Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

Tellurium Dioxide

EC Number: 231-193-1
CAS Number: 7446-07-3

CLH-O-0000006811-75-01/F

Adopted

11 June 2020

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON TELLURIUM DIOXIDE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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Substance name: tellurium dioxide
EC number: 231-193-1
CAS number: 7446-07-3
Dossier submitter: The Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
13.08.2019	Belgium	European Special Glass Association	Industry or trade association	1
Comment received				
Tellurium oxide is an indispensable element for the synthesis of special optical filter glass with functioning coloring in higher edge layers.				
Dossier Submitter's Response				
Thank you for this additional information which could be included in section 5 of the report.				
RAC's response				
Noted				

Date	Country	Organisation	Type of Organisation	Comment number
15.08.2019	Canada	<confidential>	Company-Manufacturer	2
Comment received				
These comments are submitted on behalf of both <confidential> and <confidential>. - Section 9.2.5.1. Read-across justification based on in silico data Table 9 of Te CLH report and Table 10 of TeO2 CLH Report on "OECD QSAR Toolbox profiling" / Cramer Scheme: <confidential> and <confidential> argue against the use of the Toxic hazard classification by Cramer (indicated as "high (class III)") for both tellurium and tellurium dioxide. In Lapenna and Worth, 2011, Analysis of the Cramer classification scheme for oral systemic toxicity - implications for its implementation in Toxtree, EUR 24898 EN, page 2, it is explicitly written "The tree is intended for use with all ingested, structurally defined organic and metallo-organic substances." Tellurium and tellurium dioxide are neither organic nor metallo-organic substances. - Section 1.1 Name and other identifiers of the substance				

• <confidential> and <confidential> confirm that they do not market tellurium or tellurium dioxide as nano scale products.
Dossier Submitter's Response
Thank you for your carefull review. We agree that tellurium, which belongs to the 6. main group of the periodic table (chalcogens) is neither an organic or metallo-organic substance and thus Cramer classification is not applicable. It remains unclear why this was not realised by the QSAR toolbox. This row in table 10 of the report will be deleted. And thank you for the information on nano forms, which will be included.
RAC's response
RAC agrees with the comment by the REACH Selenium & Tellurium Consortium, that the TTC concept and the concept of Cramer classes is not intended for non-essential metals / metalloids as Tellurium and its inorganic compounds. This is also in line with Brown et al., 2009 or Kroes et al., 2004. RAC further notes that the reference to Cramer class III is no key element for the read-across argumentation. The comments on section 1.1 is noted.

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2019	Germany		MemberState	3
Comment received				
The read across between tellurium dioxide and tellurium for the endpoints germ cell mutagenicity and reproductive toxicity is well justified. The read across justification is based on identical metabolites in vivo, very similar physico-chemical properties and a high degree of concordance for the toxicological properties of both substances.				
Dossier Submitter's Response				
Thank you for your comments				
RAC's response				
Noted and agreed.				

Date	Country	Organisation	Type of Organisation	Comment number
16.08.2019	Germany	REACH Selenium & Tellurium Consortium	Industry or trade association	4
Comment received				
- Section 9.2.5.1. Read-across justification based on in silico data Table 9 of Te CLH report and Table 10 of TeO2 CLH Report on "OECD QSAR Toolbox profiling" / Cramer Scheme: The Consortium argues against the use of the Toxic hazard classification by Cramer (indicated as "high (class III)") for both tellurium and tellurium dioxide. In Lapenna and Worth, 2011, Analysis of the Cramer classification scheme for oral systemic toxicity - implications for its implementation in Toxtree, EUR 24898 EN, page 2, it is explicitly written "The tree is intended for use with all ingested, structurally defined organic and metallo-organic substances." Tellurium and tellurium dioxide are neither organic nor metallo-organic substances. - Section 1.1 Name and other identifiers of the substance The members of the Consortium confirm that they do not market tellurium or tellurium dioxide as nano scale products. ECHA note – An attachment was submitted with the comment above. Refer to public attachment tellurium dioxide.pdf				

Dossier Submitter's Response
Thank you. Please see the respective responses to comment 2.
RAC's response
RAC agrees with the comment by the REACH Selenium & Tellurium Consortium, that the TTC concept and the concept of Cramer classes is not intended for non-essential metals / metalloids as Tellurium and its inorganic compounds. This is also in line with Brown et al., 2009 or Kroes et al., 2004. RAC further notes that the reference to Cramer class III is no key element for the read-across argumentation. The comments on section 1.1 are noted.

