

Paris, 18 October 2021

COMMENTS ON THE CANDIDATE LIST PROPOSAL FOR DBMC

European Space Sector Contribution to the ECHA Public Consultation on the Annex XV SVHC report of 5 August 2021 submitted by Denmark for 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol (DBMC) (EC number 204-327-1, CAS number 119-47-1)¹

1. PREFACE

This is the joint contribution of the European Space Industry, represented by ASD-EUROSPACE – with the support of European Space Agency (ESA), national space agencies and the European Defence Agency (EDA) as observer – to the ECHA Public Consultation on the Candidate List proposal submitted by Denmark for 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol (hereafter also “DBMC” or “the Substance”).²

It has been prepared by the participants of the **Energetic Materials Working Group (EMWG)**³ in co-ordination with the ESCC MPTB.

We are aware that the current consultation focuses on the intrinsic SVHC properties of DBMC, which has a new legally binding harmonised classification as **Toxic for Reproduction Category 1B** in accordance with Article 57 (c) of Regulation (EC) No 1907/2006 (REACH). Nevertheless, comments on other aspects brought forward in this paper (uses, status of alternatives, impacts of candidate listing and a future Annex XIV or Annex XVII requirement) are not precluded and in our view should be taken into account by the regulators as appropriate - pursuant to the principles of proportionality, regulatory effectiveness and consistency - when deciding on the addition of the substance to the REACH Candidate List.

¹ Available at <https://echa.europa.eu/documents/10162/82ea38b6-0773-c27b-75cb-b8c2b0c53dfc>.

² Consultation page for the Substance: <https://echa.europa.eu/substances-of-very-high-concern-identification/-/substance-rev/66503/term>.

³ A list of EMWG participants can be found in Section 4. The EMWG was initiated by the Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB) in order to establish a broader regulatory monitoring and response frame and take the required actions to determine and mitigate possible regulatory obsolescence risks (mainly but not limited to EU REACH) for space propellants and explosives (Energetic Materials). The ESCC MPTB is a partnership between the European Space Agency (ESA), national space agencies, and space industry represented by ASD-EUROSPACE; it is chaired at present by ESA.

2. SPECIFIC COMMENTS ON PART II 'INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS'

PAGE 10 ET SEQQ. OF THE ANNEX XV REPORT – SECTION 9. INFORMATION ON USES OF THE SUBSTANCE

The Substance is registered under REACH at 1,000 to 10,000 t/y by three companies, while only two are producers. Their respective products are called VULKANOX BKF and LOWINOX 22M46.

For space applications, those products are used as an important **anti-oxidizer in solid propellants** (although in low mixture ratio), e.g. for the solid booster of the **Ariane 5** and **Ariane 6** launchers. There is an impact also for **VEGA** and **VEGA C** (first flight in 2022) propellants, interfaces (liners) and thermal protections. The use in energetic powder for pyro equipment (e.g. for orbital propulsion) is being investigated.

Specifically for **military applications**, DBMC is used e.g. in propellants, interfaces and thermal protection of military motors, in adhesives and sealants.

DBMC is one of only two anti-oxidizers on the world market today for space use. The other one is DBPC (2,6-di-tert-butyl-p-cresol; CAS no: 128-37-0; EC no: 204-881-4) which is under CoRAP assessment by France as a potential endocrine disruptor.

The main function of an anti-oxidizer is to avoid the destruction of the Hydroxyl-Terminated PolyButadiene (HTPB) “polymeric network”. The anti-oxidizer is thus crucial for the **stability** of HTPB composition.

EMWG participants were also surveyed on the **volumes per use** in preparation to this contribution. The available data cannot be fully aggregated on the sector level at this point. However, it can be said that Ariane and VEGA programmes are the main contributors to the total volume for the European Space Sector. Some (rough) estimates can also be provided: For Ariane 6, around 8 tonnes of DBMC per year are needed for solid rocket motors during its product life. For VEGA, the global volume is about 500 kg per year. Further information on the underlying assumptions is available upon request.

PAGE 14 OF THE ANNEX XV REPORT – SECTION 11.2 ALTERNATIVES

The drawback for substitution is, that it takes very long to substitute an anti-oxidizer because the product acts on the shelf life of the propellant. It would be necessary to realize ageing works which can last several years. Especially for military programmes the propellants should maintain their mechanical properties for a long time.

