~~CONFIDENTIAL~~

European Chemicals Agency

Helsinki, 14 April 2011

Decision number CCH-D-0000001372-82-03/F

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For BMS296796-02 [redacted] **EC No. 445-910-2, Registration Number:** [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation, ECHA has performed a compliance check of the registration dossier for **BMS296796-02,** [redacted] **, EC No. 445-910-2** submitted by [redacted] (the "Registrant"), latest submission number [redacted], for [redacted]

The Registrant had notified the substance pursuant to the national legislation implementing Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances (as amended) by submitting a notification to the Portuguese competent authority in accordance with Article 7 of Directive 67/548/EEC. The notification number allocated was [redacted]

The Registrant has subsequently claimed a registration number under the REACH Regulation and updated the registration dossier to correspond to the tonnage level [redacted]

The compliance check was initiated on **27 May 2010**.

The draft decision was sent to the Registrant for comments on 29 September 2010.

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By 30 October 2010, ECHA did not receive any comments on the draft decision from the Registrant.

On 7 January 2011 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

By 7 February 2011 ECHA did not receive any proposals for amendments from the Competent Authorities of the Member States.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

II. Information required

Pursuant to Articles 41(1)(a), 41(3), 3(29), 10(a)(vi), 12(1)(a)-(b) and 24(2), as well as Annex VII of the REACH Regulation, the Registrant shall submit the information using the recommended test method as indicated on

- Relative density (Annex VII, 7.4.; recommended test method is A.3. of Regulation (EC) No 440/2008)
- Vapour pressure (Annex VII, 7.5.; recommended test method is A.4. of Regulation (EC) No 440/2008)
- Surface tension (Annex VII, 7.6.; recommended test method is A.5. of Regulation (EC) No 440/2008)
- Explosive properties (Annex VII, 7.11.; recommended test method is A.14. of Regulation (EC) No 440/2008)
- Self-ignition temperature (Annex VII, 7.12.; recommended test method is A.16. of Regulation (EC) No 440/2008)
- Oxidising properties (Annex VII, 7.13.; recommended test method is A.17. of Regulation (EC) No 440/2008)
- Granulometry (Annex VII, 7.14.; recommended test method is OECD Guideline 110)
- Short-term toxicity testing on invertebrates (Annex VII, 9.1.1.; recommended test method is C.2.of Regulation (EC) No 440/2008)
- Growth inhibition study aquatic plants (Annex VII, 9.1.2.; recommended test method is C.3. of Regulation (EC) No 440/2008)
- Skin sensitisation (Annex VII, 8.3): Full study summary, including IUCLID sections 'administrative data', 'data source' with 'reference information' and 'data access' and 'test materials' used. In addition, the Registrant shall provide justification for the low substance concentrations tested (max. 10%); and
- Mutagenicity (Annex VII, 8.4.): Full study summary, including IUCLID sections 'administrative data', 'data source' with 'reference information' and 'data access' and 'test materials' used.

Pursuant to Article 41(4) of the REACH Regulation, the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by 16 April 2012.

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III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance in accordance with **Article 6** of the REACH Regulation, does not comply with the requirements of **Articles 3(29), 10, 12 and 24(2) and/or with Annex VII** thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Articles 10(a)(vi), 12(1)(a) and (b) of the REACH Regulation, a registration for a substance produced in quantities of [redacted] per year shall contain as a minimum the information specified in Annex VII of the REACH Regulation.

