EUROPEAN CHEMICALS AGENCY

Helsinki, 04 July 2016

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXX-XX-XX/F)

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

For trimethoxyvinylsilane, CAS No 2768-02-7 (EC No 220-449-8)

Addressees: Registrant(s)[1] of trimethoxyvinylsilane

This decision is addressed to the Registrant(s) of the above substance with active registration 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 the Swedish Chemicals Agency as the Competent Authority of Sweden (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 27 May 2013.

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 Sweden has initiated substance evaluation for **trimethoxyvinylsilane, CAS No 2768-02-7 (EC No 220-449-8)** 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 Human health – suspected sensitiser, exposure – wide dispersive use, consumer and worker exposure, exposure of sensitive population, high risk characterisation ratio (RCR) and aggregated tonnage, trimethoxyvinylsilane was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of Sweden was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA noted additional concern related to mutagenicity and derivation of DNELs.

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 19 March 2014.

On 29 April 2014 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 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA.

The evaluating MSCA considered the comments received from the Registrant(s).

On the basis of this information section II was amended. The statement of reasons (section III) was modified accordingly.

The pre-natal developmental toxicity test and extended one-generation reproductive toxicity study, which were initially intended to be requested in the present decision, were removed because they can be more appropriately addressed under dossier evaluation.

Proposals for amendment by other MSCAs and ECHA and referral to Member State Committee

On 21 January 2016 the evaluating MSCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposal(s) for amendment.

By 22 February 2016 the evaluating MSCA received proposal(s) for amendment to the draft decision. The request to perform the local lymph node assay, OECD 429 was removed from the decision based on these reasons: i) the available information is sufficient to classify the substance as a skin sensitizer and ii) the need for requesting further information to clarify skin sensitisation potency, will be considered in the follow-up evaluation by the evaluating MSCA.

On 26 February 2016 ECHA invited the Registrant(s) to comment on the proposed amendment(s).

Referral to Member State Committee

On 7 March 2016 ECHA referred the draft decision to the Member State Committee.

By 29 March 2016, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. The Member State Committee took the comments into account and these are reflected in Section III, the statement of reasons.

A unanimous agreement of the Member State Committee on the draft decision was reached on 12 April 2016 in a written procedure launched on 1 April 2016.

ECHA took the decision pursuant to Article 51(6) and Article 52 (2) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test method (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

1. **In vivo mammalian alkaline comet assay (comet assay), test method: OECD 489. The comet assay shall be performed in rats via inhalation. DNA damage shall be assessed in lung and liver.**

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:

2. **Existing data on skin sensitisation potential after human exposure to trimethoxyvinylsilane;**

3. **Further information to support the justification for the modified assessment factors used for derivation of the critical DNEL(s);**

4. **Further information on exposure of consumers and professional users;**

5. **Further information on consumers' long term exposure; and**

6. **Further information on the risk characterisation for consumers.**

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **11 October 2017** an update of the registration(s) containing the information required by this decision[2] including robust study summaries and, where relevant, an update of the Chemical Safety Report.

[2] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

III. Statement of reasons

1. In vivo mammalian alkaline comet assay (comet assay), test method: OECD 489. The comet assay shall be performed in rats via inhalation. DNA damage shall be assessed in lung and liver

Concern
During the evaluation, the evaluating MSCA identified a further concern, i.e. a concern for mutagenic potential of trimethoxyvinylsilane.

Negative results were reported from two *in vitro* bacterial reverse mutation assays and one *in vitro* mammalian cell gene mutation assay. Positive results of the *in vitro* mammalian chromosome aberrations were reported in two studies ([redacted]). An *in vivo* follow up study, the *in vivo* micronucleus assay (chromosome aberration) with intraperitoneal administration performed according to EPA Health effects guidelines 560/6-83-001, assigned as reliable with restrictions (score 2) by the Registrant(s) was reported with negative results.

