EUROPEAN CHEMICALS AGENCY

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

For Hexyl Salicylate, CAS No 6259-76-3 (EC No 228-408-6)

Addressees: Registrant(s)[1] of hexyl salicylate (concerned registrants)

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants meeting the following criteria are not addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by Bureau REACH on behalf of the Dutch Ministry of Infrastructure and the Environment (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 does not take into account any updates of the registrations of the concerned registrants after 5 July 2013, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the concerned registrants in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the concerned registrants at a later stage, nor does it prevent 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 The Netherlands has initiated substance evaluation for hexyl salicylate CAS No 6259-76-3 (EC No 228-408-6) based on registration dossiers submitted by the concerned registrants and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health/suspected CMR; Exposure/Wide dispersive use, consumer use, high aggregated tonnage; Risk characterisation ratios close to 1 (human

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

health), hexyl salicylate was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of The Netherlands was appointed to carry out the evaluation, targeted to the above mentioned grounds for concern. The evaluating MSCA pointed out that the initial grounds for concern for human health was based on reproduction toxicity, therefore the human health endpoints carcinogenicity and mutagenicity were not considered in the course of the evaluation. However, the evaluating MSCA noted additional concern regarding the local toxicity via the inhalation route, which is addressed in this decision.

The evaluating MSCA considered that further information was required to clarify the above mentioned 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 27 February 2013.

On 4 April 2013 ECHA sent the draft decision to the concerned registrants 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.

By 6 May 2013 ECHA received comments from concerned registrants of which it informed the evaluating MSCA without delay. In addition, the evaluating MSCA considered the updated IUCLID dossier (date 5 July 2013) containing an updated Chemical Safety Report (CSR) on sections 1 to 8 but not section 9 on exposure assessment. The evaluating MSCA considered the concerned registrants' comments received and amended Section II of the draft decision. The comments were reflected in Section III of the draft decision (Statement of Reasons).

In accordance with Article 52(1) of the REACH Regulation, on 5 September 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, two Member State Competent Authorities and ECHA submitted proposals for amendment to the draft decision.

On 11 October 2013 ECHA notified the registrants of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA has reviewed the proposals for amendment received and amended the draft decision accordingly.

On 21 October 2013 ECHA referred the draft decision to the Member State Committee.

By 12 November 2013 the concerned registrants provided comments. The evaluating MSCA has reviewed the comments received on the proposed amendments and did not amend the draft decision, since no new information or data were provided. The concerned registrants did make a comment not related to the proposals for amendment submitted by Member State Competent Authorities/ECHA, which was noted in the draft decision, but did not result in amendments of the information requests (Section II). The Member State Committee took the comments of the concerned registrants into account. However, the Member State Committee did not consider the concerned registrants' comments that were not related to the proposals for amendment.

After discussion in the Member State Committee meeting on 10-13 December 2013, a unanimous agreement of the Member State Committee on the draft decision was reached on 12 December 2013. ECHA took the decision pursuant to Article 52(2) and 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. *In vitro* dermal absorption study using test method specified in test method EU B.45 of Regulation (EC) No 440/2008 or OECD 428 using freshly isolated skin and including quantification of possible metabolites, with specifications and with additional modifications of the test as specified in Section III.;

2. 28-day repeated dose toxicity study in the rat, by inhalation (test method EU B.8 of Regulation (EC) No 440/2008 or OECD 412).

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall also submit the following information in the form of an updated CSR using the specified approaches where applicable:

