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Gouda, 1 August 2014

Ref: explanation innovative seed treatment technologies Sanokote Smart and Phyto-Drip

Dear mister Van Duijn and 5.1.2.e

In the comments on the draft Guidance Document on the Authorisation of Plant Protection Products for Seed Treatment, version January 2014, Plantum proposed to the EU Commission to explicitly include other types of seed treatment than just coating, i.e. innovative techniques such as Sanokote Smart and Phyto-Drip, in the scope of the Guidance. The ideas about this seem to evolve, in particular since the UK CRD recently has changed its position regarding the use of plant protection products on non-viable seed, and these ideas seem to be not in line with previous views on this subject.

Therefore we want to explain the Sanokote Smart and Phyto-Drip concept in this letter. Furthermore we ask for clarification of this issue through the Guidance Document.

What is Sanokote Smart?

Sanokote Smart (also called 'dummy pill') is a treated and pelleted non-viable seed of a certain crop, treated with a plant protection product in the registered dose rate for seed treatment for that specific crop. Every single Sanokote Smart is sown alongside a single seed of the same species in one and the same sowing operation. More information is provided further on in this letter and in attachments.

What is Phyto-Drip?

Phyto-Drip is a high-precision seed treatment application system. During the seeding process, a single drop of seed treatment solution is dripped onto each seed, in the registered dose rate. More information is provided further on in this letter and in an attachment.

Why were Sanokote Smart and Phyto-Drip developed?

Sanokote Smart and Phyto-Drip were introduced to prevent effects of plant protection products on germination and vigour of seeds of Brassica species and lettuce. In the recent re-registration of Gaucho Tuinbouw in the Netherlands it says on page 19: "based on the use in practice it is generally known that Gaucho Tuinbouw seed treatments are causing phytotoxicity to the seedlings of cabbage varieties. Other application techniques such as Phyto-Drip and dummy pill are favored, as phytotoxicity due to these techniques is generally lower". When you coat Gaucho and Cruiser on viable Brassica seeds the phytotoxicity results in an unacceptable level of surviving seedlings. The text of the labels of Gaucho Tuinbouw and Cruiser therefore express: "seed treatment including dummy pill or Phyto-Drip", and in case of Cruiser: 'because of potential phytotoxicity for Brassica dummy pill method and Phyto-Drip method are recommended'.

Thus two innovative seed treatment techniques were developed for a very specific range of crops and seed treatment products.

Are the Sanokote Smart technique and Phyto-Drip technique seed treatment under EU Regulation 1107/2009, and are thus treated products treated seeds?

According to the CRD in the new Regulation EU 1107/2009 it is clearly stated that the purpose of the use of plant protection products in the Regulation is to protect 'living plants and seeds'. Therefore CRD states that the use of a plant protection product on a non-viable seed is not to protect a living seed, and therefore it should not be considered seed treatment. We have several arguments to refute this argumentation:

1. The definition of plants and seeds is presented in Art. 3.5 of the EU Regulation 1107/2009: "plants' means live plants and live parts of plants, including fresh fruit, vegetables and seeds". There is no change or new element in EU 1107/2009 compared to Directive 91/414/EEC that would justify a change in position since the definition of 'plants' did not change: Art. 2.6 of EU 91/414 also defined 'plants' as "live plants and live parts of plants, including fresh fruit and seeds". Based on that we can argue that when treatment of non-viable seeds was considered seed treatment in the past, that should not change under the new regulation 1107/2009. From a legal point of view there is no need nor justification to change position, based on the same definitions.
2. In our view the adjective 'live' for plants is not referring to seeds as it is not referring to fresh fruit.
3. Furthermore there are always more or less non-viable seeds present in a seed lot. So then what would be the definition of 'live seed'? (At what percentage a seed batch is considered as a viable seed batch?)
4. The purpose of the treatment on the non-viable seed IS to protect a living seed, directly, since by definition it is sown within very short distance from the living seed, in one single sowing operation. Also in risk assessments it is proven that all risks (apart from phytotoxicity) for Sanokote Smart and directly coated seeds are equal. Therefore Sanokote Smart technology can be considered a seed treatment technology, and Sanokote Smart together with the viable seed (always only sown together) as treated seed.
5. Guidance Document, 2nd Draft January 2014, par. 2.1, states: 'the treatment of seeds is considered as one of the possible uses of plant protection products' and 'the use of a plant protection product is to protect plants or plant products against all harmful organisms or preventing the action of such organisms (art. 2(1) of EU Regulation 1107/2009)'. This is exactly what Sanokote Smart and Phyto-Drip are doing: use a plant protection product to protect a seed against harmful organisms.

Rather than making the discussion on treatment techniques and 'live seed' a semantic one, we plea to return to the purpose of the Guidance Document: provide guidance for the authorisation for safe use of plant protection products for seed treatment, and this is best safeguarded by including all seed treatment techniques.

More detailed information on Sanokote Smart

Technical information

Sanokote Smart is a dead seed core coated with a plant protection product and sown together with and next to a regular seed of that same species. Since the dose rate is exactly the same as that which would be applied directly to the viable seed itself, there are no additional or other health and safety, environmental or human health concerns whether using a Sanokote Smart or a directly treated seed. In the attached documents you find some more detailed product information on Brassica Sanokote Smart and Lettuce Sanokote Smart.

Furthermore Sanokote Smart fulfills the highest product requirements being handled as a seed treatment in all aspects. The plant protection product is applied professionally in a seed treatment process certified by European Seed Treatment Assurance with special attention for minimum dust formation. The dosage of the crop protection product is checked for each batch.

Status of Sanokote Smart in registrations of Gaucho and Cruiser across Europe

- In the Netherlands both Cruiser and Gaucho Tuinbouw are registered for seed treatment applications and both labels include the Sanokote Smart concept. Recently (31-01-2014) Gaucho Tuinbouw was re-

registered for seed treatment including the Sanokote Smart concept. The Ctgb therefore maintained its view on Sanokote Smart pellets as being treated seed.

The Netherlands has a registration for the application of Cruiser on lettuce, endive and brassica seeds; the application of Gaucho Tuinbouw is allowed on lettuce and endive seeds, brassica was not re-registered 31-01-2014.

- In Germany, Cruiser is registered for lettuce and endive. In 2007 BVL confirmed acceptance of Sanokote Smart pellets as treated seed, and therefore accepts the import of Sanokote Smart pellets from The Netherlands.

The text on the labels for Cruiser 70 WS and Gaucho Tuinbouw state that it is obligatory to sow Sanokote Smart pellets and the seed of the same crop group together (in order to use the correct dose rate); and thus jointly forming a treated seed.

European Regulation 1107/2009, article 49

According to the European Regulation 1107/2009, article 49, "Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State". This implies that, according to the Dutch authorisation of Cruiser or Gaucho Tuinbouw, other Member States shall not prohibit placing on the market and use of Sanokote Smart pellets treated in the Netherlands.

The article 49 is of crucial importance for the free trade and movement of seed within the EU, bringing EU Regulation 1107/2009 in line with the EU Seed Marketing Directives.

Is registration of Sanokote Smart as granulate an alternative option?

Registration of Sanokote Smart as a plant protection product in its own right is hardly possible, because it is doubtful if and how seeds can fulfill the requirements of a kernel for a plant protection granule.

Furthermore it is not clear who should ask for the authorization and how to do it: the owner of the plant protection product has no dossier on the Sanokote Smart formulation, and the seed (treating) companies have no knowledge of and dossier for authorization of a plant protection product.

Another bottleneck is that each dose of each plant protection product from Sanokote Smart lettuce and Brassica would require a separate registration in each of the 3 zones in Europe (while for seed treatment as you know Europe is one zone). For lettuce two dosages exist for both Cruiser and Gaucho, and for brassica one dosage exists for Cruiser. Moreover it is expected to take 5 years and 1 million euro for each registration.

Last but not least, if Sanokote Smart pellets were not treated seeds, art. 49 of EU Regulation 1107/2009 would not apply. This would cause immediate problems for Brassica and lettuce growers in other Member States than the Netherlands: see next paragraph.

What are the alternatives for Sanokote Smart Brassica?

