



Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at Community level of
gallium arsenide

ECHA/RAC/CLH-0000000792-73-03/A2

Adopted
25 May 2010

Annex 2 Comments received on the Annex XV report and response to comments provided by the dossier submitter (excl. confidential information)

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Substance name: Gallium arsenide

CAS number: 1303-00-0

EC number: 215-114-8

General comments

Date	Submitted by	Organisation /MSCA	Comment	Response	Rapporteur's comment
2009/07/16		Hungary / National Institute of Chemical Safety	In view of the experimental data and the precautionary principle the proposed classification and labelling can be supported.	Thank you for your support.	Agree with MS and proposal if animal data are assessed without looking at human data for carcinogenicity, but recommend read-across to other arsenic substances and hence stricter classification for carcinogenicity: Carc. Cat. 1 T; R45 (DSD), Carc. 1A, H350 (CLP).
2009/06/23	Jean-Luc Ledys	France / SOITEC / PICOGIGA INTERNATIONAL	GaAs is a solid crystalline material which does not allow single free elements (As or Ga) to escape during normal processing operation. This material is used in any RF components (switches or Power amplifiers) utilized in wireless handsets or infrastructures. No replacement solution is known today.	This argument is not relevant in the scope of a C&L dossier.	Agree

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2009/07/24	Frauke Schröder	Germany / Baua	<p>German CA comment: In section 3 'Classification and Labelling' the CLH dossier submitted by France gives the information that the substance is currently not listed in Annex I.</p> <p>Although the substance itself with its individually assigned CAS number is not listed in Annex I, it falls under the group entry 'arsenic compounds, with the exception of those specified elsewhere in this Annex' with the index number 033-002-00-5. Under this group entry Gallium arsenide is classified as T; R23/25 and N; R50-53 (29. ATP). Although these endpoints are not addressed in the current dossier, this information should formally be provided under the respective sections dealing with the classification of the substance.</p> <p>In the presented Annex XV report harmonized classification with T; R48/23 is proposed. If harmonized C&L is proposed for another hazard class than CMR or respiratory</p>	<p>Remark taken into account. Background document changed accordingly.</p> <p>Remark taken into account. Background document changed accordingly.</p>	<p>The endpoints are addressed in the RAC opinion. T; R23/25 (DSD) is not carried over due to substance specific data resulting in no classification for acute toxicity. N; R50-53 is not carried over as this endpoint was not evaluated by RAC.</p> <p>Agree on the proposed classification T, R48/23 based on non-neoplastic effects in lungs and larynx, haematological and the heme biosynthesis effects, The background document has been slightly revised. Agree on justification.</p>