3. Worker exposure assessment
    a. Information on the worker exposure for the respective processes PROC2 and PROC15 for both scenarios 1 and 2; PROC4, PROC7, PROC8a, PROC10 and PROC13 for scenario 3; PROC4, PROC10, PROC11, and PROC13 for scenario 4; and PROC10 and PROC11 for scenario 5 is required to perform a risk assessment for these activities;
    b. Perform an enquiry amongst quality control employees to give a realistic overview of work and duration in this function. Based on the enquiry, a well-founded realistic worst case must be chosen for work and exposure durations of the exposure scenarios including quality control. Next, the exposures must be recalculated based on these input variables;
    c. Provide justification for the exposure assessment for 'unloading bulk tanker and transfer of drums/IBC to storage vessel' where exposure emission was considered to be outside the breathing zone of the worker;
    d. Provide dermal exposure estimates for spraying processes (PROC7 and PROC11).
    e. Provide inhalation exposure estimates for the following PROCs: PROC1, PROC2, PROC8a and PROC8b;
    f. Perform exposure measurements for technical services;
4. Documentation on the risk management measures for the processes mentioned under exposure scenarios 1, 2, and 3. This includes type of gloves and respiratory protection where relevant, taking into account breakthrough times for gloves and clothing and type of filter for the specified respiratory protective equipment;
5. Provide the consumer exposure assessment for product codes PC8 and PC31 for the individual products and perform an aggregate exposure assessment for the products combined;
6. Provide information on the air freshener products specifying the density of the non-volatile fraction of the product, the mass generation rate of the aerosol(s), and the particle size distribution after spraying. Subsequently, update the exposure assessment for air fresheners accordingly.
7. Provide substance-specific justification for deviating from the default assessment factors to determine the DNEL as given in ECHA guidance on REACH (Guidance on information

requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health; ECHA, 2012a).

Furthermore, pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit detailed study summaries for the information required under points 1 – 2, 3 and 6 of this Section II and update the technical dossier and CSR accordingly for all points.

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrants shall submit to ECHA by 25 May 2015 an update of the registration dossiers containing the information required by this decision.

At any time, the concerned registrants 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.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on hexyl salicylate and other relevant and available information and taking into account the comments of the concerned registrants, proposals for amendment submitted by Member State Competent Authorities/ECHA and the deliberations of the Member State Committee, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

1. *In vitro* dermal absorption study

Information on dermal absorption is required in order to enable the evaluating MSCA to assess the exposure and risk after dermal exposure to the registered substance. The dermal absorption is used to apply route-to-route extrapolation from an oral NOAEL identified in the CSR. The data on dermal absorption of the registered substance was considered to be unreliable to derive a dermal absorption percentage. The dermal absorption studies provided in the IUCLID dossier (updated dossier, date 5 July 2013) are considered to be unreliable to predict the absorption of hexyl salicylate for the following reasons. The Jimbo 1983 study was considered not well performed for a number of reasons:

1. No mass balance was made and it was noted by the authors that the salicylates may have been present in the skin or gone lost due to washing steps leading to an unknown underestimation of the dermal absorption.
2. The thickness of the skin (human excised skin) in the study was unknown.
3. Receptor fluid was saline, while salicylates dissolve poorly in saline, where the study even showed an inverse correlation between the solubility and dermal absorption. Moreover, OECD TG 428 states that the substances must be adequately soluble in the receptor fluid.
4. A too low temperature was used in the study, i.e. 21°C.
5. Main metabolites of hexyl salicylate were not determined in the study.

Furthermore, the evaluating MSCA checked the dermal absorption prediction for the other substances included in the Jimbo study, where possible, and noted that the underestimation of the Jimbo study ranged 2 to 100-fold (dermal absorption on benzyl alcohol, benzyl acetate, and cinnamic aldehyde available in the public registration website of ECHA). Based on the above, the study was not considered sufficiently reliable.

The Watkinson et al. (1992) prediction model was added to the registration IUCLID dossier, which seems to support the results found by Jimbo (1983). The mathematical model is characterised by a number of equations of which its default parameters have an unknown origin. Moreover, the domain for which the equations were derived is probably limited for the substances in sunscreens included in the study. However, the experimental data for

salicylates is scarce and little to no data exists for larger chain salicylates such as hexyl salicylate. The authors stated: "while the percutaneous penetration of salicylates has been investigated outside of these model predictions, there was little reliable information available to compare experimental and model results". In addition, the model calculates the dermal absorption using simulations of a typical exposure to sunscreens, where some crucial assumptions on release rates are made, without proper rationale. Taken the reasons above into consideration, the reliability of the model predictions for hexyl salicylate is considered highly questionable. The fact that the results by Watkinson et al. (1992) seem to support those by Jimbo (1983) is by no means a credential as the Jimbo study was not considered reliable.