The Substance has been used for decades for high reliability applications in the European space industry. Risks are well known, managed and therefore considered as negligible. As indicated above, the volume of use is relatively low, but the value is very high. New

technologies in the space industry require maturity (Technology Readiness Level; TRL) and Heritage before they can be implemented in space vehicles. Given the absence of viable alternatives the Substance is still widely used in the industry today.

3. FURTHER COMMENTS ON THE ANNEX XV REPORT: FOLLOW-UP MEASURES

PAGE 15 OF THE ANNEX XV REPORT - 11.4 PREVIOUS ASSESSMENTS BY OTHER AUTHORITIES/ONGOING REGULATORY ACTIVITIES

We understand that the new harmonised classification of the Substance as Toxic for Reproduction Category 1B is the main rationale for the proposed identification as SVHC on the Candidate List. Follow-up measures under REACH post Candidate Listing, such as Annex XIV (authorisation) and/or Annex XVII (restrictions) **have not been evaluated in detail** in the Regulatory Management Option Analysis (RMOA) by Denmark.⁴ Instead, the RMOA only points out that it may be appropriate to update the **specific migration limit value** for a group of substances, which includes DBMC in the EU legislation, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into **contact with food**. Nevertheless, the *“RMOA concludes that it would be appropriate as a next regulatory risk management (RRM) step to identify DBMC as a Substance of Very High Concern (SVHC) according to REACH Article 57c, **and subsequently to include DBMC in Annex XIV of REACH.**”* The RMOA also reiterates that DBMC has many uses in different types of products, including several types of **consumer** products. The availability of **alternatives** has **not been assessed**.

Given the (very) limited assessments conducted by Denmark so far, focusing on follow-up measures under specific EU food contact materials regulation, we believe it is **premature** to consider any general regulatory follow-up measures under REACH at this point.

We would like to stress that Candidate listing and possible future Annex XIV (authorisation) or Annex XVII (restrictions) listing would further **exacerbate the commercial obsolescence risk** for the Substance in space applications without viable alternatives. The commercial obsolescence risk for the space industry as a niche sector is increasing, as the REACH authorisation process advances. Substitution efforts would have to be accelerated to mitigate the risk. This, in turn, is negatively affecting the industry’s competitiveness in a more competitive global space market. The impact would affect the entire complex EU space systems’ supply chain. For SME and laboratories, the financial and human investment would be even more important and critical. An even higher impact is expected in case the Substance would enter REACH Annex XIV, jeopardising Europe’s independent access to space as a key point of the EU’s Space Policy.

⁴ The RMOA conclusion document by Denmark of 14 June 2021 is available at <https://echa.europa.eu/documents/10162/38e8164d-0337-856d-dd47-145d19a7a67c>.

According to the Danish RMOA **“EU-wide risk has not been proven”**. Therefore, there is no sufficient information today to initiate a restriction under REACH Article 69(1). If a restriction should be justified beyond existing legislation and pursued for the Substance in the future, it should be tailored with a **suitable derogation for essential space applications**.

4. LIST OF EMWG PARTICIPANTS

This contribution has been prepared by REACHLaw Ltd. in the frame of the Energetic Materials Working Group (EMWG), following collection of relevant use-related information from the EMWG participants and consultation of the MPTB at large. It reflects the best knowledge available from experts in their field, thanks in particular to the support of ASD-EUROSPACE,

the following corporations also represented in the MPTB:

AIRBUS DEFENCE AND SPACE

ARIANEGROUP

AVIO

RUAG SPACE

THALES ALENIA SPACE

key EU suppliers of energetic materials also part of the EMWG:

DASSAULT AVIATION

EVONIK

JAKUSZ – SPACETECH

NAMMO

PYROALLIANCE

the EUROPEAN SPACE AGENCY (ESA) and the following national space agencies:

AGENZIA SPAZIALE ITALIANA (ASI)

CENTRE NATIONAL D’ETUDES SPATIALES (CNES)

GERMAN AEROSPACE CENTER (DLR)

and the EUROPEAN DEFENCE AGENCY as an observer.

Further information about the EMWG is available on the ASD-EUROSPACE website, including News Alerts of 28 September 2020 ([link](#)) and 23 February 2021 ([link](#)).