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			<p>sensitisation, the Annex XV report should include a justification for the need of harmonized C&L for this endpoint at community level. FR has not provided a plausible and sufficient justification for harmonized classification as R 48/23. Additional information for justification is required.</p> <p>Gallium arsenide reveals an impressive toxicological profile that needs classification concerning STOT, carcinogenicity and fertility impairment.</p> <p>The current version of the annex XV-report should be improved concerning transparency and consistency. This is needed to enable the application of the CLP-criteria as precise as possible. To support the RAC committee it should become clearer in the report whether reproductive toxicity and carcinogenicity are primary effects or consequence of other toxic effects (secondary effects).</p>	<p>Thanks for your support.</p> <p>Survival of the exposed rodents in the 2 years studies were similar to those of the chamber controls. No (mice) or low (rats) decrease of mean body weight were observed in treated rats throughout the 2 years study. Therefore, for the carcinogenic endpoint there is no sign of primary toxicity.</p>	<p>GaAs clearly give toxic primary effects in the lungs and larynx, not related to decreased bodyweight. Arguments for assessing effects from GaAs as primary have been introduced into the background document.</p> <p>We agree that toxicity to reproduction can be considered a primary effect. Moreover, the mean gallium concentration at 18 months in the highest exposure group</p>
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			<p>The following points should be improved in the report: Some of the described effects are not clearly allocated to a dose in the text of the report. This should be completed.</p> <p>Tables of the central studies (14 weeks and 2 years in rats and mice) that</p>	<p>Especially in rats, reprotoxic findings such as absolute weights of the left testis, cauda epididymis and epididymis, spermatozoa motility were decreased in males exposed to 10 mg/m³ onward also mean body weights (-10% of controls) and body weight gain were significantly reduced in males of the 75 mg/m³ treated group. Therefore, reprotoxicity can be considered as primary effect.</p> <p>Remark taken into account. Background document changed accordingly.</p> <p>Would you refer to specific</p>	<p>was higher (1,5 µg/g) in the testes than in blood or serum (0,05 and 0,08 µg/g, respectively), suggesting that Gallium itself may mediate a primary effect in the testes.</p> <p>OK</p> <p>For transparency we have inserted the table of the summary of the 2-year carcinogenesis and genetic toxicology studies of gallium arsenide in the summary NTP report into the BD, as it is, with reference to NTP.</p>
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			<p>clearly assort effects to doses should be added. This would enable a transparent dose by dose correlation of haematological, gonadal and lung effects including carcinogenicity.</p>	<p>tables, thanks for letting us know? The referred studies are huge studies with multiple endpoints. Reporting of the results for haematological, gonadal and lung effects is not possible. If detailed information is needed, please refer to the NTP report directly.</p>	
2009/07/24	Sylvi Claussnitzer	Germany / Wirtschaftsvereinigung Metalle	<p>Wirtschaftsvereinigung Metalle (WVM), the German Non-Ferrous Metals' Association, represents the German non ferrous (NF) metals industry towards politics and economy. We support our members in regulatory, occupational health & safety affairs in order to maintain and establish measures at a very high level. Today, WVM has 639 member companies, including producers and processors of rare metals and compounds.</p> <p>Some of our members also produce and handle arsenic and arsenic compounds as this is a natural</p>		

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			<p>component of several non ferrous metal ores and concentrates. In addition, we represent one of the leading producers of arsenic metal. Therefore, we recently took over the role of being the secretariat for an arsenic consortium that will be functional in the coming weeks. Gallium arsenide is within the scope of this consortium on arsenic and arsenic compounds. In principle, we appreciate the involvement of stakeholders in the process of harmonized classification and would like to take the opportunity to bring our argumentation forward during this phase of internet consultation.</p> <p>At first we want to express the companies' awareness of their duties in safe handling hazardous substances and in establishing appropriate risk management measures. Industry also takes full responsibility to fulfil their obligations under the new chemicals legislation 1907/2006/EG. This means that industry will prepare the REACH registration dossiers, respecting the registration deadlines resulting from the tonnage band and classifications of</p>	<p>This proposal has been made a while ago to ECB. We</p>	<p>Agree</p>
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			<p>the respective substances. There already is a harmonized classification for Gallium arsenide (R23/25 and R50/53). Consequently, industry will fulfil their obligation and will submit the registration dossier based on the present legal classification as foreseen under REACH. This is also reflected in the envisaged registration deadlines submitted by the companies' pre-registrations.</p> <p>We would like to emphasize that the proposal for a harmonized classification for Gallium arsenide clearly interferes with the ongoing dossier generation. Until the end of 2010, industry will in any case prepare a huge amount of dossiers. The dossier for Gallium arsenide is part of our consortium work and will be finalized until the appropriate registration deadline taking into account all available data and generated new studies for identified data gaps. Any parallel discussions for a harmonized classification interfere with this process without any obvious benefit for the safety and health of workers or consumers. A scientifically sound</p>	<p>cannot take this remark into account.</p> <p>Available data already allow to propose a harmonised classification as T; R48/23 Repro. Cat. 2; R60 Carc. Cat 3; R40</p> <p>We thanks WVM for their involvement regarding this substance but unless contradictory data presented we believe that Gallium arsenide harmonised classification should be continued.</p>	<p>Agree</p>
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			evaluation of the proposed classification is not feasible within the very limited commenting period. We therefore emphasize that ongoing harmonisation process interfering with the registration process should be delayed.		
2009/07/25	Stephanie Castorina	United States / IPC	IPC comments have been uploaded on the RAC CIRCA, which also contains copies of several articles (see reference list).	Answers have been given directly into the document in track changes.	A few additional comments have been given directly into the document in track changes. Note that due to a fairly new MS Word format (2007) used by IPC, figure 1 may be invisible in the document. If so, this table may be found in the original letter from IPC.
2009/07/27		Germany / Freiberger Compound Materials GmbH	Freiberger Compound Materials GmbH has longstanding experience in the field of gallium arsenide production. We are the manufacturer with the highest tonnage in the EU and supply gallium arsenide substrates to the major semiconductor companies in the world. We are always aware of the importance of health protection and industrial safety which are an integral part of our business policy and		

