B.9.4 Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.3.2)

B.9.4.1 Acute toxicity to bees (Annex IIA 8.3.1.1)

Effect of Reg. No. 242 009 on the honeybee (*Apis mellifera* L.) in laboratory trials. (Künast Ch., 1992).

Guidelines :
UK Working Document 7/3 (1986)
GLP :
Yes
Material and Methods :
Test substance : kresoxim-methyl; purity: 93.7 %; batch: N 36
Test species : honeybees (*Apis mellifera* L.); worker bees
Number of organisms : 10 bees X 3 replicates/concentration
Type of test : acute oral and contact toxicity test (48 hours)
Applied concentrations : solvent control; 2.5, 5, 10, 15, 20 µg a.s./bee (nominal); positive control : Perfekthion (400 g Dimethoate/L)
Exposure route :
- Oral test : test substance (dispersed in sugar/water solution) was fed (0.2 mL per replicate, corresponding to 20 µL/bee) for 4 hours; then untreated solution was provided ad libitum
- Contact test : with CO_2 immobilized bees were individually dosed on the ventral thorax with a dose of 1 µL/bee
Feeding : invert sugar/water solution (1:1)
Test conditions :
temperature : 20.5 - 23.5 °C
Findings :
Mortality : In the oral test mortality was present in all the treatments but irregular and not dose-related.
In the contact test mortality was low and not dose-related.
Endpoints :
LD_{50} (*Apis mellifera*, 48 h) contact > 20 µg a.s./bee (nominal) (highest concentration tested)
NOEL (*Apis mellifera*, 48 h) contact = 20 µg a.s./bee (nominal)
LD_{50} (*Apis mellifera*, 48 h) oral = 14 µg a.s./bee (nominal)
NOEL (*Apis mellifera*, 48 h) oral < 2.5 µg a.s./bee (nominal)
Conclusion :
The study is acceptable.

Added in March 2010:

A new acute contact and oral toxicity study with honey bees according to current guidelines OECD 213/214 was performed to meet the requirements of current regulations. Also higher concentrations were tested in this study. The new study replaces the old study (Künast, 1992).

Effects of BAS 490 F (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory. (Schmitzer S. and Sekine T., 2008).

Guidelines :
OECD Guideline 213: Honeybees, Acute Oral Toxicity Test
OECD Guideline 214: Honeybees, Acute Contact Toxicity Test
EEC 96/12
EEC 91/414
GLP :
Yes
Material and Methods :
Test substance : kresoxim-methyl, chemical purity: 97.8 ± 1.0 %, batch: COD-000225
Test species : Apis mellifera carnica L., female worker honey bees
Number of organisms : 5 replicates/treatment, each containing 10 bees
Type of test : acute oral (48 h) and contact (48 h) toxicity test
Applied concentrations :
Oral test : control (aqueous sugar solution); solvent control (aqueous sugar solution with acetone); 111.0 µg a.s./bee (measured); positive control (0.06, 0.08, 0.15, 0.28 µg dimethoate/bee, measured)
Contact test : control (water with 0.5 % adhäsit); solvent control (acetone); 100.0 µg a.s./bee (nominal); positive control (0.10, 0.15, 0.20, 0.30 µg dimethoate/bee, nominal)
Exposure route :
Oral test : Appropriate amounts of kresoxim-methyl and dimethoate were mixed with syrup in order to achieve the required test concentrations in a final dilution of 50 % syrup solution (45 % water, 50 % syrup and 5 % acetone). For the water control a 50 % (w/w) aqueous sugar solution was used and for the solvent control a 50 % sugar solution (45 % water, 5 % acetone, 50 % sugar) was used. The bees were starved for 15 minutes for all treatment groups prior to application. The target dose level was 100.0 µg a.s./bee (nominal).
Contact test : Bees were anaesthetized for *ca*. 20 seconds with CO_2. A single 5 µL droplet of kresoxim-methyl in an appropriate carrier (tap water + 0.5 % Adhäsit) was placed on the dorsal bee thorax. For the water control one 5 µL droplet of tap water with 0.5 % Adhäsit was used and for the solvent control pure acetone was used. The positive control was also applied in a 5 µL droplet (dimethoate made up in acetone).
Feeding : commercial ready-to-use syrup (30 % saccharose, 31 % glucose and 39 % fructose) *ad libitum*
Test conditions :
temperature : 25 – 26 °C
relative humidity : 37 – 70 %
light : darkness
Findings :
In the oral toxicity test there was no mortality at 111.0 µg a.s./bee. In the contact toxicity test 2 % mortality was recorded after 48 hours at 100.0 µg a.s./bee. No test item related behavioural abnormalities occurred.
In the positive control adequate mortality was observed.
LD_{50} (*Apis mellifera*, 24 h) oral = 0.15 µg dimethoate/bee
LD_{50} (*Apis mellifera*, 24 h) contact = 0.22 µg dimethoate/bee
Conclusion :
The study is acceptable.
Endpoints :
LD_{50} oral (*Apis mellifera*, 48 h) > 111.0 µg a.s./bee
LD_{50} contact (*Apis mellifera*, 48 h) > 100.0 µg a.s./bee

B.9.4.2 Bee brood feeding test (Annex IIA 8.3.1.2)

The study is not required since kresoxim-methyl does not act as an insect growth regulator.

B.9.4.3 Acute toxicity of the preparations to bees (Annex IIIA 10.4.1)

Effect of BAS 490 02 F on the honeybee (*Apis mellifera* L.) in laboratory trials. (Sack D., 1994a).
Addendum to report Effect of BAS 490 02 F on the honeybee (*Apis mellifera* L.) in laboratory trials. (Sack D., 1994b).

Guidelines :
UK Working Document 7/3 (1986)
GLP :
Yes
Material and Methods :
Test substance : kresoxim-methyl; as contained in BAS 490 02 F with 500 g kresoxim-methyl/kg product - formulation CANDIT; batch: 92-5
Test species : honeybees (*Apis mellifera* L.); worker bees
Number of organisms : 10 bees X 3 replicates/concentration
Type of test : acute oral and contact toxicity test (48 hours)
Applied concentrations : solvent control; 25, 50, 100, 150, 200 µg a.s./bee (nominal)
positive control : Perfekthion (400 g Dimethoate/L)
Exposure route :
- Oral test : test substance (dispersed in sugar/water solution) was fed (0.2 mL per replicate, corresponding to 20 µL/bee) for 4 hours; then untreated solution was provided ad libitum
- Contact test : with CO_2 immobilized bees were individually dosed on the ventral thorax with a dose of 1 µL/bee
Feeding : invert sugar/water solution (1:1)
Test conditions :
temperature : 20.5 - 23.5 °C
Findings :
Mortality : In both oral and contact tests mortality was low and not dose-related.
Endpoints :
LD_{50} (*Apis mellifera*, 48 h) contact > 200 µg a.s./bee (nominal) (highest concentration tested)
NOEL (*Apis mellifera*, 48 h) contact = 200 µg a.s./bee (nominal)
LD_{50} (*Apis mellifera*, 48 h) oral > 200 µg a.s./bee (nominal)
NOEL (*Apis mellifera*, 48 h) oral = 200 µg a.s./bee (nominal)
or
LD_{50} (*Apis mellifera*, 48 h) contact > 413.5 µg CANDIT/bee (nominal) (highest concentration tested)
NOEL (*Apis mellifera*, 48 h) contact = 413.5 µg CANDIT/bee (nominal)
LD_{50} (*Apis mellifera*, 48 h) oral > 410 µg CANDIT/bee (nominal)
NOEL (*Apis mellifera*, 48 h) oral = 410 µg CANDIT/bee (nominal)
Conclusion :
The study is acceptable.

Effect of BAS 492 01 F on the honeybee (*Apis mellifera* L.) in laboratory trials. (Sack D., 1993a).
Addendum report n° 3894. (Sack D., 1993b).

Guidelines :
UK working document 7/3 of the UK Controle of pesticides regulations, 1986
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F; SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph – formulation MENTOR; batch: 93-2
Test species : honeybees (*Apis mellifera* L.); worker bees
Number of organisms : 10 bees X 3 replicates/concentration
Type of test : acute oral and contact toxicity test (48 hours)
Applied concentrations : water control; 54.76, 109.53, 219.06, 328.59, 438.12 µg MENTOR/bee; positive control : Perfekthion (400 g Dimethoate/L)

Exposure route :
Oral test : test substance (dispersed in sugar/water solution) was fed (0.2 mL per group, corresponding to 20 µL/bee) for 5 hours; then untreated solution was provided ad libitum
Contact test : with CO_2 immobilized bees were individually dosed on the ventral thorax with the appropriate test solution, diluted in deionized water, using a micro-applicator; dose applied : 1 µL/bee
Feeding : invert sugar/water solution (1:1)
Test conditions :
temperature : 21.5 - 28 °C
Findings :
Mortality : In both experiments all bees survived in the water control groups. In the treated variants some but not dose-related mortalities occurred, never exceeding 6.7 %.
Endpoints :
LD_{50} (*Apis mellifera*, 48 h) contact > 438.12 µg MENTOR/bee (nominal)
NOEL (*Apis mellifera*, 48 h) contact = 438.12 µg MENTOR/bee (nominal)
LD_{50} (*Apis mellifera*, 48 h) oral > 438.12 µg MENTOR/bee (nominal)
NOEL (*Apis mellifera*, 48 h) oral = 438.12 µg MENTOR/bee (nominal)
Conclusion :
The study is acceptable.

Toxicity testing of BAS 492 01 F to honeybee (*Apis mellifera* L.) in laboratory. (Petto R., 1994).

Guidelines :
BBA Guideline, part VI, 23-1 (1991)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F; SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test species : honeybees (*Apis mellifera L.*); worker bees
Number of organisms : 10 bees X 3 replicates/concentration
Type of test : acute toxicity (72 hours)
Applied concentrations : water control; 7 mL in 1 L water, equivalent to 1.4 L MENTOR in 200 L water/ha; positive control
Exposure route :
Vapour test : petri dishes (Ø : 9.2 cm, height: 1.7 cm) were half filled with the test substance dilution; test cages containing the bees were placed onto the petri dish
Contact test : pieces of filter paper were submerged in the test substance dilution, dried at room temperature and placed into the cages; following this, test bees were added
Spraying test : 1 mL of the test substance dilution were sprayed through the front side, where the glass plate had been substituted by a wire mash, into the cages containing the test bees
Oral test : test substance, dispersed in syrup, was fed via a pipette tip as a 0.5 % dilution (0.25 mL per group) for 3 hours; then untreated syrup was provided ad libitum; the rate of consumed test substance was determined by reweighing the pipette tips
Feeding : sugar/water solution (1:1)
Test conditions :
temperature : 28 ± 2 °C
relative humidity: 40 - 60 %
light intensity : darkness
Findings :
Endpoints :
vapour inhalation : no effects
contact test : no effects
wetting test : no effects
LD_{50} (*Apis mellifera*, 72 h) oral > 104 µg MENTOR/bee (highest dose tested)
Conclusion :
The study is acceptable.

Die Wirkung von BAS 492 01 F auf die Honigbiene (*Apis mellifera* L.) in Laborversuchen. (Sack D., 1994c).

Guidelines:
BBA Guideline, part VI, 23-1 (1991)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F; SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test species : honeybees (*Apis mellifera* L.); worker bees
Number of organisms : 10 bees X 3 replicates/concentration
Type of test : acute toxicity (72 hours)
Applied concentrations : 0.7 %, equivalent to 1.4 L MENTOR in 200 L water/ha;
oral test : 25, 50 and 100 µg MENTOR/bee
Exposure route :

Vapour test : petri dishes (Ø : 9.2 cm, height : 1.7 cm) were half filled with the test substance dilution; test cages containing the bees were placed onto the petri dish
Contact test : pieces of filter paper were submerged in the test substance dilution, dried at room temperature and placed into the cages; following this, test bees were added
Spraying test : 1 mL of the test substance dilution were sprayed through the front side, where the glass plate had been substituted by a wire mash, into the cage containing the test bees; then the bees were transferred to the untreated part of the double-cage
Oral test : test substance, dispersed in a sugar/water solution, was fed (0.2 mL per group) for 3 hours; then untreated sugar/water solution was provided ad libitum; the rate of consumed test substance was determined by reweighing the feeding tubes
Test conditions :
temperature : about 28 °C
relative humidity : about 30 - 50 %
light intensity : darkness
Feeding : sugar/water solution (1:1)
Findings :
Endpoints :
vapour phase test : no effects
contact test : no effects
wetting test : no effects
oral intake test : LD_{50} (*Apis mellifera*, 72 h) > 100 µg MENTOR/bee
Conclusion :
The study is acceptable.

Added in March 2010:

A new acute contact and oral toxicity study with honey bees according to current guidelines OECD 213/214 was performed to meet the requirements of current regulations. Also higher concentrations were tested in this study. The new study replaces the old study (Sack, 1994a and 1994b).

Assessment of Side Effects of BAS 490 02 F to the Honey Bee, *Apis mellifera* L. in the Laboratory. (Bocksch S., 2004).

Guidelines :
OECD Guideline 213: Honeybees, Acute Oral Toxicity Test
OECD Guideline 214: Honeybees, Acute Contact Toxicity Test
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F; containing 50 % nominal (50.3 % analysed) kresoxim-methyl – formulation CANDIT; batch: 3197
Test species : honeybees (*Apis mellifera mellifera*); young, adult worker bees
Number of organisms : 5 replicates/treatment, each containing 10 bees
Type of test : acute oral (48 h) and contact (48 h) toxicity test
Applied concentrations :
Oral test : water control (50 % (w/v) aqueous sucrose solution); 115.47 µg a.s./bee (measured); positive control (0.08, 0.11, 0.15, 0.21 µg dimethoate/bee, nominal)
Contact test : water control (tap water); 100.00 µg a.s./bee (nominal); positive control (0.12, 0.17, 0.24, 0.34 µg dimethoate/bee, nominal)
Exposure route :
Oral test : The test substance was dissolved in tap water and 50 % aqueous sucrose solution was added to the stock solution. The bees were starved for 2 hours. The nominal test dose was 100.00 µg a.s./bee.
Contact test : Bees were anaesthetized with CO_2. The test substance was dissolved in tap water. 2 µL of test solution was applied to the ventral side of the thorax of each bee.
Feeding : 50 % aqueous sucrose solution *ad libitum*
Test conditions :
temperature : 24.0 – 24.5 °C
relative humidity : 50 – 68 %
light : darkness
Findings :
In the oral toxicity test corrected mortality was -4.3 % at 115.47 µg a.s./bee after 48 hours. In the contact toxicity test 6.1 % corrected mortality was recorded after 48 hours at 100.0 µg a.s./bee. No test item related behavioural abnormalities occurred.
In the positive control adequate mortality was observed.
LD_{50} (*Apis mellifera*, 24 h) oral = 0.11 µg dimethoate/bee
LD_{50} (*Apis mellifera*, 24 h) contact = 0.21 µg dimethoate/bee
Conclusion :
The study is acceptable.
Endpoints :
LD_{50} oral (*Apis mellifera*, 48 h) > 115.47 µg a.s./bee (equivalent to 230.94 µg CANDIT/bee)
LD_{50} contact (*Apis mellifera*, 48 h) > 100.0 µg a.s./bee (equivalent to 200.00 µg CANDIT/bee)

The representative formulation MENTOR was replaced by the new formulation ALLEGRO, therefore new studies addressing the risk to honey bees were necessary.

Assessment of Side Effects of BAS 494 04 F to the Honey Bee, *Apis mellifera* L. in the Laboratory. (Bocksch S., 2004).

Guidelines :
OECD Guideline 213: Honeybees, Acute Oral Toxicity Test
OECD Guideline 214: Honeybees, Acute Contact Toxicity Test
GLP :
Yes
Material and Methods :
Test substance : BAS 494 04 F; containing 125.3 g/L (nominal 125.0 g/L) kresoxim-methyl and 124.8 g/L (nominal 125.0 g/L) epoxiconazole – formulation ALLEGRO; batch: 6380
Test species : honeybees (*Apis mellifera mellifera*); young, adult worker bees
Number of organisms : 5 replicates/treatment, each containing 10 bees
Type of test : acute oral (72 h) and contact (48 h) toxicity test
Applied concentrations :
Oral test : water control (50 % (w/v) aqueous sucrose solution); 15.09, 27.80, 60.34, 102.14, 173.23 µg a.s./bee (measured); positive control (0.07, 0.11, 0.15, 0.21 µg dimethoate/bee, nominal)
Contact test : water control (tap water); 100.0 µg a.s./bee (nominal); positive control (0.12, 0.17, 0.24, 0.34 µg dimethoate/bee, nominal)
The unit µg a.s./bee refers to the content of the sum of the active ingredients kresoxim-methyl and epoxiconazole.
Exposure route :
Oral test : The test substance was dissolved in tap water and 50 % aqueous sucrose solution was added to the stock solution. The bees were starved for 2 hours. The nominal test doses were 12.5, 25.0, 50.0, 100.0 and 200.0 µg a.s./bee.
Contact test : Bees were anaesthetized with CO_2. The test substance was dissolved in tap water. 2 µL of test solution was applied to the ventral side of the thorax of each bee.
Feeding : 50 % aqueous sucrose solution *ad libitum*
Test conditions :
temperature : 25 °C (oral test); 24.0 – 24.5 °C (contact test)
relative humidity : 55 – 70 % (oral test); 50 – 68 % (contact test)
light : darkness
Findings :
In the oral toxicity test corrected mortality was 14.3 %, 14.3 %, 22.4 %, 55.1 % and 91.8 % at 15.09, 27.80, 60.34, 102.14 and 173.23 µg a.s./bee after 72 hours. In the contact toxicity test 6.1 % corrected mortality was recorded after 48 hours at 100.0 µg a.s./bee. No test item related behavioural abnormalities occurred.
In the positive control adequate mortality was observed.
LD_{50} (*Apis mellifera*, 24 h) oral = 0.13 µg dimethoate/bee
LD_{50} (*Apis mellifera*, 24 h) contact = 0.21 µg dimethoate/bee
Conclusion :
The study is acceptable.
Endpoints :
LD_{50} oral (*Apis mellifera*, 72 h) = 98.52 µg a.s./bee (a.s. is the sum of kresoxim-methyl and epoxiconazole); corresponding to 428.8 µg ALLEGRO/bee
LD_{50} contact (*Apis mellifera*, 48 h) > 100.0 µg a.s./bee (a.s. is the sum of kresoxim-methyl and epoxiconazole); corresponding to > 435.2 µg ALLEGRO/bee

B.9.4.4 Effects on bees of residues on crops (Annex IIIA 10.4.2)

Not required. The risk to honey bees is fully covered by the studies submitted.

B.9.4.5 Cage tests (Annex IIIA 10.4.3)

Not required. The risk to honey bees is fully covered by the studies submitted.

B.9.4.6 Field tests to investigate special effects (Annex IIIA 10.4.4)

Not required. The risk to honey bees is fully covered by the studies submitted.

B.9.4.7 Tunnel testing to investigate effects of feeding on contaminated honey (Annex IIIA 10.4.5)

Not required. The risk to honey bees is fully covered by the studies submitted.

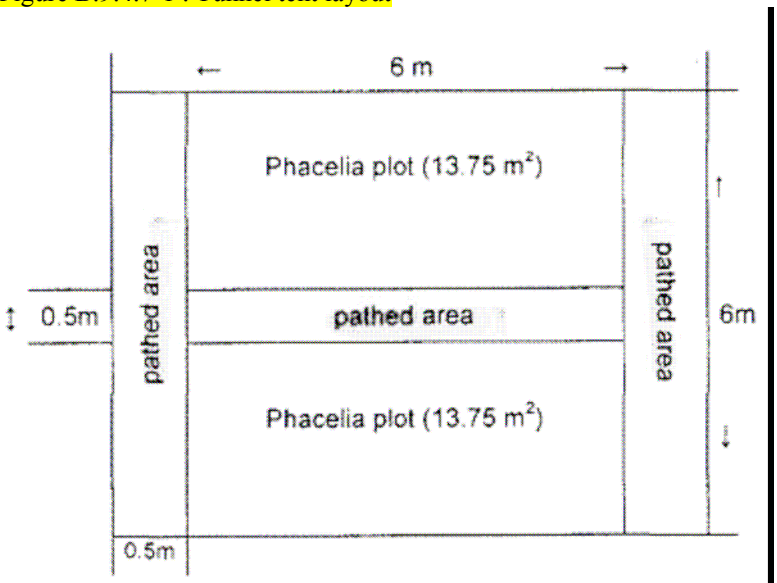
Added in March 2010:

Following study replaces an older study (Sack D., 1995; BASF Doc ID 1995/11060) by a current study conducted according to updated guideline requirements. The original study was demanded by German authorities to address a potential risk of BAS 490 02 F to honey bee colonies.

Effects of BAS 490 02 F on the honeybee *Apis mellifera* L. under semi-field conditions (tunnel tent test). (Barth M., 2008).

Guidelines :
EPPO PP 1/170 (3) (2001), EEC 91/414, EEC 96/12, SANCO/10329/2002 rev. 2 final
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F; containing 50 % nominal (48.2 % analyzed) kresoxim-methyl – formulation CANDIT; batch : 3197
Test species : honeybee (*Apis mellifera carnica*); healthy small bee colonies; each colony covered 5 frames, including at least 2 brood frames with all brood stages present and at least 1 good filled honey comb; 37 cm x 22.3 cm = 825.1 cm² per comb side; approximately 2500 – 6100 number of bees per nucleus hive; from a beekeeper in Saxony, Germany.
Test plots : The test site was located in Cunnersdorf, Germany; crop: *Phacelia tanacetifolia,* at the stage of full flowering at treatment (BBCH 65).The Phacelia field was placed on meadow land not in use for agricultural production during the past 9 years. No other pesticides beside the test item were applied for at least 9 years before and after sowing of *Phacelia*. The area covered per tunnel tent was about 36 m² (6 m x 6 m) and the plot size with flowering Phacelia 27.5 m² (2 x 13.75 m²). The distance between the tunnels was at least 0.5 m.

Figure B.9.4.7-1 : Tunnel tent layout



Test design : Honeybee semi-field test in Phacelia (*Phacelia tanacetifolia*) with three treatment groups (control, test item, reference item); exposure of the bees to the control, test item and reference item during flowering of the Phacelia in tunnel tents (6 m length x 6 m width x 2.5 m height); 1 colony per tent and 3 tunnel tents per treatment group; 4 days before application bee colonies were introduced into the tunnel tents; exposure period was 7 days; assessments on mortality (in dead bee traps and on gauze sheets next to the first and last metal frame), flight activity (on two 1 m² plots/tent), behavior, colony strength and bee brood development; after the exposure phase the colonies were removed from the tents and the further brood development was assessed on day 21 after treatment (DAT 21).

Test rates : untreated control (400 L tap water/ha); reference item (1.2 L Perfekthion EC 400 in 400 L tap water/ha; equivalent to 480 g dimethoate/ha, nominal); test item (0.300 kg CANDIT in 400 L tap water/ha; equivalent to 150 g kresoxim-methyl/ha, nominal)

Assessments : Mortality and forage activity was determined daily from -3 to 7 DAT. Changes in behavior were assessed daily. The condition of the colonies (food stores, brood status and colony strength) was determined after -2, 7 and 21 DAT.

Test conditions : Natural field conditions. Weather conditions were good during application. It was sunny (0 % clouds) and warm (25 – 27 °C) with slight wind (0.5 - 1.1 m/s) and no precipitation. Precipitation was 6.0 mm on DAT 1 and 2.0 mm on DAT 2. The weather was variable with heavy rain on DAT 3 (38.6 mm) but warm for the remaining exposure phase.

Statistics : The endpoints for statistical evaluation were mortality (number of dead bees/day) and foraging activity (number of foraging bees/m^2). The arithmetic mean and the standard deviation per replicate and treatment were calculated. Pre-treatment data were statistically evaluated using multiple testing methods, comparing treatment means (control, test item and reference item) against each other. The evaluation of pre-treatment data using the Tukey-test (α = 0.05) showed that the three treatment groups were statistically significantly different or not.

The post-treatment data were evaluated using pair-wise statistical testing methods comparing treatments (test item or reference item) separately against the control. The STUDENT-t test (for variance homogeneous data) or the WELCH-t test (for variance inhomogeneous data) was used for pair-wise comparison of treatments with the control (mortality: one-sided greater; foraging activity: one-sided smaller). For all statistical tests a significance level of α = 0.05 was used.

Findings :

Mortality :
The mortality of honeybees observed on the days before application was on a low and similar level in the control, test item and reference item treatments indicating comparable and well adapted colonies. The overall daily mean mortality during pre-exposure phase in the test item group and the control was 10.8 dead bees/cage/day. Shortly after application until the end of DAT 0 no increased mean numbers of dead bees were observed in the test item treatment compared to the control.
Also between DAT 1 and DAT 7 the mortality rates in the test item group were not increased compared to the control and were on similar levels. The overall daily mean mortality during exposure phase in the test item group was 14.8 dead bees/cage/day compared to 13.1 dead bees/cage/day in the control group. No statistically significantly higher mortality rates in the test item group compared to the control group were observed directly after application on DAT 0 until DAT 7 (Student-t test, $\alpha = 0.05$). The exposure of honeybees to the reference item resulted in a distinctly increased and statistically significant number of dead bees for at least 5 days after application (Student-t or Welch-t test, $\alpha = 0.05$). The strong effect of the reference item on honeybee mortality showed that the test system was sensitive to detect possible effects.

Foraging activity :
Foraging activity assessments before application showed, that the foraging activity was on a high and similar level. The mean daily flight intensity before application was 15.2, 16.4 and 16.6 bees/m² in the control, the test item and the reference item, respectively, indicating that bees had adapted to the new environmental conditions. Shortly before application foraging activity was 12 - 19, 16 - 19 and 14 - 18 bees/m^2 in the control, the test item and the reference item, respectively, indicating that bees were sufficiently exposed during application.
No difference of foraging activity compared to the control was observed during the assessments after the test item application on DAT 0. Also on all post-treatment assessment days the foraging activity in the test item treated tents was on a very similar level or even higher compared to the control (Student-t test, $\alpha = 0.05$). No foraging activity was observed on DAT 3 due to rainy weather conditions. Regarding the daily and overall post-treatment foraging activities no statistically significant differences were observed between the test item and the control group.
Flight intensity in the reference item group was distinctly and statistically significantly reduced for the entire assessment period after application (Student-t or Welch-t, $\alpha = 0.05$).

Bee behavior :
No abnormal behavior of the honeybees was observed around the hive or on the entrance of the hive of the test item and the control colonies. The exposure of bees to the reference item resulted in noticeable sub-lethal effects such as a reduced foraging and flight activity and general inactivity of the bees compared to the control for the entire assessment period after application.

Colony strength :
For colony strength assessments the number of bees per control and test item colony was estimated according to IMDORF *et al*. (1987) on DAT -2, DAT 7 and DAT 21. During colony assessment conducted two days before application (DAT –2), the estimated average number of bees per colony was 3420, 5280 and 4320 in the control, test item and reference item treatment, respectively. In the control and test item exposed colonies the estimated average colony strengths were not reduced on DAT 7 compared to DAT -2. On DAT 7 the estimated average number of bees per colony was 4800 and 7200 in the control and test item treatment respectively. On DAT 21 the estimated average number of bees per colony was 7020 and 7500 in the control and test item treatment, respectively. This indicates that exposure of honeybees to the test item had no effect on the colony strength if compared to the pre-application period and the control. On DAT 7 the estimated average number of bees per colony in the reference item group was 3960 and therefore distinctly reduced if compared to DAT -2. On DAT 21 the estimated average number of bees per reference item colony was 4980 and showed a recovery of colony strength comparable to the pre-treatment level.

Brood assessment :
Based on the assessments of the brood area size per colony and assessments for the presence and amounts of eggs in the test item colonies, no distinct differences in the presence of bee brood or on queen fecundity compared to the control were seen throughout the study.
The test item colonies were generally healthy, actively reproducing and similar or only slightly different in size if compared to the control colonies.

The results are summarized in Table B.9.4.7-1.

Table B.9.4.7-1 : Effects of CANDIT on honeybee mortality and foraging activity under semi-field conditions

Assessment day	Mortality [no. of dead bees]						Foraging activity [bees/m²]					
	Control		Test item		Reference item		Control		Test item		Reference item	
	Mean[1)]	± SD	Mean[1)]	± SD	Mean[1)]	± SD	Mean[1)]	± SD	Mean[1)]	± SD	Mean[1)]	± SD
DAT –3	9.0a	3.6	13.0a,b	2.6	17.0b	1.0	11.8b	1.0	13.3a	1.2	14.2a	0.8
DAT –2	14.0a	3.0	12.7a	3.2	14.3a	3.8	15.5a	1.8	16.2a	1.9	16.2a	1.3
DAT –1	10.0a,b	3.5	8.7a	2.5	15.3b	0.6	17.5a	1.0	18.7a,b	1.0	19.2b	0.8
DAT 0 (ba)	10.0a	3.0	8.7a	0.6	10.7a	5.0	16.0a	2.6	17.5a	1.2	16.8a	1.6
Daily mean DAT -3 to DAT 0 (ba)	**10.8 a**	**3.4**	**10.8a**	**3.0**	**14.3b**	**3.7**	**15.2a**	**0.9**	**16.4a**	**0.6**	**16.6a**	**0.4**
DAT 0 (aa)	15.7	3.2	13.3	5.5	321.7*	30.1	16.6	0.6	16.0	0.1	2.4*	0.0
DAT 1	13.3	4.0	18.7	6.1	286.0*	98.6	15.2	1.4	16.6	0.3	0.0*	0.0
DAT 2	7.0	4.0	8.7	4.0	102.0*	61.9	18.2	1.0	19.0	0.6	0.0*	0.0
DAT 3	15.3	4.0	16.0	4.4	41.0*	9.6	0.0 n.a.	0.0	0.0 n.a.	0.0	0.0 n.a.	0.0
DAT 4	9.0	3.6	11.0	4.0	20.7*	2.1	16.0	1.3	17.2	1.5	0.5*	0.8
DAT 5	18.7	1.5	22.0	4.4	53.7*	36.1	15.3	1.2	16.7	0.8	0.0**	0.0
DAT 6	16.3	4.2	15.7	5.0	28.0	10.6	10.3	1.0	10.8	0.8	4.7*	2.5
DAT 7	9.3	0.6	13.3	4.2	19.3	17.1	15.2	1.0	16.5	1.8	4.8*	2.6
Daily mean DAT 0 (aa) to 7	**13.1**	**4.9**	**14.8**	**5.7**	**109.0***	**123.8**	**14.8**	**0.7**	**15.1**	**0.3**	**1.7***	**0.4**

ba: before application aa: after application DAT: day after treatment [1)] mean of three replicates

Statistics:
a, b: same letters indicate that groups are not statistically significantly different (Tukey-test, α=0.05) at pre-application period.
*: statistically significantly different (STUDENT-t test or WELCH-t test, α=0.05) at post-application period; mortality: one-sided greater; foraging activity: one-sided smaller.
n.a.: statistical evaluation not applicable, due to rainy weather foraging activity has stopped.