The evaluating MSCA received a proposal for amendment to determine the risks of dermal exposure by applying default dermal absorption values as stated in ECHA guidance "Guidance on information requirements and chemical safety assessment Chapter R.7c: Endpoint specific guidance" (ECHA, 2012b) and to either re-draft the information request or to withdraw the information request. The evaluating MSCA considered the proposal for amendment and decided not to amend or withdraw the information request. ECHA notes that by applying default values (debatable if 100% or 10% is used as default) for dermal absorption, RCRs > 1 will be derived. This is in line with the comments made by the concerned registrants. A refinement for the risk related to the dermal exposure is therefore required. According to the CSR, there is dermal exposure for workers and the general public and therefore the risk related to the dermal exposure is of concern. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures.

An *in vitro* dermal absorption test with freshly isolated human excised skin is requested from the concerned registrants. Due to possible hydrolysis in viable skin, the concerned registrants are required to test for the registered substance and quantify the possibly formed metabolites. Further information regarding important points that need to be considered in dermal absorption studies can be found in guidance by the European Scientific Committee on Consumer Safety (SCCS)/1358/10 and the OECD guidance (notes) on dermal absorption.

The important points to consider are amongst others:

1. The design of the diffusion cell (technicalities and choice between static and flow throughsystem) the choice to be substantiated.
2. The choice of the receptor fluid (physiological pH, solubility and stability of chemical in receptor fluid should be demonstrated, no interference with skin/membrane integrity, analytical method, etc.) needs to be adequate and substantiated for the substance (formulation) under investigation.
3. The skin preparations should be chosen and treated with care (human skin from an appropriate site remains the gold standard).
4. Skin integrity is of key importance and should be verified.
5. Skin temperature has to be ascertained at normal human skin temperature.
6. The test substance has to be rigorously characterised.
7. Dose and vehicle/formulation should be representative for the in-use conditions. Several concentrations, including the lowest and anticipated concentrations of the test substance in an appropriate vehicle, should be included.
8. Dose and occlusion have to mimic in-use conditions.
9. Regular sampling is required over the whole exposure period.
10. Appropriate analytical techniques should be used. Their validity, sensitivity and detection limits should be documented in the report.
11. The test compound and its metabolites are to be determined in all relevant compartments:
    - product excess on the skin surface (dislodgeable dose),

- stratum corneum (e.g. adhesive tape strips),
- living epidermis (without stratum corneum),
- dermis,
- receptor fluid.

12. Mass balance analysis and recovery data are to be provided. The overall recovery of test substance (including metabolites) should be within the range of 85-115%.
13. Variability / validity / reproducibility of the method should be discussed. The European Scientific Committee on Consumer Safety (SCCS) considers that for a reliable dermal absorption study, 8 skin samples from at least 4 donors should be used. The amounts measured in the dermis, epidermis, stratum corneum and the receptor fluid will be considered as dermally absorbed and taken into account for further calculations to derive a dermal absorption percentage for route-to-route extrapolation in risk assessment.

The *in vivo* dermal absorption test was also considered by ECHA, however, it was concluded that there are at this moment no indications known that the *in vitro* method with the registered substance would provide unreliable data, and moreover the use of human skin is considered to be appropriate. Furthermore, the evaluating MSCA is of the opinion that alternatives for vertebrate testing should be always considered where possible. The concerned registrants are requested to provide a detailed study summary allowing an evaluation of the study.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to carry out the following study using the registered substance subject to this decision: *in vitro* dermal absorption study using freshly isolated human excised skin; test method: OECD 428, including the quantification of possibly formed metabolites.

2. 28-day repeated dose toxicity study, inhalation route

Information on short-term inhalation toxicity is required in order to address a concern on local toxicity via the inhalation route. The technical dossier on the registered substance contains information on a number of substances that were included in the read across, however none of the substances was tested via the inhalation route. The technical dossier does contain information on irritancy and skin sensitisation properties showing that the registered substance is a skin irritant and skin sensitizer. According to the CSR there is exposure of workers and the general public via the inhalation route and thus there is a concern that the registered substance may cause local respiratory effects.