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			<p>management system. All legal regulations have always been observed.</p> <p>GaAs substrates are used for high-frequency communication, such as in mobile phones and wireless networks. These applications will grow in the future since the amount of information being sent around the world is constantly increasing.</p> <p>We also take full responsibility to fulfil our obligations under the new chemicals legislation 1907/2006/EG. This means that we will prepare the REACH registration dossiers, respecting the registration deadlines resulting from the tonnage band and classifications of the respective substances. There already is a harmonized classification for gallium arsenide (R23/25 and R50/53). Consequently, we will fulfil their obligation and will submit the registration dossier based on the present legal classification as foreseen under REACH. This is also reflected in the envisaged registration deadline</p>	<p>This proposal has been made a while ago to ECB. The process is now ongoing. Only ECHA or the Commission could take your remark into account.</p>	<p>Agree.</p>
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			<p>submitted by our pre-registration.</p> <p>We would like to emphasize that the proposal for a harmonized classification for gallium arsenide clearly interferes with the ongoing dossier generation. Until the end of 2010, industry will in any case prepare a huge amount of dossiers. The dossier for gallium arsenide is part of our consortium work and will be finalized until the appropriate registration deadline taking into account all available data and generated new studies for identified data gaps. Any parallel discussions for a harmonized classification interfere with this process without any obvious benefit for the safety and health of workers or consumers. A scientifically sound evaluation of the proposed classification is not feasible within the very limited commenting period. We therefore emphasize that the ongoing harmonization process interfering with the registration process should be delayed.</p>	<p>Available data already allow to propose a harmonised classification as T; R48/23 Repro. Cat. 2; R60 Carc. Cat 3; R40</p> <p>We thanks Freiburger Compound Materials for their involvement regarding this substance but unless contradictory data presented we believe that Gallium arsenide harmonised classification should be continued.</p>	
2009/07/27		Ireland / Health &	The original document containing all the comments is uploaded on the RAC		

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		Safety Authority	<p>CIRCA (see reference list). Justification that action is required on a Community-wide basis. Full comment: Given that repeated dose toxicity is not a harmonised endpoint, we feel that the justification provided to classify this substance for this endpoint is not adequate. It may be beneficial to include in this section of the Annex XV report information concerning the use of the substance and the potential number of exposed workers in the EU. Also, we note that the justification refers to indium phosphide, rather than gallium arsenide.</p>	Modified in the background document.	As a rule RAC has no opinion on these justifications.
2009/07/28		United States / Recapture Metals Inc.	<p>Recapture Metals Inc. is a company located in the United States of America and is in the business of providing recycling services for the gallium arsenide industry. Of course part of this industry is located in the EU.</p> <p>It is our desire that gallium arsenide be correctly classified for REACH registration. A scientifically sound evaluation of the proposed</p>	Available data already allow to propose a harmonised classification as T; R48/23	

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			<p>classification is not feasible within the very limited commenting period. We therefore emphasize that the ongoing harmonization process interfering with the registration process should be delayed. This opinion is shared with others that are in this industry.</p> <p>Thank you for your consideration in these important matters.</p>	<p>Repro. Cat. 2; R60 Carc. Cat 3; R40</p> <p>We thanks Recapture Metals Inc. for their involvement regarding this substance but unless contradictory data presented we believe that Gallium arsenide harmonised classification should be continued.</p>	<p>Agree with MS and proposal if animal data are assessed without looking at human data for carcinogenicity, but recommend read-across to other arsenic substances and hence stricter classification for carcinogenicity: Carc. Cat. 1 T; R45 (DSD), Carc. 1A, H350 (CLP).</p>
2009/07/27	Mirko Pavela	Slovakia / CMK, s.r.o.	<p>CMK, s.r.o. is a small private company and one of not large commercial producers of Gallium arsenide in Europe. Our capacity for GaAs is more than 1 tone so we intend to register GaAs after new chemical legislation. GaAs is widely using mainly in communication industry. After all predictions GaAs applications will grow in the future permanently. We take care for health protection and industrial safety of each of our employee. This is one part of</p>		

