INFINEUM C9350 – DECISIONS ON REQUESTS FOR VARIATIONS

Evaluation of Human Toxicological Data

1a) Request for variation by Infineum

Point 1: No reliable information on the concentrations employed

Although there is no analytical confirmation of the solutions used in the study, there is some basis from Infineum biological studies, product chemistry and use patterns to support our opinion regarding sample identification and concentration and thus deem the studies valid as tested.

From attachments to the HRIPT, we can deduce that two calcium sulfonates were used in the study (*attached file* – HillTopRes SampleKey-01.pdf). The samples are designated as "DM1" MRD 92-373 (Hill Top sample F) and "DM2" MRD 92-375 (Hill Top sample H). We have determined that the samples used in the Hill Top Research study are not actually C9350. The samples are a prototype material which is very similar in nature to C9350. A note from Dominique Moulin to Nick Wells dates 12 June 2006 (*attached file* – Dominique Moulin – C9350 Early Tox Studies 2006June12b.pdf) provides analytical information about the Infineum materials in question.

C9350 is 54% calcium sulfonate by mass with approximately 2% calcium succinate. Samples DM1 and DM2 are approximately 44% by mass of calcium sulfonate with approximately 1 – 2.5% calcium formate. The remaining mass in all materials is residual calcium (probably as the oxide/hydroxide) and mineral oil.

From the study itself we can be confident that the challenge and rechallenge were conducted at 10% and 5% material, respectively. From our experience in conducting sensitization studies in all species, we are confident that at least 10% material was used during the induction phase of the testing program under discussion.

Typical Infineum C9350 as used in Australia, is present in packages at less than 5% by weight of product. The proposed new use patterns would place Infineum C9350 in the range of 1 to 10% by weight of product material. Performing the HRIPT at 25 or 50% weight material for induction with challenge and rechallenge at 10 and 5%, respectively provides hazard based information at the relevant concentration for our submission.

Therefore, although, Infineum does not have definitive information on the samples employed in the HRIPT study for the induction, we do have reasonable information which would suggest that concentrations are likely to be in the region of 25-50% product on induction and that this would apply to samples F and H in this particular set of data for C9350.

1b) Decision

Variation not approved.
For challenge and rechallenge samples it is stated in the study report (Amendment 4 November 16, 1992 and amendment 5 February 19 1993) that chemicals were diluted to 10% and 5% *"as received"* from the sponsor respectively. Thus, as the concentration of the chemicals "as received" is not provided in the study report (e.g. it could be anything up to 100 %), concentrations used at challenge and rechallenge cannot be reliably ascertained.. Furthermore, providing information on the concentration of Infineum C9350 in finished products and induction and challenge concentrations typically used in the HRIPT does not address the above mentioned uncertainty. Similarly, as the concentration of the chemicals received from the sponsor are not known the statement in the variation request that "…from our experience ….. at least 10% material was used during the induction phase…" cannot be confirmed. Thus the induction and challenge concentrations for the chemicals tested in this HRIPT study cannot be reliably ascertained.

1c) Comment

The comments below relate to the issues raised above in Infineum's request (paragraphs 2 and 3) but are not directly related to the variation requested.

Based on the information provided by the applicant the original assessment of Infineum C9350 reported that two analogues of Infineum C9350 (samples F and H) were tested in the HRIPT, this was retracted by Infineum in the secondary notification submission, stating that only sample F was Infineum C9350. Subsequent information provided by Infineum in the variations attachment contained handwritten designations of DM1 and DM2. These were not present in the HRIPT study report initially presented by Infineum for the secondary notification. In addition, it is noted that DM1 (sample F) is listed in the study report as MRD 92-732 and not MRD 92-373 as stated in the variations attachment. Similarly, DM2 (sample H) is listed as MRD 92-373 in the study report and MRD 92-375 in the variations submission. Additionally, the only reference to MRD 92-375 in the HRIPT study report is in protocol amendment 2 dated October 12, 1992 where it states "MRD 92-410 will replace MRD 92-375 as Sample E". Thus, there is confusion about the actual sponsor codes for the test materials and the identities of the substances tested in the HRIPT cannot be reliably determined.

Furthermore, the statement that DM1 and DM2 were synthesised prior to the HRIPT does not provide robust evidence that these chemicals were tested in the HRIPT, or clarify the identity of the test substances. Additionally, it is noted that these chemicals (DM1 and DM2) are referred to as prototype material and not Infineum C9350 in the variations request. Where information on a chemical other than that notified is submitted for assessment a scientific rationale is required on why information on such a chemical is considered appropriate i.e. scientific argument that the chemical has a similar structure and physicochemical properties to the notified chemical and that toxicological profiles of the two chemicals are very similar. No such rationale has been submitted by Infineum.

