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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT FOR HALOSULFURON-METHYL CONTAINING PRODUCTS

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Prepared for:

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Background:
According to Regulation 8(1)(d) and 10(3)(e) respectively, the Registrar (Act 36 of 1947) may not grant or renew a registration after 1 June 2024 if a product contains substances of concern. Halosulfuron-methyl has been classified in Europe as Repr.1B (H360D) and as such would be considered a substance of concern. However, in exceptional circumstances, the Registrar may grant a registration for a product (agricultural remedy) containing a substance of concern and the Applicant can submit a derogation to achieve this. The Regulation states:

"Before commencing an application for derogation of an agricultural remedy, the applicant must conduct a risk assessment to evaluate the risks associated with the use of the remedy according to the proposed uses for which a derogation is sought and determine whether the associated risks can be sufficiently mitigated".

The Halosulfuron-methyl Derogation Group comprising of: Farm-Ag International (Pty) Ltd, ICA International Chemicals (Pty) Ltd, UPL South Africa (Pty) Ltd, Sharda International Africa (Pty) Ltd, Villa Crop Protection (Pty) Ltd, Rainbow Agrosciences (Pty) Ltd and Green Island Investments Pty Ltd, is submitting a derogation for their water dispersible granule formulations (WG/WDG) containing 750 g/kg halosulfuron-methyl that includes dietary and non-dietary human health risk assessments as well as environmental risk assessments and hereby demonstrate safe use of these products, when used according to their recommended use pattern. This report is specifically for Villa Crop Protection (Pty) Ltd.

Executive summary:
This derogation consists of several independent core reports, the outcome of which is presented in this executive summary. The core reports are identical for the seven members of the derogation, however for each product a separate addendum was prepared that presents confidential data and/or data that are specific to the individual products.

The core reports consist of:

- A general toxicological profile of halosulfuron-methyl where the toxicological reference values used in the risk assessments are rationalised. In that toxicological section, the relevance of the Repr.1B (H360D) concluded by the EU Authorities [ECHA-CLP classification] in the context of human health risk assessments is also discussed.
- Dietary (consumer) risk assessments.
- Non-dietary (Operator, worker, bystander and resident) risk assessments.
- Environmental assessment.

It was considered appropriate, to encompass all possible uses in the risk assessments rather than conduct a risk assessment per company to present a more realistic scenario. The supported uses are presented in Appendix 1. (Good agricultural practice – GAP)

This derogation demonstrates that the hazard represented by halosulfuron-methyl Repr.1B (H360D) classification is extremely unlikely to have any negative deleterious health effect on consumers, and users when the products are used according to their recommended GAP. The exposure to consumers can be regarded as negligible.

Indeed, despite a very conservative/precautionary approach to the risk assessments, (worst case scenarios) the consumer risk assessments demonstrate safe use to consumers for all crops with a high safety margin. The non-dietary risk assessments also demonstrate safe use without the need of

PPE (personal protection equipment). It is emphasised by the derogation group that SANS 10206:2020. Ed 3: "The handling, storage and disposal of pesticides" should be strictly followed by individuals entitled to use the products.

Finally, the impact of halosulfuron-methyl on the environment is considered in another separate report and demonstrates that halosulfuron-methyl is unlikely to have any serious irreversible effects on the environment.

Toxicological assessment [Report EWC2403474.UK0-6756]

To support the derogation application and inform the human health risk assessments, a summary review of the toxicological profile of halosulfuron-methyl has been carried out, considering recent and relevant authoritative regulatory evaluations and the derivation of human health-based reference values.

In the absence of an evaluation conducted by the Joint Meeting on Pesticide Residues (JMPR), toxicological information has been sourced from evaluations by the European Union (EU) European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA).

Acute toxicity:

Halosulfuron-methyl has low acute toxicity via the oral, dermal and inhalation routes, is not irritating or corrosive to the skin or the eyes and is not sensitising to the skin.
No classification is warranted.

Carcinogenicity:

In the respective 2-year dietary studies in male and female rats and in a 78-week study in male and female mice, no oncogenic effects were observed at any dose level, indicating that halosulfuron-methyl is not carcinogenic.
No classification is warranted.