The provided *in vivo* micronucleus study is hampered by deficiencies that result in uncertainty in reliability of the study to conclude about *in vivo* effects for this endpoint. In particular due to the significantly lower number of cells analysed compared to the guideline requirement.

It is considered that the provided *in vitro* data raises the concern of the potential for mutagenicity via chromosomal aberrations and the provided *in vivo* micronucleus assay is not sufficient to clarify the concern for mutagenic potential of trimethoxyvinylsilane. Therefore an *in vivo* genotoxicity study is necessary to clarify the concern of the potential of the trimethoxyvinylsilane to cause chromosomal aberrations *in vivo*. According to the strategy reflected in the legal text, *in vivo* testing for somatic cells is triggered by positive *in vitro* tests.

Alternative approaches
Based on the consideration of the potentially relevant test protocols, the *in vivo* micronucleus assay (chromosome aberrations) according to OECD Guideline 474, the mammalian bone marrow chromosomal aberration test (CA test), OECD TG 475 and the comet assay according to the OECD Guideline 489, ECHA considers that the requested test comet assay has the following advantage: The *in vivo* comet assay is considered a useful indicator test in terms of its sensitivity to substances which cause gene mutations and/or structural chromosomal aberrations and can be used with many target tissues, including site of contact tissue, while the *in vivo* micronucleus assay requires clear evidence that the substance reaches the bone marrow, that for the substance to be investigated may be difficult to ensure.

If results of testing in somatic cells are positive, the potential for germ cell mutagenicity shall be considered. Currently the *in vivo* comet assay is not officially validated for the assessment of DNA damage in germ cells, but only for the use in somatic cells. If the comet assay is positive in somatic cells this will indicate the need to consider further investigation of germ cells mutagenicity, which will be done in the follow-up evaluation, pursuant to Article 46(3) of the REACH Regulation.

The comet assay shall be performed, using the test method OECD 489, in rats via inhalation. DNA damage shall be assessed in lung and liver.

The reason for inhalation as a route of exposure:

- Inhalation is the relevant human exposure (beside the dermal exposure);
- Substance has rapid hydrolysis rate, that is pH dependent and testing with the inhalation exposure would allow investigation of effects from the parent substance, while the oral exposure would lead to rapid hydrolysis and exposure would be mostly to hydrolysis products.

The reasons for tissue selection are as follows:

- The lung was chosen due to exposure via inhalation as the initial site of contact with the body;
- Liver was chosen to study an effect on a tissue that is exposed to systemically available substances and it is a main site of metabolism. Moreover it is a slowly dividing tissue. In response to the original draft decision the Registrant(s) agreed to this request.

The Registrant(s) in his responses to the PfAs commented that the need to perform the comet assay should be reassessed because the available *in vivo* micronucleus study for trimethoxyvinylsilane is reliable. However, as detailed above, ECHA considers the study as not reliable, in particular due to a significantly lower number of cells analysed compared to the guideline requirement.

Following a PfA, the request for analysis of the bone marrow is removed. However, in their comments on the proposals for amendment the Registrant(s) indicated that the bone marrow may be a potential site of contact for trimethyl(vinyl)silane and that they still intend to analyse this tissue. ECHA points out that the analysis of the bone marrow is not required, but the Registrant(s) may consider analysing it at their discretion.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s are required to carry out the following study using the registered substance subject to this decision: **In vivo mammalian alkaline comet assay (comet assay), test method: OECD 489 as specified in Section II. 1 and above.**

The Registrant(s) are reminded that pursuant to Article 46(3) the evaluating MSCA may – after evaluation of the results from the test required above or any other new information – identify further information required to conclude on concerns raised during the evaluation. Such further requests could for example concern germ cells mutagenicity or carcinogenicity.