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			<p>our business policy and management system.</p> <p>From this point of view we have an interest to involve in the process of harmonized classification and would like to take the opportunity to bring our opinion forward during this phase of internet consultation.</p> <p>We take full responsibility to fulfil our obligations under the new chemicals legislation 1907/2006/EG. We will prepare the REACH registration dossiers, respecting the registration deadlines resulting from the tonnage band and classifications of the respective substances. There already is a harmonized classification for gallium arsenide (R23/25 and R50/53). Consequently, we will fulfil our obligation and will submit the registration dossier based on the present legal classification as foreseen under REACH. This is also reflected in the envisaged registration deadline submitted by our pre-registration.</p> <p>We would like to emphasize that the proposal for a harmonized</p>	<p>This proposal has been made a while ago to ECB. We cannot take this remark into account.</p>	<p>OK</p>
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			<p>classification for gallium arsenide clearly interferes with the ongoing dossier generation. Until the end of 2010, will be surely prepared a lot of dossiers. The dossier for gallium arsenide is part of GaAs consortium work and will be finalized until the appropriate registration deadline taking into accounts all available data and generated new studies for identified data gaps. Any parallel discussions for a harmonized classification interfere with this process without any obvious benefit for the safety and health of workers or consumers. A scientifically sound evaluation of the proposed classification is not feasible within the very limited commenting period. We therefore emphasize that the ongoing harmonization process interfering with the registration process should be delayed.</p>	<p>Available data already allow to propose a harmonised classification as T; R48/23 Repr. Cat. 2; R60 Carc. Cat 3; R40 We thanks WVM for their involvement regarding this substance but unless contradictory data presented we believe that Gallium arsenide harmonised classification should be continued.</p>	<p>Agree with MS and proposal if animal data are assessed without looking at human data for carcinogenicity, but recommend read-across to other arsenic substances and hence stricter classification for carcinogenicity: Carc. Cat. 1 T; R45 (DSD), Carc. 1A, H350 (CLP).</p>
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Carcinogenicity

Date	Submitted by	Organisation /MSCA	Comment	Response	Rapporteur's comment
2009/07/10	Agneta Ohlsson	Sweden /	Cancer	Your remark has been taken	Agree with FR and proposal

