ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 6 June 2012

Final decision: CCH-D-0000002397-69-02/F

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

For dichloro(dimethyl)silane, CAS No 75-78-5 (EC No 200-901-0), 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 dichloro(dimethyl)silane, CAS No 75-78-5 (EC No 200-901-0) submitted by [redacted] (the "Registrant"), latest submission number [redacted], for 1000 or more tonnes per year.

The compliance check was initiated on 26 November 2010.

On 22 August 2011 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. The draft decision referred to submission number [redacted]

On 20 September 2011 the Registrant provided to ECHA comments on the draft decision and subsequently updated the registration dossier on 25 November 2011 (submission number [redacted]).

ECHA reviewed the further information received and amended the draft decision accordingly.

On 20 January 2012 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 proposals for amendment to the draft decision. ECHA reviewed the proposals for amendment received and decided not to modify the draft decision.

On 23 February 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments within 30 days of the receipt of the notification.

On 5 March ECHA referred the draft decision to the Member State Committee.

On 26 March 2012 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 24-27 April 2012, the Member State Committee modified the draft decision and a unanimous agreement of the Member State Committee on the draft decision was reached on 27 April 2012.

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

II. Information required

1) Pursuant to Articles 41(1)(a) and (b), 10(a)(vii) as well as Annex IX of the REACH Regulation, the Registrant shall submit the following information using the indicated test method:

    a) A sub-chronic repeated dose toxicity study (90-day) with the registered substance, dichloro(dimethyl)silane (Annex IX, 8.6.2. of the REACH Regulation), in the rat, by inhalation route, test method B.29 according to Commission Regulation (EC) No 440/2008 or OECD 413. The conduct of the study shall follow a stepwise approach consisting of three steps and shall be conditional on the results obtained in these steps as described in section III.1(a);
    b) A pre-natal developmental toxicity study with dimethylsilanediol, the relevant hydrolysis product of the registered substance, (Annex IX, 8.7.2. of the REACH Regulation), in the rat, by the oral route, test method B.31 according to Commission Regulation (EC) No 440/2008 or OECD 414.

2) Pursuant to 41(1)(c), 10(b) and 14(1) and (4), as well as Annex I of the REACH Regulation, the Registrant shall submit the following information in the form of an updated Chemical Safety Report:

    a) Exposure assessment and risk characterisation for humans liable to exposure indirectly via the environment, including all relevant routes and taking into account transformation and/or degradation products (Article 14(4) and Annex I, 5.2.4):

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 **6 June 2014**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage. Particularly, ECHA may need to re-assess the need to request a two generation reproductive toxicity study and/or a developmental toxicity study on a second species, in light of the findings of the sub-chronic and pre-natal

developmental toxicity studies. The Registrant may anyway come to the conclusion that further studies on reproductive toxicity are necessary and submit testing proposals accordingly.

III. Statement of reasons

Pursuant to Articles 10(a)(vii) and 12(1)(e) of the REACH Regulation, a registration for a substance produced in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X.

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 10, 12 and 14 and with Annexes I and IX 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.

1) Missing information related to endpoints

   a. Sub-chronic repeated dose toxicity study (90-day) (Annex IX, 8.6.2. of the REACH Regulation)

The REACH Regulation (Annex IX, 8.7.2) requires a Sub-chronic repeated dose toxicity study (90-day). Instead, the Registrant submitted the results of a combined 28-day repeated dose toxicity study with screening for reproduction toxicity via the oral route with dimethylsilanediol, one of the hydrolysis products of the registered substance. The Registrant is justifying the adaptation to the standard information requirements by stating that "*In accordance with Section 3 of REACH Annex XI, a 90-day repeated dose toxicity test (required in Section 8.6.2) does not need to be conducted on the grounds of exposure-based considerations. A full exposure assessment and risk characterisation have been carried out in accordance with REACH guidance, as documented in the Chemical Safety Report and supporting documents. The substance is extremely reactive and is handled under highly controlled conditions at industrial locations. It is fully consumed during use and there is no potential for exposure to the general public either from direct use or from residual unreacted substance in end products. Using a conservative approach to exposure estimation and Derived No Effect Levels (based on data available for the hydrolysis products of dichloro(dimethyl)silane and a related substance), all risk characterisation ratios are below 1.*" Indeed, in the risk characterisation for long-term effects, the Registrant used a DNEL-value derived from the 28-day study for the sub-chronic endpoint. From the above explanation it is evident that Registrant is claiming Annex XI 3.2.(a) as basis for adaptation of standard information requirements.

