WCS6 and WCS10 and WCS12 and WCS16 and WCS17: Use in batch and other process (synthesis) where opportunity for exposure arises

ES1-WCS8 and WCS9: Production of preparations or articles by tabletting, compression, extrusion, pelletisation

ES1-WCS11: Low energy manipulation of substances bound in materials and/or articles

ES1-WCS15: Use in closed batch process (synthesis or formulation)

ES1-WCS18: Use in closed, continuous process with occasional controlled exposure (e.g. sampling)

ES1-WCS19 and WCS20 and WCS22: High (mechanical) energy work-up of substances bound in materials and/or articles

ES1- WCS21 and WCS23 and WCS25: Low energy manipulation of substances bound in materials and/or articles

ES1-WCS24: Roller application or brushing

The situation described in which DBP is used may be characterized as a well controlled work-place. DBP is added to specific propellant formulations. The amount of DBP used annually for the manufacture of propellants and motor charges for rockets and tactical missiles is very low (< 0.01 tonnes per annum).

There is potential for combined exposure for workers across contributing scenarios 1 to 9. For the purpose of this risk assessment, RAC used the following exposure values:

Inhalation exposure:

0.0062 mg/m^3 - combined inhalation exposure for WCS 1 to 9

[1] 'WCS' denotes worker contributing scenario in the applicant's CSR.

Dermal exposure:

0.114 mg/kg bw/d - combined dermal exposure for WCS 1 to 9

Higher inhalation exposure was modelled for WCS20 and 22. It was the highest of all contributing scenarios: 0.02 mg/m^3. The highest dermal exposure was for WCS1 – 0.069 mg/kg bw/day, which is lower than the combined dermal exposure for WCS 1 to 9.

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

☒ YES

☐ NO

Justification:

For the purpose of this risk assessment, workers were considered as the only relevant population. The direct exposure of the general public and indirect exposure via the environment were considered negligible and were 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.

No monitoring data was available to support the conclusions on worker exposure made by modelling tools (ECETOC TRA Worker v3, Extended TRA and ART1.5).

There is potential for combined exposure for workers across WCS 1 to 9. The applicant calculated a Risk Characterisation Ratio (RCR) for these scenarios of 0.047 for exposure by inhalation and a RCR of 0.6 for dermal contact. The combined RCR for workers over these nine scenarios is thus 0.647.

For individual tasks, the highest combined (for inhalation and dermal exposure) RCR is 0.388 in WCS 1, with respectively inhalation and dermal RCRs of 0.361 and 0.027.

There is a potential for cumulative effects for workers from exposure to DBP and DEHP. Both DEHP and DBP are used in the propellant mixtures and workers may be exposed to both during an 8-hr shift. The RCR for combined exposure (inhalation and dermal) to DEHP from the industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles was 0.123 (combining WCS 1 to 8). The RCR for combined exposure (dermal and inhalation) to DBP from the industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles was 0.647 (over WCS 1to 9). The RCR for cumulative effects following exposure to both DEHP and DBP was 0.77 and adequate control for cumulative effect was therefore shown. According to the applicant, there is no potential for exposure to the same group of workers from activities under this use and Use 3 (Industrial use within a speciality paint in manufacture of motors for rockets and tactical missiles) of the same application. RAC concluded that for this specific use the health risk of DBP 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:

Based on the information provided in the application, it was not possible to draw any firm conclusions regarding the risks of any of the possible alternatives (four carboxylic acid esters). The applicant did not perform a detailed hazard, exposure and risk assessment for these alternatives; however, they noted that the carboxylic acid esters are “not classified for any hazard endpoint”. Due to the limited information included by the applicant, 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 in risk.

