Message

From: Redacted
Sent: 8/23/2011 12:03:13 PM
To: DE BILLOT, MAURICE R [AG/5040]; Redacted; SALTMIRAS, DAVID A [AG/1000]; Redacted
CC: Redacted
Subject: RE: Dermal penetration study argumentation for applicability to MON 79991

Hi Maurice,

I'm a bit confused because I thought we discussed this before I left on vacation.

We were well aware of the issue with UK-POEM in combination with the 3% dermal uptake so we refined the UK-specific GAP to make it work. We agreed that the real critical UK-GAP was 2.16 kg/ha for most uses except the hand held uses in Rhododendon (3.6 kg/ha) which typically is a spot application. 80 L/ha was for the UK an essential spray volume (feedback Manda). For the hand held uses we have the Spanish biomonitoring study that I plugged in demonstrating safe use. With this set of ingredients we can demonstrate safe uses for the UK-GAP.

For the other Member States we can refer to the BBA-model which shows safe uses even at 3.6 kg/ha and using the 3% dermal uptake, so there is no need for further refinement.

At this point in time (it is with an existing EU endpoint of 3% and with the new data not yet reviewed at EU-level), it will not be easy to defend the 1% dermal uptake number for 79991 since we have no product specific study. The formulations for which we have tested dermal uptake according to latest guidance (G3 – 79351-79545) are different formulation types, contain different salts of glyphosate and different surfactants and have different glyphosate loadings. This may be good in a way (1% reconfirmed even with completely different formulations) and it will be our ambition during the EU review to refine the current endpoint based on this information (also referring to other companies dermal studies conducted according to the same guidance), but at MS level we may face some push back even with sound scientific argumentation.

If we need the 1% dermal uptake for Sahara, the safe bet would be for instance to run in parallel to our submission a 79991 in vitro dermal study. When our argumentation is challenged we can than submit the product specific study.

Lets discuss when you are back in the office.

Regards,

C.

From: DE BILLOT, MAURICE R Redacted
Sent: Tuesday, August 16, 2011 10:05 AM
To: SALTMIRAS, DAVID A Redacted
Cc: Redacted
Subject: Dermal penetration study argumentation for applicability to MON 79991

David

In Europe we are getting prepared to submit MON 79991 (720g/kg) for approval under the new Reg 1107/2009. We ran the UKPOEM model using a dermal penetration value of 3% and do not pass when applying 3.6kg/ha for the tractor mounted sprayer. I am aware of the set of studies that you ran on dermal absorption using pure K-salt and IPA-salt and also MON 52276 and MON 79351 which showed dermal absorption values of 1%. Putting 1% in the model we get a good result, so will need to show that the 1% dermal absorption numbers are equally valid for the MON 79991 formulation. This will need some argumentation to bridge between salts of glyphosate. That is, from the tested salts to NH4-salt. Also we will need to argue that the type or loading of the surfactant plays no/or an equal role in dermal absorption between formulations (MON52276 vs MON79351) and that absorption of glyphosate in MON 79991 is therefore likely to be similarly influenced.

Sarah has updated version section 3, operator exposure for MON 79991 with 1% and dose rate 3.6 kg as/ha. Please check and insert the extrapolation arguments and the 2010 Ward study summary.

We have attached the Final version, section 3, MON 76473 as an example where you have included the 1% dermal absorption and where the dermal absorption summary is included.

If you can manage this by the last week in August, it would be greatly valued.

Greatly appreciated.

Maurice