Conclusion :
The formulation CANDIT was applied during bee flight activity at full flowering of *Phacelia tanacetifolia*. The formulation CANDIT applied under semi-field conditions at a rate of 300 g/ha in 400 L/ha (equivalent to 150 g kresoxim-methyl/ha) to *Phacelia tanacetifolia* during active foraging conditions caused no adverse effects on honeybee mortality, foraging activity, behavior and condition of the colonies as well as on bee brood. No significant treatment related alterations on mortality, foraging activity, behavior and condition of colonies were detectable directly after the application, nor after 21 DAT.

The reference item Perfekthion EC 400 caused significantly higher number of dead bees as well as a statistically significant reduction in forage activity. In addition, the overall strength of the colony was clearly lower after Perfekthion EC 400 application, although the colonies were slightly recovered after 21 days post treatment. Therefore it can be concluded that CANDIT did not adversely affect bee brood development and colony strength when applied at a rate of 300 g/ha in 400 L water/ha (equivalent to 150 g kresoxim-methyl/ha).

B.9.4.8 Exposure and risk assessment for bees (Annex IIIA 10.4)

Revised in March 2010:

Table B.9.4.8-1 : Summary of effects of kresoxim-methyl to bees

Test species	Test system	Endpoints	References
Apis mellifera	48 h oral toxicity test	LD_{50} oral = 14 µg a.s./bee	Künast Ch., 1992
	48 h contact toxicity test	LD_{50} contact > 20 µg a.s./bee	
Apis mellifera	48 h oral toxicity test	**LD_{50} oral > 111.0 µg a.s./bee**	Schmitzer S. and Sekine T., 2008
	48 h contact toxicity test	**LD_{50} contact > 100.0 µg a.s./bee**	

Table B.9.4.8-2 : Summary of effects of formulations containing kresoxim-methyl to bees

Test species	Test system	Formulation	Endpoints	References
Apis mellifera	48 h oral toxicity test	BAS 490 02 F - CANDIT	LD_{50} oral > 410 µg/bee	Sack D., 1994a/1994b
	48 h contact toxicity test		LD_{50} contact > 413.5 µg/bee	
Apis mellifera	48 h oral toxicity test	BAS 490 01 F - MENTOR	LD_{50} oral > 438.12 µg/bee	Sack D., 1993a/1993b
	48 h contact toxicity test		LD_{50} contact > 438.12 µg/bee	
Apis mellifera	72 h oral toxicity test	BAS 490 01 F - MENTOR	LD_{50} oral > 104 µg/bee	Petto R., 1994
Apis mellifera	72 h oral toxicity test	BAS 490 01 F - MENTOR	LD_{50} oral > 100 µg/bee	Sack D., 1994b
Apis mellifera	48 h oral toxicity test	BAS 490 02 F - CANDIT	**LD_{50} oral > 230.94 µg/bee**	Bocksch S., 2004
	48 h contact toxicity test		**LD_{50} contact > 200.00 µg/bee**	
Apis mellifera	72 h oral toxicity test	BAS 494 04 F - ALLEGRO	**LD_{50} oral > 428.8 µg/bee**	Bocksch S., 2004
	48 h contact toxicity test		**LD_{50} contact > 435.2 µg/bee**	

The formulation MENTOR is no longer supported in the resubmission dossier and thus no risk assessment is conducted.

The risk assessment for bees is based on the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC.

1- Kresoxim-methyl

The hazard quotients for the active substance are based on the toxicity values based on the most recent study of Schmitzer S. and Sekine T. (2008).

Table B.9.4.8-3 : Hazard quotients of the active substance kresoxim-methyl for bees

Application rate	Crop	Route of exposure	LD_{50} (µg a.s./bee)	Hazard Quotient	Annex VI Trigger Value
125 g a.s./ha	pome fruit, cereals	oral	> 111.0	< 1.13	50
		contact	> 100.0	< 1.25	50
150 g a.s./ha	grapevine	oral	> 111.0	< 1.35	50
		contact	> 100.0	< 1.5	50

The hazard quotients based on the endpoints for the active substance kresoxim-methyl are far below the trigger value of 50, indicating acceptable risk for bees.

2- Formulation CANDIT

The formulation CANDIT (BAS 490 02 F) is a fungicidal product, which contains the active substance kresoxim-methyl with a nominal content of 50 % w/w.

Table B.9.4.8-4 : Proposed use pattern of the formulation CANDIT

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate (kg a.s./ha) [1)]	Application rate (kg product/ha) [1)]
Pome fruit (apple, pear)	1 - 4	7	53 - 79	0.100 - 0.125	0.200 - 0.250
Grapevine	1 - 3	8	19 - 81	0.100 - 0.150	0.200 - 0.300

[1)] application rate increases with plant growth stage

For simplification reasons, the risk assessment is only conducted for the higher application rates. This covers the increase in application rate during season.

The hazard quotients for the formulation CANDIT are based on the toxicity values based on the most recent study of Bocksch S. (2004) expressed as formulation.

Table B.9.4.8-5 : Hazard quotients of the formulation CANDIT for bees

Application rate	Crop	Route of exposure	LD_{50} (µg/bee)	Hazard Quotient	Annex VI Trigger Value
250 g/ha	pome fruit	oral	> 230.94	< 1.08	50
		contact	> 200.00	< 1.25	50
300 g/ha	grapevine	oral	> 230.94	< 1.30	50
		contact	> 200.00	< 1.5	50

The hazard quotients based on the endpoints for the formulation CANDIT are far below the trigger value of 50, indicating acceptable risk for bees.

Although all acute HQ values in the tier 1 assessment are below the trigger value of 50 and no further testing is required, a tunnel test was performed with the formulation CANDIT evaluating mortality, flight activity, behavior and bee brood. Neither directly after the application, nor after 21 DAT, significant treatment related alterations on mortality, foraging activity, behavior and condition of colonies were detectable.

3- Formulation ALLEGRO

The formulation ALLEGRO (BAS 494 04 F) is a fungicidal product, which contains the active substances
- kresoxim-methyl (BAS 490 F) with a nominal content of 125 g a.s./L
- epoxiconazole (BAS 480 F) with a nominal content of 125 g a.s./L

Table B.9.4.8-6 : Proposed use pattern of the formulation ALLEGRO

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate		
				BAS 494 04 F [L/ha]	Kresoxim-methyl (BAS 490 F) [kg a.s./ha]	Epoxiconazole (BAS 480 F) [kg a.s./ha]
Cereals	2	21	25 - 69	1.0	0.125	0.125

The hazard quotients for the formulation ALLEGRO are based on the toxicity values based on the study of Bocksch S. (2004) expressed as formulation.

Table B.9.4.8-7 : Hazard quotients of the formulation ALLEGRO for bees

Application rate [1)]	Crop	Route of exposure	LD_{50} (µg/bee)	Hazard Quotient	Annex VI Trigger Value
1088 g/ha	cereals	oral	> 428.8	< 2.53	50
		contact	> 435.2	< 2.50	50

1) taking into account a density of 1.088 g/cm³

The hazard quotients based on the endpoints for the formulation ALLEGRO are far below the trigger value of 50, indicating acceptable risk for bees.

In conclusion, the risk of kresoxim-methyl and the formulations CANDIT and ALLEGRO to bees is acceptable for the intended uses.

B.9.5 Effects on other arthropod species (Annex IIA 8.3.2; Annex IIIA 10.5)

B.9.5.1 Effects of the active substance on non-target terrestrial arthropods (Annex IIA 8.3.2)

Added in March 2010:

Studies on non-target terrestrial arthropods are generally not performed with the pure active ingredient, but with the formulation. Studies have been conducted with the formulation BAS 490 02 F, containing kresoxim-methyl only and with the formulation BAS 494 04 F, containing kresoxim-methyl and epoxiconazole. New studie for *Aphidius rhopalosiphi* and *Typhlodromus pyri* have been conducted with BAS 490 02 F (Pussell S., 2003; Rosenkranz B., 2004a; Vaughn R., 2007; Noe J., 2007) to replace old studies which were no more compliant with the current testing guidelines. The studies performed with BAS 494 04 F (Moll M., 2004; Rosenkranz B., 2004b) are required for risk evaluation of this particular formulation.

Study of the side effects of BAS 490 02 F on the predatory mite *Typhlodromus pyri* Scheuten (Acari, Phytoseidae) in the laboratory. (Kühner Ch., 1993).

Guidelines :
IOBC test recommendation, according to Overmeer; IOBC/WPRS XI/4 (1988)
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g kresoxim-methyl/kg (nominal) - formulation CANDIT; batch: 92-5
Test species : Typhlodromus pyri (predatory mites); protonymphs
Number of organisms : 20 protonymphs X 5 replicates/concentration
Type of test : laboratoy test
Applied and measured rates :
- 0.15 %, corresponding to 300 g /haCANDIT in 200 L water/ha, equivalent to 150 g a.s./ha (nominal);
- water control
The amount of spray solution (0.15 % w/w) applied to the glass plates was in average 1.97 mg/cm², corresponding to a field application rate of 295.5 g CANDIT/ha (measured).
Exposure route : 8 days of exposure on treated glass plates + 8 days for oviposition on treated glass plates with aged residues
Test conditions : incubation at 25 ± 2 °C and 65 ± 10 % relative humidity; photoperiod : 16 hours light, 8 hours dark, more than 3000 lux
Findings :

Table B.9.5.1-1 : Effects on *Typhlodromus pyri (*predatory mite) exposed to kresoxim-methyl, as contained in CANDIT, in a laboratory trial

Evaluation criteria	**Control**	**Treat-ment**	**Endpoints**
Survival rate (%) (day 8)	94 %	86 %	corrected mortality = 8.5 %
Number of offspring/female (day 16)	8.11	7.52	Reproduction factor = 0.93
			Reduction of beneficial capacity = 14.91 %

Observations : No pecularities in behavior were observed after the placing of the test organism on the treated plates either in the control group or in the test substance variant. The activity of the test organism was normal on all test dishes.
Conclusion :
Kresoxim-methyl as a.s. of the formulation CANDIT is harmless (E1) to *Typhlodromus pyri* at the application rate of 150 g a.s./ha.

Laboratory determination of the side effects of BAS 490 02 F on *Trichogramma cacoeciae* Marchal (*Hym. Trichogrammatidae*) as a representative of the Microhymenoptera, test on Imagines. (Kühner Ch., 1994a)

Guidelines :
IOBC test recommendation, according to Hassan; BBA Guideline, VI, 23-2.1.1 (1989)
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g kresoxim-methyl/kg (nominal) - formulation CANDIT; batch: 92-5
Test species : Trichogramma cacoeciae (parasitic Hymenoptera), adults, 24 hours old
Number of organisms : 487 wasps in treatment and 558 wasps in control, 3 replicates/concentration
Type of test : laboratory test
Applied and measured rates :
- 0.15 %, corresponding to 300 g CANDIT/ha in 200 L water/ha equivalent to 150 g a.s./ha (nominal);
- water control
The amount of spray solution (0.15 % w/w) applied on to the glass plates was in average 2.02 mg/cm², corresponding to a field application rate of 303 g CANDIT /ha (measured).
Exposure route : 7 days of exposure on treated glass plates
Test conditions :
eggs of *Sitotroga cerealella* moths were offered to the wasps for parasitization for a given period, eggs were glued on cards, change of cards each 1-2 days
Incubation : at 26 ± 2 °C and 60 - 80 % relative humidity
Photoperiod : 16 hours light, 8 hours dark
Wasps were fed with a honey/water/agar mixture
Findings :

Table B.9.5.1-2 : Effects on *Trichogramma cacoeciae* (parasitoids) exposed to kresoxim-methyl, as contained in CANDIT, in a laboratory trial

Evaluation criteria	**Control**	**Treatment**	**Endpoints**
Number of parasitized eggs	15812	15891	
Number of wasps	558	487	
Number of *Sitotroga* eggs parasitized/wasp	28 ± 5.29	33 ± 3.00	Reduction of parasitic ability = -17.86 %

Endpoints :
Reduction of parasitic ability = -17.86 %; A negative value indicates that the parasitic ability of the test organism was not reduced as a result of the exposure.
Conclusion :
Kresoxim-methyl as a.s. of the formulation CANDIT is harmless (E1) to *Trichogramma cacoeciae* at the application rate of 150 g a.s./ha.

Testing toxicity to beneficial arthropods ladybird - *Coccinella septempunctata L.*/adults; BAS 490 02 F. (Kleiner R., 1993a).
Addendum to report Testing toxicity to beneficial arthropods ladybird - *Coccinella septempunctata L.*/adults; BAS 490 02 F. (Kleiner R., 1993b).

Guidelines :
BBA Guideline, VI 23-2.1.5 (1989)
GLP :
Yes
Material and Methods :
Test substance : kresoxim-methyl, as contained in BAS 490 02 F with 500 g a.s./kg (nominal) - Formulation CANDIT; batch: 92-5
Test species : Coccinella septempunctata (plant dwelling predator)
Number of organisms, age : 10 beetles X 5 replicates/concentration, adults 3 up to 19 days
Type of test : laboratory test
Applied rates :
- 300 g product/ha in 200 L water/ha (= 0.15 % w/v), equivalent to 150 g a.s./ha (nominal);
- water control
Exposure route : 14 days of exposure on treated surface + 21 days for oviposition + 5 days for hatching
Test conditions :
Incubation : at 19 - 25 °C and 53 - 87 % relative humidity
Photoperiod : 16 hours light, 8 hours dark; about 1000 lux
Beetles were fed with aphids (*Aphis fabae* and *Acyrthosiphon pisum*)
Findings :

Table B.9.5.1-3 : Effects on *Coccinella septempunctata* (plant dwelling predators) exposed to kresoxim-methyl, as contained in CANDIT, in a laboratory trial

Evaluation criteria	**Control**	**Treat-ment**	**Endpoints**
Mortality	0 %	0 %	Mortality (Schneider-Orelli) = 0 %
Number of larvae/female	42.2	17.0	Fertility (Abbot) = 59.7 %
			Overall effect (E) = 59.7 %

Conclusion :
CANDIT is classified as slightly harmful (E2) to *Coccinella septempunctata* at the dose of 150 g a.s./ha

Effect of BAS 490 04 F on the mortality of the ground beetle *Poecilus cupreus*. (Schlosser E., 1993a).

Guidelines :
BBA Guideline, VI 23-2.1.8
GLP :
Yes
Material and Methods :
Test substance : kresoxim-methyl, as contained in BAS 490 04 F, SC with 500 g a.s./L (nominal); batch: 92-2
Test species : Poecilus cupreus (ground dwelling predator), adults
Number of organisms : (10 male and 10 female insects) X 3 replicates/concentration
Type of test : laboratory test
Applied rates :
- 0.075 %, corresponding to 0.3 L product/ha in 400 L water/ha equivalent to 150 g a.s./ha (nominal);
- water control
- positive standard : Afugan (pyrazophos, 293 g/L), dose : 0.25 %, equivalent to 1 L/ha in 400 L water
Exposure route : 14 days exposure in containers filled with quartz sand

Test conditions :
Incubation : at 20 ± 3 °C, 37 - 71 % relative humidity
Light regime : 16 hours light, 8 hours dark, 500 to 1500 lux
Beetles were fed with fly pupae.
Findings :

Table B.9.5.1-4 : Effects on *Poecilus cupreus* (ground dwelling predators) exposed to kresoxim-methyl, as contained in BAS 490 04 F, in a laboratory trial

Evaluation criteria	Control	Treatment	Endpoints
Mortality	0 %	0 %	
Consumed pupae/beetle	4.94	4.94	Overall effect : E (14d) = 0 %

Conclusion :
Kresoxim-methyl as a.s. of the formulation BAS 490 04 F is harmless (E1) to *Poecilus cupreus* at the application rate of 150 g a.s./ha

B.9.5.2 Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests) (Annex IIIA 10.5.1)

Effect of BAS 492 01 F on the predatory mite (*Typhlodromus pyri* Scheuten) in laboratory trials. (Ufer A., 1994a).

Guidelines :
IOBC test recommendations; IOBC/WPRS (1988, 1992)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F, SE containing 153.94 g/L kresoxim-methyl and 309.59 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test species : Typhlodromus pyri (predatory mite); protonymphs
Number of organisms : n = 5, with 20 mites each
Type of test : laboratory test
Applied rates :
application of MENTOR at a dose of 1.5 mg/cm², equivalent to 0.7 L MENTOR/ha in 150 L water/ha (105 g kresoxim-methyl/ha)
Exposure route : 7 days of exposure on treated glass plates plus additional 7 days for oviposition on treated glass plates with aged residues
Test conditions :
Incubation at 24 ± 2 °C, 80 ± 20 % relative humidity
Light regime : 16 hours light, 8 hours dark
Mites were fed with fresh pollen (*Pinus sp.*)

Findings :

Table B.9.5.2-1 : Effects on *Typhlodromus pyri* (predatory mites) exposed to MENTOR in a laboratory trial

Evaluation criteria	**Control**	**Treat-ment**	**Endpoints**
Mortality (%) (day 7)	20 ± 7.1	26 ± 16.4	corrected mortality = 7.5 %, std 20.4 %
Number of offspring/female/day (day 14)	0.9 ± 0.1	0.9 ± 0.2	
Hatched eggs (%)	94 %	95 %	
			Overall effect (E) = 5.8 %

Conclusion :
According to the IOBC - classification Scheme MENTOR could be considered as harmless (W1/1) to populations of the predatory mite *Typhlodromus pyri*, up to 0.7 L product/ha in 150 L water/ha.

Effect of BAS 492 01 F on the lacewing *Chrysopa (Chrysoperla) carnea (Chrysopidae, Neuroptera)* in laboratory trials. (Künast Ch., 1994b).

Guidelines :
IOBC/WPRSworking group "Pesticides and beneficial organisms" (Hassan S. 1985)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F, SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test species : *Chrysopa carnea* (foliage dwelling predator), larvae 2 to 3 days old
Number of organisms : 30, separately kept
Type of test : laboratory test
Applied rates :
Equivalent to 0.7 L MENTOR/ha in 400 L water/ha; positive standard; water control
Exposure route :
Lacewing larvae (*Chrysopa carnea*) were exposed to MENTOR via a treated glass plate with dried spray deposit over a period of about 3 weeks. The following life span was monitored resulting in an entire test period of 9 weeks (pupation in week 3, adult life span in weeks 3 to 8, oviposition in weeks 3 to 7, offspring in weeks 5 to 9)
Test conditions :
Test unit : glass plate with inserted plastic rings containing 1 larvae/ring
pupae were transferred to glass jars, adult stage and oviposition in jars as well
Larvae were fed with moth eggs (1. week) and aphids (2. week), adults were fed with a specified feed mixture applied on filter paper
Incubation at 24 ± 2 °C, 80 ± 10 % relative humidity
Light regime : 16 hours light, 8 hours dark
Findings:

Table B.9.5.2-2 : Effects on the lacewing *Chrysopa carnea* exposed to MENTOR in a laboratory trial

Evaluation criteria	**Control**	**Treatment**	**Endpoints**
Survival rate (%)	100	96.7	Preimaginal mortality : 3.3 %
Number of larvae/female	210.1	80.6	Fertility = 61.6 %
			Overall effect (E) = 63.3 %

Conclusion :
According to the IOBC-classification scheme MENTOR could be considered as slightly harmful (W2/1) to populations of the lacewing *Chrysopa carnea*, up to 0.7 L product/ha in 400 L water/ha.

Testing toxicity to beneficial arthropods - parasitic wasp *Aphidius matricariae* Hal./imagines; BAS 492 01 F. (Kleiner R., 1994b).

Guidelines :
IOBC guideline (Polgar 1988)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F, SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph – formulation MENTOR; batch: 93-2
Test species : *Aphidius matricariae Hal*. (parasitic wasp); imagines, about 2 days old
Number of organisms : 10 female wasps X 4 replicates/concentration
Type of test : laboratory test
Applied rates :
0.35 % (v/v), equivalent to 0.7 L MENTOR/ha in 200 L water/ha; water control
Exposure route :
Exposure via the dried off residue on the inner surfaces of the glass plates; total mortality of the wasps within 1 day for the treatment; duration of test for control : 7 days
Test conditions :
Incubation at 20 ° C, 64 - 84 % relative humidity,
Light regime : 16 hours light, 8 hours dark, about 1000 lux
Findings and Conclusion :
Corrected mortality : M (24 h) = 100 %
Beneficial effectivity (E) = 100 %
According to the IOBC-classification scheme MENTOR could be considered as harmful (W4/1) to populations of the parasitoid *Aphidius matricariae* at 0.7 L product/ha in 400 L water/ha.

Testing toxicity to beneficial arthropods - parasitic wasp *Aphidius matricariae Hal.*; semi field; BAS 492 01 F. (Kleiner R., 1994a).

Guidelines :
IOBC guideline (Polgar 1988; Naton and Hassansada 1988)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F, SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test species : *Aphidius matricariae Hal*. (parasitic wasp); imagines, about 2 days old
Number of organisms : 25 female wasps X 4 replicates/concentration
Type of test : semi-field test (15 days)
Applied rates :
0.35 % (v/v), equivalent to 0.7 L MENTOR/ha in 200 L water/ha; water control
Exposure route :
Wheat seedlings, cultivated in plastic boxes (40 x 65 x 18 cm), and infested with aphids (*Rhopalosiphum padi*) were treated. Then 25 females of the parasitoid were transferred to each box, which was covered by a gauze cage. All seedling boxes were placed randomly in a tent.
Test conditions :
Incubation at 8 - 33 °C, 34 - 100 % relative humidity; field conditions

Findings:

Table B.9.5.2-3 : Effects on the parasitic wasp *Aphidius matricariae* exposed to MENTOR in a semi-field trial

Evaluation criteria	Control	Treatment	Endpoints
Mean number of parasitized aphids	161.3	100.5	
Number of parasitized aphids /wasp	6.45	4.02	Overall effect (E) = 37.7 %

Conclusion :
According to the IOBC-classification scheme MENTOR could be considered as slightly harmful (W2/2) to populations of the parasitoid *Aphidius matricariae* up to 0.7 L product/ha in 200 L water/ha.

Effect of BAS 492 01 F on the parasitoid *Aphidius rhopalosiphi* in an extended laboratry test (laboratory test on less vunerable life stage. (Ufer A., 1996a).

Guidelines :
IOBC guideline (Polgar 1988; Mead Briggs 1994)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F, SE containing 148.75 g/L kresoxim-methyl and 304.54 g/L fenpropimorph – formulation MENTOR; batch: 95-1
Test species : Aphidius rhopalosiphi (parasitic wasp); mummies (parasitized aphid)
Number of organisms :
25 mummies X 4 replicates/treatment for the hatching rate investigation
5 wasps X 4 replicates/treatment for the toxicity test
1 female wasp X 10 replicates/treatment for the reproduction test
Type of test : extended laboratory test
Applied rates :
0.7 L MENTOR/ha in 400 L water/ha; water control; dimethoate as positive control
Exposure route :
Exposure to the test substance was achieved:
- by treatment of parasitized mummies
- by contact of the emerged adult wasps with aged residues on wheat seedlings over a period of 48 hours
Test conditions :
Controlled climatic chamber with 16 hours prhotoperiod, temperature of 18.8 - 22.4 °C,
relative humidity of 53.3 - 90.2 %
Findings:

Table B.9.5.2-4 : Effects on the parasitic wasp *Aphidius rhopalosiphi* exposed to MENTOR in an extended lab test

Evaluation criteria	Control	Treatment	Endpoints
percentage of hatched mummies (%)	95	99	
Mortality of adult wasps	0	0	
Number of parasitized aphids /wasp	13.1	10.6	Effect on reproduction : R = 81 %

Conclusion :
From this study no effects on the hatchability of the mummies, the survival of the adults and the reproduction capacity of the parasitoid *Aphidius rhopalosiphi* were observed up to 0.7 L MENTOR/ha in 400 L water/ha.

Effect of BAS 492 01 F on the staphylinid beetle *Aleochara bilineata Gyll.* in a laboratory trial. (Künast Ch., 1994a).

Guidelines :
IOBC/WPRS Bulletin 1992/XV/3
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F, SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test species : *Aleochara bilineata Gyll*. (ground dwelling species)
Number of organisms : (10 male and 10 female insects) X 3 replicates/concentration
Type of test : laboratory test (35 days)
Applied rates :
0.35 % (v/v), equivalent to 0.7 L MENTOR/ha in 400 L water/ha; water control
Exposure route :
Exposure via treated sand surface.
Sand filled glass vessel (Ø : 14 cm; height : 10 cm; 600 mL (sand) contained test beetles (10 couples each)
Female beetles laid eggs near onion fly puparia which were offered as host, 500 pupae at days 8, 15 and 22 after treatment each.
Beetles were fed with frozen midge larvae 5 times the week.
Test conditions : -
Findings:

Table B.9.5.2-5 : Effects on the staphylinid beetle *Aleochara bilineata Gyll.* exposed to MENTOR in a laboratory trial

Evaluation criteria	Control	Treatment	Endpoints
% number of parasitized puparia	25.4 %	25.2 %	parasitization rate : R = 99.2 %
			Overall effect (E) = 0.8 %

Conclusion :
According to the IOBC-classification scheme MENTOR could be considered as harmless (W1/1) to populations of the ground dwelling arthropod *Aleochara bilineata* up to 0.7 L product/ha in 400 L water/ha.

Added in March 2010:

A rate-response laboratory test to determine the effects of BAS 490 02 F on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). (Fussell S., 2003).

Guidelines :
Mead-Briggs *et al*. (2000). A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) (Hymenoptera, Braconidae)
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, WG containing 50.0 % nominal (50.5 % analyzed) kresoxim-methyl – formulation CANDIT; batch: 99-2
Test species : Aphidius rhopalosiphi (parasitoid wasp)
Number of organisms :
Exposure phase : 4 replicates per treatment, each containing 10 wasps (minimum 5 female wasps), adults, < 48 hours old at test start
Reproduction phase : 15 individually-confined female wasps per treatment
Type of test : 14-day laboratory test
Applied rates :
control (200 L water/ha); positive control (0.25 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 200 L water/ha); treatment at 100, 170, 300, 520, 900 g CANDIT/ha (equivalent to 50, 85, 150, 260, 450 g a.s./ha)
Exposure route :
Exposure phase : 2 days exposure by contact to freshly dried spray residues on glass plates
Reproduction phase : untreated potted barley seedlings (*Hordeum vulgare*) infested with more than 100 cereal aphids (mixed culture of *R. padi* and *M. dirhodum*) of mixed ages; 1 day parasitisation of aphid hosts, removal of female wasps followed by 11 days development of mummies
Feeding : 1:3 v/v solution of honey and water
Assessments : Mortality was assessed after 2, 24 and 48 hours. The number of parasitized aphids (mummies) was assessed 11 days after the parasitisation phase.
Test conditions :
temperature : 19 – 21 °C (exposure); 19 – 23 °C (reproduction)
relative humidity : 64 – 74 % (exposure)
photoperiod : 16/8 hours light/dark cycle
light intensity : 700 – 1000 lux (exposure); 6800 – 7700 lux (reproduction)
Findings :

Table B.9.5.2-6 : Effects of the formulation CANDIT on *Aphidius rhopalosiphi* in a laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (g BAS 490 02 F/ha)**				
			100	**170**	**300**	**520**	**900**
% mortality after 48 h	0	100	0	13	25	13	45
% corrected mortality	-	100	0	13	25	13	45
Mean number of mummies per female ± SD	24.2 ± 10.5	-	-	-	12.0* ± 5.9	19.4 ± 6.9	12.9* ± 6.4
Reduction in reproduction relative to control (%)	-	-	-	-	50	20	47

* statistically significantly different from control (one-way ANOVA and Dunnett's test, $p < 0.01$)
Reduction in reproduction relative to control (%): reduction (positive values) and enhancement (negative values)

Conclusion :
The study is acceptable.
LR_{50} (*Aphidius rhopalosiphi*, 48 h) > 900 g CANDIT/ha (450 g a.s./ha)
No unacceptable effects on reproduction of *Aphidius rhopalosiphi* were observed up to 900 g CANDIT/ha.

Effects of BAS 494 04 F on the Parasitoid *Aphidius rhopalosiphi* in the Laboratory – Dose Response Test. (Moll M., 2004).

Guidelines :
Mead-Briggs *et al*. (2000). A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) (Hymenoptera, Braconidae)
GLP :
Yes
Material and Methods :
Test substance : BAS 494 04 F, containing 125.3 g/L (nominal 125.0 g/L) kresoxim-methyl and 124.8 g/L (nominal 125.0 g/L) epoxiconazole – formulation ALLEGRO; batch: 6380
Test species : Aphidius rhopalosiphi (parasitoid wasp)
Number of organisms : 4 replicates per treatment, each containing 10 wasps (5 females and 5 males), adults, < 48 hours old at test start
Type of test : 48-h laboratory test
Applied rates :
control (200 L water/ha); positive control (0.3 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 200 L water/ha); treatment at 250, 500, 1000, 2000, 3000 mL ALLEGRO/ha
Exposure route : 48 hours exposure by contact to freshly dried spray residues on glass plates
Feeding : a solution of fructose (10 %)
Assessments : Mortality was assessed after 2, 24 and 48 hours.
Test conditions :
temperature : 19 – 21 °C
relative humidity : 69 – 88 %
photoperiod : 16/8 hours light/dark cycle
light intensity : 400 – 780 lux
Findings :

Table B.9.5.2-7 : Effects of the formulation ALLEGRO on *Aphidius rhopalosiphi* in a laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (mL BAS 494 04 F/ha)**				
			250	**500**	**1000**	**2000**	**3000**
% mortality after 48 h	0	100*	5.0	15.0	0.0	10.0	5.0
% corrected mortality	-	100	5.0	15.0	0.0	10.0	5.0

* statistically significantly different from control (Mann & Whitney-U-test, $p < 0.05$)

Conclusion :
The study is acceptable.
LR_{50} (*Aphidius rhopalosiphi*, 48 h) > 3000 mL ALLEGRO/ha

Effects of BAS 490 02 F on the Predatory Mite *Typhlodromus pyri* in the Laboratory – Dose Response Test. (Rosenkranz B., 2004a).

