

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPSAL ON DIANTIMONY TRIOXIDE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Substance name: Diantimony trioxide

CAS number: 1309-64-4

EC number: 215-175-0

General comments

Date	Submitted by	Organisation/MSCA	Comment	Response	Rapporteur's comment
26/02/2009	Carsten DIETSCHKE	Germany/ Halle University Research Centre For The Environment	<p>Dear Sir or Madam,</p> <p>so now I have questions concerning Articles:</p> <p>1) Are [parts contain Diantimony Trioxide] labels needed in the future? My question refers to automotive interior trims, dashboards or car seats, if applicable.</p> <p>2) For these articles, Safety Data Sheets are not applicable. How can workers or consumers be informed about (possibly) latent dangers and (if applicable) personal protective equipment? By reference in the Owner's Manual?</p> <p>3) What info needs to be communicated to car dismantlers and recyclers then?</p> <p>Thank you in advance.</p>	<p>These comments are questions regarding required information and labelling of articles containing diantimony trioxide. Please, see the provisions in the substance directive (67/548) and the CLP and REACH regulations.</p>	<p>These comments and questions do not relate to aspects of the CLH proposal being considered by RAC. The submitter might consider contacting his/her national REACH helpdesk for advice.</p>
02/04/2009	Karine Van de Velde	Belgium /International	<p>The International Antimony Association (i2a) supports the</p>	<p>We thank i2a for the support.</p>	<p>It is noted that the International Antimony Association agrees</p>

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		Antimony Association vzw	<p>Classification & Labelling on skin irritation proposal from the Swedish Rapporteur Kemi, as it is completely in line with the outcome of the Risk Assessment Report of antimony trioxide under the Existing Substance Regulation 793/93 (see attached submission). The International Antimony Association (i2a) is a non-profit association whose mission is to conduct studies and to disseminate information concerning the safety and benefits of antimony compounds, by way of giving access to data, sharing and providing information on the content of data, for the benefit of producers and importers of antimony compounds world-wide regarding environmental, health and safety regulations of these antimony compounds. i2a closely cooperated with the Swedish Rapporteur Keml on the EU Risk Assessment Report (RAR) of Diantimony Trioxide under Existing Substance Regulation 793/93. In this process Keml concluded that antimony trioxide has to be classified with Xi (irritant) and R38 (Irritating to skin) according to Directive 67/548/EEC and its amendments based on the following information: "The only animal study which can be used for</p>		<p>to classification with Xi: R38 on the basis of the historical human case reports. However, it is also noted (i) there is no further evidence from the workplace of the skin irritation potential of diantimony trioxide, and (ii) that the ESR review concluded this hazard is only applicable "under conditions that evoke sweating".</p>

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			<p>assessment of the skin irritation potential of antimony trioxide shows that antimony trioxide is not irritating to rabbit skin. However, several human case studies indicate that antimony trioxide may cause dermatitis on skin damp with perspiration and thus the lesions seem to be closely related to sweat ducts. The lack of dermal irritation in rabbits may be explained by the fact that rabbits lack sweat glands (Brewer and Cruise, 1994). In conclusion, antimony trioxide should be regarded as a skin irritant in humans (R38) under conditions that evoke sweating.” The following publicly available documents support this conclusion:</p> <ul style="list-style-type: none"> - SIDS Initial Assessment Profile approved at OECD level - Annex XV dossier: Proposal For Harmonised Classification and Labelling (Swedish Chemicals Agency, 2009) <p>i2a supports this classification. As industry is obliged to classify its substances based on available information and given the above conclusions, i2a has advised its members to start classifying antimony trioxide at latest by the end of 2008, by which all its members had to add the</p>		