Mutagenicity/ Genotoxicity:

Halosulfuron-methyl is not genotoxic based on the findings of a standard battery of *in vitro* and *in vivo* studies.
No classification is warranted.

Reproductive toxicity:

Fertility and sexual function: Halosulfuron-methyl does not affect fertility, mating or gestation.
Development toxicology:
In the consideration of the available data, the ECHA Committee on Risk Assessment (RAC) concluded that there was sufficient evidence of a substance-mediated effect on development based on experimental US EPA test guideline studies conducted in rats and in rabbits (comparable in design to OECD Test Guideline 414). The development of rat foetuses was impaired at high dose levels and rat foetal body weight was dramatically reduced. There was a biologically significant increase in early resorptions which impacted on the rat post-implantation loss and this effect was also noted in the rabbit developmental study. Several widespread developmental variations were observed and there were indications of malformations in both rats and rabbits. The RAC could not exclude a direct effect on the developing foetus, as the maternal toxicity was considered insufficient to explain the degree of severity of the effects observed in the foetuses from high dose dams.

Consequently, halosulfuron-methyl was classified as a reproductive toxicant Category 1B H360D (May damage the unborn child) in accordance with the relevant EU Regulation (EC) No 1272/2008 (CLP Regulation).

Within the EU legislative framework, the CLP Regulation serves as a hazard identification process, with direct risk management consequences, to ensure that the hazards presented by chemical substances are clearly communicated to workers and consumers in the EU, across the supply chain. As such, the CLP Regulation does not facilitate the assessment of exposures to the chemical substances, the characterisation of the hazards (i.e.: via health-based reference values) or the assessment of health risks.

Regulation (EC) No. 1107/2009, regulating pesticides in Europe has set several hazard-based "cut-off" criteria. The classification for reproductive toxicity Cat 1A or B is one of the hazard-based "cut-off" criteria. Although the RAC opinion was issued in 2017, it is noted that halosulfuron-methyl is still approved in Europe despite its classification, inferring that European Member States consider that the hazard-based classification of this active substance does not impact on the safety of the authorised halosulfuron-methyl products.

Neurotoxicity and endocrine disruption
Halosulfuron-methyl is not neurotoxic and has not been considered as having endocrine disruption potential in any regulatory jurisdiction.

Reference values:
To assess the potential risk caused using a pesticidal product, reference values are derived from experimentally determined "no-observed-adverse-effect levels "(NOAELs). The NOAEL for the most critical effect is often referred to as the "point of departure" (POD). The reference values are derived by dividing the POD by an appropriate safety factor (SF, also referred to as an uncertainty factor (UF)), which, as the name conveys, ensures that the derived reference value is sufficiently conservative and protective towards human health, based on the effects observed in the studies.

<u>Consumer risk assessments: ADI and ARfD</u>
The ADI (Acceptable Daily Intake) is commonly defined as the amount of a chemical to which a person can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect.

The potential health risk to consumers is considered to mainly result from the long-term exposure to residues of halosulfuron-methyl in food. In accordance with internationally accepted procedures, during the EU evaluation of halosulfuron-methyl as a pesticide active substance, the Acceptable Daily Intake (ADI) was derived, taking into account the critical effects and most relevant effects observed in the toxicological database, the NOAEL determined for the most sensitive species and an appropriate safety factor.

Following the peer review of the pesticide risk assessment of the active substance halosulfuron-methyl and expert consultation, the critical effect for the derivation of the ADI was determined to be offspring effects: reduced pup body weight gain in the F1, F2a and F2b generations observed in the two-generation reproduction toxicity study conducted in rats (EFSA, 2012). Based on these findings, the lowest NOAEL was determined to be 6.3 mg/kg bw/day. Applying a standard safety factor of 100 (10 to account for interspecies variability and 10 to account for intraspecies

variability) to the NOAEL of 6.3 mg/kg bw/day, the EU agreed ADI was determined to be 0.063 mg/kg bw/day.

The ARfD (Acute Reference Dose) of a chemical is an estimate of the amount a substance in food and/or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risk to the consumer.