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
15.08.2019	Canada	<confidential>	Company-Manufacturer	5
Comment receivedjhjhjhjh				
<confidential> and <confidential> supports the "no classification" conclusion for ththis hazard class for tellurium dioxide.				
Dossier Submitter's Response				
Thank you for your comment. We assume that this comment refers to the endpoints "Mutagenicity and Carcinogenicity".				
RAC's response				
Noted. Though RAC identified a positive reverse bacterial mutation assay for tellurium dioxide (Yagi & Nishioka, 1977) as well as some deficiencies in the presented *in vitro* genotoxicity studies, RAC agrees that the available data do not support classification for germ cell mutagenicity.				

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2019	Germany		MemberState	6
Comment received				
Based on the available data the proposal for no classification is supported. The available data shows negative results for bacterial reverse mutation assay (OECD TG 471), in vitro mammalian cell gene mutation test (OECD TG 476) and in vitro mammalian chromosome aberration test (OECD TG 473).				
Dossier Submitter's Response				
Thank you for your comment				
RAC's response				
Noted. Though RAC identified a positive reverse bacterial mutation assay for tellurium dioxide (Yagi & Nishioka, 1977) as well as some deficiencies in the presented *in vitro* genotoxicity studies, RAC agrees that the available data do not support classification for germ cell mutagenicity.				

Date	Country	Organisation	Type of Organisation	Comment number
16.08.2019	Germany	REACH Selenium & Tellurium Consortium	Industry or trade association	7
Comment received				
Mutagenicity and Carcinogenicity The Consortium supports the "no classification" conclusion for these two endpoints for the two substances. ECHA note – An attachment was submitted with the comment above. Refer to public attachment tellurium dioxide.pdf				
Dossier Submitter's Response				
Thank you for your comment				
RAC's response				
Noted. Though RAC identified a positive reverse bacterial mutation assay for tellurium dioxide (Yagi & Nishioka, 1977) as well as some deficiencies in the presented *in vitro* genotoxicity studies, RAC agrees that the available data do not support classification for germ cell mutagenicity.				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
15.08.2019	Canada	<confidential>	Company-Manufacturer	8
Comment received				
a. Developmental toxicity (Repro 1B, H360D): <confidential> and <confidential> supports the classification as Repro 1B, H360D. This classification has been provided in the registration dossiers for tellurium and tellurium dioxide and implemented in the Safety Data Sheets for these substances. b. Adverse effects on sexual function and fertility (Repro 1B, H360F): <confidential> and <confidential> based the below on a recent third-party expert toxicologist review. Our interpretation is to differentiate effects on fertility (= up to implantation) from developmental effects (fetal and beyond). CLH report Section 10.10.2 Short summary and overall relevance of the provided information on adverse effects on sexual function and fertility OECD TG 421 – Arguments against maternal toxicity at the MD (120 mg/kg bw/day) In the CLH report, it is indicated that "gestation index and gestation length were also observed at doses (MD), which did not cause severe toxicity. Further, the marked effects on the structure of the female reproductive organs are also considered to be substance related and not secondary to maternal toxicity". However, no abnormalities, apart from hepatotoxicity, were observed in the histopathological analysis of the MD group (the ovary appeared to be normal). Table extracted from the TG 421 full study report (page 92) and provided to the Dutch authorities.				

Furthermore, in this MD group, the "fertility ss" parameters (pre-mating, mating and implantation) are not significantly (in the statistical sense) different from the controls. The deviation is minimal (+/- 5 %) and could be due to biological variation.

Table extracted form the TG 421 full study report (page 36) - provided to the Dutch authorities.

The reduced gestation index can be explained due to developmental effects (4/12 dams had still-born pups, so categorized un foetal toxicity and not fertility).