It is well known that seed treatment is the best method to protect seedlings during early seedling development. It is effective, well targeted and uses very little active ingredient, thus a perfect tool for Integrated Pest Management

However direct application of either Cruiser or Gaucho on viable seeds results in phytotoxicity and less viable seedlings. Therefore the innovative high-tech seed treatment technologies Sanokote was developed. If Sanokote Smart is not available anymore, growers will have to use foliar applications to control the pests. This will lead to less effective use, therefore increase of use of plant protection products and more damage to the crop. Most important is that for Brassica there is no foliar application available which can protect the crop during the whole crop cycle. Therefore there is a big agronomic and economical implication for all European Brassica growers.

More detailed information on Phyto-Drip

Technical information

Phyto-Drip is an application system for the accurate dosing and placement of plant protection products onto seeds for transplanted vegetable production. Since the dose rate is exactly the same as that which would be applied as a filmcoating, there are no additional or other health and safety, environmental or human health concerns.

Phyto-Drip is designed specifically for use on seeding and potting lines. It is a seed treatment technique and not a drench application since:

- The treatment is done at the moment of sowing, onto the seed, on the seeding / potting line, and not after germination, in the field or at transplanting of the young plant, as is done in drench applications.
- Just a single drop of plant protection product is dripped onto the seed. Only the soil directly surrounding the seed is slightly moistened, so not the complete plug or tray as it would be in drench application.
- Much more precise, accurate dosage per seed (at least equal to film coating) possible in comparison with a drench application.
- The machinery to prepare and apply the plant protection product onto the seed during seeding, is a closed system, comparable to seed coating machinery.

In the attached document you find the detailed product information with regard to Phyto-Drip.

Status of Phyto-Drip in registrations of Gaucho and Cruiser across Europe

- In the Netherlands both Cruiser and Gaucho Tuinbouw are registered for seed treatment applications and both labels include the Phyto-Drip concept. The Netherlands has a registration for the application of Cruiser on lettuce, endive and brassica seeds; the application of Gaucho Tuinbouw is allowed on lettuce and endive seeds, brassica was not re-registered 31-01-2014.
- In Belgium Cruiser is registered on lettuce, endive and brassica seeds and Gaucho Tuinbouw on lettuce and endive seeds. Both authorisations are 'for use both before as well as for during sowing', thus including the Phyto-Drip method.
- Cruiser as a seed treatment is also registered in Lettuce and Brassica in Hungary, including the Phyto-Drip application.
- Syngenta has applied for adding the Phyto-Drip application on the Cruiser labels in Germany.
- Syngenta has applied for registration of Cruiser SB for the application in Lettuce and Brassica in France (to be applied with filmcoating, Sanokote Smart or Phyto-Drip technology).

Is registration of Phyto-Drip as drench an alternative option?

Is it complicated, since other dossier might be needed. Moreover the characteristics of the application method are more in line with conventional seed treatment methods (see explanation on above and annex).

Conclusion

Sanokote Smart and Phyto-Drip represent a seed treatment type of application with exactly the same environmental, health and safety aspects as 'conventional' seed treatment, it offers the growers an economical way of pest management in Brassica and some lettuce varieties and it provides a very effective and efficient way of applying plant protection products to these crops. Therefore Sanokote Smart and Phyto-Drip offer very smart and innovative solutions which meet all requirements of all stakeholders involved.

We urgently demand the Ctgb and the Working Group involved in the Guidance Document on the Authorisation of Plant Protection Products for Seed Treatment to take into account the above arguments and include Sanokote Smart and Phyto-Drip as seed treatment techniques in the Guidance.

Of course we are willing to further clarify the concepts and our position, and discuss arguments and options. We'll await your invitation for that.



Attachments:

- Product information Brassica Sanokote Smart
- Product information Lettuce Sanokote Smart
- Product information Phyto-Drip Application Technology for Seed Treatment

cc. Ministry of Economic Affairs, att. mrs. 



LETTUCE

SANOKOTE™ SMART

General info

- Product form a dead lettuce seed core coated with plant protection products. This product is to be sown together with and next to regular (coated) lettuce seed and will not germinate.
- Suitable for greenhouse plant raising

Seed Norms

- Minimum order quantity 250.000 pellets
- Minimum leadtime 13 working days, based upon availability of capacity

Coating

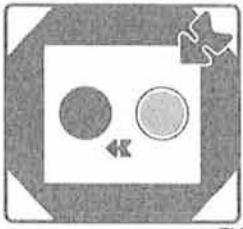
- Plant protection product treatment Proseed; 0,75 g a.i. Thiram / kg seed can be combined with the following plant protection products:

per 100.000 seeds	Pill color
Cruiser 70WS: Thiamethoxam 60 g a.i.	Red
Cruiser 70WS: Thiamethoxam 80 g a.i.	Blue
Gaucho 70WS: Imidacloprid 80 g a.i.	Red
Gaucho 70WS: Imidacloprid 120 g a.i.	Blue

- Recovery/loading norm > 90% registered amount of Imidacloprid / Thiamethoxam

Packing and Storage

- Packing units tin can, tin bucket



sanokoteTM
smart

LETTUCE

SANOKOTE™ SMART

Remarks

Imidacloprid and Thiamethoxam for application on lettuce seed or certain dosages there-off, is not registered in all European countries. Please refer to current information from the respective registration authorities.

No combinations with other plant protection products on the Sanokote™ Smart are allowed.

Sanokote™ Smart can effectively be used in combination with coated lettuce seed.

Before accepting the first order INCOTEC requires a signed quality charter.

ESA advice for safe use of treated seed



Do not use for human or animal consumption



Wash hands



Keep out of reach of children, livestock and wildlife



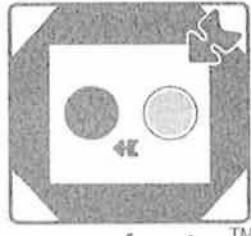
Do not contaminate surface water or ditches



Wear suitable protective equipment



Minimize dust generated at drilling



sanokoteTM
smart

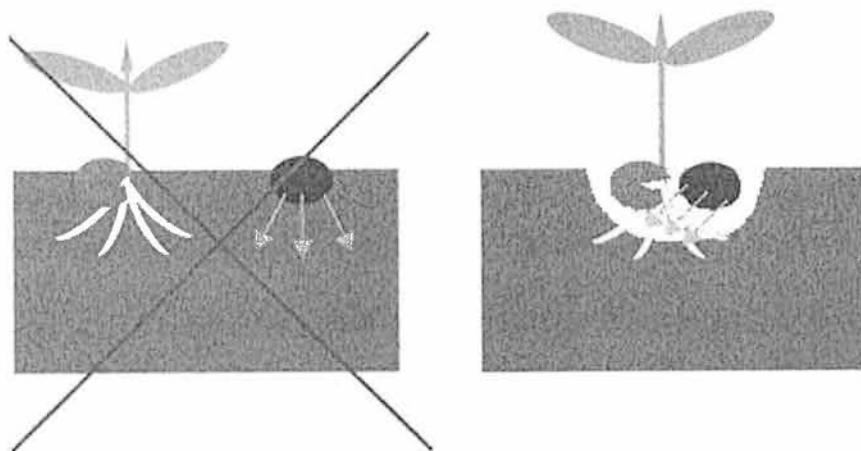
LETTUCE

SANOKOTE™ SMART

Disclaimer:

- 1) "Sanokote™ Smart has been acknowledged by the Ctgb and BVL as seed treatment and has the same effectiveness as a seed treatment on condition that the seed is planted directly next to the seed which needs the seed protection."
- 2) "Use of Sanokote™ Smart is limited for use on species for which the plant protection product has been registered."
- 3) "Sanokote™ Smart has to be planted as a dual seed/pellet directly next to the seed of the species concerned."

Plant Instruction:





BRASSICA

SANOKOTE™ SMART

General info

- Product form a dead brassica seed core coated with plant protection products. This product is to be sown together with and next to regular (coated) brassica seed and will not germinate.
- Suitable for greenhouse plant raising

Seed Norms

- Minimum order quantity 500.000 pellets
- Minimum leadtime 20 working days, based upon availability of capacity

Coating

- Plant protection product treatment Proseed; 2,4 g a.i. Thiram / kg seed can be combined with the following plant protection product:

per 100.000 seeds	Pill color
Cruiser 70WS; Thiamethoxam 140 g a.i	Red

- Recovery/loading norm > 90% registered amount of Thiamethoxam

Packing and Storage

- Packing units tin can, tin bucket



BRASSICA

SANOKOTE™ SMART

Remarks

Thiamethoxam for application on brassica seed or certain dosages there-off, is not registered in all European countries. Please refer to current information from the respective registration authorities.