Guidelines :
Blümel *et al*. (2000). Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari : Phytoseiidae) for regulatory testing of plant protection products.
Deviation from the study protocol: Protonymphs in the test item treatment groups and positive control were older than 24 hours.
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50.0 % nominal (50.3 % analyzed) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : Typhlodromys pyri (predatory mite)
Number of organisms : 5 replicates for the control, 3 replicates per treatment and for the positive control, each containing 20 mites, protonymphs
Type of test : 7-day laboratory test
Applied rates :
control (200 L water/ha); positive control (9 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 200 L water/ha); treatment at 75, 150, 300, 600, 900 g CANDIT/ha (equivalent to 37.7, 75.0, 150, 300, 450 g a.s./ha)
Exposure route : 7 days exposure by contact to freshly dried spray residues on glass plates
Feeding : a mixture of pine (*Pinus nigra*) and birch (*Betula* sp.) pollen (3:1) *ad libitum* on the day of the test start and on day 2
Assessments : Mortality was assessed after 2 and 7 days.
Test conditions :
temperature : 25 – 27 °C
relative humidity : 66 – 85 %
photoperiod : 16/8 hours light/dark cycle
light intensity : 260 – 470 lux
Findings :

Table B.9.5.2-8 : Effects of the formulation CANDIT on *Typhlodromys pyri* in a laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (g BAS 490 02 F/ha)**				
			75	**150**	**300**	**600**	**900**
% mortality after 7 d	4.0	83.3	11.7	8.3	6.7	25.0*	16.7
% corrected mortality	-	82.6	8.0	4.5	2.8	21.9	13.2

* statistically significantly different from control (Bonferroni t-Test and Holm, α = 0.05)

Conclusion :
The study is acceptable.
LR_{50} (*Typhlodromys pyri*, 7 d) > 900 g CANDIT/ha (450 g a.s./ha)

Effects of BAS 494 04 F on the Predatory Mite *Typhlodromus pyri* in the Laboratory – Dose Response Test. (Rosenkranz B., 2004b).

Guidelines :
Blümel *et al*. (2000). Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari : Phytoseiidae) for regulatory testing of plant protection products.
GLP :
Yes
Material and Methods :
Test substance : BAS 494 04 F, containing 125.3 g/L (nominal 125.0 g/L) and 124.8 g/L (nominal 125.0 g/L) epoxiconazole – formulation ALLEGRO; batch: 6380
Test species : Typhlodromys pyri (predatory mite)
Number of organisms : 5 replicates for the control, 3 replicates per treatment and for the positive control, each containing 20 mites, protonymphs
Type of test : 7-day laboratory test
Applied rates :
control (200 L water/ha); positive control (9 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 200 L water/ha); treatment at 250, 500, 1000, 2000, 3000 mL ALLEGRO/ha
Exposure route : 7 days exposure by contact to freshly dried spray residues on glass plates
Feeding : a mixture of pine (*Pinus nigra*) and birch (*Betula* sp.) pollen (3:1) *ad libitum* on the day of the test start and on day 2
Assessments : Mortality was assessed after 2 and 7 days.
Test conditions :
temperature : 25 – 27 °C
relative humidity : 66 – 85 %
photoperiod : 16/8 hours light/dark cycle
light intensity : 210 – 710 lux
Findings :

Table B.9.5.2-9 : Effects of the formulation ALLEGRO on *Typhlodromys pyri* in a laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (mL BAS 494 04 F/ha)**				
			250	**500**	**1000**	**2000**	**3000**
% mortality after 7 d	4.0	100.0	10.0	16.7	1.7	5.0	6.7
% corrected mortality	-	100.0	6.3	13.2	-2.4	1.0	2.8

* statistically significantly different from control (Bonferroni t-Test and Holm, $\alpha = 0.05$)

Conclusion :
The study is acceptable.
LR_{50} (*Typhlodromys pyri*, 7 d) > 3000 mL ALLEGRO/ha

BAS 490 02 F : Toxicity to the Ground Beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) in the Laboratory. (Staebler P., 2003).

Guidelines :
Heimbach U. *et al*. (2000). A method for testing effects of plant protection products on the carabid beetle *Poecilus cupreus* (Coleoptera Carabidae) under laboratory and semi-field conditions;
EEC 91/414;
Barrett K.L. *et al*. (1994). Guidance Document on regulatory testing procedures for pesticides with non-target arthropods;
EEC 96/12
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % nominal (50.5 % analyzed) kresoxim-methyl – formulation CANDIT, batch: 99-2
Test species : Poecilus cupreus (carabid beetle)
Number of organisms : 5 replicates per treatment, each containing 3 pairs of beetles (3 males and 3 females), adults, about 4 weeks old
Type of test : 14-day laboratory test
Applied rates :
control (400 L water/ha); positive control (1.0 L BAS 152 11 I (nominal 400 g/L dimethoate) in 400 L water/ha); treatment at 900 g CANDIT/ha (equivalent to 450 g a.s./ha)
Exposure route : 14 days exposure by contact to freshly dried spray residues on quartz sand
Feeding : frozen *Delia antiqua* pupae
Assessments : Mortality was assessed after 1 and 3 hours and on day 1. Mortality and food consumption were assessed on days 2, 4, 7, 10 and 14.
Test conditions :
temperature : 19.0 – 22.0 °C
relative humidity : 74 – 94 %
photoperiod : 16/8 hours light/dark cycle
light intensity : 800 – 1000 lux
Findings :

Table B.9.5.2-10 : Effects of the formulation CANDIT on *Poecilus cupreus* in a laboratory test

Evaluation criteria	**Control**	**Positive control**	**900 g BAS 490 02 F/ha**
% mortality after 14 d	0.00	100*	3.33
% corrected mortality	-	100	3.33
Mean number of fly pupae consumed per beetle (day 0 – 14)	4.77	0.43*	4.80
Effect on food consumption compared to the control (%)	-	90.99	-0.63

* statistically significantly different from control (Kruskal-Wallis test, $\alpha = 0.05$ for mortality; Dunnett's test, $\alpha = 0.05$ for food consumption)
Reduction in food consumption relative to control (%): reduction (positive values) and enhancement (negative values)

Behaviour of the test organisms : The beetles in the control and the test item treatment group showed normal activity during the entire exposure period. In the positive control symptoms of paralysis were first observed 3 hours after application.

Conclusion :
The study is acceptable.
LR_{50} (*Poecilus cupreus*, 14 d) > 900 g CANDIT/ha (450 g a.s./ha)
No adverse effects on mortality or food consumption were observed at an application rate of 900 g CANDIT in 400 L water/ha.

A rate-response extended laboratory test to determine the effects of BAS 490 02 F on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae). (Vaughan R., 2007).

Guidelines :
Blümel *et al*. (2000). Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari : Phytoseiidae) for regulatory testing of plant protection products.
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % nominal (48.2 % analyzed) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : Typhlodromys pyri (predatory mite)
Number of organisms : 5 replicates for the control, 3 replicates per treatment and for the positive control, each containing 20 mites, protonymphs
Type of test : 14-day extended laboratory test
Applied rates :
control (200 L water/ha); positive control (30 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 200 L water/ha); treatment at 150, 300, 600, 900, 1250 g CANDIT/ha (equivalent to 75, 150, 300, 450, 625 g a.s./ha)
Exposure route : 14 days exposure by contact to freshly dried spray residues on leaf discs from bean plants (*Phaseolus vulgaris*). For the reproduction assessment, the number of male and female mites in each replicate were recorded at 7 days after treatment, this ensured that there was at least one male present per 5 females in each replicate. Any eggs that were produced prior to 7 DAT were removed and discarded.
Feeding : a 1:1 v/v mixture of walnut (*Juglans regia*) and apple (*Malus* sp.) pollen
Assessments : Mortality of the mites was assessed approximately 24 hours and 7 days after treatment. Assessments of oviposition activities were carried out at 9, 11 and 14 days after treatment.
Test conditions :
temperature : 25 – 26 °C (mortality assessment and fecundity assessment)
relative humidity : 65.7 – 73.6 % (mortality assessment); 45.1 – 72.1 % (fecundity assessment)
photoperiod : 16/8 hours light/dark cycle
light intensity : 800 – 1100 lux
Findings :

Table B.9.5.2-11 : Effects of the formulation CANDIT on *Typhlodromys pyri* in an extended laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (g BAS 490 02 F/ha)**				
			150	**300**	**600**	**900**	**1250**
% mortality after 7 d	14.0	93.3*	16.7	25.0	20.0	31.7*	21.7
% corrected mortality	-	92.2	3.1	12.8	7.0	20.5	8.9
Mean number of eggs per female	5.1	-	4.1	3.8	4.4	4.4	3.3
Effects on reproduction (%)	-	-	20.1	24.9	13.7	13.6	34.4

* statistically significantly different from control (Fisher's Exact Test, $\alpha = 0.05$ for mortality; one-way ANOVA, $\alpha = 0.05$ for fecundity)
Reduction in reproduction relative to control (%): reduction (positive values) and enhancement (negative values)

Conclusion :
The study is acceptable.
LR_{50} (*Typhlodromys pyri*, 7 d) > 1250 g CANDIT/ha (625 g a.s./ha)
Under extended laboratory test conditions, CANDIT had no significant effects on reproduction of mites at rates up to and including 1250 g BAS 490 02 F/ha.

Effects of BAS 490 02 F on the parasitic wasp *Aphidius rhopalosiphi* (DeStephani-Perez) (Hymenoptera: Braconidae) in an extended laboratory trial – dose response design – (Noe J., 2007).

Guidelines :
Mead-Briggs M. A. *et al*. (2002). An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (DeStephani-Perez) (Hymenoptera, Braconidae). Draft of 3 October 2002, unpublished.
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % nominal (48.2 % analyzed) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : Aphidius rhopalosiphi (parasitoid wasp)
Number of organisms :
Exposure phase : 6 replicates per treatment, each containing 5 female wasps, adults, ≤ 48 hours old at test start
Reproduction phase : 15 individually-confined female wasps per treatment
Type of test : 14-day extended laboratory test
Applied rates :
control (400 L water/ha); positive control (14.0 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 400 L water/ha); treatment at 150, 300, 600, 900, 1250 g CANDIT/ha (equivalent to 75, 150, 300, 450, 625 g a.s./ha)
Exposure route :
Exposure phase : The exposure plants were seedlings of barley (*Hordeum vulgare*) at BBCH 12. Before application, the seedlings were lightly sprayed with a 10 % w/w fructose solution and were left to dry. The sugar provides both food and a foraging stimulus for the wasps. The seedlings were treated and were covered by a clear polyacrylic cylinder.
Reproduction phase : The plants used for the assessment of reproduction were untreated barley seedlings (*Hordeum vulgare*) at BBCH 11. They were infested with ≥ 100 host aphids (*Rhopalosiphum padi*) of all developmental stages. The wasps were transferred from the exposure test units to the reproduction test units. 24 hours after release into the reproduction test units, the parasitisation period was finished and the wasps were removed from the test units again.
Assessments : Mortality was assessed after 2, 24 and 48 hours. To determine whether the residue of the test item is repellent to the wasps, observations on the position of the individual insects were made during the initial 2.5 hours after their release. The number of parasitized aphids (mummies) was assessed 11 days after the parasitisation phase.
Test conditions :
temperature : 17.9 – 19.9 °C (exposure phase); 17.9 – 21.1 °C (reproduction phase)
relative humidity : 55.0 – 75.6 % (exposure phase)
photoperiod : 16/8 hours light/dark cycle (exposure + reproduction phase)
light intensity : 690 – 870 lux (exposure phase); 900 – 1180 lux (parasitisation phase); 8300 – 10900 lux (post-parasitisation phase)

Findings :

Table B.9.5.2-12 : Effects of the formulation CANDIT on *Aphidius rhopalosiphi* in an extended laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (g BAS 490 02 F/ha)**				
			150	**300**	**600**	**900**	**1250**
% mortality after 48 h	0.00	80.00*	3.33	0.00	0.00	0.00	0.00
% corrected mortality	-	80.00	3.33	0.00	0.00	0.00	0.00
Mean number of mummies per female ± SD	13.79 ± 11.19	-	-	-	12.62 ± 7.60	10.85 ± 7.15	7.93 ± 4.68
Reproduction relative to control (%)	-	-	-	-	8.49	21.32	42.45

* statistically significantly different from control (Fisher's Exact Test, α = 0.05 for mortality; Bonferroni t-Test, α = 0.05 for reproduction)
Reduction in reproduction relative to control (%): reduction (positive values) and enhancement (negative values)

Repellency effects: During the initial 2.5 hours after release into the test units 80.00 % of the wasps settled on the plants in the control treatment. In the different CANDIT treatments 72.00 % - 82.00 % of the wasps settled on the plants. It can be concluded that CANDIT has no repellency effects on *Aphidius rhopalosiphi* when applied at application rates of 150 g/ha up to 1250 g/ha.

Conclusion :
The study is acceptable.
LR_{50} (*Aphidius rhopalosiphi*, 48 h) > 1250 g CANDIT/ha (625 g a.s./ha)
No unacceptable effects on reproduction of the parasitic wasp *Aphidius rhopalosiphi* were observed when CANDIT was applied up to and including a rate of 1250 g/ha in 400 L water/ha.

An Extended Laboratory Study to Evaluate the Effects of BAS 490 02 F on the Ladybird Beetle, *Coccinella septempunctata* L. (Coleoptera, Coccinellidae). (Hirth N., 2001).

Guidelines :
Schmuck R. *et al*. (Draft 02/2000) Laboratory test system using the plant dwelling non-target insect *Coccinella septempunctata* (Coleoptera: Coccinellidae) to generate data for registration of plant protection products;
Barrett K.L. *et al*. (1994) Guidance Document on regulatory testing procedures for pesticides with non-target arthropods
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % nominal (50.5 % analyzed) kresoxim-methyl – formulation CANDIT, batch: 99-2
Test species : Coccinella septempunctata (ladybird beetle)
Number of organisms:
Exposure phase : 50 replicates per treatment, each containing 1 larvae, 3-4 days old (1st to 2nd instars)
Reproduction phase :
Control : one reproduction unit : 8 females, 10 males
100 g/ha : two reproduction units : 6 females, 7 males and 4 females, 7 males
240 g/ha : two reproduction units : 8 females, 11 males for both units
540 g/ha : two reproduction units : 8 females, 7 males and 11 females, 9 males
The reproduction performance of the positive control was not assessed
Type of test : extended laboratory test
Applied rates :
control (200 L water/ha); positive control (30 mL Afugan EC 30 (nominal 294 g/L pyrazophos) in 200 L water/ha); treatment at 100, 240, 540 g CANDIT/ha (equivalent to 50, 120, 270 g a.s./ha)

Exposure route :
Exposure phase : exposure by contact to freshly dried spray residues on apples leaves
Reproduction phase : Glass terrariums containing potted broad bean plants (*Vicia faba*) with aphids (*Acyrthosiphon pisum* and *Megoura viciae*), a mixture of different pollen types and honey-water solution (1:1) were used as reproduction units.
Assessments : The survival and development of the larvae was recorded at intervals of 1 to 3 days until metamorphosis was completed. Egg counting was conducted for 14 days (8 assessment days) and the viability of the eggs was evaluated by recording the hatching rate.
Test conditions :
temperature : 22 – 27 °C
relative humidity : 56 – 78 %
photoperiod : 16/8 hours light/dark cycle
light intensity : 2320 – 2546 lux
Findings :

Table B.9.5.2-13 : Effects of the formulation CANDIT on *Coccinella septempunctata* in an extended laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (g BAS 490 02 F/ha)**		
			100	**240**	**540**
Mean mortality (%)	20.00	52.00*	18.00	10.00	8.00
Corrected mortality (%)	-	40.00	-2.50	-12.50	-15.00
Fecundity (mean number of eggs/female/day	9.85	-	8.46	13.47	6.95
Fertility (mean hatching rate) (%)	75.18	-	88.07	92.63	94.27
Mean number of fertile eggs/female/day	7.31	-	8.32	12.65	6.46
Reproduction relative to control (%)	-	-	-13.8	-73.1	11.6

* statistically significantly different from control (Fisher's Exact Test, $p \leq 0.05$ for mortality)
Reduction in reproduction relative to control (%): reduction (positive values) and enhancement (negative values)

Conclusion :
The study is acceptable.
No unacceptable effects on mortality or reproduction were observed for the foliage dwelling predator *Coccinella septempunctata* when applied at rates up to 540 g CANDIT/ha (270 g a.s./ha).

An Extended Laboratory Study with Freshly Applied and Aged Residues to Evaluate the Effects of BAS 490 02 F on the Ladybird Beetle, *Coccinella septempunctata* L. (Coleoptera, Coccinellidae) – Aged Residue Trial – (Warmers C., 2003).

Guidelines :
Schmuck R. *et al.* (Draft 02/2000) Laboratory test system using the plant dwelling non-target insect *Coccinella septempunctata* (Coleoptera: Coccinellidae) to generate data for registration of plant protection products;
EEC 91/414;
Barrett K.L. *et al.* (1994) Guidance Document on regulatory testing procedures for pesticides with non-target arthropods;
Candolfi *et al.* 2001
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % nominal (50.5 % analyzed) kresoxim-methyl – formulation CANDIT, batch: 99-2
Test species : Coccinella septempunctata (ladybird beetle)

Number of organisms :
Exposure phase : 50 replicates per treatment, each containing 1 larvae, 3-5 days old
Reproduction phase :
Control; 600, 900 g CANDIT/ha : up to two reproduction units, considered as one replicate
The reproduction performance of the positive control was not assessed
Type of test : aged residue laboratory test
Bioassays were initiated using freshly-treated foliage at 0 days after treatment (0 DAT) and using aged residues on foliage collected 7 DAT. As the corrected mortality in the first bioassay for both test item treatments was < 30 % and no effects on reproduction capacity were observed, the second bioassay initiated 7 days after treatment (7 DAT) was terminated and is not reported.
Applied rates :
control (400 L water/ha); positive control (10 mL BAS 152 11 I (nominal 400 g/L dimethoate) in 400 L water/ha); treatment at 600, 900 g CANDIT/ha (equivalent to 300, 450 g a.s./ha)
Exposure route :
Exposure phase : exposure by contact to freshly dried spray residues on apples leaves
Reproduction phase : Glass terrariums containing potted broad bean plants (*Vicia faba*) with aphids (*Acyrthosiphon pisum*), a mixture of different pollen types and honey-water solution (1:1) were used as reproduction units.
Assessments : The survival and development of the larvae was recorded at intervals of 1 to 3 days until metamorphosis was completed. Egg counting was conducted for 12 days (8 assessment days) and the viability of the eggs was evaluated by recording the hatching rate.
Test conditions :
temperature : 24 – 26 °C
relative humidity : 30 – 86 %
photoperiod : 16/8 hours light/dark cycle
light intensity : 1400 – 2000 lux
Findings :

Table B.9.5.2-14 : Effects of the formulation CANDIT on *Coccinella septempunctata* in an extended laboratory test

Evaluation criteria	**Control**	**Positive control**	**Test rate (g BAS 490 02 F/ha)**	
			600	**900**
Mean mortality (%)	2.0	90.0*	2.0	12.0
Corrected mortality (%)	-	89.8	0.0	10.2
Fecundity (mean number of eggs/female/day	18.03	-	14.36	19.32
Fertility (mean hatching rate) (%)	83.82	-	94.68	83.08
Mean number of fertile eggs/female/day	14.92	-	13.20	15.49
Reproduction relative to control (%)	-	-	11.5	-3.8

* statistically significantly different from control (Fisher's Exact Test, α = 0.05 for mortality)
Reduction in reproduction relative to control (%): reduction (positive values) and enhancement (negative values)

Conclusion :
The study is acceptable.
No unacceptable effects on mortality or reproduction were observed for the foliage dwelling predator *Coccinella septempunctata* when exposed to rates up to 900 g CANDIT/ha (450 g a.s./ha) (fresh residues).

B.9.5.3 Effects of the formulations on non-target terrestrial arthropods (field tests) (Annex IIIA 10.5.2)

The field studies concerning the effects of CANDIT on *Typhlodromus pyri* were included in the monograph because they dealt with the effects of the a.s. kresoxim-methyl for one of its main use (orchard and vines) in the conditions of the practice.

Biological evaluation of BAS 490 02 F (WG - 50% kresoxim-methyl) on apple and pear - Trials 1992-1993-1994. (Research Station of Gorsem, 1995).

Guidelines :
IOBC/Working group "Pesticides and beneficial organisms"
GLP :
No
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g/kg kresoxim-methyl - formulation CANDIT
Test species :
The trials were realized in orchards with a sufficient number of *Typhlodromus pyri*, at least a mean value of 1 predatory mite on 2 leaves is required. All the predatory mites in the testing orchards are from the same origin, an organophosphates and carbamates resistant strain from the Netherlands.
Experimental design :
- 3 field trials in orchard were performed in 1993 and 1994; the trials were designed as randomized blocks with 4 replications of at least 10 trees. Near CANDIT, formulations containing captan, thiram, mancozeb, metiram,... were tested.
- In each object 4 times 50 leaves were examined with binocular. The Henderson-Tilton formula was applied on these results. Henderson-Tilton criteria < + 25 % means that the product is harmless.
- Maximum and minimum temperatures, sunshine and rainfall were recorded.
Findings :
3 trials were performed in apples orchard in Belgium. The calculation of the effect criteria showed that kresoxim-methyl has a low impact on *Typhlodromus pyri*.
- Effects > 25 % observed transiently in one case in the trial in Wijer.
- In the 3rd trial performed in Rummen the application of CANDIT was made in association with other plant protection products having their own impact on *Typhlodromus* (E > 25 % in one case after 9 appl.).

Table B.9.5.3-1 : Overview of 3 trials in orchard evaluating the effects of CANDIT on *Typhlodromus pyri*

Location	Kozen (Belgium)		Wijer (Belgium)	Rummen (Belgium)
Crop	apple Jonagold		apple Jonagold	apple Jonagold
Experimental design	4 replicates/treatment 10 trees/object		4 replicates/treatment 18 trees/object	4 replicates/treatment 10 trees/object
Number of applications	4 applications between 20/07/93 and 11/08/93		6 applications between 04/07/94 and 16/08/94	12 applications between 21/03/94 and 18/07/94
Application rate	100 g a.s./ha 1500 L water/ha	200 g a.s./ha 1500 L water/ha	100 g a.s./ha 1500 L water/ha	100 g a.s./ha 1500 L water/ha (in association with 800 g/ha metiram from 10/06/94)
Henderson-Tilton coefficient	E (after 2 appl.) = -25.1 % E (after 4 appl.) = -13.3 %	E (after 2 appl.) = -20.0 % E (after 4 appl.) = 10.1 %	E (after 2 appl.) = -15.6 % E (after 4 appl.) = -26.5 % E (after 6 appl.) = **33.6 %**	E (after 9 appl.) = **32.45 %** E (after 12 appl.) = 18.53 % E (60 d after last appl.) = -11.49 %

bold : E > 25 % slightly harmful

Conclusion :
Kresoxim-methyl is harmless to *Typhlodromus pyri* in the field.

Field study of the effects of BAS 490 02 F on predaceous mites *(Typhlodromus pyri*) on grape vines with two pre-bloom and four post-bloom applications. (Lipps H., 1994).
Field study of the effects of BAS 490 02 F on predaceous mites *(Typhlodromus pyri*) on grape vines with two pre-bloom and four post-bloom applications. (Ipach R., 1994).

Guidelines :
BBA guidelines 23-2.3.4 : "Testing the effects on predatory mites in grapes"
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g/kg kresoxim-methyl - formulation CANDIT
Test species : Typhlodromus pyri (predatory mites)
Experimental design :
- The trials were designed as randomized blocks with 4 replicates/treatment.
Water control and formulation TOPAS (penconazol, a fungicide harmless to *Typhlodromus*, 53-220 g a.s./ha) were used as control.
- 6 applications were made (2 pre-bloom and 4 post-bloom) with increasing rates of the formulation.
- 7 days and 28 days after last application, 4 X 25 leaves were taken from each trial variant. *Typhlodromus pyri* were washed off the leaves and counted. The results were computed after the equation of Abbot.
- Weather conditions data were collected from a climatic station near the study site.

Findings :

Table B.9.5.3-2 : Overview of 2 trials in vineyards evaluating the effects of CANDIT on *Typhlodromus pyri*

Location	Bad Kreuznach (Germany)	Neustadt (Germany)
Crop	Müller-Thurgau grapes	Riesling grapes
Experimental design	4 replicates/treatment 30 vines/object	4 replicates/treatment 24 vines/object
Applications	25/05/93 pre-bloom 73 g a.s./ha 400 L/ha 04/06/93 pre-bloom 113 g a.s./ha 600 L/ha 14/06/93 post bloom 181 g a.s./ha 1000 L/ha 28/06/93 post bloom 213 g a.s./ha 1200 L/ha 12/07/93 post bloom 263 g a.s./ha 1400 L/ha 26/07/93 post bloom 297 g a.s./ha 1600 L/ha	19/05/93 pre-bloom 74 g a.s./ha 400 L/ha 02/06/93 pre-bloom 114 g a.s./ha 600 L/ha 16/06/93 post bloom 190 g a.s./ha 1000 L/ha 25/06/93 post bloom 228 g a.s./ha 1200 L/ha 09/07/93 post bloom 266 g a.s./ha 1400 L/ha 27/07/93 post bloom 304 g a.s./ha 1600 L/ha
Abbot coefficient	E (7 d after last appl.) = - 39 % E (28 d after last appl.) = 22 %	E (7 d after last appl.) = - 10 % E (28 d after last appl.) = **35 %**

Conclusions :
Kresoxim-methyl is harmless to *Typhlodromus pyri* in vineyards.

Field study of the side effects of BAS 490 02 F on predatory mites *(Typhlodromus pyri*). (Rohner R., 1994).

Guidelines :
BBA guidelines 23-2.3.4 : "Testing the effects on predatory mites in grapes"
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g/kg kresoxim-methyl - formulation CANDIT
Test species : Typhlodromus pyri (predatory mites). Before treatment mean values per leaf sample (50 leaves) varied between 14.7 and 21.3 individuals.
Experimental design :
- The trial was designed as randomized blocks with 3 replicates/treatment.
- 3 kg product/ 2000 L /ha DITHANE DG (75 % mancozeb) were used as toxic standard;
  2 kg product/ 2000 L / ha TOPAS C (2.5 % penconazol, 47.5 % captan) was used as neutral standard.
- 7 days and 28 days after last application, 50 leaves were taken from each trial variant. *Typhlodromus pyri* were washed off the leaves and counted. The results were computed after the Henderson-Tilton method.
- Weather conditions data were collected during the applications and recorded in the report.
Findings :

Table B.9.5.3-3 : Overview of a trial in apples evaluating the effects of CANDIT on *Typhlodromus pyri*

Location	Riddes (Switzerland)
Crop	apple Jonagold
Experimental design	3 replicates/treatment 7-10 trees/object
Number of applications	8 applications between 18/06/93 and 14/08/93
Application rate	150 g a.s/ha 2000 L water /ha
Henderson-Tilton coefficient	E (7 days after last appl.) = 25.3 % E (28 days after last appl.) = 15.8 %

Conclusion :
Kresoxim-methyl is harmless to *Typhlodromus pyri* in apple.

Assessment of side effects of BAS 490 02 F on the predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) in apple orchard. (Kühner C., 1994b).

Guidelines :
BBA guidelines 23-2.3.4 : "Testing the effects on predatory mites in grapes"
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g/kg kresoxim-methyl - formulation CANDIT
Test species : predatory mites (*Typhlodromus pyri*) and spider mites (*Tetranychus urticae, Panonychus ulmi*)
For each sampling the following data were recorded :
- condition of the leaf sample
- number of eggs of predatory mites
- number of nymphs and adults of predatory mites (*Typhlodromus pyri* and other species)
- number of eggs of spider mites
- number of spider mites

Experimental design :
- The trial was designed as randomized blocks with 4 replicates/treatment.
- A control not treated and DITHANE Ultra WG (75 % mancozeb) as toxic standard were used.
- 25 leaves per plot were taken from each trial variant. Mites were washed off the leaves and counted. The results were computed after the method of Feurer and Kast.
- Weather conditions data were collected from a climatic station near the study site.

Findings :

Table B.9.5.3-4 : Overview of a trial in apples evaluating the effects of CANDIT on *Typhlodromus pyri*

Location	Pfinztal-Söllingen (Germany)
Crop	apple Jonagold
Experimental design	4 replicates/treatment
Number of Applications	8 applications between 26/05/94 and 01/08/93
Application rate	150 g a.s/ha 1500 L water /ha
Feurer and Kast coefficient	E (16/06/94) = 4.3 % E (30/06/94) = 26.5 % E (19/07/94) = -13.3 % E (08/08/94 - 7 days after last appl.) = 16.8 % E (29/08/94 - 28 days after last appl.) = **54.3 %**

Table B.9.5.3-5 : Results of a field trial in apples evaluating the effects of CANDIT on *Typhlodromus pyri*

sam-pling dates	Predatory mites						Spider mites					
	number of eggs			number of mites			number of eggs			number of mites		
	water control	Candit	Dithane	water control	Candit	Dithane	water control	Candit	Dithane	water control	Candit	Dithane
17/05	13.0	16.5	13.8	12.3	15.5	14.0	0.2	0.0	0	0.2	0.0	0.2
16/06	4.2	4.5	0.2	32.7	31.3	20.5	0.0	0.0	0	0.0	0.0	0.5
30/06	12.5	5.7	1.5	59.2	43.5	9.0*	0.0	0.0	0	0.0	0.2	0.0
19/07	15.5	20.8	1.3	54.7	62.0	7.0*	0.0	0.2	0	0.0	0.5	0.2
08/08	3.5	4.0	0.8	51.7	43.0	3.0*	0.2	0.5	6.7	0.8	1.3	7.7
29/08	4.5	2.0	0.5	45.5	**20.8***	2.5*	0.0	0.0	11.3	0.8	0.2	10.8

- The evolution of the populations of *Typhlodromus pyri* in the water control and CANDIT were almost parallel : As in the control, the number of mites increased in the CANDIT variant after the first assessment. As in the control, there was also a decline in August. However, unlike in the control, the increase was slightly retarded, the maximum value was reached 2 weeks later and the decline in August was more pronounced resulting in a significantly smaller number of mites at the last assessment (28 days after last appl.).

- The populations of spider mites were very low in the water control and in CANDIT treatment. At no time a significant increase of the spider mite populations occurred in the CANDIT treatment which might indicate that predatory mite population was depressed in an ecological significant degree. In the mancozeb reference an important increase of the spider mites populations was observed from 19/07/94.

Conclusion :
The experiment was made in a worst case situation (8 applications; rate higher than the recommended GAP). In these conditions effects of CANDIT on predatory mites were observed at one of the sampling dates. CANDIT seems therefore harmless to *Typhlodromus pyri*.

Evaluation by field test of the side effects of CANDIT 50 WG on predatory bugs Anthocoridae. (Research Station of Gorsem, 1996).