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			additional phrase on the ATO safety data sheet (SDS) and the label. In this way the members fulfill their legal obligations and respect the official proposal from the Rapporteur of the Risk Assessment report of ATO, Keml.		
08/04/2009	John Sharp	USA	Pp.11-14. The conclusions reached by the Swedish Chemicals Agency seem to have no bearing on the data presented in their own document. While I do not have any issue with antimony trioxide being labelled as a Skin Irritant, it seems that the science in this document is poorly done at best. If this document is allowed to set the bar for what an Annex XV Dossier should be, environmental protection in the EU will continue to be made by political decisions, and not by scientific enquiry. The Swedish Chemicals Agency needs to revisit this document and its conclusions, and improve their reasoning to arrive at their conclusions. Currently, there is a large gap between the data presented, and the conclusions either reached or not reached.	<p>According to Directive 67/548/EC and the CLP (Regulation (EC) nr 1272/2008) classification can be based on animal data and/or human experience. When there are data from different sources a weight of evidence determination should be conducted. If both animal and human data exist, human data shall take precedence.</p> <p>Regarding diantimony trioxide an evaluation of both animal data and human data has been made. One animal study (Gross et al, 1955), identifying diantimony trioxide as a non-irritant, is regarded as conclusive. However, four human case reports give indications that diantimony trioxide gives rise to dermatitis on damp skin. In particular the observations in White et al. (1993) clearly indicate that the dermatitis is linked to diantimony trioxide exposure. This evidence in humans is concordant and cannot be neglected. As human data shall take precedence over</p>	<p>It is clear from Mr Sharp's comments that he feels the available evidence was not assessed adequately by Kemi.</p> <p>RAC will base its recommendation on the available scientific evidence, matched against the classification criteria.</p>

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				<p>animal data, according to the criteria in both Dir. 67/548 and the CLP, classification based on human data is proposed.</p> <p>A possible explanation to the negative outcome in the animal test may be that rabbits do not have sweat glands; thus the humid conditions which appear to be necessary for an irritant reaction to occur were never present. Further, in the animal test the physical activity is low.</p>	
09/04/2009	Jan Averbeck	Germany	<p>Page No18- In the present Annex XV dossier proposal for harmonised classification and labelling other hazard class of effects than CMR or as respiratory sensitizer is addressed. Classification with Xi; R38 (Irritating to skin)/ Skin Irrit. 2, H315 (Causes skin irritation) is proposed.</p> <p>According to Article 115 of the Regulation (EC) No. 1907/2006 (REACH) harmonised classification and labelling of other effects than CMR or as respiratory sensitizer may also be added to Annex I of Regulation (EC) No. 1272/2008 (CLP) “on a case-by-case-basis, if justification is provided demonstrating the need for action on Community level” (Article 36(3) CLP). In the</p>	<p>Thank you for the support.</p>	<p>RAC agreed that the dossier was in accordance with the requirements in the CLP Regulation – this was based on the view presented by Kemi that industry's self-classification and labelling of DAT for skin irritation varies, some duty holders include R38, some do not.</p>

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			<p>case of consideration justification is provided that there is a need for such action on Community-wide action for this proposed classification.</p> <p>SE has provided a plausible justification for harmonised classification of DAT.</p>		
09/04/2009	Jana Cohrs	Belgium / FEICA - Association of European Adhesives and Sealants Manufacturers	Diantimony Trioxide is sometimes used as a flame retardant in adhesives.	Thank you for the information. It will be added as a foot note to Table 2 in the background document.	Noted.
09/04/2009	French CA	France/ BERPC	<p>Human data provide evidence that diantimony trioxide induces skin irritation in combination with sweating. In White 1993, observation that lesions appear and disappear when antimony is introduced or avoided confirms that dermatitis is linked to diantimony trioxide. Human data are therefore sufficiently conclusive to take precedence over the negative animal studies. Besides, none of the animal studies have been performed on pure substance although the dose used in Gross 1955 is high.</p> <p>We therefore agree with classification proposal Xi; R38.</p> <p>➤ <u>Labelling</u></p> <p>An additional labelling with S24 "Avoid skin contact" is proposed.</p>	<p>Thank you for agreeing with the classification proposal.</p> <p>Considering the labelling, we agree with your suggestion not to label with S24. The current labelling with S36/37 is sufficient. The labelling proposal (S24-28) will therefore be retracted in the background document.</p>	<p>The human data are particularly informative about the way in which exposure to DAT may lead to adverse skin reactions. However, they do not indicate that DAT has the inherent potential to act as a skin irritant; special conditions are required. S24 is not required.</p>

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			Diantimony trioxide is already labelled with S36/37 "Wear suitable protective clothing and gloves" so as to prevent from skin contact. S24 is therefore not considered necessary and is not recommended in this case as specified in the criteria for use of Directive 67/548/CEE. It should not be added in order to limit the number of precautionary statements on the label.		