Notes for consideration by the Registrant(s):

Registrant(s) may consider examining gonadal cells when conducting the comet assay (OECD TG 489), as it would optimise the use of animals. ECHA notes that a positive result in whole gonads is not necessarily reflective of germ cell damage since gonads contain a mixture of somatic and germ cells. However, such positive result would indicate that the substance and/or its metabolite(s) have reached the gonads and caused genotoxic effects. This type of evidence may be relevant for the overall assessment of possible germ cell mutagenicity including classification and labelling according to the CLP Regulation.

The Registrant(s) are reminded that according to Annex IX, Section 8.4., column 2 of the REACH Regulation, if positive results from an *in vivo* somatic cell study are available, "the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered."

In parallel to the substance evaluation of trimethoxyvinylsilane, the evaluating MSCA is performing a substance evaluation of trimethoxy(methyl)silane (EC No 214-685-0). As a result of that evaluation, the Registrant(s) of trimethoxyvinylsilane are also requested to perform an *in vivo* comet assay in rats via the inhalation route. The Registrant(s) of both substances have indicated they are members of the same group of substances. However, currently no read-across is proposed or justification provided in the registration dossiers. The addressees of this decision are invited to consider whether read-across between the substances could be justified and under such conditions perform only one *in vivo* comet assay, to reduce animal testing. It is however stressed that it is the Registrant(s)' responsibility to justify the read-across. The plausibility of the read-across can only be assessed by the evaluating MSCA in a follow-up evaluation on the basis of the documentation and justification provided by the Registrant(s).

In their comments on the PfAs, the Registrant(s) disagreed to these "notes for consideration". ECHA therefore further clarifies that the points included in these notes (examination of the gonadal cells and read-across analysis) are not requested, but rather suggested and advised to be considered by the Registrant(s).

2. Existing data on human skin sensitisation potential after exposure to trimethoxyvinylsilane

Concern

The concern is related to skin sensitisation potency of trimethoxyvinylsilane that needs to be clarified. No information referring to the experiences from human exposure to the trimethoxyvinylsilane or structurally similar substances has been considered in the registration(s).

Available information indicates that humans have been exposed to trimethoxyvinylsilane and/or structurally similar substances at work places and through consumer products. However, no data referring to the experiences from human exposure to the trimethoxyvinylsilane or structurally similar substances has been provided.

The already existing experiences from human data, if adequately analysed and reported, could add to the weight of evidence. There is ambiguity in the results of the *in vivo* testing for the skin sensitisation potential with the use of trimethoxyvinylsilane and structurally similar substances and the weight of evidence approach may be necessary to conclude about the skin sensitisation concern.

Reporting of already existing and available information on human on skin sensitisation potential of the trimethoxyvinylsilane is required.

Types of information possibly relevant for evaluation, reported and well documented include: consumer experience and comments, preferably followed up by professionals; diagnostic clinical studies (e.g. patch tests, repeated open application tests); records of workers' experience, accidents, and exposure studies including medical surveillance; case reports in the general scientific and medical literature; consumer tests (monitoring by questionnaire and/or medical surveillance); epidemiological studies; human experimental studies (only historical data) such as the human repeat insult patch test and the human maximisation test.

In response to the draft decision the Registrant(s) provided this information: *"Over the course of 18 years production of trimethoxyvinylsilane, 18 people have been in contact with the manufacturing process continuously without any indication of sensitization. An additional 24 people have been in contact with the substance during a 2 shift operational function. There is no evidence of any potential sensitization in the health files of all those individuals over the full manufacturing time. Therefore during many years of production, handling and use of trimethoxyvinylsilane, no single case of suspected contact allergy has been recorded."*

In the evaluating MSCA's view this information is not satisfactory to address the skin sensitisation potential concern. This information does not include methodical analysis of the populations exposed to trimethoxyvinylsilane at work or as consumers. Hence, it cannot be used in the weight of evidence analysis.

In response to the draft decision the Registrant(s) also indicated the intention to provide further information on the potential for skin sensitisation after human exposure.