Guidelines :
Own procedure of the station.
GLP :
The study is not GLP.
Material and Methods :
Test substance : BAS 490 02 F, WG containing 500 g/kg kresoxim-methyl - formulation CANDIT
Test species : Anthocoris species, predatory bugs of the pear sucker (*Psylla pyri*), larvae and adults
Experimental design :
- The trial was designed as randomized blocks with 4 replicates/treatment.
- A control not treated and DECIS (deltamethrin, 11 g/ha) as toxic standard were used.
- Monitoring was done by 3 short but powerful knockings on the main branch, keeping a white tray (45 X 60 cm) under it to collect fallings arthropods. 5 trees/object at both row sides were investigated. The results were computed after the method of Abbot.
- Weather conditions data were reported.
Findings :

Table B.9.5.3-6 : Overview of a field trial in pears evaluating the effects of CANDIT on *Anthocorid* species

Location	Halmaal (Belgium)	
Crop	pear Conference	
Experimental design	4 replicates/treatment 5 trees/object	
Number of applications	5 applications on 12/06/96, 21/06/96, 02/07/96, 16/07/96, 22/07/96	
Application rate	100 g a.s/ha 1500 L water /ha	
Abbot coefficient	nymphs E (14/06/96) = 19.4 % E (21/06/96) = **25.0 %** E (28/06/96) = **42.5 %** E (26/07/96) = **40.7 %**	adults E (14/06/96) = -32.6 % E (21/06/96) = **31.4 %** E (28/06/96) = 23.3 % E (26/07/96) = -2.7 %

Conclusion :
5 succesive treatments with an interval of 10 days were slightly harmful for nymphs and adults of predatory bugs according to IOBC criteria used for field tests.

Added in March 2010:

According to the risk assessment scheme no field studies would be necessarily required for CANDIT as representative formulation of kresoxim-methyl. However, in the previous dossier field studies had been submitted. In the meanwhile the guideline for such field studies was revised. Therefore, new studies compliant with the new guideline were conducted to replace the old studies. The replacement was done to keep the information given in the original dossier on an updated scientific level.
This applies to the studies Lehmus J., 2008a; Lehmus J., 2007; Lehmus J., 2008d and 2008e; Lehmus J., 2008b and Lehmus J., 2008c and 2008f.

A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Southern France - 4 applications. (Lehmhus J., 2008a).

Guidelines :
Bluemel *et al*. (2000)
BBA VI 23-2.3.4
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % (w/w) (nominal) or 48.2 % (w/w) (analytical) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : predatory mites (Acari: Phytoseiidae), naturally established field population
Test site : The field study was performed in Southern France, Departement Haute Savoie, 74330 Annecy-Poisy, located in a region typical for cultivation of apples. Crop: apple, variety: Idared, 1111 plants/ha, plant height 3.0 m, 4.5 m distance between the rows, 2.0 m distance between the plants; plot size: 6 trees in one row, 1 buffer row between the plots. The agricultural practices and variety were in accordance with the local farming practices. The test site received some pesticides during trial period (actives: Sulphur, Captan, Bupirimate).
Test design : Natural occurring populations of predatory mites were treated with 4 applications of **CANDIT** in an apple orchard. The study comprised 3 treatment groups (test item, water treated control and a reference item) with 5 replicates (plots) for the test item and the control and 3 replicates (plots) for the reference item. The plots were distributed according to a fully randomized block design. The number of predatory mites per leaf in each plot was assessed 3 days before the 1st application. Plots with similar mite population density were assigned to the same block. Each treatment included plots from each block (except the reference item, as it consists only of 3 plots). To avoid contamination of the neighboring plots during application due to drift an untreated buffer row was included between the plots. Furthermore, only the 4 apple trees within the centre of each plot were used for evaluation to provide a buffer zone between neighboring plots in the same row. The population development of predatory mites was assessed determining the total number of mites on flower bud clusters or leaf samples. Assessments were carried out 7 days after the 1st, 6 days after the 2nd and 6 and 27 days after the 4th (last) application.

Table B.9.5.3-7 : Treatments, replicates and plot specifications

Design	Fully randomized blocks
Treatments	1. water control = C 2. test item (BAS 490 02 F) = T 3. reference item (Decis Protech) = R
Replicates per treatment	C, T : 5 (a, b, c, d, e) R : 3 (a, b, c)
Size of the plots	6 apple trees in one row
Distance between plots	In one row : none In different rows : 1 buffer row
Minimum distance between plot and end of the apple orchard	2.0 m

Applications :
- Control (900 L tap water/ha)
- Test item (CANDIT) was applied 4 times between end of April and end of May, with application intervals of 9 to 12 days (1st application at BBCH 65, 2nd application at BBCH 69, 3rd application at BBCH 71-72, 4th application at BBCH 73-74; 0.20 kg in 900 L water/ha for 1st and 2nd application, 0.25 kg in 900 L water/ha for 3rd and 4th application)
- Reference item (Decis Protech, 15 g/L deltamethrin) was applied 2 times, at the 1st and 3rd application of the test item at application rates of 0.7 L in 900 L water/ha

Test conditions : The climatic conditions (temperature, humidity and rain) were recorded throughout the experimental period at a local weather station.

Findings :

In total, 228 mites were identified. 99.6 % of the mites investigated were determined as *Typhlodromys pyri* and 0.4 % as *Paraseilus talbii*. The fluctuations in mite numbers observed during the course of this study were within the normal range for predatory mite populations in an apple orchard.

Table B.9.5.3-8 : Mean number of predatory mites exposed to CANDIT under field conditions

Assessment	Date	Mean number of mites per sample component		
		Control	BAS 490 02 F	Reference item
3 days before 1st application	18.4.2007	0.67	0.89 *	0.64
7 days after 1st application	28.4.2007	0.44	0.42	0.03 *
6 days after 2nd application	6.5.2007	0.43	0.44	0.02 *
6 days after 4th application	28.5.2007	1.00	0.94	0.17 *
27 days after 4th application	18.6.2007	1.05	1.02	0.43 *

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Table B.9.5.3-9 : Effects on predatory mites in an apple orchard exposed to CANDIT in a field trial according to Abbott and Henderson & Tilton

Assessment	Effects [%]			
	Abbott		Henderson & Tilton	
	BAS 490 02 F	Reference item	BAS 490 02 F	Reference item
3 days before 1st application	-31.6*	4.5	--	--
7 days after 1st application	4.5	94.0*	27.5	93.7*
6 days after 2nd application	-2.3	95.3*	22.3	95.1*
6 days after 4th application	5.6	82.7*	28.3	81.9*
27 days after 4th application	2.3	58.7*	25.8	56.7*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Spider mites and special observations : Spider mites (*Panonychus ulmi*) occurred in low numbers in all treatment groups from the 2nd to the 5th assessment. The highest mean spider mite density of 0.22 mites per leaf was found in the reference item treatment at the 5th assessment (27 DAA4). Few other mites occurred throughout the trial.

Conclusion :

The study is acceptable.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if CANDIT was applied 4 times at application rates of 0.20 kg/ha CANDIT at the 1st and 2nd application and 0.25 kg/ha CANDIT at the 3rd and 4th application at water volumes of 900 L/ha in an apple orchard in Southern France.

A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Germany - 4 early applications. (Lehmhus J., 2007).

Guidelines :
Bluemel *et al*. (2000)
BBA VI 23-2.3.4
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % (w/w) (nominal) or 48.2 % (w/w) (analytical) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : predatory mites (Acari: Phytoseiidae), naturally established field population
Test site : The field study was performed in South West Germany, Walzbachtal-Wössingen, Baden-Württemberg, located in a region typical for cultivation of apples. Crop: apple; variety: Jonika, 2079 plants/ha, plant height 2.2 m, 3.7 m distance between the rows, 1.3 m distance between the plants; plot size: 8 trees in one row, 1 buffer row between the rows. The agricultural practices and variety were in accordance with the local farming practices. The test site received some fertilizes and pesticides (actives: *Bacillus thuringiensis*, Dithianon, Flusilazol, Penconazol, Granulosis virus).
Test design : Natural occurring populations of predatory mites were treated with 4 applications of CANDIT in an apple orchard. The study comprised 3 treatment groups (test item, water treated control and a reference item) with 5 replicates (plots) for the test item and the control and 3 replicates (plots) for the reference item. The plots were distributed according to a fully randomized block design. The number of predatory mites per leaf in each plot was assessed 1 day before the 1st application. Plots with similar mite population density were assigned to the same block. Each treatment included plots from each block (except the reference item, as it consists only of 3 plots). To avoid contamination of the neighboring plots during application due to drift an untreated buffer row was included between the plots. Furthermore, only the 6 apple trees within the centre of each plot were used for evaluation to provide a buffer zone between neighboring plots in the same row. The population development of predatory mites was assessed determining the total number of mites on leaf samples. Assessments were carried out 7 days after the 1st, 6 days after the 2nd and 6 and 26 days after the 4th (last) application.

Table B.9.5.3-10 : Treatments, replicates and plot specifications

Design	Fully randomized blocks
Treatments	1. water control = C 2. test item (BAS 490 02 F) = T 3. reference item (Decis flüssig) = R
Replicates per treatment	C, T : 5 (a, b, c, d, e) R : 3 (a, b, c)
Size of the plots	8 apple trees in one row
Distance between plots	In one row : minimum none, maximum 12 trees In different rows : 1 buffer row
Minimum distance between plot and end of the apple orchard	2.60 m

Applications :
- Control (tap water; same amount used for test item and reference item)
- Test item (CANDIT) was applied 4 times between mid-April and beginning of May, with application intervals of 7 to 9 days (1st application at BBCH 57, 2nd application at BBCH 65, 3rd application at BBCH 71, 4th application at BBCH 72; 0.20 kg in 900 L water/ha for 1st application, 0.20 kg in 1000 L water/ha for 2nd application, 0.25 kg in 1100 L water/ha for 3rd and 4th application)
- Reference item (Decis flüssig, 25 g/L deltamethrin) was applied 2 times, at the 1st and 3rd application of the test item at application rates of 0.7 L/ha in same amount of water used for test item
Test conditions : The climatic conditions (temperature, humidity and rain) were recorded throughout the experimental period at a local weather station.

Findings :

In total, 255 mites were identified. 99.6 % of the mites investigated were determined as *Typhlodromys pyri* and 0.4 % as *Euseius finlandicus*. The fluctuations in mite numbers observed during the course of this study were within the normal range for predatory mite populations in an apple orchard.

Table B.9.5.3-11 : Mean number of predatory mites exposed to CANDIT under field conditions

Assessment	Date	Mean number of mites per leaf		
		Control	BAS 490 02 F	Reference item
1 day before 1st application	10.4.2007	1.27	1.34	1.31
7 days after 1st application	18.4.2007	0.56	0.61	0.01*
6 days after 2nd application	24.4.2007	0.37	0.37	0.00*
6 days after 4th application	10.5.2007	0.40	0.41	0.00*
26 days after 4th application	30.5.2007	0.57	0.67	0.01*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Table B.9.5.3-12 : Effects on predatory mites in an apple orchard exposed to CANDIT in a field trial according to Abbott

Assessment	BAS 490 02 F [%]	Reference item [%]
1 day before the 1st application	-5.2	-3.0
7 days after the 1st application	-8.2	98.2
6 days after the 2nd application	0.5	100.0
6 days after the 4th application	-4.0	100.0
26 days after the 4th application	-17.4	98.8

Spider mites and special observations : Spider mites (*Panonychus ulmi*) occurred in low numbers. The highest mean spider mite density of 1.0 mites per leaf was found in the reference item treatment at the 5th assessment (26 DAA4). Few Eriophyidae occurred in the 1st and 2nd assessment and a single Acarid mite was found at the 2nd assessment (6DAA1).

Conclusion :

The study is acceptable.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if CANDIT is applied 4 times at application rates of 0.20 kg/ha CANDIT in 900 L/ha water for the 1st application, of 0.20 kg/ha CANDIT in 1000 L/ha water for the 2nd application and 0.25 kg/ha CANDIT in 1100 L/ha water for the 3rd and 4th application in an apple orchard.

A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Germany - 4 late applications. (Lehmhus J., 2008d).
Report amendment No 1 to study 20071146/G2-NFTp: A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Germany - 4 late applications. (Lehmhus J., 2008e).

Guidelines :
Bluemel *et al*. (2000)
BBA VI 23-2.3.4
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % (w/w) (nominal) or 48.2 % (w/w) (analytical) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : predatory mites (Acari: Phytoseiidae), naturally established field population
Test site : The field study was performed in South West Germany, Walzbachtal-Wössingen, Baden-Württemberg, located in a region typical for cultivation of apples. Crop: apple; variety: Jonika, 2079 plants/ha, plant height 2.4 m, 3.7 m distance between the rows, 1.3 m distance between the plants; 8 trees in one row, 1 buffer row between the rows. The agricultural practices and variety were in accordance with the local farming practices. The test site received some pesticides (actives: Captan, Penconazol).
Test design : Natural occurring populations of predatory mites were treated with 4 late applications of CANDIT in an apple orchard. The study comprised 3 treatment groups (test item, water treated control and a reference item) with 5 replicates (plots) for the test item and the control and 3 replicates (plots) for the reference item. The plots were distributed according to a fully randomized block design. The number of predatory mites per leaf in each plot was assessed on the day of the 1st application. Plots with similar mite population density were assigned to the same block. Each treatment included plots from each block (except the reference item, as it consists only of 3 plots). To avoid contamination of the neighboring plots during application due to drift an untreated buffer row was included between the plots. Furthermore, only the 6 apple trees within the centre of each plot were used for evaluation to provide a buffer zone between neighboring plots in the same row. The population development of predatory mites was assessed determining the total number of mites on leaf samples. Assessments were carried out 8 days after the 1st, 6 days after the 2nd and 5 and 26 days after the 4th (last) application.

Table B.9.5.3-13 : Treatments, replicates and plot specifications

Design	Fully randomized blocks
Treatments	1. water control = C 2. test item (BAS 490 02 F) = T 3. reference item (Decis flüssig) = R
Replicates per treatment	C, T : 5 (a, b, c, d, e) R : 3 (a, b, c)
Size of the plots	8 apple trees in one row
Distance between plots	In one row : minimum none, maximum 14 trees In different rows : 1 buffer row
Minimum distance between plot and end of the apple orchard	7.80 m

Applications :
- Control (1200 L tap water/ha)
- Test item (CANDIT) was applied 4 times between the beginning of July and the beginning of August, with application intervals of 8 to 9 days (1st application at BBCH 75-76, 2nd application at BBCH 76-77, 3rd application at BBCH 79, 4th application at BBCH 79; 0.25 kg in 1200 L water/ha for all four applications)
- Reference item (Decis flüssig, 25 g/L deltamethrin) was applied 2 times, at the 1st and 3rd application of the test item at application rates of 0.7 L in 1200 L water/ha
Test conditions : The climatic conditions (temperature, humidity and rain) were recorded throughout the experimental period at a local weather station.

Findings :

In total, 256 mites were identified. 99.6 % of the mites investigated were determined as *Typhlodromys pyri* and 0.4 % as *Euseius finlandicus*. The fluctuations in mite numbers observed during the course of this study were within the normal range for predatory mite populations in an apple orchard.

Table B.9.5.3-14 : Mean number of predatory mites exposed to CANDIT under field conditions

Assessment	Date	Mean number of mites per leaf		
		Control	BAS 490 02 F	Reference item
on the day of 1st application before application	8.7.2007	0.89	1.04	1.01
8 days after 1st application	16.7.2007	1.61	1.39	0.04*
6 days after 2nd application	23.7.2007	1.06	1.02	0.00*
5 days after 4th application	8.8.2007	1.53	1.48	0.00*
26 days after 4th application	29.8.2007	1.46	1.32	0.00*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Table B.9.5.3-15 : Effects on predatory mites in an apple orchard exposed to CANDIT in a field trial according to Abbott

Assessment	BAS 490 02 F [%]	Reference item [%]
on the day of 1st application before application	-17.8	-14.0
8 days after 1st application	13.7	97.5*
6 days after 2nd application	3.8	100.0*
5 days after 4th application	2.9	100.0*
26 days after 4th application	10.0	100.0*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Spider mites and special observations : Spider mites (*Panonychus ulmi*) occurred in low numbers at the beginning of the study. The mean spider mites numbers stayed below 0.20 mites per leaf in the control and below 0.31 mites per leaf in the test item treatment throughout the study. However, spider mite numbers increased markedly in the reference item treatment over the last three assessments up to a mean number of 7.66 spider mites per leaf at the 5th assessment (26DAA4). Eriophyidae and Tydaeidae occurred in all treatments throughout the study. Single Acaridae, Anystidae, Tarsonemidae and Stigmaeidae occurred in sinlge plots during the study.

Conclusion :
The study is acceptable.
No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if CANDIT was applied 4 times at application rates of 0.25 kg/ha CANDIT in 1200 L/ha water in an apple orchard in South West Germany.

A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in a vineyard in Germany - 3 applications. (Lehmhus J., 2008b).

Guidelines :
Bluemel *et al*. (2000)
BBA VI 23-2.3.4
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % (w/w) (nominal) or 48.2 % (w/w) (analytical) Kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : predatory mites (Acari: Phytoseiidae), naturally established field population
Test site : The field study was performed in South West Germany, Neckarwestheim, Baden-Württemberg, located in a region typical for cultivation of grapevine. Crop: vine; variety: Schwarzriesling, 3968 plants/ha, plant height 2.0 m, 1.8 m distance between the rows, 1.4 m distance between the plants; plot size: 15 grapevines in one row, at least 1 buffer row between the rows. The agricultural practices and variety were in accordance with the local farming practices. The test site received some fertilizers and pesticides (actives: Dithianon, Penconazol, Fenarimol, Quinoxyfen, Fenhexamid).
Test design : Natural occurring populations of predatory mites were treated with 3 applications of CANDIT in a vineyard. The study comprised 3 treatment groups (test item, water treated control and a reference item) with 5 replicates (plots) for the test item and the control and 3 replicates (plots) for the reference item. The plots were distributed according to a fully randomized block design. The number of predatory mites per leaf in each plot was assessed 4 days before the 1st application. Plots with similar mite population density were assigned to the same block. Each treatment included plots from each block (except the reference item, as it consists only of 3 plots). To avoid contamination of the neighboring plots during application due to drift at least one untreated buffer row was included between the plots. Furthermore, only the 11 grapevines within the centre of each plot were used for evaluation to provide a buffer zone between neighboring plots in the same row. The population development of predatory mites was assessed determining the total number of mites on leaf samples. Assessments were carried out 5 days after the 1st and 2nd and 8 and 28 days after the 3rd (last) application.

Table B.9.5.3-16 : Treatments, replicates and plot specifications

Design	Fully randomized blocks
Treatments	1. water control = C 2. test item (BAS 490 02 F) = T 3. reference item (Decis flüssig) = R
Replicates per treatment	C, T : 5 (a, b, c, d, e) R : 3 (a, b, c)
Size of the plots	15 grapevines in one row
Distance between plots	In one row : none (only plot 3 and 4 are together in one row) In different rows : at least 1 buffer row
Minimum distance between plot and end of the vineyard	1.80 m

Applications :
- Control (tap water; same amount used for test item and reference item)
- Test item (CANDIT) was applied 3 times between the mid of May and the beginning of June, with application intervals of 8 to 9 days (1st application at BBCH 53-55, 2nd application at BBCH 61, 3rd application at BBCH 69-71; 0.3 kg in 600 L water/ha for 1st application, 0.30 kg in 800 L water/ha for 2nd and 3rd application)
- Reference item (Decis flüssig, 25 g/L deltamethrin) was applied 2 times, at the 1st and 3rd application of the test item at application rates of 0.7 L in same amount of water used for test item
Test conditions : The climatic conditions (temperature, humidity and rain) were recorded throughout the experimental period at a local weather station.

Findings :

In total, 259 mites were identified. All mites investigated were determined as *Typhlodromys pyri*. The fluctuations in mite numbers observed during the course of this study were within the normal range for predatory mite populations in a vineyard.

Table B.9.5.3-17 : Mean number of predatory mites (*Typhlodromus pyri*) exposed to CANDIT under field conditions

Assessment	Date	Mean number of mites per leaf		
		Control	BAS 490 02 F	Reference item
4 days before 1st application	14.5.2007	4.99	5.04	5.08
5 days after 1st application	23.5.2007	5.38	6.74	1.07*
5 days after 2nd application	31.5.2007	5.91	5.08	0.08*
8 days after 3rd application	12.6.2007	3.83	5.04	0.00*
28 days after 3rd application	2.7.2007	4.80	4.65	0.00*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Table B.9.5.3-18 : Effects on predatory mites (*Typhlodromus pyri*) in a vineyard exposed to CANDIT in a field trial according to Abbott

Assessment	BAS 490 02 F [%]	Reference item [%]
4 days before 1st application	-1.0	-1.8
5 days after 1st application	-25.1	80.2*
5 days after 2nd application	14.1	98.7*
8 days after 3rd application	-31.5	100.0*
28 days after 3rd application	3.2	100.0*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Spider mites and special observations : Throughout the study spider mites (*Panonychus ulmi*) occurred in low numbers with means below 0.1 spider mites per leaf. Few Eriophyidae occurred in some plots from 2nd assessment (5DAA1) onwards.

Conclusion :
The study is acceptable.
No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if CANDIT was applied 3 times at application rates of 0.30 kg/ha CANDIT in 600 L/ha water for the 1st application and 0.30 kg/ha in 800 L/ha water for the 2nd and 3rd application in a vineyard in South West Germany.

A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in a vineyard in Southern France - 3 early applications. (Lehmhus J., 2008c).
Report amendment No. 1 to study 20071146/F2-NFTp: A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in a vineyard in France - 3 early applications. (Lehmhus J., 2008f).

Guidelines :
Bluemel *et al.* (2000)
BBA VI 23-2.3.4
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F, containing 50 % (w/w) (nominal) or 48.2 % (w/w) (analytical) kresoxim-methyl – formulation CANDIT, batch: 3197
Test species : predatory mites (Acari: Phytoseiidae), naturally established field population
Test site : The field study was performed in Southern France, department of Rhône 69220 Cercié, located in a region typical for cultivation of grapevine. Crop: vine; variety: Gamay, 10000 plants/ha, plant height 0.3 - 0.7 m, 1.0 m distance between the rows, 1.0 m distance between the plants; plot size: 15 grapevines in one row, 3 buffer rows between the rows. The agricultural practices and variety were in accordance with the local farming practices. The test site received some pesticides (active: Copper).
Test design : Natural occurring populations of predatory mites were treated with 3 early applications of CANDIT in a vineyard. The study comprised 3 treatment groups (test item, water treated control and a reference item) with 5 replicates (plots) for the test item and the control and 3 replicates (plots) for the reference item. The plots were distributed according to a fully randomized block design. The number of predatory mites per leaf in each plot was assessed 4 days before the 1st application. Plots with similar mite population density were assigned to the same block. Each treatment included plots from each block (except the reference item, as it consists only of 3 plots). To avoid contamination of the neighboring plots during application due to drift three untreated buffer rows were included between the plots. Furthermore, only the 11 grapevines within the centre of each plot were used for evaluation to provide a buffer zone between neighboring plots in the same row. The population development of predatory mites was assessed determining the total number of mites on leaf samples. Assessments were carried out 8 days after the 1st application, 7 days after the 2nd and 6 and 31 days after the 3rd (last) application.

Table B.9.5.3-19 : Treatments, replicates and plot specifications

Design	Fully randomized blocks
Treatments	1. water control = C 2. test item (BAS 490 02 F) = T 3. reference item (Decis protech) = R
Replicates per treatment	C, T : 5 (a, b, c, d, e) R : 3 (a, b, c)
Size of the plots	11 grapevines in one row
Distance between plots	In one row : none In different rows : 3 buffer rows In different rows : at least 1 buffer row
Minimum distance between plot and end of the vineyard	1.00 m

Applications :
- Control (800 L tap water/ha)
- Test item (CANDIT) was applied 3 times between the beginning of May and end of May, with application intervals of 9 to 10 days (1st application at BBCH 53, 2nd application at BBCH 53-61, 3rd application at BBCH 71, 0.3 kg in 800 L water/ha for all three applications)
- Reference item (Decis Protech, 15 g/L deltamethrin) was applied 2 times, at the 1st and 3rd application of the test item at application rates of 0.7 L in 800 L water/ha

Test conditions : The climatic conditions (temperature, humidity and rain) were recorded throughout the experimental period at a local weather station.

Findings :

In total, 230 mites were identified. 99.1 % of the mites investigated were determined as *Typhlodromys pyri* and 0.9 % as *Paraseiulus talbii*. The fluctuations in mite numbers observed during the course of this study were within the normal range for predatory mite populations in a vineyard.

Table B.9.5.3-20 : Mean number of predatory mites (*Typhlodromus pyri*) exposed to CANDIT under field conditions

Assessment	Date	Mean number of mites per leaf		
		Control	BAS 490 02 F	Reference item
4 days before 1st application	29.4.2007	0.85	0.87	0.85
8 days after 1st application	11.5.2007	1.01	1.01	0.10*
7 days after 2nd application	19.5.2007	1.98	1.70	0.32*
6 days after 3rd application	28.5.2007	1.92	1.70	0.13*
31 days after 3rd application	22.6.2007	2.36	2.31	0.53*

* statistically significant different compared to the control (Dunnett' s T-test, $\alpha = 0.05$)

Table B.9.5.3-21 : Effects on predatory mites (*Typhlodromus pyri*) in a vineyard exposed to CANDIT in a field trial according to Abbott

Assessment	BAS 490 02 F [%]	Reference item [%]
4 days before 1st application	-2.3	-0.2
8 days after 1st application	-0.4	90.1
7 days after 2nd application	14.2	83.8
6 days after 3rd application	11.3	93.1
31 days after 3rd application	2.0	77.4

Spider mites and special observations : Spider mites (*Panonychus ulmi*) occurred in low numbers. The highest mean spider mite density of 0.44 mites per leaf was found in the reference item treatment at the 5th assessment (31DAA3). From the 2nd assessment onwards Tydeidae occurred in low numbers throughout all treatments, and in the 5th assessment Tydeidae occurred in high numbers in the reference treatment. Few other mites occurred throughout the trial.

Conclusion :

The study is acceptable.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if CANDIT was applied 3 times at application rates of 0.30 kg/ha CANDIT in 800 L/ha water in a vineyard in Southern France.

B.9.5.4 Summary of effects, exposure and hazard assessment for non-target terrestrial arthropods

Revised in March 2010:

Kresoxim-methyl
4 lab tests (each of the non target arthropod groups) were submitted in the dossier of the a.s. These tests were performed with the formulation CANDIT, at the highest dose for cereals crop (150 g a.s./ha) to assess the risk resulting from the use of the a.s. in this crop.

Formulation MENTOR (SE containing 150 g/kg kresoxim-methyl and 300 g/kg fenpropimorph)
6 lab, extended lab and semi-field tests were submitted in the dossier of MENTOR - These tests were performed at the dose of 0.7 L formulation/ha (105 g a.s./ha) to assess the risk resulting from the use of MENTOR in cereals.

Formulation CANDIT (WG containing 500 g/kg kresoxim-methyl)
The main results of the studies submitted in the dossier CANDIT (authorized in Belgium in apples) were added to this monograph since the application in orchards is one of the main uses of kresoxim-methyl:
- 3 lab and semi-field studies summarized in table B.9.5.4-1 (lower part: no detailed description in the monograph)
- 3 field tests were performed in Belgium to evaluate the effects of the formulation on *Typhlodromus pyri* (summary table B.9.5.4-3).
- 2 field studies were performed in Germany to evaluate the effects of the formulation on *Typhlodromus pyri* in vines (summary table B.9.5.4-3)
- 2 field studies were performed in Switserland and Germany to evaluate the effects of the formulation on *Typhlodromus pyri* in apples (summary table B.9.5.4-3)
- 1 field test was performed in Belgium to evaluate the effects of the formulation on *Anthocoris nemoralis* and *Anthocoris nemorum* in pear (summary table B.9.5.4-3)

Table B.9.5.4-1 : Effects of kresoxim-methyl on non-target terrestrial arthropods - All the tests were performed with the formulation CANDIT(*), in order to evaluate the risk of the use of the a.s. in cereals crop

Test species	Test system	Duration of exposure	Results	Hazard Assessment	References
Studies from the Annex II dossier					
Typhlodromus pyri	Lab test	(16 days)	E = 14.91 % (dose: 148 g a.s./ha in 200 L water)	harmless	Kühner Ch., 1993
Trichogramma cacoeciae	Lab test	(7 days)	E = -17.86 % (dose: 150 g a.s./ha in 200 L water)	harmless	Kühner Ch., 1994a
Coccinella septempunctata	Lab test	(40 days)	E = 59.7 % (dose : 150 g a.s./ha in 200 L water)	slightly harmful important reduction of the adults fertility	Kleiner R., 1993a
Poecilus cupreus[1]	Lab test	(14 days)	E = 0 % (dose: 150 g a.s./ha in 200 L water)	harmless	Schlosser E., 1993a
Studies from the Annex III dossier of CANDIT[2]					
Typhlodromus pyri	Lab test (different stages)	(2-4 days)	eggs : E = 4.1 % larvae : E = - 3.1 % males : E = 18.8 % females : E = - 3.0 % (dose 0.3 kg formulation/ha in 150 L water)	harmless	Ufer A., 1994b
Coccinella septempunctata	Semi-field test	(40 days)	E = - 23.4 % (dose : 0.3 kg formulation/ha in 300 L water)	harmless	Kleiner R., 1993c
Orius insidiosus	Lab test (second nymph stage to adult)	(10 days as nymph + 10 days as adult)	mortality and reproduction : E = 5.5% (dose : 2 appl. of 0.2 kg formulation/ha)	harmless	Ufer A., 1996b

[1] The study on *Poecilus* was performed wit a SC 500 g a.s./L

[2] Main results of studies submitted in Belgium for the provisional authorisation of CANDIT (apples); no summary available in the DAR

Table B.9.5.4-2 : Summary of effects of the formulation MENTOR on non-target terrestrial arthropods

Test species	Test system	Duration of exposure	Results	Hazard Assessment	References
Typhlodromus pyri	Lab test	14 days	E = 5.8 % (dose : 0.7 L formulation/ha in 150 L water)	harmless	Ufer A., 1994a
Aleochara bilineata	Lab test	35 days	E = 0.8 % (dose : 0.7 L formulation/ha in 400 L water)	harmless	Künast Ch., 1994a
Aphidius matri-cariae	Lab test	24 hours	E = 100 % (dose : 0.7 L formulation/ha in 200 L water)	harmful	Kleiner R., 1994b
Aphidius matri-cariae	Semi-field test	15 days	E = 37.7 % (dose : 0.7 L formulation/ha in 200 L water)	slightly harmful	Kleiner R., 1994a
Aphidius rhopalosi-phi	Extended lab test	8 d (hatching) 2 d (adult tox) 1 d (aphid para-sitization) 12 d (mummies development)	Not statistically different (dose : 0.7 L formulation/ha in 400 L water)	harmless	Ufer A., 1996a
Chrysopa carnea	Lab test	9 weeks	E = 63.3 % (dose : 0.7 L formulation/ha in 400 L water)	slightly harmful important reduction of the adults fertility	Künast Ch., 1994b

Table B.9.5.4-3 : Summary of effects of the formulation CANDIT on non-target terrestrial arthropods (field studies)

Test species	Test system	Results	References
Typhlodromus pyri	apples 4 applications 0.1 kg a.s. /ha 1500 L water/ha	E(2 appl.) = -25.1 % E(4 appl.) = -13.3 %	Research Station of Gorsem (1995)
	apples 4 applications 0.2 kg a.s./ha 1500 L water/ha	E(2 appl.) = -20.0 % E(4 appl.) = 10.1 %	
	apples 6 applications 0.1 kg a.s./ha 1500 L water/ha	E(2 appl.) = -15.6 % E(4 appl.) = -26.5 % E(6 appl.) = 33.6 %	
	apples 12 applications 0.1 kg a.s./ha 1500 L water/ha (in association with meti-ram)	E(9 appl.) = 32.45 % E(12 appl.) = 18.53 % E(60 d after last appl.) = -11.49 %	
Typhlodromus pyri	vines 6 applications 0.073 kg to 0.297 kg a.s./ha 400 L to 1600 L water/ha	E (7 d after last appl.) = - 39 % E (28 d after last appl.) = -22 %	Lipps H.P., 1994
	vines 6 applications 0.074 kg to 0.304 kg a.s./ha 400 L to 1600 L water/ha	E (7 d after last appl.) = - 10 % E (28 d after last appl.) = 35 %	Ipach R., 1994
Typhlodromus pyri	apples 8 applications 0.15 kg a.s./ha 1500 L water/ha	E (7d after last appl.) = 25.3 % E (28 d after last appl.) = 15.8 %	Rohner R., 1994
	apples 8 applications 0.15 kg a.s./ha 1500 L water/ha	E (7 d after last appl.) = 16.8 % E (28d after last appl.) = 54.3 %	Kühner Ch., 1994b
Anthocoris species	pears 5 applications 0.15 kg a.s./ha 1500 L water/ha	E (4 days after last appl. - nymphs) = 40.7 % E (4 days after last appl. - adults) = -2.7 %	Research Station of Gorsem, 1996

The formulation MENTOR is no longer supported in the resubmission dossier and thus no risk assessment is conducted.