Carcinogenicity

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Mutagenicity

Date	Submitted by	Organisation/MSCA	Comment	Response	Rapporteur's comment

Toxicity to reproduction

Date	Submitted by	Organisation/MSCA	Comment	Response	Rapporteur's comment

Respiratory sensitisation

Date	Submitted by	Organisation/MSCA	Comment	Response	Rapporteur's comment

Other hazards and endpoints

Date	Submitted by	Organisation/MSCA	Comment	Response	Rapporteur's comment
08/04/2009	John Sharp	USA	p. 11. Section 5.3.1.1. Animal	The study is very poorly reported.	Animal data:

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			<p>Studies (Rabbit) - There is no reason given for the statement "No conclusions on the irritating potential of diantimony trioxide can be drawn from this study." in the second paragraph of this section. The data shows no irritation, but the Swedish Chemicals Agency says that they can draw no conclusions without any reason given.</p> <p>p. 11. Section 5.3.1.1. Animal Studies (Guinea Pig) - Again, the Swedish Chemicals Agency cannot make a conclusion when the data shows no irritation, citing that the study didn't meet OECD Guideline 404. The study was done in 1970 and OECD Guideline 404 was not adopted until May 12, 1981. The conclusions should not be invalidated because later guidelines were adopted. This is the data we have to work with at this time, and we should not dismiss it so lightly.</p> <p>p. 12. Section 5.3.1.1. Animal Studies (Guinea Pig) - Again, the Swedish Chemicals Agency dismisses another older study due to non-conformance with OECD Guideline 404. Then, in a completely irrelevant statement with no data or scientific</p>	<p>There is no information on e.g. volume of the dose, duration of exposure, pretreatment of rabbit skin and eventual controls. These parameters would influence the outcome of the study. As they are absent in the report it is not possible to assess the relevance of the negative outcome of the study.</p> <p>The study is poorly reported. There is no information on e.g. duration of exposure, occlusivity or not, pretreatment of rabbit skin and eventual controls. The criteria for classification for skin irritation are based on the standardised conditions and scoring in OECD TG 404. As the test conditions in this guinea pig test deviate considerably from the standardised (e.g. by reduced test volume and test concentration) the test protocol is not comparable to that of TG 404 and hence it is not possible to assess the relevance of a negative outcome of the study.</p> <p>See previous comment above. As the test volume was only 10% of the standardised and the tested concentration was low (<10%), in contrast to the undiluted test</p>	<p>The studies in rabbits and guinea pigs show no evidence of DAT being a skin irritant, but there are limitations in the level of information they provide. Consequently, it is appropriate to consider whether there is evidence from the workplace to justify classification.</p> <p>Human data: The original proposal from Kemi did not provide sufficient evidence to justify the claim that "fumes from antimony, presumably antimony trioxide, may cause dermatitis in humans". In the revised version, Kemi replaced the word "presumably" with the phrase "most likely predominantly containing". Although it appears to be common knowledge that antimony oxidises easily, it is clear that there is uncertainty about the nature of the chemical exposures that took place.</p> <p>The available evidence seems to indicate that irritation was seen on skin damp with perspiration, exposed to antimony-derived fumes. As indicated by Kemi in their dossier, Stevenson (1965) presented evidence to indicate that heat did seem to be a factor too.</p>