In their comments on the proposal for amendments related to the request for the local lymph node assay, the Registrant(s) stated that they are of the opinion that the available data does not warrant the need for further testing nor for classifying the substance as a skin sensitiser. The Registrant(s) also indicated that by April 2016, they will submit a dossier update, including a weight of evidence analysis of the data on the skin sensitisation potential of the substance.

In reply to the above comment, ECHA clarifies that the evaluating MSCA will in the follow up evaluation assess the need for further testing of skin sensitisation by taking into account any provided information on skin sensitisation, including information on the potency after human exposure and the outcome of the comet assay. The Local lymph node assay (LLNA) OECD 429 may be requested if the available information is not sufficient to assess the skin sensitisation potency and there is a concern that the proper risk management is not in place.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **existing data on human skin sensitisation potential after exposure to trimethoxyvinylsilane.**

3. Further information to support the justification for the modified assessment factors used for derivation of the critical DNEL(s)

Concern
The concern is related to the risk characterisation ratios (RCRs).

The DNEL for systemic effects following single exposure via the dermal route is determined on the basis of results from the acute dermal toxicity study in rabbits ([redacted]). The DNEL for systemic effects following single exposure via the inhalation route is determined based on results from the acute inhalation study in rats (BRRC, 1986). The long term exposure DNEL for systemic effects via the inhalation, dermal and oral routes are determined on the basis of a 90-day inhalation study in rats ([redacted]).The risks of systemic toxicity for several use scenarios for workers and consumers have been assessed. The RCR calculations were based on DNELs derived with the use of assessment factors (AF) for intraspecies and interspecies extrapolation lower than ECHA's guidance recommendation. In all cases the interspecies and intraspecies extrapolation was performed with the use of AF lower than recommended by ECHA guidance. Specifically, AF 1 instead of AF 2.5 was used for remaining differences in interspecies extrapolation; AF 5 instead of AF 10 for intraspecies for general population and AF 3 instead of AF 5 for intraspecies for workers.

In response to the original draft decision the Registrant(s) proposed to change the AFs used for derivation of the DNELs to 3.2 and 2.2 for general population and workers, respectively but have not updated the dossier accordingly. Following justification for deviation from recommendation was provided: "The intraspecies assessment factor takes account for the variability in sensitivity between individuals. This AF also covers differences between ethnic and age groups. The default intraspecies factors are typically broken down into equal factors accounting for toxicodynamic and toxicokinetic differences, respectively. Accordingly, an interspecies factor of 10 is composed of two identical factors of $\sqrt{10} = 3.2$.
Likewise, the default for workers (AF = 5) can be split into AFs of $\sqrt{5} = 2.2$. As discussed above, the conversion of siloxanes to silanols and their excretion proceeds without enzymatic involvement. Individual genetic dispositions are therefore without effect on these processes. As a result, the toxicokinetic components ([redacted] and [redacted] for general population and workers, respectively) can be eliminated from the intraspecies AF."

It is noted that no *in vivo* toxicokinetics data are available for trimethoxyvinylsilane to address the fate of the substance or its hydrolysis products following different routes of exposure. trimethoxyvinylsilane hydrolysis in water with a half-life of approximately 0.2h at pH 7, generating vinylsilanetriol. Based on Quantitative Structure-Property Relationship (QSPR) analysis it is predicted that upon inhalation (the most relevant route of exposure), trimethoxyvinylsilane can be absorbed across the lungs and taken up to the systemic circulation. It can also be dissolved in the respiratory tract mucus and absorbed to the blood.

These predictions are supported by inhalation studies where systemic toxicity is observed ([redacted]). The QSPR analysis also predicts that both the parent substance and the hydrolysis product are mainly eliminated via the kidney in urine.

