Submission form for phytosanitary treatments

(Reviewed by TPPT March 2016)

Czech Republic, Central Institute for Supervising and Testing in Agriculture (UKZUZ)

Click here to find the IPPC Procedure Manual for Standard Setting on the IPP (www.ippc.int), where you can download this form.

Submission number (Secretariat Use Only):

Complete the following form, preferably in electronic format, and submit by e-mail to the IPPC Secretariat (ippc@fao.org). The call will remain open, but if you wish your submission to be considered by the TPPT in their next meeting, please send it before the 5 June 2017.

Please use one form per phytosanitary treatment. An electronic version of this form is available on the International Phytosanitary Portal (IPP) at https://www.ippc.int/en/publications/1089/. Incomplete submissions will be returned. Please save the completed submission form with the following file name: COUNTRY or RPPO NAME –Title of treatment.doc, prior to submitting to the IPPC Secretariat via e-mail. The words "Call for Phytosanitary Treatments" should be placed in the subject line of the email message.

(Text in brackets given for explanatory purposes)

Name of treatment	*Hydrogen cyanide fumigation treatment for rodents, insects and mites in containers*

Submitted by: Central Institute for Supervising and Testing in Agriculture (UKZUZ), Czech Republic

Contact:

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Treatment description

Active ingredient	Hydrogen cyanide (HCN)
Treatment type	Chemical - fumigation
Target pest	**1)** Rodents, including Norway rat (*Rattus norvegicus* Berk.), Black rat (*Rattus rattus* L.) and House mouse (*Mus musculus* L.) **2)** Insects, including: German cockroach (*Blattella germanica*) confused flour beetle (*Tribolium confusum*) red flour beetle (*Tribolium castaneum*)

	sawtoothed grain beetle (*Oryzaephilus surinamensis*) Indian meal moth (*Plodia interpunctella*) Mediterranean flour moth (*Ephestia kuehniella*) **3)** Mites, including: the flour mite (*Acarus siro*) storage mite (*Lepidoglyphus destructor*) cheese mite (*Tyrophagus putrescentiae*)
Target regulated articles	The treatment is intended for using in empty containers, without any regulated article uploaded.
Treatment schedule	Active substance- hydrogen cyanide (HCN) in preparation “Uragan D2” (new trade name BLUEFUME, hereinafter BLUEFUME). BLUEFUME is a mixture (stabilized liquid hydrogen cyanide) of approx. 98 % of hydrogen cyanide with stabilizing additives. Package: Cylinder; up to 27.5 kg of BLUEFUME Fumigation by using of pressure cylinders. Composite pressure cylinders consisting of stainless steel 316L liner and fiberglass overwrap. Cylinder is equipped with stainless steel 316L dual port valve with dip tube for liquid HCN outlet and gas port for nitrogen pressuring. Elastomeric sealing is from polychlorotrifluoroethene (PCTFE). The cylinders contain up to 27.5 kg of HCN. BLUEFUME is produced and filled into a cylinder as liquid. Due to fumigation conditions (application by spraying nozzles, temperature, pressure), the liquid evaporates (and does not condense back) and so the active substance is gas. **1) Rodents** Application rate: 10 g/m^3 Fumigation time: min 24 hrs Ventilation time: min 24 hrs **2) Insects** Application rate: 10 g/m^3 Fumigation time: min 24 hrs Ventilation time: min 24 hrs **3) Mites** Application rate: 20 g/m^3 Fumigation time: min 24 hrs Ventilation time: min 24 hrs The fumigation may be performed only by specifically trained professional personnel. Efficacy: not less than 100%
Other relevant information	X
References	**1) Rodents** a) One laboratory study in rats was performed. This acute inhalation toxicity study with hydrogen cyanide in the rat (nose-only) was performed by WIL Research Europe B.V. in 2015. Following documents relate to this study: DOC III-5.1.b_efficacy_lab_PT14

