TO CAUSE A HAZARD IN THE USE, STORAGE OR DISPOSAL OF THIS SUBSTANCE IS AN OFFENCE.

PRECAUTIONS:

- 1. Handle with care and avoid any skin contact. Poisonous by swallowing or inhalation.
- Do not eat, drink or smoke while mixing, applying, handling or before washing hands and face.
- WEAR PROTECTIVE CLOTHING, i.e. overalls, rubber gloves, and rubber boots and a facemask while mixing, spraying and cleaning up.
- Do not inhale fumes or spray mist.
- May cause damage to organs (liver) through prolonged or repeated exposure.
- May cause sensitization by skin contact.
- May cause an allergic skin reaction.
- 8. Remove protective clothing on completion of spraying, wash skin thoroughly with soap and water and dress in clean clothing and wash contaminated clothing daily.
- Clean applicator after use, dispose of wash water where it will not contaminate crops, grazing, rivers and dams.
- 10. KEEP APART FROM FOOD AND FEEDSTUFFS.
- 11. KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- 12. STORE IN A COOL DRY PLACE IN ORIGINAL CONTAINER AND KEEP UNDER LOCK AND KEY.
- 13. TOXIC TO FISH AND WILD LIFE, DO NOT CONTAMINATE DRINKING POOLS, DAMS, RIVERS AND WATERWAYS.
- 14. SPILLAGE Use protective clothing when dealing with spillages. Prevent entry into drains, water or soil. Soak up spilled product with absorbent material such as dry soil, sawdust or sand and place into a labeled closeable container for safe disposal. Use damp cloth to clean the floor and contaminated parts. Place used cleaning materials into closable container for safe disposal.
- 15. **CONTAINER DISPOSAL** Triple rinse container emptying washings into spray tank and spray onto crop. Perforate and flatten rinsed container to make it unsuitable for further use or burn it and bury crushed container or ashes in a recommended disposal pit in a secure location away from water sources or arable land. Do not use empty container for any other purpose.
- 16. RE-ENTRY: Do not enter treated area until spray deposit has dried unless wearing protective clothing.

SYMPTOMS OF POISONING: To date no symptoms are known.

FIRST AID:

Description of first aid measures

General advice: Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove

contaminated clothing immediately and dispose of safely. Inhalation: Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center

Skin contact: Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400.

subsequently rinse with water.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove

contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.

Do NOT induce vomiting. Call a physician or poison control center immediately. Rinse mouth, Ingestion:

NOTE TO PHYSICIAN:

Indication of any immediate medical attention and special treatment needed:

Treatment:

Gastric lavage is not normally required. However, if a significant amount (more than a mouthful) has been ingested, administer activated charcoal and sodium sulphate.

There is no specific antidote.

DIRECTIONS FOR USE: USE ONLY AS DIRECTED.

Packed For: Baver Zimbabwe (Pvt) Ltd P.O. Box AY 78, Amby, Harare, Zimbabwe,

Tel. 487211/487242

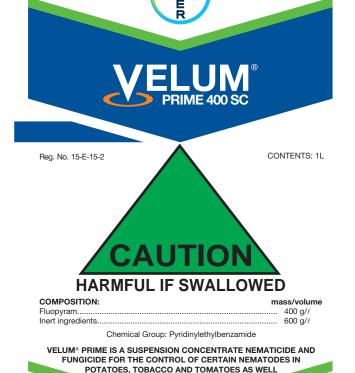
IN CASE OF POISONING PLEASE PHONE: +27(0) 861 555 777

Manufactured by Baver AG, Germany

Velum® is a registered trademark of the Bayer Group.

Baver

Batch No.: See on pack Zim/1218/Velum Prime 400SC 1L/Label Booklet Date of Manufacture: See on pack Code: 85397966D



BAYER













AS EARLY BLIGHT IN

POTATOES.













TO CAUSE A HAZARD IN THE USE, STORAGE OR DISPOSAL OF THIS SUBSTANCE IS AN OFFENCE.

