

Document Title

Tier 2 Summary Further Information of the Classification, Labelling, Risk and Safety Phrases 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

Annex IIIA Section 1, Point 11 Document M

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

Date

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Tier 2, IIIA, Sec. 1, Point 11: Flupyradifurone (Sivanto) SL 200, Spec. No.: 102000021884

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IIIA111 Further information

IIIA1 11.1 Information on authorizations in other countries

Flupyradifurone and its formulation Sivanto SL 200 are submitted for the first time to The Netherlands as Rapporteur Member State for the EU. A later submission to a number of countries (Australia, Brazil, Canada, Mexico and USA) as Global Joint Review is planned for August 1st 2012. The Ctgb from The Netherlands will participate as observer to this GJR. No authorizations from any other country in the world have been granted so far.

IIIA1 11.2 Information on established MRLs in other countries

Flupyradifurone and its formulation Sivanto SL 200 are submitted for the first time to The Netherlands as Rapporteur Member State for the EU. A later submission to a number of countries (Australia, Brazil, Canada, Mexico and USA) as Global Joint Review is planned for August 1st 2012. The Ctgb from The Netherlands will participate as observer to this GJR. The Ctgb also agreed to evaluate the residue studies coming from the GJR countries with the aim to establish Import Tolerances/MRLs in the EU for the crops being traded in order to allow international trade of treated agricultural commodities.

IIIA1 11.3 Proposals for classification and labelling

Please refer to point IIIA1 11.4

IIIA1 11.4 Proposals for risk and safety phrases

Report: KIIIA1 4.1/01, Anonymus; 2012

Title: Bayer CropScience Safety Data Sheet for Sivanto SL 200 (Spec. No.: 102000021884)

Report No & <u>M-423030-02-1</u> Document No <u>M-423030-02-1</u>

Guidelines: Regulation (EC) No. 1907/2006

GLP n.a.

According to EC Directive 1999/45/EC:

Risk symbols:	Xn	Harmful
	N	Dangerous in the environment
Risk phrases:	20	harmful by inhalation
	43	may cause sensitization by skin contact
	50/53	Very toxic to aquatic organisms may cause long-term adverse

effects in the aquatic environment

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Safety phrases:

24 Avoid contact with skin.

35 This material and its container must be disposed of in a safe way

37 Wear suitable gloves

57 Use appropriate container to avoid environmental contamination

According to Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended:

Classified as hazardous for supply/use





Risk symbols:

Signal Word: Warning

Hazard Statements: H332 harmful if inhaled

H317 may cause an allergic skin reaction

H410 Very toxic to aquatic life with long lasting effects

EUH410 To avoid risk to human health and the environment, comply

with the instructions for use

Precautionary Statements:

P280 Wear protective gloves/protective clothing/eye protection/

face protection

P304 + IF INHALED: Remove victim to fresh air and keep at rest in a

P340 position comfortable for breathing

P309 + If exposed or if you feel unwell: Call a POISON CENTER or doctor

P311 physician

P501 Dispose of contents/container in accordance with local regulation

IIIA1 11.5 Proposed label

Specimens of the proposed label will be provided locally upon request.

IIIA1 11.6 Specimens of proposed packaging

Specimens of the proposed packaging will be provided locally upon request