	07_HCN_WIL RESEARCH_rat report_2015 04_HCN_WIL RESEARCH_anal.method validation_2015 b) Two field studies were performed in real empty storage tray and breeding hall. These tests were performed as a part of a routine application of the biocidal product BLUEFUME by certified pest control specialist who followed the instructions on the product label (routine treatment of an infested facility using an authorized product – deratization). Following documents relate to these field studies: 05_HCN_LZD_mouse, field test_2017 Appendix H_Structure 10 Biological Report (Rattus norvegicus) **2) Insects** a) File Biological report Biological efficacy of HCN was tested at all developmental stages of German cockroach (*Blattella germanica* L., confused flour beetle (*Tribolium confusum*), red flour beetle (*Tribolium castaneum*), sawtoothed grain beetle (*Oryzaephilus surinamensis*), Indian meal moth (*Plodia interpunctella*) and Mediterranean flour moth (*Ephestia kuehniella*) in laboratory and field conditions. Real fumigation in field conditions were performed by both HCN formulations (cans and cylinders). Biological reports are attached. 100% efficacy was achieved in laboratory and field conditions. b) File DOC III These biological data was submitted for evaluation of successful biocidal registration. There are summaries of HCN efficacy on above mentioned pest species and summary study from field test. **3) Mites** a) File Biological report Biological efficacy of HCN was tested at all developmental stages of the flour mite (*Acarus siro*), storage mite (*Lepidoglyphus destructor*) and cheese mite (*Tyrophagus putrescentiae*)) in laboratory and field conditions. Real fumigation in field conditions were performed by both HCN formulations (cans and cylinders). Biological reports are attached. 100% efficacy was achieved in laboratory and field conditions. b) File DOC III These biological data was submitted for evaluation of successful biocidal registration. There are summaries of HCN efficacy on above mentioned pest species and summary study from field test. Safety data sheets for BLUEFUME - cylinders Validation report confirms the suitability of GC method in laboratory conditions and IR method in field conditions

The following form must be completed in accordance with ISPM 28 *Phytosanitary treatments for regulated pests*, the IPPC Strategic Framework and the *Procedure and criteria for identifying topics for inclusion in the IPPC standard setting work programme*.

Copies of all relevant supporting information and publications should be supplied with the treatment submission, preferably in PDF format, for ease of subsequent distribution.

The following form refers to the relevant sections of ISPM 28 and are numbered accordingly.

3.2 Efficacy data in support of the submission of a phytosanitary treatment

1) Rodents insect pests

Efficacy data are based on laboratory and field tests and studies which were submitted to support for biocidal registration of stabilized hydrogen cyanide (biocidal product BLUEFUME) as product time – PT14.

2) Insects

Efficacy data are based on laboratory and field tests and studies which were submitted to support for biocidal registration of stabilized hydrogen cyanide (biocidal product BLUEFUME) as product time – PT18.

3) Mites

Efficacy data are based on laboratory and field tests and studies which were submitted to support for biocidal registration of stabilized hydrogen cyanide (biocidal product BLUEFUME) as product time – PT18.

Overview of all support submitted documents is attached to this form.

3.2.1 Efficacy data under laboratory/controlled conditions (Treatments may be considered without efficacy data under laboratory/controlled conditions if sufficient efficacy data is available from the operational application of the treatment (section 3.2.2) and if no data under laboratory/controlled conditions exists this section may be left blank.)

Pest information

Identity of the pest to the appropriate level, life stage, and if a laboratory or field strain was used

1) Rodents

5 Males and 5 females of laboratory rats
Rat: Crl:WI(Han) (outbred, SPF-Quality, recognised by international guidelines as the recommended test system (e.g. OECD, EC) Source: Charles River Deutschland, Sulzfeld, Germany
young adult animals (9 weeks old), body weight variation did not exceed +/- 20% of the sex mean

2) Insects

German cockroach (*Blattella germanica* L.) – 1^{s}t-2nd instar nymph; 3rd-4th instar nymph, male and female

confused flour beetle (*Tribolium confusum*) - (egg, larva, pupa, adult)

Indian meal moth (*Plodia interpunctella*) - (egg, larva, pupa, adult)

Mediterranean flour moth (*Ephestia kuehniella*) - (egg, larva, pupa, adult)

red flour beetle (*Tribolium castaneum*) - (egg, larva, pupa, adult)

sawtoothed grain beetle (*Oryzaephilus surinamensis*) - (egg, larva, pupa, adult)

3) Mites

the flour mite (*Acarus siro*) – (egg, nymph, adult)

storage mite (*Lepidoglyphus destructor*) – (egg, nymph, adult)

cheese mite (*Tyrophagus putrescentiae*) – (egg, nymph, adult)

Conditions under which the pests are cultured, reared or grown

1) Rodents

Conditions
Environmental controls for the animal room were set to maintain 18 – 24°C, a relative humidity of 40 to 70%, at least 10 air changes/hour, and a 12-hour light/12-hour dark cycle. Any variations to these conditions were maintained in the raw data and had no effect on the outcome of the study.

Accommodation
Group housing of five animals per sex per cage in labelled Makrolon cages (type iv; height 18 cm) containing sterilized sawdust as bedding material (Lignocel S 8-15, JRS – J.Retternaier & Söhne GmbH + CO. KG, Rosnberg, Germany) and paper as cage-enrichment (Enviro-dri, Wm. Lillico & Son (Wonjam Mill Ltd), Surrey, United Kingdom).
Acclimatisation period was at least 5 days before start of treatment under laboratory conditions.

