

Renewal Assessment Report

beta-cyfluthrin

Montur Forte FS 230

Volume 3 – B.4 Further information

07 March 2017

Rapporteur Member State: Germany

Co-Rapporteur Member State: Hungary

Version history

When	What

Table of contents

B.4	Further information.....	4
B.4.1	Safety intervals and other precautions to protect humans, animals and the environment	4
B.4.2	Recommended methods and precautions	5
B.4.2.1	Procedures for cleaning application equipment and protective clothing	5
B.4.2.2	Handling procedures for the storage	5
B.4.2.3	Transport	6
B.4.2.4	Fire	6
B.4.2.5	Protective clothing and equipment.....	6
B.4.3	Emergency measures in case of an accident	7
B.4.3.1	Containment of spillages.....	7
B.4.3.2	Decontamination of areas, vehicles and buildings.....	7
B.4.3.3	Disposal of damaged packaging, absorbents and other materials.....	7
B.4.3.4	Protection of emergency worker and residents, including bystanders.....	7
B.4.3.5	First aid measures	8
B.4.4	Packaging, compatibility of the plant protection product with proposed packaging materials.....	8
B.4.4.1	Packaging	8
B.4.4.2	Compatibility of the plant protection product with proposed packaging materials.....	9
B.4.5	Procedures for destruction or decontamination of the plant protection product and its packaging	9
B.4.5.1	Neutralisation procedure	10
B.4.5.2	Controlled incineration	10
B.4.6	References relied on.....	11

B.4 Further information

B.4.1 Safety intervals and other precautions to protect humans, animals and the environment

Based on the risk assessment for Montur Forte FS the risk mitigation measures/safety instructions shown in Table 4.1-1 are deemed necessary.

Table 4.1-1: Summary of risk assessment for operators, workers, bystanders and residents

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<ul style="list-style-type: none"> - Avoid any unnecessary contact with the product. Misuse can lead to health damage. - The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. - Wear standard protective gloves (plant protection) when handling/applying the product. - Wear a protective suit for plant protection products and sturdy shoes (e.g. rubber boots) when applying/handling the product. - While sacking the treated seed protective suits against pesticides and standard protective gloves (plant protection) must be worn. - While cleaning the seed dressing appliance standard protective gloves (plant protection) and a protective suit against pesticides must be worn. - Wear a rubber apron when handling the undiluted product. - Wear particle-filtering half mask FFP2 or half mask with particle filter P2 (identification colour: white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when applying/handling the product. - Wear particle-filtering half mask FFP2 or half mask with particle filter P2 (identification colour: white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when bagging the seeds. - Wear particle-filtering half mask FFP2 or half mask with particle filter P2 (identification colour: white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when cleaning the seed-dressing equipment. - The seed treatment shall only be performed in professional seed treatment facilities, which are registered in the index of "Seed Treatment Facilities with Quality Assurance Systems to Minimise Dust" of the Julius Kühn-Institute (visit the homepage of the Julius Kühn-Institute). - If the plant protection product comes into contact with skin (especially facial), it can cause burning or itching, without external signs of irritation. These effects must be regarded as a warning to avoid further exposure at all costs. If the symptoms do not disappear, or if they are joined by further symptoms, a doctor must be consulted. - Mixing/loading and seed coating must not be conducted by the same operator on one day.

	Result	PPE / Risk mitigation measures
Workers	Acceptable	<ul style="list-style-type: none"> - Wear standard protective gloves and a protective suit against pesticides when handling dressed seeds. - Wear particle-filtering half mask FFP2 or half mask with particle filter P2 (identification colour: white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when handling dressed seeds.
Bystanders	Acceptable	None
Residents	Acceptable	None

B.4.2 Recommended methods and precautions

Reference:

Anonymous (2014), Safety data sheet – beta-cyfluthrin + imidacloprid FS 230, Report No.: M-401897-04-1, Bayer CropScience (BVL no 2633232)

B.4.2.1 Procedures for cleaning application equipment and protective clothing

Statement of applicant:

All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted 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 of safely according to local regulations.

Protective clothing:

All contaminated clothing should be washed/ cleaned through 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.

