EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114290253-52-01/F Helsinki, 18 December 2014

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

**For Ethylene Carbonate, CAS No 96-49-1 (EC No 202-510-0), 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 (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for ethylene carbonate, CAS No 96-49-1 (EC No 202-510-0), submitted by [redacted] (Registrant). ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes VII to X was done on the lead registrant dossier of this joint submission.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes per year. This decision does not take into account any updates submitted after 24 July 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 7 October 2013.

On 18 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision

On 17 December 2013 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments regarding the information requirements in the draft decision. Section II was not amended. The Statement of Reasons (Section III) was changed to reflect the Registrant's comments.

The Registrant's comment on the deadline set in the draft decision and on his willingness to update the registration dossier after the lead company has updated his dossier (following receipt of the final decision) was taken into consideration by ECHA and the deadline was amended. These considerations are reflected in Section III of the draft decision.

On 24 July 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposals for amendment to the draft decision were submitted.

On 29 August 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 8 September 2014 ECHA referred the draft decision to the Member State Committee.

By 29 September 2014 in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 28-29 October 2014, a unanimous agreement of the Member State Committee on the draft decision was reached 29 October 2014.

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

II. Information required

## A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1)(a), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

Name in the IUPAC nomenclature or other international chemical name (Annex VI, 2.1.1.).

## B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised DNELs for workers and for the general population using the recommended assessment factors by ECHA and deriving a DNEL long-term local inhalation for workers
   or
   A full justification for not using the recommended assessment factors in DNEL derivation and a qualitative assessment of local inhalation effects (Annex I, 1.4.1 of the REACH Regulation), as specified in section III B.1;

2. Revised exposure assessment (Annex I, 5.) with respect to a revised exposure assessment and risk characterisation for dermal route (Annex I, section 5.2.4. and 6.), as specified in section III B.2.

3. Revised consumer exposure assessment and risk characterisation:
   a. Taking into account the consumers' activities and the duration and frequency of their exposure (Annex I, Sections 5 and 6).
   b. Using the fraction released to air recommended by ECHA Guidance R.15 (Annex I, Section 5.2.4) or a full justification for not using the recommended values in the consumer exposure estimates.

**C. Deadline for submitting the required information**

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **2 January 2017**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

**A. Information in the technical dossier related to the identity of the substance**

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Name in the IUPAC nomenclature or other international chemical name(s) (Annex VI, 2.1.1.)

"Name in the IUPAC nomenclature or other international chemical name(s)" is an information requirement as laid down in Annex VI, Section 2.1.1. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant provided in the IUPAC name field of IUCLID Sections 1.1 and 1.2 the name "2-(carboxyoxy)ethylcarbonate" to identify the registered substance. This IUPAC name does not correspond to the IUPAC name of the registered substance which appears to be "1,3-dioxolan-2-one" according to the IUPAC rules.

ECHA notes that in his comments according to Article 50(1) the Registrant expressed his willingness to amend the name of the substance under the IUPAC name field within the next dossier update.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct naming as specifically explained in the present decision. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the chemical name, the information shall be included in the IUPAC name field in IUCLID section 1.1 and 1.2.

## B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. Revised DNELs for workers and for the general population using the recommended assessment factors by ECHA and deriving a DNEL long-term local inhalation for workers or a full justification for not using the recommended assessment factors in DNEL derivation and a qualitative assessment of local inhalation effects (Annex I 1.4.1. of the REACH Regulation), as further specified below.

Annex I, 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The ECHA Guidance on information requirements and chemical safety assessment, R.8 (version 2.1, November 2012) provides further details and specifically provides default factors which should be applied to derive derived no effect levels (DNELs) in the absence of substance specific information.

The assessment factors (AF) applied by the Registrant and the default assessment factors recommended in the ECHA Guidance R.8 are given in detail in Annex I attached to this decision.

ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1. In particular, ECHA notes that for the systemic long term DNELs for inhalation route and dermal route both for workers and the general population the AF for duration of exposure is 1. The starting point for these DNELs is a prenatal developmental toxicity study which uses an exposure period corresponding to a sub-acute study and therefor the default AF of 6 should have been applied.

Furthermore, ECHA notes that the Registrant has not derived a DNEL for long-term local inhalation to demonstrate that in industrial or professional spray application the risk for respiratory tract is controlled. The Registrant justifies the omission of this DNEL with the argument that no local irritant effects were observed in the oral prenatal developmental toxicity study. ECHA considers this argument not valid as the gastrointestinal tract with its low pH is not as sensitive to local irritation as the respiratory tract. ECHA further observes that the substance is irritating to the eye indicating irritative potential. Therefore a risk characterisation is needed for long-term local inhalation effects either quantitatively based on a DNEL or qualitatively according to *Practical Guide 15 How to to undertake a qualitative human health assessment and document it in a chemical safety report*[1].