Table B.9.5.4-4 : Summary of rate-response laboratory tests conducted with the formulations CANDIT and ALLEGRO on standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri	BAS 490 02 F - CANDIT	Mortality	LR_{50} (7 d) > 900 g BAS 490 02 F/ha
Typhlodromus pyri	BAS 494 04 F - ALLEGRO	Mortality	LR_{50} (7 d) > 3000 mL BAS 494 04 F/ha
Aphidius rhopalosiphi	BAS 490 02 F - CANDIT	Mortality	LR_{50} (48 h) > 900 g BAS 490 02 F/ha
Aphidius rhopalosiphi	BAS 494 04 F - ALLEGRO	Mortality	LR_{50} (48 h) > 3000 mL BAS 494 04 F/ha

Table B.9.5.4-5 : Summary of the formulations CANDIT and ALLEGRO on non-target arthropods : further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1]	End point	% effect[2]	Trigger value
Poecilus cupreus	adults	BAS 490 02 F – CANDIT, quartz sand, 14 d	900 g form/ha, initial	Corrected mortality Reproduction	3.33 % -0.63 %	50 % 50 %
				LR_{50} > 900 g CANDIT/ha (450 g a.s./ha)		
Typhlodro-mus pyrus	proto-nymphs	BAS 490 02 F – CANDIT, bean leaves, 14 d	150 g form/ha, initial	Corrected mortality Reproduction	3.1 % 20.1 %	50 % 50 %
			300 g form/ha, initial	Corrected mortality Reproduction	12.8 % 24.9 %	50 % 50 %
			600 g form/ha, initial	Corrected mortality Reproduction	7.0 % 13.7 %	50 % 50 %
			900 g form/ha, initial	Corrected mortality Reproduction	20.5 % 13.6 %	50 % 50 %
			1250 g form/ha, initial	Corrected mortality Reproduction	8.9 % 34.4 %	50 % 50 %
				LR_{50} > 1250 g CANDIT/ha (625 g a.s./ha)		
Aphidius rhopalo-siphi	adults	BAS 490 02 F – CANDIT, barley plants, 14 d	150 g form/ha, initial	Corrected mortality Reproduction	3.33 % -	50 % 50 %
			300 g form/ha, initial	Corrected mortality Reproduction	0.00 % -	50 % 50 %

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1]	End point	% effect[2]	Trigger value
			600 g form/ha, initial	Corrected mortality Reproduction	0.00 % 8.49 %	50 % 50 %
			900 g form/ha, initial	Corrected mortality Reproduction	0.00 % 21.32 %	50 % 50 %
			1250 g form/ha, initial	Corrected mortality Reproduction	0.00 % 42.45 %	50 % 50 %
				LR_{50} > 1250 g CANDIT/ha (625 g a.s./ha)		
Coccinella septem-punctata	larvae	BAS 490 02 F – CANDIT, apple leaves, 1-3 days until metamorphosis was completed	100 g form/ha, initial	Corrected mortality Reproduction	-2.50 % -13.8 %	50 % 50 %
			240 g form/ha, initial	Corrected mortality Reproduction	-12.50 % -73.1 %	50 % 50 %
			540 g form/ha, initial	Corrected mortality Reproduction	-15.00 % 11.6 %	50 % 50 %
				LR_{50} > 540 g CANDIT/ha (270 g a.s./ha)		
Coccinella septem-punctata	larvae	BAS 490 02 F – CANDIT, apple leaves, 1-3 days until metamorphosis was completed	600 g form/ha, initial	Corrected mortality Reproduction	0.0 % 11.5 %	50 % 50 %
			900 g form/ha, initial	Corrected mortality Reproduction	10.2 % -3.8 %	50 % 50 %
				LR_{50} > 900 g CANDIT/ha (450 g a.s./ha)		

[1] indicate whether initial or aged residues
[2] Corrected mortality : positive values : adverse effects
Reproduction, food consumption : positve values : reduction; negative values : enhancement

Table B.9.5.4-6 : Summary of effects on predatory mites (*Typhlodromus pyri*) exposed to BAS 49002 F – formulation CANDIT in apple orchards and grapevines

Species	Crop	Maximum application rate [g/ha]	Sampling time[1)]	Effects [2)] [%]	Reference
predatory mites	Apple orchard	2 x 200 + 2 x 250	7 DAA 1 6 DAA 2 6 DAA 4 27 DAA 4	+4.5 / +27.5 [3)] -2.3 / +22.3 [3)] +5.6 / +28.3 [3)] +2.3 / +25.8 [3)]	Lehmhus, 2007/1017533
predatory mites	Apple orchard	2 x 200 + 2 x 250	7 DAA 1 6 DAA 2 6 DAA 4 26 DAA 4	-8.2 +0.5 -4.0 -17.4	Lehmhus, 2007/1017531
predatory mites	Apple orchard	4 x 250	8 DAA 1 6 DAA 2 5 DAA 4 26 DAA 4	+13.7 +3.8 +2.9 +10.0	Lehmhus, 2007/1017532 + 2008/1020041 (Amendment)
predatory mites	Grapevine	3 x 300	5 DAA 1 5 DAA 2 8 DAA 3 28 DAA 3	-25.1 +14.1 -31.5 +3.2	Lehmhus, 2007/1017534
predatory mites	Grapevine	3 x 300	8 DAA 1 7 DAA 2 6 DAA 3 31 DAA 3	-0.4 +14.2 +11.3 +2.0	Lehmhus, 2007/1017535 + 2008/1034511 (Amendment)

1) DAA = Days After Application.
2) Effects calculated according to Abbott (1925). Negative values indicate a higher population development compared to the control.
3) Effects calculated according to Henderson-Tilton as the mite population in the different treatment groups was statistically significant different before the 1st application.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 4 times at application rates of 0.20 kg/ha BAS 490 02 F at the 1st and 2nd application and 0.25 kg/ha BAS 490 02 F at the 3rd and 4th application at water volumes of 900 L/ha in an apple orchard in Southern France.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F is applied 4 times at application rates of 0.20 kg/ha BAS 490 02 F in 900 L/ha water for the 1st application, of 0.20 kg/ha BAS 490 02 F in 1000 L/ha water for the 2nd application and 0.25 kg/ha BAS 490 02 F in 1100 L/ha water for the 3rd and 4th application in an apple orchard.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 4 times at application rates of 0.25 kg/ha BAS 490 02 F in 1200 L/ha water in an apple orchard in South West Germany.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 3 times at application rates of 0.30 kg/ha BAS 490 02 F in 600 L/ha water for the 1st application and 0.30 kg/ha in 800 L/ha water for the 2nd and 3rd application in a vineyard in South West Germany.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 3 times at application rates of 0.30 kg/ha BAS 490 02 F in 800 L/ha water in a vineyard in Southern France.

The risk assessment for non-target arthropods is based on the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC.

1- Formulation CANDIT

The formulation CANDIT (BAS 490 02 F) is a fungicidal product, which contains the active substance kresoxim-methyl with a nominal content of 50 % w/w.

Table B.9.5.4-7 : Proposed use pattern of the formulation CANDIT

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate (kg a.s./ha) [1)]	Application rate (kg product/ha) [1)]
Pome fruit (apple, pear)	1 - 4	7	53 - 79	0.100 - 0.125	0.200 - 0.250
Grapevine	1 - 3	8	19 - 81	0.100 - 0.150	0.200 - 0.300

[1)] application rate increases with plant growth stage

For simplification reasons, the risk assessment is only conducted for the higher application rates. This covers the increase in application rate during season.

Exposure :

According to the Guidance Document, the exposure is calculated as :

In-field exposure = application rate * MAF

Off-field exposure = application rate * MAF * (drift factor / vegetation distribution factor) * correction factor

In-field and off-field exposure levels are determined by the application rate and the MAF.
For leaf substrates a default half-life : spray interval ratio of 2.3 : 1 is recommended to be used for the calculation of a MAF. For 4 (pome fruit) and 3 (grapevine) applications, the corresponding MAFs are 2.7 and 2.3 respectively.

The off-field exposure is calculated based on 3 m distance for pome fruit and grapevine. According to ESCORT II (Ganzelmeier *et al*., 2000), the drift factor for 4 applications in pomefruit (early application) is 0.2361 and for 3 applications in grapevine (late application) is 0.069.

For the off-field exposure calculation, the vegetation distribution factor (VDF) is default 10, taking into account the 3-dimensional structure of the off-field vegetation (see ESCORT II).

For the off-field exposure calculation, the correction factor is set at 10 (see ESCORT II).

Table B.9.5.4-8 : In-and off-field PEC calculation for the relevant exposure scenario of the formulation BAS 490 02 F – CANDIT

Field crops	Number of applications	Deposits / Drift [1] [%]	1-fold rate [g/ha]	Maximum initial PEC value [3] [g/ha]
Pomefruit: early scenario (MAF = 2.7) [2]				
in-field	4	100	250	675
off-field (3 m)	4	23.61	59	159.4
Grapes: late scenario (MAF = 2.3) [2]				
in-field	3	100	300	690
off-field (3 m)	3	6.90	20.7	47.6

1) According to Ganzelmeier *et al.* (2000), the drift values are based on a four-fold application in pomefruit (loading by drift using the 74th percentile), and a three-fold application in grapes (loading by drift using the 77th percentile), respectively.
2) MAF calculated according to MAF = $(1-e^{-0.069ni}) / (1-e^{-0.069i})$ based on 4, respective 3 applications, assuming a half-life : spray interval ratio of 2.3:1 for leaf substrates (see Appendix III, ESCORT II).
3) Maximum initial PEC value calculated by multiplying the 1-fold rate with the refined MAF.

Risk assessment :

According to the Guidance Document, the risk is calculated as :

In-field HQ = in-field exposure / LR_{50}

Off-field HQ = (off-field exposure / LR_{50})

Table B.9.5.4-9 : In-field and off-field Hazard Quotients (HQ) for BAS 490 02 F – CANDIT

Single application rate (g/ha)	Crop	Test species	LR_{50} (g/ha)	MAF	% drift	HQ in-field	HQ off-field	Trigger value
250	pomefruit (early)	*Typhlodromus pyri*	> 900	2.7	0.2361	< 0.75	< 0.18	2
		Aphidius rhopalosiphi	> 900	2.7	0.2361	< 0.75	< 0.18	2
300	grapes (late)	*Typhlodromus pyri*	> 900	2.3	0.0690	< 0.77	< 0.05	2
		Aphidius rhopalosiphi	> 900	2.3	0.0690	< 0.77	< 0.05	2

The hazard quotients for the formulation CANDIT and the two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value of 2, indicating acceptable risk.

No further studies with soil-dwelling and foliage-dwelling arthropods are required, however such studies are available, which represent specific ecological compartments (guilds). The studies provide additional information for the risk assessment.

Indicator species – higher-tier tests :

In an extended laboratory test (bean leaves), no unacceptable effects on ***Typhlodromus pyri*** were observed up to an application rate of 1250 g CANDIT/ha, exceeding the intended application rates.

To investigate short- and long-term effects on natural occurring populations of predatory mites CANDIT was applied under standard agricultural conditions at different sites, i.e. three field studies in apple orchards and two field trials in vineyards were carried out.

The three studies conducted in apple orchards comprised 4 applications of either 2 x 200 g/ha + 2 x 250 g/ha CANDIT (Germany and Southern France) or 4 x 250 g/ha (Germany), resulting in a total maximum amount of 900 g/ha or 1000 g/ha, respectively. The cumulative amount applied in these studies covers a worst-case use pattern of up to 4 x 250 g/ha in pomefruit. All investigations resulted in effects below 29 % (according to Abbott and Henderson & Tilton).

Two studies were carried out in grapevine in Germany and Southern France comprising application rates of 3 x 300 g/ha, resulting in a total maximum amount of 900 g/ha CANDIT. The cumulative amount applied in these studies covers a worst-case use pattern of up to 3 x 300 g/ha in grapevine. In these studies a maximum effect of 14.2 % was observed. On the last sampling date 28 and 31 days after the 3rd (last) application, effects of 3.2 % and 2.0 % were recorded.

The population density of predatory mites was determined by counting the total number of mites on leaf or flower bud cluster samples for all field studies. No unacceptable effects on predatory mite populations occurred during the study and 4 weeks after the last application, the differences to the control were always below the ESCORT II trigger of 50 %. There is no indication for any harmful effects on populations of predatory mites after exposure up to 4 x 250 g/ha in pomefruit and to 3x 300 g/ha CANDIT in grapevine.

Therefore, taking into account all available results, no unacceptable effects or risk is expected for *Typhlodromus pyri* if CANDIT is applied according to good agricultural practice.

In an extended laboratory test (barley plants), no unacceptable effects on ***Aphidius rhopalosiphi*** were observed up to an application rate of 1250 g CANDIT/ha, exceeding the intended application rates.

Foliage-dwelling predator species :

In two extended laboratory tests (apple leaves), no unacceptable effects on ***Coccinella septempunctata*** were observed up to application rates of 540 and 900 g CANDIT/ha respectively, exceeding the intended application rates.

Soil-dwelling arthropod species :

In a worst-case laboratory test (inert quartz sand), no unacceptable effects on ***Poecilus cupreus*** were observed up to an application rate of 900 g CANDIT/ha.

2- Formulation ALLEGRO

The formulation ALLEGRO (BAS 494 04 F) is a fungicidal product, which contains the active substances
- kresoxim-methyl (BAS 490 F) with a nominal content of 125 g a.s./L
- epoxiconazole (BAS 480 F) with a nominal content of 125 g a.s./L

Table B.9.5.4-10 : Proposed use pattern of the formulation ALLEGRO

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate		
				BAS 494 04 F [L/ha]	Kresoxim-methyl (BAS 490 F) [kg a.s./ha]	Epoxiconazole (BAS 480 F) [kg a.s./ha]
Cereals	2	21	25 - 69	1.0	0.125	0.125

Exposure :

According to the Guidance Document, the exposure is calculated as :

In-field exposure = application rate * MAF

Off-field exposure = application rate * MAF * (drift factor / vegetation distribution factor) * correction factor

In-field and off-field exposure levels are determined by the application rate and the MAF.

For leaf substrates a default half-life : spray interval ratio of 2.3 : 1 is recommended to be used for the calculation of a MAF. For 2 applications (cereals), the corresponding MAF is 1.7.

The off-field exposure is calculated based on 1 m distance for cereals. According to ESCORT II (Ganzelmeier *et al*., 2000), the drift factor for 2 applications is 0.0238.

For the off-field exposure calculation, the vegetation distribution factor (VDF) is default 10, taking into account the 3-dimensional structure of the off-field vegetation (see ESCORT II).

For the off-field exposure calculation, the correction factor is set at 10 (see ESCORT II).

Table B.9.5.4-11 : In-and off-field PEC calculation for the relevant exposure scenario of the formulation BAS 494 04 F – ALLEGRO

Field crops	**Number of applications**	**Deposits / Drift [1] [%]**	**1-fold rate [mL/ha]**	**Maximum initial PEC value [3] [mL/ha]**
Cereals (MAF = 1.7) [2]				
in-field	2	100	1000	1700
off-field (1 m)	2	2.38	23.8	40.5

1) According to Ganzelmeier *et al.* (2000), the drift values are based on a two-fold application (loading by drift using the 82nd percentile), respectively.
2) MAF calculated according to MAF = $(1-e^{-0.069ni}) / (1-e^{-0.069i})$ based on 2 applications and assuming a half-life : spray interval ratio of 2.3:1 for leaf substrates (see Appendix III, ESCORT II).
3) Maximum initial PEC value calculated by multiplying the 1-fold rate with the refined MAF.

Risk assessment :

According to the Guidance Document, the risk is calculated as :

In-field HQ = in-field exposure / LR_{50}

Off-field HQ = (off-field exposure / LR_{50})

Table B.9.5.4-12 : In-field and off-field Hazard Quotients (HQ) for BAS 494 04 F – ALLEGRO

Single application rate (mL/ha)	**Crop**	**Test species**	**LR_{50} (mL/ha)**	**MAF**	**% drift**	**HQ in-field**	**HQ off-field**	**Trigger value**
1000	cereals	*Typhlodromus pyri*	> 3000	1.7	0.0238	< 0.57	< 0.01	2
		Aphidius rhopalosiphi	> 3000	1.7	0.0238	< 0.57	< 0.01	2

The hazard quotients for the formulation ALLEGRO and the two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value of 2, indicating acceptable risk.

In conclusion, the in-field and off-field risk of kresoxim-methyl and the formulations CANDIT and ALLEGRO to non-target arthropods is acceptable for the intended uses.

B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.3.6)

B.9.6.1 Acute toxicity to earthworms (Annex IIA 8.4.1)

Effect of Reg. No. 242 009 on the mortality of the earthworm *Eisenia foetida*. (Dohmen G.P., 1992b).

Guidelines :
OECD 207 (1984)
GLP :
Yes
Material and Methods :
Test substance : kresoxim-methyl; purity : 93.7 %; batch: N36
Test species : earthworms (*Eisenia foetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/concentration; animals with developed clitellum, weight about 300 mg
Type of test : acute toxicity test in artificial soil (14 days)
Applied concentrations : water control; positive control (chloracetamide); 93.7, 234.25, 468.5, 702.75, 937.0 mg a.s./kg (nominal)
Soil type and test conditions :
test substrate : composed of 10 % sphagnum, 20 % kaolin, 1 % $CaCO_3$ and 69 % quartz sand
water content : 36 % (of the dry soil weight)
temperature : 21 ± 2 °C
light regime : continuous illumination
Findings :
Mortality : No mortality was observed throughout the entire test period neither in the control groups nor in the treated groups.
Observations : With regard to the biomass a slight decrease of the average weight was obvious in all variants, including the control, and was considered not to be treatment related.
Endpoints :
LC_{50} (*Eisenia foetida*, 14 d) > 937 mg a.s./kg substrate (nominal)
NOEC (*Eisenia foetida*, 14 d) = 937 mg a.s./kg substrate (nominal)
Conclusion :
The study is acceptable.
No effects of the a.s. nor mortality were observed up to 937 mg a.s./kg, the highest concentration tested.

Effect of BAS 490-1 on the mortality of the earthworm *Eisenia foetida*. (Dohmen G.P., 1994c).

Guidelines :
OECD 207 (1984)
GLP :
Yes
Material and Methods :
Test substance : BF 490-1, free-acid metabolite of kresoxim-methyl (Reg.No. 262 451); purity: 99.3 %
Test species : earthworms (*Eisenia foetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/concentration; worms with developed clitellum, minimum weight 250 mg, not older than 1 year
Type of test : acute toxicity test in artificial soil (14 days)
Applied concentrations :
In the range finding test, no mortality was recorded within the range of 10 mg/kg to 1000 mg/kg. Therefore limit test was performed:
- concentration 1000 mg BF 490-1/kg soil
- control
- positive control : chloroacetamide

Soil type and test conditions :
test substrate : composed of 10 % sphagnum, 20 % kaolin, 1 % $CaCO_3$ and 69 % quartz sand
water content : 33 % (of soil dry weight)
temperature : 21 ± 2 °C
light regime : continuous illumination
Findings :
Mortality : No mortality occurred neither in the control nor in the groups treated with 1000 mg/kg substrate.
Observations : There was no negative effect of the test substance (weight change : + 6.3 %) on worm biomass relative to the control (weight change : -3.4 %).
Endpoints :
LC_{50} (*Eisenia foetida*, 14 d) > 1000 mg BF 490-1/kg substrate (nominal) (highest concentration tested)
NOEC (*Eisenia foetida*, 14 d) = 1000 mg BF 490-1/kg substrate (nominal) (highest concentration tested)
Conclusion :
The study is acceptable.
No effects of the a.s. nor mortality were observed up to 1000 mg BF 490-1/kg, the highest concentration tested.

Added in March 2010:

Metabolite BF 490-5 has been detected in a new soil metabolism study at levels above 5 % and has therefore been checked for its ecotoxicological potential for soil organisms. Hence, this new study is now included to meet latest testing requirements (soil metabolite > 5 %).

Acute toxicity (14 days) of Reg.No. 286404 (metabolite of BAS 490 F, BF 490-5) to the earthworm *Eisenia fetida* in artificial soil with 5 % peat. (Luehrs U., 2008).

Guidelines :
OECD 207
GLP :
Yes
Material and Methods :
Test substance : BF 490-5; metabolite of kresoxim-methyl (Reg. No. 286404); purity: 99.2 %; batch: L76-100
Test species : earthworms (*Eisenia fetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/treatment; animals with developed clitellum, weight between 300 mg and 600 mg, age between 10 to 11 months
Type of test : acute toxicity test in artificial soil (14 days)
Applied concentrations :
control (untreated); 62.5, 125, 250, 500, 1000 mg BF 490-5/kg dry soil (nominal)
positive control (2-chloroacetamide) evaluated in a separate study
Soil type and test conditions :
test substrate : composed of 5.0 % sphagnum-peat, 20 % kaolin clay, 0.2 % $CaCO_3$ and 74.8 % fine quartz-sand
water content : 21.8 - 22.1% (of soil dry weight) at test initiation, 20.9 - 21.4 % (of soil dry weight) at test termination
pH : 5.5 – 5.7
temperature : 19 - 20 °C
photoperiod : continuous illumination
light regime : 400 – 570 lux
Assessments : Assessments of worm mortality and behavioural effects were made after 7 and 14 days, assessments of weight change as sub-lethal parameter were made 14 days after application.

Findings :

Table B.9.6.1-1 : Effect of BF 490-5 on earthworm (*Eisenia fetida)* mortality and biomass (14 d)

Concentration [mg/kg soil dry weight]	**Control**	**62.5**	**125**	**250**	**500**	**1000**
Mortality [%]	0	0	0	0	0	0
Weight change [%]	-0.3	0.5	1.2	2.8	4.4	3.1
Endpoints [mg BF 490-5/kg soil dry weight]						
LC_{50}	> 1000					
NOEC	1000					

No statistically significant differences compared to the control (Dunnett-test, multiple comparison, two-sided, $\alpha = 0.05$)

Observations : No behavioural abnormalities were observed.
Conclusion :
The study is acceptable.
Endpoints :
LC_{50} (*Eisenia fetida*, 14 d) > 1000 mg BF 490-5/kg substrate (nominal)
NOEC (*Eisenia fetida*, 14 d) = 1000 mg BF 490-5/kg substrate (nominal)

B.9.6.2 Sublethal effects on earthworms (Annex IIA 8.4.2)

Study is not required.

B.9.6.3 Acute toxicity of the formulations to earthworms (Annex IIIA 10.6.1.1)

Effect of BAS 492 01 F on the mortality of the earthworm *Eisenia foetida*. (Dohmen G.P., 1994f).

Guidelines :
OECD 207 (1984)
GLP :
Yes
Material and Methods :
Test substance : BAS 492 01 F; SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph – formulation MENTOR; batch: 93-2
Test species : earthworms (*Eisenia foetida*)
Number of organisms, weight, length, age : 10 worms X 4 replicates/concentration; worms with developed clitellum, minimum weight 250 mg, not older than 1 year
Type of test : acute toxicity test in artificial soil (14 days)
Applied concentrations : 100, 250, 400, 500, 750 mg MENTOR/kg substrate
Soil type and test conditions :
test substrate : composed of 10 % sphagnum, 20 % kaolin, 1 % $CaCO_3$ and 69 % quartz sand
water content : 32.8 % (of soil dry weight)
pH : 5.86
temperature : 18 - 21 °C
light regime : continuous illumination
Findings :
Mortality : No mortality occurred, neither in the control groups nor in the treated variants with exception of the highest dose level, i.e. 750 mg/kg, resulting in 12.5 % dead earthworms.
Observations : With regard to the biomass, a slight decrease was obvious in some test groups, independently of the dose, and in the control. No particular physical or behavioral changes were observed.

Endpoints :
LC_{50} (*Eisenia foetida*, 14 d) > 750 mg MENTOR/kg substrate (nominal) (highest concentration tested)
LC_0 (*Eisenia foetida*, 14 d) = 550 mg MENTOR/kg substrate (nominal)
NOEC (*Eisenia foetida*, 14 d) ~ 550 mg MENTOR/kg substrate (nominal) (related to mortality)
NOEC (*Eisenia foetida*, 14 d) = 750 mg MENTOR/kg substrate (nominal) (related to biomass)
Conclusion :
The study is acceptable.
NOEC (*Eisenia foetida*, 14 d) = 550 mg MENTOR/kg due to mortality at the dose 750 mg/kg

Added in March 2010:

Effect of BAS 490 02 F on the mortality of the earthworm *Eisenia foetida*. (Dohmen G.P., 1993).

Guidelines :
OECD 207
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F; containing 50 % nominal (48.37 % analyzed) kresoxim-methyl – formulation CANDIT; batch: 92-5
Test species : earthworms (*Eisenia fetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/treatment; animals with developed clitellum, weight > 250 mg, age: less than one year old
Type of test : acute toxicity test in artificial soil (14 days)
Applied concentrations :
control (untreated); 100.0, 250.0, 500.0, 750.0, 1000.0 mg CANDIT/kg dry soil (nominal)
positive control (2-chloroacetamide) evaluated in a separate study
Soil type and test conditions :
test substrate : artificial soil according to OECD 207
water content : 32.7 % of dry weight at test initiation, 32.6 % at test end
pH : 6.4
temperature : 22.0 ± 2 °C
photoperiod : continuous illumination
Assessments : Assessment of worm mortality and behavioral effects was carried out after 7 and 14 days, measurement of weight change as sub-lethal parameter after 14 days.
Findings :

Table B.9.6.3-1 : Effects of CANDIT on earthworm (*Eisenia fetida*) mortality and biomass (14 d)

BAS 490 02 H [mg/kg dry soil]	**Control**	**100.0**	**250.0**	**500.0**	**750.0**	**1000.0**
Mortality [%]	0.0	0.0 n.s.	2.5 n.s.	25.0*	67.5*	82.5*
Weight change [%]	-5.8	-8.4 n.s.	-6.5 n.s.	-12.8 n.s.	-9.1 n.s.	-17.9 n.s
Endpoint [mg/kg dry soil]						
LC_{50} 1)	644					
NOEC	250					

1) median lethal concentration calculated using probit analysis (with 95% Confidence limits)
n.s. = not statistically significant different
* statistically significant differences compared to the control (Dunnett´s multiple comparison-test, $\alpha = 0.05$)

Observations : No particular observations on physical or behavioural changes were made.
Conclusion :
The study is acceptable.
Endpoints :
LC_{50} (*Eisenia fetida*, 14 d) = 644 mg CANDIT/kg substrate (nominal)
NOEC (*Eisenia fetida*, 14 d) = 250 mg CANDIT/kg substrate (nominal) related to mortality and biomass

The acute toxicity on soil macro-organisms was tested with the formulation BAS 494 02 F. As BAS 494 02 F is a minor change to BAS 494 04 F (details are given in document JM3), this study is considered relevant to assess the potential risk arising from uses of BAS 494 04 F.

Effect of BAS 494 02 F on the mortality of the earthworm *Eisenia foetida*. (Dohmen G.P., 1995b).

Guidelines :
OECD 207
GLP :
Yes
Material and Methods :
Test substance : BAS 494 02 F; containing 126.25 g/L (nominal 125 g/L) kresoxim-methyl and 126.22 g/L (nominal 125 g/L) epoxiconazole – formulation ALLEGRO; batch: 93-1
Test species : earthworms (*Eisenia fetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/treatment; animals with developed clitellum, weight > 250 mg, age: less than one year old
Type of test : acute toxicity test in artificial soil (14 days)
Applied concentrations :
control (untreated); 100, 250, 500, 750, 1000 mg ALLEGRO/kg dry soil (nominal)
positive control (2-chloroacetamide) evaluated in a separate study
Soil type and test conditions :
test substrate : artificial soil according to OECD 207
water content : 32.9 % of dry weight at test initiation, 34.1 % at test end
pH : 6.4
temperature : 20 - 21 °C
photoperiod : continuous illumination
Assessments : Assessment of worm mortality and behavioral effects was carried out after 7 and 14 days, measurement of weight change as sub-lethal parameter after 14 days.
Findings :

Table B.9.6.3-2 : Effects of ALLEGRO on earthworm (*Eisenia fetida*) mortality and biomass (14 d)

BAS 494 02 F [mg/kg dry soil]	**Control**	**100**	**250**	**500**	**750**	**1000**
Mortality [%]	0	0	2.5	2.5	7.5*	22.5*
Weight change [%]	-12.95	-10.28	-6.74	-4.75	-11.73	-7.3
	Endpoints [mg/kg dry soil]					
NOEC	500					
LC_{50}	> 1000					

* statistically significant differences compared to the control (ANOVA, followed by students t-test for mortality data; p = 0.03)

Observations : No particular observations on morphological or behavioural changes were made.
Conclusion :
The study is acceptable.
Endpoints :
LC_{50} (*Eisenia fetida*, 14 d) > 1000 mg ALLEGRO/kg substrate (nominal)
NOEC (*Eisenia fetida*, 14 d) = 500 mg ALLEGRO/kg substrate (nominal) related to mortality and biomass

B.9.6.4 Sublethal effects of the formulation on earthworms (Annex IIIA 10.6.1.2)

Added in March 2010:

Study is not required for CANDIT. However, for ALLEGRO such a test on sub-lethal effects on earthworms is triggered according to SANCO/10329/2002 rev2 final, because the DT_{90} value for epoxiconazole and its metabolites is above 365 days.