OECD TG 421 – Arguments against maternal toxicity being a secondary effect of systemic toxicity at the HD (600 mg/kg bw/day)

Even if the following statement 'The reproductive organ effects in females are not considered to be secondary effects of systemic toxicity.' is rightly reported in the CLH reports to be in the executive summary of the registration dossiers, a recent third-party toxicologist expert judgement challenged this interpretation with the following arguments:

- A motivation for this statement is lacking, considering it is known that already mild food deprivation can affect the estrous cycle of rats.
- Several clinical signs of toxicity (intestinal, hepatic and mesenteric lymph node toxicity, with some effects in kidney and thymus, and pigment deposits in a number of affected tissues) were noted which could provide explanations for the effects on reproductive organ as secondary effects
- The histopathological evaluation was only performed on 2 rats (available) for the HD group while in all other groups at least 10 animals were evaluated per group.
- In the report of the pathological evaluation (appendix 3- based on only 6 animals, see below table), ovarian atrophy was observed in 4 (1 minimal and 3 mild) of the 6 animals (with no distinction between the pregnant / non-pregnant animals). There is no description of the observed ovarian 'atrophy' (eg follicle size distribution, atresia of primordial follicles, ….). This makes it impossible to judge whether exposure to tellurium / tellurium dioxide might cause primary effect on the ovary.

Based on this information, our interpretation is that there are no arguments to overrule the secondary effects due to overt toxicity and assign primary reproductive toxicity at the HD group. The effects noted on the uterus and vagina are (probably) due to the inactivity of the ovary (so a secondary effect).

Table extracted from the TG 421 full study report (page 261 – Appendix 3 – Pathology evaluation) - provided to the Dutch authorities.

We agree with the statement in the CLH report that "Whether the effects on reproduction observed in the screening study are (partially) secondary to general toxicity is a matter of discussion".

We contend, based on the above, that effects observed on tellurium and tellurium dioxide are not enough so that the substances are classified as H306 F Cat. 1B.

As the primary data from the TG 421 full study report do not provide evidence that such effects on female reproductive organs cannot be unequivocally considered NOT to be secondary non-specific consequence of the other toxic effects, we recommend no classification for the fertility.

We therefore contend that for the reproductive toxicity, only developmental effects should be taken into consideration, with a H360 D, Cat. 1B classification.

Dossier Submitter's Response

Thank you for your comprehensive comments and data on this topic, which has also been addressed by others (see comments below). Please, find our answer below:

Regarding the question if the observed effects are only secondary to maternal toxicity and therefore not relevant for classification different aspects have to be discussed:

- With respect to the histopathologic findings of the reproductive organs of high dose females it is concluded in the OECD 421 study report: „The reproductive organ effects in females are not considered to be secondary effects of systemic toxicity." This opinion is shared by the dossier submitter.
- It has to be noted that no histopathological evaluations of the ovary of the low and mid dose group were performed although you and the REACH Se&Te Consortium claim in your responses that at least 10 animals were evaluated in all other groups. But in fact, apart from the high dose group and the control group, only organs with macroscopic findings were histopathologically investigated. From the original study report it becomes obvious that not ovaries, uteri or vaginals of animals of the low and mid dose group were examined histopathologically. Therefore, it remains unclear if mild histopathologic effects of the ovary or other female reproductive organs would have been detectable in these dose groups.
- As a more in depth analysis of the ovarian ‚atrophy' is missing you and the REACH Se&Te Consortium argue that these findings are not appropriate to evaluate if the findings are a primary effect on the ovary. However, in combination with the mechanistic considerations as outlined in the report (possible effect of tellurium/tellurium dioxide on hormone level) there remains suspicion that this could be a direct effect, which cannot be ruled out on basis of the existing data.
- Also the further arguments provided (e.g. effect of food deprivation on estrous cycle or effects of pigment deposits) to support that the effects on the reproductive organs are only secondary, are lacking support from experimental evidence that the observed effects are only secondary. It cannot be ruled out with certainty that they are primary effects as indicated in the study report (see above).
- However, it is recognised that ovary atrophy is only observed in high dose females, i.e. in the dose group where already relevant systemic toxicity (lethality) occurred. It would be in accordance with the CLH Guidance document not to base the classification on these observations in the high dose group.
- Alltogether, this might lead to the consequence that no Cat. 1B classification for

effects on fertility should be suggested.