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			<p>justification given, says that the lack of skin irritation could be due to not following OECD 404 again.</p> <p>p. 12 Section 5.3.1.2 Human Studies - The conclusion "This study indicates that fumes from melted antimony, presumably antimony trioxide, may cause dermatitis in humans." has no justification in the data presented. The substance in the preceding data was about antimony, not antimony trioxide. The phrase "presumably antimony trioxide" has no justification for being added, other than a patently obvious attempt to use data from another substance to apply to antimony trioxide. Interestingly enough, no reference is given to OECD Guidelines 404 to determine if the exposure scenario for the workers met the requirements of this guideline.</p> <p>p. 12-13 Section 5.3.1.2 Human Studies - The conclusion "This study suggests that workers exposed to antimony trioxide are liable to develop a transient skin eruption affecting areas most exposed to heat and where sweating occurs." seems not to be supported by the data presented.</p>	<p>material being the standard, it is not possible to assess the relevance of the outcome of the study (mild erythema in some animals).</p> <p>Antimony oxidizes easily and from a chemical point of view it is highly likely that the fumes predominantly contain diantimony trioxide.</p> <p>Regarding OECD TG404, it is a guideline for testing in rabbits. Human experience can be e.g. epidemiological data, well-documented case reports and observations.</p> <p>The observed dermatitis is in accordance with the in literature described "antimony spots", a rash consisting of pustules around sweat and sebaceous glands. Heat or sweat seems to be a condition for "antimony spots" to appear. This is in accordance with the</p>	<p>It should be added that there are no reliable reports of skin irritation in workers exposed to diantimony trioxide in the absence of heat.</p>
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			<p>The data says that heat seems to be the main culprit. "The eruption occurs in the warm summer months and is rarely seen in the winter." Assuming that the same job is being done in both winter and summer, that the temperature near a furnace is not affected by the relatively slight differences in summer and winter temperatures, it seems that there is some other mechanism in play here. It is also interesting that 5 of the 23 workers developed the same symptoms doing a different job (presumably not working with antimony trioxide near a furnace), but in hot conditions.</p> <p>The second and third conclusions on p. 13 is much the same - mixing antimony and antimony trioxide exposures, with little data given, but somehow the Swedish Chemicals Agency is able to draw conclusions that support their position, as opposed to their inability to draw any conclusions from data that doesn't support their position. These symptoms seem to be more related to exposure to high heat, which MAY be exacerbated by exposure to antimony in some form or another, or by other substances that may be present. pp. 13-14 shows that the SCA</p>	<p>conditions described in the study. Although it is recognized that high temperatures and sweating may cause skin irritation the appearance of this "heat rash" is not identical to "antimony spots". Furthermore, in the study by White et al. (1993) it is evident that the dermatitis observed was not caused just by heat exposure as skin lesions appeared only when antimony was introduced and not when other metals were used in the same heat process.</p> <p>See the response to comments above regarding exposure to antimony/diantimony trioxide and combined exposure to diantimony trioxide and heat.</p>	

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			<p>easily dismisses any studies that do not support its position.</p> <p>Two studies that show no irritation are dismissed because "the amount of antimony trioxide applied was not given and there is no information on how much of the antimony trioxide in the fibre that came into contact with the skin." Again, it is easy for the SCA to accept other studies which have very little supporting data if the study shows skin irritation. However, if a study shows no irritation, it is always dismissed because there is some minor lack of data.</p> <p>In summary, I don't have an issue with antimony trioxide being listed as an irritant if the data supports this. The issue is the lack of scientific justification in this dossier, and the lack of credibility that will occur should documents as biased and poorly researched as this one is, be accepted as the scientific basis for setting substance restrictions</p>	<p>The poor description of the test conditions (patch test) makes it impossible to assess the relevance of the test results. The dosage is crucial for the outcome of the patch test and the dosage has not been fully described.</p> <p>The assembled human data are sufficient to meet the criteria for classification for skin irritation according to Dir. 67/548/EC as well as the CLP (Regulation (EC) nr 1272/2008).</p>	
09/04/2009	Jan Averbeck	Germany	<p>Page No 11-16</p> <p>The following classification was proposed: based on Directive 67/548/EEC criteria: Xi; R38 (Irritating to skin); and based on GHS criteria: Skin Irrit. 2, H315 (Causes skin irritation).</p>		