Effectiveness of the cleaning procedures:

The product is removable with water and detergent, which can be used to clean surfaces effectively

B.4.2.2 Handling procedures for the storage

Advice on safe handling:

Use only in area provided with appropriate exhaust ventilation.

Hygiene measures:

Avoid contact with skin, eyes and clothing. Keep working clothes separately. 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).

Requirements for storage areas and containers:

Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Store in a place accessible by authorised persons only. Keep away from direct sunlight.

Advice on common storage:

Keep away from food, drink and animal feedingstuffs.

Suitable materials:

HDPE (high density polyethylene)

B.4.2.3 Transport

Land transport ADR/RID:	Environmentally hazardous substance, liquid, N.O.S. (beta-cyfluthrin, imidacloprid solution) UN No.: 3082; Class: 9; Packing Group: III Environm. hazardous mark: yes (hazard no.: 90, tunnel code: E)
Maritime transport IMDG:	Environmentally hazardous substance, liquid, N.O.S. (beta-cyfluthrin, imidacloprid solution) UN No.: 3082; Class: 9; Packing Group: III Marine pollutant: yes
Air transport IATA:	Environmentally hazardous substance, liquid, N.O.S. (beta-cyfluthrin, imidacloprid solution) UN No.: 3082; Class: 9; Packing Group: III Environm. hazardous mark: yes

B.4.2.4 Fire

Extinguishing media:	Water spray, Carbon dioxide (CO ₂), Foam, Sand
Special hazards arising from the substance or mixture:	In the event of fire the following may be released: Hydrogen chloride (HCl), Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Carbon monoxide (CO), Nitrogen oxides (NO _x)
Special protective equipment for fire-fighters:	In the event of fire and/or explosion do not breathe fumes. 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.

B.4.2.5 Protective clothing and equipment

General protective and hygienic measures:	In normal use and handling conditions please refer to the label and/or leaflet. In all other cases the following recommendations would apply.
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:	Wear CE Marked (or equivalent) nitrile rubber gloves (minimum thickness of 0,4 mm). Wash when contaminated and 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.
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.
If chemical protection suit is splashed, sprayed or significantly contaminated, decontaminate as far as possible, then carefully remove and dispose of as advised by manufacturer.

B.4.3 Emergency measures in case of an accident

Reference:

Anonymous (2014), Safety data sheet – beta-cyfluthrinuthrin + imidacloprid FS 230, Report No.: M-401897-04-1, Bayer CropScience (BVL no 2633233)

B.4.3.1 Containment of spillages

Person-related precaution measures: Avoid contact with spilled product or contaminated surfaces. Use personal protective equipment.
Environment precautions: Do not allow to get into surface water, drains and ground water.
Methods for cleaning up/taking up: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal. Clean contaminated floors and objects thoroughly, observing environmental regulations.

B.4.3.2 Decontamination of areas, vehicles and buildings

Please refer to B.4.3.1

B.4.3.3 Disposal of damaged packaging, absorbents and other materials

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.
Contaminated packaging: Not completely emptied packagings should be disposed of as hazardous waste.
Waste key for the unused product: 020108 (agrochemical waste containing dangerous substances)

B.4.3.4 Protection of emergency worker and residents, including bystanders

Use the recommended personal protective equipment.
No sufficient information regarding the protection of residents and bystanders in case of an emergency has been provided.