No combinations with other plant protection products on the Sanokote™ Smart are allowed.

Sanokote™ Smart can effectively be used in combination with coated brassica seed.

Before accepting the first order INCOTEC requires a signed quality charter.

ESA advice for safe use of treated seed



Do not use for human or animal consumption



Wash hands



Keep out of reach of children, livestock and wildlife



Do not contaminate surface water or ditches



Wear suitable protective equipment



Minimize dust generated at drilling



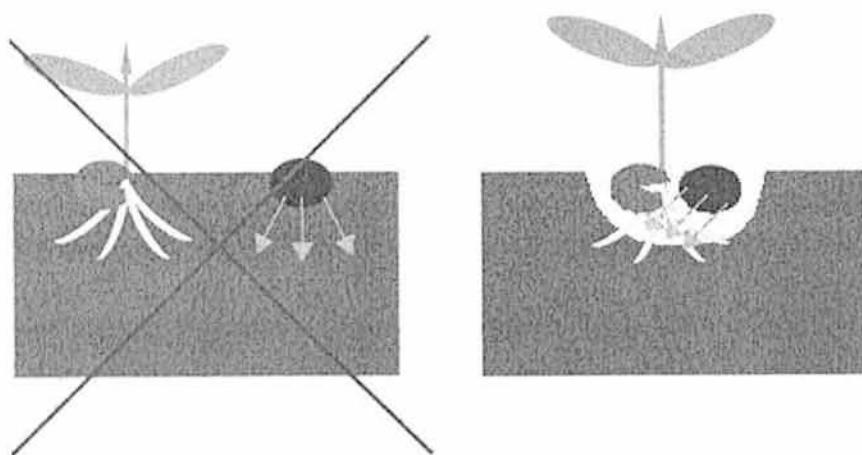
BRASSICA

SANOKOTE™ SMART

Disclaimer:

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- 2) "Use of Sanokote™ Smart is limited for use on species for which the plant protection product has been registered."
- 3) "Sanokote™ Smart has to be planted as a dual seed/pellet directly next to the seed of the species concerned."

Plant Instruction:



Phyto-Drip®

Application Technology for Seed Treatment



PHYTO-DRIP®
INNOVATION IN SEED TREATMENT

Syngenta Crop Protection AG
Schwarzwaldallee 215
CH-4002 Basel
Switzerland

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Introduction

Cruiser 70 WS is a registered plant protection product for seed treatment use on lettuce and endive in Germany. It is approved for conventional seed coating technology.

Besides conventional seed coating there are two other seed application technologies currently used for the treatment of lettuce and brassica seeds (and others). These are Dummy Pills (the use of a dead seed which is treated with the product and sown along with a germinating seed) and Phyto-Drip® which is the application of the product with a precise volume of the product solution directly on the seed at the time of sowing. Phyto-Drip® is used for transplanted vegetables only. In the Netherlands other registered products such as Gaucho and Mundial are also used though Phyto-Drip®.

In other EU member states (e.g. NL) all three application technologies are included on the label of Cruiser 70 WS.

It is Syngenta's intention to have Phyto-Drip® registered as an alternative seed treatment technology for Cruiser on lettuce and endive in Germany.

An expansion to other transplanted vegetables (e.g. brassicas, tomatoes) may follow.

Given the safety and convenience of this application technology Syngenta is assessing other products as well as other countries within the EU where this technology could bring benefits to the vegetable producers.

Purpose of this document

The purpose of this document is to

- explain the Phyto-Drip® technology
- demonstrate the equivalence of biological efficacy and seed safety for Cruiser compared to conventional seed coating
- discuss exposure and safety to humans and the environment

Benefits of the Phyto-Drip® Technology

The Phyto-Drip® technology offers a number of benefits to growers and plant raisers as well as operators, consumers and the environment.

Benefits for the Grower

- "Last minute" ordering of plants is possible (decision for treatment just in time before sowing; lead time for Phyto-drip is 2 weeks compared to 8 – 10 weeks for seed coating).
 - Alignment with the weather conditions
 - Decision to treat dependent on the expected pest pressure (e.g. aphids)
 - Ability to switch to most suitable variety at short notice (*Bremia* situation)
 - sow only treated seeds when needed
- "Last minute" rate selection possible dependent on the expected pest pressure and crop size.
- Each seed is treated with an accurate dose (less than 5 % variability in dosing)
- Performance as good as with coating
 - Long protection against aphids with Cruiser (8-10 weeks after sowing)
- Small quantities of seeds can be treated

- Diminish phytotoxicity effects which can occur with coated seeds.

Benefits for the Plant Raiser

- "Last minute" ordering from seed company possible
 - Seed companies sell less Stock Keeping Units (SKU's; variety with fungicide base treatment only with / without priming)
 - Less complex storage (less SKU's)
 - Better shelf-life of stored seeds (better shelf-life of seed treated with fungicide only)
- "Last minute" ordering by growers becomes feasible
 - More customer oriented deliveries become possible
 - Better varietal fit with weather conditions
 - Varieties with correct resistance (*Bremia*)
 - Alignment with specific regional requirements or conditions
- Less seeds needed to obtain the number of deliverable plants
 - Excellent germination of seeds, comparable with untreated pelleted seeds
 - Better than with insecticide coated seeds
- More plants per tray or box
 - Less trays or boxes needed
 - Less space needed in the greenhouse
- Customer made seed quantities can be treated

Benefits for the Operator, Worker and Consumer

- Less exposure to operators due to little manual interaction with the system and lower amounts of PPP handled per day
- Little exposure to workers as delivered trays or boxes are not chemically contaminated (different to drench application).
- Reduced exposure to consumers compared to conventional seed treatment.

Benefits for the Environment

- No higher exposure risk compared to conventional seed treatment.
- No let over unused treated seed which would require special disposal.
- No transport of treated seed.

Phyto-Drip® Application Technology

Phyto-Drip® is an application system for the accurate dosing and placement of Seed Treatment products onto seeds or pelleted seeds for transplanted vegetable production.

Phyto-Drip® equipment

The Phyto-Drip® equipment consist of a Drip unit mounted on the seeding line after the seeding drum, a touch screen control panel and a tank for the drip liquid incl. pump and piping for the movement of the drip liquid. Schematic overviews of the components of the Phyto-Drip® machine and a flow chart of the liquid streams are included at the end of this section.

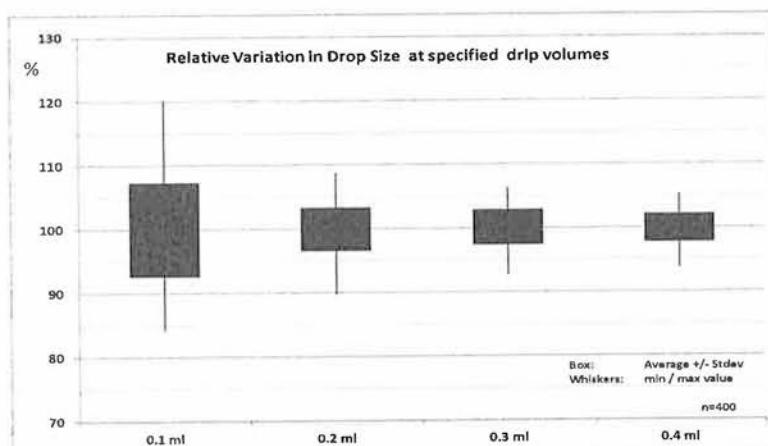
Drip unit

The Drip unit consists of a number of drip nozzles; this number is adjustable and depends on the tray size that the Young Plant Raiser uses. Each individual drip nozzles contains a high precision electromagnetic valve that is responsible for the accuracy of the final droplet size. The opening times of the valves can be controlled individually per millisecond through the control panel, allowing a very precise fine tuning of the various nozzles in the drip unit. The best accuracy range in individual droplet sizes can be obtained in the range from 0.15 to 0.50 ml (see graph 1).