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			<p>Based on the effects seen in human skin after repeated exposure to diantimony trioxide (DAT), we agree to the necessity of classifying the substance. However, in our view it would be worth to consider, whether data presented in the Annex XV report rather militate in favour of specific target organ toxicity arising from a repeated exposure (STOT RE). DAT would then be classified as T, R48/24 - STOT RE 1/H372, which is substantiated below.</p> <p>Firstly, we see the possibility, that the effects on the human skin described in the document represent an allergic response rather than irritation. It is known from metals like nickel that sweating enhances the allergic effect of the compound. The description given for diantimony trioxide shows that heat in this case also favours the dermatosis described.</p> <p>We would like to ask the Swedish Rapporteur to comment on this question on the possible mode of action (primary irritation versus sensitisation) of the dermatitis observed (rashes, pustules, papules, itching).</p>	<p>The skin effects described for diantimony trioxide are local effects and are therefore relevant for classification for skin irritation. Classification for Specific Target Organ Toxicity, STOT, is usually based on systemic effects and is therefore not considered.</p> <p>No documentation is available suggesting that the skin effects caused by diantimony trioxide should be of allergic origin. One animal study, performed according to OECD Guideline 406, showed that diantimony trioxide does not have sensitising properties.</p> <p>The lesions observed are indeed more severe than just a slight irritation, but are compatible with the classification criteria for skin irritation.</p>	<p>The RAC rapporteur agrees with the rationale presented by Kemi that the issue to be addressed is whether classification as a skin irritant is justified or not.</p> <p>It is noted that animal data are available suggesting specifically that diantimony trioxide is not a skin sensitiser. Perhaps, if this substance was a skin sensitiser, one would have expected at least a few reports in the literature of skin effects in other groups of exposed workers.</p>
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			<p>Severe skin lesions (local vesicular and papular inflammatory reaction, and chronic dermatosis) in humans were reported in case reports and from clinical examinations of workers in various production processes and are considered beyond those characteristic for skin irritation. The skin was clearly identified as the specific target organ and skin effects were observed arising from repeated exposure to antimony. The skin effects occurred under special conditions such as high temperature at the workplace with concomitant increase in skin hydration. When exposure to antimony was avoided, skin inflammation was reversible but residual hyperpigmentation remained. Therefore, it is concluded that the observed skin lesions - manifested as dermatitis - were induced following repeated exposure under conditions of normal use at workplace that evoke sweating.</p> <p>The only animal study used for risk assessment of the skin irritation potential of DAT shows no irritating effect to rabbit skin. This appears plausible due to the lack of sweat glands in rabbit skin</p>	We agree.	Noted.

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			<p>and the absence of high temperatures during exposure.</p> <p>However, it stayed quite unclear, whether diantimony trioxide is the active chemical that is responsible for the dermatosis. The composition of airborne dust present at a smelting plant is given in one study [1] . Its chemical analysis showed up to approx. 89 % of diantimony trioxide, up to approx. 8 % of diantimony pentoxide and (due to the fact that antimony is accompanied by arsenic) up to approx. 6.5 % of diarsenic trioxide. The water solubility of diarsenic trioxide exceeds by far the solubility of diantimony trioxide (37 g/l[2] vs. approx. 20 mg/l) which might be one factor leading to a more pronounced exposure of the target cells. Diarsenic trioxide is classified as corrosive and might at least be involved in the irritating effect observed at the workplace. Based on the process elementary antimony might have been present additionally. Thus we would like to ask the Swedish Rapporteur to additionally elaborate on the substance-related exposure conditions resulting in dermatosis at the workplace and to discuss</p>	<p>We agree that in some cases it can not be completely ruled out that exposure to another substance such as diarsenic trioxide could have contributed to the dermatitis observed. However, in the report by White et al. (1993) pure (99.86%) antimony metal was used in the melting process. It was also indicated in that report that it was the exposure to fumes, and not to dust containing antimony metal, that caused the dermatitis. When antimony is heated under aerobic conditions it is easily oxidized to diantimony trioxide and it can thus be assumed that antimony present in the fumes is predominantly in the form of diantimony trioxide.</p>	<p>It is recognised that substances in addition to, or other than antimony trioxide may have contributed to the irritant reactions observed.</p>
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			<p>whether the antimony metal, diantimony trioxide or diarsenic trioxide might be the cause of the cases of dermatitis observed.</p> <p>Conclusion: We suggest re-considering the appropriateness of the proposed classification.</p> <p>[1] Potkonjak V, Pavlovich M, Antimoniosis: A Particular Form of Pneumoconiosis, Int Arch Occup Environ Health (1983) 51: 199-207 [2] Weast, Handbook of Chemistry and Physics, 64th Edition, CRC Press 1983-84</p>	<p>After taking all comments into consideration, we maintain the proposed classification.</p>	<p>There are grounds to reconsider the proposal from Kemi.</p>
09/04/2009	Irish CA	Ireland / HAS	<p>Irish CAs comments on Diantimony Trioxide (EC No. 215-175-0): The Irish CA is not in agreement with the proposed classification for skin irritancy for diantimony trioxide (Sb₂O₃). Our position is based on a review of the physical chemical characteristics of the substance and the conditions under which it is used.</p> <p>The Swedish CA, in its conclusion, stated that antimony trioxide should be regarded as a skin irritant in humans under conditions that evoke sweating. This indicates that the substance</p>	<p>We do not agree that diantimony trioxide only meets the classification criteria “in an extreme physical form”; it is rather that humidity is needed for diantimony trioxide to exert its irritating properties.</p> <p>This property needs to be adequately handled by classification and hazard communication. A note is a weaker form of hazard communication. It is not</p>	<p>Agree with Irish CA. The available evidence suggests that DAT is irritating to skin only under certain conditions, i.e. that it does not possess the inherent hazard of a skin irritant itself.</p>