Pursuant to Article 24(2) of the REACH Regulation, if the quantity of a substance notified under national legislation implementing Directive 67/548/EEC (in this case Portuguese legislation) reaches the next tonnage threshold, the additional required information corresponding to that tonnage threshold, as well as, to all the lower tonnage thresholds, shall be submitted in accordance with Article 10 and 12 of the REACH Regulation.
For detailed guidance on how to update your dossier, we invite you to consult the following manual:

Questions and Answers for the registrants of previously notified substances (release 5) (http://echa.europa.eu/doc/reachit/prev_not_sub_registrants_qa.pdf)

a. The technical dossier contained "data waivers" for the endpoints on:

- Vapour pressure (Annex VII, 7.5.)
- Relative density (Annex VII, 7.4.)
- Surface tension (Annex VII, 7.6.)
- Explosive properties (Annex VII, 7.11.)
- Self-ignition temperature (Annex VII, 7.12.)
- Oxidising properties (Annex VII, 7.13.)
- Granulometry (Annex VII, 7.14.)
- Short-term toxicity testing on invertebrates (Annex VII, 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, 9.1.2.)

ECHA notes that the presented adaptations to the standard testing regime ("data waivers") are based on missing request by the relevant MSCA under Directive 67/548/EEC and by ECHA and are not based on the specific rules for adaptation, contained in respective Column 2 of Annex VII or Annex XI to the REACH Regulation, according to which the required standard information may be omitted. Therefore, the "waiving" suggested by the Registrant cannot be accepted.

The Registrant is accordingly requested to submit the information for those endpoints performed with the registered substance. ECHA recommends the use of the test methods indicated under Section II above.

b. Missing information related to the study summaries

According to Article 3(29) of the REACH Regulation, **a study summary** means "a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study".

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For the endpoints listed below the data on test conditions, protocol deviations and/or conclusions were not sufficient to make an assessment of the relevance of the study and thus did not meet the requirements of a study summary within the meaning of Article 3(29).

- Skin Sensitisation (Annex VII, 8.3)

Section 7.4.1 of the IUCLID dossier suggests to omit the standard information requirement for "Skin sensitisation" with the following justification: "This information was neither submitted in the previous notification, nor required or requested by the MSCA under Directive 67/548/EEC, nor requested by ECHA." However, the endpoint study record on "Skin sensitisation" has been provided in Section 7.9.3 of the IUCLID dossier under "Specific investigations".

ECHA points out that the adaptation presented by the Registrant is not based on the specific rules for adaptation, contained in Column 2 of Annex VII, 8.3, or Annex XI. Therefore, it is not acceptable.

With regard to the endpoint study record on "Skin sensitisation" provided by the Registrant, ECHA observes that the information under the IUCLID sections 'administrative data', 'data source' with 'reference information' and 'data access' as well as 'test materials' identity were not provided.

Moreover, the doses selected in the study were very low (0.1 to 10%) and the range finding study has not been reported. ECHA refers to Annex VII, 8.3, according to which the Murine Local Lumph Node Assay (LLNA) is the first choice method for *in vivo* testing. According to the LLNA guideline, the doses should be selected as the highest soluble concentration that does no cause systemic toxicity or excessive skin irritation.

For detailed guidance on the conduct and interpretation of the LLNA test protocol, we invite you to consult the following manual:

> Guidance on information requirements and chemical safety assessment. Volume 4: Endpoint Specific Guidance for physico-chemical properties and human health (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r7a_en.pdf?vers=02_02_10)

The Registrant is accordingly required to fill in the endpoint study record in Section 7.4.1 of the IUCLID dossier for the "Skin sensitisation" endpoint, provide the missing 'administrative data', 'data source' with 'reference information' and 'data access' and 'test materials' used as well as to provide justification for the low substance concentrations tested (max. 10%).

- Mutagenicity (Annex VII, 8.4)

Regarding the endpoint for mutagenicity (Annex VII, 8.4), ECHA observes that the IUCLID sections 'administrative data', 'the data source' with 'reference information' and 'data access' and 'test materials' are not provided in section 7.6.1 of the IUCLID dossier.

The Registrant is accordingly required to submit the above missing information on the endpoint for mutagenicity (Annex VII, 8.4) performed with the registered substance.

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IV. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

> "*Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.*"

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 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 ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Done at Helsinki,

[redacted]

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