However, in order for substance-tailored exposure-driven testing to apply (Annex XI, section 3), all of the conditions set in Annex XI, 3.2(a) need to be fulfilled, which is not the case here. Firstly, condition (i) requires that the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses. This condition has not been fulfilled by the Registrant, as there is a mention of low levels of exposure on a repeated basis as the typical pattern of worker exposure in the Chemical Safety Report (page 49), whilst all intended uses are industrial. Secondly, condition (ii) is not fulfilled, as the footnote to Annex XI, 3.2(a) states "*For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of*

section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study" and the Registrant used a DNEL-value derived from the 28 day study for the subchronic endpoint.

On these grounds, the adaptation of the standard information requirement cannot be accepted. The Registrant is accordingly requested to submit the missing information on sub-chronic repeated dose toxicity (90 days) performed with the registered substance, in the rat, inhalation route. The recommended test method is method B.29 according to Commission Regulation (EC) No 440/2008 or OECD 413. The registered substance hydrolyses rapidly in water. Nevertheless, the test should be performed with the registered substance, as there is a concern and the parent compound would be expected to have more serious local adverse effects than the dimethylsilanediol. Taking into account the vapour pressure and exposure pattern, the 90-day repeated dose toxicity study should be conducted via inhalation route, as the concern is, in this case, for local effects during inhalation by exposed workers. See below for conditional approach.

ECHA notes that in the comments, submitted during the 30-days commenting period, the Registrant has agreed on the need to perform further testing for the sub-chronic repeated dose toxicity. The Registrant has however proposed to perform a 90-day repeated dose toxicity study with either dimethylsilanediol, or with a suitable alkoxysilane material which generates the same hydrolysis product, for example dimethoxydimethylsilane.

ECHA considers it of importance to obtain information for the toxicity of the registered substance for the inhalation route. Only with such route specific information it will be possible to determine quantitatively the expected local effect in the respiratory tract and to derive an appropriate DNEL for worker protection. The proposal received from the Registrant to use dimethysilanol or dimethoxydimethylsilane was therefore analysed starting from this need.

ECHA considers dimethylsilanediol (one hydrolysis product of the registered substance) as proposed test substance instead of the registered substance as not acceptable for the purpose of determining the local effects in the respiratory tract. The dossier contains information on the speed of hydrolysis of dichloro(dimethyl)silane in water while no information on the speed of hydrolysis in air is provided. It can be assumed that in air not all the parent compound will be hydrolysed immediately to dimethylsilanediol and hydrochloric acid but rather a mixture of the three substances in air is to be expected to reach the respiratory system. Hence, testing the dimethylsilanediol would not provide information on the possible interaction between the three substances (the registered substance and the two hydrolysis products) and would not allow the investigation of the all possible toxic effects of the dichloro(dimethyl)silane via the inhalation route. In fact due to the very low vapour pressure of the dimethylsilanediol (7 Pa at 25 ºC) compared to the dimethyldichlorosilane (14600 Pa at 20 ºC), a 90-day study with the hydrolysis product would need to be conducted via the oral route, thus providing no information on the local toxic effects of the registered substance in the respiratory tract. In fact, there is a concern that the parent compound would have local adverse effects in the respiratory system. The Registrant has not demonstrated that the local inhalation effects of dichloro(dimethyl)silane would be adequately addressed by just applying the OEL of one of the hydrolysis products (HCl) instead of testing the registered substance, deriving the DNEL accordingly and thus covering also the potential interaction of the three substances (the registered substance and the two hydrolysis products) on the absorption and local inhalation effects in the respiratory system. Hence, dimethylsilanediol cannot

be accepted as test substance instead of the registered substance for the purpose of this test.

ECHA considers dimethoxydimethylsilane as proposed test substance instead of the registered substance as not acceptable since dichloro(dimethyl)silane and dimethoxydimethylsilane hydrolyse at different speed and produce different hydrolysis products. Dichloro(dimethyl)silane has a speed of hydrolysis of 0.3 min at 1,5 °C, pH 7 and releases one mole of dimethylsilanediol and two moles of hydrochloric acid, while dimethoxydimethylsilane has an hydrolysis half life of <0.6 hours at 25 °C, pH 7, releasing one mole of dimethylsilanediol and two moles of methanol. Hence, the kinetics of dimethylsilanediol formation in the respiratory tract is considered to be very different after exposure to dichloro(dimethyl)silane and dimethoxydimethylsilane. Additionally, dichloro(dimethyl)silane gives rise to hydrochloric acid whereas dimethoxydimethylsilane does not give rise to hydrochloric acid but rather to methanol. Therefore, the systemic effects as well as the local effects of dimethoxydimethylsilane on the respiratory tract are expected to differ from the effects caused by dichloro(dimethyl)silane. On these grounds, dimethoxydimethylsilane cannot be accepted as test substance instead of the dichloro(dimethyl)silane for the purpose of this test.

