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Oosterhout, 12 april 2017

REF: UAR/77/04/17

Dear [redacted]

On behalf of Valto B.V. we send you a reaction on the notification of incomplete: V10 20160057 ZTG.

The following issues were addressed:

Fys. Chem.
1. The concentration of the persistent foaming test is specified and covers the highest in-use concentration of 10%. The following is mentioned in the study of Lanata (2014), "*The mass of sample taken was that required to make 200 ml of a suspension with a concentration recommended in the directions for use supplied with the product. 180 ml of standard water C were put into a 250 ml cylinder standing on a top pan balance and the required amount of suspension concentrate were weighed in.*" The physical, chemical and technical property table in Part B section 1 is amended.

About the possibility of clogging of the spraying equipment due to the synthetic sand the following prescription is given on the Dutch label (in Dutch):

Let goed op dat tijdens het spuiten de nozzles niet verstopt raken. Dit is eenvoudig te zien omdat de straal dan niet meer evenwijdig is. Controleer dit ook voor het bespuiten van de planten.

About the uniform distribution of the synthetic sand in the spraying solution the following prescription is given on the Dutch label (in Dutch):
Mengsel goed mengen, ook de slang goed doorspuiten, gebruik bij voorkeur een plunjerpomp, filters iedere keer goed schoon maken, synthetisch zand bezinkt, dus laag wegzuigen en zorg voor roering in de tank.

Further phys-chem properties are not considered relevant because synthetic sand is only added to V10 shortly before application. Once added the tankmix has to be used within 6

hours. Synthetic sand is only added as an abrasive to cause minor physical damage to the tomato leaves through which the virus can enter the plant cells and has no other effects.

The phys-chem table is amended as follows:
Physical compatibility of tank mixes: Synthetic sand should be added to the spray/rub solution to create some minor damage on leaves, enabling the virus to enter the plant. The physical compatibility is not tested, however prescriptions are given on the label to ensure physical compatibility.
Label prescriptions to ensure physical compatibility:

- Use preferably a piston pump, clean filter every time, synthetic sand will deposit in the spray solution, therefore make sure of movement in the tank.
- Be aware of obstruction of the nozzles. This is easy to see because the spray jet is no longer parallel. Also control this before spraying the tomato plants.

Chemical compatibility of tank mixes: Not applicable as there is no chemical reaction taking place between V10 and synthetic sand.

The application for synthetic sand to be registered as adjuvant is pending, 20170235 TT synthetisch zand. For information purposes the MSDS of synthetic sand will be submitted.

Efficacy
2. Considering the mode of action of the product, V10 cannot be seen as a standard plant protection product whose effect is directly measured in the percentage control of pest or disease. Rather the effect of this product depends fully on the ability of the formulation to infect tomato plants. Inoculation is therefore key to the effectiveness of the product. The percentage infected plants that is determined by use of the ELISA method is equal to the success rate of the product. If the set norm of 70% infected plants is reached (set as quality criterion), sufficient infection is obtained to protect the crop against PepMV, as was demonstrated in the available efficacy trials. It is therefore considered appropriate to demonstrate that the changes to the formulation that have been made since conducting the efficacy trials, do not affect the infectivity of V10.
Nevertheless, bridging trials are planned and will be submitted upon request.

The preliminary trial reports have been adapted, together with the Biological Assessment Dossier and dRR Part B3 Core Assessment, to clarify which formulations were used in the trials.

The following files are submitted:

Annex point	**Author**	**Year**	**Title** **Source Company,** **Report No.** **GLP/GEP status, (un)published**
-	FEPA	2012	Material Sicherheitsdatenblatt aluminiumoxid Treibacher Schleifmittel Zschornewitz GmbH
IIIM 2 IIIM 4.11.5	Linge agroconsultancy	2017	dRR Part B1 Core assessment
IIIM 2.1-01	[redacted]	2014	Stability testing at T<-15°C on V10 Groen Agro Control Report No. 2014/38Ami GLP, unpublished
IIIA1 6	[redacted]	2017	dRR Part B7 Core Assessment
IIIA 6.0	[redacted]	2017	Biological Assessment Dossier for V10. Valto B.V non GEP, unpublished

IIIA 6.1.1/01	[redacted]	2013	Bio-assay infectivity PepMV SPV A519 non GEP, unpublished
IIIA 6.1.1/02	[redacted]	2013	Validation of bio-assay to determine the infectivity of pepino mosaic virus Groen Agro Control VAL 507 non GEP, unpublished
IIIA 6.1.1/03	[redacted]	2017	Infectivity of VX1and VC1 batches using phosphate as buffer Groen Agro Control non GEP, unpublished
IIIA 6.1.1/04	[redacted]	2017	Comparison of the infectivity of VC1 batches, with high and with low nicotine content Groen Agro Control non GEP, unpublished
IIIA 6.1.1/05	[redacted]	2017	Comparison of the infectivity of VX1 batches, with high and with low nicotine content Groen Agro Control non GEP, unpublished
IIIA 6.1.1/06	[redacted]	2017	Comparison of infectivity efficiency after high-pressure spraying of V10 with carborundum and with synthetic sand Groen Agro Control non GEP, unpublished
IIIA 6.1.1/07	[redacted]	2012	Protocol for the determination of indices of VC1, VX1 and PepMv by qRT-PCR Laboratorium Delft Research Group non GEP, unpublished
IIIA 6.1.1/08	[redacted]	2017	Infectivity of V10 with phosphate as buffer and low nicotine content, after inoculation of tomato plants by high-pressure spraying and rubbing leaves Groen Agro Control non GEP, unpublished

If there are any questions, please do not hesitate to contact the undersigned.

Kind regards,

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Registratie Specialist

Linge Agroconsultancy