The concerned registrants commented that irritant properties as a result of repeated exposure are sufficiently covered in the technical dossier by the dermal repeated dose study by Webb (1963), the oral repeated dose study using analogue isoamyl salicylate (Drake et al. 1974) and the lack of irritant effects in the Drake et al. study. However, the technical dossier contains no study record of any dermal repeated dose study. Furthermore, the analogue substance isoamyl salicylate is not an irritant thus one would not expect irritant effects in the Drake et al. study. Moreover, according to ECHA guidance, route-to-route extrapolation from the oral to the inhalation route to derive an inhalation DNEL for local effects should not be applied.

The concerned registrants further commented that the respiratory sensitization endpoint cannot be covered by a 28-day inhalation study nor any other accepted study. ECHA notes that possible effects resulting from hypersensitive reactions to the registered substance might be observed in an inhalation 28-day study, for example in gross pathology of the draining lymph nodes of the lung, possibly resulting in the most critical endpoint for the derivation of an inhalation DNEL for local effects. ECHA acknowledges that the 28-day inhalation study cannot be used as stand-alone for classification of the registered substance

as a respiratory sensitizer.

One Member State Competent Authority made a proposal for amendment to either re-draft the statement of reasons or to withdraw the information request as the Member State Competent Authority considered that the concern of local respiratory effect is not well founded since it is only based on skin irritation and sensitisation. No irritation was observed after ocular instillation and after repeated dose oral studies. Furthermore, even if an inhalation exposure cannot be ruled out due to spraying scenarios, the vapour pressure is considered as relatively low (0.077 Pa) indicating a low potential of inhalation exposure. ECHA does not agree that the concern of local respiratory effect is not well founded for the following reasons:

1. Ocular irritation was reported, though being of slight severity and reversible. Nevertheless, the ocular irritation (or the lack thereof) cannot preclude the possible local effects in the respiratory tract as a result of possible irritation or sensitization effects.
2. The derived DNEL for repeated exposure is based on an oral study with isoamyl salicylate, which is not considered as an irritant at all.
3. The (lack of) effects as a result of oral exposure of irritants are not predictive for possible local irritation effects in airways tissues.
4. According to ECHA guidance, route-to-route extrapolation from oral to inhalation should not be applied in case of possible local effects.

ECHA agrees that the vapour pressure is relatively low, however ECHA notes that the substance is sprayed during certain activities and which might result in inhalation exposure. Whether or not the resulting exposures can be considered negligible cannot be determined if there is no inhalation DNEL established covering also possible local effects.

ECHA remains with its conclusion that there is a data gap on inhalation toxicity in the hexyl salicylate dossier. No animal free tests exist to investigate the possible local respiratory effects after inhalation exposure. In view of worker and consumer safety the requested 28-d inhalation study is deemed necessary.

Since the concerns are based on local irritation effects, either being mediated by irritation or hypersensitivity, it is considered by ECHA that a 28-day inhalation study is appropriate. This information is needed to establish whether the suspected concern may be realised or not. Without the requested information it will not be possible to verify whether there remains an uncontrolled risk with the substance that should be subject to further risk management measures.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to carry out the following study using the registered substance subject to this decision: 28-day repeated dose toxicity study in the rat (the preferred rodent species), by inhalation (test method EU B.8 of Regulation (EC) No 440/2008 or OECD 412).

3. Worker exposure assessment

The information requested on worker exposure is required to evaluate the exposure and risks of workers working with or exposed to the registered substance. The information requests have been subdivided below to address specifically concerns resulting from lacking information on worker exposure. Pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to update the technical dossier and the CSR with the relevant information for points a) to f).

The evaluating MSCA received notice of an update of the technical dossier (date 5 July 2013) containing an updated CSR on sections 1 to 8 but not section 9 on exposure

assessment. As section 9 on exposure assessment was not updated, most information requests remained unchanged. However, in section 2 of the updated technical dossier, in line with comments received from the concerned registrants, the PROCs assigned per scenario were changed. The eMSCA compared the unchanged section 9 on exposure assessment with the updated list of PROCs to determine if any omissions in exposure calculations remained. This led to the amendment of 3a where PROCs were added or removed according to the update. In addition, one information request regarding discrepancies between the use of PROC1 and PROC2 interchangeably was removed as the update made the request redundant. Information request 3f was amended, where cleaners during cleaning activities were no longer included as a subpopulation in the information request.

