Document Title

Tier 2 Summary of the Further Information on the Plant Protection Product for

Sivanto 200 SL

(Flupyradifurone/BYI 02960) 200 SL

Specification number 102000021884

Submission to RMS The Netherlands as representative use in the EU

(Hops (F) and Lettuce (F, GH)

Data Requirements

Regulation (EC) No 1107/2009

Regulatory Directive 2003-01/Canada/PMRA
OPPTS guidelines/US/EPA

Annex IIIA
Section 1, Point 4
Document M

According to OECD format guidance for industry data submissions on plant protection products and their active substances

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M-428755-02-1

OWNERSHIP STATEMENT

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IIIA1 4.1 Packaging and compatibility with the preparation

Report:	**KIIIA1 4.1/01, Anonymus; 2012**
Title:	Bayer CropScience Safety Data Sheet for Sivanto SL 200 (Spec. No.: 102000021884)
Report No & Document No	M-423030-02-1 M-423030-02-1
Guidelines:	Regulation (EC) No. 1907/2006
GLP	n.a.

IIIA1 4.1.1 Description and specification of the packaging

Specific Requirement:	**Examples:**
▪ Material (declare the primary packaging material from **inside to outside**)	Bottle / Canister: HDPE
▪ Capacity:	Standard bottle / canister up to 10 liter, packed in outer corrugated fibreboard: • 20 x 0.250 liter • 20 x 0.500 liter • 12 x 1 liter • 4 x 3 liter • 4 x 5 liter • 2 x 10 liter Standard canister / IBC over 10 liter such as: • 20 liter • 25 liter • 50 liter • 200 liter • 640 liter • 1000 liter
▪ Type of closure and size of opening	Screw cap 36-50-63 mm (with HF seal or internal wad) - to fit container neck as defined in ECPA One Trip Container Guidelines. Tri – Sure, S 56 x 4 mm, guarantees closure. Screw cap DN 50 guarantees closure and DN 150 guarantees closure.
▪ Application devices	None

IIIA1 4.1.2 Suitability of the packaging and closures

Statement of compliance:

All packagings used by Bayer CropScience for plant protection products comply with ADR regulations and have been tested using the ADR test methods appropriate to the pack type and material and classification of the contents.

IIIA1 4.1.3 Resistance of the packaging material to its contents

The resistance of the packaging material is addressed by the shelf-life study data submitted under Annex III (2.7.3) and has been found to be acceptable.
The resistance of packaging material to its contents has been tested in accordance with GIFAP Technical Monograph No 17 (May 1993); M-402996-01-1

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IIIA1 4.2 Procedures for cleaning application equipment

All application equipment and contaminated protective clothing should be washed/cleaned with water or a dilute detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed safely according to local regulations.

IIIA1 4.2.1 Procedures for cleaning application equipment and protective clothing

Application equipment

Field spraying equipment should be sufficiently cleaned in order to avoid product left over. Cleaning of field spaying equipment is in general an essential part of the recommendations for use of plant protection products.
Empty the contents of the spraying equipment completely onto the field just sprayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into the tank to cover the agitator and add about 0.5% liquid detergent. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and

spray out onto the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Plant protection equipment should always be stored in a properly designated storage facility.

Protective clothing
All contaminated clothing should be washed / cleaned with a dilute detergent solution and thoroughly rinsed with clean water.
Impermeable overalls, boots and face shields should be washed clean and dried.
Permeable overalls should be laundered after use.
Disposable overalls and gloves should be washed and disposed of as contaminated waste.
Gloves and boots should be washed clean, if necessary on the insides as well.

IIIA1 4.2.2 Effectiveness of the cleaning procedures

The product is dispersible in water. Therefore it can be removed from surfaces with water. Adding a dilute detergent solution will enhance the effectiveness of the cleaning process.
The SL-formulation contains considerable amounts of propylene-carbonate, due to which the formulation may adhere to the wall of the container. Consequently, the rinsed residue of the SL-formulation will be somewhat higher than for the standard SC-formulations. Therefore, in case that material has dried on surfaces, the use of heated water (25°C) will improve the cleaning effectiveness also.
Nevertheless, under practical conditions of use in the EU and given that the rinsing water is not colder than 7°C the rinsed residues will be negligible.