Elimination of the "toxicokinetics element", which leads to less conservative DNELs is not sufficiently supported, i.e. by data on absorption, distribution or excretion of the substance. Using these modified AFs results in higher DNEL values and reduces the RCRs considerably. For example, for the consumer use of sealants, when current Consexpo exposure estimates for dermal acute dose (not yearly average) are used:

Suggested modified AF (2 x 2.5 x 3.2=16), Dermal DNEL=0.19 mg/kg bw/day --> RCR=3
Default AF (2 X 2.5 X 10=50), Dermal DNEL=0.06 mg/kg bw/day --> RCR=10

It should be noted that requests 4-6 in this decision are relevant for exposure estimations and thus also for the RCR values. Reliable exposure estimates together with adequate DNEL derivation would determine whether there is risk (RCRs above 1) for the different use scenarios.

The request for information to support the use of modified AFs is considered suitable and necessary to obtain information that will allow clarifying whether there is a risk (RCRs above 1). If no adequate justifications for the use of modified AF is provided the default values shall be used. In such case the foreseen risk management measure would be adjustment of the use scenarios by the Registrant(s) to reach acceptable RCRs. If the Registrant(s) will not sufficiently justify the modified AFs, the evaluating MSCA will carry out the evaluation based on default AFs, which may result in identification of risk.

In their comments to the proposal for amendments the Registrant(s) agreed with the proposal that the concern and the information requested should be further specified. The decision was amended accordingly.

Conclusion
The hydrolysis rate of trimethoxyvinylsilane in the respiratory tract is not determined, neither are the levels of absorption through lungs, distribution in the body or excretion rates. Because of the lack of this information it cannot be excluded that the toxicokinetics components, i.e. absorption, distribution and excretion can vary in the exposed population. The justification for elimination of the toxicokinetics component from the AFs should be supported by sufficient information. The information is needed to ensure that intraspecies extrapolation steps have been sufficiently reflected in the DNEL(s) derivation.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **further information to support the justification for the modified assessment factors used for the derivation of the critical DNEL(s) for** the registered substance subject to this decision.

4. Further information on exposure of consumers and professional users

Concern
Assessment of exposure of professional users and consumers due to the use of products containing trimethoxyvinylsilane has been reported in the registration(s). The methodology used and/or clarification provided is however considered not sufficient to conclude that the exposure assessment covers expected uses and that the risks are controlled.

As an example, for the estimation of exposure in scenario "Professional and consumer use of sealants" a modifying factor is used to the CONSEXPO modelled results. This factor is based on the comparison of the results from the experimental study simulating the use of sealant ([redacted]) and CONSEXPO output with the input parameters reflecting the experimental study. Although it is likely that the result of tier 1 exposure model would overestimate the exposure, the use of the factor of 0.1 as presented is considered not well substantiated. This extrapolation from the modelled data to the real exposures based on a single study with conditions different from the real situation exposure is not considered adequate, specifically in the situation when the resulting RCRs are close to 1. As an alternative approach for the estimation of exposure in scenario "Professional and consumer use of sealants" the assumption is made that the storage of the products results in cross linking of the substance leading to decrease of actual concentration to 0.1% from the nominal concentration 2.5%. The analytical data to support this assumption has not been registered at the time of evaluation. Based on the information available this approach is considered not well substantiated.

Furthermore, for the calculation of exposure in scenarios "Professional and consumer use of coatings" and "Professional and consumer use of sealants" using CONSEXPO the "typical concentration" of the substance in the product(s) is used. The evaluating MSCA noted that those concentrations do not reflect maximum nominal concentration as reported for some of the market products.

The request for information to support the modified values is considered suitable and necessary to obtain information that will allow clarifying whether there is a risk (RCRs above 1). Where the data, once obtained, confirms that there is risk of RCRs above 1, it will allow risk management by adjustment of the use scenarios to reach acceptable RCRs. If the Registrant(s) will not sufficiently justify the modified parameters, the evaluating MSCA will carry out the evaluation based on the default values, which may result in identification of risk.

Conclusion
Refinement of the exposure estimation is needed for more accurate exposure assessment.