Although NICNAS cannot reliably determine what was tested in this HPIRT study, a review of DM2 (sample H) was undertaken. As sample F was reviewed initially for the secondary notification it has not been reviewed again for this variation request.

Overall, the results for sample H showed similar responses to those seen with sample F. Mild to moderate erythema was seen to sample H in 34 subjects at least once (often with papules present) at induction, and of these spreading skin reactions were seen in 23. Furthermore, of these 34 subjects, 31 also showed skin reactions to sample F at induction. At challenge, mild erythema with papules was seen in 11 subjects 96 h after challenge with sample H compared with sample F where skin reactions were seen in 6 subjects. However, while similar results to sample F were seen with sample H, the study limitations as described above are still applicable and, overall, no reliable conclusions can be drawn from this study on the skin sensitisation potential of Infineum C9350.

The assessment of sample H will be included in the assessment report.

2a) Request for variation by Infineum

Point 2: For the 13 subjects whose participation in the study was discontinued, clinical notes are provided for 8 volunteers, of these, skin reactions were considered likely to be due to sensitization in 5 subjects, though it is not reported which test product or products was/were the causative agent (i.e. no clinical testing to determine such appears to have been undertaken)

After further review of the data, it was determined that for both Infineum C9350 materials tested, Samples F (MRD-92-372) and H (MRD-92-373), there was sufficient information to determine whether samples F or H were causing reactions on induction and so caused withdrawal from the study prior to challenge. The information for each of these subjects not completing the study is shown below

Subject number	Observed reaction to Infineum C9350 (sample F or H)
7	Dropped before first induction
9	Dropped before first induction
55	Dropped before first induction
58	No reaction to H or F after the 9 inductions did not challenge
66	Had limited residual effect to 4th induction, dropped at 7th induction, but no reaction to F or H after any other induction
71	Had limited residual effect to 1st induction, dropped at 5th induction, but no reaction to F or H after any other induction
94	Limited residual from 3rd induction but no adverse reaction to F or H after any other induction, did not complete challenge
96	Limited residual from 5th induction but no adverse reaction to F or H after any other induction, did not complete challenge

97	Had residual effect from 2nd induction and for 9th induction (F and H) had mild reaction, papules, and some spreading (did not challenge)
98	No reaction from F or H after all 9 inductions did not challenge
108	No effect from F or H only completed 1 induction
109	No effect from F or H only completed 3 induction
122	Had limited residual effect to 1st induction, did not complete 9th induction or challenge and no reaction to F or H after any other completed induction

Although the comment is made by the dermatologist that the 13 reactions were probably test compound related (2 definite, 11 probable), this data shows that only subject 97 had exhibited even a mild effect from exposure to sample F or H., Therefore, only one subject in this group showed a mild response to Infineum C9350. All other subjects did not show a response to Infineum C9350. Thus these individuals and their withdrawal does not affect the outcome or statistics from the remainder of the study with regard to C9350.

2b) Decision

Variation not approved.
The study report makes a clear distinction between subjects who were 'dropped' from the study for reasons unrelated to the study (e.g. changed mind, broke wrist etc) and those who were not challenged due to residual/adverse reactions seen at induction (referred to as 'discontinued" in the study report). It is noted that the subjects referred to in this variation request (subject 7, 9, 55, 58, 66, 71, 94, 96, 97, 98, 108, 109 and 122) are those who were dropped not discontinued. For sample F table 1F in the study report shows that for the 13 discontinued subjects (No. 2, 11, 32, 38, 42, 44, 63, 64, 50, 75, 78, 93 and 100) skin residual/adverse skin reactions were seen and NICNAS's original comment is warranted. Furthermore, Table 1H in the study report shows that in these 13 discontinued subjects residual/adverse skin reactions were also seen to sample H. Thus, skin reactions were seen to both sample F and sample H in the 13 discontinued subjects for which clinical notes are available in 8 that state skin reactions are considered likely to be due to sensitisation in 5 subjects, though the causative agent is not identified. Thus, the request for variation does not address the correct sub-set of subjects and NICNAS's original comments on discontinued subjects are applicable for both sample F and sample H.