The general procedure for cleaning field sprayers is described below. For spray equipment the manufacturer's manual must describe how to clean and/or flush the pumps and pipes and control gauges whilst spray mixture is still present in the tank or the sprayer have to be cleaned for the next crop completely. The basic technical steps have to be defined for every sprayer type separately by the manufacturer:

General requirements:

- The cleaning procedure has to be done immediately after spraying the product.
- Empty the sprayer down to the technical leftover
- The technical rest liquid have to be diluted with clear water (in minimum 10% of the total tank capacity) and have to be sprayed out - ensure that the inside walls of sprayer will be cleaned thoroughly – best option to use a rotating cleaning nozzle.
- This step have to be repeated in case of products will be sensitive regarding crop safety or residues in succeeded treated crops
- Filters have to be removed and cleaned separately.
- The cleaning procedure has to be done in an untreated part of the field.
- Personal protective clothing is required for the cleaning procedure.

According to Efficacy Guideline 302, proposed by PSD and published in December 2001 by the European and Mediterranean Plant Protection Organization as document 02/9740, specific studies to prove the cleaning efficacy of application equipment is not required, if the product is not expected to

cause plant damage at recommended use rates. This holds true for almost all insecticides and fungicides and specifically for the Flupyradifurone SL 200.
Therefore, further studies are not considered to be necessary.

IIIA1 4.3 Re-entry periods to protect man, livestock and the environment

IIIA1 4.3.1 Pre-harvest interval (in days) for each relevant crop

Crop	Pre-harvest Interval (PHI)
hop:	21
lettuce, field	10
lettuce, glasshouse	3

IIIA1 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

Re-entry period needs not to be established as the representative crops are not grazed.

IIIA1 4.3.3 Re-entry period for man to crops, buildings or spaces treated

A safe re-entry or handling of treated crops is possible when spray deposit has dried.

IIIA1 4.3.4 Withholding period (in days) for animal feedingstuffs

Lettuce:
Due to the time between last treatment and harvest, as defined by the GAPs, it is not necessary to set a withholding period for use of treated plants as animal feeding stuffs. The withholding period is covered by the vegetation period of the crop. However, a poultry feeding study with parent BYI 02960 was conducted at dose rates which reflect maximum possible exposure to livestock based on uses in numerous crops, many of which will be submitted in a separate document. That study covers all aspects of residues in livestock and thus no specific withholding period is required.

Hops:
Not relevant for hops since they are not used as animal feeding stuffs.

IIIA1 4.3.5 Waiting period between application and handling treated products

Given the toxicological profile of the product and the residue levels at harvest in treated agricultural commodities, there is no need to define a waiting period between application and handling treated products.

IIIA1 4.3.6 Waiting period for sowing or planting succeeding crops

A full program of residue trials in rotational crops is presented either in this dossier (the "main", multi-crop, multi-rotation study) or in a separate document (multiple additional crops). The data collected in these studies yield information on the level of residues to be expected in following crops, and are reflected in the dietary risk assessment. Therefore, no waiting period needs to be specified.

IIIA1 4.3.7 Conditions under which the preparation may or may not be used

Product should not be used in windy conditions in order to avoid drift into water bodies.

IIIA1 4.4 Risks from recommended methods, precautions & procedures to minimize

IIIA1 4.4.1 Warehouse storage

Keep out of the reach of children.
Keep away from food, drink and animal feeding stuffs.
When using, do not eat, drink or smoke.
Keep away from source of ignition.
Store in the original container under usual warehouse conditions! Keep containers tightly closed in a cool, well-ventilated place.
Store in a place accessible by authorized persons only! Keep away from direct sunlight and protect again frost.
For more information see:

- Guidelines for the safe handling of pesticides during their formulation, packing, storage and transport (GCPF).
- Guidelines for the safe warehousing of crop protection products (GCPF).