An additional comment was included in the concerned registrants' comments to the proposals for amendment from Member State Competent Authorities and ECHA concerning information request 3b. This comment was not related to any of the proposals for amendment from Member State Competent Authorities or ECHA and therefore it was not considered in detail. Moreover, the CSR was not updated in accordance to the comment made by the concerned registrants. As a consequence the draft decision was not amended.

a) Missing PROCs in exposure calculations

Hexyl salicylate is classified as hazardous according to self-classification by the concerned registrants and consequently exposure scenarios and exposure assessment that address all identified uses of the concerned registrants shall be provided. It appears that the exposure estimates as provided in the dossier do not cover all activities performed during industrial use. Consequently, it is unclear whether risks to hexyl salicylate during all worker activities are adequately controlled.

Information on the worker exposure for the respective processes PROC2 and PROC15 for both scenarios 1 and 2; PROC4, PROC7, PROC8a, PROC10 and PROC13 for scenario 3; PROC4, PROC10, PROC11, and PROC13 for scenario 4; and PROC10 and PROC11 for scenario 5 were lacking in the registration dossier. This information is required to perform a risk assessment for these activities and to assess if the risks for workers are controlled.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to provide information on the worker exposure for the respective processes PROC2 and PROC15 for both scenarios 1 and 2; PROC4, PROC7, PROC8a, PROC10 and PROC13 for scenario 3; PROC4, PROC10, PROC11, and PROC13 for scenario 4; and PROC10 and PROC11 for scenario 5 and to perform a risk assessment for these activities.

b) Perform enquiry for quality control employees to provide realistic exposure assessment

Exposure estimations for quality control employees were calculated using exposure modelling. There are concerns about the input variables chosen for the calculations. It appears that the exposure duration was underestimated. Consequently, it cannot be assessed if there is a risk during worker exposure and if exposure is adequately controlled.

The inhalation exposure during quality control (PROC2) in various exposure scenarios is based on an exposure duration of 15 minutes and divided by 32 to obtain the TWA 480 minutes. So, during the rest of the working day the exposure is set to zero. The scenario description however is broader than quality control only, e.g. manufacture – sampling – quality control. Besides exposure during Quality Control there may be also exposure to hexyl salicylate during other activities (e.g. manufacturing and sampling), but this was not incorporated in the activity class in the Advanced Reach Tool (ART) model. The exposure duration for this function is not realistic.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to perform an enquiry among workers that, next to quality control, perform other activities, e.g. manufacture and sampling. This enquiry must give an overview of work and duration in this function and must be a realistic reflection of reality. Based on the enquiry, a well-founded realistic worst case must be chosen for work and exposure durations of the exposure scenarios including quality control. Next, the exposure estimations shall be recalculated based on these input variables.

c) Provide justification for the exposure assessment for 'unloading bulk tanker and transfer of drums/IBC to storage vessel' where exposure emission was considered to be outside the breathing zone of the worker
For 'unloading bulk tanker and transfer of drums/IBC to storage vessel' it is stated that the primary emission source is not located in the breathing zone of the worker. However, in the exposure scenario it was described that workers at smaller sites can be exposed to the substance during manual operations (e.g. filling containers using a bucket). Also discharge of waste/effluent might lead to emission in the breathing zone according to the evaluating MSCA. The difference in the exposure estimate might be significantly underestimated by assuming that the primary emission zone is outside the breathing zone of workers.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are required to provide a justification for the decision to calculate the inhalation exposure during 'unloading bulk tanker and transfer of drums/IBC to storage vessel' under the assumption that the primary emission zone is outside the breathing zone of workers.

d) Provide dermal exposure estimates for spraying processes
To assess whether exposure to hexyl salicylate is adequately controlled, all exposure routes must be taken into account for every exposure scenario. No dermal exposure was calculated for PROC7 (industrial spraying) and PROC11 (professional spraying). However, dermal exposure may be rather high for these PROCs (see also ECETOC TRA worker model). The concerned registrants must calculate dermal exposure for PROC7 and PROC11.

e) Provide inhalation exposure estimates for the specified PROCs
To assess whether exposure to hexyl salicylate is adequately controlled, all exposure routes must be taken into account for every exposure scenario. No inhalation exposure was calculated for work containing the following PROCs: PROC1, PROC2, PROC8a and PROC8b. Since the critical DNEL cannot be determined yet (see information requirement under point 2) it is unknown if risks are sufficiently controlled for exposure via inhalation from activities described in PROC 1, PROC2, PROC8a and PROC8b. Therefore, the concerned registrants must calculate inhalation exposure for work containing these PROCs.