PRECAUTIONS:

- 1. Handle with care and avoid any skin contact. Poisonous by swallowing or inhalation.
- Do not eat, drink or smoke while mixing, applying, handling or before washing hands and face.
- WEAR PROTECTIVE CLOTHING, i.e. overalls, rubber gloves, and rubber boots and a facemask while
 mixing, spraying and cleaning up.
- Do not inhale fumes or spray mist.
- May cause damage to organs (liver) through prolonged or repeated exposure.
- 6. May cause sensitization by skin contact.
- May cause an allergic skin reaction.
- Remove protective clothing on completion of spraying, wash skin thoroughly with soap and water and dress in clean clothing and wash contaminated clothing daily.
- Clean applicator after use, dispose of wash water where it will not contaminate crops, grazing, rivers and dams.
- 10. KEEP APART FROM FOOD AND FEEDSTUFFS.
- 11. KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- 12. STORE IN A COOL, DRY PLACE IN ORIGINAL CONTAINER AND KEEP UNDER LOCK AND KEY.
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- 15. CONTAINER DISPOSAL Triple rinse container emptying washings into spray tank and spray onto crop. Perforate and flatten rinsed container to make it unsuitable for further use or burn it and bury crushed container or ashes in a recommended disposal pit in a secure location away from water sources or arable land. Do not use empty container for any other purpose.
- 16. RE-ENTRY: Do not enter treated area until spray deposit has dried unless wearing protective clothing.

WARNINGS:

POTATOES: DO NOT HARVEST WITHIN 100 DAYS OF APPLICATION.
TOMATOES: DO NOT HARVEST WITHIN 47 DAYS OF APPLICATION

FOR ALL CROPS: DO NOT EXCEED AN APPLICATION RATE EQUIVALENT TO 2.5 //HA. (SEE DOSAGE IN APPLICATION TABLE).

NOTE: The recommended withholding period between the last application and harvest meets local residue requirements but may not meet export requirements. If the crop to be treated is intended for the export market, consult the relevant exporting organization regarding MRL requirements and withholding periods. When this product is used according to the label recommendations set herein, the local MRL will not be exceeded. Bayer (Pty) Ltd can however not be held liable for export crops exceeding the import tolerances of other countries.

WARRANTY: ALTHOUGH THIS REMEDY HAS BEEN EXTENSIVELY TESTED UNDER A LARGE VARIETY OF CONDITIONS THE REGISTRATION HOLDER DOES NOT WARRANT THAT IT WILL BE EFFICACIOUS UNDER ALL CONDITIONS BECAUSE THE ACTION AND EFFECT THEREOF MAY BE AFFECTED BY FACTORS SUCH AS ABNORMAL CLIMATIC AND STORAGE CONDITIONS; QUALITY OF DILUTION WATER; COMPATIBILITY WITH OTHER SUBSTANCES NOT INDICATED ON THE LABEL AND THE OCCURRENCE OF RESISTANCE OF THE PATHOGEN AGAINST THE REMEDY CONCERNED AS WELL AS BY THE METHOD, TIME AND ACCURACY OF APPLICATION. THE REGISTRATION HOLDER FURTHERMORE DOES NOT ACCEPT RESPONSIBILITY FOR DAMAGE TO CROPS, VEGETATION, THE ENVIRONMENT OR HARM TO MAN OR ANIMAL OR FOR LACK OF PERFORMANCE OF THE REMEDY CONCERNED DUE TO FAILURE OF THE USER TO FOLLOW THE LABEL INSTRUCTIONS OR TO THE OCCURRENCE OF CONDITIONS WHICH COULD NOT HAVE BEEN FORESEEN IN TERMS OF THE REGISTRATION. CONSULT THE SUPPLIER IN THE EVENT OF ANY UNCERTAINTY.

SYMPTOMS OF POISONING: No symptoms known or expected.

