EUROPEAN CHEMICALS AGENCY

Helsinki, 15 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350942-48-01/F
Substance name: Pentanol, branched and linear
EC number: 305-536-1
CAS number: 94624-12-1
Registration number: [redacted]
Submission number: [redacted]
Submission date: 03.06.2013
Registered tonnage band: [redacted]

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1; test method: Bacterial reverse mutation test, EU B.13/14 /OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 with the registered substance;**

2. **Extended one-generation reproductive toxicity study (Annex IX/X, Section 8.7.3; test method: OECD TG 443) in rats, oral route with the registered substance; specified as follows:**

   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **23 December 2019. You shall also update the chemical safety report, where relevant.** The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/guest/regulations/appeals.

Authorised[2] by Ofelia Bercaru, Head of Unit, Evaluation E3

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at [redacted] per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

According to paragraph 13 of the current OECD TG 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

You have provided a test on the registered substance from the year 1983 according to OECD TG 471 and GLP with an assigned reliability score of 2. The test used five different strains of S. typhimurium TA 1535, TA 1537, TA 1538, TA 98 and TA 100 and it did not include tests with strains S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). However, since the test was conducted, significant changes have been made to OECD TG guideline 471 so that additionally testing with S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101) is now required. Therefore, the provided study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2 of the REACH Regulation.

ECHA concludes that a test using *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 has not been submitted and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria.

You have also sought to adapt this information requirement according to Annex XI, Section 1.5 of the REACH Regulation. Specifically, you have provided a supporting study on the analogue substance 1-pentanol, from the year 1986, according to OECD TG 471, with an assigned reliability score of 2. The test used five different strains of *S. typhimurium* TA 1535, TA 1537, TA 97, TA 98 and TA 100. However, this study is also missing information on *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

Annex XI, Section 1.1.2(2) and Annex XI, Section 1.5 require for non-GLP studies and studies used for read-across purposes *"adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test method referred to in Article 13(3)"*, Annex XI, Section 1.1.2(2) and (3) and Annex XI, Section 1.5 require for non-GLP studies and studies used for read-across purposes *"reliable coverage"* and *"reliable documentation"*. Given that the read-across study does not include information on *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102, ECHA concludes that the source study, does not provide the information required by Annex VII, Section 8.4.1, because it does not meet the requirements of Annex XI, Section 1.1.2 and Annex XI 1.5.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to complete following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

2. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at [redacted] per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

a) The information requirement

You have not provided any study record of an extended one-generation reproductive toxicity study in the dossier that would meet the information requirement of Annex X, Section 8.7.3.

While you have not explicitly claimed a weight of evidence adaptation using read across information from other substances, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.2 and Section 1.5. You provided the following studies in the dossier:

- A combined repeated dose toxicity study with reproduction/developmental toxicity screening test, OECD TG 422, done using the analogue substance 3-methylbutan-1-ol, CAS number 123-51-3;
- A sub-chronic toxicity study, OECD TG 408, done using the analogue substance pentan-1-ol, EC number 200-752-1, CAS number 71-41-0;
- A sub-chronic toxicity study, OECD TG 408, done using the analogue substance 3-methylbutan-1-ol, CAS number 123-51-3.

In addition, you provided the following justification for the adaptation, considering that the study is scientifically unjustified:

"There are no studies available concerning toxicity to reproduction with pentanol, branched and linear, but its structural analogues pentan-1-ol and 3-methylbutan-1-ol were tested in two 90d repeated dose studies ([redacted] 1990), in a Combined Repeated-Dose / Reproductive Developmental Toxicity study according to OECD TG 422 ([redacted] 2008), and in prenatal developmental studies in rats and rabbits (Nelson et al. 1989; [redacted] 1990). In addition, there are experimental data available from the structural analogue primary amyl acetate (reaction mass of 2-methyl butyl acetate and pentyl acetate, EC No. 908-918-1) which was shown in in-vivo and in-vitro studies to be rapidly hydrolyzed by liver metabolism into the corresponding alcohols ([redacted] 2004 [redacted] 1993). Primary amyl acetate was tested in a 14-weeks repeated dose study by the inhalation route ([redacted] 1985), and in prenatal developmental studies in rats and rabbits ([redacted] 1994). None of these studies showed any concern regarding reproductive toxicity of pentan-1-ol, 3-methylbutan-1-ol or primary amyl acetate, respectively. Thus, a two-generation study is not necessary. This waiving argument is in line with the guidance document R7a and scientifical argumentation as below.

Because of a high correlation, histopathology data and organ weights from repeated dose studies may be used to assess male fertility (Mangelsdorf, 2003). These parameters, taken from 90 day studies, were in fact shown to be more sensitive than fertility parameters that were measured during multi-generation studies. It could also be shown that exposure for 4 weeks suffices for an assessment of male fertility, although 90 day studies have been regarded as superior in the past because they cover a complete cycle of spermatogenesis (Mangelsdorf, 2003). If such a 28 day study shows neither relevantly elevated testis or ovary weights nor histopathological alterations in those organs, the weight of the evidence is that effects on reproduction are also not expected (BAuA Forschungsbericht Fb 984, 2003). A comparison of more than one hundred 90 day studies with two-generation studies that used the same test substance additionally showed that the NOAELs differed by less than the variation limit of studies, i.e. a factor of two (Janer, 2007). Therefore, the information gained from a two-generation study can be regarded as minimal if a 90 day study has been performed."