Diet
Free access to pelleted rodent diet (SM R/M-Z from SSNIFF® Spezialdiäten GmbH, Soest, Germany) except during exposure to the test substance.

Water

Free access to tap water except during exposure to the test substance.

Animal husbandry on the day of exposure
The animals were moved to the inhalation area to in order to perform the exposure. During the exposure, there was no access to food and water. After exposure, the surviving animals were returned to their cages which were placed in a fume cupboard to allow test substance remnants to evaporate.

Diet, water, bedding and cage enrichment evaluation for contaminants and/or nutrients was performed according to facility standard procedures. There were no findings that could interfere with the study.

2) Insects
All species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

3) Mites
All species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

Biological traits of the pest relevant to the treatment

X

Method of natural or artificial infestation

1) Rodents
Artificial - laboratory test of laboratory species of rats

2) Insects
Artificial - all species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

3) Mites
Artificial - all species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

Determination of most resistant species/life stage (in the regulated article where appropriate)

Details of tests are described in attached biological reports for individual species.

Regulated article information

Type of regulated article and intended use

1) Rodents
Any articles were not used because this study was provided as an acute inhalation toxicity with hydrogen cyanide in the rat (nose-only)

2) Insects
Any articles were not used. These tests were provided as efficacy tests.

3) Mites
Any articles were not used. These tests were provided as efficacy tests.

Botanical name for plant or plant product (where applicable)

X

Conditions of the plant or plant product

X

Experimental parameters

Level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation

1) Rodents
The study was performed in GLP regime.

Observations/measurements in the study were recorded electronically using the following programs:

- REES Centron Environmental Monitoring system version SQL 2.0 (REES Scientific, Trenton, NJ, USA): Environmental monitoring.
- TOXDATA version 8.0 (WIL Reaserch Europe B.V., ´s-Hertogenbosch, The Netherlands): Mortality / Body weights. Clinical signs during exposure or not defined in TOXDATA were recorded manually.

System control, data acquisition and data processing was performed using the following programme:

- MassHunter GCMS Version B.07 (Agilent Technologies, Palo Alto, CA, USA)

2) Insects

95% LC

The results were statistically evaluated using statistical program XLSTAT (Addinsoft, France, Paris, France) by regression of mortality model (χ2-test) for LT_{50} and LT_{99} and using statistical program STATISTICA 12 (Statsoft, USA) by ANOVA statistical model for repeated measurements.

The results of the biological tests were evaluated in cooperation with:

Crop Research Institute (CRI)
Drnovská 507
Prague 6
Czech Republic - 161 06

3) Mites

95% LC

The results were statistically evaluated using statistical program XLSTAT (Addinsoft, France, Paris, France) by regression of mortality model (χ2-test) for LT_{50} and LT_{99} and using statistical program STATISTICA 12 (Statsoft, USA) by ANOVA statistical model for repeated measurements.

The results of the biological tests were evaluated in cooperation with:

Crop Research Institute (CRI)
Drnovská 507
Prague 6
Czech Republic - 161 06

Experimental facilities and equipment

1) Rodents

The study was performed in WIL Research Europe B.V., The Netherlands

In study were used following equipment:

- Exposure chamber (design of the xposure chamber is based on the flow past nose-noly inhalation chamber - Am. Ind. Hyg Assoc. J. 44(12): 923-928, 1983; volume approximately 150 mL)
- Gas chromatograph 7890B (Agilent Technologie, Palo Alto, CA, USA), Mass selective detector (MSD) 5977A (agilent Technologies); Column- CP-porabond Q, 25 m x 250 µm i.d., d_f = 3 µm (Varian Chrompack International, Middelburg, The Netherlands)

2) Insect pests

All experiments were performed in a fumigation chamber localised within the Draslovka Kolín a.s.
Unique hermetical fumigation chamber (size 120x90x60cm, made of stainless steel sheets, (material 17240) with a thickness of 2 mm);
gas chromatograph (Shimadzu GC-17A, RT-QPLOT, 30 m, ID 0.53 mm,GC Software Clarity DataApex, Kyoto, Japan);
statistical analysis (two way and one-way ANOVA, regression analysis; Statistica 12, StatSoft, Inc., Tulsa, USA, 2013);
and common laboratory equipment.