B.4.3.5 First aid measures

General information:	Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
After 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. Warm water may increase the subjective severity of the irritation/paresthesia. This is not a sign of systemic poisoning. Apply soothing eye drops, if needed anaesthetic eye drops. Get medical attention if irritation develops and persists.
After skin contact:	Immediately wash with plenty of soap and water for at least 15 minutes. Warm water may increase the subjective severity of the irritation/paresthesia. This is not a sign of systemic poisoning. In case of skin irritation, application of oils or lotions containing vitamin E may be considered. If symptoms persist, call a physician.
After inhalation:	Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center immediately.
After ingestion:	Rinse mouth. Do not induce vomiting. Call a physician or poison control center immediately.
Most important symptoms and effects, both acute and delayed:	Local:, Skin and eye paraesthesia which may be severe, Usually transient with resolution within 24 hours, Skin, eye and mucous membrane irritation, Cough, Sneezing Systemic:, Discomfort in the chest, Tachycardia, Hypotension, Nausea, Abdominal pain, Diarrhoea, Vomiting, Dizziness, Blurred vision, Headache, Anorexia, Somnolence, Coma, Convulsions, Tremors, Prostration, Airway hyperreaction, Pulmonary oedema, Palpitation, Muscular fasciculation, Apathy
Indication of any immediate medical attention and special treatment needed:	Risks: This product contains a pyrethroid. Pyrethroid poisoning should not be confused with carbamate or organophosphate poisoning. Treatment: Local treatment: Initial treatment: symptomatic. Systemic treatment: Initial treatment: symptomatic. Monitor: respiratory and cardiac functions. In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable. Keep respiratory tract clear. Oxygen or artificial respiration if needed. In case of convulsions, a benzodiazepine (e.g. diazepam) should be given according to standard regimens. If not effective, phenobarbital may be used. Contraindication: atropine. Contraindication: derivatives of adrenaline. There is no specific antidote. Recovery is spontaneous and without sequelae.

B.4.4 Packaging, compatibility of the plant protection product with proposed packaging materials

B.4.4.1 Packaging

Reference:

Forster, Heideker (2015), MCP 4.4 packaging, compatibility of the plant protection product with proposed packaging materials - Montur Forte FS 230 - beta-cyfluthrinuthrin + imidacloprid FS 230

(80+150 g/L), Report No.: M-M-538277-01-1, Bayer CropScience (BVL no 2963417)

The following containers are proposed for the product:

200 L drum:

Material:	HDPE (not packed in an outer corrugated fibre board)
Shape/size:	Tight head drum / Diam. 578 - 584 mm x Height 960 mm
Capacity:	200 litres
Size opening:	BCS 56 x 4 / 70 x 6mm, G2, G2/3
Type of closure:	Screw cap
Seal:	Crimped screw cap
Size and wall thickness:	≥ 3.6 mm
Manner of construction:	extruded, blow moulded
Application devices:	None

Suitability of the packaging and closures

Packaging materials & solutions have been tested and comply with Annex A.5 of ADR (1) respectively Annex V of RID respectively of IMDG – Code. Therefore an appropriate UN certificate has been issued and the numbers, as required by PSD (2) are provided below:

1 x 200L: i.e. UN 1H1/Y/...

Statement of compliance: The packaging complies with ADR regulations having been tested using the ADR test methods appropriate to the pack type and material and classification of the contents and an appropriate UN certificate issued.

B.4.4.2 Compatibility of the plant protection product with proposed packaging materials

References:

Gueldner, Hoppe (2014), Storage stability at elevated temperature and cold stability of beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) - Packaging material: HDPE - Final report (14 days), Report No.: M-481012-02-1, Bayer CropScience (BVL no 2963416)

Gueldner (2005), Storage stability and shelf life of Montur Forte FS 230 - (Packaging material: HDPE) - Final report, Report No.: 06200-0219, Bayer CropScience (BVL no 2633234)

The resistance of packaging material to its contents has been tested in accordance to GIFAP Technical Monograph No 17 within the shelf life studies.

No negative effects on the packaging have been observed except for a temporary ballooning immediately after removal from storage after 14 days at 54 °C (Gueldner, Hoppe (2014)). This effect was dedicated to the combination of the high temperature with the special design of the 1 Liter bottle used in the test.

As a consequence the applicant has initiated an 8 weeks testing at 40 °C, which can be submitted when available.

B.4.5 Procedures for destruction or decontamination of the plant protection product and its packaging

Combustible containers

Rinse empty containers very thoroughly with plenty of water, and either burn them in an authorised incineration plant or treat in the same way as non-combustible containers. In the case of field applications, the rinsing should be added to the spray liquids; otherwise they should also be burned in an authorised incineration plant.

Non-combustible containers

Rinse empty containers very thoroughly with plenty of water, and render them unusable by crushing or any other means to ensure that they cannot be further used. Transport these containers to a waste disposal plant. In the case of field applications, the rinsing should be added to the spray liquids; otherwise they should also be burned in an authorised incineration plant.