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		<p>Swedish Chemicals Agency</p>	<p>IARC has evaluated gallium arsenide 2006 in the monograph number 86 to be carcinogenic to humans (Group 1). There are two reasons for their decision 1) there are two separate mechanisms of action possible for gallium arsenide to cause cancer (gallium ion moiety causing lung cancer and arsenic and its compounds are Group I carcinogens according to IARC) and 2) the gallium arsenide once in the body releases a small amount of its arsenic and also gallium.</p> <p>It is difficult to understand how the proposal to classify gallium arsenide as carcinogenic at all when it is assumed that no release of either ion moiety is foreseen. However, it is reported in the proposal that arsenic and gallium concentrations have been measured in urine and faeces in rat and hamster after intratracheal instillation of gallium arsenide. It seems to be very clear that both gallium and arsenic ions can act in the body.</p> <p>In contrast to what is said in the French proposal IARC consider</p>	<p>into account. The background document has been modified. However, based on 67/548 and 1272/2008 directives criteria and based on available data, we propose gallium arsenide to be classified as Carc. Cat. 3, R40 and Carc. 2 – H351 respectively.</p>	<p>if animal data are assessed without looking at human data for carcinogenicity, but recommend read-across to other arsenic substances and hence stricter classification for carcinogenicity: Carc. Cat. 1 T; R45 (DSD), Carc. 1A, H350 (CLP).</p>
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			<p>gallium arsenide to be released as its two ion moieties in biological fluids. They say “Although the solubility of gallium arsenide in pure water is very low, its dissolution in body fluids is greatly enhanced by endogenous chelating molecules. When incubated in artificial body fluid (Gamble’s solution), gallium arsenide progressively releases both gallium and arsenic. A selective leaching appears to take place, probably by chelating components of the solution, whereby more arsenic than gallium is found in solution. The gallium arsenide particle surface is enriched in arsenic, which migrates from the bulk, and which is ultimately oxidized to arsenic oxide (Pierson et al., 1989). When dissolution of gallium arsenide was tested in vitro in phosphate buffer and various acids and bases, the amount of dissolved arsenic was highest in phosphate buffer (Yamauchi et al., 1986). These observations help to explain how arsenic may be released from inhaled gallium arsenide particles.”</p> <p>Therefore, the classification of gallium</p>		<p>Agree with commenting MSCA.</p>
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			arsenide should be in agreement of IARC; Carc. Cat. 1; R45.		
2009/06/23	Jean-Luc Ledys	France / SOITEC / PICOGIGA INTERNATI ONAL	Picogiga is using large quantity of that material since 1985 with a drastic medical follow up of the concerned people: No demonstrated impact.		
2009/07/24	Frauke Schröder	Germany / Baua	<p>Carc. Cat 3; R40 is proposed.</p> <p>Based on the data described for carcinogenicity the justification for classification of gallium arsenide is not fully plausible. No data on human cancer were available and the reported data in experimental animals were considered as borderline for carcinogenicity.</p> <p>In the “Summary and discussion of carcinogenicity” section 5.7.5 only a short summary is provided whereas some discussions are expected for the proposed classification and assumed mode of action/ mechanisms to explain and support the conclusion for classification.</p> <p>In the German CA's opinion justification solely based on the results in experimental animals is insufficient. The evidence of carcinogenicity in</p>	Your remark has been taken into account. The background document has been modified. Detailed MoA taken into account into IARC evaluation has been added together with an explanation why effects might be restricted to one specie, one sex.	Agree with MS and proposal if animal data are assessed without looking at human data for carcinogenicity, but recommend read-across to other arsenic substances and hence stricter classification for carcinogenicity: Carc. Cat. 1 T; R45 (DSD), Carc. 1A, H350 (CLP)..

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			<p>animal studies was considered of limited value since these results did not provide sufficient evidence for carcinogenicity of gallium arsenide. The data suggest a carcinogenic effect for gallium arsenide based on increased incidence of benign and malignant neoplasms in the lung, and increased incidences of benign neoplasms of the adrenal medulla and increased incidences of mononuclear cell leukaemia in female rats. But these data are limited for making a definitive evaluation because the evidence of carcinogenicity is restricted to one species and to one sex only (female F344/N rats) in one study; additionally it was reported that no evidence of carcinogenic activity in male rats, or in male or female mice was provided. Therefore, additional data are required to provide sufficient evidence for carcinogenicity of gallium arsenide. Furthermore, additional considerations and other contributing factors should be used in evaluating the tumour findings to justify the classification proposal.</p>		
2009/07/27		Ireland / Health &	The original document containing all the comments is uploaded on Circa		

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		Safety Authority	(see reference list). We can agree to classification of gallium arsenide as Carc. Cat 3 R40 (Carc. 2 H351). However, we feel that the extent/severity and incidence of the non-neoplastic lesions in the exposed animals could be further described.		Summary table from NTP-study is inserted in the BD
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Mutagenicity

Date	Submitted by	Organisation /MSCA	Comment	Response	Rapporteur's comment
2009/06/23	Jean-Luc Ledys	France / SOITEC / PICO GIGA INTERNATIONAL	Picogiga is using large quantity of that material since 1985 with a drastic medical follow up of the concerned people: No demonstrated impact.		

Toxicity to reproduction

Date	Submitted by	Organisation /MSCA	Comment	Response	Rapporteur's comment
2009/07/10	Agneta Ohlsson	Sweden / Swedish Chemicals Agency	The proposed classification as T; R48/23 and Repro. Cat. 2; R60 is supported. The serious damage to the lungs and male sex organs and sperm quality and production that are reported to occur at low doses in two	Thanks for your support.	