3) Mites

All experiments were performed in a fumigation chamber localised within the Draslovka Kolín a.s.
Unique hermetical fumigation chamber (size 120x90x60cm, made of stainless steel sheets, (material 17240) with a thickness of 2 mm);
gas chromatograph (Shimadzu GC-17A, RT-QPLOT, 30 m, ID 0.53 mm,GC Software Clarity DataApex, Kyoto, Japan);
statistical analysis (two way and one-way ANOVA, regression analysis; Statistica 12, StatSoft, Inc., Tulsa, USA,

2013);
and common laboratory equipment.

Experimental design

1) Rodents

The study was designed to follow a step wise exposure scenario. The target concentrations were selected based on the cut off concentration values specified in the UN and EC classification guidelines for gases (100, 500, 2500 or 20000 ppm). Based on the test substance data, the study was initiated with the exposure of five animals of each sex for 4 hours to a target concentration of 100 ppm (112 µg/L). Based on the results, no further exposure levels were tested at the request of the Sponsor.
The design of the exposure chamber is based on the flow past nose-only inhalation. The chamber (volume approximately 150 mL) consisted of three animal sections with eight animal ports each. Each animal port had its own atmosphere inlet and exhaust outlet. The animals were placed in restraining tubes and connected to the animal ports. The number of animal sections and number of open inlets were adapted to the air flow in such a way that at each animal port the theoretical air flow was at least 1 L/min, which ensures an adequate oxygen supply to the animals. The main inlet of the test atmosphere was located at the top section and the main outlet was located at the bottom section. The direction of the flow of the test atmosphere guaranteed a freshly generated atmosphere for each individual animal.
Prior to exposure the animals were restrained in polycarbonate restraining tubes; these tubes were connected to the exposure chamber. Eighteen minutes after the last animal was placed the generation of the test atmosphere was started. The exposure time was 4 hours.

2) Insects

HCN fumigation of samples containing above mentioned pest species. Details of tests are described in attached reports for individual species.

General experimental design:
Testing took place in a small fumigation chamber with the volume of 650 liters. The tests monitored the efficacy of BLUEFUME with active substance hydrogen cyanide (HCN) in the initial dose of 1.1 g/m3 on the developmental stages of all pest species. During testing, the temperature was maintained in the range of 19 - 24 °C. Efficacy monitoring was performed in several exposure times, in range 15 - 300 minutes. Each developmental stage was divided into groups (group number depends on pest species) and experiments were repeated (number of repetitions depends on pest species).

The studies were designed to determine:

1. Determine the efficacy on the various developmental stages of the tested species and to determine LT50, LT99 and CT products in a laboratory fumigation chamber.
2. Verify the efficacy of BLUEFUME with active substance hydrogen cyanide (HCN) on the tested species in field conditions during a treatment of a whole building.

Result:

1. LT_{50} and LT_{99} values were determined for the developmental stages of all pest spieces mentioned above and 1 initial concentration (i.e. 1 000 ppm of HCN).
2. CT values were determined for the developmental stages of of all pest spieces mentioned above

Details of tests are described in attached reports for individual species.

3) Mites

HCN fumigation of samples containing above mentioned pest species. Details of tests are described in attached reports for individual species.

General experimental design:
Testing took place in a small fumigation chamber with the volume of 650 liters. The tests monitored the efficacy of BLUEFUME with active substance hydrogen cyanide (HCN) in the initial dose of 1.1 g/m3 on the developmental stages of all pest species. During testing, the temperature was maintained in the range of 19 - 24 °C. Efficacy monitoring was performed in several exposure times, in range 15 - 720 minutes. Each developmental stage was divided into groups (group number depends on pest species) and experiments were repeated (number of repetitions depends on pest species).

The studies were designed to determine:

3. Determine the efficacy on the various developmental stages of the tested species and to determine LT50, LT99 and CT products in a laboratory fumigation chamber.

4. Verify the efficacy of BLUEFUME with active substance hydrogen cyanide (HCN) on the tested species in field conditions during a treatment of a whole building.

Result:

3. LT_{50} and LT_{99} values were determined for the developmental stages of all pest spieces mentioned above and 1 initial concentration (i.e. 1 000 ppm of HCN).
4. CT values were determined for the developmental stages of of all pest spieces mentioned above

Details of tests are described in attached reports for individual species.

Experimental conditions

1) Rodents

HCN concentration: 0-100 ppm
Temperature values in chamber during exposures were between 21.1 – 21.8°C
Relative humidity was 9%

2) Insects

Hydrogen cyanide (HCN) in the initial dose of 1.1 g/m3.
During testing, the temperature was maintained in the range of 19 - 24 °C. Efficacy monitoring was performed in several exposure times, 15-300 minutes.
fumigation time: depends on experiment; sampling: depends on experiment (see attached reports)

3) Mites

Hydrogen cyanide (HCN) in the initial dose of 1.1 g/m3.
During testing, the temperature was maintained in the range of 19 - 24 °C. Efficacy monitoring was performed in several exposure times, 15-720 minutes.
fumigation time: depends on experiment; sampling: depends on experiment (see attached reports)

Monitoring of critical parameters

1) Rodents

Details of measuring of HCN concentrations is described in attached report 07_HCN_WIL RESEARCH_rat report_2015.