The drip unit has two vertical positions, the upper position for calibration, rinsing and cleaning and the lower position for the actual dripping on the seeds in trays.

The drip nozzles are positioned closely to the main liquid circulation piping to avoid any risk of still standing liquid with a consequent sedimentation potential.

Regular cleaning after, and a volumetric calibration before each new application is strongly recommended (see for details in section rinsing and cleaning).



Graph 1, relative variation in drop size of individual nozzles

Control panel

The control panel is user friendly and easy to operate. A logic program will lead the operator through all necessary steps before the actual application can start (a by-pass of any step is possible for the experienced user but will be recorded by the internal PLC). The operator only has to select the tray type and nozzle opening time that corresponds with the required droplet size (calculated on the basis of the drip liquid). An obligatory calibration step will warn the operator about false settings.

Tank and tubing

The liquid tank which is used for the product solution may contain up to 100 liters, a volume sufficient for ±500,000 drips with a droplet size of 0.2 ml. The tank has an opening for filling at the top and a connection with the piping at its lowest point at the bottom. A filling and mixing unit is available on the lid of the tank and can be used for the entry of liquid Plant Protection Product (PPP). A high precision circulation pump is positioned close to the tank at the lowest point to provide a constant flow of the liquid. The system requires a minimum filling of 4 liters for the pump to circulate the liquid through the piping (this liquid will remain in the machine and cannot be used for the actual dripping! It can however be collected at the end of an application / working day and be reused for a new application). From the tank the liquid is pumped through a filter system to eliminate any impurities^{1*} from the liquid to avoid damage to the drip nozzles and potential inconsistencies in droplet sizes. Approximately 80% of the liquid will go back into the tank to ensure a constant mixing and movement of the liquids thereby avoiding any sedimentation. The other 20% will go to the drip beam and returns to the tank from there. A pressure meter inside the piping directly before the drip unit communicates with the precision pump to ensure a constant pressure of 0.1 bars is maintained. The diameter of the return stream is deliberately made smaller to increase the speed of the liquid stream and thereby avoiding sedimentation inside the tubing.

Seeding line

The seeding line itself is not part of the Phyto-Drip® machine but the line will communicate with Phyto-Drip® through a pulse generator that is to be built in to the axis of the transportation belt of the seeding trays. In this way an accurate placement of the droplets on the moving tray can be guaranteed.

Approximately 2 cm above the transportation belt of the seeding line, Phyto-Drip® has two electronic eyes that will spot the tray from the beginning till the end. The double observation is a safety precaution that prevents Phyto-Drip® from starting an application whilst spotting a passing insect or small dirt droppings on the belt.

Safety features

All Phyto-Drip® machines are standard equipped with an emergency STOP for immediate switch-off and an internet connection for remote assistance and supervision. Furthermore Phyto-Drip® carries several electronic safety features to avoid miss use and/or spillage of PPP-contaminated liquids. All safety warnings will be displayed on screen once activated. In addition a double stage warning light will be blinking on top of the machine (orange for operator issues, red for system failures). All warnings are recorded in the internal memory of the system and can be retrieved at any time (both locally and remote).

Specific machine settings can only be modified by authorized personnel after entering a user specific password. Modification of program settings or software updates can be conducted online by the manufacturer of the machine, Van Der Ende Phyto-Drip® BV.

Seed Treatment by Phyto-Drip® Application

Preparation of PPP mixture

Before the start of an application the young plant raiser has to calculate the right amount of PPP's that he/she needs to apply. This amount will depend on the crop, the product and the volume of the droplet that he/she intends to use. It is advisable to prepare a concentrated mixture of water and PPP in a

¹ Impurities can be soil particles from the substrate or agglomerates of the inert materials in a PPP formulation.

beaker or bucket that will be transferred into the Phyto-Drip® tank and diluted with the right amount of water. Preparation of the slurry in a beaker does allow the use of a precision balance for a more precise dosing of the PPP's compared to a direct injection of pure formulation into the tank (it is recommended to use a balance with at least 1 decimal number). Due to the high dilution rate of PPP's with Phyto-Drip®, the total amount that is required for the application is low (\pm 0.5 to 2 liters/day depending on crop and # plants).

The preset program for *filling and mixing* requires 5 minutes for a thorough mixing of the PPP's in the water. It is strongly recommended to allow for this time to get the most optimal mixing results.

Precautions for handling PPP's

All general precautions for handling PPP's have to be respected during the preparation of the drip liquid and operation of Phyto-Drip®.

At the end of an application with Phyto-Drip® there will be an amount of drip liquid left over in the machine (minimum of 4 liters that is required for the machine to function). This residue must be drained from the piping and the storage tank and collected in a suitable container. Remaining product has to be stored as a chemical and can be used for later applications. It is advisable to thoroughly agitate the container before returning the liquid into the Phyto-Drip® tank. Product drained from the filters contains dirt and unsolvable parts and can therefore not be reused.

All contaminated waste has to be disposed accordingly, this includes rising water, filter deposits etc.

Method of application

At the end of the start-up program the Phyto-Drip® machine automatically goes into production mode (display shows: "Phyto-Drip® ready for production"). The actual dripping will be initiated when the trays pass the electronic eyes on the seeding line.

The tray sizes (# cells, length, width and borders) have to be saved in the program of the Phyto-Drip® machine. At installation of the machine this service is provided by the manufacturer of the equipment. In the instruction manual one can also find the explanation how to do this yourself in case the young plant raiser starts to use a new tray type.

With the right tray type selected, the Phyto-Drip® nozzles will place a droplet, containing the PPP's, exactly on top on the seeds a few seconds after the seed has been sown in the growing media. The surface area of the cells in the tray varies generally between 2 to 16 cm² depending on the tray type.

The registered rate for use of Cruiser 70 WS for conventional film coating of lettuce seeds is 114 gram of Cruiser 70 WS / 100,000 (= 80 g Thiamethoxam / 100,000) seeds. This rate is the same for both application technologies. The slurry content for both application methods however is quite different. A general slurry volume range for film coating lettuce seeds is between 300 – 500 ml / 100,000 seeds.

When applying through Phyto-Drip® with a droplet size between 0.2 and 0.25 ml the total slurry volume is between 20 – 25 liter / 100,000 seeds. The Phyto-Drip® slurry is strongly diluted with water to allow for an optimal distribution of the active compound in the slurry and in the individual droplets.

Application	Rate per single seed		Slurry vol. (l)/ 100,000 seeds	Max. use per day	
	Cruiser 70 WS	Thiamethoxam		# seeds (million)	Cruiser 70 WS
Filmcoating	1.14 mg	0.8 mg	0.3 – 0.5	10 – 20	11.4 – 22.8 kg
Phyto-Drip®	1.14 mg	0.8 mg	20 – 25	1	1.14 kg

Operational procedures and general risk management are the same for all registered PPP's that can be used with the Phyto-Drip® equipment.

The size of the droplets coming out of the Phyto-Drip® equipment is of crucial importance for the preparation of the drip liquid and the accuracy of the individual seed loading with PPP's.

Due to the liquid application method, no dust will be generated during the application process, seeding or transplanting.

Rinsing and Cleaning

After each application the Phyto-Drip® machine needs to be cleaned properly. The first step is to drain the machine by following the instructions from the emptying program. Drained product should be collected in a suitable and labeled container and stored as chemical. This product can be used for later applications. Important: the buffer tank for draining can only hold up to 5 liters of product. When more liquid needs to be drained, additional draining steps have to be undertaken. For this reason it is important to prepare the right amount of liquid required for the application.