2c) Comment

It is noted that the MRD codes for samples F and H are now reported in the variation request as MRD 92-372 and MRD 92-373 respectively, while the code for sample F is reported as MRD 92-373 and for sample H MRD 92-375 earlier in the variation request. Furthermore, samples F and H are now referred to as Infineum C9350 while earlier in the variations request the samples were reported not to be Infineum C9350 but a prototype material. Thus, again it is

not clear what sample codes apply to samples F and H and consequently what chemicals were tested in this HRIPT study.

3a) Request for variation by Infineum

Point 3: not all the volunteers who exhibited questionable skin reaction at challenge with the chemical were re-challenged.

Again there is a distinction to be made here regarding the particular samples involved in producing questionable skin reactions. As far as subjects exposed to samples F or H not being rechallenged, the table below shows the subjects with positive scores for challenge exposure to samples F or H and the corresponding rechallenge results or comments.

Subject #	Sample	Challenge/Rechallenge result or comment
3	H	No adverse clinical dermal reaction after rechallenge
10	H	No adverse clinical dermal reaction after rechallenge
12	F and H	No adverse clinical dermal reaction after rechallenge
17	F	No adverse clinical dermal reaction after rechallenge
18	F and H	No adverse clinical dermal reaction after rechallenge
20	H	No adverse clinical dermal reaction after rechallenge
27	F and H	After challenge, no observable effect at 48 hours and only exhibited a minor effect at 96 hours similar to or less than effects observed with inductions. Was not rechallenged
34	F and H	No adverse clinical dermal reaction after rechallenge
74	H	No adverse clinical dermal reaction after rechallenge
76	F	Subject 76 experienced mild to moderate erythema, papules, and fissuring as a result of exposure to samples D, E, F, G, and H and application of patches was discontinued. The results for sample F were considered mild and this subject did not have a response from the sample H challenge, therefore, other material(s) likely caused the adverse results.
82	H	No adverse clinical dermal reaction at rechallenge
85	H	No observable effect at 48 hours, only exhibited a minor effect at 96 hours similar to or less than effects observed with inductions and showed no response to sample F after the inductions or challenges.
87	H	No observable effect at 48 hours, only exhibited a minor effect at 96 hours and showed no response after the inductions and challenge to sample F.
104	F	No observable effect at 48 hours, only exhibited a minor effect at 96 hours and showed no response after the inductions and challenge to sample H.

Infineum C9350 was present on patch locations F and H, the above results from the five subjects not rechallenged (subjects 27, 76, 85, 87, and 104) show the limited dermal sensitization potential of Infineum C9350;

- subject 27 showed a limited dermal response after the challenge patch to both samples F and H, and these were below those levels from induction, hence rechallenge was not deemed necessary

- All other subjects that were not rechallenged only showed a positive dermal response for one of the two Infineum C9350 samples (F or H). Additionally, the reported challenge responses were all minimal. As both samples contained C9350, the mild reaction in one only was considered most likely due to other tested products in proximity rather than to C9350 itself, where reaction to both was expected.

3b) Decision

Variation not approved
The assessment report comments on subjects not rechallenged. The table included with this variation clearly shows that 5 subjects with questionable skin reactions at challenge, were not rechallenged. This is consistent with the assessment report.

4a) Request for variation by Infineum

Point 4: six subjects wore the patch for less time than required by the protocol but there is no discussion by the study authors on whether this protocol deviation was significant

With regard to the six subjects who wore patches for less than 24 hours and the effect on the evaluation of exposure to sample F or H, below is a table illustrating the six subjects and the corresponding effect.

Subject #	Induction #	Sample affected	Time of contact	Comment
29	1	H	22 hrs	Finished all inductions and challenges – only had some residual reaction to the 7th induction with sample H and no adverse effects after other inductions or the challenge period.
39	1	F	Unknown	Unknown Finished all inductions and challenges – only had some residual reaction to the 5th induction with sample F
70	1	F	Unknown	Unknown Finished all inductions and challenges – only minimal adverse reaction to sample F after inductions 4, 8, and 9, no reaction

				after the challenge
123	2	F	5 hrs	Finished all inductions and challenges – no adverse reactions to sample F following the inductions or challenge periods
82	5	All	22 hrs	Very close to 24 hours of exposure, showed mild reaction after 9th induction but no adverse reactions after challenge.
82	Challenge	All	20 hrs	Very close to 24 hours of exposure, showed mild reaction after 9th induction for samples F or H and 96 hours after the challenge for sample H, but no adverse reactions following the sample F challenge or after the sample F and H rechallenge.

