EUROPEAN CHEMICALS AGENCY

Helsinki, 10 June 2016

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For Shale Oil Bitumen, CAS No N/A (EC No 447-780-2)

Addressees: Registrant(s)[1] of Shale Oil Bitumen (Registrant(s))

This decision is addressed to the Registrant(s) of the above substance with active registrations pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by Health Board as the Competent Authority of Estonia (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 15 October 2012, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Estonia has initiated substance evaluation for Shale Oil Bitumen, CAS No N/A (EC No 447-780-2) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to possible CMR and PBT/vPvB properties and Exposure to workers and to environment, Shale Oil Bitumen was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of Estonia was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA identified an additional concern regarding the identification of the substance.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 26 March 2015.

On 4 May 2015 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant commenting phase

By 10 June 2015 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the comments received from the Registrant(s). On basis of this information, the draft decision was amended in sections I, II and III accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 3 March 2016 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Neither Competent Authorities of the Member States nor ECHA proposed amendments to the draft decision and ECHA took the decision pursuant to Articles 52(2) and 51(3) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information for the registered substance:

- Detailed information on the composition of the registered substance and its fume, as specified further in Section III.

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **17 April 2017** an update of the registration(s) containing the information required by this decision, and, where relevant, an update of the read-across justification and Chemical Safety Report, including exposure and PBT assessment.

This deadline is proposed taking into account the Registrant(s)' comments on the capacity of the laboratories to perform the required analytical studies and the timing difficulties for performing updates.

Depending on the assessment of the requested data above, the evaluating Member State may consider proposing to request further information related to the identified concerns.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on Shale Oil Bitumen and other relevant and available information, it is concluded that further information is required in order to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

Detailed information on the composition of the registered substance and its fume.

Establishing the concern
After thorough analysis of the submitted information it is concluded that clarification on the composition of the substance and its fume is required in order to further assess toxicological endpoints as well as exposure, and to conclude on the potential PBT properties of the substance.

The composition of the registered substance and its fume is essential to clarify the CMR concern and the plausibility of read-across approach because the substance subject to this decision as well as the analogue substances may have significant variations in the compositions as well as in the intrinsic properties. Additionally, the detailed description of the substance identity is the precondition for further assessment of PBT properties and exposure.

Justification why new information is needed
The information in the registration dossier provides a very generic description of the substance identity as being a complex [redacted]. This information is supported with the spectral data as IR, NMR and UV spectra as required by REACH Regulation. Also the NMR spectral data on volatiles of the registered substance is available. However, no specific quantitative data on the composition has been provided for the substance. Therefore, the available analytical data does not allow more specific description of the composition and the concentrations, neither at constituents nor at hydrocarbon classes' level.

In general bitumens and their fumes have chemically complex composition. Temperature clearly affects both the volume and the chemical constituents of the fume (Kriech et al. 2007; Cavallari et al. 2012) and as a result may influence both the intrinsic properties of the substance as well its fume. Human health risks can be expected to arise from inhaling the substance fumes and from the dermal exposure to the fume/fume condensate since the main uses of Shale Oil Bitumen foresee heating of the substance and include exposure at industrial as well as professional level; bystander exposure cannot be excluded. Data for carcinogenicity and reproductive toxicity endpoints (Fuhst et al. 2007; Freeman at al. 2011; Parker at al. 2011) provided in the dossiers is based on the experiments conducted with petroleum derived bitumen fume/fume condensate and the results seem to depend largely on the composition of the tested material. Additionally, as discussed in the registration dossier for the registered substance, available data on the mutagenic potential of fumes within read-across substances reveal contradictory test results showing both positive and negative outcomes.

Regardless that the carcinogenic/mutagenic potential of bitumens is generally associated with the content of PAHs, the identification of all known constituents, especially constituents of toxicological relevance of the substance and its fume, is crucial for the evaluation of the intrinsic properties as well as the read-across plausibility. The Registrant(s) stated that the similarity between the composition of the fumes derived from the petroleum bitumens and Shale Oil Bitumen enables the use of read-across. The Registrant(s) submitted justification for read-across concept in the supporting document "Expert report concerning possible post base set testing" included in the registration dossier. However, the read-across approach contains deficiencies and uncertainties. Only generic information, including the description of manufacturing process and the composition of the substance subject to this decision, is considered in the expert document in comparison with the read-across substances. There are also differences in the physical-chemical (e.g. melting point) properties and the toxicity (e.g. skin sensitisation, subacute toxicity, mutagenic potential) (see Table 1) between Shale Oil Bitumen and bitumens that could be attributed to the discrepancies in the composition of the substances. Thus, it is not possible to conclude on the appropriateness of the applied read-across and assess whether the taken approach would not lead to an underestimation of hazards.