- Already in the mid dose group, which did not elicit marked systemic toxicity, a reduced gestation index was observed. You and the REACH Se&Te Consortium argued that this is rather due to the developmental toxicity also observed at this dose. However, the dossier submitter notes that it cannot unequivocally distinguished if the effects on the gestation index are due to developmental or fertility effects. As this effect on the gestation reveals a clear dose-response it is regarded as relevant. There remains some suspicion that the gestation index could be affected due to effects on fertility which could not be ruled out with certainty.
- Taking into account
    - that it cannot unequivocally be demonstrated that the observed effects are due to primary toxicity of tellurium,
    - that the effects observed are very specific and consistently observed in different types of studies (also supported by findings of epithelial atrophy in the vagina of rats after subacute exposure),
    - that the existing data do not unequivocally rule out (due to missing histopathological investigations at lower dose groups) that effects already occur at non-lethal doses
    - the dossier submitter considers this a borderline case for a classification for effects on fertility as Cat. 1B or Cat. 2.
    - Due to the fact that atrophy in the reproductive organs was only observed at doses which also cause excessive (>10%) lethality the dossier submitter could follow the argumentation of the German authority, the Canadian manufacturer and the REACH Se&Te Consortium who concluded that a classification for effects on fertility as Cat. 1B might not be appropriate.
    - Due to the uncertainty for some endpoints and the remaining suspicion as outlined above the dossier submitter does not agree with you and the REACH Se&Te Consortium that the substance should not be classified for effects on fertility. In fact, a classification in accordance with the recommendation of the German CA (reproductive toxicant Cat.2 for effects on fertility (H361f)) might be more appropriate to account for the observed effects.
- In accordance with the commentators the dossier submitter further supports a classification for developmental effects as Cat. 1B (H360D).

RAC's response
RAC notes the support for classification as Repr. 1B; H360D. In contrast to the dossier submitter, RAC is not in favour of classification as Repr. 1B; H360F, but proposes classification as Repr. 2; H361f instead. RAC is of the opinion that the available evidence is not sufficient to support classification as Repr. 1B for fertility. Effects on reproductive parameters and reproductive organs were seen in the high dose females, where severe toxicity and 50% mortality was observed (6/12 animals died, but one death was due to a gavage error, Anonymous, 2013). Though the observed atrophy of ovaries, uterus and / or vagina seen in 10 out of 12 animals is considered not secondary to the general toxicity, as it is a very specific and uncommon finding, it only occurred at doses that also induce severe general toxicity in these animals. From the original study report, RAC concludes that the reproductive organs have been evaluated for the high dose females, including those animals that died. Atrophy of ovaries, uterus and / or vagina was reported in 9/12 animals, with one not evaluated (due to cannibalisation). No information on histological changes is available for the mid dose group (120 mg/kg bw/day), but only macroscopic assessment of females reproductive organs was performed in low dose and mid dose. No histopathological examination was performed (only in control and top dose and in those organs which appeared affected by macroscopic examination). Therefore your conclusion that "the ovary appeared to be normal" is correct. However, the gestation period was statistically significantly prolonged by 0.7 days (Control: 22.73 days, mid dose: 23.42 days). Also in the two females of the top dose that delivered, the gestation period was prolonged to 24 days. Also in a 28-day toxicity study (Anonympus, 2013, OECD TG 407, REACH registration dossier) the top dose of 600 mg/kg bw/day, the same as in the reproduction screening study (Anonympus, 2013c), induced vaginal atrophy in 2 of 4 females. Also in this study no histopathological investigations of the mid dose group were conducted. On that basis RAC is of the opinion that the evidence is not sufficient to support a classification as Repr 1B for fertility. RAC agrees with the statement that oestrus cycle can be easily affected by external causes, like e.g. mild food deprivation. This is however not the case for the other observed effects (gestation index, gestation length, atrophy of reproductive organs). RAC agrees with the dossier submitter that an endocrine mechanism could be the cause for the observed effects on reproductive organs, gestation index, gestation duration and oestrus cycle. A plausible endocrine mechanism could be the interference with steroid hormone synthesis due to the demonstrated inhibition of squalene epoxidase by tellurium. Squalene epoxidase catalyses the first and rate limiting step of cholesterol synthesis, which is the basis of steroid hormone synthesis. However, in line with the dossier submitter, RAC is of the opinion that this mechanism is not sufficiently demonstrated, as e.g. no hormone measurements were conducted.