The above data shows the patches worn for less than 24 hours were primarily during the 1st or 2nd induction. Only subject #82 had a shorter exposure period later in the study and this subject completed both a challenge and rechallenge.

4b) Decision

Variation not approved
Comments noted, however, the issue is that while the study protocol was not followed here is no discussion in the study report of the significance of this deviation from the protocol. Consequently, the statement made by NICNAS is still valid.

5a) Request for variation by Infineum

Point 5: a total of 96 subjects actually completed the study. It is unlikely this number of subjects is sufficient to produce valid data.

Because Infineum C9350 was present as two samples (F and H), this provides more insight into the HRIPT results than is implied by these subject numbers. As each individual was patched with two separate aliquots of C9350 (F and H) at separate locations, this is effectively doubling the total number of cases to 192 observations. It is quite legitimate to multiple-product test on one subject in human patch testing and does not usually invalidate results provided responses are suitably localized. Therefore although the number of subjects is not high, there are sufficient responses to the product to provide information on the probable hazard or response for these particular product samples.

Classically, a positive response for dermal sensitizers would be characterized by an increase in the score after the challenge period as compared to the induction results. Of the 96 individuals completing the HRIPT, 3 subjects (subjects # 17, 87, and 104)

exhibited an increased dermal response after the challenge patch relative to the induction scores. However, after the rechallenge patch, subject # 17 showed no dermal response to Infineum C9350. Alternatively, subject # 87 scored positive (mild score of 1 with papules) with sample H but was negative for sample F and subject #104 had a score of 1 after the challenge with sample F but had a 0 after challenge with sample H. Collectively, we feel these results conclusively illustrate Infineum C9350 is a dermal irritant and not a dermal sensitizer.

5b) Decision

Variation approved.
Comments noted, however, the NICNAS position on the ability to reliably identify the test substance in the HRIPT is applicable (i.e. are samples F and H Infineum C9350 or a prototype material). Dot point 5 on page 19 of the assessment report will be deleted from the draft PEC report.

Two further points are raised by Infineum in their variations request:

- It is Infineum's recommendation that C9350 can be used up to 10% by mass without designating it as a sensitizer, and no R43 designation needs to be made for C9350 under these conditions.

NICNAS Response

With regards to cut-offs for classification and labelling of skin sensitisers in mixtures see the comment given below (i.e. a default value of 1% or greater would be applicable in this instance).

- Infineum will consider the following future course of action to further define C9350 and any possible hazards related to skin sensitisation

    1. Submit currently produced C9350 for detailed chemical analysis and prepare an accurate certificate of analysis.
    2. Conduct a new study (mLLNA – mouse Local Lymph Node Assay) to determine concentrations which may be sensitizing and non-sensitizing. This proposed study would be in accord with OECD Guideline 429.

NICNAS Response

1. It is not immediately clear how a certificate of analysis would assist in determining the skin sensitisation potential of Infineum C9350. Furthermore, such information would not assist in determining the chemical identity of samples F and H that were tested in 1992.

2. As a regulatory test method the LLNA only determines whether a chemical is a hazard for skin sensitisation. If the chemical is deemed to be a sensitiser then, as stated above, a default cut off value of 1 % or greater is obligatory for the classification of industrial mixtures containing that chemical. Thus, the

basis for proposing to conduct a LLNA is unclear. As Infineum C9350 was positive in a well conducted Buehler study NICNAS cannot support further testing of this chemical in a LLNA for animal welfare reasons.

Exposure & PPE

6a) Request for variation by WorkSafe Victoria

Throughout the document, comments are made about the use or non use of personal protective equipment in certain industries.

- Page vi – 2nd para: 'Exposure to workers in the metalworking industries is potentially significant but it is expected these workers will wear appropriate PPE, hence occupational exposure will be minimal';
- Page vii – 2nd para: 'Occupational risk from use of products containing Infineum C9350 in heavy metal working is moderate due to the higher concentrations of the chemical used in these types of products, however workers in these industries generally use PPE';
- Page vii – 2nd para: 'Workers involved in the automotive repair industry are unlikely to use PPE and are expected to be repeatedly exposed to the chemical. Because of the additive nature of exposure these workers are at risk of skin sensitisation';
- Page 9 – 4th para: 'It is anticipated there would be a high number of metalworking facilities that would use products containing Infineum C9350 and hence a large number of workers could potentially be exposed to low concentrations of the chemical but it is not possible to estimate the numbers. It is expected however that workers would wear appropriate personal protective equipment to minimise contact'.
- Page 9 – 5th para: 'Workers in the automotive service industry such as mechanics and their assistants doing regular maintenance and repair work on motors are unlikely to use protective clothing apart from overalls in their daily work. Therefore, repeated dermal exposure to the low concentration of Infineum C9350 in the final lubricating oil can occur for these workers.'