7.2 Are the alternatives technically and economically feasible for the applicant?

☐ YES

☒ NO

Justification:

The applicant compiled a list of possible alternatives based on specialist knowledge and outcome of various R&D programmes over the last 40-50 years. The applicant identified 4 possible alternatives based on known propellant additives with similar properties, the primary property being stability in mixtures with nitrocellulose and nitroglycerine. The four candidate substances to replace DBP (and DEHP) discussed in detail by the applicant are carboxylic acid esters. The substances are well-known

propellant or casting liquid ingredients with no adverse reaction with the two based energetic ingredients. Alternative 2 is already used by the applicant in a number of propellant formulations. According to the applicant, the technical feasibility of the alternatives can only be determined with the formal testing and requalification programme.

Technical feasibility

Based on the limited information provided on the four potential alternatives, it was not possible for SEAC to conclude whether any of them are already technically feasible. Thus, SEAC considered the technical feasibility of the alternatives based on information provided by the applicant for requalification requirements of propellants and motor charges. The applicant indicated that "*typically 5-10 years is required for development and qualification of a new rocket motor design, while production […] has an additional start up time requirement of 1 to 2 years*". Regarding the replacement of DBP in an already existing propellant, the applicant provided information on their replacement programme (including a requalification). If trials are successful, the applicant estimated that the reformulated, DBP-free powder and charge will be available in 2017. Thus, SEAC concluded that the four possible alternatives are currently not technically feasible alternatives for the applicant, as they would need to undergo requalification as per requirements in the defence industry.

Economic feasibility

The applicant provided an estimate of the DBP replacement programme. Some information on the pricing difference of some of the alternatives and DBP was also provided. The need for and cost of process modifications required to transition to the potential alternatives were not evaluated by the applicant. SEAC concluded that to transition to potential alternatives, the applicant would need to allocate additional financial resources for the requalification of the potential alternative. SEAC deemed that no further assessment of the economic feasibility of the alternatives was necessary in the light of the conclusions on their technical feasibility.

SEAC concluded that there are currently no suitable alternatives for the applicant on the basis that any potential substitutes to DBP in this use will need to meet requalification requirements for defence industry products.

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 described in general terms the technical characteristics required by potential alternatives in order to be deemed technically feasible as "substances that are stable in mixtures with nitrocellulose and nitroglycerine and are likely to have similar chemistry and functionality". A list of performance characteristics, without

specified acceptable ranges, is provided in section 2.2 of the Analysis of Alternatives (AoA). The applicant outlined the necessary legal/customer requirements for a suitable alternative to DBP in section 3.1 of the AoA report.

The applicant selected the four alternatives based on consolidated knowledge within Roxel and that, based on available information, are likely to have similar chemistry and functionality to DBP. No detailed information on the process for the identification of possible alternatives was provided by the applicant. The public consultation did not reveal additional potential alternatives. SEAC asked the applicant whether alternatives such as ethyl centralite or other diphenyl urea derivatives identified in literature were considered in their screening for possible alternatives. The applicant responded that due to the different functionalities of these substances, they are not a primary candidate for replacing DBP in these systems.

The brief analysis of the technical and economic feasibility of the alternatives presented by the applicant does not allow for an independent assessment of the suitability of the alternatives. Thus, SEAC concluded on the feasibility of the alternatives on the basis that the reformulated powder needs to undergo requalification prior to being placed on the market.

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

☐ YES

☐ NO

☒ NO SUITABLE ALTERNATIVES EXIST

Justification:
SEAC concluded that no suitable alternatives exist at the present stage.

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 were recommended by RAC.

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

10. Proposed review period:

☐ Normal (7 years)

☐ Long (12 years)

☒ Short (4 years)

☐ Other:

Justification for the suggested review period:

SEAC's starting point for determining the length of the review period was RAC's conclusion that adequate control is demonstrated (cumulative RCR for workers of 0.77).

SEAC considered plausible the applicant's claims that in the event of no authorisation minimum-smoke exhaust propellants would not be available to defence industry clients within the EU. This could have socio-economic implications for the applicant and its supply chain in the short term.

SEAC concluded that at a minimum the applicant would need to meet requalification requirements prior to placing a DBP-free propellant and charge on the market. The applicant's proposed replacement programme suggests that the reformulation could be commercially available in 2017 if no obstacles are encountered during testing and manufacture. The applicant did not clearly justify the necessity for a longer review period.