The specific behaviour of the registered substance in contact with water, already described in this decision, was discussed during the Member State Committee meeting leading to the conclusions described below. The registered substance hydrolyses rapidly in water forming HCl and dimethylsilanediol. The Registrant claims that it also hydrolyses rapidly in air and claims that local effects in the respiratory tract can be attributed to the formation of HCl and therefore the protection of workers is ensured by the application of the OEL of HCl. However, no evidence is available on the rate and degree of the hydrolysis of dichloro(dimethyl)silane in air. Furthermore, no information is available on the behaviour of the registered substance in the respiratory tract when it reaches the breathing zone. Therefore it is uncertain whether HCl indeed dominates the inhalation toxicity. In view of this uncertainty the following stepwise approach to the conduct of the requested inhalation 90-day study is required. These steps are required to obtain meaningful results in conducting the study according to test method EU B.29 or OECD 413.

Step 1

As a prerequisite for the conduct of the study with the registered substance the Registrant shall determine whether the registered substance is actually present in the breathing zone of the test animals under the test conditions or if the registered substance has already hydrolysed at that stage coming from the mixing device to achieve the intended exposure concentration. The Registrant shall use adequate analytical methods to determine the concentration of the registered substance and/or its hydrolysis products in the animal breathing zone. If analytical determination results indicate that eighty percent or more of the originally intended exposure concentration has hydrolysed before it reaches the breathing zone, ECHA assumes that HCl will dominate the inhalation toxicity profile and steps 2 and 3 will not be necessary. In this context it is noted that one mole of registered substance will hydrolyse and result in two moles of HCl and one mole of dimethylsilanediol. However, if analytical determination results indicate that less than eighty percent of the originally intended exposure concentration has hydrolysed before it reaches the breathing zone, the Registrant shall proceed to step 2. ECHA underlines that the above-described conclusion on the degree of hydrolysis shall be based on a concentration similar to the concentrations expected to be used in step 2.

Step 2

No reliable repeated dose inhalation studies are available for the registered substance. Therefore it is necessary to determine the exposure concentrations in a range finding study. Due to the uncertainty on the rate of hydrolysis of the registered substance in the respiratory tract specific investigations are necessary to determine whether the potential effects can be predicted by results obtained with HCl alone. In order to be able to reliably decide whether step 3 is necessary ECHA considers that the range-finding study shall be performed according to the following specifications:

- at least two groups of animals with different exposure concentrations of the registered substance and one control group shall be included,
- each group shall have at least six animals per sex,
- study duration shall be no less than 28 days,
- histopathological evaluation of the upper and lower respiratory tract shall be performed.

The results of the range-finding study shall be compared with results of repeated dose and long-term toxicity studies available for HCl. The findings may indicate that the effects of the registered substance are similar to the findings observed for HCl. In particular HCl has been observed to act mainly on the upper respiratory tract. If histopathology indicates adverse effects similar to HCl only in the upper respiratory tract ECHA assumes that HCl will dominate the inhalation toxicity profile of dichloro(dimethyl)silane and step 3 will not be necessary. However, if histopathology indicates an inhalation toxicology profile different from HCl, ECHA concludes that step 3 is needed to investigate the repeated dose toxicity of the registered substance via inhalation route.

Step 3

Continue with the conduct of the sub-chronic repeated dose toxicity study (90-day) with the registered substance, dichloro(dimethyl)silane (Annex IX, 8.6.2. of the REACH Regulation), in the rat, by inhalation route.

The Registrant is accordingly requested to submit the missing information on sub-chronic repeated dose toxicity (90 days) performed with the registered substance dichloro(dimethyl)silane, in the rat, via the inhalation route by the test method B.29 according to Commission Regulation (EC) No 440/2008 or OECD 413. The conduct of the study shall follow a stepwise approach consisting of three steps and shall be conditional on the results obtained in these steps as described above.

b. Pre-natal developmental toxicity study (Annex IX, 8.7.2 of the REACH Regulation):