However, ECHA notes that your adaptation does not meet the general rules for adaptation of Annex XI, Section 1.2, because it is not possible to assume/conclude based on the information if the registered substance has not a hazardous property on sexual function and fertility.
Your weight of evidence approach is based on information from *in vitro* and *in vivo* toxicokinetics investigations, a 14-day study, 90-day studies, a screening studies (OECD TG 422), and prenatal developmental toxicity studies in rats and rabbits using proposed structurally analogous substances to the registered substance.

ECHA has assessed the weight of each of these lines of evidence separately and together and the conclusions of this assessment are reported below.

Many study types provided may be relevant providing piece of elements for weighing evidence for reproductive toxicity. The information for the following elements critical for reproductive toxicity required at this Annex level have been evaluated weighing the evidence in this specific case: 1) effects on the histopathologically observable changes in reproductive organs in the parental and F1 generation; 2) functional fertility and reproductive performance of the parental generation; 3) postnatal development and sexual maturation and endocrine disruption mode of action.

Furthermore, your justification "the information gained from a two-generation study can be regarded as minimal if a 90-day study has been performed" with literature references is addressed.

1) Screening study (OECD TG 422) and 90-day and 14-week (referred study [redacted], 1985 not found in the dossier) repeated dose toxicity studies may provide information on histopathology of reproductive organs but at a lower statistical power than required at Annex X information requirement. In addition, the spermatogenesis and the folliculogenesis are not fully covered by the screening study. There is no information on the histopathologically observable effects in reproductive organs in F1 generation from any of the studies provided. Lack of hazardous properties on sexual function and fertility cannot be assumed solely based on this information.
2) Limited information on male and female reproductive performance such as gonadal function, mating behaviour, conception, development of the conceptus and parturition is provided from screening study (OECD TG 422). The statistical power is limited and the premating exposure duration and postnatal period is shorter than that required at Annex X, 8.7.3 information requirement. Information from the pre-natal developmental toxicity study (OECD TG 414) regarding to sexual function and fertility is limited to the maintenance of the pregnancy from implantation up to close to the parturition. The sub-chronic toxicity or the 14-week study does not provide any information on functional fertility and reproductive performance. Lack of hazardous properties on sexual function and fertility cannot be assumed solely based on this information or in combination with the information above.
3) The studies do not provide information on hazardous properties to the postnatal development including sexual maturation for the F1 generation. Furthermore, information on sperm parameters and information on endocrine modes of action is missing. Lack of information on these aspects does not allow to assume on hazardous properties on sexual function and fertility regarding to these aspects alone or in combination with the information above.

Regarding to claims that 1) histopathology data and organ weights from repeated dose toxicity studies may be used to assess male fertility, 2) and are in fact more sensitive than fertility parameters, 3) and that exposure for 4 weeks suffices for an assessment of male fertility, 4) and if a 28-day study shows neither relevantly elevated testis or ovary weight nor histopathological alterations, then effects on reproduction are not expected, 5) and results from 90-day and two-generation studies differ less than a factor 2, ECHA notes that you have not provided a justification on why and how these claims can be read across to your registered substance and the information requirement in question you attempt to adapt. The publications and some studies referred to in the adaptation justification were not included in the dossier.

Taking together, you have not provided a justification why and how the information from proposed structurally analogous substances and published literature from other substances could be used to predict the reproductive toxicity properties of the registered substance. Furthermore, the studies provided do not cover critical information on reproductive toxicity such as reproductive toxicity in generation exposed *in utero* and postnatal period and you have not explained how and why the lacking information can be predicted based on the information provided.

Thus, the information from these studies do not allow to assume/conclude that the substance has not hazardous properties with regard to sexual function and fertility.

In your comments to the draft decision, you agreed that there is a data gap concerning postnatal development and only limited information on fertility available from a screening study (OECD TG 422), and therefore you agreed to perform an extended one-generation reproductive toxicity study. However, regarding the choice of the test material, you stated the following:

". But in order to make most use of this study for the category, we propose to perform the study using pentan-1-ol (CAS 71-41-0). Pentan-1-ol is the main constituent of pentanol, branched and linear, usually accounting for [redacted]% of the multiconsituent substance. Considering the similarity of the category members, effects of pentanol, branched and linear are thought to be mainly triggered by pentan-1-ol. Additionally, while a study on pentan-1-ol can be used to assess pentan-1-ol itself as well as pentan-1-ol, branched and linear and the other structurally similar members of the Pentanols category. Using a study on pentan-1-ol, branched and linear for the assessment of pentan-1-ol is more difficult, since the pentan-1-ol concentration is below [redacted]%. Using a pure substance also avoids any obstacles arising from differences in composition.
Tanking animal welfare seriously, the registrant proposes to perform an extended one-generation reproductive toxicity study with the read across substance pentan-1-ol, the results of which will then be used for the assessment of pentan-1-ol, pentan-1-ol, branched and linear as well as 3-methylbutanol and 2-methylbutanol."