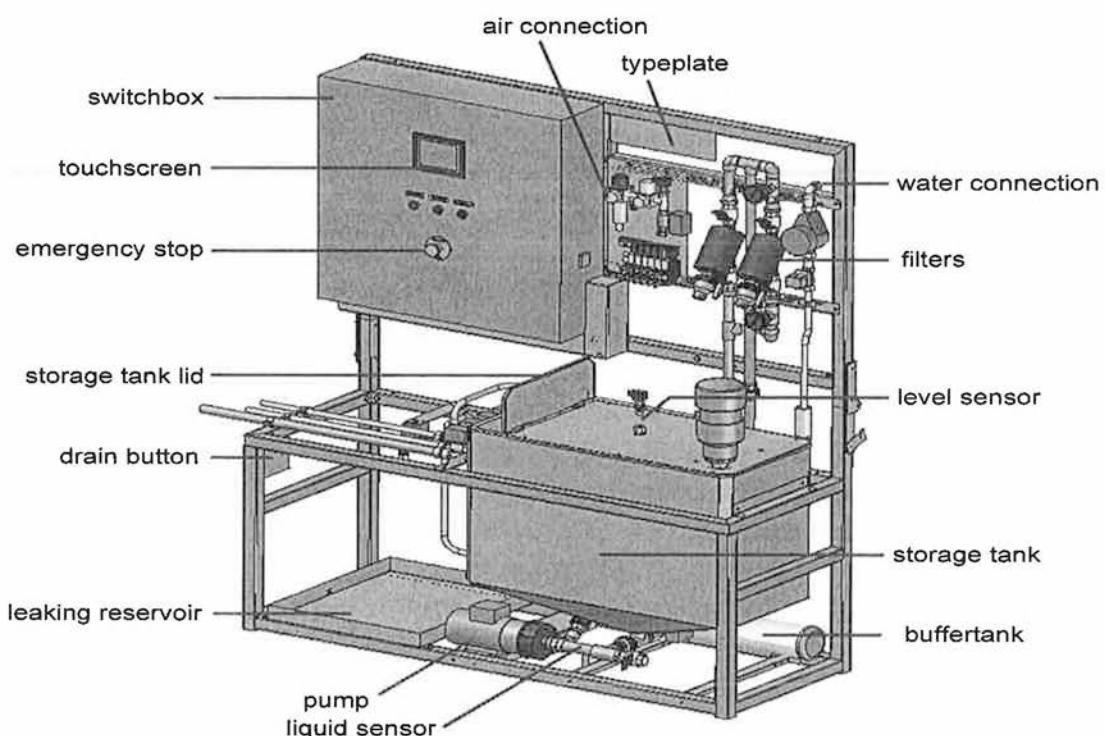
The next step is to clean the filters and filter housing. The filters may contain dirt particles and some liquid residue. It's important always to wear protective clothing when opening the filter housing!

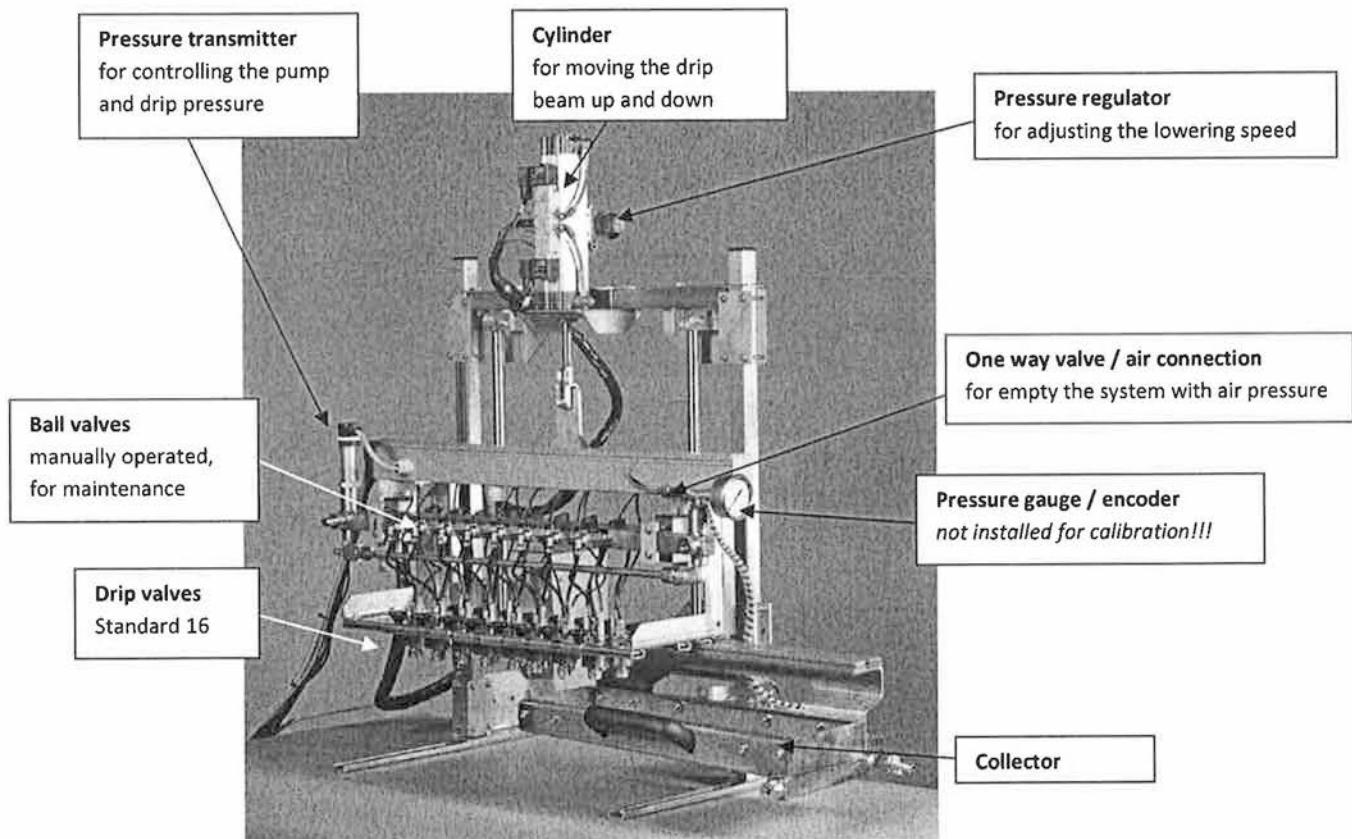
The filters themselves can be cleaned with warm water or in an ultrasonic bath.

The entire machine can now be rinsed using clean water, it is advisable to use warm water of $\pm 45^{\circ}\text{C}$.

Avoid strong foaming detergents for the cleaning since this will inevitably lead to a lot of foam.

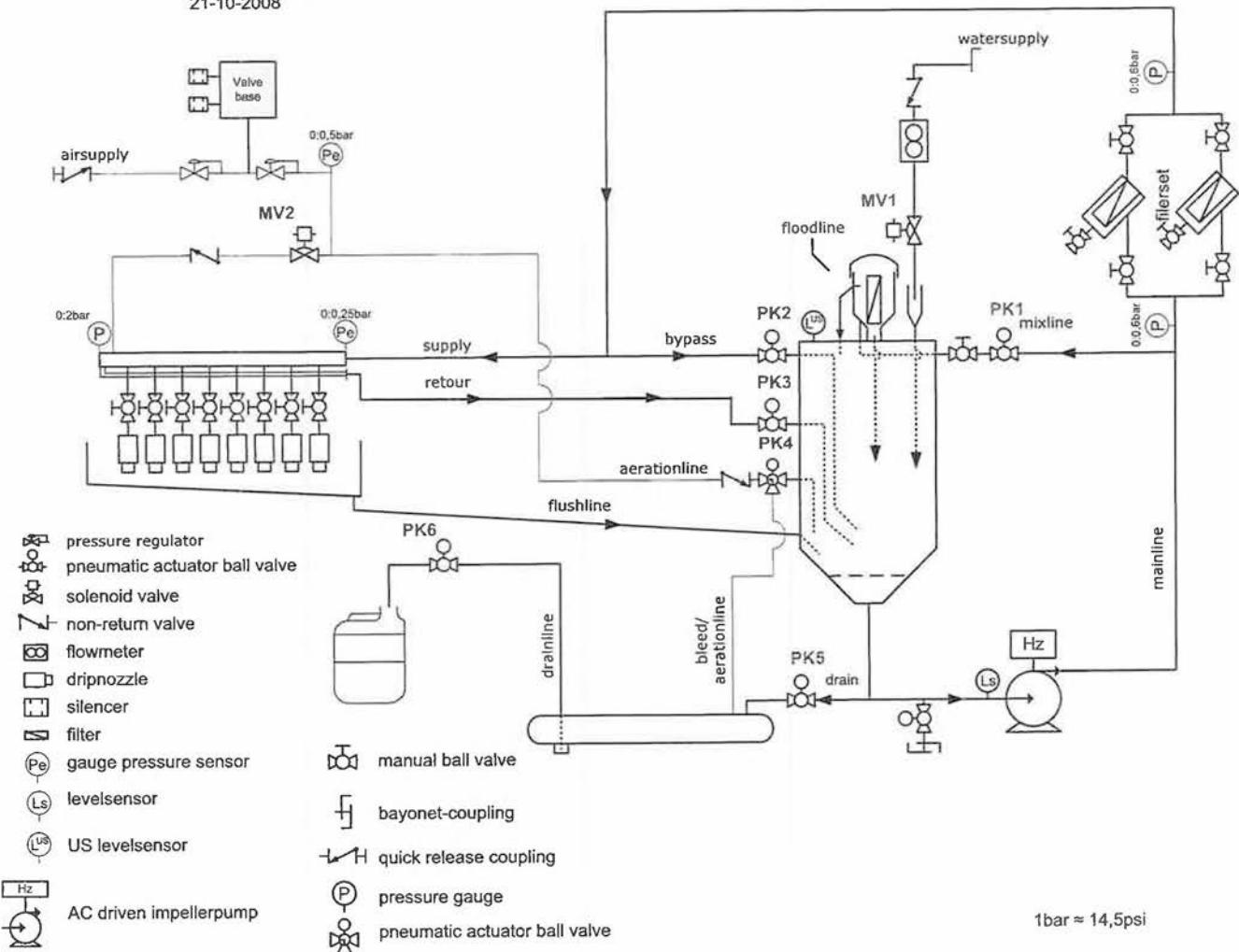
Rinse the machine including the nozzles for at least 5 minutes in order to get all of the crop protection product out. The rinsing has to be considered contaminated and should be disposed accordingly. The rinsing water has to be drained from the machine as described before.