The REACH Regulation (Annex IX, 8.7.2) requires a pre-natal developmental toxicity study. Instead, the Registrant submitted the results of a combined 28-day repeated dose toxicity study with screening for reproduction toxicity via the oral route. The Registrant is justifying the adaptation of the standard information requirements by stating that "*In accordance with Section 3 of REACH Annex XI, a developmental toxicity test (required in Section 8.7.2) does not need to be conducted on the grounds of exposure-based considerations. A full exposure assessment and risk characterisation have been carried out in accordance with REACH guidance, as documented in the*

Chemical Safety Report and supporting reports. The substance is extremely reactive and is handled under highly controlled conditions at industrial locations. It is fully consumed during use and there is no potential for exposure to the general public either from direct use or from residual unreacted substance in end products. Using a conservative approach to exposure estimation and Derived No Effect Levels (based on data available for the hydrolysis products of dichloro(dimethyl)silane), all risk characterisation ratios are below 1." Indeed, in the assessment the Registrant used a DNEL-value derived from the screening study for the developmental endpoint. From the above explanation it is evident that Registrant is claiming Annex XI 3.2.(a) as basis for adaptation of standard information requirements.

However, in order for substance-tailored exposure-driven testing to apply (Annex XI, section 3), all of the conditions set in Annex XI, 3.2(a) need to be fulfilled, which is not the case here. Firstly, condition (i) is not fulfilled by the Registrant, as there is a mention of low levels of exposure on a repeated basis as the typical pattern of worker exposure in the Chemical Safety Report (page 49), whilst all intended uses are industrial. Secondly, condition (ii) is not fulfilled as the footnote to Annex XI, 3.2(a) states "*For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study*" and the Registrant used a DNEL-value derived from the screening study for the developmental endpoint.

On these grounds, adaptation of the standard information requirement cannot be accepted. The Registrant is accordingly requested to submit the information on pre-natal developmental toxicity, in the rat, oral route, using test method B.31 according to Commission Regulation (EC) No 440/2008 or OECD 414. However, the above testing should be performed with the dimethylsilanediol, not with the registered substance, for the following reasons:

REACH Regulation requires that the Registrant's dossier contains relevant physicochemical, toxicological and ecotoxicological information (Article 12(1)). REACH Recital (63) also gives ECHA the responsibility to ensure the generation of information that is tailored to real information needs. The registered substance hydrolyses in water with a half-life of minutes to dimethylsilanediol and hydrochloric acid. Therefore the degradation products of the hydrolysis reaction are the most relevant substance for assessing the reproductive toxicity in a pre-natal developmental toxicity test. In fact, the Registrant has already provided data in the registration dossier for the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test carried out on the hydrolysis product, dimethylsilanediol. Testing with the parent compound would not provide relevant information on the potential long-term systemic effects concerning this endpoint, while this could be achieved with the breakdown product, as

- the registered substance is classified as corrosive, and according to the fourth paragraph of Annex IX of the REACH Regulation *in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. The use of the breakdown product helps in avoiding testing of an agent at a concentration or dose level that causes corrosivity (i.e. the parent compound).

- a higher systemic dose of the breakdown product may be achieved when dosing is not limited by the corrosive effect, and this will avoid the risk of underestimating the long term effects due to lower doses;

- dosing with the breakdown compound appears more reliable, as uncontrolled reaction of the parent compound with vehicle, or variation caused by differences in pH of vehicle as a result of dilution may interfere with dosing of the parent compound

ECHA notes that dimethylsilanediol fulfils the conditions set in Annex XI, 1.5 to be considered as a read-across chemical for performing the pre-natal developmental toxicity study and can, therefore, be used to predict the human health effects of the registered substance. The Registrant is, thus, requested to perform the pre-natal developmental toxicity study with dimethylsilanediol.

ECHA notes that in the comments, submitted during the 30-days commenting period, the Registrant has agreed on the need to perform further testing on the pre-natal developmental toxicity of the substance and proposed to perform a pre-natal developmental toxicity study with either dimethylsilanediol, or with a suitable alkoxysilane material which generates the same hydrolysis product, for example dimethoxydimethylsilane.

ECHA considers dimethoxydimethylsilane as proposed test substance instead of the registered substance as not acceptable since dichloro(dimethyl)silane and dimethoxydimethylsilane hydrolyse at different speed. Hence, the kinetics of dimethylsilanediol formation after administration is considered to be very different after exposure to dichloro(dimethyl)silane and dimethoxydimethylsilane. Additionally, dichloro(dimethyl)silane gives rise to hydrochloric acid whereas dimethoxydimethylsilane does not give rise to hydrochloric acid but rather to methanol. Therefore, the systemic effects of dimethoxydimethylsilane are expected to differ from the effects caused by dichloro(dimethyl)silane. On these grounds, dimethoxydimethylsilane cannot be accepted as test substance instead of the registered substance for the purpose of this test.