ECHA first notes your agreement to perform the requested study. In addition, ECHA has considered your proposal to perform the study using the substance 1-pentanol, instead of the registered substance.

ECHA notes that you have submitted an improved read-across justification as well as introduced a category approach in your dossier. ECHA notes based on this information that you have demonstrated structural similarity, as well as similarity in physico-chemical as well as toxicological properties of the substance for other endpoints that we requested in the draft decision, specifically the sub-chronic toxicity study and the pre-natal developmental toxicity study. Your read-across justification for those two endpoints is backed up by the available information on the proposed category members for those two particular endpoints. The results of those studies demonstrate similarity of properties for those particular endpoints.

ECHA notes that in contrast to the sub-chronic toxicity study and pre-natal developmental toxicity endpoints, the only information on the reproductive toxicity of the proposed category members is a screening study on reproductive/developmental toxicity of 3-methylbutanol. As noted in the draft decision, this study is insufficient to address the parameters of an extended one generation reproductive toxicity study. No other reproductive toxicity studies are available to support the notion that the proposed category members have similar properties in an extended one generation reproductive toxicity studies. Therefore, there is insufficient evidence in the dossier and the registrant's comments on the draft decision to demonstrate that the toxicity of the proposed category members is the same with respect to reproductive toxicity. Therefore, read-across for this endpoint is not sufficiently justified among the individual constituents, or from the individual constituents to the registered substance.
Therefore, ECHA cannot conclude that a single extended one generation study performed on 1-pentanol can be used to address the properties of all members of the category or of the registered substance.

At the same time, ECHA notes your arguments that read-across from the pure 1-pentanol to the mixture that is the registered substance may be easier to justify compared to read-across from the registered substance to 1-pentanol. ECHA, however, also notes the following:

- Due to the absence of evidence, it is not possible to determine which member of the category may represent a worst case in an extended one generation reproductive toxicity study. In addition, as noted above, there is insufficient evidence to conclude that members of the category have similar effects in this study.

- Although you favor performing the study on 1-pentanol, you have not demonstrated why read-across from this particular substance would be easier/more suitable, or would demonstrate a worst case scenario for the category.

- Testing 1-pentanol rather than the registered substance may also create some additional uncertainty compared to the situation where the test is performed on the registered substance. Specifically, there will be uncertainty regarding the effects of 2-methylbutanol, or the possible effects of co-exposure for this particular endpoint. As noted above, you have addressed ECHA's concerns for the sub-chronic toxicity study as well as the pre-natal developmental toxicity studies. However, due to the absence of information on this endpoint for the category members demonstrating similarity of effects in this endpoint, these uncertainties remain.

Taking these considerations into account, there is insufficient evidence to justify testing 1-pentanol, instead of the registered substance. Conversely, testing the registered will result in co-exposure to all three constituents and will provide useful information on the possible effects of co-exposure to these different constituents in the context of reproductive toxicity, and may also serve to consolidate your read-across argument. Therefore, you are requested to perform the study using the registered substance.

Therefore, your adaptation of the information requirement cannot be accepted.

Hence, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) The specifications for the study design

Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to ECHA Guidance, the starting point for deciding on the length of premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required because there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.0, July 2015).

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.
It is recommended that results from a range-finding study (or range finding studies) for the extended one-generation reproductive toxicity study are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Species and route selection

According to the test method EU B.56/ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, July 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

c) Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;

Notes for your consideration

The conditions to include the extension of Cohort 1B are currently not met. Furthermore, no triggers for the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) were identified. However, you may expand the study by including the extension of Cohort 1B, Cohorts 2A and 2B and/or Cohort 3 if new information becomes available after this decision is issued to justify such an inclusion. Inclusion is justified if the new information shows triggers which are described in column 2 of Section 8.7.3., Annex X and further elaborated in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.0, July 2015). You may also expand the study to address a concern identified during the conduct of the extended one-generation reproduction toxicity study and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the expansion must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 42 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2), a pre-natal developmental toxicity study (Annex IX, Section 8.7.2) in a first species, and a pre-natal developmental toxicity study (Annex X, Section 8.7.2) in a second species. In addition, in your comments to the draft decision you requested an extension of the total deadline from 42 months to 52 months – with the justification that studies such as range-finding studies, a palatability study need to be performed.
As the sub-chronic toxicity and pre-natal developmental toxicity studies are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration, taking into account the issues that you raised, is 36 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 20 October 2015

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:]

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account your comments, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance composition manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.

4. ECHA notes this registration dossier is undergoing an adaptation of the substance identifiers. This adaptation is not yet complete as the dossier has not yet been updated with these new identifiers. Nevertheless, if completed successfully it is expected to result in a change of the EC number from the current number to List number 903-139-3 and a change of the name from "Pentanol, branched and linear" to "Reaction mass of 2-methylbutan-1-ol and pentan-1-ol". As this process is not yet complete, the final decision refers to the current identifiers. This eventual change in identifiers does not impact the information request in this decision.