Effects of BAS 494 04 F on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil with 5 % Peat. (Luehrs U., 2004).

Guidelines :
BBA VI 2-2, ISO 11268-2 (1998), EEC 96/12
Deviations : substrate with 5 % peat
GLP :
Yes
Material and Methods :
Test substance : BAS 494 04 F; containing 125.3 g/L (nominal 125.0 g/L) kresoxim-methyl and 124.8 g/L (nominal 125.0 g/L) epoxiconazole – formulation ALLEGRO; batch: 6380
Test species : earthworms (*Eisenia fetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/treatment; animals with developed clitellum, weight: 302 - 500 mg, age: approximately 11 – 12 months old
Type of test : chronic toxicity test in artificial soil (56 days)
Applied concentrations :
control (untreated); 1.45, 2.89, 5.78, 11.56, 23.13 mg ALLEGRO/kg soil dry weight
positive control Derosal SC 360 (360 g/L carbendazim) evaluated in a separate study
Soil type and test conditions :
test substrate : artificial soil according to OECD 207 (but with reduced content of peat i.e. 5 % instead of 10 %)
water content : 22.5 - 23.4 % of dry weight at test initiation, 26.3 - 27.5 % at test end
pH : 6.3 - 6.4 (at test start); 6.0 – 6.2 (at test end)
temperature : 19 - 21 °C
photoperiod : 16/8 hours light/dark cycle
light intensity : 450 – 760 lux
feeding : cattle manure
Assessments : Assessment of worm mortality, behavioral effects and measurement of weight change was carried out after 28 days of exposure in treated artificial soil. After an additional 28 days, determination of the number of offspring was conducted.

Findings :

Table B.9.6.4-1 : Effect of ALLEGRO on earthworm (*Eisenia fetida*) in a 56 day reproduction study

BAS 494 04 F [mg/kg dry soil [3]]	**Control**	**1.45**	**2.89**	**5.78**	**11.56**	**23.13**
Mortality (28 d) [%]	0.0	0.0	0.0	0.0	0.0	0.0
Weight change (28 d) [%]	+41.6	+30.4*[1)]	+32.7	+37.1	+35.6	+29.5
Number of juveniles (56 d)	289	270	237	257	263	201*[2)]
Reproduction in percent of control (56 d) [%]	--	93.6	82.0	88.9	91.2	69.8*
Food consumption [g]	25.0	25.0	25.0	25.0	25.0	25.0
	Endpoints [mg BAS 494 04 F / kg dry soil]					
NOEC (56 d)	11.56 (equivalent to 8.0 L/ha)					
EC_{50}	> 23.13 (equivalent to > 16.0 L/ha)					

1) statistically significant differences compared to the control (Bonferroni-t test, $\alpha = 0.05$)
2) statistically significant differences compared to the control (Dunnett-test, $\alpha = 0.05$)
3) based on a soil density of 1.5 g/cm³, a soil depth of 5 cm and a test item density of 1.084 g/cm³

Observations : No behavioural abnormalities were observed and all worms did burrow into the soil within 30 minutes after introduction.
Conclusion :
The study is acceptable.
Endpoints :
NOEC (*Eisenia fetida*, 56 d) = 11.56 mg ALLEGRO/kg substrate (nominal) related to mortality and biomass

B.9.6.5 Field tests - residue content of earthworms (Annex IIIA 10.6.1.3)

Study is not required.

B.9.6.6 Summary and risk assessment for earthworms (Annex III, 10.6.1.1)

Revised in March 2010:

Table B.9.6.6-1 : Summary of effects of kresoxim-methyl and its metabolites on earthworms

Test species	Test system	Test substance	Endpoints	References
Eisenia foetida	14 d acute toxicity	kresoxim-methyl	LC_{50} > 937 mg a.s./kg	Dohmen G.P., 1992b
Eisenia foetida	14 d acute toxicity	BF 490-1	LC_{50} > 1000 mg/kg	Dohmen G.P., 1994c
Eisenia foetida	14 d acute toxicity	BF 490-5	LC_{50} > 1000 mg/kg	Luehrs U., 2008

Table B.9.6.6-2 : Summary of effects of the formulations containing kresoxim-methyl on earthworms

Test species	Test system	Test substance	Endpoints	References
Eisenia foetida	14 d acute toxicity	BAS 490 01 F - MENTOR	LC_{50} > 750 mg/kg	Dohmen G.P., 1994f
Eisenia foetida	14 d acute toxicity	BAS 490 02 F - CANDIT	LC_{50} = 644 mg/kg	Dohmen G.P., 1993
Eisenia foetida	14 d acute toxicity	BAS 494 02 F - ALLEGRO	LC_{50} > 1000 mg/kg	Dohmen G.P., 1995b
Eisenia foetida	56 d long-term toxicity	BAS 494 04 F - ALLEGRO	NOEC = 11.56 mg/kg	Luehrs U., 2004

The formulation MENTOR is no longer supported in the resubmission dossier and thus no risk assessment is conducted.
The acute toxicity on soil macro-organisms was tested with the formulation BAS 494 02 F. As BAS 494 02 F is a minor change to BAS 494 04 F (details are given in document JM3), this study is considered relevant to assess the potential risk arising from uses of BAS 494 04 F.

A soil factor of 2 (f_{oc}) was included for the active substance, in order to address the organic content in the artificial soil, since the log P_{ow} value is > 2 (i.e. log P_{ow} 3.4 for Kresoxim-methyl).
The log P_{ow} values for BF 490-1 and BF 490-5 considered to be < 2 in the majority of agricultural soils and therefore the toxicity data derived from these studies had not been re-adjusted.

Table B.9.6.6-3 : Summary of endpoints used in the risk assessment, taking into account the soil correction factor

Test species	Test system	Test substance	Endpoints	References
Eisenia foetida	14 d acute toxicity	kresoxim-methyl	**$LC_{50\ corr}$ > 469 mg a.s./kg**	Dohmen G.P., 1992b
Eisenia foetida	14 d acute toxicity	BF 490-1	**LC_{50} > 1000 mg/kg**	Dohmen G.P., 1994c
Eisenia foetida	14 d acute toxicity	BF 490-5	**LC_{50} > 1000 mg/kg**	Luehrs U., 2008
Eisenia foetida	14 d acute toxicity	BAS 490 02 F - CANDIT	**$LC_{50\ corr}$ = 322 mg/kg (161 mg a.s./kg)**	Dohmen G.P., 1993

Exposure

The PECsoil values for the active substance and its metabolites are obtained from the section on fate and behaviour.

Table B.9.6.6-4 : PECsoil values for kresoxim-methyl and its metabolites

Test substance	Crop	Initial PECsoil (multiple applications)
kresoxim-methyl	apple	Initial PECsoil (after 4 appl.) = 0.050 mg a.s./kg
	grapevine	Initial PECsoil (after 3 appl.) = 0.100 mg a.s./kg
	cereals	Initial PECsoil (after 2 appl.) = 0.083 mg a.s./kg
BF 490-1	apple	Initial PECsoil (after 4 appl.) = 0.130 mg a.s./kg
	grapevine	Initial PECsoil (after 3 appl.) = 0.175 mg a.s./kg
	cereals	Initial PECsoil (after 2 appl.) = 0.085 mg a.s./kg
BF 490-5	apple	Initial PECsoil (after 4 appl.) = 0.022 mg a.s./kg
	grapevine	Initial PECsoil (after 3 appl.) = 0.034 mg a.s./kg
	cereals	Initial PECsoil (after 2 appl.) = 0.017 mg a.s./kg

Risk assessment

The risk assessment for earthworms is based on the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC.

1- Kresoxim-methyl and metabolites

Table B.9.6.6-5 : First Tier Toxicity Exposure Ratio's (TER's) for earthworms exposed to kresoxim-methyl and its metabolites

Test substance	Scenario	Test species	Time-scale	Endpoint (mg a.s./kg)	initial PEC_{SOIL} (mg a.s./kg)	TER	Annex VI Trigger Value
kresoxim-methyl	apple	*Eisenia foetida*	acute	$LC_{50\ corr}$ > 469 mg a.s./kg	0.050	> 9380	10
	grapevine				0.100	> 4690	10
	cereals				0.083	> 5651	10
BF 490-1	apple	*Eisenia foetida*	acute	LC_{50} > 1000 mg/kg	0.050	> 7692	10
	grapevine				0.100	> 5714	10
	cereals				0.083	> 11765	10
BF 490-5	apple	*Eisenia foetida*	acute	LC_{50} > 1000 mg/kg	0.050	> 50000	10
	grapevine				0.100	> 29412	10
	cereals				0.083	> 58824	10

The TER values for kresoxim-methyl and its metabolites BF 490-1 (major) and BF 490-5 (minor) are far above the trigger, indicating acceptable risk for earthworms.

2- Formulation CANDIT

The formulation CANDIT (BAS 490 02 F) is a fungicidal product, which contains the active substance kresoxim-methyl with a nominal content of 50 % w/w.

Table B.9.6.6-6 : Proposed use pattern of the formulation CANDIT

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate (kg a.s./ha) [1)]	Application rate (kg product/ha) [1)]
Pome fruit (apple, pear)	1 - 4	7	53 - 79	0.100 - 0.125	0.200 - 0.250
Grapevine	1 - 3	8	19 - 81	0.100 - 0.150	0.200 - 0.300

[1)] application rate increases with plant growth stage

For simplification reasons, the risk assessment is only conducted for the higher application rates. This covers the increase in application rate during season.

Table B.9.6.6-7 : First Tier Toxicity Exposure Ratio's (TER's) for earthworms exposed to the formulation BAS 490 02 F - CANDIT

Test substance	Scenario	Test species	Time-scale	Endpoint	initial PEC_{SOIL} (mg a.s./kg)	TER	Annex VI Trigger Value
BAS 490 02 F	apple	*Eisenia foetida*	acute	$LC_{50\ corr}$ = 161 mg a.s./kg	0.050	3220	10
	grapevine				0.100	1610	10

The TER values for the formulation CANDIT are far above the trigger, indicating acceptable risk for earthworms.

Further studies on sub-lethal effects on earthworms were not triggered, since:

- The acute toxicity to earthworms is low (TER > 10). Thus the 91/414/EEC Annex VI trigger value was exceeded.
- In aerobic soil studies kresoxim-methyl dissipated very fast with a DT_{90} value of less than three days. This value was confirmed by field dissipation studies. Thus, the test on 'sub-lethal effects on earthworms' was not triggered.
- Kresoxim-methyl degraded to the main metabolite BF 490-1, which itself degraded to the minor metabolite BF 490-5.
- Normalized data - deriving from field dissipation studies at German test sites – resulted in DT_{90} values for the metabolite BF 490-1 of <100 days.

3- Formulation ALLEGRO

The formulation ALLEGRO (BAS 494 04 F) is a fungicidal product, which contains the active substances
- kresoxim-methyl (BAS 490 F) with a nominal content of 125 g a.s./L
- epoxiconazole (BAS 480 F) with a nominal content of 125 g a.s./L

Table B.9.6.6-8 : Proposed use pattern of the formulation ALLEGRO

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate		
				BAS 494 04 F [L/ha]	Kresoxim-methyl (BAS 490 F) [kg a.s./ha]	Epoxiconazole (BAS 480 F) [kg a.s./ha]
Cereals	2	21	25 - 69	1.0	0.125	0.125

Risk assessment of the notifier:
The notifier presented a risk assessment for the formulation ALLEGRO based on the acute toxicity test with BAS 494 02 F and the reproductive toxicity test with BAS 494 04 F. In the study with BAS 494 04 F, a soil with 5 % peat was used and therefore the toxicity data derived from this study have not been re-adjusted.
For the exposure to epoxiconazole and its metabolite BF 480-16 (1,2,4-Triazole) initial soil concentrations (PEC_{ini}) as well as concentrations considering multi-year use ($PEC_{accu\ overall}$) were calculated.
DT_{90} field for epoxiconazole were above 365 days. Thus, the test on sublethal effects on earthworms was triggered for epoxiconazole. Also, risk assessment for macro-organisms (springtails) was conducted for the metabolite BF 480-16.
Additionally, in a biological field monitoring program potential effects on naturally occurring earthworm communities after a multi-year usage of epoxiconazole (maximum test rate: 3 x 125 g a.s./ha/year) were examined. A solo formulation of epoxiconazole had been applied in sugar beet, oilseed rape and cereals. Different earthworm community parameters were continuously evaluated from 1998 to 2002. From these results it could be concluded that the use of epoxiconazole is unlikely to pose sustained adverse effects on earthworm communities up to a field rate of 375 g a.s./ha. Also a litter-bag study was performed in the context of the biological field monitoring program (3 x 0.167 mg a.s./kg dry soil). Overall degradation rates after one year were about 80 % in winter oilseed rape and winter wheat plots, demonstrating no adverse effects on the organic matter decomposition following multi-year use of epoxiconazole in arable crops.
For epoxiconazole a comprehensive data package – including field data – is available, demonstrating the low risk to soil organisms exposed to epoxiconazole.
The proposed use of BAS 494 04 F will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern of twice 1.0 L/ha.

Risk assessment of the RMS:
The risk assessment for the formulation ALLEGRO was only conducted for kresoxim-methyl, based on the risk assessment of the active substance for use in cereals (see Table B.9.6.6-5).
For epoxiconazole, RMS refers to the risk assessment in the DAR of epoxiconazole.

In conclusion, the risk of kresoxim-methyl, its metabolites BF 490-1 (major) and BF 490-5 (minor) and the formulations CANDIT and ALLEGRO to earthworms is acceptable for the intended uses.

B.9.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)

Revised in March 2010:

Further studies on other soil non-target organisms are not triggered, since:

- The acute toxicity to earthworms is low (TER > 10) and earthworm reproduction studies were not triggered
- In aerobic soil studies kresoxim-methyl dissipated very fast with a DT_{90} value of less than three days. This value was confirmed by field dissipation studies. Thus, the test on 'sub-lethal effects on earthworms' was not triggered.
- Kresoxim-methyl degraded to the main metabolite BF 490-1, which itself degraded to the minor metabolite BF 490-5.
- Normalized data - deriving from field dissipation studies at German test sites – resulted in DT_{90} values for the metabolite BF 490-1 of <100 days

A study on organic matter decomposition is not triggered, since:

- The $DT90_{field}$ values for kresoxim-methyl and its soil metabolites BF 490-1 and BF 490-5 are < 365 days.

B.9.8 Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)

B.9.8.1 Impact of the active substance on soil microbial activity (Annex IIA 8.5)

Effect of Reg. No. 262 451 on the nitrogen turnover in the soil. (Reinhard K., 1993a).

Guidelines:
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance : BF 490-1; free acid metabolite of kresoxim-methyl (Reg. No. 262 451); purity: 99.7 %
Test soils : 4 replicates/concentration;
Biologically active agricultural soils
1) sandy loam (Limburgerhof Landwirtschaftliche Versuchsstation)
2) sandy clay loam (Limburgerhof, Bruch West)
Type of test : short-term nitrogen turnover test (28 days)
Applied concentrations : 0.2 mg and 2.0 mg BF 490-1/kg soil
This fortification is based on the application of 0.15 kg and 1.5 kg kresoxim-methyl/ha since the a.s. quickly and almost completely yields the free-acid metabolite when applied on soil.
Test conditions :
soil moisture : 50 % of its water holding capacity
soils (control and treatment) were amended with 0.5 % lucerne meal, corresponding to 18.5 mg N/100 g soil (dry weight)
soil samples were incubated at 20 ± 2 °C in plastic bottles
Sampling scheme : 0, 14, 28 and 42 days after treatment, aliquots were withdrawn and subjected to the measurement
Test principle : NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process were determined by using an ammonia-electrode and a nitrate-electrode, respectively
Findings :

Table B.9.8.1-1 : Effects on the nitrogen turnover rates of 2 biologically active soils exposed to kresoxim-methyl metabolite BF 490-1, over 28 days

Incubation	**Nitrogen Turnover Rates [1] and % of Control**							
(days)	**0 (mg a.s./kg soil)**		**0.2 (mg a.s./kg soil)**			**2.0 (mg a.s./kg soil)**		
	NO_3-N	**NH_4-N**	**NO_3-N**	**NH_4-N**	**(%)[2]**	**NO_3N**	**NH_4-N**	**(%)[2]**
sandy loam, 1.0 % OC, pH 6.6, CEC 5.5 meq/100g								
0	1.74	0.36	1.64	0.34	-	1.68	0.32	-
14	5.81	0.17	5.11	0.17	88.0	5.13	0.19	88.3
28	8.09	0.17	7.43	0.17	**91.8**	7.55	0.17	**93.3**
sandy clay loam, 1.9 % OC, pH 7.5, CEC 17.9 meq/100g								
0	2.36	1.08	2.28	1.17	-	2.30	1.17	-
14	6.71	0.17	5.37	0.20	80.0	5.57	0.17	83.0
28	7.97	0.13	6.60	0.16	82.8	6.91	0.16	86.7
42	8.79	0.14	7.67	0.14	**87.3**	7.80	0.14	**88.7**

1) nitrogen turnover rate in mg NO_3-N resp. NH_4-N/100 g soil (dry weight)
2) % of control - only NO_3-N values

In the sandy loam inhibition rates smaller than 10 % after 258 days were observed (9.2 - 6.7 %)
In the sandy clay loam the inhibition rates of 12.7 - 11.3 % after 42 days were observed. This inhibition is not dose-related.

Endpoints :
Effective dose (28d) > 2.0 mg BF 490-1/kg soil corresponding to > 1.5 kg kresoxim-methyl/ha (ten-fold field application rate)
Conclusion :
The study is acceptable.
Negligible effects of metabolite BF 490-1 on the nitrogen turnover were observed.

Added in March 2010:

Metabolite BF 490-5 has been detected in a new soil metabolism study at levels above 5 % and has therefore been checked for its ecotoxicological potential for soil organisms. Hence, this new study is now included to meet latest testing requirements (soil metabolite > 5 %).

Effects of Reg. No. 286404 (metabolite of BAS 490 F, BF 490-5) on the activity of soil microflora (nitrogen transformation test). (Schulz L., 2008b).

Guidelines:
OECD 216 (2000); EEC 96/12; EEC 91/414; Guidance document on Terrestrial Ecotoxicology (2002)
GLP :
Yes
Material and Methods :
Test substance: BF 490-5, metabolite of kresoxim-methyl (Reg. No. 286404); purity: 99.2%; batch: L76-100
Test soil : 3 replicates/treatment;
biologically active agricultural soil: loamy sand soil, 50.6 % sand, 39.5 % silt, 9.8 % clay
pH 6.7, 1.43 % C_{org}, 0.13 % total-N, WHC: 37.86 g/100 g dry soil
Type of test : short-term nitrogen turnover test (28 days)
Applied concentrations : control (untreated); 0.042 mg BF 490-5/kg dry soil (corresponding to the maximum single application rate of 0.032 kg BF 490-5/ha) and 0.42 mg BF 490-5/kg dry soil (corresponding to an application rate of 0.32 kg BF 490-5/ha). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
positive control Dinoterb evaluated in a separate study
Test conditions :
soil moisture : 46.59 - 48.17 % of its maximum water holding capacity
pH : 6.5 – 6.6
soil samples were incubated at 18.8 - 21.4 °C in a climatic room while stored in glass flasks in the dark
Sampling scheme : 0, 7, 14 and 28 days after treatment, sub-samples were withdrawn from the bulk batches and subjected to measurement
Test principle : Soils (control and treatment) were amended with 0.5 % lucerne meal (C/N ratio 15/1). NH_4-nitrogen formed from organically bound nitrogen and if appropriate NO_3-nitrogen from the nitrification process and NO_2-nitrogen were determined by using the Autoanalyzer II (Braun & Luebbe).

Findings :

Table B.9.8.1-2 : Effects of BF 490-5 on soil micro-organisms (nitrogen transformation) on days 0, 7, 14 and 28 of incubation

Soil (days)	Control	0.042 mg BF 490-5 per kg dry soil, equivalent to 0.032 kg/ha		0.42 mg BF 490-5 per kg dry soil, equivalent to 0.32 kg/ha	
	NO_3-N [mg/kg dry soil]	NO_3-N [mg/kg dry soil]	% Deviation from the control [1)]	NO_3-N [mg/kg dry soil]	% Deviation from the control [1)]
Loamy sand soil (0 d)	1.2	1.22	+1.7	1.21	+1.4
Loamy sand soil (7 d)	3.31	3.35	+1.1	3.32	+0.2
Loamy sand soil (14 d)	3.84	3.85	+0.2	3.83	-0.2
Loamy sand soil (28 d)	4.89	4.95	+1.1	4.84	-1.2

1) Based on NO_3-nitrogen production; - = inhibition; + = stimulation

The toxic standard Dinoterb caused effects of +27.7 %, +60.8 % and +68.1 % (required ≥ 25 %) on the nitrogen transformation at the tested concentrations of 6.80, 16.00 and 27.00 mg/kg soil dry weight, respectively, 28 days after application and thus demonstrates the sensitivity of the system.

Conclusion :
The study is acceptable.
BF 490-5 (soil metabolite of BAS 490 F) caused no short-term and no long-term effects on the soil nitrogen transformation (measured as NO_3-N production) in a field soil tested up to a concentration of 0.42 mg/kg dry soil, equivalent to 0.32 kg BF 490-5/ha.

Effect of Reg. No. 262 451 on soil respiration. (Reinhard K., 1993b).

Guidelines :
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance: BF 490-1; free acid metabolite of kresoxim-methyl (Reg. No. 262 451); purity: 99.7 %
Test soils : 4 replicates/concentration;
Biologically active agricultural soils
1) sandy loam (Limburgerhof Landwirtschaftliche Versuchsstation)
2) sandy clay loam (Limburgerhof, Bruch West)
Applied concentrations : untreated control; positive control (Aretit flüssig); 0.2 mg and 2.0 mg BF 490-1/kg soil
This fortification is based on the application of 0.15 kg and 1.5 kg kresoxim-methyl/ha since the a.s. quicly and almost completely yields the free-acid metabolite when applied on soil.
Type of test : short-term soil respiration test (28 days)
Test conditions :
soil moisture : 50 % of its water holding capacity
soil samples were incubated at 20 ± 2 °C in plastic bottles
Sampling scheme : 0, 14 and 28 days after treatment, aliquots were withdrawn and subjected to the respiration rate measurement
Test principle : a sapromat was used to measure the oxygen consumption over a period of 12 hours at different sampling intervals

Findings :

Table B.9.8.1-3 : Effects on the respiration rates of biologically active sandy loam and sandy clay soils exposed to kresoxim-methyl metabolite BF 490-1, over 28 days

Incubation (days)	**O_2 - Consumption Rates (mg O_2/100 g dry soil) and % of Control**				
	0 (mg a.s./kg dry soil)	**0.2 (mg a.s./kg dry soil)**		**2.0 (mg a.s./kg dry soil)**	
	(mg)	**(mg)**	**(%)**	**(mg)**	**(%)**
sandy loam, 1.0 % OC, pH 6.6, CEC 5.5 meq/100g					
0	8.6	8.8	102.3	8.8	102.3
14	9.8	8.8	**89.8**	9.1	92.9
28	7.9	7.7	97.5	7.6	96.2
sandy clay loam, 1.9 % OC, pH 7.5, CEC 179 meq/100g					
0	19.5	19.1	97.9	19.5	100
14	23.0	22.3	97.0	22.5	97.8
28	22.0	21.0	95.5	21.5	97.7

No significant influences of the test substance on the oxygen consumption were observed at neither application rate (single and ten-fold dose of 0.2 mg and 2.0 mg kresoxim-methyl/kg soil) in both soils : highest reduction of activity -10.2 %.

Endpoints : Effective dose (28d) > 2.0 mg BF 490-1/kg soil corresponding to > 1.5 kg kresoxim-methyl/ha (ten-fold field application rate)
Conclusion :
The study is acceptable.
Negligible effects of kresoxim-methyl metabolite BF 490-1 on the soil respiration were observed.

Added in March 2010:

Metabolite BF 490-5 has been detected in a new soil metabolism study at levels above 5 % and has therefore been checked for its ecotoxicological potential for soil organisms. Hence, this new study is now included to meet latest testing requirements (soil metabolite > 5 %).

Effects of Reg. No. 286404 (metabolite of BAS 490 F, BF 490-5) on the activity of soil microflora (carbon transformation test). (Schulz L., 2008a).

Guidelines:
OECD 217 (2000); EEC 91/414; EEC 96/12; Guidance document on Terrestrial Ecotoxicology (2002)
GLP :
Yes
Material and Methods
Test substance: BF 490-5, metabolite of kresoxim-methyl (Reg. No. 286404); purity: 99.2 %; batch: L76-100
Test soil : 3 replicates/treatment;
biologically active agricultural soil: loamy sand soil, 50.6 % sand, 39.5 % silt, 9.8 % clay
pH 6.7, 1.43 % C_{org}, 0.13 % total-N, WHC: 37.86 g/100 g dry soil
Type of test : short-term soil respiration test (28 days)
Applied concentrations : control (untreated); 0.042 mg BF 490-5/kg dry soil (corresponding to the maximum single application rate of 0.032 kg BF 490-5/ha) and 0.42 mg BF 490-5/kg dry soil (corresponding to an application rate of 0.32 kg BF 490-5/ha). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
positive control Dinoterb evaluated in a separate study
Test conditions :
soil moisture : 47.05 - 48.68 % of its maximum water holding capacity
pH : 6.5 – 6.7

soil samples were incubated at 18.8 - 21.4 °C in a climatic room while stored in glass flasks in the dark
Sampling scheme : 0, 7, 14 and 28 days after treatment, sub-samples were withdrawn from the bulk batches and subjected to measurement
Test principle : Determination of carbon-transformation in soil after addition of glucose (concentration in soil: 0.4 %). A "BSB-digi" respirometer system was used to measure the oxygen consumption over a period of maximum 24 hours at different sampling intervals.
Findings :

Table B.9.8.1-4 : Effects of BF 490-5 on soil micro-organisms (carbon transformation) on days 0, 7, 14 and 28 of incubation

Soil (days)	**Control**	**0.042 mg BF 490-5 per kg dry soil, equivalent to 0.032 kg /ha**		**0.42 mg BF 490-5 per kg dry soil, equivalent to 0.32 kg/ha**	
	O_2 [mg/kg dry soil]	**O_2 [mg/kg dry soil]**	**% Deviation from the control [1)]**	**O_2 [mg/kg dry soil]**	**% Deviation from the control [1)]**
Loamy sand soil (0 d)	13.06	12.91	-1.2	13.31	+1.9
Loamy sand soil (7 d)	11.82	12.00	+1.5	11.88	+0.4
Loamy sand soil (14 d)	11.23	11.21	-0.2	11.11	-1.1
Loamy sand soil (28 d)	10.23	10.14	-0.8	9.91	-3.1

1) Based on O_2 consumption; - = inhibition; + = stimulation

The toxic standard Dinoterb caused effects of -24.8 %, -42.0 % and -49.0 % (required ≥ 25 %) on the carbon transformation at the tested concentrations of 6.80, 16.00 and 27.00 mg/kg soil dry weight, respectively, 28 days after application and thus demonstrates the sensitivity of the system.

Conclusion :
The study is acceptable.
BF 490-5 (soil metabolite of BAS 490 F) caused no short-term and long-term effects on carbon transformation in a field soil tested up to a concentration of 0.42 mg/kg dry soil, equivalent to a field application rate of 0.32 kg BF 490-5 per ha.

B.9.8.2 Impact of the formulations on soil microbial activity (laboratory) (Annex IIIA 10.7.1)

Resubmitted in March 2010:

Effect of BAS 490 02 F on the nitrogen turnover in the soil. (Reinhard K., 1993c)

Guidelines :
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance: BAS 490 02 F; formulation containing 50 % nominal (48.37 % analyzed) kresoxim-methyl – formulation CANDIT; batch: 92-5
Test soils : 3 replicates/concentration;
Biologically active agricultural soils
1) clay sand soil (Limburgerhof Landwirtschaftliche Versuchsstation)
pH 6.5, 1.1 % C_{org}, water content of soil: 10.1 % WHC
2) sandy loam soil (Limburgerhof, Bruch West)
pH 7.5, 2.0 % C_{org}, water content of soil: 21.4 % WHC

Type of test : short-term nitrogen turnover test (28 days)
Applied concentrations : control (untreated); 0.4 mg CANDIT/kg dry soil (corresponding to a single application rate of 0.3 kg CANDIT/ha) and 4.0 mg CANDIT/kg dry soil (corresponding to an application rate of 3.0 kg CANDIT/ha). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
positive control N-Serve 24 E evaluated in a separate study
Test conditions :
soil moisture : 50 % of its water holding capacity
pH : 6.47 – 6.91 (clay sand soil); 7.71 – 8.08 (sandy loam soil)
soils (control and treatment) were amended with 0.5 % lucerne meal, corresponding to 19 mg N/100 g soil (dry weight)
soil samples were incubated at 20 ± 2 °C and were stored in the dark
Sampling scheme : 0, 15 and 28 days after treatment, aliquots were withdrawn and subjected to the measurement
Test principle : NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen formed from the nitrification process was determined by using an expandable Ion Analyzer.
Findings :

Table B.9.8.2-1 : Effects of CANDIT on soil micro-organisms (nitrogen transformation) on days 0, 15 and 28 of incubation

Soil (days)	Control	0.4 mg BAS 490 02 F per kg dry soil		4.0 mg BAS 490 02 F per kg dry soil	
	NO_3-N [mg/100 g dry soil]	NO_3-N [mg/100 g dry soil]	% Deviation from control[1]	NO_3-N [mg/100 g dry soil]	% Deviation from control[1]
clay sand soil (0 d)	2.29	2.00	-12.7	2.13	-7.0
clay sand soil (15 d)	6.45	6.13	-5.0	6.51	+0.9
clay sand soil (28 d)	8.56	7.76	-9.3	8.35	-2.5
sandy loam soil (0 d)	2.59	2.59	±0	2.59	±0
sandy loam soil (15 d)	7.23	7.31	+1.1	7.51	+3.9
sandy loam soil (28 d)	7.91	8.15	+3.0	8.31	+5.1

[1]Based on NO_3-nitrogen production; +- = stimulation; - = inhibition,

- Slight reduction of the NO_3- level (-9.3 %) after 28 days at the single-dose application. As no concomitant increase of the NH_4- was found this effect could be caused by an inhibition of the ammonification. This effect was not observed at the ten-fold dose.
- No significant effect observed in the second soil.