2) Insects

Values of HCN concentration inside of the fumigation chamber were measured by GC technique (Shimadzu GC-17A, RT-QPLOT, 30 m, ID 0.53 mm, GC Software Clarity DataApex).

3) Mites

Values of HCN concentration inside of the fumigation chamber were measured by GC technique (Shimadzu GC-17A, RT-QPLOT, 30 m, ID 0.53 mm, GC Software Clarity DataApex).

Methodology to measure the effectiveness of the treatment

1) Rodents

Mortality/Viability: Twice daily. Animals showing pain, distress or discomfort, which was considered not transient in nature or was likely to become more severe, were sacrificed for humane reasons based on OECD guidance document on humane endpoints (ENV/JM/MONO/2000/7). The time of death was recorded as precisely as possible.
Clinical signs – During exposure: Three times during exposure for mortality, behavioural signs of distress and effects on respiration.
Clinical signs – After exposure: On Day 1 only, since no animal survived this day. The clinical signs were graded according to fixed scales and the time of onset, degree and duration were recorded: Maximum grade 4: grading slight (1) to very severe (4); Maximum grade 3: grading slight (1) to severe (3); Maximum grade 1: presence is scored (1).
Body weights – Days 1 (pre-administration)
Necropsy: The moribund animals were sacrificed by an intraperitoneal injection with Euthasol® (AST Farma BV, Oudewater, The Netherladns). All animals assigned to the study were subjected to necropsy and descriptions of all internal macroscopic abnormalities were recorded. Particular attention was given to any changes in the respiratory tract.

Results:
None of the animals survived the day of exposure (Day 1). Two females were found dead during exposure and two males and one female were found dead at completion of the exposure period. One female was found dead and the remaining two males and two females were sacrificed for ethical reasons, 1 hour after exposure.
The inhalatory LC50, 4h value of Hydrogen cyanide in Wistar rats was established to be below 100 ppm (112 ug/L).

2) Insects

HCN fumigation of samples containing above mentioned pest species. Details of tests are described in attached reports for individual species.

After the end of the experiment, all the dishes were ventilated and after the experiment, check of mortality all developmental stages was performed. The results were statistically evaluated using statistical program XLSTAT (Addinsoft, France, Paris, France) by regression of mortality model (χ2-test) for LT50 and LT99 and using statistical program STATISTICA 12 (Statsoft, USA) by ANOVA statistical model for repeated measurements.

100% efficacy at all developmental stages was achieved in samples during all tests in real fumigations.

3) **Mites**

HCN fumigation of samples containing above mentioned pest species. Details of tests are described in attached reports for individual species.

After the end of the experiment, all the dishes were ventilated and after the experiment, check of mortality all developmental stages was performed. The results were statistically evaluated using statistical program XLSTAT (Addinsoft, France, Paris, France) by regression of mortality model (χ2-test) for LT50 and LT99 and using statistical program STATISTICA 12 (Statsoft, USA) by ANOVA statistical model for repeated measurements.

100% efficacy at all developmental stages was achieved in samples during all tests in real fumigations.

Determination of efficacy over a range of critical parameters, where appropriate
X
Methodology to measure phytotoxicity, when appropriate
X
Dosimetry system, calibration and accuracy of measurements,

1) Rodents

It is described in 04_HCN_WIL RESEARCH_anal. method validation_2015.

2) Insects

Accuracy of measurement of above-mentioned gas chromatograph is ± 0,05 vol. %.
Method is described in attached in file validation analytical report- GC validation_analytical report.

3) Mites

Accuracy of measurement of above-mentioned gas chromatograph is ± 0,05 vol. %.
Method is described in attached in file validation analytical report- GC validation_analytical report.

3.2.2 Efficacy data using operational conditions (historical data, may in some cases substitute for the requested information below)
Pest information
Identity of the pest to the appropriate level, life stage, and if a laboratory or field strain was used

1) Rodents

Mus musculus, natural population

2) Insects

The same pest species were tested in field conditions. The total of two field tests for each below mentioned pest species were performed verify the efficacy of the product applied from cans and applied from cylinders.

Details of all tests are described in attached biological reports and summary report 2015 and summary report 2017.