FIRST AID:

Description of first aid measures

General advice: Move out of dangerous area. Place and transport victim in stable position (lying sideways).

Remove contaminated clothing immediately and dispose of safely.

Inhalation: Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center

Skin contact: Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.

Ingestion: Do NOT induce vomiting. Call a physician or poison control center immediately. Rinse mouth.

NOTE TO PHYSICIAN:

Indication of any immediate medical attention and special treatment needed:

Treatment:

Treat symptomatically.

Gastric lavage is not normally required. However, if a significant amount (more than a mouthful) has been indested administer activated charcoal and sodium sulphate.

There is no specific antidote.

RESISTANCE MANAGEMENT:

In order to maintain the efficacy of **Velum Prime 400 SC** it is necessary to prevent the development of resistance by following good agricultural practices.

Soil application of **Velum Prime 400 SC** against nematodes can deliver fungicidal activity against certain foliar pathogens (e.g. Potato - *Alternaria* spp., *Botrytis cinerea* and Powdery mildew).

Therefore, as a precautionary measure in order to limit the risk of fungal resistance development, we advise:

- to consider the soil application of Velum Prime 400 SC as one of the total foliar fungicidal SDHI applications
 per crop indicated in the FRAC SDHI quidelines.
- to use another mode of action for the first foliar fungicide application, which provide satisfactory disease control
 against the fungal pathogen targeted by Velum Prime 400 SC.
- not to exploit the period of fungicidal activity of soil-applied Velum Prime 400 SC to its very end.
- to continue with foliar applications with alternating mode of actions for the remaining growing period.
- to minimize the selection pressure by shortening the time interval between nematicidal application and first foliar fungicide application.

DIRECTIONS FOR USE: USE ONLY AS DIRECTED.

USE RESTRICTIONS:

. Do not apply Velum Prime 400 SC through the irrigation system

COMPATIBILITY - Potatoes:

- Velum Prime 400 SC can be used on potatoes in tank mixtures with Confidor 70 WG, and Monceren 250 SC.
- The compatibility of Velum Prime 400 SC was not tested with other products.

<u>WARNING:</u> When **Velum Prime 400 SC** is used in tank mixture with **Confidor 70 WG** ensure that the potato tubers are not covered by the spray mixture.

MIXING INSTRUCTIO

- Pour the required quantity of Velum Prime 400 SC into the water while agitating.
- Ensure thorough agitation of the mixture in the tank during application and do not allow the tank mixture to stand still for any period of time.
- Do not use brackish water.

APPLICATION: Ensure that the application equipment is in a good working condition and not contaminated with other chemicals. (FOR FURTHER DETAILS SEE APPLICATION TABLE BELOW).

CROP	PEST	DOSAGE	REMARKS
TOBACCO TRB Certificate No. 18-21-E-12 Root-knot nematodes (Meloidogyne spp.)		At Transplant (Single Application): Mix 250 mℓ Velum Prime 400 SC / 100 ℓ water (1125 mℓ Velum Prime 400 SC/ha) based on 15000 plants/ha	Cup treatment: Apply 30 m ℓ (one 30 size fertilizer cup) of the mixture to the planting hole immediately after the planting water. Transplant the seedling and close the hole or apply 30 m ℓ of the mixture as a drench to the base of the plant at transplanting.
		Split Application: Mix 125 mℓ Velum Prime 400 SC / 100 ℓ water (562.5 mℓ Velum Prime 400 SC/ha) based on 15000 plants/ha. Follow up with a 2nd application 4 - 6 weeks later as above.	Cup treatment: Apply 30 m ℓ (one 30 size fertilizer cup) of the mixture to the planting hole immediately after the planting water. Transplant the seedling and close the hole or apply 30 m ℓ of the mixture as a drench to the base of the plant at transplanting.
TOMATOES	Root-knot nematode (Meloidogyne spp.) Lesion nematode Pratylenchus spp.) Spiral nematode (Helicotylenchus spp.)	At Transplant: 0.075 mℓ/plant At a plant rate of 33,333 plants/ha this is equivalent to 2.5 ℓ/ha. DO NOT EXCEED A RATE OF 2.5 ℓ/ha	Apply as a soil drench at or 1 day after transplanting. Mix 30 m ℓ Velum Prime 400 SC with 20 ℓ water and apply 50 m ℓ of this mixture to the soil around the base of the stem of each plant. Irrigate within 24 hours after application.
		Pre-plant band application: Apply 25 mℓ / 2.5 ℓ water / 100 linear m in a 30 cm band over the planting row. At a plant row spacing of 1 m this is equivalent to 2.5 ℓ/ha DO NOT EXCEED A RATE OF 2.5 I/ha.	Ensure the applicator is calibrated. Apply immediately before planting. Either lightly incorporate with mechanical equipment and plant within one day of the treatment and irrigate, OR transplant straight after application and irrigate by means of overhead irrigation to incorporate the product.

