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For final decision: TPE-D-0000001392-80-03/F Helsinki, 12 April 2011

DECISION ON TESTING PROPOSALS SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For C8-C26 branched and linear hydrocarbons – Distillates *(GTL Diesel)*, CAS [redacted] (EC No 481-740-5), 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 (REACH Regulation).

I. Procedure

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined testing proposals set out in the registration dossier for ***C8-C26 branched and linear hydrocarbons – Distillates (GTL DIESEL), CAS [redacted] (EC NO 481-740-5)*** submitted by [redacted] (the "Registrant"), latest submission number [redacted] for [redacted]

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annexes IX and X:

(a) Annex IX, 7.17 Viscosity according to OECD Guideline 114 (Viscosity of Liquids);
(b) Annex IX, 9.2.1.3 Biodegradation in soil according to OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil);
(c) Annex IX, 9.3.2 Bioaccumulation in aquatic species according to OECD Guideline 305 (Bioconcentration: Flow-through Fish test); proposed test material: individual constituent C13 to C14 range;

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(d) Annex X, 9.5.1 Sediment toxicity according to OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment) and OECD guideline 225 (Sediment-Water Lumbriculus Toxicity Test using Spiked Sediment);
(e) Annex IX, 9.4.1 Toxicity to soil macro-organisms except arthropods according to OECD Guideline 222 (Earthworm Reproduction Test);
(f) Annex IX, 9.4.2 Toxicity to soil microorganisms according to OECD Guideline 216 (Soil microorganisms: Nitrogen Transformation Test);
(g) Annex IX, 8.7.3 Toxicity to reproduction according to OECD Guideline 416 (Two-generation Reproductive Toxicity Test).

The examination of testing proposals was initiated on 19 January 2010. ECHA held a public consultation for the testing proposal for bioaccumulation in aquatic species from 11 May 2010 until 25 June 2010. ECHA received two comments covering separate reports (see the attached document on third party information).

The following information that addresses the endpoint bioaccumulation in aquatic species was received:

1. Molcode ([redacted]), 2010. JRC QSAR Model Inventory Data Base (Ref Q8-10-14-2007);
2. ECEAE ([redacted]). 2010. Comments on 'Testing proposals involving vertebrate animals: requests for information from third parties.'

On 16 July 2010 ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

On 12 August 2010 the Registrant provided to ECHA comments on the draft decision. The Registrant indicated that conducting a bioaccumulation test in aquatic species according to OECD Guideline 305 (Bioconcentration: Flow-through Fish test) or Fish Dietary Accumulation test on synthesized radiolabelled alkane(s) in a range C13 to C14 fulfils the data requirement for REACH Annex IX 9.3.2 bioaccumulation in aquatic species and addresses the concern of bioaccumulation potential of GTL Diesel constituents. Based on the information provided by the Registrant ECHA did not amend the draft decision.

On 29 October 2010 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. Subsequently, Competent Authorities of the Member States submitted comments and proposals for amendment on the draft decision.

ECHA has reviewed the proposals for amendment of the Member State Competent Authorities and has amended the draft decision.

On 1 December 2010 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposed amendments within 30 days of the receipt of the notification.

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On 13 December 2010 ECHA referred the draft decision to the Member State Committee pursuant to Article 51(4) of the REACH Regulation.

On 22 December the Registrant sent a letter via REACH-IT asking ECHA to extend the timeline for commenting by a further two weeks (14th January 2011) as they have been granted access to new information from [redacted] and the detailed analysis of the new data could not be performed in time. On 14 of January 2011, the Registrant provided comments that did not address the proposed amendments but other issues.