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			<p>is irritant only under certain conditions ie. specific work practices. In addition, Sb2O3 does not fully meet the criteria for classification as a skin irritant ie. it causes irritation in an extreme physical form, fume at a high temperature and this leads us to the conclusion that labelling as an irritant is inappropriate in this case.</p> <p>We do, however, feel that in order to ensure good protection for workers, the use of a Note and appropriate precautionary statements may be warranted.</p> <p>It may be of interest to note that discussions have previously taken place at the Technical Committee for Classification and Labelling Group on the issue of applying Notes to substances which do not correctly meet the criteria for classification as a skin irritation. In March 2006 the TC C&L confirmed their decision to de-classify both Man-made mineral fibres (MMMF) and Special purpose fibres (SPF) entries (650-016-00-2 and 650-017-00-8) in Annex I to Directive 67/548/EEC with respect to Xi; R38, as the mechanical irritation from the fibres did not correctly meet the criteria for classification on</p>	<p>sufficient as it does not involve classification and consequently a symbol would not be needed and eventual downstream consequences would not be triggered. However, it is important that the specific conditions needed for irritation to occur are communicated via the Safety Data Sheet.</p>	<p>The RAC has not been tasked to address the question of worker protection, beyond giving an opinion on whether DAT should be classified as a skin irritant or not. However, if a workplace problem is perceived, the creation of a unique note along the lines suggested by the Irish CA might merit further consideration by the industry and/or relevant authorities, along with any other options.</p>
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			<p>condition that the concern regarding irritancy was covered by another legally binding instrument, in this case, a Note. Discussions on photo-irritants and photo-sensitisers also took place and, again, based on a lack of criteria to classify such substances with R38, the related wording for a new Note X was agreed (as below).</p> <p>For photosensitisers: May cause sensitisation by skin contact after subsequent exposure to light.</p> <p>For photoirritants: May cause irritation by skin contact after subsequent exposure to light.</p> <p>Mechanical skin irritants: May cause mechanical irritation of the skin.</p> <p>In conclusion, we do not agree to classify diantimony trioxide as R38 (Skin Irrit. Cat. 2 H315). We believe that the irritation is caused by the physical chemical properties of the substance under specific work practices only (ie. in the instances where workers are sweating), as opposed to an intrinsic property of the</p>	<p>After taking all comments into consideration, we maintain the proposed classification.</p>	

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			<p>substance. Therefore, we also do not agree with the proposed labelling with S24-28 and, as mentioned above, we propose that a new Note and appropriate precautionary statements should be considered to be included on the label.</p>		
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