Following the peer review of the pesticide risk assessment of the active substance halosulfuron-methyl and expert consultation, the critical effect for the derivation of the ARfD was determined to be maternal toxicity observed in the rabbit pre-natal developmental toxicity study (EFSA, 2012). Based on these findings, the lowest NOAEL was determined to be 50 mg/kg bw/day. Applying a standard factor of 100 to the NOAEL of 50 mg/kg bw/day, the EU agreed ARfD was determined to be 0.5 mg/kg bw/day.

Operator/worker bystanders and residents risk assessments: AOEL and AAOEL
The AOEL (Acceptable Operator Exposure Level) is the minimum amount of active substance to which human may be exposed without adverse health effects over an extended period.
The AAOEL (Acute Acceptable Operator Exposure Level) of a chemical is an estimate of the amount a substance, normally expressed on a body weight basis, a human can be exposed to over a short time period without appreciable health risk.

Following the peer review of the pesticide risk assessment of the active substance halosulfuron-methyl and expert consultation, the critical effect for the derivation of the ADI was determined to be offspring effects: reduced pup body weight gain in the F1, F2a and F2b generations observed in the two-generation reproduction toxicity study conducted in rats (EFSA, 2012). Based on these findings, the lowest NOAEL was determined to be 6.3 mg/kg bw/day. Applying a standard safety factor of 100 to the NOAEL of 6.3 mg/kg bw/day, the EU agreed ADI was determined to be 0.063 mg/kg bw/day.

During the peer review evaluation for the active substance approval in 2012, EFSA concluded that a reference value for acute operator exposures (i.e.: an Acute Acceptable Operator Exposure Level, AAOEL value) was not required.

The following health-based reference values are considered to be relevant to inform the dietary and non-dietary risk assessments for WG products containing 750g/kg halosulfuron-methyl and are sufficiently conservatively protective in respect of human health:

Reference endpoint	**Derived value**	**Source**
ADI	**0.063 mg/kg bw/day**	EFSA (2012)
ARfD	**0.5 mg/kg bw/day**	EFSA (2012)
AOEL	**0.063 mg/kg bw/day**	EFSA (2012)
AAOEL	Not required	-

Dietary exposure assessment [Report EWC 2403474.UK0-8048]
The uses supported in South Africa by the halosulfuron derogation group, are presented in the Good Agricultural Practice (GAP) Appendix 1. The supported edible crops are Avocado, Citrus fruit, Corn/Maize grain, Mango, Sorghum grain, Sugarcane and Wheat grain.

The traces pesticides leave in treated products are called "residues". A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly (Good Agricultural Practice).

Using the Bryant Christie (BC) Global database for pesticide (Maximum residue level) MRLs, a report has been run for halosulfuron-methyl on all supported crops.

The highest Global MRLs (Maximum Residue levels) for each crop are listed in the table below. It should be noted that different methods of MRL calculation are used in different countries, and sometimes even the same dataset may result in a different MRL value. However, it is true in all countries that the MRL is a highly conservative value used to facilitate trade between countries and to monitor GAP compliant application, whereas the lower STMR (Supervised Trial Median Residue) and HR (Highest Residue) values are intended for risk assessment calculations.

Table 1: MRLs for halosulfuron-methyl around the world

Crop	**MRL (mg/kg)**					**Comments**
	Codex	**USA**	**Canada**	**Mexico**	**South Africa**	
Avocado	N.E	N.E	**0.1 (default)**	N.E	0.01	South African MRL taken from EU deferral
Citrus fruit	N.E	N.E	**0.1 (default)**	N.E	0.01	Data collated from representative commodities (Grapefruit, Lemon, Limes, Mandarin, Oranges)
Corn/Maize grain	N.E	0.05	0.05	**0.5**	0.01	South African MRL taken from EU deferral
Mango	N.E	N.E	**0.1 (default)**	N.E	0.01	South African MRL taken from EU deferral
Sorghum grain	N.E	0.05	0.05	**0.1**	0.01	South African MRL taken from EU deferral
Sugarcane	N.E	0.05	**0.1 (default)**	0.05	0.01	South African MRL taken from EU deferral
Wheat grain	N.E	N.E	**0.1 (default)**	N.E	0.01	South African MRL taken from EU deferral