The Member State Committee took the comments of the registrant into account. After discussion in the Member State Committee meeting on 1-3 February 2011, the amended draft decision was modified by the Member State Committee and a unanimous agreement of the Member State Committee on the amended and modified draft decision was reached on 3 February 2011.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following tests:

(a) Annex IX, 7.17 Viscosity (OECD Guideline 114 (Viscosity of Liquids));
(b) Annex IX, 9.2.1.3 Biodegradation in soil (EU test method C.23 of Regulation (EC) No 440/2008; OECD test guideline 307 (Aerobic and Anaerobic Transformation in Soil)). Due to potential technical challenges of testing UVCB components in this method the registrant shall determine before initiating the testing:
    i. Whether the whole complex test substance being unknown, of variable composition, or of biological origin (UVCB) or specific constituents should be tested;
    ii. How results for the degradation pathway and/or the kinetic part of the simulation degradation test should be used for informing possible subsequent testing of bioaccumulation.
(c) Annex X, 9.5.1 Sediment toxicity (OECD test guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment) and OECD test guideline 225 (Sediment-Water Lumbriculus Toxicity Test using Spiked Sediment));
(d) Annex IX, 9.4.1 Toxicity to soil macro-organisms except arthropods (OECD test guideline 222 (Earthworm Reproduction Test));
(e) Annex IX, 9.4.2 Toxicity to soil micro-organisms (EU test method C.21 of Regulation (EC) No 440/2008; OECD test guideline 216 (Soil micro-organisms: Nitrogen Transformation Test)).

The Registrant shall carry out one of the following tests on relevant constituents and/or degradation/transformation products of the substance:

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Either

(f) pursuant to Article 40(3)(a) and (b) of the REACH Regulation under modified conditions depending on the outcome of the biodegradation testing in soil Annex IX, 9.3.2 Bioaccumulation in aquatic species (OECD Guideline 305 (Bioconcentration: Flow-through Fish test));

or

g) pursuant to Article 40(3)(c) and (d) of the REACH Regulation depending on the necessity to modify the exposure conditions of the bioaccumulation test Annex IX, 9.3.2 Bioaccumulation in aquatic species (Method such as Fish Dietary Accumulation test) while the originally proposed OECD Guideline 305 test (Bioconcentration: Flow-through Fish test) is rejected.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by 3 years from the date of the decision an update of the registration containing the information required by this decision.

III. Statement of reasons

a) Tests (a), (b), (c), (d), (e) referred to in Section II

The decision of ECHA is based on the examination of the testing proposals of the Registrant for the registered substance. The proposed tests (a) to (e) referred to in Section II above are part of the information requirements as laid down in Annex IX and X of the REACH Regulation. As the information on these endpoints is not available for the registered substance but need to be present in the technical dossier to meet the information requirements it is necessary to generate the data and to perform the tests.

Test (b) referred to in Section II

The method described in EU test method C.23 (Aerobic and Anaerobic Transformation in Soil) is designed to determine the rate of transformation of the test substance, and the nature and rates of formation and decline of transformation products to which plants and soil organisms may be exposed. Therefore, measuring total hydrocarbons as suggested by the registrant is not considered to describe the degradation of the registered UVCB substance in necessary detail that is needed for further bioaccumulation testing. The registrant should therefore apply the most suitable analytical technique to quantify to the extent possible those constituents and relevant transformation/degradation products that are present or being generated in individual amounts ≥ 0.1 % (w/w). This is in line with the threshold triggering a chemical safety assessment for substances in mixtures meeting PBT or vPvB criteria (Article 14(2)(f) and Annex XIII of the REACH Regulation).

In case quantification of degradation products of the UVCB substance would be demonstrated to be technically impossible, the registrant should consider to perform relevant degradation testing of particular hydrocarbon blocks and/or individual components (linear and branched) which could be identified for instance based on (Q)SAR model predictions and other relevant available non test information. Focus

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should be on relevant constituents most likely meeting both the PBT and vPvB criteria as specified in Annex XIII.

If testing by use of the soil biodegradation simulation test method is found to be unfeasible, justified alternative simulation type of degradation testing should be performed.

b) Test (f) referred to in Section II

ECHA has examined the scientific information submitted by the third parties on bioaccumulation in aquatic species, as follows:

The information submitted by the third parties on the substance *C8-C26 branched and linear hydrocarbons – Distillates (GTL DIESEL)* do not provide specific information to fulfil the information requirements of the REACH Regulation at this tonnage level related to vertebrate testing (i.e. data on bioaccumulation in aquatic species (Annex IX, 9.3.2).