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2019	Germany		MemberState	9

Comment received

1. Fertility
The classification of tellurium dioxide as Repr. 1B, H360F, is not supported. The proposal is based on effects observed in an OECD 421 Screening study (NN, 2013) in rats orally exposed to tellurium dioxide. The effects are a decrease of the fertility-, mating- and gestation index of females in the highest dose group (600 mg TeO2/kg bw/d). However, at this dose 5 out of 12 females died during the experiment, corresponding to 40 % of the animals. The increased mortality indicates a severe toxicity of the substance. According to the guidance, effects as-sociated with such severe toxicity should not be included in the evaluation:

Annex I: 3.7.2.4.4.
"Maternal mortality:
An increased incidence of mortality among the treated dams over the controls shall be considered evidence of maternal toxicity if the increase occurs in a dose-related man-ner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10 % is considered excessive and the data for that dose level shall not normally be considered for further evaluation. "

Maternal toxicity is further demonstrated by the reduced body weight of 18 % (MD) and 30 % (HD) below controls.

Under consideration of the very specific and uncommon nature of effects observed in the OECD TG 421 study (e.g., atrophy of ovary, uterus, and/or vagina) plus similar effects ob-served in an OECD TG 407 study at 600 mg/kg bw/d (TeO2, rat, oral, study report, 2013: epi-thelial atrophy of the vagina in 2 of 4 HD females, mortality 1) we agree with NL and the authors of the OECD TG 421 study report, that the reproductive organ effects in females are most likely not secondary effects of systemic toxicity. Additionally, histopathology of repro-ductive organs has only been performed for HD and control animals and thus potential simi-lar effects on the reproductive organs in the MD group could have been unnoticed. Further-more, effects on gestation index and gestation length were also observed at doses (MD), which did not cause mortality.

Taking into account the uncertainties resulting from the severe toxicity of tellurium in the high dose of the TG 421 study, the German CA considers the observed reproductive effects in the MD as consistent to effects in the HD - also accounting for vaginal atrophy in surviving animals of the TG 407 study - to support a classification as Repr. 2, H361f.

2. Developmental toxicity
The classification proposal of tellurium dioxide as Repr. 1B, H360D is supported.
There are two prenatal developmental toxicity studies (Johnson et al., 1988) conducted in rat and rabbit, respectively and five supporting studies in rats. The studies were performed with tellurium and the read across substance tellurium dioxide. In all of the studies on rats and rabbits severe effects on the development of the foetuses were observed. For both, rats and rabbits, severe malformations such as hydrocephali were found after administration of tellurium resp. tellurium dioxide. Hydrocephali have also been identified in supportive stud-ies in rats. In addition, in rats a greatly increased fetal mortality was observed. Maternal toxicity can be considered as low, as feed intake and weight gain was only slightly reduced and no mortality of the dams were observed. Accordingly, malformations and increased fetal mortality in rats may result from exposure to tellurium or tellurium dioxide and is not

considered a secondary effect.
Dossier Submitter's Response
Thank you for your comprehensive comments and data on this topic, which has also been addressed by others. We refer to the answer provided to comment number 8.
RAC's response
RAC agrees with the analyses of the German CA and supports the proposed classification as Repr. 1B; H360Df.