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			species, justifies this classification.		
2009/06/23	Jean-Luc Ledys	France / SOITEC / PICOGIGA INTERNATI ONAL	Picogiga is using large quantity of that material since 1985 with a drastic medical follow up of the concerned people: No demonstrated impact.		
2009/07/27		Ireland / Health & Safety Authority	The original document containing all the comments is uploaded on Circa (see reference list). We can agree to classification of gallium arsenide as Repr. Cat. 2 R60 (Repr. Cat. 1B H360F).		

Respiratory sensitisation

Date	Submitted by	Organisation /MSCA	Comment	Response	Rapporteur's comment
2009/06/23	Jean-Luc Ledys	France / SOITEC / PICOGIGA INTERNATI ONAL	Picogiga is using large quantity of that material since 1985 with a drastic medical follow up of the concerned people: No demonstrated impact.		

Other hazards and endpoints

Date	Submitted by	Organisation /MSCA	Comment	Response	Rapporteur's comment
2009/07/10	Agneta Ohlsson	Sweden / Swedish	The proposed classification as T; R48/23 and Repro. Cat. 2; R60 is	Thanks for you support	

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		Chemicals Agency	supported. The serious damage to the lungs and male sex organs and sperm quality and production that are reported to occur at low doses in two species, justifies this classification.		
2009/07/24	Frauke Schröder	Germany /Baua	The German CA agrees on the proposed classification as T, R48/23. However, in our view the justification of observed toxic effects reported in the “Summary and discussion of repeated dose toxicity” section 5.5.4 was not adequately and sufficiently described for classification as T, R48/23. The observed findings should shortly refer and describe the observed severe toxic effects, which clearly indicate functional disturbance or morphological changes at generally low exposure concentrations. Critical effects considered to be indicative of serious damage to health for gallium arsenide are non-neoplastic lung lesions in rats and mice, non- neoplastic lesions in the larynx of male rats and hyperplasia of the tracheobronchial lymph node in mice, haematotoxicity and toxic effects on the male reproductive organs in rats and mice.	Taken into account, background document modified accordingly.	OK

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2009/07/27		Ireland / Health & Safety Authority	<p>The original document containing all the comments is uploaded on Circa (see reference list).</p> <p>Therefore, without further details of the magnitude of the effects observed, we feel it is not possible to decide whether STOT-SE classification is warranted for gallium arsenide.</p> <p>Full comment: Acute toxicity We feel that there is insufficient detail concerning the magnitude of effects following oral or intra-tracheal administration of gallium arsenide in the dossier to allow us to make a final decision concerning classification of the substance for non-lethal acute effects e.g. classification with R39 (STOT-SE Cat. 1 or 2). It is stated in the Annex XV report that <i>“a single administration of gallium arsenide by inhalation (i.t. installation) or oral route causes delayed specific haematological and immunological toxicity. Due to a lack of mortality, a specific acute toxicity classification does not apply. Moreover, a</i></p>	<p>Magnitude of the effects were reported when available. The effects reported were considered to belong to those described in 3.8.2.1.8 ie adaptative responses of minimal toxicological importance. This point has been clarified in the background document.</p>	OK