Highest Global MRL for each crop presented in **bold**
Default MRL - When a specific MRL has not been set on a commodity for a pesticide, some markets defer to a set default MRL value. Policies regarding the use of default MRLs vary by country.
N.E – Not established

To present a worst-case risk assessment for consumers, the highest global MRL for each crop has been used in chronic and acute consumer risk assessment calculations (see bold values in Table X). The current Codex toxicological reference values: Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD), which were agreed by EFSA in 2012 and further elaborated on in the main body of toxicological assessment are as follows:

- ADI = 0.063 mg/kg bw/day used for chronic risk assessment
- ARfD = 0.5 mg/kg bw used for acute risk assessment

The WHO models have been used for the chronic (IEDI – International Estimated Daily Intake) and acute (IESTI – International Estimate of Short-Term Intake) calculations. The results from each assessment are presented below.

Chronic risk assessment	Acute risk assessment
Maximum IEDI (based on G12 diet):	

3.1% of ADI	Maximum IESTI = 3% of ARfD (based on consumption of maize in the Canadian Child < 6 years diet)
Maximum IEDI for South Africa (G05 diet): 1.7% of ADI	

This assessment uses the most conservative approach to dietary risk assessment (i.e. the highest worldwide MRLs have been used as the input values for each crop) and demonstrates that there is no unacceptable dietary chronic or acute risk to consumers.

Currently the registered South African GAP for halosulfuron does not trigger the need for an MRL greater than the LOQ (0.01 mg/kg). As part of this assessment, it was not possible to obtain the GAPs used in Canada and Mexico that led to the current MRLs which are the highest globally. Therefore, we cannot make a formal comparison of the GAPs. However, since the South African use does not require an MRL >0.01 mg/kg, then it can be assumed that the South African GAP is less critical than the Canadian and Mexican GAPs that underpin the high MRLs. Therefore, as mentioned above, the consumer risk assessment carried out here represents a true worse-case scenario for halosulfuron in the selected crops.

In addition to the above risk assessment, potential contamination of drinking water following the halosulfuron uses has also been explored and a drinking water assessment conducted.

The Predicted Environmental Concentration in ground water, PECgw values for halossulfuron have been determined in a separate document (2403474.UK0 – 12947 FOCUS PECgw report). All PECgw values for halosulfuron were ≤0.001 µg/L for all crops and all FOCUS scenarios modelled following applications made in accordance with each GAP. To determine the consumer exposure to halosulfuron-methyl through drinking water, the following exposure calculations have been presented below.

$$\left(\left(\frac{concentration\ in\ water\ x\ consumption}{bodyweight}\right) \div ADI\right) \times 100$$

- Exposure to infants (5kg bodyweight, consumption 0.75 L/day) = <0.001% of the ADI
- Exposure to children (10 kg bodyweight, consumption 1 L/day) = <0.001% of the ADI
- Exposure to adults (60kg bodyweight, consumption 2 L/day) = <0.001% of the ADI

The most conservative approach for consumer risk assessment was taken and an acute and chronic assessment was conducted using the highest Global MRL for each crop. This highly conservative risk assessment demonstrated that there is no unacceptable risk to consumers using the highest MRLs as input values for the assessment. This conclusion applies also to drinking water. Exposure is negligible.

Non-dietary exposure assessment [Report EWC 2403474.UK0-0380]
A risk assessment has been conducted in accordance with the newly updated EFSA (European Food Safety Agency) (2022) guidance[1] on the assessment of exposure of operators, workers, residents, and bystanders to plant protection products.

The EFSA (2022) guidance document is designed to assist risk assessors when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). To support users in performing the assessment of exposure and risk, an online calculator (reflecting the guidance content) was also developed. The underlying principles of the guidance document and the related exposure calculator are the transparency of data, the traceability of information and the reproducibility of the outcomes. In establishing the guidance document and calculator, the EFSA working group considered only databases of raw data or peer-reviewed publications that could be accessed (if requested) by third parties in accordance with the Aarhus Convention2. The EFSA guidance is based on a comprehensive, peer reviewed dataset and is continually reviewed and amended as and when new data become available.