Flowchart Phyto-Drip

21-10-2008



Registration of Phyto-Drip® Technology by JKI

The Phyto-Drip® machine has been registered by Julius Kühn-Institute in the German "Pflanzenschutzgeräteliste" in 2007 (see below).

Institut für Anwendungstechnik im Pflanzenschutz
Institute for Application Techniques in Plant Protection

JKI, Messeweg 11/12, 38104 Braunschweig, Germany

van der Ende Phyto-drip BV
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E-Mail at@jki.bund.de
Ihr AZ/
Ihr Schr. v.

Unser AZ E1565
Datum 15.01.2008

Bestätigung der Eintragung in die Pflanzenschutzgeräteliste

Sehr geehrte Damen und Herren,

auf Ihre Anfrage vom 15. November 2007 teile ich Ihnen mit, dass mir für Ihren Gerätetyp

- Phyto-drip

eine Erklärung gemäß § 25 Pflanzenschutzgesetz vorliegt und ich den genannten Typ nach Prüfung der Unterlagen in die Pflanzenschutzgeräteliste eingetragen habe.

Die Eintragung in die Pflanzenschutzgeräteliste wurde im Bundesanzeiger vom 25. April 2007 Nummer 78 Seite 4316 bekannt gemacht.

Mit freundlichem Gruß

im Auftrag

Dr.-Ing. 5.1.2.e

Phyto-Drip® Efficacy and Seed Safety Information

Currently there are three seed application technologies used for treating lettuce and brassica seeds (and others) with Cruiser 70 WS (Thiamethoxam – FarMore I100). These application technologies are: seed coating (in the case of lettuce after pelleting the seed), Dummy Pill (the use of a dead seed which is treated with the product and sown along with a germinating seed) and Phyto-Drip® which as explained above consists on the application of the product with a precise volume of solution directly on the seed at time of sowing.

Work has been carried out to assess these three applications methods regarding seed safety, uptake of the active ingredient by the plant and the biological efficacy of the product. Studies were conducted with either of two commercial formulations, Cruiser 70 WS and Cruiser 600 FS, both of which are solo formulations of thiamethoxam.

The studies performed show:

- 1) a clear benefit regarding seed germination and reduction of phyto toxic effects of Thiamethoxam when applied through Phyto-Drip® or Dummy Pill (Sanokote Pill) compared to seed coating
- 2) slight differences on product uptake by the plant when product is applied through the three application technologies however
- 3) no difference in biological efficacy against aphids, the major pest.

Seed safety

Methodology

Seeds were sown and grown according to the standard procedure used by a professional young plant raiser during 2006-2007. Sowing of endive was done in standard 4 * 4 cm peat blocks. Brassica (cauliflower) seeds were sown in a 228 plug tray. The treatments of Cruiser 70 WS (Thiamethoxam - FarMore I100) were either through seed coatings, Phyto-Drip® (0.25ml solution applied at seeding) or through the commercial Dummy (Sanokote Smart) Pill. The seeds were germinated at 18°C for two days in a germination chamber. The trays with seedlings were then placed in random order in a greenhouse. Assessments were conducted 6-7 days after sowing counting number of healthy (usable) plants and number of small/deformed plants.

Results

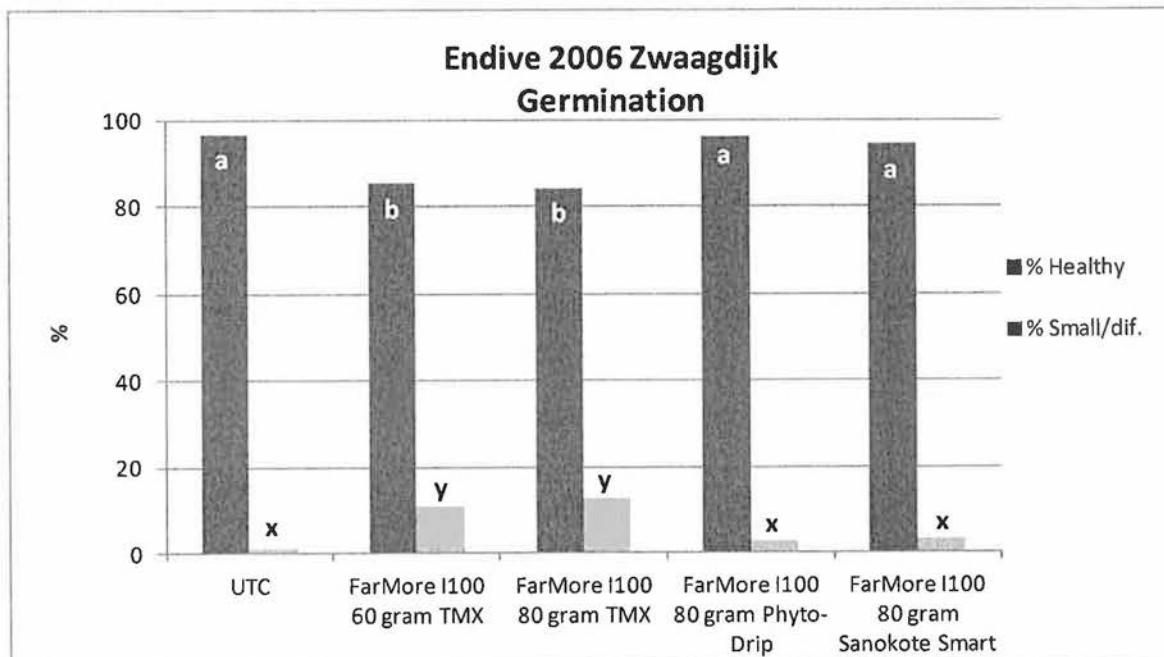


Figure 1. Percent healthy and percent small/deformed seedlings of endive plants treated with Thiamethoxam at 60 and 80g ai/100,000 seeds through seed coating, Phyto-Drip® or Dummy Pill (Sanokote Smart). Different letters showing statistical differences at $P < 0.001$