The concerned registrants are requested to provide the information following the ECHA guidance on occupational exposure estimation (chapter R.14).

f) Perform exposure measurements for technical services
Information on the worker exposure for technical services is required to perform a risk assessment for these activities (for all relevant exposure scenarios). Technical services are currently not covered in the CSR by the concerned registrants.

No separate dermal and inhalation exposure assessment was made for workers in technical services. It is general knowledge that exposures during repair and maintenance are relatively high. There is no PROC in ECETOC-TRA that covers exposure of technical services. So, dermal exposure of technical services must be measured or calculated with a higher tier model. Also inhalation exposure must be measured or calculated for workers in technical services.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to perform exposure measurements. The exposure measurements shall be performed according to the internationally accepted guidelines, such as NEN-EN 689 or according to the guidance 'Testing Compliance with Occupational Exposure Limits for Airborne Substances' (http://www.arbeidshygiene.nl/~uploads/text/file/2011-12%20BOHS-NVvA%20Sampling%20Strategy%20Guidance.pdf)[2], or similar. Alternatively, the concerned registrants may decide to perform an enquiry amongst technical service workers to obtain data for higher tier modelling. This approach is only valid if the concerned registrants can scientifically justify the input values required for exposure modelling and if the concerned registrants document that this choice would not lead to an underestimation of the exposure estimates. For calculations of inhalation exposure it is suggested to use the Advanced Reach Tool (ART); for calculations of dermal exposure it is suggested to use RISKOFDERM. The input variables for both models shall be gathered by way of an enquiry among workers in technical services. The enquiry shall include amongst others information on the tasks performed, their respective frequency and duration and all other parameters that are needed to calculate the exposure (see also ECHA guidance[3]). The study shall be a realistic and robust reflection of reality. Based on the enquiry, a well-founded realistic worst case must be chosen for every input variable and the exposures must be calculated based on these input variables.

4. Documentation of risk management measures

Information on risk management measures (RMMs) is required in order to evaluate whether the measures taken are sufficient to control the risks of workers exposed to the registered substance and to communicate to downstream users about what risk management measures to take. It was considered by the evaluating MSCA that risk management measures to reduce hexyl salicylate exposure are especially important when used in high concentrations. Therefore, the information on RMMs requested is limited to those applied under the exposure scenarios 1 to 3 of the CSR.

The personal protective equipment, gloves, clothing and respiratory protection, are mentioned in the technical dossier including their effectiveness, however lacks detailed information. For skin protection, this includes amongst others the type of material and its thickness, the typical or minimum breakthrough times of the glove material and the type and quality of other protection equipment required, such as a coverall. For respiratory protection amongst others the type of equipment shall be specified.

The concerned registrants are therefore requested to provide information on type of gloves and respiratory protection where relevant, taking into account breakthrough times for gloves and clothing and type of filter for the specified respiratory protective equipment.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to update the technical dossier and the CSR with the relevant information.

5. Missing consumer exposure and risk assessment for product codes PC8 and PC31

The evaluating MSCA received notice of an update of the technical dossier (date 5 July 2013) containing an updated CSR on sections 1 to 8 but not section 9 on exposure assessment. However, in section 2 of the update technical dossier, in line with comments received from the concerned registrants, the PCs assigned for consumer use were changed. The evaluating MSCA compared the unchanged section 9 on exposure assessment with the

[2] Both guidelines are made for airborne exposure measurements. However, the method of measuring compliance with limit values can also be applied to dermal exposure measurements.
[3] Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational exposure estimation, R.14.5.2 RISKOFDERM dermal model and R.14.5.3 Advanced REACH Tool (ART), Version 2.1, November 2012.

updated list of PCs to determine if any omissions in exposure calculations remained. This led to the amendment of the information request where PCs were added or removed according to the update.