German cockroach (*Blattella germanica* L.) –nymph, male and female

confused flour beetle (*Tribolium confusum*) - (egg, larva, pupa, adult)

Indian meal moth (*Plodia interpunctella*) - (egg, larva, pupa, adult)

Mediterranean flour moth (*Ephestia kuehniella*) - (egg, larva, pupa, adult)

red flour beetle (*Tribolium castaneum*) - (egg, larva, pupa, adult)

sawtoothed grain beetle (*Oryzaephilus surinamensis*) - (egg, larva, pupa, adult)

3) Mites

The same pest species were tested in field conditions. The total of two field tests for each below mentioned pest species were performed verify the efficacy of the product applied from cans and applied from cylinders.

Details of all tests are described in attached biological reports and summary report 2015 and summary report 2017.

flour mite (*Acarus siro*) – (egg, nymph, adult)
storage mite (*Lepidoglyphus destructor*) – (egg, nymph, adult)
cheese mite (*Tyrophagus putrescentiae*) – (egg, nymph, adult)

Conditions under which the pests are cultured, reared or grown

1) Rodents

Details about origin of rodents were unknown because all strains of rodents constituted natural population.

2) Insects

All species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

3) Mites

All species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

Biological traits of the pest relevant to the treatment

1) Rodents

Commonly occurring wild rodents

2) Insects

X

3) Mites

X

Method of natural or artificial infestation

1) Rodents

natural infestation – facility naturally infested by house mouse in field conditions

2) Insects

Artificial - all species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

3) Mites

Artificial - all species which were mentioned above came from the strain bred in the Crop Research Institute and were kept under laboratory conditions for several generations.

Determination of most resistant species/life stage (in the regulated article where appropriate)

1) Rodents

In case of rodents - all stages are equally sensitive

2) Insects

X

3) Mites

X

Regulated article information

Type of regulated article and intended use

1) Rodents

To be used by trained professionals only.
The treatment is intended for using in empty containers, without any regulated article uploaded.

2) Insect pests

The treatment is intended for using in empty containers, without any regulated article uploaded.

3) Wood boring pests

The treatment is intended for using in empty containers, without any regulated article uploaded.

Botanical name for plant or plant product (where applicable)

X

Conditions of the plant or plant product

X

Experimental parameters

Level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation

1) Rodents

The results of the biological tests were evaluated in cooperation with:

Crop Research Institute (CRI)
Drnovská 507
Prague 6
Czech Republic - 161 06

2) Insects

95% LC

The results of the biological tests were evaluated in cooperation with:

Crop Research Institute (CRI)
Drnovská 507
Prague 6
Czech Republic - 161 06

3) Mites

95% LC

The results of the biological tests were evaluated in cooperation with:

Crop Research Institute (CRI)
Drnovská 507
Prague 6
Czech Republic - 161 06

Experimental facilities and equipment

1) Rodents

The application was performed by a professional pest control company licensed for professional fumigation.

2) Insects

The application was performed by a professional pest control company licensed for professional fumigation.

3) Mites

The application was performed by a professional pest control company licensed for professional fumigation.

Experimental design

1) Rodents

Test was performed in one single- floor building determined for poultry and egg farming in furnished cages.

Whole building was covered from outside by silage foil (in 50 x 18 m reels). The foil was unwrapped from the reel across the whole width of the roof and was cut when long enough that touched the ground. The foil was then unfolded and attached to another foil strip by means of clamps. This procedure was repeated on the whole surface of the roof. On the ground and on the roof, sandbags were used to weigh down the foil. The building gables were covered with two pieces of foil clamped together. The conveyor route leading to a sump near the building was sealed using bags filled with straw and silage foil pieces.

BLUEFUME was applied from cylinders. The dosage was calculated using the “volume under the foil” (i.e. the volume of the building + adjacent space next to it covered with the foil). The sealed volume was greater than the volume of the farm building – it increased to 7000 m^3. The total of 7 kg BLUEFUME was applied (i.e. 10 g/m^3).

The planned duration of the treatment was 24 hours. Cleaning began after ventilation; during this activity the number of dead mice was counted.

2) Insects

Two test were performed for each pest species; in first was used the formulation of BLUEFUME in pressure cylinders and in second was used the formulation of BLUEFUME in cans. The application of BLUEFUME was performed according to the Fumigation manuals (for application by cylinders and cans). Application rate of 10 g/m^3 was used in all tests and application doses were calculated from cubic capacity of structures.

Measurement of HCN concentration was performed by IR detector (model 7300A, producer Teledyne Analytical Instruments).

Detailed description of test designs are written in summary report 2017 and biological reports.
The validation protocol of IR method is attached in support file.

