This submission relates to the proposed amendments referred for scheduling advice to the joint ACMS-ACCS as follows:

2.3 Methylisothiazolinone and methylchloroisothiazolinone

2.4 Isothiazolinones

Proposal 2.3 indicates an amendment to the Schedule 6 entry to decrease the cut-off for methylisothiazolinone and for methylchloroisothiazolinone from 0.1 per cent to 0.05 per cent on the basis of the known skin sensitisation properties of these substances, while 2.4 indicates an amendment to include isothiazoinones in a similar Schedule 6 entry. The decrease in the cut-off takes into account the minimum patch test concentrations used to elicit skin sensitisation reactions in patients with allergies.

In addition, the change to the Schedule 6 entry proposes that preparations containing any concentration of these substances be labelled with the statements: CONTAINS ISOTHIAZOLINES. REPEATED EXPOSURE MAY CAUSE SENSITISATION. This labelling is mandated by inclusion in Appendix F for the scheduled concentrations, and by a requirement of the exemption from Scheduling for those preparations containing 0.05 per cent.

Isothiazolinones, including methylisothiazolinone and methylchloroisothiazolinone are present in a number of agvet chemicals as non-active constituents. This information is not published on PubCRIS, as the composition of the formulation is commercial in confidence information. Further information on the number of products which may be affected by a change in labelling is being gathered, and will be presented to the Scheduling secretariat.

Labelling for agvet products is determined on a product by product basis. The evaluation undertaken to determine all label statements is conducted on consideration of the risk associated with the proposed use of the product, both from acute hazards and from systemic exposure. In many cases, the acute hazard evaluation is based on consideration of acute toxicity studies carried out on the proposed formulation, including sensitisation studies. Information from such studies is used to determine appropriate safety directions and warning statements, based on the identified hazard. In some cases, where studies are not available, a determination of the acute hazard of the formulation is determined on the basis of extrapolation from the toxicity of the components of the formulation. The acute hazard is determined on a conservative basis: potential skin sensitisers would be identified, and would result in consideration of the requirement for a standard sensitisation statement, and recommendations for the use of appropriate protective equipment. Protective equipment may also be required to address systemic risk from the use of products, based on either measured exposure or calculated exposure from use in accordance with label directions.

Recommendations for appropriate first aid instructions and safety directions for products are made by the APVMA, and are published on a quarterly basis on the APVMA website (https://apvma.gov.au/node/26586). While these first aid instructions and safety directions are broadly consistent with those in the Poisons Standard, it should be noted that Appendix F of the Poisons Standard does not apply to agricultural and veterinary chemicals. The amendments to the SUSMP to include additional Warning Statements for these substances would not, therefore, automatically apply to agricultural and veterinary chemicals.

The requirement for the inclusion of a hazard based warning statement, without consideration of the proposed use of a product (including the level of training of users and associated engineering controls), and the likely exposure scenarios resulting from this use, is not consistent with the

approach taken to the labelling of agvet chemicals by the APVMA. It is therefore proposed that agvet chemicals be exempt from the requirement for warning statements for preparations containing less than 0.05 per cent of methylisothiazolinone, methylchloroisothiazolinone and isothiazolinones based on the assessment of risk likely to arise from the hazard undertaken by the APVMA as part of the registration process for agvet chemicals.

An amended example entry could be as follows:

METHYLCHLOROISOTHIAZOLINONE except:

a.in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylchloroisothiazolinone and methylisothiazolinone in total; or

b. in agricultural or veterinary products containing 0.05 per cent or less of isothiazolinones in total; or

c.in other preparations that are not intended for direct application to the skin containing ~~0.1~~ 0.05 per cent or less of ~~methylchloroisothiazolinone and methylisothiazolinone in total~~. isothiazolinones in total when labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)