1.

CROP	PEST	DOSAGE			REMARKS	
POTATOES	Root-knot nematodes (Meloidogyne spp.) and Early Blight (Alternaria solani)	In-Furrow at planting: 18.75 - 25 mℓ, dependent on row width (see table below) / 2.5 ℓ water / 100 linear m in the furrow spraying from ridge-tip to ridge-tip.			Apply at planting in the open furrow either before tuber placement or directly after. Spray the Velum Prime 400 SC onto the total furrow area, from ridge-tip to ridge-tip. Close the furrows thereafter.	
		Row width (m)	Rows/ha	Rate/ 100 meter	Rate/ha	In situations where severe nematode infestation is expected, an additional nematicidal treatment, like preceding soil fumigation, is recommended.
		1.8	55.6	25 mℓ	1.39 L	Control of <i>Alternaria solani</i> can be expected up to
		1.65	60.6	25 mℓ	1.52 L	10 weeks after emergence. For resistance management it is however mandatory to commence at 6 weeks after
		1.2	83.3	25 mℓ	2.1 L	emergence with chemicals with an alternative mode of
		1.0	100	25 mℓ	2.5 L	action. Do not exploit the period of fungicidal activity of soil applied Velum Prime 400 SC to its very end.
		0.9	111	22.5 mℓ	2.5 L	applied Volumn Time 100 00 to its very ord.
		0.8	125	20 mℓ	2.5 L	
		0.75	133	18.75 mℓ	2.5 L	
		NOTE: DO NOT EXCEED A RATE OF 2.5 ℓ/ha OR 25 mℓ/100 m row length.				

NOTES:

- Irrespective of treatment rate or methodology, the persistency and nematicidal activity of Velum Prime 400 SC is strongly influenced by factors beyond the manufacturer's control, such as monocropping, soil type and the amount of irrigation or rainfall. Some nematode damage must be expected in the crops listed. In potatoes, severe losses can occur.
- It is advisable to lift the potatoes 120 days after application or as soon as possible thereafter to avoid damage from recurrence of nematodes.

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name VELUM PRIME SC400

Product code (UVP) 80978235

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use Nematicide, Fungicide

1.3 Details of the supplier of the safety data sheet

Supplier Bayer (Pty) Ltd.

27 Wrench Road, P.O. Box 143

1600 Isando South Africa

Telephone +27 (011) 921 5911 **Telefax** +27 (011) 921 5766

Responsible Department QHSE - Nigel, South Africa

+27 (011) 365 8675 (during business hours only)

1.4 Emergency telephone no.

Emergency telephone no. +27 (0861) 555 777 (Western Cape Poisons Helpline)

Global Incident Response

Hotline (24h)

+1 (760) 476 3964 (Company 3E for Bayer AG, Crop Science Division)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Chronic aquatic toxicity: Category 2

H411 Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Hazard label for supply/use required.

Hazardous components which must be listed on the label:

Fluopyram



Hazard statements

H411 Toxic to aquatic life with long lasting effects.