3) Mites

Two test were performed for each pest species; in first was used the formulation of BLUEFUME in pressure cylinders and in second was used the formulation of BLUEFUME in cans. The application of BLUEFUME was performed according to the Fumigation manuals (for application by cylinders and cans). Application rate of 10 g/m^3 was used in all tests and application doses were calculated from cubic capacity of structures.

Measurement of HCN concentration was performed by IR detector (model 7300A, producer Teledyne Analytical Instruments).

Detailed description of test designs are written in summary report 2017 and biological reports.
The validation protocol of IR method is attached in support file.

Experimental conditions

1) Rodents

Temperature and relative humidity: Temperature and relative humidity were measured with automatic digital meters located inside and outside the building. During the treatment the average outside temperature was 2.7 ± 0.49°C (range -1.8 – 11.9°C) and relative humidity 81.9 ± 1.95 % (range 47.3 – 100%). Inside the building the average temperature during the treatment was 11.0 ± 0.39°C (range 8.1 – 16.5°C) and relative humidity 86.1% ± 1.16% (range 74.9 – 98.2%).

2) Insects

H The values of temperature and relative humidity were measured by dataloggers (producer Gemini DATA LOGGERS, type Tinytag Plus IS Dual Channel Temperature/Relative Humidity (-40 to +85°C (0 to 100% RH)).

There are written ranges of values of temperature and relative humidity from all performed tests:
Temperature values were in range: 14.8 °C – 25.5 °C
Relative humidity values were in range: 47.6% - 100.0%

Details of tests are described in attached reports for individual species and summary report 2017.

3) Mites

The values of temperature and relative humidity were measured by dataloggers (producer Gemini DATA LOGGERS, type Tinytag Plus IS Dual Channel Temperature/Relative Humidity (-40 to +85°C (0 to 100% RH)).

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Temperature values were in range: 14.8 °C – 25.5 °C
Relative humidity values were in range: 47.6% - 100.0%

Details of tests are described in attached reports for individual species and summary report 2017.

Monitoring of critical parameters

1) Rodents

HCN concentration during fumigation – Analytical method for measuring gas concentration using infrared spectroscopy was used. measured by detector Teledyne Analytical Instruments Model 7300A – calibrated by producer for HCN

2) Insect pests

The most important parameter of fumigation is concentration of active substance HCN.
Therefore, HCN concentration values during each tests were measured by IR detector (model 7300A, producer Teledyne Analytical Instruments).

Details of tests are described in attached reports for individual species and summary report 2017.

3) Wood boring pests

The most important parameter of fumigation is concentration of active substance HCN.
Therefore, HCN concentration values during each tests were measured by IR detector (model 7300A, producer Teledyne Analytical Instruments).

Details of tests are described in attached reports for individual species and summary report 2017.

Methodology to measure the effectiveness of the treatment

1) Rodents

Feeding method – before the treatment was count quantity of all rodents by consumed amount from baits. The same procedure was repeated after treatment. Theoretical and practical methods were used. Theoretical number of death rodents was counted from excess of feed. As this theoretical method is not absolutely suitable for fumigation, therefore, practical method was used- number of death rodents was count during cleaning of the structure.

2) Insects

After the end of the fumigation and ventilation of structures were checked mortality of all biological samples (all species and developmental stages).
The results were statistically evaluated using statistical program STATISTICA 12 (Statsoft, USA) by ANOVA statistical model for repeated measurements.

Even though the theoretical concentration under field conditions was achieved only for the duration of 275 - 700 minutes (application from cans) and for 105 - 750 minutes (application from cylinders), the mortality in all pests in the structures reached 100 % even at lower temperatures (8.4 - 10.9 °C, Structure 10- see summary report 2017). These results prove that biological efficacy of BLUEFUME is excellent and a 24-hour fumigation is fully sufficient.

Details of tests are described in attached reports for individual species and summary report 2017.

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Details of tests are described in attached reports for individual species and summary report 2017.

Determination of efficacy over a range of critical parameters, where appropriate

X

Methodology to measure phytotoxicity, when appropriate

X

Dosimetry system, calibration and accuracy of measurements

IR method was used in field tests. Suitability of IR method for measurement of HCN is confirmed in attached Validation report.

Factors that affect the efficacy of the treatment

HCN concentration and amount of sorption materials
Due to toxicologist properties of HCN depends mainly on ensurement of product dosage.

Special procedures that affect the success of the treatment, if applicable

X

3.3 Feasibility and applicability (Information should be provided where appropriate on the following items)

Procedure for carrying out the phytosanitary treatment

Fumigation is provided by a professional pest control company licensed for professional fumigation.