[1] Link to ECHA Practical Guide 15 is: http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf

As explained above, the information provided on DNELs for the registered substance in the CSR does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1. because the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. and the deviations are not fully justified. Furthermore a DNEL has not been derived for long-term local inhalation for workers. Consequently it is necessary to revise the DNELs or to provide a full justification.

As regards assessment factors, the Registrant is given two options: The Registrant shall revise the DNELs for workers and for the general population by applying the assessment factors recommended by ECHA that are appropriate in this case . Subsequently, the Registrant shall re-assess related risks.In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the current DNEL derivation for workers and for the general population provided in the CSR by specifying how the following has been taken into account:

- the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- the nature and severity of the effect;
- the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
- and that the DNELs reflect the likely route(s), duration and frequency of exposure.

As regards DNEL for long-term local inhalation for workers, the Registrant is given two options: The Registrant shall derive a DNEL according ECHA Guidance on information requirements and chemical safety assessment, R.8 (version 2.1, November 2012). In the alternative, the Registrant shall perform a qualitative assessment of local inhalation effects.

ECHA notes that the Registrant expressed in his official comments according to Article 50(1), the willingness to amend the DNELs derivation and to include a detailed read-across justification to show that ethylene glycol can be used as read-across substance to assess the toxicity of ethylene carbonate. ECHA notes that in his comment the Registrant justifies the read across with a reference to a rapid conversion of ethylene carbonate to ethylene glycol (half-life of 15 minutes) and summary of adverse effects observed in a chronic study on the analogue susbtance and carcinogenicity study on the registered substance. ECHA further observes that the Registrant stated in Section 5 of the Chemical Safety Report, with respect to the repeated dose toxicity and reproductive toxicity properties of ethylene carbonate, that "*Toxicokinetics demonstrated the rapid metabolisation of ethylene carbonate to ethylene glycol (CAS 107-21-1) (Hanley, 1989). Sufficient data are available on the repeated dose toxicity of ethylene glycol, which is demonstrated to be more toxic than its precursor. The key study for this endpoint is a chronic study in which male Wistar rats are exposed to ethylene glycol via the diet for a period of 12 months (Corley et al, 2008).*" ECHA notes that in the CSR the Registrant has supported the argument of rapid metabolisation with a toxicokinetic study in rats showing a half-life of 0.25 hours for ethylene carbonate. Nevertheless ECHA notes that the Registrant has not provided any justification why a half-life of 0.25 hours would exclude any toxic effects of non-metabolised ethylene carbonate and thus would allow predicting the repeated dose toxicity of ethylene carbonate from data available on ethylene glycol. ECHA further considers that the comparison of dose levels in a chronic study on the analogue substance and a carcinogenicity study on the registered substance does not remove this uncertainty concerning toxic effects of the registered substance before conversion to the analogue substance. Therefore, the proposed read-across approach does not fulfil requirements of Annex XI, section 1.5., and consequently does not allow predicting the toxicological properties of the registered substance ethylene carbonate from the data available for the analogue substance ethylene glycol.

Moreover, ECHA notes that the Registrant in his official comments indicated the intention to consider as new starting point for the DNEL derivation the NOAEL of 150 mg/kg/d from a repeated dose chronic toxicity study with ethylene glycol. The Registrant also explained the correction of the NOAEL due to the different molecular weight of ethylene carbonate compared to ethylene glycol (88.06 vs 62.07 g/mol) obtaining as a starting point a NOAEL of 212.9 mg/kg/d for ethylene carbonate. ECHA underlines, as already explained above, that the justification for the read-across approach from ethylene glycol to ethylene carbonate does not fulfil requirements of Annex XI, section 1.5., and consequently does not allow predicting the toxicological properties of the registered substance ethylene carbonate from the data available for the analogue substance ethylene glycol. Consequently the information on the analogue substance is not appropriate to predict the DNELs of the substance subject to the present decision. For these reasons, the Registrant shall calculate the DNELs for workers and for the general population using as starting point the lowest NOAEL obtained in toxicological studies with the registered substance and apply the assessment factors recommended by ECHA that are appropriate or provide a full justification for not using the recommended assessment factors. Subsequently, the Registrant shall re-assess related risks.

