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20th September 2018

Medicines Scheduling C/O TGA, 136 Narrabundah Lane, Symonston ACT 2609, Australia

Dear Scheduling Committee

## Details of Proposed Amendments Referred for Scheduling Advice to the Joint ACMS-ACCS #20 – Naphthalene

I wish to oppose the Naphthalene change of Scheduling from Schedule 6 to Schedule 7 as proposed until clarification is provided in respect to what is meant by the term in the statement "...except in liquid hydrocarbons as an impurity."

The issue being that Naphthalene occurs naturally in petroleum crude oil and like all components the amount varies depending upon the source (and hence type) of the crude oil.

Naphthalene will be found in naphtha and distillate fractions and can be present in reasonable quantities in Aromatic solvents. It would not be uncommon to see 5 to 10% Naphthalene in a solvent such as Heavy aromatic, petroleum, solvent naphtha with a nominal boiling range of 150°C to 215°C. This is a common solvent type that is used in many domestic and industrial products including Automotive and Agricultural products.

With the Appendix G exclusion concentration of 1mg per litre or kilogram it could cause undue concern and hardship to Industry to have such a blanket statement as proposed. It could mean that a number of Automotive and Agricultural products would then become Schedule 7 Poisons. This being dependent upon what an individual's interpretation is.

This is the only inclusion of such an "impurity" statement in the SUSMP Schedules and I have asked previously for clarification from the Scheduling Secretariat and was told that this would constitute a legal opinion and cannot be given. This Consultation provides the opportunity for this statement to be clarified.

I have spoken to a number of people since this Consultation commenced and a number have said that the presence of Naphthalene in a solvent would be as an impurity, yet a number have said that as it is naturally occurring it is therefore not an impurity. That means that there is uncertainty in the use of the current terminology.

Therefore, I request clarity be sought in respect to the use of the term "...except in liquid hydrocarbons as an impurity." Depending upon the clarification that there be a differentiation between the Naphthalene options referenced in Schedule F, Part 3a and that potentially a separate Scheduling Proposal be determined for Naphthalene when present in Hydrocarbon solvents.





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I would suggest the possibility of the proposed change of Schedule 6 to 7 be reserved for the "solid" options as referenced in Schedule F, Part 3a and that Naphthalene when present in liquid hydrocarbons remain as a Schedule 6 entry with a potential exclusion of except when present at less than 0.5% Naphthalene in the liquid hydrocarbon.

I am available to discuss this further on if you would like clarity or to discuss this further.

Yours sincerely