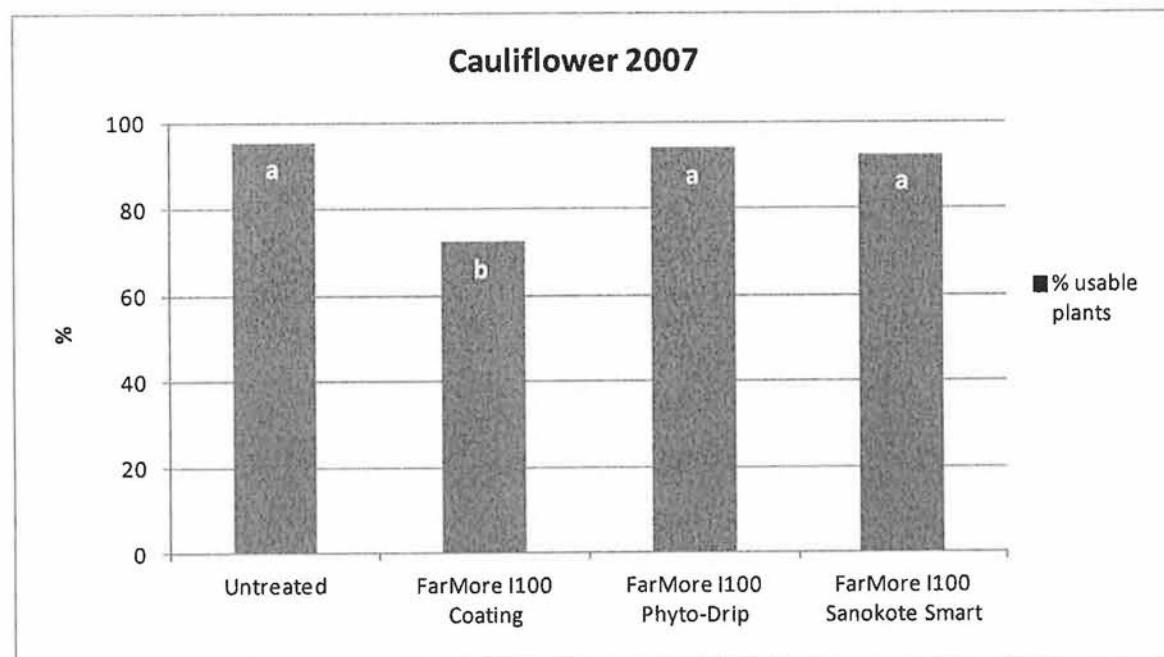


Figure 2. Percent usable seedlings of Cauliflower plants treated with Thiamethoxam at 140g ai/100,000 seeds through seed coating, Phyto-Drip® or Dummy Pill (Sanokote Smart). Different letters showing statistical differences at $P < 0.001$

For both endive and cauliflower (Figure 1 & 2) a significant number of plants were healthy (usable) when the treatment was done either with Phyto-Drip® or Dummy (Sanokote Smart) Pill. Both these treatments provided the same number of healthy plants as the untreated. In contrast coating seeds with Thiamethoxam – FarMore I100 caused a reduction on the number of healthy plants.

Product uptake by the plant

Methodology

Seeds were sown and grown according to the standard procedure used by a professional young plant raiser in June 2010. Sowing of lettuce was done in standard 4 * 4 cm peat blocks. The treatments with Cruiser 600 FS (0.8mg Thiamethoxam/seed) were either done through seed coatings, Phyto-Drip® (0.2ml solution applied at seeding) or through the commercial Dummy (Sanokote Smart) Pill. Seedlings were transplanted in the field in July and grown according to a commercial grower practices. In order to determine the amount of active ingredient in the plants, leaf samples were collected during the growing period on a weekly basis. Samples were processed (extraction with acetonitrile:water (80:20)) and analysis carried out using LC-MS/MS to quantify Thiamethoxam. Parallel to the field trial, a lab aphid (*Myzus persicae*) test was conducted to establish the amount of active ingredient required in the leaf in order to provide 50, 90 and 98% control (EC) of the pest.

Results

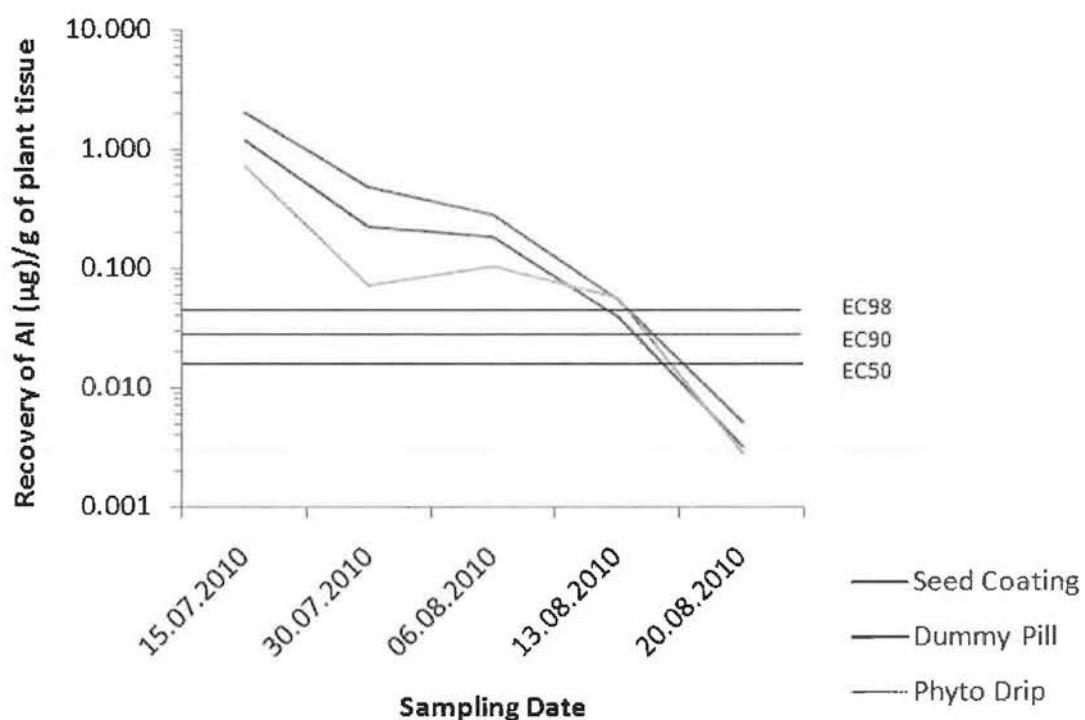


Figure 3. Amount of Thiamethoxam ($\mu\text{g}/\text{g}$ leaf tissue) measured at various dates from field grown lettuce which were treated through seed coating, Phyto-Drip® (0.2ml solution at sowing) or Dummy (Sanokote Smart) Pill. Date of sowing: 24.06.10. The three lines (EC50 – 98) represent the amount of Thiamethoxam required in the leaf to kill 50 – 98 % of the aphid (*Myzus persicae*) population.

According to Figure 3 all three application methods provided more than 98% aphid control 43 days after sowing, (6.8.10). Fifty days after planting (13.8.10) seed coating and Phyto-Drip® provided more than 98% control whereas the Dummy pills provided 90 % control.

At 57 days after planting (20.8.10) aphid control in all three application methods was below 50%. Although the amount of Thiamethoxam during the early growth of the plant was shown to be highest on plants treated with seed coating, compared to the other two application methods, this was not carried through the later growth of the plant where the critical amounts to control the pest are most important.

Efficacy trials

Methodology

A series of field trials have been conducted in the Netherlands during 2003-2007 to assess aphid control when applying Cruiser 600 FS (Thiamethoxam) through the three different application technologies (seed coating, Phyto-Drip® and Dummy Pill) in lettuce. Trials were done at different fields during different times of the year with different varieties.

Results

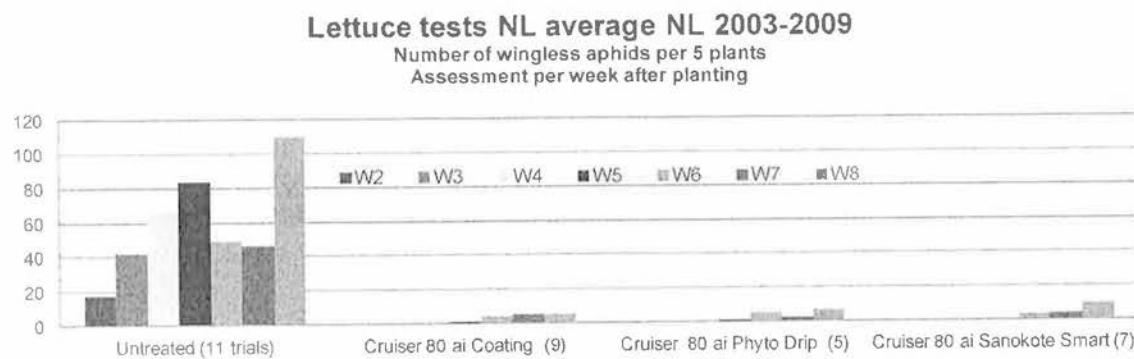


Figure 4. Biological efficacy of Thiamethoxam against aphids when product is applied at the recommended 0.8mg thiamethoxam/seed through seed coating, Phyto-Drip® or Dummy (Sanokote Smart) Pill.