As regards the DNEL for long-term local inhalation for workers, ECHA observes that the Registrant proposes in his official comments to made use of a local occupational exposure level of 26 mg/m3 derived by the MAK Commission for ethylene glycol for a daily eight hour exposure. The Registrant further corrected the local OEL due to the different molecular weight of ethylene carbonate in contrast to ethylene glycol (88.06 vs 62.07 g/mol) and obtained as local OEL for ethylene carbonate 36.9 mg/m3. However ECHA notes that Appendix 8-13 of the Guidance on information requirements and chemical safety assessment, R.8 (version 2.1, November 2012), does provide for the use of an OEL in place of developing a DNEL for the same substance and for the same exposure route, duration and population. Nevertheless ECHA notes that there is no provision in that Guidance that would allow the Registrant making use of an OEL of a proposed analogue substance (not fulfilling requirements of Annex XI, section 1.5.).

Finally, ECHA acknowledges the Registrant's willingness to perform a qualitative risk assessment and to include it in the exposure section of the chemical safety report within the next dossier update to demonstrate that the risk for the local inhalation effects is controlled.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report either of the following information: Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA, and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation. In addition the Registrant is requested to submit in the CSR either of the following information: A DNEL long-term local inhalation for workers and re-assessment of related risks *or* a qualitative assessment of local inhalation effects.

*Notes for consideration by the Registrant*

Any relevant new information on toxicological studies shall be taken into account when revising the DNELs.

2. Revised exposure assessment (Annex I, 5.) with respect to
   a) A revised exposure assessment for dermal route and risk characterisation (Annex I, sections 5.2.4. and 6.)

Pursuant to sections 0.6.2. and 0.6.3. of Annex I of the REACH Regulation the chemical safety assessment (CSA) performed by a Registrant shall include an exposure assessment according to section 5. of Annex I and risk characterisation according to section 6 of Annex I. Annex I, section 5.2.4. of the REACH Regulation requires the Registrant to perform an estimation of the exposure levels for all human populations (workers, consumer and humans liable to exposure via the environment) for which exposure to the substance is known or reasonably foreseeable. Each relevant route of exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. In addition, Annex I, section 5.2.5. of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

ECHA notes that the Registrant has used ECETOC TRA version 2 to estimate exposure for a variety of worker and consumer exposure scenarios. More precisely the Registrant has used the local exhaust ventilation (LEV) exposure modifier even when inappropriate such as for estimating dermal exposure.

ECHA underlines that the Guidance on information requirements and chemical safety assessment, R.14 (version 2.1, November 2012, section R.14.4.8, page 21) advises against the use of the LEV modifier for dermal exposure estimation.

ECHA notes that when using the LEV modifier the calculated exposure estimates are likely to be unrealistically low as explained further in the above mentioned Guidance and therefore the worker exposure assessment for the dermal route needs to be revised. Taking into account the need to revise the calculated DNEL(s), the Registrant shall ensure that the calculated risk characterisation ratios will still be below 1, in order to demonstrate the safe use of the registered substance.

As explained above, the information provided on the dermal exposure estimates for the registered substance in the CSR does not meet the general provisions for preparing a CSR as described in Annex I. Consequently it is necessary to revise the dermal exposure estimates.

Based on the above the Registrant shall revise the exposure assessment for dermal route and assess related risks. The revised DNELs requested under section II.B.1 shall be taken into account when assessing the related risks. The CSR shall be amended accordingly.

3. Revised consumer exposure assessment and risk characterisation:
    a. Taking into account consumers' activities and the duration and frequency of their exposure (Annex I, Sections 5 and 6)

According to Annex I, Section 5.2.4 of the REACH Regulation the estimation of exposure shall take into account duration and frequency according to operational conditions. According to Annex I, Section 6.3 the risk characterisation consists of a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL.

ECHA notes that the Registrant reported a frequency of exposure for consumers of 2 days/year and, in his consumer exposure calculations, has used a function within the exposure tool to average out exposure over a year, in order to compare the resulting average "long-term systemic exposure" to a corresponding DNEL and achieve risk characterisation ratios below 1. However, as noted in the REACH Guidance on information requirements and chemical safety assessment, (ECHA (November 2012); Chapter R.8: Characterisation of dose [concentration]-response for human health, p.8): 'The actual daily dose is independent of the exposure frequency. This means that if for a certain scenario, worker or consumer exposure is for instance only for a number of days per year, the

exposure value is the actual dose on the exposure days, and not the daily dose averaged out (and thus divided!) over the whole year.' Therefore, the long term exposure to be compared to the DNEL long term is not the exposure level calculated by averaging exposure events over the year, but the actual daily exposure. The annual averaging factor appears to have been used for a number of the exposure scenarios reported within the CSR.