IIIA1 4.4.2 User level storage

Keep out of the reach of children.
Keep away from food, drink and animal feeding stuffs.
When using, do not eat, drink or smoke.
Keep away from source of ignition.

IIIA1 4.4.3 Transport

Risks during transport of product are minimal. Follow the general rules and good practice for transport and the Dangerous Goods regulations. Do not stow the product together with food, feed and consumable items.
Transport classification of the product in Europe is:
Road and rail (ADR and RID): UN3082 (environmentally hazardous substance), Hazard No. 90.

IIIA1 4.4.4 Fire

Extinguish fires with foam or carbon dioxide (CO2), sand or water spray. Do not allow run-off from fire fighting to enter drains or water courses, e.g. by bundling the area with sand or earth.
Wear a self-contained breathing apparatus. Remove product from areas of fire or otherwise cool containers with water in order to avoid pressure being built up due to heat.
Water should be used as sparingly as possible and if contaminated it must not come in contact with surface water. It must be collected and burned in a commercial incinerator. If burning facilities are inadequate, obtain the manufacturer's advice on decontamination methods.

IIIA1 4.4.5 Protective clothing and equipment – Nature

If product is handled such that there is a risk:

Respiratory protection:	If product is handled while not enclosed, and if skin contact may occur: Full mask Multi-range filter ABEK/P2
Hand protection:	PVC or other plastic material gloves
Eye protection:	Safety glasses with side-shields
Hygiene measures:	Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and at the end of workday. Wash hands immediately after work, if necessary take a shower. Remove soiled or soaked clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

IIIA1 4.4.6 Protective clothing and equipment – characteristics

Respiratory protection	If product is handled while not enclosed, and if skin contact may occur: Full mask Multi-range filter ABEK/P2
Hand protection	PVC or other plastic material gloves
Eye protection	Safety glasses with side-shields

IIIA1 4.4.7 Suitability and effectiveness of the protective clothing and equipment

Safety glasses with side-shields are recommended to protect eyes from contact with the product.
Protective clothing is recommended as routine hygienic measure. Chemical resistant gloves are well known to sufficiently protect hands from contact with the product handled.

IIIA1 4.4.8 Procedures to minimize the generation of waste

Product

To minimise product waste, users are required not to prepare more than they will use for the treatment.

Package

To minimise package waste, empty and rinsed containers should be delivered to a local container collection programme, where available. Otherwise, they should be rendered unusable, e.g. by puncturing, and disposed in accordance with local regulations.
Packaging that cannot be cleaned should be disposed of as product waste. It must be incinerated in an authorised special waste incineration plant. Comply with local legislation.
To minimise generation of leftovers, users are recommended to store not more than will be consumed within the shelf life period of the product.

IIIA1 4.4.9 Information on likely combustion products in the event of fire

The following can be released in case of fire:

Carbon dioxide (CO_2)
Carbon monoxide (CO)
Nitrous gases (NOx)
Hydrogen cyanide (hydrocyanic acid)

IIIA1 4.5 Detailed procedures in the event of an accident during transport

IIIA1 4.5.1 Containment of spillages

Keep people and animals away.

Do not discharge into drains / surface water / groundwater. Cover any spilled liquid with absorbent material such as sand, earth or a proprietary absorbent material. After the liquid has been absorbed, carefully sweep it up into a disposable container and tightly seal. Dispose by incineration in an authorised special waste incineration plant. Comply with local legislation.
For larger quantities, please contact manufacturer.

If spillage enters drains leading to sewage works, inform local company immediately. If spillage enters rivers or watercourses, inform the Environmental Agency.

IIIA1 4.5.2 Decontamination of areas, vehicles and buildings

Take up with adsorbent material (e.g. sand, earth or a proprietary absorbent material).
Transfer collected material to heavy duty plastic drums and keep safe for disposal.
Clean contaminated floors and objects thoroughly, observing environmental regulations.

