

The Secretariat
ACCS/ACMS Committee
Therapeutic Goods Administration
Department of Health
Email: chemicals.scheduling@health.gov.au ; medicines.scheduling@health.gov.au

10 February 2020

Dear Secretariat,

Re: Proposal to add “a definition of marker dyes and pigments in Part 1 of the Poisons Standard”.

CropLife is pleased to assist in informing the TGA on the proposed amendments to the Poisons Standard regarding marker dyes and pigments, scheduled for discussion at the March 2020 ACCS/ACMS Committee meeting. It is, however, disappointing that the TGA did not directly engage with, or alert CropLife to this matter, as peak industry body for the agricultural chemical industry.

The following comments relate only to the proposed amendments that specifically relate to agricultural chemical products. Regarding the proposed amendments relating to veterinary chemical products, CropLife defers to the expertise of Animal Medicines Australia.

CropLife is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife member companies are the innovators, developers, manufacturers and formulators of chemical and biological crop protection products (including fungicides, herbicides and insecticides), and agricultural biotechnologies for plant breeding. The plant science industry is worth more than \$20 billion a year to the Australian economy and directly employs thousands of people across the country¹.

¹ https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf



CroLife notes that the proposal to create a definition for marker dyes and pigments in agricultural chemical products does not seek to alter any current entries in the Poisons Standard, nor does it seek to exempt marker dyes and pigments from scheduling.

CroLife would like to provide the following comments regarding the proposal.

The proposal incorrectly identifies a number of active constituents as marker dyes

The proposal refers to 36 registered agricultural chemical products sold as marker dyes and lists a number of active constituents and “other constituents”. This list, however, contains a number of chemicals that are, in fact, neither marker dyes nor pigments. These include:

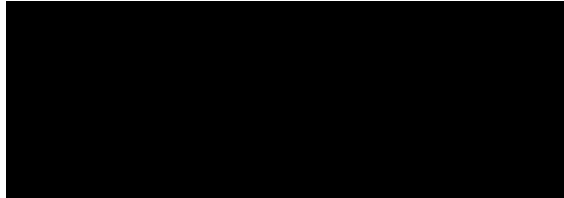
- sodium alkyl ether sulfate (detergent, foaming agent)
- 1-dodecanol (alcohol; pheromone)
- sodium lauryl ether sulfate (detergent)
- fatty alcohol (nonionic surfactant)
- diethylene glycol (solvent)
- diethylene glycol monobutyl ether (stabilising agent)

Some of these chemicals appear to have been included in the proposal simply because they are registered as a “MARKER” with the APVMA, however, these constituents are often used as foam markers, not marker dyes. Others appear to have been included because they are co-formulants in products containing a marker dye.

In order to ensure that the proposed definition of marker dyes and pigments contained in agricultural chemical products is accurate and meaningful, CropLife recommends that the above active constituents are removed from the proposal and a revised proposal is released for stakeholder consultation.

Definition of agricultural product

The proposed amendment refers to marker dyes or pigments used to impart colour to an ‘agricultural product.’ While the SUSMP includes a definition for ‘Agricultural Chemical Product’ and ‘Agricultural Chemical’, there is currently no definition provided for ‘Agricultural Product’. The proposed amendment should use terminology consistent with current definitions and ensure that those definitions align with those used by the APVMA.



The scope of the proposed definition is unclear

It is unclear whether the proposed amendment would apply to products that do not require registration with the APVMA. Currently, there is a number of pigments and dyes sold separately from agricultural chemical products, which do not require registration with the APVMA and, as such, appear to have been overlooked by the TGA. These include pigments and dyes used to:

- add to grain during seed treatment processes to distinguish treated seed from untreated seed
- add to grain during seed treatment processes to highlight the thoroughness of treatment (seed coverage)
- add to grain during seed treatment processes to distinguish seeds with certain traits from seeds with other traits, or to distinguish one combination of agricultural chemical seed treatments from another.

Furthermore, CropLife is concerned that the term 'any substance' when referring to a marker dye or pigment could result in substances being applied post-registration to agricultural chemicals, which are not appropriate for use on potential food crops.

CropLife appreciates that the TGA's proposed definition aligns with that of APVMA for dyes, which specifies spot- and boom-spraying applications methods. Again, further clarity is required regarding whether the TGA's proposed definition applies only to products registered with the APVMA. If not, it seems inappropriate to include reference to any particular application method in the proposal.

CropLife welcomes the opportunity to assist the TGA in the development of a revised proposed definition of marker dyes and pigments in agricultural chemical products.

Please do not hesitate to contact me at [redacted] should you require clarification or elaboration in respect to any of this information.

Yours sincerely

[redacted]

[redacted]

[redacted]