Date	Country	Organisation	Type of Organisation	Comment number
16.08.2019	Germany	REACH Selenium & Tellurium Consortium	Industry or trade association	10

Comment received

Reproductive toxicity:

a. Developmental toxicity (Repro 1B, H360D):

The consortium agrees with the classification Repro 1B, H360D. This classification is consistent with the self-classification provided in the dossiers for tellurium and tellurium dioxide and implemented in the Safety Data Sheets for these substances.

b. Adverse effects on sexual function and fertility (Repro 1B, H360F):

The Consortium based the below on a recent third-party expert toxicologist review.

Our interpretation is to differentiate effects on fertility (= up to implantation) from developmental effects (fetal and beyond).

CLH report Section 10.10.2 Short summary and overall relevance of the provided information on adverse effects on sexual function and fertility

OECD TG 421 – Arguments against maternal toxicity at the MD (120 mg/kg bw/day)
In the CLH report, it is indicated that "gestation index and gestation length were also observed at doses (MD), which did not cause severe toxicity. Further, the marked effects on the structure of the female reproductive organs are also considered to be substance related and not secondary to maternal toxicity".

However, no abnormalities, apart from hepatotoxicity, were observed in the histopathological analysis of the MD group (the ovary appeared to be normal).

Table extracted from the TG 421 full study report (page 92): see attachment.

Furthermore, in this MD group, the "fertility ss" parameters (pre-mating, mating and implantation) are not significantly (in the statistical sense) different from the controls. The deviation is minimal (+/- 5 %) and could be due to biological variation.
Table extracted from the TG 421 full study report (page 36): see attachment.

The reduced gestation index can be explained due to developmental effects (4/12 dams had still-born pups, so categorized un foetal toxicity and not fertility).

OECD TG 421 – Arguments against maternal toxicity being a secondary effect of systemic toxicity at the HD (600 mg/kg bw/day)

Even if the following statement 'The reproductive organ effects in females are not considered to be secondary effects of systemic toxicity.' is rightly reported in the CLH reports to be in the executive summary of the registration dossiers, a recent third-party toxicologist expert judgement challenged this interpretation with the following arguments:

- A motivation for this statement is lacking, considering it is known that already mild food deprivation can affect the estrous cycle of rats.
- Several clinical signs of toxicity (intestinal, hepatic and mesenteric lymph node toxicity, with some effects in kidney and thymus, and pigment deposits in a number of affected tissues) were noted which could provide explanations for the effects on reproductive organ as secondary effects
- The histopathological evaluation was only performed on 2 rats (available) for the HD group while in all other groups at least 10 animals were evaluated per group.
- In the report of the pathological evaluation (appendix 3- based on only 6 animals, see below table), ovarian atrophy was observed in 4 (1 minimal and 3 mild) of the 6 animals (with no distinction between the pregnant / non-pregnant animals). There is no description of the observed ovarian 'atrophy' (e.g. follicle size distribution, atresia of primordial follicles, ….). This makes it impossible to judge whether exposure to tellurium / tellurium dioxide might cause primary effect on the ovary.

Based on this information, our interpretation is that there are no arguments to overrule the secondary effects due to overt toxicity and assign primary reproductive toxicity at the HD group. The effects noted on the uterus and vagina are (probably) due to the inactivity of the ovary (so a secondary effect).

Table extracted from the TG 421 full study report (page 261 – Appendix 3 – Pathology evaluation): see attachment.

We agree with the statement in the CLH report that "Whether the effects on reproduction observed in the screening study are (partially) secondary to general toxicity is a matter of discussion".

We contend, based on the above, that effects observed on tellurium and tellurium dioxide are not enough so that the substances are classified as H306 F Cat. 1B.

As the primary data from the TG 421 full study report do not provide evidence that such effects on female reproductive organs cannot be unequivocally considered NOT to be secondary non-specific consequence of the other toxic effects, we recommend no classification for the fertility.

We therefore contend that for the reproductive toxicity, only developmental effects should be taken into consideration, with a H360 D, Cat. 1B classification.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment tellurium dioxide.pdf

Dossier Submitter's Response
Thank you for your comprehensive comments and data on this topic, which has also been addressed by others. We refer to the answer provided to comment number 8.
RAC's response
Please refers to the response to comment 8.

PUBLIC ATTACHMENTS
1. tellurium dioxide.pdf [Please refer to comment No. 4, 7, 10]