IIIA1 4.5.3 Disposal of damaged packaging, adsorbents and other material

After the liquid has been absorbed (sand, earth or proprietary absorbent material), carefully sweep it up into a disposable container and tightly seal. Damaged packaging and adsorbents should be collected into heavy duty plastic drums.
Containers and drums can be taken to waste disposal site or incineration plant, after consultation with site operator and/or with the responsible authority. Dispose of by incineration in an authorised special waste incineration plant. Comply with local legislation. For larger quantities, contact manufacturer.

IIIA1 4.5.4 Protection of emergency workers and bystanders

Keep people and animals away. Avoid contact with spilled product or contaminated surfaces and wear personal protective equipment (see Section IIIA1 4.4.6).
In the event of fire and/or explosion, do not breathe fumes. Wear self-contained breathing apparatus for fire fighting if necessary. Remove product from area of fire or otherwise cool containers with water in order to avoid pressure being built up due to heat.
When dealing with a spillage, do not eat, drink or smoke. Remove soiled or soaked clothing immediately. Clean hands and face at work intervals and after work.

IIIA1 4.5.5 First aid measures

General advice:	Move out of dangerous area. If the patient is likely to become unconscious, place and transport in stable sideways position. Remove soiled or soaked clothing immediately.
After inhalation:	Move the patient to fresh air and keep at rest. Call a physician immediately.
After eye contact:	In the case of contact with eyes, rinse immediately with plenty of water. Call a physician immediately.
After skin contact:	After contact with skin, wash immediately with soap and plenty of water. Call a physician immediately.
After ingestion:	Do not induce vomiting. Wash out mouth with water. Call a physician immediately.

IIIA1 4.6 Neutralization procedures for use in the event of accidental spillages

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.6.1 Details of proposed procedures for small quantities

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.6.2 Evaluation of products of neutralization (small quantities)

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.6.3 Procedures for disposal of neutralized waste (small quantities)

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.6.4 Details of proposed procedures for large quantities

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.6.5 Evaluation of products of neutralization (large quantities)

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.6.6 Procedures for disposal of neutralized waste (large quantities)

No neutralization procedure (e.g. reaction with alkali to form less toxic compounds) is necessary for Flupyradifurone SL 200.

IIIA1 4.7 Pyrolytic behaviour under controlled conditions at 800°C

Report:	**KIIIA1 4.7/01, Nuesslein, F., 2012**
Title:	Flupyradifurone, Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions
Report No & Document No	M-422993-01-1 M-422993-01-1
Guidelines:	EU Directive 1107/EEC Annex II, Point 3.8.1
GLP	**n.a.**

Incineration of Flupyradifurone is recommended as the way of safe disposal by controlled incineration at an approved chemical waste facility. Since the halogen content of Flupyradifurone (13 % w/w halogens) is higher than 1%, the standard process are: temperature higher than 1100°C, residence time higher than 2 seconds, oxygen excess higher than 6% (according to European Directive EC/94/67; Article 6).
Moreover, hydrofluoric acid exhaust gases should not exceed 1 mg.m-3 as an average on 24 hours (according to European Directive EC/94/67; Article 7).

IIIA1 4.8 Disposal procedures for the plant protection product

IIIA1 4.8.1 Detailed instructions for safe disposal of the product & its packaging

Leftover quantities of the product have to be burned in an authorised special waste incineration plant. Comply with local legislation.
As containers are combustible (HDPE): Burn these emptied containers in an authorised special waste incineration plant. Comply with local legislation.
Otherwise, they should be rendered unusable after cleaning, e.g. by puncturing, and disposed of in accordance with local regulations.
Note that empty containers can be land filled after cleaning, when in compliance with local regulations.

IIIA1 4.8.2 Methods other than controlled incineration for disposal

No methods other than controlled incineration are recommended for disposal.

IIIA1 4.9 Other/special studies

No other / special studies have been conducted.