Therefore pursuant to Article 14(4) and Annex I, Sections 5 and 6 of the REACH Regulation, the Registrant is requested to provide in the CSR revised consumer exposure estimations, i.e. actual daily doses and risk characterisations for exposures to take account of the duration and frequency of exposure resulting from the registered substance within consumer products.

b. Using the fraction released to air recommended by ECHA Guidance R.15 (Annex I, Section 5.2.4) or a full justification for not using the recommended values in the consumer exposure estimates.

Annex I, 5.2.4 of the REACH Regulation requires that the exposure estimation shall take account matrix dependent release/migration of the substance. In the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.15, the vapour pressure bands and the related percentage of compound released to air are listed just as they are implemented in the ECETOC TRA tool.

The Registrant has identified two consumer uses of ethylene carbonate (waterborne latex wall paints and removers (PC 9a)) and has used for consumer exposure estimates the calculation model of ECETOC TRA. In the chemical safety report the vapour pressure is described to be 1 Pa. For the vapour pressure range between 0.1 and 1 Pa a fraction released to air of 0.01 g/g is recommended by the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.15, Table R.15-5, as described in the ECETOC TRA tool. Whilst ECHA notes that the Registrant used in the consumer exposure estimations a fraction release factor of 0.0001 g/g, which is 100-fold lower than the recommended factor. ECHA underlines that the Registrant has indicated, in the relevant consumer scenarios, the following justification for the fraction released to air: *"Fraction release to air = 0.0001 g/g. Since vapour pressure of ethylene carbonate is low (VP = 1 Pa). It is expected that a limited fraction of the substance will be released to air"*. Nevertheless, ECHA underlines that the low vapour pressure of 1 Pa is already considered in the banding approach of 0.1 g/g in the ECETOC TRA model, in accordance with the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.15.

Therefore, pursuant to article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report either of the following information: revision of the consumer exposure assessment and risk characterizations using the fraction released to air as recommended by the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.15, and reassessment of related risks or a full justification for not using the recommended fraction released to air in the consumer exposure estimates.

## C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 6 months from the date of adoption of the decision. In his comments on the draft decision of 18 November 2013, the Registrant indicated that the issues related to chemical safety assessment will be prepared in a coordinated manner with the lead registrant and therefore an update of the registration dossier will be provided only after the lead company has updated his dossier following adoption of the lead registrant decision. Given the need to ensure consistent DNELs by all the registrants as well as the read across considerations linked to that, ECHA considers the request reasonable and justified by the need to have coordinated updates of relevant information requirements requested in the draft decision of lead and member registrants. Therefore, ECHA modified the deadline of the decision and set the deadline first to 36 months. Following proposals for amendment made by Member States, the deadline set in the relevant decision to the lead Registrant was changed from 36 months to 24 months from the date of the adoption of the decision. Therefore, to ensure consistency in DNELs and co-ordination of updates, also the deadline of the present decision was modified accordingly.

## IV. Information on right to appeal

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

[redacted]
Leena Ylä-Mononen
Director of Evaluation

Annex I.

Assessment factors (AF) applied by the Registrant:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5
- exposure duration: 1
  (overall AF: 12.5)

For workers - systemic long term – dermal route:
- interspecies: 10
- intraspecies: 5
- exposure duration: 1
- absorption difference dermal-oral: 1
  (overall AF: 50)

For the general population - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 10
- exposure duration: 1
  (overall AF: 25)

For the general population - systemic long term – dermal route:
- interspecies: 10
- intraspecies: 10
- exposure duration: 1
- absorption difference dermal-oral: 1
  (overall AF: 100)

For the general population - systemic long term – oral route:
- interspecies: 10
- intraspecies: 10
- exposure duration: 1
  (overall AF: 100)

The default assessment factors recommended in the ECHA Guidance, R.8:

For workers - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 6 (sub-acute to chronic)
  (overall AF: 75)

For workers - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 5 (workers)
- exposure duration: 6 (sub-acute to chronic)
- absorption difference dermal-oral: 1
  (overall AF: 300)

For the general population - systemic long term – inhalation route:
- interspecies: 2.5 (remaining differences between species non related to allometry)

- intraspecies: 10 (general population)
- exposure duration: 6 (sub-acute to chronic)
  (overall AF: 150)

For the general population - systemic long term – dermal route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 6 (subchronic to chronic)
- absorption difference dermal-oral: 1
  (overall AF: 600)

For the general population - systemic long term – oral route:
- interspecies - allometric correction: 4 (rat to human)
- interspecies - remaining differences: 2.5 (non-related to allometry)
- intraspecies: 10 (general population)
- exposure duration: 1 (a chronic study)
  (overall AF: 100)