Conclusion :
The study is acceptable.
CANDIT caused no short-term and no long-term effects on the soil nitrogen transformation (measured as NO_3-N production) in two field soils tested up to a concentration of 4.0 mg/kg dry soil, equivalent to a field application rate of 3.0 kg CANDIT per ha.

Effect of BAS 490 02 F on soil respiration. (Reinhard K., 1993d).

Guidelines :
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance : BAS 490 02 F; formulation containing 50 % nominal (48.37 % analyzed) kresoxim-methyl – formulation CANDIT; batch: 92-5
Test soils : 4 replicates/concentration;
Biologically active agricultural soils
1) clay sand soil (Limburgerhof Landwirtschaftliche Versuchsstation)
pH 6.5, 1.1 % C_{org}, water content of soil: 10.1 % WHC
3) sandy loam soil (Limburgerhof, Bruch West)
pH 7.5, 2.0 % C_{org}, water content of soil: 21.4 % WHC
Type of test : short-term soil respiration test (28 days)
Applied concentrations : control (untreated); 0.4 mg CANDIT/kg dry soil (corresponding to a single application rate of 0.3 kg CANDIT/ha) and 4.0 mg CANDIT/kg dry soil (corresponding to an application rate of 3.0 kg CANDIT/ha). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
positive control Aretit Flüssig evaluated in a separate study
Test conditions :
soil moisture : 50 % of its water holding capacity
pH : 6.59 – 6.68 (clay sand soil); 7.79 – 7.86 (sandy loam soil)
soil samples were incubated at 20 ± 2 °C and were stored in the dark
Sampling scheme : 0, 14 and 28 days after treatment, aliquots were withdrawn and subjected to the respiration rate measurement
Test principle : Determination of carbon transformation in soil after addition of glucose (concentration in soil 2 % - 4 %). A "Sapromat B 12" (Voith, Heidenheim, Germany) respirometer was used to measure the O_2-consumption over a period of maximum 20 hours at different sampling intervals.
Findings :

Table B.9.8.2-2 : Effects of CANDIT on soil micro-organisms (carbon transformation) on days 0, 14 and 28 of incubation

Soil (days)	Control	0.4 mg BAS 490 02 F per kg dry soil		4.0 mg BAS 490 02 F per kg dry soil	
	O_2 consumption [mg/12 h/ 100 g dry soil]	O_2 consumption [mg/12 h/ 100 g dry soil]	% Deviation from the control [1)]	O_2 consumption [mg/12 h/ 100 g dry soil]]	% Deviation from the control [1)]
clay sand soil (0 d)	9.1	8.8	-3.3	9.1	±0
clay sand soil (14 d)	7.3	7.5	+2.7	7.3	±0
clay sand soil (28 d)	8.1	8.3	+2.5	8.3	+2.5
sandy loam soil (0 d)	20.0	20.9	+4.5	20.8	+4.0
sandy loam soil (14 d)	19.0	18.8	-1.1	19.5	+2.6
sandy loam soil (28 d)	20.4	20.3	-0.5	20.7	+1.5

1) Based on O_2 consumption; - = inhibition, + = stimulation

Conclusion :
The study is acceptable.
CANDIT caused no short-term and long-term effects on carbon transformation in two field soils tested up to a concentration of 4 mg/kg dry soil, equivalent to a field application rate of 3.0 kg CANDIT per ha.

Effect of BAS 492 01 F on soil respiration. (Reinhard K., 1993e).

Guidelines :
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance: BAS 492 01 F, SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Soils : 4 replicates/concentration;
Biologically active agricultural soils
1) sandy loam (Limburgerhof Landwirtschaftliche Versuchsstation)
2) sandy loam (LUFA Speyer, 2.3 F31993)
Type of test : short-term soil respiration test (28 days)
Applied concentrations :
0.93 and 9.3 µL MENTOR/kg dry soil. This fortification is based on the application of 0.7 L and 7 L MENTOR/ha, an incorporation depth of 5 cm and a soil density of 1.5 g/cm³;
untreated control; positive control (Aretit Flüssig)
Test conditions :
soil moisture : 40 % of its water holding capacity
soil samples were incubated at 20 ± 2 °C in plastic bottles
Sampling scheme : 0, 14 and 28 days after treatment, aliquots were withdrawn and subjected to the respiration rate measurement
Test principle : Both soils were amended with glucose. A sapromat was used to measure the oxygen consumption over a period of 12 hours at different sampling intervals.
Findings :

Table B.9.8.2-3 : Effects on the respiration rates of 2 biologically active sandy loam soils exposed to formulation MENTOR, over 28 days

Incu-bation (days)	**O_2 - Consumption Rates (mg O_2/100 g dry soil) and % of Control**				
	0 µL formulation/kg dry soil	**0.93 µL formulation/kg dry soil**		**9.3 µL formulation/kg dry soil**	
	(mg)	**(mg)**	**(%)**	**(mg)**	**(%)**
sandy loam, 0.9 % OC, pH 6.5, CEC 5.7 meq/100g					
0	5.4	5.8	107.4	5.6	103.7
14	5.2	5.4	103.8	5.1	98.1
28	5.7	5.3	93.0	5.3	93.0
sandy loam, 1.4 % OC, pH 6.7, CEC 10.5 meq/100g					
0	14.3	13.5	94.4	13.5	94.4
14	13.6	13.1	96.3	12.9	94.9
28	13.6	12.9	94.9	12.8	94.1

Throughout the study the differences in oxygen consumption between the treated and untreated samples never exceeded 7.4 %. After 28 days only negligible reduction rates of about 7 % and 5.1 - 5.9 % respectively for each soil were recorded.
At the end of the study only negligible effects of MENTOR on soil respiration rates could be measured, according the BBA-classification scheme (deviations smaller than ± 15 % from control values).

Endpoints:
Effective dose (28d) > 9.3 µL MENTOR/kg dry soil equivalent to > 7.0 L MENTOR/ha (ten-fold field application rate)
Conclusion :
The study is acceptable.
Negligible effects of MENTOR on the soil respiration were observed.

Effect of BAS 492 01 F on the nitrogen turnover in the soil. (Reinhard K., 1994).

Guidelines :
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance: BAS 492 01 F, SE containing 151.15 g/L kresoxim-methyl and 305.37 g/L fenpropimorph - formulation MENTOR; batch: 93-2
Test soils : 3 replicates/concentration;
Biologically active agricultural soils
1) sandy loam (Limburgerhof Landwirtschaftliche Versuchsstation)
2) sandy loam (Limburgerhof, Bruch West)
Type of test : short-term nitrogen turnover test (28 days)
Applied concentrations :
0.93 and 9.3 µL MENTOR/kg dry soil. This fortification is based on the application of 0.7 L and 7 L MENTOR/ha, an incorporation depth of 5 cm and a soil density of 1.5 g/cm³;
untreated control; positive control (N-Serve 24E (nitrapyrin))
Test conditions :
soil moisture : 45 % of its water holding capacity
soil samples were incubated at 20 ± 2 °C, while stored in plastic bottles
Sampling scheme : 0, 14 and 28 days after treatment, aliquots were withdrawn and subjected to the measurement
Test principle : Both soils were amended with lucerne meal (0.5 % of soil dry weight). NH_4 - nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process were determined by using an ammonia-electrode and a nitrate-electorde, respectively.
Findings :

Table B.9.8.2-4 : Effects on the nitrogen turnover rates of 2 biologically active sandy loam soils exposed to formulation MENTOR, over 28 days

Incubation	**Nitrogen Turnover Rates [1] and % of Control**							
(days)	**0 (µL/kg soil)**		**0.93 (µL/kg soil)**			**9.3 (µL/kg soil)**		
	NO_3-N	**NH_4-N**	**NO_3-N**	**NH_4-N**	**(%)[2]**	**NO_3N**	**NH_4-N**	**(%)[2]**
sandy loam, 1.1 % OC, pH 6.5, CEC 6.1 meq/100g								
0	2.18	1.03	2.87	1.03	-	2.79	0.98	-
14	6.49	0.20	7.81	0.20	**120.3**	7.47	0.20	**115.1**
28	7.74	0.16	8.59	0.16	**111.0**	8.44	0.16	**109.0**
sandy loam, 2.0 % OC, pH 7.5, CEC 17.1 meq/100g								
0	2.12	0.48	2.14	0.41	-	2.10	0.39	-
14	5.90	0.20	6.29	0.22	**106.6**	5.93	0.22	**100.5**
28	7.43	0.17	7.91	0.17	**106.5**	7.89	0.17	**106.2**

1) nitrogen turnover rate in mg NO_3-N resp. NH_4-N/100 g soil (dry weight)
2) % of control - only NO_3-N values

In both soils, MENTOR caused a slight stimulation of the nitrogen turnover.

In the first soil (75 % sand) the nitrate values rose by 15.1 - 20.3 % after 14 days, compared to the untreated control. At the end of the study the stimulative effect was still obvious, i.e. 9 - 11 %. As regards the second soil (55 % sand), the nitrate values did not rise by more than 6.2 % during the entire study period.
Endpoints :
Effective dose (28d) > 9.3 µL MENTOR/kg dry soil equivalent to > 7.0 L MENTOR/ha (ten-fold field application rate)
Conclusion :
The study is acceptable.
Negligible effects of MENTOR on the nitrogen turnover were observed.

Added in March 2010:

Soil microbial activity was tested with the formulation BAS 494 02 F. As BAS 494 02 F is a minor change to BAS 494 04 F (details are given in document JM3), these studies are considered relevant to assess the potential risk arising from uses of BAS 494 04 F.

Effect of BAS 494 02 F on the nitrogen turnover in the soil. (Reinhard K., 1994).

Guidelines:
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance : BAS 494 02 F; formulation containing 126.25 g/L (nominal 125.0 g/L) kresoxim-methyl and 126.22 g/L (nominal 125.0 g/L) epoxiconazole – formulation ALLEGRO; batch: 93-1
Test soil : 3 replicates/treatment;
Biologically active agricultural soils
1) clay sand soil: pH 6.5, 1.0 % C_{org}, WHC 32 %
2) sandy loam soil : pH 6.6, 1.3 % C_{org}, WHC 31%
Type of test : short-term nitrogen turnover test (28 days)
Applied concentrations : control (untreated); 1.33 µL ALLEGRO/kg dry soil (corresponding to an application rate of 1 L ALLEGRO/ha) and 13.33 µL ALLEGRO/kg dry soil (corresponding to the 10-fold application rate, namely 10 L ALLEGRO/ha). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
positive control N-Serve 24 E evaluated in a separate study
Test conditions :
soil moisture : 50 % of its maximum water-holding capacity
pH : 6.45 – 6.94 (clay sand soil); 6.51 – 6.94 (sandy loam soil)
soil samples were incubated at 20 ± 2 °C while stored in vessels in the dark
Sampling scheme : 0, 14 and 28 days after treatment; subsamples were withdrawn from the bulk batches and subjected to the measurement.
Test principle : Determination of the N-transformation (NO_3-nitrogen production) in soil enriched with lucerne meal (concentration in soil 0.5 %). The NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process was determined by using an Expandable Ion Analyzer.

Findings :

Table B.9.8.2-5 : Effects of ALLEGRO on soil micro-organisms (nitrogen transformation) in sandy loam and clay sand after 0, 14 and 28 days of incubation

Soil (days)	Control	1.33 µL BAS 494 02 F per kg dry soil equivalent to 1 L/ha		13.33 µL BAS 494 02 F per kg dry soil equivalent to 10 L/ha	
	NO_3-N [mg/kg dry soil]	NO_3-N [mg/kg dry soil]	% Deviation from the control [1)]	NO_3-N [mg/kg dry soil]	% Deviation from the control [1)]
Sandy loam soil (0 d)	7.59	7.59	0.0	7.56	-0.4
Sandy loam soil (14 d)	11.7	11.5	-1.7	11.8	+0.9
Sandy loam soil (28 d)	13.1	12.9	-1.5	13.2	+0.8
clay sand soil (0 d)	1.26	1.18	-6.4	1.11	-11.9
clay sand soil (14 d)	5.32	5.07	-4.7	4.59	-13.7
clay sand soil (28 d)	7.99	7.97	-0.3	7.51	-6.0

1) Based on NO_3-nitrogen production; - = inhibition, + = stimulation

The reference item N-SERVE 24 E produced a clear effect after 28 days (-75.6 % and -92.8 % at 10 and 20 µL N-SERVE 24 E /kg dry soil).

Conclusion :
The study is acceptable.
ALLEGRO causes no short-term and no long-term effects on the soil nitrogen transformation (measured as NO_3-N production) in two different field soils tested up to a concentration of 13.33 µL ALLEGRO/kg dry soil (equivalent to a field application rate of 10 L ALLEGRO/ha).

Effect of BAS 494 02 F on soil respiration. (Sedlaczek B., 1994).

Guidelines :
BBA Guideline part VI, 1-1 (1990)
GLP :
Yes
Material and Methods :
Test substance : BAS 494 02 F; formulation containing 126.25 g/L (nominal 125.0 g/L) kresoxim-methyl and 126.22 g/L (nominal 125.0 g/L) epoxiconazole – formulation ALLEGRO; batch: 93-1
Test soil : 4 replicates/treatment;
Biologically active agricultural soils
1) clay sand soil : pH 6.5, 1.0 % C_{org}, WHC 32 %
2) sandy loam soil : pH 6.6, 1.3 % C_{org}, WHC 31%
Type of test : short-term soil respiration test (28 days)
Applied concentrations : control (untreated); 1.33 µL ALLEGRO/kg dry soil (corresponding to an application rate of 1.0 L ALLEGRO/ha) and 13.33 µL ALLEGRO/kg dry soil (corresponding to the 10.0 L ALLEGRO/ha). The test rates were equivalent to 250 g a.s./kg dry soil and 2500 g a.s./kg dry soil, respectively. Test concentrations are related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
positive control Aretit Flüssig evaluated in a separate study

Test conditions :
soil moisture : 50 % of its maximum water holding capacity
pH : 6.45 – 6.64 (clay sand soil); 6.69 – 6.73 (sandy loam soil)
soil samples were incubated at 20 ± 2 °C while stored in plastic bottles in the dark
Sampling scheme : 0, 14 and 28 days after treatment, subsamples were withdrawn from the bulk batches and subjected to the measurement
Test principle : Determination of carbon-transformation in soil after addition of glucose. A "Sapromat B 12" respirometer system was used to measure the oxygen consumption over a period of maximum 12 hours at different sampling intervals.
Findings :

Table B.9.8.2-6 : Effects of ALLEGRO on soil micro-organisms (carbon transformation) on days 0, 14 and 28 of incubation

Soil (days)	Control	1.33 µL BAS 494 02 F per kg dry soil equivalent to 1 L/ha		13.33 µL BAS 494 02 F per kg dry soil equivalent to 10 L/ha	
	O_2 [mg/12h/100g dry soil]	O_2 [mg/12h/100g dry soil]	% Deviation from the control [1)]	O_2 [mg/12h/100g dry soil]	% Deviation from the control [1)]
Sandy loam soil (0 d)	11.2	10.9	-2.7	10.2	-8.9
Sandy loam soil (14 d)	10.1	9.9	-2.0	10.0	-1.0
Sandy loam soil (28 d)	9.8	9.5	-3.1	9.6	-2.0
clay sand soil (0 d)	9.1	8.8	-3.3	8.0	-12.1
clay sand soil (14 d)	7.2	6.9	-4.2	6.2	-13.9
clay sand soil (28 d)	6.6	6.2	-6.1	5.8	-12.1

1) Based on O_2 consumption; - = inhibition, + = stimulation

In a separate study the reference item "Aretit Flüssig" produced the expected level of effect (-23.9 %, -40.0 % and -48.6 % inhibition in a sandy loam/clay sand soil with 25 µL a.s./kg dry soil and -3.4 %, -28.6 % and -47.1 % in a clay sand soil with 10 µL a.s./kg dry soil)

Conclusion :
The study is acceptable.
ALLEGRO caused no short-term and long-term effects on carbon transformation in two different field soils tested up to a concentration of 13.33 µL ALLEGRO/kg dry soil (equivalent to a field application rate of 10 L ALLEGRO/ha).

B.9.8.3 Further laboratory, glasshouse or field testing to investigate impact on soil microbial activity (Annex IIIA 10.7.2)

Not required.

B.9.8.4 Summary of studies on non-target micro-organisms - exposure and risk assessment for non-target micro-organisms

Revised in March 2010:

The effects of kresoxim-methyl metabolites BF 490-1 and BF 490-5 were evaluated at the maximum application rate (150 g kresoxim-methyl/ha in cereals) and at a ten-fold rate. These experiments showed that the effects on the soil respiration and the nitrogen turnover were negligible.

Table B.9.8.4-1 : Effect on non-target soil micro-organisms exposed to kresoxim-methyl metabolites

Soil type	Test system	Exposure period	Results	Reference
kresoxim-methyl metabolite (BF 490-1)				
- sandy loam soil - sandy clay loam soil	Nitrogen turnover 0.2 and 2.0 mg/kg	42 days	Only negligible effects at both doses (not dose-related effects in the 2nd soil)	Reinhard K., 1993a
- sand loam soil - sandy clay loam soil	Soil respiration 0.2 and 2.0 mg/kg	28 days	Only negligible effects at both doses	Reinhard K., 1993b
kresoxim-methyl metabolite (BF 490-5)				
loamy sand soil	Nitrogen turnover 0.042 and 0.42 mg/kg soil	28 days	effects < 25 %	Schulz L., 2008b
loamy sand soil	Soil respiration 0.042 and 0.42 mg/kg soil	28 days	effects < 25 %	Schulz L., 2008a

Table B.9.8.4-2 : Effect on non-target soil micro-organisms exposed to formulations CANDIT, MENTOR and ALLEGRO

Soil type	Test system	Exposure period	Results	Reference
CANDIT				
- clay sand soil - sandy loam soil	Nitrogen turnover 0.4 mg and 4.0 mg/kg soil	28 days	effects < 25 %	Reinhard K., 1993c
- clay sand soil - sandy loam soil	Soil respiration 0.4 mg and 4.0 mg/kg soil	28 days	effects < 25 %	Reinhard K., 1993d
MENTOR				
- 2 sandy loam soils	Nitrogen turnover 0.93 and 9.3 µL/kg dry soil	28 days	Only negligible effects at both doses	Reinhard K., 1994
- 2 sandy loam soils	Soil respiration 0.93 and 9.3 µL/kg dry soil	28 days	Only negligible effects at both doses	Reinhard K., 1993e
ALLEGRO				
- clay sand soil - sandy loam soil	Nitrogen turnover 1.33 and 13.33 µL/kg dry soil	28 days	effects < 25 %	Reinhard K., 1994
- clay sand soil - sandy loam soil	Soil respiration 1.33 and 13.33 µL/kg dry soil	28 days	effects < 25 %	Sedlaczek B., 1994

Risk assessment

The risk assessment for soil micro-organisms is based on the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC.
No effects on nitrogen turnover and soil respiration were observed at the application rate and tenfold the application rate. Therefore, the risk of kresoxim-methyl and the metabolites BF 490-1 and BF 490-5 and the formulations CANDIT and ALLEGRO to soil micro-organisms is acceptable.

B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6; Annex IIIA 10.8)

Added in March 2010:

In the original dossier no specific study on non-target plants was submitted. In the meantime two vegetative vigour studies with the formulated products were performed (Oberwalder C., Schmidt O., 2001 and Dutillie H., Sack D., 2008) and submitted to meet current testing requirements. Due to technical reasons pure active ingredient cannot be tested in foliar spray applications. Hence, the formulated products were used.

BAS 490 02 F: Effects on non-target plants in the greenhouse - A limit test. (Oberwalder C., Schmidt O., 2001).

Guidelines :
OECD 208, EPA 850.4000, EPA 850.4150, EPA 712-C-96-151, EPA 712-C-96-163
GLP :
No
Material and Methods :
Test substance : BAS 490 02 F; formulation containing 515.3 g/kg (nominal 500 g/kg) kresoxim-methyl – formulation CANDIT; batch: 95-3
Test species : 6 terrestrial plant species
monocotyledonous plants : corn (*Zea mays*), oats (*Avena sativa*); onion (*Allium cepa*)
dicotyledonous plants : cabbage (*Brassica oleracea*); pea (*Pisum sativum*); carrot (*Daucus carota*)
Test design : 4 replicates/treatment group; 1 pot/replicate, 3-5 plants per pot (species dependent); greenhouse cultivation; CANDIT was applied post-emergence at growth stage BBCH 12-16 using a laboratory spray cabin at a water rate of 400 L/ha. Following the application the plants were cultivated for 14 days in the greenhouse.
Type of test : vegetative vigour test (limit test, 14 days)
Applied rates : control (untreated); 0.3 and 0.9 kg CANDIT /ha (corresponding to 0.15 and 0.45 g a.s./ha nominal)
Test conditions :
temperature : 20 – 31 °C (day), > 14 °C (night)
humidity : 40 - 60 %
photoperiod : 16/8 hours light/dark cycle
light intensity : additional light when outdoor illumination was less than 4500 lux
Assessments : Assessments for phytotoxicity (e.g. scorch, stunting and deformations) were done approximately 7 DAA and 14 DAA. 14 DAA the fresh weight of the plant biomass above ground was determined.

Findings :

Table B.9.9-1 : Effects of CANDIT on plant fresh weight and plant damage

Treatment	Carrot	Cabbage	Pea	Corn	Oats	Onion
Mean plant weight [% of control] 14 DAA						
Control	100	100	100	100	100	100
0.3 kg/ha	100.8	98.8	107.7	97.4	96.5	111.0
0.9 kg/ha	115.1	97.3	96.6	96.5	93.8	111.9
Mean visible damage [% damage compared to control] 14 DAA						
Control	0.0	0.0	0.0	0.0	0.0	0.0
0.3 kg/ha	0.0	1.3	0.0	0.0	0.0	0.0
0.9 kg/ha	2.5	0.0	0.0	0.0	0.0	0.0

No statistically significant difference compared to the control (Dunnett´s test, p> 0.05)

No visible phytotoxic effects could be observed up to and including a rate of 0.9 kg CANDIT, except for some slight damages in carrot and cabbage (1.3 – 2.5 %), which were within the normal variation of the test system. For all plant species plant weight was at the same level as the weight of the control plants (maximum reduction of 6.2 %, oats, higher rate). No statistically significant differences in both, plant weight and visible damages, were detected (Dunnett´s-test, $\alpha = 0.05$).

Conclusion :
The study is acceptable.
NOER (carrot, cabbage, pea, corn, oats, onion) = 0.9 kg CANDIT/ha (based on plant fresh weight)
ER_{50} (carrot, cabbage, pea, corn, oats, onion) > 0.9 kg CANDIT/ha (based on plant weight)

BAS 494 04 F: Effects on non-target plants in the greenhouse - A multiple dose test. (Dutillie H., Sack D., 2008).

Guidelines :
OECD 227 July 2006
GLP :
No
Material and Methods :
Test substance : BAS 494 04 F; SC formulation containing 125 g/L (nominal) kresoxim-methyl and 125 g/L (nominal) epoxiconazole – formulation ALLEGRO; batch: 6383
Test species : 6 terrestrial plant species
monocotyledonous plants : onion (*Allium cepa*), oats (*Avena sativa*),
dicotyledonous plants : pea (*Pisum sativum*), rapeseed (*Brassica napus*), carrot (*Daucus carota*), sunflower (*Helianthus annuus*)
Test design : 6 replicates/variant (control: 24 replicates/variant); 1 pot/replicate, 1-5 plants per pot (species dependent); ALLEGRO was applied post-emergence at growth stage BBCH 11-14 using a laboratory spray cabin at a water rate of 375 L/ha. Following the application the plants were cultivated for 21 days in the greenhouse.
Type of test : vegetative vigour test (multiple dose test, 21 days)
Applied rates : control (untreated); 0.25, 0.5, 1 and 2 L ALLEGRO/ha (equivalent to 62.5, 125, 250 and 500 g a.s./ha nominal)
Test conditions :
temperature : 31 °C (day), > 14 °C (night)
humidity : approximately 80 %
photoperiod : 16/8 hours light/dark cycle
light intensity : additional light when outdoor illumination was less than 4500 lux
Assessments : Assessments for phytotoxicity were done 7 and 21 days after application (DAA). 21 DAA the fresh weight of the plant biomass above ground was determined.

Findings :

Table B.9.9-2 : Effects of ALLEGRO F on onion, oats, pea, carrot, rapeseed and sunflower under greenhouse conditions

Treatment	Onion	Oats	Pea	Corn	Rapeseed	Sunflower
			Mean plant weight [% of control]			
Control	100	100	100	100	100	100
0.25 L/ha	108	97	111	98	99	99
0.5 L/ha	116	110	103	103	108	106
1 L/ha	101	97	97	108	104	103
2 L/ha	89	92	104	98	100	93*
			Mean visible damage [% damage compared to control]			
Control	0	0	0	0	0	0
0.25 L/ha	0	0	0	0	0	6
0.5 L/ha	0	0	0	0	0	8
1 L/ha	1	0	0	0	0	10
2 L/ha	2	0	0	3	0	16

* Statistically significant difference compared to the control (Bonferroni t-Test, $\alpha = 0.05$)

No visible phytotoxic effects could be observed up to and including a rate of 2 L ALLEGRO/ha, except for some slight damages (16 % at 2 L/ha) in sunflower, which were not statistically significant. Statistically significant reductions of plant weight were only found in sunflower with a maximum reduction of 7 % at the highest test rate of 2 L ALLEGRO/ha.

Conclusion :
The study is acceptable.
ALLEGRO has negligible phytotoxic potential to non-target plants, if applied at a rate of maximum 2 L/ha. The ER_{50} value for all plant species was determined to be > 2 L ALLEGRO/ha.
NOAER (no observed adverse effect rate) = 2.0 L ALLEGRO/ha (500 g a.s./ha) for onion, oats, pea, carrot and rapeseed based on visible damages. For sunflower a NOAER could not be determined.
NOAER = 2.0 L ALLEGRO/ha (500 g a.s./ha) for onion, oats, pea, carrot and rapeseed based on fresh weight
NOAER = 1.0 L ALLEGRO/ha (500 g a.s./ha) for sunflower

First tier risk assessment for non-target terrestrial plants :

The risk assessment for non-target terrestrial plants is based on the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC of October 2002.

1- Formulation CANDIT

The formulation CANDIT (BAS 490 02 F) is a fungicidal product, which contains the active substance kresoxim-methyl with a nominal content of 50 % w/w.

Table B.9.9-3 : Proposed use pattern of the formulation CANDIT

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate (kg a.s./ha) [1)]	Application rate (kg product/ha) [1)]
Pome fruit (apple, pear)	1 - 4	7	53 - 79	0.100 - 0.125	0.200 - 0.250
Grapevine	1 - 3	8	19 - 81	0.100 - 0.150	0.200 - 0.300

[1)] application rate increases with plant growth stage

For simplification reasons, the risk assessment is only conducted for the higher application rates. This covers the increase in application rate during season.

2- Formulation ALLEGRO

The formulation ALLEGRO (BAS 494 04 F) is a fungicidal product, which contains the active substances
- kresoxim-methyl (BAS 490 F) with a nominal content of 125 g a.s./L
- epoxiconazole (BAS 480 F) with a nominal content of 125 g a.s./L

Table B.9.9-4 : Proposed use pattern of the formulation ALLEGRO

Crop	Number of applications	Minimum Interval (days)	Growth stage (BBCH)	Application rate		
				BAS 494 04 F [L/ha]	Kresoxim-methyl (BAS 490 F) [kg a.s./ha]	Epoxiconazole (BAS 480 F) [kg a.s./ha]
Cereals	2	21	25 - 69	1.0	0.125	0.125

Six different terrestrial plant species were tested with the formulation CANDIT: corn, oats, onion, cabbage, pea and carrot.
ER_{50} (carrot, cabbage, pea, corn, oats, onion) > 0.9 kg CANDIT/ha (based on plant weight)
Six different terrestrial plant species were tested with the formulation ALLEGRO: onion, oats, pea, rapeseed, carrot and sunflower.
ER_{50} (onion, oats, pea, rapeseed, carrot and sunflower) > 2 L CANDIT/ha

To calculate the exposure, the % drift values for pomefruit, grapevine and cereals correspond to the 90th percentiles of the Ganzelmeier curves.
The off-field exposure is calculated based on 3 m distance for pome fruit and grapevine. According to ESCORT II (Ganzelmeier *et al.*, 2000), the drift factor for 4 applications in pomefruit (early application) is 0.2361 and for 3 applications in grapevine (late application) is 0.069.
The off-field exposure is calculated based on 1 m distance for cereals. According to ESCORT II (Ganzelmeier *et al.*, 2000), the drift factor for 2 applications is 0.0238.

Table B.9.9-5 : First Tier Toxicity Exposure Ratio's (TER's) for non-target terrestrial plants exposed to the formulations CANDIT and ALLEGRO

Single application rate	**Crop**	**Test species**	**Type of test**	**ER_{50} (formulation)**	**MAF**	**% drift**	**TER**	**Annex VI Trigger value**
250 g CANDIT/ha	pomefruit	carrot, cabbage, pea, corn, oats, onion	Vegetative vigour	> 900 g/ha	2.7	0.2361	5.65	5
300 g CANDIT/ha	grapevine				2.3	0.069	18.9	5
1 L ALLEGRO/ha	cereals	onion, oats, pea, rapeseed, carrot and sunflower	Vegetative vigour	> 2 L/ha	1.7	0.0238	49.4	5

The TER values for the formulations CANDIT and ALLEGRO are all above the trigger, indicating acceptable risk for non-target plants.

B.9.10 Effects on biological methods of sewage treatment (Annex IIA 8.7)

Effect of Reg. No. 242 009 on the oxygen consumption of *Pseudomonas putida*. (Schlosser E., 1993a).
Addendum to report Effect of Reg. No. 242 009 on the oxygen consumption of *Pseudomonas putida*. (Schlosser E., 1993b).