ECHA considers dimethylsilanediol (one hydrolysis product of the registered substance), as already explained above, as proposed test substance instead of the registered substance, as acceptable for the purpose of maximising systemic exposure as, in this case, administration is oral. This will fulfill the endpoint of Annex IX 8.7.2. of the REACH Regulation. Concerning the pre-natal developmental toxicity effects of hydrochloric acid, ECHA notes that there is an OECD SIDS report for hydrochloric acid concluding that *"No reliable studies have been reported regarding toxicity to reproduction and development in animals after oral, dermal or inhalation exposure to hydrogen chloride/hydrochloric acid. Because protons and chloride ions are normal constituents in the body fluid of animal species, low concentrations of hydrogen chloride gas/mist or solution do not seem to cause adverse effects to animals. In fact, the cells of gastric glands secrete hydrochloric acid into the cavity of the stomach and orally administered sulfuric acid, which results in pH change as well, did not cause developmental toxicity to laboratory animals. These facts indicate that hydrogen chloride/hydrochloric acid is not expected to have developmental toxicity"*. The test results on dimethylsilanediol, in combination with the available information on the pre-natal developmental toxicity effects of hydrochloric acid, should allow to conclude on the pre-natal developmental toxicity of the registered substance.

The Registrant is accordingly requested to submit the information on pre-natal developmental toxicity, in the rat, oral route, using test method B.31 according to

Commission Regulation (EC) No 440/2008 or OECD 414. using dimethylsilanediol as test substance.

2) Missing information related to Chemical Safety Report

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR).

a. Indirect exposure of humans via the environment

Annex I, point 5.2.4 of the REACH Regulation provides that "*An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable*".
The Registrant has stated that "*There is no exposure of humans to dichloro(dimethyl)silane via the environment, as the substance is highly reactive*". On this basis the Registrant appears to conclude that no exposure to humans is foreseeable and that no exposure estimate is needed.

However, Annex I, point 5.2.4 clearly indicates that the exposure estimation shall inter alia take account of "*transformation and/or degradation products*" and "*the likely pathways to the environment and environmental distribution and degradation and/or transformation*'. ECHA notes that the registered substance hydrolyses quickly and that therefore the Registrant already conducted a quantitative exposure assessment and risk characterisation for the environment for both hydrolysis products, which showed that there is an exposure to the environment. Therefore, it may be assumed that exposure of humans indirectly via the environment is foreseeable.

ECHA notes that in the updated dossier, the Registrant has updated the Chemical Safety Report providing new information on the indirect exposure of humans via the environment to the dimethylsilanediol for all relevant exposure scenarios. The Registrant has provided a summary of the exposure of humans via the environment for all exposure scenarios, calculating the daily doses through intake arising from different types of food: drinking water, fish, crops, meat, milk and air. The Registrant has also provided a risk characterisation for the indirect exposure of humans via the environment for all exposure scenarios, including relevant routes of exposure. Nevertheless, ECHA notes that leaf crops and root crops have been excluded from the risk characterisation in all exposure scenarios without providing a proper justification. ECHA further observes that the comparison of the exposure concentration via the leaf crops with the DNEL(oral) would give a risk characterisation ratio above 1 for exposure scenarios 2 and 3. The Registrant should provide a justification for the missing risk characterisation of the indirect exposure of humans via the environment including the exposure via crops for all exposure scenarios and be able to demonstrate that the risk arising from the exposure of humans via leaf crops is controlled.

Taking into account the above, ECHA concludes that the Registrant is therefore requested to revise the exposure assessment and the risk characterisation of the indirect exposure of humans via the environment, including the exposure via crops. The Registrant shall be able to justify the missing risk characterisation with appropriate risk management measure and/or demonstrate that the risks are controlled.

IV. Adequate identification of the composition of the tested material

ECHA notes that this dossier is the lead dossier of a joint submission. The evaluation process set out in Article 41 of the REACH Regulation aims to ensure that the generation of information is tailored to real information needs in order to prevent unnecessary testing. In relation to the tests imposed, the sample of substance to be used for these tests must be suitable for use by all the joint registrants. Hence the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. The outcome of the studies should be shared by the joint registrants concerned.

V. 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 ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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. The procedure is described in the Board of Appeal's "Preliminary instructions to Appellants" that can be found at the ECHA website. 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.

[redacted]

Jukka Malm
Director of Regulatory Affairs