EUH208 Contains 1,2-benzisothiazolin-3-one, reaction mass of:

5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1). May



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produce an allergic reaction.

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P501 Dispose of contents/container in accordance with local regulation.

2.3 Other hazards

No other hazards known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Chemical nature

Suspension concentrate (=flowable concentrate)(SC) Fluopyram 400 g/l

Hazardous components

Hazard statements according to Regulation (EC) No. 1272/2008

Name	CAS-No. /	Classification	Conc. [%]
	EC-No. / REACH Reg. No.	REGULATION (EC) No 1272/2008	
Fluopyram	658066-35-4 619-797-7	Aquatic Chronic 2, H411	34,5
1,2-Benzisothiazol-3(2H)- one	2634-33-5	Skin Sens. 1, H317 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400	>= 0,005 - < 0,05
Mixture of: 5-chloro-2-methyl-4-isothi azolin-3-one and 2-methyl-4-isothiazolin-3- one	55965-84-9	Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	> 0,0002 - < 0,0015

Further information

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation Move to fresh air. Keep patient warm and at rest. Call a physician or

poison control center immediately.

Skin contact Wash off thoroughly with plenty of soap and water, if available with

polyethyleneglycol 400, subsequently rinse with water. Get medical

attention if irritation develops and persists.



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Eye contact Rinse immediately with plenty of water, also under the eyelids, for at

least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation

develops and persists.

Ingestion Do NOT induce vomiting. Call a physician or poison control center

immediately. Rinse mouth.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms No symptoms known or expected.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment Treat symptomatically. Gastric lavage is not normally required.

However, if a significant amount (more than a mouthful) has been ingested, administer activated charcoal and sodium sulphate. There is

no specific antidote.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable High volume water jet

5.3 Advice for firefighters

Special protective equipment for firefighters

In the event of fire, wear self-contained breathing apparatus.

Further information Contain the spread of the fire-fighting media. Do not allow run-off from

fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Precautions Avoid contact with spilled product or contaminated surfaces. Use

personal protective equipment.

6.2 Environmental

precautions

Do not allow to get into surface water, drains and ground water.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning upSoak up with inert absorbent material (e.g. sand, silica gel, acid binder,

universal binder, sawdust). Clean contaminated floors and objects thoroughly, observing environmental regulations. Keep in suitable,

closed containers for disposal.

6.4 Reference to other

sections

Information regarding safe handling, see section 7.

Information regarding personal protective equipment, see section 8.

Information regarding waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling



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Advice on safe handling Use only in area provided with appropriate exhaust ventilation.

Advice on protection against No special precautions required.

fire and explosion

Hygiene measures Avoid contact with skin, eyes and clothing. Keep working clothes

separately. Wash hands before breaks and immediately after handling the product. Wash hands immediately after work, if necessary take a shower. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containersKeep containers tightly closed in a dry, cool and well-ventilated place.

Store in original container. Store in a place accessible by authorized

persons only. Keep away from direct sunlight. Protect from frost.

Advice on common storage Keep away from food, drink and animal feedingstuffs.

Suitable materials HDPE (high density polyethylene)7.3 Specific end use(s) Refer to the label and/or leaflet.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components	CAS-No.	Control parameters	Update	Basis
Fluopyram	658066-35-4	0,34 mg/m3 (TWA)		OES BCS*
1,2-Propanediol	57-55-6	10 mg/m3 (TWA)	1995	ZA REL
(Particulate.)		, ,		
1,2-Propanediol	57-55-6	470 mg/m3/150 ppm (TWA)	1995	ZA REL
(Total vapour and particulates.)				

^{*}OES BCS: Internal Bayer AG, Crop Science Division "Occupational Exposure Standard"

8.2 Exposure controls

Respiratory protection Respiratory protection is not required under anticipated circumstances

of exposure.

Respiratory protection should only be used to control residual risk of short duration activities, when all reasonably practicable steps have been taken to reduce exposure at source e.g. containment and/or local extract ventilation. Always follow respirator manufacturer's

instructions regarding wearing and maintenance.

