Appraisal

Data submitted were in accordance with the FAO/WHO Manual (2002, First Edition) and supported the proposed specifications.

Paraquat dichloride specifications were previously developed under the prior FAO procedure in 1995 (TK and SL) and published by FAO. Revised FAO specifications (TK and SL) and an additional specification (SG) for paraquat dichloride have been proposed under the new procedure by Syngenta Crop Protection AG.

Paraquat dichloride is no longer under patent.

Paraquat dichloride is a non-selective contact herbicide, highly soluble and stable in water (pH 5-9), only very slowly subject to photolysis and essentially non-volatile. It readily binds to soils and plant matter.

The proposer provided the meeting with commercially confidential information on the manufacturing processes for paraquat dichloride and concomitant impurities. Data for five batches from each of the two manufacturing processes were provided for the TK. Addition of water and an emetic after reactions are complete finish the TK manufacturing process. Mass balances were quite good as 99.0-99.3% characterizes one manufacturing process with an unknown of 0.7-1.0%, while a mass balance of 98.1-99.0% is reflective of the second process in which the unknown component is 1.0-1.9%. The proposer identifies two relevant impurities of manufacturing: both are below 0.5 g/kg (4: 4'-bipyridyl and total terpyridines). Minimum levels are specified for the emetic additive and maximum levels for the two proposed relevant impurities in the specifications for paraquat dichloride TK, SL and SG. Data submitted for manufacturing and concomitant impurities and the emetic were found similar to data submitted for registration in the UK. Slight differences exist in the UK specifications since terpyridines were not included because they are below 1 g/kg and the emetic is at a lower level in the UK document. Both terpyridines and 4, 4' bipyridyl are below 1 g/kg in data submitted to FAO regardless of which of the two current manufacturing processes are employed. (A third process is no longer in use). While terpyridines are highly toxic, 4, 4'-bipyridyl is apparently of similar toxicity to that of paraquat dichloride and is set at a 0.1% w/w limit, below the level of the FAO Specification (56/TK/S/F-1994). Perhaps the rationale should be reviewed at the meeting on relevance of this impurity.

The method of analysis for paraquat dichloride is based on a colorimetric procedure, where the blue paraquat radical formed upon addition of alkaline sodium dithonate is measured (CIPAC Handbook E, p. 167). Methods for impurities are based on GC-FID (4,4' bipyridyl, CIPAC Handbook E, p.168 and CIPAC Handbook 1A, p. 1245) and GC/MS (terpyridines, in peer review study). The emetic, PP796, method is also in the peer review process.

The proposer indicates that physiochemical properties of paraquat dichloride were essentially determined using OECD methods, with CIPAC procedures used for formulation assessments.

Paraquat dichloride has been evaluated by WHO IPCS (1983 and 1991) with a hazard classification of moderately hazardous assigned. The estimated acceptable daily intake is 0-0.006 mg/kg. The USEPA has assigned a Category II acute toxicity to paraquat dichloride, which indicates it is moderately toxic. EPA has put paraquat dichloride in its highest toxicity class, Category I, for inhalation, but the agency finds the particle size produced in agricultural use is beyond the respiratory range. Paraquat dichloride is moderately toxic to aquatic invertebrates, slightly toxic to fish, moderately toxic to avian species and relatively non-toxic to bees.

As a result of evaluation of paraquat under 91/414/EEC the EU Commission is proposing to make a dye, an effective emetic and a stanching agent or other olfactory alerting agents, mandatory for paraquat formulations. The proposer recommends the revised specifications be amended to reflect these same standards. This is a point for consideration by the meeting.

Paraquat dichloride is not mutagenic and EPA places it in Group E for chemicals showing evidence of being noncarcinogenic to humans. Further, it appears that paraquat dichloride has no effect on reproduction parameters and is found to be non-teratogenic.

Packaging requires that paraquat dichloride does not come into contact with metals. Details are contained in each specification.

Recommendations

The meeting recommended that the draft specifications for paraquat dichloride TK and formulations SL and SG, with consideration of certain points and amendments as needed, should be adopted by FAO.