It appears from the above-mentioned comments, conclusions are drawn about the adequacy of controls in certain industries, and hence the expected risk to health from the use of Infineum C9350 in workplaces.

- Page 29 – 2nd para: 'During use in metal working applications, worker exposure is expected to be low. Risk in these occupations is also considered to be low';
- Page 29 – 3rd para: 'Exposure and risk to workers in the automotive repair industry is expected to be low'.

Caution needs to be taken with the reliance on personal protective equipment when conducting risk assessments. The unreliability of PPE is demonstrated by it being the least preferred risk control in modern OHS legislation. For example, in metalworking other factors such as loss of grip strength, manual dexterity and increased entanglement risk on manual machines often work against glove usage. This is in addition to the usual barriers to PPE usage. Therefore a cautious approach is needed as any of these factors may invalidate the conclusion that the risk to health is low. In

summary, assumptions about the extent of PPE usage in industry need to be either supported or qualified.

Infineum C9350 is classified as 'R43 May cause sensitisation by skin contact'. Reliance on personal protective equipment alone is unlikely to prevent skin sensitisation.

The use of the term 'low' in relation to concentration of Infineum C9350 also needs to be qualified. Does this mean low as below the 1% concentration cut-off as a sensitiser or does it mean low because it is below the concentration cut-off as a skin irritant?

6b) Decision

Variation approved. It will be clarified that the exposure scenarios and use of PPE are based on information provided by the applicants. It will be emphasised in the sections referred to in the variation that PPE of itself is not sufficient protection for a chemical classified as a skin sensitiser.

The report will also be amended to include changes below.

Page 9 – 4th para will be amended to: 'It is anticipated there would be a high number of metalworking facilities that would use products containing Infineum C9350 and hence a large number of workers could potentially be exposed to ~~low~~ Infineum C9350 at concentrations of ~~the chemical~~ <1% to 10%. ~~but~~ It is not possible to estimate the number~~s~~ of workers in metal working facilities. It is expected however that appropriate engineering controls will be in place and workers would wear appropriate personal protective equipment to minimise contact.

Page 9 – 5th para: 'In most cases, in the automotive service industry engineering controls are unlikely to be in place and workers such as mechanics and their assistants doing regular maintenance and repair work on motors are unlikely to use protective clothing apart from overalls in their daily work. Therefore, repeated dermal exposure to the low concentration of Infineum C9350 in the final lubricating oil can occur for these workers.

Classification under the *Approved Criteria for Classifying Hazardous Substances*

Request for variation by Australian Government Department of Employment and Workplace Relations

7a) Clarification is sought on the recommended hazard classification for Infineum C9350. In particular, it appears that the allocation of the symbol Xn and indication of danger 'Harmful' based on the hazard endpoint of skin sensitisation (R43) is inconsistent with the NOHSC *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)](the Approved Criteria). Paragraph 4.42 of the

Approved Criteria states that the symbol Xi and indication of danger 'irritant' should be assigned to substances and preparations that meet the criteria for sensitisation by skin contact (R43).

7b) Decision

Variation approved. Amendments will be made to the draft report as follows (Deleted text is struck through):

Page viii & 30

Risk Phrases*	Concentration Cut-off
~~Xn~~,Xi, R43	Conc ≥ 1%
Xi, R38	Conc ≥ 20%

*Xi, Irritant; ~~Xn, Harmful~~

Classification under the GHS

8a)

The reference provided for the GHS should be the first revised edition, not the OECD amendment to the GHS. The GHS includes criteria for classification of physical hazards and environmental hazards as well as health hazards. It is not clear from the report if Infineum C9350 has been classified against all GHS hazard criteria or only some of them, because the classification provided in Appendix 1 includes only health hazard endpoints, and it is the Health Hazards section of the report (section 12.1) that reads "Infineum C9350 is classified as a hazardous substance under the GHS". Could NICNAS clarify which GHS hazard criteria Infineum C9350 has been classified against and reflect that classification in the report.