Table 1. Summary of toxicity data for bitumens

Test	Shale Oil Bitumen	Bitumens (CAS no 8052-42-4; 64742-93-4)
Melting range	23-37°C	
Vapour pressure	0.003 Pa at 25°C	
Water solubility	<1.15 mg/L at 20°C	
Skin sensitisation	Positive (LLNA)	
Sub acute toxicity	LOAEL at lowest dose tested: 15 mg/kg bw/d (rat; oral)	
Bacterial assay	Negative with and without activation (DMSO)	
Mutagenicity – in vitro mammalian cytogenetics in human lymphocytes	Negative with and without activation (Acetone)	
Mutagenicity – In vitro point mutation in mammalian	Negative with and without activation (DMSO)	

Mutagenicity – In vitro micronucleus test		[redacted]
Mutagenicity – In vitro		
Mutagenicity – in vivo micronucleus following intratracheal administration of condensate to mouse		
Mutagenicity – In vivo cytogenetics in rat		
Mutagenicity – In vivo mouse skin and DNA from skin and lung investigated using 32P post labelling		

With regards to the PBT properties, the assessment has not been possible due to the lack of detailed information on the composition of the substance and there is an uncertainty whether the substance satisfies the PBT criteria. The registered substance is considered toxic and meets the P-screening criterion. No experimental data on bioaccumulation is available since the substance is very complex and it consists of a number of different constituents which are not chemically well defined (UVCB). Taking into account the Pow value and predicted BCF value the substance may also have bioaccumulation potential. Therefore, it is important to clarify the possible PBT/vPvB properties of the registered substance based on its detailed chemical composition.

The level of exposure of the affected individuals and/or of the environmental compartments has been in most part modelled and the current approaches taken in the course of the exposure assessment might present underestimations and conceal actual risks. Substance identity is the prerequisite for high quality risk assessment. Currently, the actual composition of the substance is not known in detail and the requested information must be taken into account during further refinement of the exposure assessment.

Therefore, a concern based approach must be taken by the Registrant(s) to identify the substance and its fume in order to further assess the intrinsic properties of the substance, the read-across applicability and the exposure.

What is the request
The Registrant(s) shall provide an adequate and detailed information on the composition of the registered substance and substance fume applying the best available analytical methods.

Considering the variable composition of the registered substance, initially, five batch analysis was requested for identification purposes of the substance. However, the Registrant(s) indicated in their comments that the costs for analysing five batches are considerable and takes long time and proposed to test three batches instead of five because it gives the same overview and statistical data about the substance. Therefore, in identifying the substance and its fume three batch analysis is requested for each. The Registrant(s) must ensure that the analysed batches are representative of all grades of the registered substance.
In particular, given the intrinsic compositional variability of the test substance, information

as specified below has to be provided:

- Detailed information on the composition of the Shale Oil Bitumen and its fume generated at temperature 200°C.
  This must include information on the "major hydrocarbon classes" of the substance (e.g. saturated hydrocarbons, mono/di/tri and higher aromatic hydrocarbons, resins, asphaltenes); the identity (including all relevant identifiers), the typical concentration and the concentration ranges of all known constituents of the substance and its fume. Specifically constituents of toxicological relevance (fulfilling the classification criteria as CMR in CLP annex VI, are in the candidate list or in Annex XVII of REACH Regulation, e.g. certain Polycyclic Aromatic Hydrocarbons) within the achievable limit of quantification must be identified and the sum of typical concentrations of all determined constituents must be close to 100%.
- The molecular weight range (g/mol) and carbon number distribution as well as the elemental analysis (heteroatoms such as oxygen, nitrogen and sulphur; additionally metals, e.g. nickel, iron, vanadium) of the substance.
- Detailed description of the manufacturing process which justifies the composition of the substance.

It is considered that submitting this information is a minimum condition for the ultimate compliance of the read-across approach with the requirements set out in the section 1.5 of REACH Annex XI to be able to conclude on the toxicological endpoints. On the grounds of the substance identification information the Registrant(s) shall refine exposure and PBT assessment according to available guidance.

The substance identification according to Annex VI of REACH Regulation is a basic requirement for the evaluation of the substance properties. The outcome of the evaluation of the submitted information may trigger further information requests that will be addressed in future decision(s).

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out analytical studies for the registered substance subject to this decision and its fume using best available analytical methods to determine detailed composition of the substance and its fume generated at temperature of 200°C. Also the molecular weight range (g/mol), the elemental analysis and carbon number distribution for the substance shall be determined. Detailed description of the manufacturing process which justifies the composition of the substance shall be presented.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[13] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

[13] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

References

Cavallari J.M. et al. (2012). Temperature-dependent emission of PAH in paving and built-up roofing asphalts. Ann. Occup. Hyg., Vol. 56, No. 2, pp. 148–160 (Oxford University Press on behalf of the British Occupational Hygiene Society).

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