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			<p><i>classification with R39 is not justified.”</i></p> <p>We note that point 3.8.2.1.7.3 in Annex I to CLP Regulation states that a “<i>consistent and significant adverse change in clinical biochemistry, haematology, or urinalysis parameters</i>”, may be sufficient to justify classification with STOT-SE Cat 1 or 2. Therefore, without further detail of the magnitude of the effects observed, we feel it is not possible to decide whether STOT-SE classification is warranted for gallium arsenide.</p> <p>Repeat dose toxicity inhalation</p> <p>We feel that it is not possible for us to base a decision for classification for this endpoint on the information provided in the dossier. The reasons are as follows:</p> <p>Physical state in which the substance was administered. Full comment: There is no information on the physical state in which the substance was administered by the inhalation route, i.e. gas, vapour or</p>	<p>Information provided as follows: MMAD range: 0.8-1.6µm which means that GaAs was administered in a form of particulate aerosols with a mass median aerodynamic diameter of 0.8</p>	<p>OK</p>
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			<p>dust/fume/mist. There are different guidance values assigned in Table 3.9.2 of the CLP regulation for classifying as a Cat 1 STOT-RE dependent on the physical state in which the substance was administered.</p> <p>Effective concentrations Full comment: The summary of the repeat dose toxicity describes the effects as warranting classification as T, R48/23, without reference to effective concentrations. The effective concentrations at which toxicologically significant lesions have occurred should be summarised to justify the classification (i.e. $\leq 0.025\text{mg/l}$, 6hr/day).</p> <p>Mg/l vs mg/ m³ Full comment: Throughout section 5.5.2 the dose units are quoted as mg/m³, whereas the dose units for inhalation are normally quoted as mg/l for 6 hr exposures for classification purposes. Expression of the doses as mg/l would have facilitated the interpretation of</p>	<p>to 1.6 μm at concentrations of...</p> <p>These information have been added in the background document.</p> <p>Data were reported as described in the study. This is only a matter of conversion as $\text{mg/l} = 1000\text{mg/m}^3$.</p>	<p>Converting concentrations of particulate aerosols to relevant units in corresponding guidance values assigned in Table 3.9.2 of the CLP regulation supports the proposed classification as STOT-RE 1.</p>
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			<p>the results with respect to classification.</p> <p>Information on organ weight, doses at which effects were noted, statistical, biological significance...</p> <p>Full comment: Information on the extent of the changes in organ weights in exposed animals, the doses at which effects were noted, the statistical and/or biological significance for the effects observed and the degree/severity of histopathological changes observed, in particular microcytic anaemia, is missing from the summaries.</p> <p>Physico-chemical properties Full comment: Reference is made in Table 1 to IUCLID sections 3.1 et seq, however, these are now numbered 4.1 et seq in IUCLID 5. The information contained in the table is not included in the IUCLID file for the substance.</p>	<p>These data are given as information and we cannot give all the results of these huge studies.</p> <p>The remark concerning IUCLID references in table 1 has been taken into account and the background document has been changed accordingly. Concerning the remark that information of table 1 are not reported in IUCLID, sections 1 and 2 only are warranted in the technical dossier for Annex VI dossier of "hand-over" substance from ECB such as</p>	<p>Summary table from NTP-study is inserted in the BD</p> <p>OK</p>
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				Gallium arsenide.	
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LIST OF ORIGINAL DOCUMENTS RECEIVED AS COMMENTS

FROM MSCA

IRELAND: CLH_COM_IRELAND_GALLIUM ARSENIDE

http://echa.europa.eu/doc/about/organisation/rac/ie_comments_rcom_gallium_arsenide.pdf

UNITED STATES / IPC:

IPC COMMENTS DOCUMENT DATED 24 JULY 2009

http://echa.europa.eu/doc/about/organisation/rac/ipc_comments_rcom_gallium_arsenide.pdf

AIR POLLUTION DATA BY COUNTRY: URBAN POPULATION WEIGHTED AVERAGE PM10 CONCENTRATIONS (MICRO GRAMS PER CUBIC METER) IN RESIDENTIAL AREAS OF CITIES LARGER THAN 100,000

HETLAND ET AL. SILICA-INDUCED CYTOKINE RELEASE FROM A549 CELLS: IMPORTANCE OF SURFACE AREA VERSUS SIZE, HUMAN & EXPERIMENTAL TOXICOLOGY (2001) 20, 46-55

POPE ET AL. LUNG CANCER, CARDIOPULMONARY MORTALITY, AND LONG-TERM EXPOSURE TO FINE PARTICULATE AIR POLLUTION, JAMA. 2002;287(9):1132-1141 (ONLINE ARTICLE AND RELATED CONTENT CURRENT AS OF JUNE 17, 2009.)

Annex 2 Comments received on the Annex XV report and response to comments provided by the dossier submitter (excl. confidential information)

WHO WORKING GROUP REPORT ON HEALTH ASPECTS OF AIR POLLUTION WITH PARTICULATE MATTER, OZONE AND NITROGEN DIOXIDE, BONN, GERMANY, 13–15 JANUARY 2003, PP 94