Approved by the National Authority for Biocide Registration as a biocidal preparation of the type:

Type 14 – Rodenticides
Preparations used for the regulation of mouse, rat and other rodent populations.
Does not include preparation used exclusively for the protection of plants on agricul-tural fields and plant products stored temporarily on fields.

Type 18 – Insecticides, acaricides and products for control of other arthropods. Control of arthropods populations (e.g. insect, mites, ticks, spiders, crustaceans), in empty structures

Cost of typical treatment facility and operational running costs if appropriate

The price is not available, however, it may be provided later following an agreement with a professional company carrying out fumigation.

Commercial relevance, including affordability

Costs of using hydrogen cyanide are lower than of using methyl bromide.

Extent to which other NPPOs have approved the treatment as a phytosanitary measure

X

Availability of expertise needed to apply the phytosanitary treatment

x

Versatility of the phytosanitary treatment

The preparation BLUEFUME (active substance hydrogen cyanide) is registered as a biocide in 13 states of EU, but is fully adaptable to the usage for phytopathological treatment.

In terms of its originality – efficiency, capacity and rate of the application process, BLUEFUME with hydrogen cyanide as the active substance has no comparable and acceptable alternative regarding the health protection (substance without CMR effects on humans), environmental protection and social-economical aspects.

BLUEFUME is in selected areas of usage a fully effective substitute for methyl bromide. HCN is not classified as substance hazardous to the ozone layer, and is a very important strategic material for the Czech Republic.

BLUEFUME is the only fully effective substitute for methyl bromide in the above mentioned usages.

The degree to which the phytosanitary treatment complements other phytosanitary measures

Due to simplicity of use and high efficacy to many species and developmental stages of various pests is usage seeming like a full-fledge substitute of methyl bromide. Moreover due to smaller structure of molecule HCN offers more possible field of application.

Summary of available information of potential undesirable side-effects

Human exposure may occur by inhalation of hydrogen cyanide vapours or absorption through the skin upon contamination of work clothing by vapours or liquid hydrogen cyanide.
The risk of exposure applies to workers in the production when exposure limits are exceeded, or in case of accident.
Workers carrying out fumigation shall use protective equipment; exposure should not occur if operating procedure is observed.
Bystanders or other persons may not be exposed to hydrogen cyanide, since it is intended only for professional use in empty secured spaces.
Due to the form in which hydrogen cyanide is supplied – pressure cylinder – accidental exposure of employees or other persons is beyond consideration.

Professional exposure
Since hydrogen cyanide is applied as gas, its main route of entry is inhalation and dermal exposure.
HCN is intended to be used for fumigation – to control insect pests and smaller rodents in closed structures and insect pests damaging various natural materials (in gas-tight application chambers).

If used professionally as intended, no adverse impacts to humans or animals, except target organisms, are expected.

Risks for employees in production, fumigation workers and bystanders
The risk of inhalation of hydrogen cyanide during production and processing is minimised by automatic monitoring of the workplace atmosphere and signalisation of danger if permissible exposure limits are exceeded. Employees shall use specified personal protective equipment.

Workers carrying out fumigation shall use protective equipment and personal detectors and are bound to strictly observe specified operating procedures.

Hydrogen cyanide is intended for authorised professional use only. It may be neither sold nor provided in any other way to unauthorised persons, including unauthorised persons from among professional users. The initial exclusion zone is set to protect bystanders and other once-in-a-lifetime exposed persons (limit 3 mg/m3). If specified

organisational measures, ensuring that non-professional users will not come into contact with HCN as the result of uncontrolled entry into fumigated area, or ingestion of food or drinks treated with HCN, are observed, exposure of non-professional users does not occur. In consequence of absent possibilities of exposure, hydrogen cyanide as fumigant does not present any real risk to the health of non-professional users.
Applicability of treatment with respect to specific regulated article/pest combinations
The 100% effective against all species of rodents occurring individually or in various combinations due to more- times higher applicate dosage than is the LC_{50} of rodents.
Technical viability
BLUEFUME shall be stored in dry, cool, ventilated, separate storeroom. Due to the danger or accidental release of HCN, only personnel authorised to handle HCN may enter the storeroom, and only with a gasmask with suitable filter and a measuring device. Keep container tightly closed. Use explosion-proof electrical/ventilating/light/equipment. Take precautionary measures against static discharge. Shelf life At site practice storage stable. No decomposition. The shelf-life of BLUEFUME is set to 12 months.
Phytotoxicity and other effects on the quality of regulated articles, when appropriate
X
Consideration of the risk of the target organism having or developing resistance to the treatment
Due to toxicologist properties of HCN, by this time, no case of resistance has been proven.

Send submissions to:

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(preferred)

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