Considering the above, the EFSA web calculator has been selected as the most appropriate model to assess non-dietary exposure to halosulfuron-methyl resulting from the application of the product water dispersible granule formulations (WG/WDG) containing 750 g/kg halosulfuron-methyl using vehicle mounted and/or handheld spraying equipment.

The EFSA web calculator is publicly available and accessible at: https://r4eu.efsa.europa.eu/

Non-dietary risk assessments have been undertaken for the product considering the endpoints listed below in Table 2 and the product uses detailed in Appendix 1 (proposed GAP).

Table 2: Product information and toxicological reference values used for exposure assessment.

Product code and name	Halosulfuron 75 WDG (and similar products)
Formulation type	Water dispersible granule (WG)
Category	Herbicide
Packaging	All products are supplied in water soluble bag
Active substance (incl. content)	Halosulfuron-methyl 750 g/kg
AOEL systemic	0.063 mg/kg bw/d
AAOEL systemic	None set
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	EFSA (2017) default dermal absorption values for an WG formulation: Concentrate: 10% Dilution: 50%
	Experimentally derived values for 750 g/kg WDG formulation Concentrate: 0.22% Dilution: 0.34% (0.075 g/kg)

[1] EFSA (2022) Guidance on the assessment of exposure of operators, workers, residents, and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032
[2] UN (1998) Convention on access to information, public participation in decision making and access to justice in environmental matters.

A summary of the risk assessment for operators, workers, residents and bystanders is presented in table 3. It should be noted that in the absence of actual studies with products to derive a dermal absorption value and conduct more realistic risk assessments, the latter relied upon default values that are in essence extremely conservative.

The default values for a WG formulation are respectively 10% (concentrate) and 50 % (dilution). It is noted that for their human health risk assessment of halosulfuron methyl, the US EPA considered the available data on dermal absorption for a range of sulfonylurea substances. Percent dermal absorption for product concentrates ranged from 0.021% to 9% across substances and for dilutions from 1% to 21%, supporting the conclusion that for sulfonylurea substances, EFSA's default dermal absorption values for WG formulations are likely to overestimate actual levels of dermal absorption.

Dermal absorption data are available for a 750 g/kg WDG formulation of halosulfuron-methyl, a higher (Tier 2) exposure and risk assessment was also performed using these experimentally derived dermal absorption values[3]. [0.22% (concentrate) and 0.34% (dilution)].

All supported uses (Appendix 1) are for a single application of 0.067 kg product in 200 to 400L water per ha. The products are commercialised in water soluble bags, each containing 0.067 kg of formulated product. According to the EFSA's exposure guidance (EFSA, 2022) application to amenity grassland (Kikuyu and/or Cynodon lawn) is presented as the worst case for vehicle mounted spray applications. This scenario selects the higher work rates (ha treated per day) used by the EFSA model for vehicle mounted application and includes the additional resident scenario of entry into treated areas through recreation. The exposure assessment for this crop use therefore provides a risk envelope for the other uses included in the GAP.

Table 3: Amenity grassland (covering all uses)

	Result	**PPE **/ Risk mitigation measures Dermal absorption: default values**	**PPE **/ Risk mitigation measures Dermal absorption: experimental values**
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted and knapsack: None* Hand-held equipment: None*	**Results of risk assessment:** Vehicle mounted and knapsack: None* Hand-held equipment: None*
Workers	Acceptable	None*	None*
Residents	Acceptable	None	None
Bystanders	Acceptable	None	None

None* means no PPE required but standard workwear (arms, body and legs covered) are worn.
** PPE = Personal Protective Equipment

[3] EFSA-Q-2023-00183

The most conservative approach for the risk assessment was taken. The risk assessments demonstrate that no health hazard to humans is expected when the products are used according to the recommendations. The safety margin is high and even higher when actual dermal absorption data are used. Levels of exposure to halosulfuron-methyl are low and predicted to be within the AOEL for all proposed application methods and crops. No PPE are required for any application scenario.

Potential precautionary measures based on classification and labelling:

- ✓ As Halo 750 WDG is warranted a skin irritation classification (Category 3) gloves, protective clothing should be worn by the operator for mixing and loading.
- ✓ As the product is warranted an eye irritation classification (Category 2) in addition to the above, eye protection/face protection should be worn by the operator for mixing and loading.