Both comments suggest using qualitative or quantitative structure-activity relationship models ((Q)SARs) for aquatic bioaccumulation. Additionally comment 2 of ECEAE suggests using combined data from QSAR models with other existing data (e.g. invertebrate tests, field monitoring studies, mammalian studies, in vitro tests) in a Weight of Evidence approach. In the present case ECHA concludes that the submitted comments did not contain information that would be relevant for not performing the study on bioaccumulation as the submitted dossier already contains the results of QSAR modelling on bioaccumulation in aquatic species from which the registrants concludes that further testing on bioaccumulation is necessary in order to confirm or reject the PBT status for a certain range of the registered UVCB substance; also tests in invertebrates were not considered to give sufficiently comprehensive and reliable results.

The proposed test (f) concerning bioaccumulation in aquatic species referred to in Section II above is part of the information requirements as laid down in Annex IX, 9.3.2 of the REACH Regulation. As the information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements it is in principle necessary to generate the data and to perform the tests. The additional information received in the public consultation did not contain elements that would allow a deviating decision.

Modifications of the conditions under which the test is to be carried out

However, based on Article 40(3)(b) of the REACH Regulation, the proposed test as such shall be modified: the Registrant shall consider taking into account the results of the biodegradation testing in soil that has been requested to test above in section II (b) (Annex IX, 9.2.1.3 of the REACH Regulation) before starting the bioaccumulation test in order to justify the identification of the relevant constituents and/or transformation/degradation products meeting the P or vP criteria as specified in Annex XIII to be tested for bioaccumulation. As a general principle of the PBT assessment of a substance, the potential for persistence should be clarified first. The registrant has proposed to perform the test on the specific constituents in the C13 to C14 range; nevertheless, the outcome of the biodegradation testing shall be assessed first to be

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able with enough certainty to justify the reasons why a representative (group of) constituent(s) was/were used in the bioaccumulation testing.

Moreover, depending on the relevant constituents and/or transformation/degradation products which will be identified for testing, the registrant shall consider modifying the exposure conditions of the bioaccumulation test. More specifically, the registrant shall consider performing the Fish Dietary Accumulation test (specified in REACH guidance on information requirements and chemical safety assessment Chapter R.7.10.3.1) instead of the OECD test guideline 305 Bioconcentration: Flow-through Fish test to cover the REACH requirement in Annex IX 9.3.2. The REACH guidance is recommending the Fish Dietary Accumulation test Study for certain types of substances due to their specific physical chemical properties (e.g. low water solubility, high log Kow value). For substances with log Kow >6 a dietary study as a replacement to estimate BCF is recommended. Before making final decision on which type of bioaccumulation test to perform the registrant should consider the relative feasibility and uncertainties for the BCF determination by employment of either type of test. If on that basis the Fish Dietary Accumulation test is found to be the most appropriate way to fulfil the information requirement for bioaccumulation, this test shall be performed in accordance with Article 40(3)(c) and (d) of the REACH Regulation. Consequently, the proposed bioaccumulation test to cover Annex IX, 9.3.2 of the REACH Regulation would be rejected and replaced by the Fish Dietary Accumulation test.

c) Two-generation Reproductive Toxicity Test

The Registrant claims that the two-generation reproductive toxicity test is already ongoing for Chinese regulatory purposes. Because of that reason, the current proposal for testing cannot be regarded as a formal testing proposal under Article 40 of the REACH Regulation. Within the legislative framework of the REACH Regulation a test can only be proposed by a registrant and ECHA can only take a decision on the proposed test where no testing has been carried out yet. Otherwise, the different options to decide on a testing proposal would not be available in full and the aim of the testing proposal examination to approve tests on Annex IX and X level of the REACH Regulation prior to performing testing could not be achieved. The Registrant is reminded to update the dossier after finalising the test with relevant test results bearing in mind the general requirements for the generation of information mentioned and Good Laboratory Practice in Section IV of this decision.

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

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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 1907/2008 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 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://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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