8b) Decision

Variation approved. Amendments will be made to the draft report as follows (Deleted text is struck through, added text is underlined):

Appendix 1 will be amended as follows:

Classification under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

In this report, Infineum C9350 has been classified against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 2004) ~~and, in the case of physicochemical hazards, the *Australian Dangerous Goods Code* (ADG Code) (FORS, 1998).~~ However, classifications under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (~~OECD, 2002~~ UNECE, 2005) will come into force when the GHS is adopted by the Australian Government and promulgated into Commonwealth legislation. GHS documentation is available at:

http://www.unece.org/trans/danger/danger.htm

GHS classification for Infineum C9350.

Physical hazards – not classifiable

Environmental hazards

Environmental Hazard	**Classification**	**Hazard Communication**
Acute toxicity	Not classifiable	**Symbol:** no symbol **Signal Word:** no signal word **Hazard Statement:** no hazard statement
Chronic toxicity	Chronic 4	**Symbol:** no symbol **Signal Word:** no signal word **Hazard Statement:** may cause long lasting harmful effects to aquatic life

Health hazards

Health Hazard	**Classification**	**Hazard Communication**
Skin Sensitisation	Category 1	**Symbol:**  **Signal Word:** Warning **Hazard Statement:** May cause an allergic skin reaction
Skin Irritation	Category 2	**Symbol:**  **Signal Word:** Warning **Hazard Statement:** Causes skin irritation

Page 42 – References

Delete reference

OECD (Organisation for Economic Cooperation and Development) (2002) Amendment to the GHS. Sub-Committee of Experts on the Globally

Harmonized System of Classification and Labelling of Chemicals. Third Session, 10-12 July, 2002). UN/SCEGHS/3/INF.16. 6 pp. Prepared as Annex 3 of OECD Document ST/SG/AC.10/C.4/2001/26.

Add reference

UNECE (2005) First Revised Edition of the Globally Harmonized System of Classification and Labelling of chemicals (GHS), English version. Available electronically at http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html. Accessed 23 August 2006

Classification under the *Australian Dangerous Goods Code*

9a) Clarification is also sought on the inclusion of the statement in Appendix 1 that "In this report, Infineum C9350 has been classified against…in the case of physicochemical hazards, the *Australian Dangerous Goods Code"*. As the report does not include any recommendations for dangerous goods classification, this statement does not seem relevant. It is also recommended that 'harmonised' (in reference to the GHS) should be spelt consistently throughout the report.

9b) Decision

Variation approved. The word 'harmonised' will be spelt 'harmonized' wherever the GHS is referred to in the report. Other amendments will be made to the draft report as follows (additional text is underlined):

Appendix 1

Delete text as shown under variation 8b

References page 41.

Delete

~~FORS (Federal Office of Road Safety) (1998) Australian code for the transport of dangerous goods by road and rail (ADG Code), 6th ed. Canberra, AGPS.~~

Terminology

10a) Terminology used throughout the report is inconsistent and in some cases incorrect. The term 'hazardous substance' is incorrectly interchanged with 'hazardous chemical' through the report and risk phrases are incorrectly referred to as symbols in section 11.1.1

10b) Decision

Variation approved. The term 'hazardous substance' will replace the term 'hazardous chemical' wherever it appears in the draft report.

Other amendments will be made to the draft report as follows (Deleted text is struck through, added text is underlined):

Delete text

~~A review of the information on health hazards shows the symbol for skin irritation (R38) is missing as is the correct risk phrase (irritating to skin). Though the symbol (R43) is given for skin sensitisation, the risk phrase (may cause sensitisation by skin contact) does not immediately follow the symbol.~~

Insert text

A review of the information on health hazards shows the risk phrase for skin irritation (R38 irritating to skin) is missing. Though part of the risk phrase for skin sensitisation (R43) is given, the remainder of the risk phrase (may cause sensitisation by skin contact) is missing.

MSDS

11a) DEWR recommends that comment on the adequacy of the submitted MSDS in Section 11.1.1 also include comment on the omission of the relevant Australian national exposure standards (page 3 of 6 of the MSDS refers to an ACGIH TLV for mineral oil mist, not the relevant NOHSC NES for oil mist, refined mineral).

11b) Decision

Variation approved. Amendments will be made to the draft report as follows (additional text is underlined):

Section 11.1.1 Add text:

Page 3 of 6 of the supplied MSDS refers to an ACGIH TLV for mineral oil mist, not the relevant NOHSC NES for oil mist, refined mineral. The NOHSC national exposure standard should be referred to instead of or in addition to the ACGIH TLV.