Measured exposure data for representative and specific scenarios or estimated data from suitable models; and

Assessment of exposure from the use of products reflecting maximum supported concentrations are therefore required.

The Registrant(s) did not comment on this request.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **further information on exposure of consumers and professional users.**

5. Further information on consumers' long term exposure

Concern
Assessment of exposure of consumers due to the use of products containing trimethoxyvinylsilane has been reported in the registration. The methodology used and/or clarification provided is however considered not sufficient to conclude that the exposure assessment covers expected uses and the risks are controlled.

Estimation of long term exposure concentration of consumers from the short term use (min < 2h) that occurs 3 times per year by averaging them over the whole year is reported in the registration. This is not considered to be a proper approach to estimate consumer long term exposure.

According to the ECHAs' Guidance on information requirements and chemical safety assessment (ECHA, 2012): "It is to be noted that for products used infrequently, use frequency should not be used to average out exposure over a longer time period. In the first instance, exposure should be calculated for the actual duration of an event (event exposure), and then expressed as that concentration per day."

Furthermore the assessment of RCR for consumers' long-term systemic effects based on short-exposures (faulty extrapolated over the whole year) and long-term DNELs is performed.

The request for information to support the modified values is considered suitable and necessary to obtain information that will allow clarifying whether there is a risk (RCRs above 1). Where the data, once obtained, confirms that there is risk (RCRs above 1), it will allow risk management by adjustment of the use scenarios to reach acceptable RCRs. If the Registrant(s) will not sufficiently justify the modified parameters, the evaluating MSCA will carry out the evaluation based on the default values, which may result in identification of risk.

Conclusion
The data on consumers' long term exposure and risk due to the repeated use of products containing the trimethoxyvinylsilane is considered not sufficient to conclude that the risks are controlled.

Further information on consumers' long term exposure and risk characterisation is required.

The Registrant(s) did not comment on this request.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **further information on consumers' long term exposure.**

6. Further information on the risk characterisation for consumers

Concern
Assessment of risks for consumers due to the use of products containing trimethoxyvinylsilane has been reported in the registration. The methodology used and/or clarification provided is however considered not sufficient to conclude that the risk assessment covers expected uses and that the risks are controlled.

Risk characterisation for consumer uses was based on acute (24h) DNELs as a second tier approach as the risk characterisation based on chronic DNELs resulted in RCR > 1.

Expected consumer use pattern including duration and frequency of the use of products containing trimethoxyvinylsilane (and/or structurally similar substances) indicates potential of repeated exposure over a period longer than acute/24h.

Considering the expected consumer use patterns the risk assessment based on acute/24h DNELs is considered not sufficient to conclude that the risk assessment covers expected uses and that the risks are controlled.

Information on the risk characterisation for consumers based on further consideration of the expected use pattern is required. Use of DNEL based on repeated study or DNEL based on acute study with further AF for duration of exposure extrapolation, as supported by information on the consumers use and exposure pattern information should be considered.

The request for information is considered suitable and necessary to obtain information that will allow clarifying whether there is a risk (RCRs above 1). Where the data, once obtained, confirms that there is risk of RCRs above 1, it will allow risk management by adjustment of the use scenarios to reach acceptable RCRs. If the Registrant(s) will not sufficiently justify the modified parameters, the evaluating MSCA will carry out the evaluation based on the default values, which may result in identification of risk.

The Registrant(s) did not comment on this request.

Conclusion
Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide **further information on the risk characterisation for consumers.**

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the test(s) must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental studies the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing .

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrant(s) to perform the stud(y/ies) on behalf of all of them.

VI. 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://echa.europa.eu/regulations/appeals . The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[3] 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.

[3] 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

[redacted]

ECHA Guidance on information requirements and chemical safety assessment. Chapter R.8 Characterisation of dose –response for human health. Version : 2.1 November 2012

[redacted]