Hand protection Please observe the instructions regarding permeability and

breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the

contact time.

Wash gloves when contaminated. Dispose of when contaminated inside, when perforated or when contamination on the outside cannot be removed. Wash hands frequently and always before eating,

drinking, smoking or using the toilet.

Material Nitrile rubber



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Rate of permeability > 480 min Glove thickness > 0,4 mm Protective index Class 6

Directive Protective gloves complying with EN

374.

Eye protection Wear goggles (conforming to EN166, Field of Use = 5 or equivalent).

Skin and body protection Wear standard coveralls and Category 3 Type 6 suit.

If there is a risk of significant exposure, consider a higher protective

type suit.

Wear two layers of clothing wherever possible. Polyester/cotton or cotton overalls should be worn under chemical protection suit and

should be professionally laundered frequently.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form suspension

Colour white to beige

Odour characteristic

pH 5,5 - 8,0 at 100 % (23 ℃)

Flash point $> 85 \, ^{\circ}$ C Auto-ignition temperature $430 \, ^{\circ}$ C

Density ca. 1,16 g/cm³ at 20 ℃
Partition coefficient: Fluopyram: log Pow: 3,3

n-octanol/water

Oxidizing properties No oxidizing properties

Explosivity Not explosive

92/69/EEC, A.14 / OECD 113

9.2 Other information Further safety related physical-chemical data are not known.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Thermal decomposition Stable under normal conditions.

10.2 Chemical stability Stable under recommended storage conditions.

10.3 Possibility ofNo hazardous reactions when stored and handled according to prescribed instructions.



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10.4 Conditions to avoid Extremes of temperature and direct sunlight.

10.5 Incompatible materials Store only in the original container.

10.6 Hazardous

decomposition products

No decomposition products expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity LD50 (Rat) > 2.000 mg/kg
Acute inhalation toxicity LC50 (Rat) > 3,34 mg/l

Exposure time: 4 h

Highest attainable concentration.

Determined in the form of a respirable aerosol.

Acute dermal toxicityLD50 (Rat) > 2.000 mg/kgSkin irritationNo skin irritation (Rabbit)Eye irritationNo eye irritation (Rabbit)SensitisationNon-sensitizing. (Mouse)

OECD Test Guideline 429, local lymph node assay (LLNA)

Assessment STOT Specific target organ toxicity - single exposure

Fluopyram: Based on available data, the classification criteria are not met.

Assessment STOT Specific target organ toxicity - repeated exposure

Fluopyram did not cause specific target organ toxicity in experimental animal studies.

Assessment mutagenicity

Fluopyram was not mutagenic or genotoxic in a battery of in vitro and in vivo tests.

Assessment carcinogenicity

Fluopyram caused at high dose levels an increased incidence of tumours in rats in the following organ(s): Liver.

Fluopyram caused at high dose levels an increased incidence of tumours in mice in the following organ(s): Thyroid.

The tumours seen with Fluopyram were caused through a non-genotoxic mechanism, which is not relevant at low doses. The mechanism that triggers these tumours is not relevant to humans.

Assessment toxicity to reproduction

Fluopyram caused reproduction toxicity in a two-generation study in rats only at dose levels also toxic to the parent animals. The reproduction toxicity seen with Fluopyram is related to parental toxicity.

Assessment developmental toxicity

Fluopyram caused developmental toxicity only at dose levels toxic to the dams. The developmental effects seen with Fluopyram are related to maternal toxicity.

Further information

The toxicological data refer to a similar formulation.



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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)) > 284 mg/l

Exposure time: 96 h

Tested up to its maximum solubility.

Toxicity to aquatic invertebrates

EC50 (Daphnia magna (Water flea)) > 77,7 mg/l

Exposure time: 48 h

Tested up to its maximum solubility.