It is noted that all users of pesticides should in any case comply with SANS 10206 :2020. Ed 3: "The handling, storage and disposal of pesticides" and that the above-mentioned PPEs for sensitizer for mixing and loading activities are strongly recommended in all cases when handling pesticides to provide additional protection against spills and splashes.

Environmental assessment [Report EWC 2402474.UK0-0851]

The assessment of the environmental risks caused by agricultural remedies becomes increasingly important in practical environmental protection. Ecotoxicological risk assessment is used to assess the potential hazard of existing or new environmental chemicals regarding the ecosystem. The combination of exposure assessment and hazard assessment allows the assessment of hazards induced by an environmental chemical and the analysis and final evaluation of the existing risk.

<u>Exposure: what are the environmental concentrations the non target organisms are exposed to?</u>

The expected environmental concentration is assessed with the aid of computer models and Predicted Environmental Concentrations (PECs) are derived for surface water PECsw, for soil PECsoil and for groundwater PECgw.

<u>Hazard:</u>

The hazard of a substance considers various ecotoxicological effects such as acute toxicity, chronic toxicity and bioaccumulation. Tests on non-target organisms are conducted according to widely accepted OECD guidance to determine the acute (LD/LC/EC50) or chronic (NOEC/NOEL) toxicity endpoints. The LD/LC/EC50 is the "Concentration or dose where 50 % effect or mortality was observed/calculated "and the NOEC is the "No Observed Effect Concentration or Dose".

The assessment of the risks of agricultural remedies for the terrestrial environment is based on the calculation of risk indicators (e.g. TER, HQ) which compare the acute (LD/LC/EC50) or chronic (NOEC/NOEL) toxicity endpoints generated from experimental data with the formulation or the active substance to the potential exposure in the environment. Currently TER 'Toxicity exposure ratio' values are used for the risk assessments of terrestrial vertebrates, earthworms and non-target

plants when HQ ‘Hazard quotients’ values are used for the risk assessment of bees and non-target arthropods.

If the risk indicators (TER, HQ) are above the TER trigger or below the HQ trigger then the risk is considered acceptable.

The assessment of the risks of agricultural remedies for the aquatic environment is based on the calculation of PEC/RAC ratios. RAC is the “regulatory acceptable concentrations “which is derived by applying an assessment factor (AF) of 100 or 10 to the lowest acute or chronic toxicity value obtained from the respective tests. Both the trigger values and the assessment factors are conservative.

To assess the environmental risk to non-target organisms following the supported uses of the WG products containing 750 g/kg halosulfuron-methyl, the European model has been followed: The European model is well known for being very conservative in order to achieve the highly ambitious protection goal set out by the European commission. Furthermore, it is noted that the European guidance sets are revised regularly, in order to reflect changes of test guidelines and of scientific knowledge. in EU Guidance documents (EFSA, SANCO, EPPO, etc.).

The risk assessments conducted reflect the South African Data requirements as per Appendix A&B “Toxicological Requirements for Registration of New Pesticides RSA”, in order to cover all relevant areas considered under the South African Jurisdiction.

Overview of the risk assessment outcome

An assessment has been conducted to evaluate the environmental risks associated with the uses of the water dispersible granule products containing 750g halosulfuron-methyl/kg

The comprehensive overview of the uses supported by the members of the derogation group as well as the outcome of the risk assessments for all non-target organisms in scope are presented below in Table. 4

Table 4: Outcome of the risk assessment for all non-target organisms for all supported uses

Use No.	Crop and/or situation	F, Fn, Fpn G, Gn, Gpn or I	Application				Application rate			PHI (days)	Conclusion						
			Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
1	Maize	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-16 (2-6 leaf stage) of the crop	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R
2	Grain sorghum	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-16 (2-6 leaf stage) of the crop	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R
3	Wheat	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-21 (2 leaf stage to beginning of tillering) of the crop	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R
4	Sugarcane	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-16 (2-6 leaf stage) of the crop	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R

