

Etheramine Working Group Meeting Notes - December 10 1999

Intellectual Property

A generic product (Glinar) from Spain when tested for composition. The test indicated that this product could possibly have Ethonolamine in it raising questions around our MEA patent filing.

Jim Forbes outlined 3 scenarios:

1/ Product is DEA based - no patent impact

2/ Product is MEA/DEA mix in which case we would have a patent issue if the MEA is the higher concentration.

3/ Product is MEA. In this case we have an issue. If the product was launched after 23 November 1998 then we can put the company concerned on notice of patent and request the patent office to expedite the patent hearing.

If the product was commercial prior to our patent filing then we may need to amend our filing.

NOTE : Information to hand after the meeting shows this product was registered in 1994 and the registration submission(document 19.742) claimed the product as "Glifosato (sal isopropilamina) 36%".

This would seem to indicate that the salt will be IPA or alternately if it is MEA then the product is not correctly registered.

Action: Ascertain precise formulation details asap and then take next steps decision based on factual result.

European Surfactant Review - Update and Decision Background

Donna Farmer to input issues summary and group recommendation to undertake Etheramine test internally asap but no external disclosure until all parties consulted. Expect in January.

The genotoxicity of glyphosate, glyphosate-based formulations and the inert ingredients has been an ongoing issue in Europe for several years based on a number of reports in the open literature suggesting a mutagenic potential of some formulations of glyphosate. Activists (some who were authors of those reports) raised these concerns to regulatory agencies in the Nordics and this led to a re-review of the all the available data regarding possible mutagenic effects by the German Rapporteur during the EU re-registration process of glyphosate. An addendum summarizing and discussing the evaluation was produced and it was concluded:

1) Glyphosate technical is not mutagenic

- 2) A few formulations tested in a limited number of scientifically valid studies were not mutagenic
- 3) The published data did not provide convincing evidence that glyphosate formulations exhibit a genotoxic potential
- 4) Some indications of DNA damage observed in different test systems are due to cytotoxicity properties of the formulations tested than to actual mutagenicity
- 5) The cytotoxicity as well as general toxicity of glyphosate formulations appear to be mediated to a large extent by the surfactants.

Although the rapporteur concluded there was no evidence of mutagenicity, DNA damage secondary to cytotoxicity of the surfactants was highlighted. In addition, the Italian government has requested genotoxicity studies (UDS - Unscheduled DNA Synthesis studies) on glyphosate and MON 52276.

It appears that this is continuing to be an issue in Europe and it was deemed important to develop relationships with 3rd party genotox experts in Europe. [REDACTED] contacted Dr. Parry (U. Wales Swansea). Dr. Parry evaluated the potential genotoxicity of surfactants and concluded that none of the surfactants were capable of inducing mutations in bacteria but there was not enough data to evaluate the vitro or in vivo clastogenicity of the surfactants. Dr. Parry offered to conduct the in vitro testing in his laboratory.

In order to further develop the relationship with Dr. Parry it was recommended that surfactant samples be provided to him for testing. However before sending Dr. Parry any samples it was recommended that they undergo in-house testing first in a similar in vitro screen. The cocoamine surfactant recently tested was negative in this assay. A request was made by toxicology to include an etheramine in the test samples. The request was granted and results will be available in January. There will be no external disclosure until all parties consulted.

Product Registrations and EPA Update

EPA review of the Huntsman AGM550 etheramine surfactant has started. This work will be ongoing thru first quarter and if there are no issues would expect publication in the Federal register in June/July.

The EPA has previously approved the AGM550 for non-crop uses and a label has been received for Mon 78063.

Witco are completing tox tests on their etheramine in first quarter and expect to submit to EPA at that stage for an expedited decision.

The MEA salt manufacturing use product submission is still with EPA awaiting approval. This was filed in January 1999. Similarly the Mon 77859 end use registration for preplant is still pending.

Product chemistry on Mon 78128 was finished in first week of December and has been sent to Canada. Expect registration package to go in this week.

The US organisation will be testing a phosphate ester /etheramine formulation at 445grms in green house thru first quarter and then in field with view to fall 2001 launch.

Manufacturing and Supply

Manufacturing will do MEA:EA plant tests in late 2000 anticipating a Canada launch for summer of 2001. Anticipate Muscatine as production unit.

Huntsman have approached Monsanto again re facilities expansion from current 10 million lb plant. They have requested a decision by 2nd quarter 2000. We do not see this as urgent for us at this stage. Intended purchases in 2000 are:

Huntsman	6 Million pound
Witco	4 Million pounds
Tomah	2.2 Million pounds.

Commercial Plans and Feedback

Argentina has successfully launched Mon 78128 - the first MEA:EA formulation commercialised globally. The team did a “blind” substitution for Mon 77280 and report that the new product is performing very well and no adverse grower comments have appeared.

Malaysia will launch MEA:EA highload in 2000 positioned around theme “the most powerful”.