Toxicity to aquatic plants EC50 (Raphidocelis subcapitata (freshwater green alga)) 22,9 mg/l

Growth rate; Exposure time: 72 h

EC50 (Lemna gibba (gibbous duckweed)) 13,4 mg/l

Growth rate; Exposure time: 7 d

NOEC (Lemna gibba (gibbous duckweed)) 0,294 mg/l

Growth rate; Exposure time: 7 d

12.2 Persistence and degradability

Biodegradability Fluopyram:

Not rapidly biodegradable

Koc Fluopyram: Koc: 279

12.3 Bioaccumulative potential

Bioaccumulation Fluopyram: Bioconcentration factor (BCF) 18

Does not bioaccumulate.

12.4 Mobility in soil

Mobility in soil Fluopyram: Moderately mobile in soils

12.5 Results of PBT and vPvB assessment

PBT and vPvB assessment Fluopyram: This substance is not considered to be persistent,

bioaccumulative and toxic (PBT). This substance is not considered to be

very persistent and very bioaccumulative (vPvB).

12.6 Other adverse effects

Additional ecological

information

The ecological data refer to a similar formulation.

No other effects to be mentioned.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product In accordance with current regulations and, if necessary, after

consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant.



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Contaminated packaging Not completely emptied packagings should be disposed of as hazardous

waste.

SECTION 14: TRANSPORT INFORMATION

SANS 10231

14.1 UN number **3082**

14.2 Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(FLUOPYRAM SOLUTION)

14.3 Transport hazard class(es) 9
14.4 Packing group III
14.5 Environm. Hazardous Mark YES

IMDG

14.1 UN number 3082

14.2 Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(FLUOPYRAM SOLUTION)

14.3 Transport hazard class(es)
14.4 Packing group
14.5 Marine pollutant
YES

IATA

14.1 UN number **3082**

14.2 Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(FLUOPYRAM SOLUTION)

14.3 Transport hazard class(es) 9
14.4 Packing group III
14.5 Environm. Hazardous Mark YES

14.6 Special precautions for user

See sections 6 to 8 of this Safety Data Sheet.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No transport in bulk according to the IBC Code.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Further information

WHO-classification: III (Slightly hazardous)

SECTION 16: OTHER INFORMATION

Text of the hazard statements mentioned in Section 3

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.



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H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H318 Causes serious eve damage.

H331 Toxic if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.H411 Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms

ADN European Agreement concerning the International Carriage of Dangerous Goods by

Inland Waterways

ADR European Agreement concerning the International Carriage of Dangerous Goods by

Road

ATE Acute toxicity estimate

CAS-Nr. Chemical Abstracts Service number

Conc. Concentration

EC-No. European community number ECx Effective concentration to x %

EINECS European inventory of existing commercial substances

ELINCS European list of notified chemical substances

EN European Standard EU European Union

IATA International Air Transport Association

IBC International Code for the Construction and Equipment of Ships Carrying Dangerous

Chemicals in Bulk (IBC Code)
Inhibition concentration to x %

IMDG International Maritime Dangerous Goods

LCx Lethal concentration to x %

LDx Lethal dose to x %

ICx

LOEC/LOEL Lowest observed effect concentration/level

MARPOL: International Convention for the prevention of marine pollution from ships

N.O.S. Not otherwise specified

NOEC/NOEL No observed effect concentration/level

OECD Organization for Economic Co-operation and Development

RID Regulations concerning the International Carriage of Dangerous Goods by Rail

TWA Time weighted average

UN United Nations

WHO World health organisation

The information contained within this Safety Data Sheet is in accordance with the guidelines established by Regulation (EU) 1907/2006 and Regulation (EU) 2015/830 amending Regulation (EU) No 1907/2006 and any subsequent amendments. This data sheet complements the user's instructions, but does not replace them. The information it contains is based on the knowledge available about the product concerned at the time it was compiled. Users are further reminded of the possible risks of using a product for purposes other than those for which it was intended. The required information complies with current EEC legislation. Addressees are requested to observe any additional national requirements.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.