Guidelines :
DIN 38 404 (part 2); DIN 38 412 (part 8) (1986)
GLP :
Yes
Material and Methods :
Test substance: kresoxim-methyl; purity: 93.7 %; batch: N36
Test species : bacteria (*Pseudomonas putida*) Berlin 33/2 (DSM 50026)
Number of replicates : 4 replicates/concentration
Applied concentrations : solvent control; reference substance (potassium dichromate); 50, 100, 250, 500, 1000 mg a.s./L (nominal)
Type of test : short-term respiration test (16 hours)
Test conditions :
Incubation at 20 °C, pH : 7 ± 0.5
Test principle : a sapromat was used to measure the oxygen consumption of the incubated bacterial suspension
Findings :

Table 9.10-1 : Effects of kresoxim-methyl on the oxygen consumption of *Pseudomonas putida*

	Concentrations (mg a.s./L)					
	0	**50**	**100**	**250**	**500**	**1000**
mg O_2 consumption/100 mL bacterial suspension	251	254	244	241	241	251
% inhibition	0	-1	3	4	4	0

No significant dose-related effects were observable, with mean O_2-consumption rates of 240 to 250 mg O_2 per 100 mL suspension. The highest dose level tested, i.e. 1000 mg/L, resulted in an inhibition rate of 0 %.
Endpoints :
EC_{50} (*Pseudomonas putida*, 16 h) > 1000 mg a.s./L (nominal) (highest concentration tested)
EC_{10} (*Pseudomonas putida*, 16 h) > 1000 mg a.s./L (nominal)
NOEC (*Pseudomonas putida*, 16 h) = 1000 mg a.s./L (nominal)
Conclusion :
The study is acceptable.
No inhibition of the bacterial growth at 1000 mg a.s./L.

Effect of Reg. No. 262 451 on the growth of *Pseudomonas putida*. (Schlosser E., 1994a).
Addendum to report Effect of Reg. No. 262 451 on the growth of *Pseudomonas putida*. (Schlosser E., 1994b).

Guidelines :
DIN 38412 (part 8) (1986)
GLP :
Yes
Material and Methods :
Test substance: BF 490-1 (Reg. No. 262 451, kresoxim-methyl metabolite, free acid); purity: 99.3 %; batch: 665-1
Test species : bacteria (*Pseudomonas putida*) Berlin 33/2 (DSM 50026)
Number of replicates : 5 replicates/concentration, 1 mL bacterial inoculum
Applied concentrations : water control; 100, 250, 500, 1000 mg a.s./L (nominal)

Type of test : short-term growth test (17 hours)
Test conditions :
Incubation at 22 °C, constant shaking at 190 rpm, pH : 7.5
Test principle : photometrical measurement of the cell density and comparison of the photometer extinction values (at 436 nm) in the control and treatment samples
Findings :

Table 9.10-2 : Effects of kresoxim-methyl metabolite BF 490-1on the oxygen consumption of *Pseudomonas putida*

	Concentrations (mg a.s./L)				
	0	**100**	**250**	**500**	**1000**
Photometer extinction	1.981	1.953	1.959	1.936	1.940
% growth inhibition	0	1	1	2	2

The highest dose level tested, i.e. 1000 mg/L, resulted in an inhibition rate of 2 %.
Endpoints :
EC_{50} (*Pseudomonas putida*, 17h) > 1000 mg BF 490-1/L (nominal) (highest concentration tested)
EC_{10} (*Pseudomonas putida*, 17h) > 1000 mg BF 490-1/L (nominal)
Conclusion :
The study is acceptable.
No inhibition of the bacterial growth at 1000 mg kresoxim-methyl metabolite BF 490-1/L.

Risk assessment :

Revised in March 2010:

Table 9.10-3 : Effects of kresoxim-methyl on biological methods of sewage treatment

Test species	**Test system**	**Duration of exposure**	**Results (mg/kg water) (nominal concentrations)**	**References**
kresoxim-methyl				
Pseudomonas putida	oxygen consumption test Liquid cultures (50 to 1000 mg a.s./L)	16 hours	EC_{50} > 1000 EC_0 > 1000 NOEC = 1000	Schlosser E., 1993a/1993b
kresoxim-methyl metabolite (BF 490-1)				
Pseudomonas putida	growth test liquid cultures (100 to 1000 mg/L)	17 hours	LC_{50} > 1000 LC_0 > 1000	Schlosser E., 1994a/1994b

Disturbances in the bio-degradation process of activated sludge are not to be expected if the test item is correctly introduced into adapted wastewater treatment plants at low concentrations.

B.9.11 References relied on *[revised in March 2010]*

B.9.11.1 Active substance

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.1.1/1	Munk R.	1993a	Avian single-dose oral LD50 of Reg.No. 242 009 (= test compound No. 91/180) on the bobwhite quail (Colinus virginianus) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/10286 Yes unpublished	N	BASF
II A 8.1.2/1	Munk R.	1993d	Avian dietary LC50 test of Reg.No. 242 009 in chicks of the bobwhite quail (Colinus virginianus) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/11057 Yes unpublished	N	BASF
II A 8.1.3/1	Munk R.	1993i	Avian dietary LC50 test of Reg.No. 242 009 in chicks of the mallard duck (Anas platyrhynchos L.) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/11105 Yes unpublished	N	BASF
II A 8.1.4/1	Munk R.	1994b	1-Generation reproduction study with Reg. No. 242 009 on the bobwhite quail (Colinus virginianus) by administration in the diet BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/10877 Yes unpublished	N	BASF
II A 8.2.1.1/1	Munk R.	1992	Report on the study of the acute toxicity of Reg.Nr. 242 009 on rainbow trout (Oncorhynchus mykiss WALBAUM 1792) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1992/10211 Yes Unpublished	N	BASF
II A 8.2.1.1/2	Munk R.	1993h	Addendum: Acute toxicity on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of Reg.No. 242 009 of January 28, 1992 BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/11444 Yes Unpublished	N	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.2.1.1/3 *[Added in March 2010]*	Graves W.C. et al.	1995a	A 96-hour flow-through acute toxicity test with the rainbow trout (Oncorhynchus mykiss) BASF Corp.; Research Triangle Park NC; United States of America 1995/5167 Yes Unpublished	Y	BASF
II A 8.2.1.2/1	Munk R.	1993c	Acute toxicity study on the bluegill (Lepomis macrochirus RAF.) of Reg.No. 242 009 in a static system (96 hours) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/10483 Yes Unpublished	N	BASF
II A 8.2.1.2/2	Munk R.	1993f	Addendum to the report project No. 14F0180/915079: Acute toxicity on the bluegill (Lepomis macrochirus RAF.) of Reg.No. 242 009 of May 14, 1993 BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/11442 Yes Unpublished	N	BASF
II A 8.2.1.2/3	Munk R.	1993b	Acute toxicity study on the common carp (Cyprinus carpio L.) of Reg.No. 242 009 in a static system (96 hours) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/10457 Yes Unpublished	N	BASF
II A 8.2.1.2/4	Munk R.	1993g	Addendum to the report project No. 11F0180/915083: Acute toxicity on the common carp (Cyprinus carpio L.) of Reg.No. 242 009 of may 12,1993 BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/11443 Yes unpublished	N	BASF
II A 8.2.1.2/5 *[Added in March 2010]*	Graves W.C. et al.	1995b	BAS 490 F: A 96-hour flow-through acute toxicity test with the bluegill (Lepomis macrochirus) BASF Corp.; Research Triangle Park NC; United States of America 1995/5168 Yes unpublished	Y	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.2.1.3/1	Munk R.	1994a	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of Reg.No. 262 451 in a static system (96 hours) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/10621 Yes unpublished	N	BASF
II A 8.2.3/1	Munk R.	1994c	Sublethal toxic effects on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of Reg.No. 242 009 in a flow-through system (28 days) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/10921 Yes unpublished	N	BASF
II A 8.2.4/1 *[Added in March 2010]*	Graves W.C. et al.	1996b	BAS 490 F: An early life-stage toxicity test with the fathead minnow (Pimephales promelas) BASF Corp.; Research Triangle Park NC; United States of America 1996/5155 Yes unpublished	Y	BASF
II A 8.2.6.1/1	Mayo B.C.	1994	14C-BAS 490 F (14C-Reg.No. 242 009): The bioaccumulation and metabolism in rainbow trout Huntingdon Research Centre Ltd.; Huntingdon Cambridgeshire PE18 6ES; United Kingdom 1994/10725 Yes unpublished	N	BASF
II A 8.3.1.1/1	Jatzek H.-J.	1993	Determination of the acute toxicity of Reg 242 009 techn. to the water flea Daphnia magna STRAUS BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/10497 Yes unpublished	N	BASF
II A 8.3.1.1/2 *[Added in March 2010]*	Graves W.C. et al.	1995c	BAS 490 F: A 48-hour flow-through acute toxicity test with the Cladoceran (Daphnia magna) BASF Corp.; Research Triangle Park NC; United States of America 1995/5169 Yes Unpublished	Y	BASF
II A 8.3.1.1/3	Dohmen G.P.	1994b	Effect of BF 490-1 on Daphnia magna STRAUS in an acute toxicity test BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10622 Yes Unpublished	N	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.3.1.1/4 *[Added in March 2010]*	Janson G.-M.	2008	Acute toxicity of Reg.No. 286404 (metabolite of BAS 490 F) to Daphnia magna STRAUS in a 48 hour static test BASF SE; Limburgerhof; Germany Fed.Rep. 2008/1037017 Yes Unpublished	Y	BASF
II A 8.3.2.1/1	Elendt-Schneider B.	1993	Determination of the chronic toxicity of Reg 242 009 techn. to the water flea Daphnia magna STRAUS BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1993/10335 Yes Unpublished	N	BASF
II A 8.3.2.1/2 *[Added in March 2010]*	Graves W.C. et al.	1996a	BAS 490 F: A flow-through life-cycle toxicity test with the Cladoceran (Daphnia magna) BASF Corp.; Research Triangle Park NC; United States of America 1996/5154 Yes Unpublished	Y	BASF
II A 8.3.3/1 *[Added in March 2010]*	Dohmen G.P.	1995	The effects of BAS 490 02 F in an aquatic ecosystem - An outdoor microcosm study BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1995/11150 Yes Unpublished	Y	BASF
II A 8.4/1	Dohmen G.P.	1992a	Effect of Reg.No. 242 009 on the growth of the green alga Ankistrodesmus bibraianus BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1992/11598 Yes Unpublished	N	BASF
II A 8.4/2	Dohmen G.P.	1994a	Effect of BF 490-1 on the growth of the green alga Pseudokirchneriella subcapitata BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10616 Yes Unpublished	N	BASF
II A 8.4/3 *[Added in March 2010]*	Thompson S.G. et al.	1995	BAS 490 F: A Tier II 5-day toxicity test with the freshwater alga (Selenastrum capricornutum) BASF Corp.; Research Triangle Park NC; United States of America 1995/5051 Yes Unpublished	Y	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIA 8.4 IIA 8.6	Hughes J.S., Jackson S.H.	1994	Tier 1 non-target aquatic plant toxicity study on BAS 490 F (242 009) Apden Laboratories Inc., Jacksonville, FL; USA BASF Reg. Doc. 1994/5003 Yes unpublished	N	BASF
II A 8.7.1/1 *[Added in March 2010]*	Schmitzer S., Sekine T.	2008	Effects of BAS 490 F (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2008/1010702 Yes unpublished	Y	BASF
II A 8.7.2/1 *[Added in March 2010]*	Schmitzer S., Sekine T.	2008	Effects of BAS 490 F (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2008/1010702 Yes unpublished	Y	BASF
IIA 8.8	Schlosser E.	1993a	Effect of BAS 490 04 F on the mortality of the ground beetle *Poecilus cupreus* BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. 1993/11439 Yes unpublished	N	BASF
IIA 8.8	Kühner Ch.	1994a	Laboratory determination of the side effects of BAS 490 02 F on *Trichogramma cacoeciae Marchal* (*Hym. Trichogrammatidae*) as a representative of the Microhymenoptera, test on Imagines GAB & IFU GmbH, Niefern - Öschelbronn, Germany BASF Reg. Doc. 1994/10593 Addendum Yes unpublished	N	BASF
IIA 8.8	Kleiner R.	1993a	Testing toxicity to beneficial arthropods ladybird - *Coccinella septempunctata L.*/adults; BAS 490 02 F Biochem GmbH, Karlsruhe, Germany BASF Reg. Doc. 1993/10683 Yes unpublished	N	BASF
IIA 8.8	Kleiner R	1993a	Testing toxicity to beneficial arthropods ladybird - *Coccinella septempunctata* L./adults Biochem GmbH, Karlsruhe, Germany BASF Reg. Doc. 1993/10959 Addendum Yes unpublished	N	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIA 8.8	Kühner Ch.	1993	Study of the side effects of BAS 490 02 F on the predatory mite *Typhlodromus pyri* Scheuten (Acari, Phytoseidae) in the laboratory GAB & IFU GmbH, Niefern-Öschelbronn, Germany BASF Reg. Doc. 1993/11615 Yes unpublished	N	BASF
IIA 8.8	Kühner Ch.	1994a	Laboratory determination of the side effects of BAS 490 02 F on *Trichogramma cacoeciae* Marchal (*Hym. Trichogrammatidae)* as a representative of the Microhymenoptera, test on Imagines GAB & IFU GmbH, Niefern - Öschelbronn, Germany BASF Reg. Doc. 1994/11122 Yes unpublished	N	BASF
II A 8.8.1.1/1 *[Added in March 2010]*	Fussell S.	2003	A rate-response laboratory test to determine the effects of BAS 490 02 F on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae) Mambo-Tox Ltd.; Southampton SO16 7PX; United Kingdom 2003/1004505 Yes unpublished	N	BASF
II A 8.8.1.1/2 *[Added in March 2010]*	Moll M.	2004	Effects of BAS 494 04 F on the parasitoid Aphidius rhopalosiphi in the laboratory - Dose response test Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2004/1025719 Yes unpublished	N	BASF
II A 8.8.1.2/1 *[Added in March 2010]*	Rosenkranz B.	2004a	Effects of BAS 490 02 F on the predatory mite Typhlodromus pyri in the laboratory - Dose response test Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2004/1025725 Yes unpublished	N	BASF
II A 8.8.1.2/2 *[Added in March 2010]*	Rosenkranz B.	2004b	Effects of BAS 494 04 F on the predatory mite Typhlodromus pyri in the laboratory - Dose response test Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2004/1027234 Yes unpublished	N	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.9.1/1	Dohmen G.P.	1992b	Effect of Reg.No. 242 009 on the mortality of the earthworm Eisenia foetida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1992/11722 Yes unpublished	N	BASF
II A 8.9.1/2	Dohmen G.P.	1994c	Effect of BF 490-1 on the mortality of the earthworm Eisenia foetida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10811 Yes unpublished	N	BASF
II A 8.9.1/3 *[Added in March 2010]*	Luehrs U.	2008	Acute toxicity (14 days) of Reg.No. 286404 (metabolite of BAS 490 F, BF 490-5) to the earthworm Eisenia fetida in artificial soil with 5 % peat Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2008/1010608 Yes unpublished	Y	BASF
IIA 8.10	Reinhard K.	1993a	Effect of BAS 490 02 F on soil respiration BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. 1993/11471 Yes unpublished	N	BASF
IIA 8.10.1	Reinhard K.	1993c	Effect of BAS 490 02 F on the nitrogen turnover in the soil BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. 1993/11452 Yes unpublished	N	BASF
II A 8.10.1/1	Reinhard K.	1993a	Effect of Reg.No. 262 451 on the nitrogen turnover in the soil BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/10899 Yes unpublished	N	BASF
II A 8.10.1/2 *[Added in March 2010]*	Schulz L.	2008b	Effects of Reg. No. 286404 (metabolite of BAS 490 F, BF 490-5) on the activity of soil microflora (nitrogen transformation test) BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany Fed.Rep. 2008/1010665 Yes unpublished	Y	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.10.2/1	Reinhard K.	1993b	Effect of Reg.No. 262 451 on soil respiration BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/10900 Yes unpublished	N	BASF
II A 8.10.2/2 *[Added in March 2010]*	Schulz L.	2008a	Effects of Reg. No. 286404 (metabolite of BAS 490 F, BF 490-5) on the activity of soil microflora (carbon transformation test) BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany Fed.Rep. 2008/1010664 Yes unpublished	Y	BASF
II A 8.12/1 *[Added in March 2010]*	Oberwalder C., Schmidt O.	2001	BAS 490 02 F: Effects on non-target plants in the greenhouse - A limit test BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 2001/1014599 No unpublished	N	BASF
II A 8.12/2 *[Added in March 2010]*	Dutillie H., Sack D.	2008	BAS 494 04 F: Effects on non-target plants in the greenhouse - A multiple dose test BASF SE; Limburgerhof; Germany Fed.Rep. 2008/1018059 No, not subject to GLP regulations unpublished	Y	BASF
II A 8.15/1	Schlosser E.	1993a	Effect of Reg.No. 242 009 on the oxygen consumption of Pseudomonas putida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/10877 Yes unpublished	N	BASF
II A 8.15/2	Schlosser E.	1993b	Addendum No. 1: Effect of Reg.No. 242 009 on the oxygen consumption of Pseudomonas putida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/11303 Yes unpublished	N	BASF
II A 8.15/3	Schlosser E.	1994a	Effect of Reg.No. 262 451 on the growth of Pseudomonas putida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10126 Yes unpublished	N	BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.15/4	Schlosser E.	1994b	Addendum No. 1: Effect of Reg.No. 262 451 on the growth of Pseudomonas putida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10211 Yes unpublished	N	BASF

B.9.11.2 Plant protection products ALLEGRO (BAS 494 02 F) and BAS 494 04 F

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 10.2.2.1/1 *[Added in March 2010]*	Munk R.	1994	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of BAS 494 02 F in a static system (96 hours) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/11213 Yes unpublished		BASF
III A 10.2.2.2/1 *[Added in March 2010]*	Dohmen G.P.	1995a	Effect of BAS 494 02 F on Daphnia magna STRAUS in an acute toxicity test BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1995/10269 Yes unpublished		BASF
III A 10.2.2.3/1 *[Added in March 2010]*	Dohmen G.P.	1995c	Effect of BAS 494 02 F on the growth of the green alga Pseudokirchneriella subcapitata BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1995/10291 Yes unpublished		BASF
III A 10.2.5.1/1 *[Added in March 2010]*	Munk R.	1995	Sublethal toxic effects on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of BAS 494 02 F in a flow-through (28 days) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1995/10267 Yes unpublished		BASF
III A 10.2.6.1/1 *[Added in March 2010]*	Jatzek J.	1995	Determination of the chronic toxicity of BAS 494 02 F to the water flea Daphnia magna STRAUS BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1995/10234 Yes unpublished		BASF
III A 10.4.2.1/1 *[Added in March 2010]*	Bocksch S.	2004	Assessment of side effects of BAS 494 04 F to the honey bee, Apis mellifera L. in the laboratory GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2004/1025724 Yes unpublished		BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 10.4.2.2/1 *[Added in March 2010]*	Bocksch S.	2004	Assessment of side effects of BAS 494 04 F to the honey bee, Apis mellifera L. in the laboratory GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2004/1025724 Yes unpublished		BASF
III A 10.6.2/1 *[Added in March 2010]*	Dohmen G.P.	1995b	Effect of BAS 494 02 F on the mortality of the earthworm Eisenia foetida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1995/10284 Yes unpublished		BASF
III A 10.6.3/1 *[Added in March 2010]*	Luehrs U.	2004	Effects of BAS 494 04 F on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat Institut fuer Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. 2004/1027253 Yes unpublished		BASF
III A 10.7.1/1 *[Added in March 2010]*	Reinhard K.	1994	Effect of BAS 494 02 F on the nitrogen turnover in the soil BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10526 Yes unpublished		BASF
III A 10.7.1/2 *[Added in March 2010]*	Sedlaczek B.	1994	Effect of BAS 494 02 F on soil respiration BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10527 Yes unpublished		BASF

B.9.11.2 Plant protection product CANDIT (BAS 490 02 F)

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 10.2.2.1/1 *[Added in March 2010]*	Munk R.	1994a	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of BAS 490 02 F in a static system (96 hours) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/10532 Yes Unpublished		BASF
III A 10.2.2.1/2 *[Added in March 2010]*	Munk R.	1994b	Acute toxicity study on the common carp (Cyprinus carpio L.) of BAS 490 02 F in a static system (96 hours) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/10620 Yes Unpublished		BASF
III A 10.2.2.2/1 *[Added in March 2010]*	Dohmen G.P.	1994b	Effect of BAS 490 02 F on Daphnia magna STRAUS in an acute toxicity test BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10479 Yes Unpublished		BASF
III A 10.2.2.3/1 *[Added in March 2010]*	Dohmen G.P.	1994a	Effect of BAS 490 02 F on the growth of the green alga Pseudokirchneriella subcapitata BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10472 Yes unpublished		BASF
III A 10.2.3/1	Dohmen G.P.	1995	The effects of BAS 490 02 F in an aquatic ecosystem - An outdoor microcosm study BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1995/11150 Yes unpublished		BASF
III A 10.2.5.1/1 *[Added in March 2010]*	Munk R.	1994c	Sublethal toxic effects on the rainbow trout (Oncorhynchus mykiss WALBAUM 1792) of BAS 490 02 F in a flow-through system (28 days) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. 1994/11123 Yes unpublished		BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 10.2.6.1/1 *[Added in March 2010]*	Dohmen G.P.	1994c	Effect of BAS 490 02 F on the reproduction of Daphnia magna STRAUS in a chronic toxicity test BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1994/10604 Yes unpublished		BASF
III A 10.4.2.1/1 *[Added in March 2010]*	Bocksch S.	2004	Assessment of side effects of BAS 490 02 F to the honey bee, Apis mellifera L. in the laboratory GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2004/1025691 Yes unpublished		BASF
III A 10.4.2.2/1 *[Added in March 2010]*	Bocksch S.	2004	Assessment of side effects of BAS 490 02 F to the honey bee, Apis mellifera L. in the laboratory GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2004/1025691 Yes unpublished		BASF
III A 10.4.4/1 *[Added in March 2010]*	Barth M.	2008a	Effects of BAS 490 02 F on the honeybee Apis mellifera L. under semi-field conditions (tunnel tent test) BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany Fed.Rep. 2007/1023041 Yes unpublished		BASF
III A 10.5.1/1 *[Added in March 2010]*	Staebler P.	2003	BAS 490 02 F: Toxicity to the ground beetle, Poecilus cupreus L. (Coleoptera, Carabidae) in the laboratory GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2003/1006405 Yes unpublished		BASF
IIIA 10.5.2	Kleiner R.	1993a	Testing toxicity to beneficial arthropods; ladybird - *Coccinella septempunctata* L./adults; BAS 490 02 F Biochem GmbH, Karlsruhe, Germany BASF Reg. Doc. 1993/10683 Yes unpublished		BASF

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IIIA 10.5.2	Kleiner R.	1993b	Testing toxicity to beneficial arthropods ladybird - *Coccinella septempunctata* L./adults Biochem GmbH, Karlsruhe, Germany BASF Reg. Doc. 1993/10959 Addendum Yes unpublished		BASF
IIIA 10.5.3	Kleiner R.	1993c	Testing toxicity to beneficial arthropods; ladybird - *Coccinella septempunctata* L./Semi-field; BAS 490 02 F Biochem GmbH, Karlsruhe, Germany BASF Reg. Doc. 1993/11396 Yes unpublished		BASF
IIIA 10.5.3	Kleiner R.	1993c	Testing toxicity to beneficial arthropods; ladybird - *Coccinella septempunctata* L./Semi-field; BAS 490 02 F Biochem GmbH, Karlsruhe, Germany BASF Reg. Doc. 1994/10123 Addendum Yes unpublished		BASF
IIIA 10.5	Kühner Ch.	1993	Study of the side effects of BAS 490 02 F on the predatory mite *Typhlodromus pyri* Scheuten (Acari, Phytoseidae) in the laboratory GAB & IFU GmbH, Niefern-Öschelbronn, Germany BASF Reg. Doc. #93/11615 Yes unpublished		BASF
IIIA 10.5	Kühner Ch.	1994a	Laboratory determination of the side effects of BAS 490 02 F on *Trichogramma cacoeciae* Marchal (Hym. Trichogrammatidae) as a representative of the Microhymenoptera, test on Imagines GAB & IFU GmbH, Niefern - Öschelbronn, Germany BASF Reg. Doc. 1994/11122 Yes unpublished		BASF
IIIA 10.5	Kühner Ch.	1994a	Laboratory determination of the side effects of BAS 480 02 F on *Trichogramma cacoeciae* Marchal (Hym. Trichogrammatidae) as a representative of the Microhymenoptera, test on Imagines GAB & IFU GmbH, Niefern, - Öschelbronn, Germany BASF Reg. Doc. 1994/10593 Addendum Yes unpublished		BASF

OECD data point(s)	Author(s)	Date Year / Month / Day	Title Source BASF DocID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
IIIA 10.5	Schlosser E	1993a	Effect of BAS 490 04 F on the mortality of the ground beetle *Poecilus cupreus* BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. 1993/11439 Yes unpublished		BASF
IIIA 10.5	Ufer A.	1994b	Mortality of different life stages of the predatory mite *Typhlodromus pyri* Scheuten (Phytoseidae) after a treatment with BAS 490 02 F BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. 1994/11069 No unpublished		BASF
IIIA 10.5	Ufer A.	1996b	Laboratory contact toxicity test with the predator, *Orius insidiosus* (Heteroptera: Anthocoridae), based on the IOBC approved method of Stäubli and Pasquier (1988) BASF Aktiengesellschaft, Limburgerhof, Germany BASF Reg. Doc. 1996/10897 Yes unpublished		BASF
III A 10.5.2/1 *[Added in March 2010]*	Vaughan R.	2007	A rate-response extended laboratory test to determine the effects of BAS 490 02 F on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae) Mambo-Tox Ltd.; Southampton SO16 7NP; United Kingdom 2007/1017503 Yes unpublished		BASF
III A 10.5.2/2 *[Added in March 2010]*	Noe J.	2007	Effects of BAS 490 02 F on the parasitic wasp Aphidius rhopalosiphi (DeStephanie-Perez) (Hymenoptera: Braconidae) in an extended laboratory trial - Dose response design BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 2007/1018742 Yes unpublished		BASF
III A 10.5.2/3 *[Added in March 2010]*	Hirth N.	2001	An extended laboratory study to evaluate the effects of BAS 490 02 F on the ladybird beetle, Coccinella septempunctata L. (Coleoptera, Coccinellidae) GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2001/1015076 Yes unpublished		BASF

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III A 10.5.2/4 *[Added in March 2010]*	Warmers C.	2003	An extended laboratory study with freshly applied and aged residues to evaluate the effects of BAS 490 02 F on the ladybird beetle, Coccinella septempunctata L. (Coleoptera, Coccinellidae) - Aged residue trial GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2003/1006409 Yes unpublished		BASF
III A 10.5.4/1 *[Added in March 2010]*	Lehmhus J.	2008a	A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Southern France - 4 applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2007/1017533 Yes unpublished		BASF
III A 10.5.4/2 *[Added in March 2010]*	Lehmhus J.	2007	A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Germany - 4 early applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2007/1017531 Yes unpublished		BASF
III A 10.5.4/3 *[Added in March 2010]*	Lehmhus J.	2008d	A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Germany - 4 late applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2007/1017532 Yes unpublished		BASF
III A 10.5.4/4 *[Added in March 2010]*	Lehmhus J.	2008e	A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in an apple orchard in Germany - 4 late applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2008/1020041 Yes unpublished		BASF
III A 10.5.4/5 *[Added in March 2010]*	Lehmhus J.	2008b	A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in a vineyard in Germany - 3 applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2007/1017534 Yes unpublished		BASF

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III A 10.5.4/6 *[Added in March 2010]*	Lehmhus J.	2008c	A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in a vineyard in Southern France - 3 early applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2007/1017535 Yes unpublished		BASF
III A 10.5.4/7 *[Added in March 2010]*	Lehmhus J.	2008f	Report amendment No. 1 to study 20071146/F2-NFTp: A field study to evaluate the effects of BAS 490 02 F on predatory mites (Acari: Phytoseiidae) in a vineyard in France - 3 early applications Eurofins-GAB GmbH; Niefern-Oeschelbronn; Germany Fed.Rep. 2008/1034511 Yes unpublished		BASF
IIIA 10.5.4	Ipach R.	1994	Field study of the effects of BAS 490 02 F on predacious mites (*Typhlodromus pyri*) on grape vines with two pre-bloom and four post-bloom applications Staatliche Lehr- und Forschungsanstalt, Neustadt/W., Germany BASF Reg. Doc. 1994/11121		BASF
IIIA 10.5.4	Ipach R.	1994	Field study of the effects of BAS 490 02 F on predaceous mites (*Typhlodromus pyri*) on grape vines with two pre-bloom and four post-bloom applications Staatliche Lehr- und Forschungsanstalt, Neustadt/W., Germany BASF Reg. Doc. 1994/10933 addendum		BASF
IIIA 10.5.4	Kühner Ch.	1994b	Assessment of side effects of BAS 490 02 F on the Predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseidae) in an apple orchard GAB Biotechnologie GmbH Niefern-Öschelbronn, Germany BASF Reg. Doc. 1994/11013		BASF
IIIA 10.5.4	Lipps H.P.	1994	Study of the effects of BAS 490 02 F on predaceous mites (*Typhlodromus pyri*) on grape vines with two pre-bloom and four post-bloom applications Staatliche Lehr- und Forschungsanstalt, Neustadt/W., Germany BASF Reg. Doc. 1994/11120		BASF

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IIIA 10.5.4	Lipps H.P.	1994	Field study of the effects of BAS 490 02 F on predaceous mites (*Typhlodromus pyri*) on grape vines with two pre-bloom and four post-bloom applications Staatliche Lehr- und Forschungsanstalt, Neustadt/W., Germany BASF Reg. Doc. #94/10934 Addendum		BASF
IIIA 10.5.4	Research Station of Gorsem	1995	Biological evaluation of BAS 49002F (WG - 50% kresoxim-methyl) on apple and pear - Trials 1992-1993-1994. BASF Reg. Doc. 1995/10838		BASF
IIIA 10.5.4	Research Station of Gorsem	1996	Evaluation by field test of the side effects of CANDIT 50 WG on predatory bugs, Anthocoridae BASF Reg. Doc. 1995/10838		BASF
IIIA 10.5.4	Rohner R.	1994	Field study on the side effects of BAS 490 02 F on predatory mites (*Typhlodromus pyri*) RCC Umweltchemie GmbH, Rossdorf, Germany BASF Reg. Doc. 1994/10965		BASF
III A 10.6.2/1 *[Added in March 2010]*	Dohmen G.P.	1993	Effect of BAS 490 02 F on the mortality of the earthworm Eisenia foetida BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/11555 Yes unpublished		BASF
III A 10.7.1/1	Reinhard K.	1993d	Effect of BAS 490 02 F on soil respiration BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/11471 Yes unpublished		BASF
III A 10.7.1/2	Reinhard K.	1993c	Effect of BAS 490 02 F on the nitrogen turnover in the soil BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. 1993/11452 Yes unpublished		BASF