B.4.5.1 Neutralisation procedure

Any chemical treatment at the location of an accidental spillage would be difficult to control in terms of efficiency and safety and is therefore not recommended. In this event collect and dispose of the residues and contaminated materials through controlled incineration according to the procedure described under B.4.5.2.

B.4.5.2 Controlled incineration

References:

Volkman (2014), Imidacloprid - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions, Report No.: M-436136-01-1, Bayer CropScience (BVL no 2633237)
Bascou (2004), Imidacloprid - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions, Report No.: M-436136-01-1, Bayer CropScience (BVL no 2633236)

Since the halogen content of both active substances is below 60 %, combustion under controlled conditions at 1100 °C with residence time higher than 2 seconds and an oxygen excess higher than 6 % in a waste incineration plant is unlikely to result in the formation of halogenated dibenzo-dioxins and dibenzo-furans at unacceptable levels. Special studies are not triggered.

B.4.6 References relied on

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.2 /01 KCP 4.3 /01	Anonymous	2014	Safety data sheet - beta-cyfluthrinuthrin + imidacloprid FS 230 Bayer CropScience, Report No.: M-401897-04-1, Edition Number: M-401897-04-1 Date: 2014-03-04 GLP/GEP: no, unpublished 2633232 / 2633233	N	N		Bayer CropScience
KCP 4.4 /01	Gueldner, W.	2005	Storage Stability of Montur Forte FS 230 - (Packaging material: HDPE) - Final report Bayer CropScience, Report No.: 06200-0219, Edition Number: M-090776-02-1 Date: 2005-03-31 GLP/GEP: no, unpublished 2633234	N	N		Bayer CropScience
KCP 4.4 /02	Gueldner, W.; Hoppe, M.	2014	Storage stability at elevated temperature and cold stabil- ity of beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) - Packaging material: HDPE - Draft report (14 days) Bayer CropScience, Report No.: FM0078(ACF01)N01, Edition Number: M-481012-01-1 Date: 2014-03-25 GLP/GEP: yes, unpublished 2633235	N	Y	data not submit- ted on EU level	Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies
Black Studies indicate Supplementary Dossier Studies

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP status (where relevant), published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.4 /02	Gueldner, W.; Hoppe, M.	2014	Storage stability at elevated temperature and cold stability of beta-cyfluthrin + imidacloprid FS 230 (80+150 g/L) - Packaging material: HDPE - Final report (14 days) Bayer CropScience, Report No.: FM0078(ACF01)N01, Edition Number: M-481012-02-1 Date: 2014-04-22 GLP/GEP: no, unpublished 2963416	N	Y		Bayer CropScience
KCP 4.4 /03	Forster, C.; Heideker, H. T.	2015	MCP 4.4 packaging, compatibility of the plant protection product with proposed packaging materials - Montur Forte FS 230 - beta-cyfluthrinuthrin + imidacloprid FS 230 (80+150 g/L) Bayer CropScience Bayer CropScience, Report No.: M-538277-01-1, Edition Number: M-538277-01-1 Date: 2015-11-09 GLP/GEP: no., unpublished 2963417	N	Y		Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies
Black Studies indicate Supplementary Dossier Studies

Annex point / reference number	Author(s)	Year	Title Source <i>(where different from company)</i> Company name, Report No., Date, GLP status <i>(where relevant)</i> , published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.5.2 /01	Bascou, J. P.	2004	Beta-cyfluthrinuthrin - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience S.A., Lyon, France TF- BCS-Irvita, Report No.: MO-04-004460, Edition Number: M-066091-01-1 Date: 2004-04-23 GLP/GEP: no, unpublished 2633236	N	N		TF- BCS-Irvita
KCP 4.5.2 /02	Volkman, T.	2012	Imidacloprid - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience, Report No.: M-436136-01-1, Edition Number: M-436136-01-1 Date: 2012-08-09 GLP/GEP: no, unpublished 2633237	N	N		Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies
Black Studies indicate Supplementary Dossier Studies