In accordance with results obtained from leaf analysis of Thiamethoxam (see above) the efficacy of the product when applied to the seed through the three application technologies provides equal control of the pest in the field (Figure 4).

Safety and Exposure Information

The formulation to be applied with the Phyto-Drip® technology will be the same Cruiser 70 WS which is already registered in Germany for seed treatment use on lettuce and endive. All data submitted with the product for its initial registration are considered to be valid also for its use extension to the Phyto-Drip® technology (product chemistry, toxicology, ecotoxicology, environmental fate, metabolism and residues).

Occupational Exposure

The Phyto-Drip® application rate of Cruiser is the same as the registered rate for seed coating (0.8 mg thiamethoxam/seed). The amount of seed that can be treated at maximum per day is 10-20 fold less compared to conventional seed coating. The Phyto-Drip® application solution is about 50-fold more diluted than the slurry for seed coating. The total amount of Cruiser handled per day is at maximum 1/10 of that handled for seed coating.

Potential exposure scenarios are:

- Mixing/loading
- Drip application
- Handling of trays after seeding and treatment
- Cleaning

Mixing/loading:

Basically this exposure scenario is identical to the same process for seed coating. However, due to the lower amount of product handled per day it can be assumed that the total daily exposure resulting from this step is not more than 1/10 of that for conventional seed coating.

Drip application:

After loading the tank with the treatment solution all of the remaining process occurs in a closed system. The drip application itself is of high precision with very small volumes in a very narrow environment. The risk for drift of application solution is considered to be negligible. There is no formation of dust.

Therefore, actual Phyto-Drip® application process is considered to result in negligible exposure to the operator.

Handling of trays after seeding and treatment:

Right after treatment the seeds are covered with growth media. All steps up to this point are performed by an automated system on a conveyer belt. There is no manual interaction by an operator needed.

After coverage of the seeds the trays are transferred to a climatic chamber and thereafter to the green house for the initial growth of the seedlings. Trays may be handled manually during this phase.

Due to the high precision of the drip technology it can be reasonably assumed that there is no contamination with the PPP at the outer surface of the tray or the covering substrate. Therefore, exposure to operators during this step is very unlikely.

Cleaning:

Draining and cleaning of the Phyto-Drip® tank and tubing system is conducted at the end of every work day as described above. The drained product is collected and re-used for next applications.

In particular the cleaning steps may result in some contamination of the operator. It is therefore required to wear appropriate PPE (coverall and chemically resistant gloves) during the cleaning process to minimize exposure. However, due to the much lower concentration of the treatment solution and the much lower amount of product handled per day the potential exposure should be significantly less compared to that during the cleaning of conventional seed treatment equipment.

In conclusion, the exposure risk to operators during the entire process is considered to be lower than that to an operator involved in conventional seed coating. Conventional seed coating is approved in Germany and considered to pose no risk for the operators provided PPE is worn. For reasons of good agricultural practice it is recommended that operators wear the same PPE as recommended for conventional seed coating during mixing loading, application and tray handling and cleaning.

Consumer Exposure

No specific residue trials were conducted with Cruiser applied to lettuce (or endive) by the Phyto-Drip® technology.

The Phyto-Drip® application rate of Cruiser is the same as the registered rate for seed coating (0.8 mg thiamethoxam/seed). Also the application timing and the location of the product very close to the seed are the same for seed coating and Phyto-Drip®. Therefore, residue levels are expected to be comparable following seed coating and Phyto-Drip®.

The EU MRL in lettuce is driven by the foliar use of thiamethoxam products. Seed coating was shown to result in substantially lower residue levels than foliar application and the risk of foliar and seed coating uses to consumers in Germany was concluded to be acceptable².

In conclusion, it can be assumed that the Phyto-Drip® technology will not result in any additional risk to consumers and that the current EU MRL covers the Phyto-Drip® application.

Environmental Exposure

Exposure to the environment may occur at the earliest after the seedlings have been transplanted to the field. The application rate by Phyto-Drip® is identical to that for conventional seed treatment. Therefore, the application rate by means of active ingredient per hectare can be assumed to be the same for both application techniques. The exposure to soil and groundwater is assumed to be the same for the two seed treatment technologies under worst case conditions. Taking into account the time periods for germination and transplanting into the field, soil and groundwater exposure will, however, be equal to seed coating.

Exposure to surface water bodies is generally low for seed treatment uses as a major exposure route such as spray drift is not relevant. Furthermore the incorporation into soil leads to a negligible run-off or erosion transport potential and minimizes exposure via drainage. In case of the envisaged indoor Phyto-Drip® application of seeds none of the above surface water exposure routes is relevant at all. This fact is also true at a later stage once the crops are transplanted into the field.

² A9567C, Thiamethoxam 70% w/w WS, Document M-III, Section 4. 12 Oct. 2009

Exposure to Non-Target Organisms

Exposure to non-target organisms may occur at the earliest after the seedlings have been transplanted to the field. This phase is however, in no way different to that after conventional seed coating. Therefore, it is reasonable to assume that the Phyto-Drip® technology results in no additional risks to any environmental organisms compared to risks described for the registered use of Cruiser by conventional seed coating. Risk assessments for the conventional seed treatment use on lettuce seeds at identical treatment rate demonstrate that the registered use does not pose an unacceptable risk to any non-target species. The risks assessments are considered valid also for the application of the product using the Phyto-Drip® technology.

Further Information

Other registrations

Currently the Phyto-Drip® is approved as alternative seed treatment technology in the Netherlands, Belgium and Spain. As next steps Syngenta would like to establish the technology also in Germany, Hungary, Switzerland, Poland, Austria, France and UK.

Currently Syngenta is focusing on getting approval for the use of this application technology for treating seeds with Cruiser (FarMore I100) on crops including lettuce, endive, brassicas, leek, cucurbits. In addition other development products which could provide a benefit for the production of vegetables are being also considered for application though this technology on additional crops.

The Phyto-Drip® technology is currently also used for the application of other non-Syngenta products.

Proposed label

It is Syngenta's intention to have Phyto-Drip® registered as an alternative seed treatment technology for Cruiser on lettuce and endive in Germany along with the conventional seed coating. The approved label for Cruiser 70 WS in the Netherlands is an example for how this could look like:

Excerpt of the approved label in the Netherlands:



GEBRUIKSAANWUZING

Sla (met uitzondering van veldsla) en andijvie, ter voorkoming van aantasting door bladluizen (o.a. *Nasonovia ribisnigri*, *Macrosiphum euphorbiae*, *Myzus persicae*) en wortelluis (*Pemphigus bursarius*).
Het middel heeft een werkingsduur van minimaal 6 weken vanaf het moment van zaaien.
In de laatste weken voor de oogst kan het noodzakelijk zijn nog enkele keren te sputten tegen luizen met een daarvoor toegelaten middel.
Dosering: 85 tot 115 gram middel per eenheid zaden (= 100.000 zaden).

Voor botersla zal een dosering van 85 gram per eenheid zaden veelal afdoende zijn.
Voor slasoorten met een langere teeltduur (bijvoorbeeld ijsbergsla) en andijvie kan het raadzaam zijn een dosering van 115 gram per eenheid zaden aan te houden.

Toepassingsmethoden

Bij het toepassen van Cruiser® 70 WS in sla en andijvie kan gebruik worden gemaakt van één van de onderstaande methoden:

- a) zaadcoating
- b) dummy-pil methode
Uitsluitend een dummy-behandeling uitvoeren met zaad van hetzelfde gewas.
- c) phyto-drip methode (tijdens het oppotten)