Use No.	Crop and/or situation	F, Fn, Fpn G, Gn, Gpn or I	Application				Application rate			PHI (days)	Conclusion						
			Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
5	Avocado	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 00-99 of the crop)	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R
6	Citrus	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 00-99 of the crop)	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R
7	Mango	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 00-99 of the crop)	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R
8	Kikuyu and/or Cynodon lawn	F	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 21-65 of the crop)	1	-	1	50	200 - 400	NA	A	A	R	A	A	A	R

Explanation for column “Conclusion”

A	Acceptable, Safe use
R	Risk mitigation measures required: **Aquatics** low risk to aquatic organisms following the uses of Halosulfuron-methyl 75WG when using a 5 m buffer zone. **Non target plants**: acceptable risk at a distance of 5 m with the use of 75% drift reducing nozzles or at a distance of 10 m with the use of 50% drift reducing nozzles or at a distance of 15 m without drift reduction.

Appendix 1: All intended uses

GAP rev. 1, date: 29.09.2019

PPP (product name/code):	**Halo 750 WDG**	Formulation type:	WG [a, b]
Active substance 1:	**Halosulfuron-methyl**	Conc. of as 1:	750g/kg [c]
Safener:	**NA**	Conc. of safener:	NA
Synergist/adjuvant	Recommended with a registered surfactant	Conc. of adjuvant:	NA
Applicant:	Villa Crop Protection (Pty) Ltd	Professional use:	☒
		Non professional use:	☐

Herbicide

1	2	3	4	5	6	7	8	9	10	11*	12	13	14
					Application				**Application rate**				
Use No.	**Country**	**Crop and/or situation**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	Product-sachet/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** product variant, other dose rate expressions dose range (min-max)
1	ZA	Maize	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp., Tagetes minuta*.	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-16 (2-6 leaf stage) of the crop	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*. 3-5 weeks after planting of the crop.
2	ZA	Grain sorghum	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp., Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-16 (2-6 leaf stage) of the crop	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*.

3	ZA	Wheat	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp*., *Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-21 (2 leaf stage to beginning of tillering) of the crop	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*. 3 to 5 weeks after planting of the crop.
4	ZA	Sugarcane	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp*., *Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) BBCH 12-16 (2-6 leaf stage) of the crop	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*.
5	ZA	Avocado	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp*., *Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 00-99 of the crop)	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*. Between the rows, avoid contact with crop foliage.
6	ZA	Citrus	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp*., *Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 00-99 of the crop)	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*. Between the rows, avoid contact with crop foliage.
7	ZA	Mango	F	*Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp*., *Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 00-99 of the crop)	1	-	1	50	200 - 400	NA	Post emergence (of the weeds). Prior to flowering of *Cyperus spp*. Between the rows, avoid contact with crop foliage.
8	ZA	Kikuyu and/or Cynodon lawn	F	*such as Cyperus spp*., *Bidens pilosa, Cleome monophyla, Galinsoga spp*., *Tagetes minuta*	Knapsack sprayers or tractor mounted boom sprayers	Post emergence of the weeds (BBCH 10-14) (BBCH 21-65 of the crop)	1	-	1	50	200 - 400	NA	Post emergence (of the weeds).

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
	(c)	g/kg or g/l
	(d)	Select relevant
	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references
	2	Use official codes/nomenclatures of EU Member States
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	8	The maximum number of application possible under practical conditions of use must be provided.
	9	Minimum interval (in days) between applications of the same product
	10	For specific uses other specifications might be possible, e.g.: g/m^3 in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	13	PHI - minimum pre-harvest interval
	14	Remarks may include: Extent of use/economic importance/restrictions

Appendix 2: Members of the halosulfuron derogation group and their product

Company	Product	Registration number
Farm-Ag International (Pty) Ltd	Brigadier 750 WG	L9218
ICA International Chemicals (Pty) Ltd	WeedO 750 WG	L11149
UPL South Africa (Pty) Ltd	Cyprex WG	L7665
Sharda International Africa (Pty) Ltd	Halosulfuron 750 WDG	L10855
Villa Crop Protection (Pty) Ltd	**Halo 750 WDG**	**L8283**
Rainbow Agrosciences (Pty) Ltd	Flagship 750 WDG	L10539
Green Island Investments Pty Ltd	Halo-Fron WG	L10152