The information on consumer exposure and risk assessment from consumer products covered by the following codes PC8 and PC31 are required in order to assess the risks of using products belonging to these categories. The substance is classified as dangerous according to the CLP Regulation (EC) No 1272/2008 for skin irritancy and skin sensitisation. Consequently, pursuant to article 14(4) of the REACH Regulation, exposure scenarios, exposure assessments and risk characterisation shall address all identified uses of the concerned registrants.

The concerned registrants notify the use of the registered substance in several products, but provide an exposure assessment for PC3 and PC35 only, without any statement and justification that the exposure from any other product is at maximum equal to that of the worked out exposure assessments. For this reason, there is insufficient information to conclude on consumer exposure assessment to evaluate if risks are sufficiently controlled. Furthermore, there is a possibility that the products listed will be used at the same time or on the same day. The concerned registrants are therefore requested to perform an aggregated exposure assessment taking into account exposure from multiple products and multiple routes.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to update the CSR by carrying out and clearly document in the CSR consumer exposure assessment and risk assessment for all identified consumer uses. In addition, an aggregated consumer exposure assessment for the combined identified uses should be included in the CSR.

6. Provide detailed information on the air freshener products.

The evaluating MSCA received notice of an update of the technical dossier (date 5 July 2013) containing an updated CSR on sections 1 to 8 but not section 9 on exposure assessment. As section 9 on exposure assessment was not updated, this information request remained unchanged.

Information on the consumer exposure assessment of the registered substance from the use of air fresheners by aerosols (aqueous and non-aqueous) is required to determine whether the use of the substance in air fresheners might lead to risks. According to the CSR the exposure and risk to the air fresheners by aerosol are relatively high. ECHA further notes that if the ECHA guidance was used to derive an inhalation DNEL, the RCR would increase four-fold. In the first-tier approach, the exposure estimate for air fresheners by aerosols was generated using the AISE REACT consumer tool in combination with the TWA BAMA tool. According to the concerned registrants the first-tier approach led to a RCR >1 and therefore the ConsExpo 5.0 model was used in a higher tier assessment (a RCR of 0.25 for aqueous aerosol is derived according to the CSR). To assess the exposure from air fresheners the concerned registrants relied on the data from the pest control products fact sheet – air space applications, where specific product information was required. ECHA is of the opinion that data specific for the air fresheners should have been used or evidence should be provided that the particle size distribution of an air space spray for pest control is comparable to that of an air freshener.

The concerned registrants are requested to provide information on the air freshener products specifying the density of the non-volatile fraction of the product, the mass generation rate of the aerosol(s), and the particle size distribution after spraying. If measurements are to be performed to generate the data, the concerned registrants are

required to provide the test results allowing an evaluation of the data. Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to update the technical dossier and the CSR with the relevant information.

7. Provide substance specific justification for deviating from ECHA guidance for default assessment factors.

The evaluating MSCA received a proposal for amendment to include an information request for a substance-specific justification for deviating from the ECHA guidance default assessment factors as suggested in ECHA guidance "Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health" (ECHA, 2012a). The evaluating MSCA decided to amend the decision by including the suggested information request.

The concerned registrants have preferred the use of default assessment factors based on ECETOC Technical Report No 86 (ECETOC, 2003), resulting in lower assessment factors and lower RCRs than if REACH assessments factors had been used. If the ECHA guidance assessments had been applied, RCRs > 1 could be derived and thus risks may not be sufficiently controlled.

The concerned registrants are requested to provide substance-specific justification for the use of assessment factors that deviate from the default assessment factors as suggested in the ECHA guidance. Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned registrants are requested to update the technical dossier and the CSR with the relevant information.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the required tests, the sample of substance used for the new studies shall have a composition that is within the specifications of the substance composition that are given by all concerned registrants. It is the responsibility of all the concerned registrants to agree on the tested materials to be subjected to the tests 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 studies must be shared by the concerned registrants.

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

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between concerned registrants. Since several concerned registrants of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other concerned registrants and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the concerned registrants to perform the tests on behalf of all of them. If a concerned registrant performs a test on behalf of other concerned registrants, they shall share the cost of that study equally and the concerned registrant performing the test shall provide each of the

others concerned with copies of the full study reports.

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/datasharing_en.asp.

VI. General requirements regarding Good Laboratory Practice

ECHA always reminds concerned 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.

VII. Information on right to appeal

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

[redacted]

Jukka Malm
Deputy Executive Director

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.