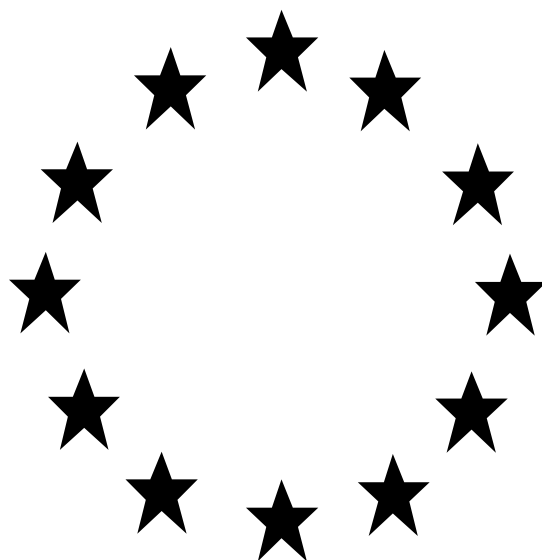




Draft Assessment Report (DAR)

- public version -

**Initial risk assessment provided by the rapporteur Member State
The Netherlands for the existing active substance**

PYRIDABEN

**of the third stage (part B) of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

Volume 3, Annex B, part 6, Appendices

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APPENDIX 1

PYRIDABEN

PART 1: Standard terms and abbreviations

PART 2: Organisations and publications

PART 3: Preparation (formulation) types and codes

Part 1 Standard terms and abbreviations

A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD ₅₀	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulfophthalein
Bt	bacillus thuringiensis
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi- ($\times 10^{-2}$)
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand

CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRES	dietary risk evaluation system
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC ₅₀	median effective concentration
ECD	electron capture detector
ECU	European currency unit
ED ₅₀	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F ₀	parental generation
F ₁	filial generation, first
F ₂	filial generation, second
FIA	fluorescence immunoassay
FID	flame ionisation detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography

GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high-energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H _s	Shannon-Weaver index
Ht	haematocrit
I	indoor
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilisation concentration or median inhibitory concentration
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	in vitro fertilisation
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole, see also H)
K _{ads}	adsorption constant
K _{des}	apparent desorption coefficient
K _{oc}	organic carbon adsorption coefficient
K _{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography

LC-MS	liquid chromatography- mass spectrometry
LC ₅₀	lethal concentration, median
LCA	life cycle analysis
LC _{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LD _{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration) or number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorous pesticide
Pa	Pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _S	predicted environmental concentration in soil
PEC _{SW}	predicted environmental concentration in surface water
PEC _{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P _{OW}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion (10 ⁻⁹)
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
ppq	parts per quadrillion (10 ⁻²⁴)
ppt	parts per trillion (10 ⁻¹²)
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r ²	coefficient of determination
RBC	red blood cell
REI	restricted entry interval

Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL ₅₀	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short-term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
t _½	half-life (define method of estimation)
T ₃	tri-iodothyroxine
T ₄	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC _{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD _{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	toxicity exposure ration
TER _i	toxicity exposure ration for initial exposure
TER _{ST}	toxicity exposure ration following repeated exposure
TER _{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
T _{lm}	median tolerance limit
TLV	threshold limit value

TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
=	less than or equal to
>	greater than
=	greater than or equal to

Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupeement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network

HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organisation for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Programme (USA)
OECD	Organisation for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unités
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

Part 3: Preparation (formulation) types and codes

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block blits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic)spraying
EO	Emulsion. water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion. Oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 μ m.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or seed treatment after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.

Code	Description	Definition
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 µm.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glasshouses.
GR	Hot fogging concentrate	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Cold fogging concentrate	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle size range from 100 to 600 µm.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension (= flowable concentrate)	A stable suspension of active substance(s) in a fluid intended for dilution with water before use
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but many contain insoluble inert ingredients.

Code	Description	Definition
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of active substance after dissolution in water but many contain insoluble inert ingredients.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small flat plates for dissolution in water.
TP	tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

APPENDIX 2

PYRIDABEN

SPECIFIC TERMS AND ABBREVIATIONS

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Specific terms and abbreviations

a	absolute organ weight
AAP	Algal Assay Procedure medium
aerob	aerobic test conditions
a-GT	alpha-glutamyl-transferase
ALAT	alanine aminotransferase
ALP	alkaline phosphatase
amu	atomic mass units
anaer	anaerobic test conditions
AR	applied radioactivity
ASAT	aspartate aminotransferase
ASTM	American Society for Testing and Materials
B	bacteria
biodeg	biodegradation
Chr. ab.	chromosome aberrations
CMC	carboxymethylcellulose
CoE	Council of Europe
crit.	criterion
d	decreased, but not statistically significantly
dc	statistically significantly decreased
DFI	Daily Food Intake
DMF	dimethylformamide
DO	Dissolved Oxygen
dr	dose-related
DWI	Daily Water Intake
E	total effect of mortality and fecundity/parasitic capacity, used in arthropod toxicity tests
E. coli	<i>Escherichia coli</i>
equal	used when the values given by the notifier are expressed in mg/kg bw/day.
equivalent	used when values given by the notifier are only expressed in mg/kg food, not in mg/kg bw/day, as species-dependent factor is used to translate these data to mg/kg bw/day.
ETE	Estimated Theoretical Exposure
GCP	good clinical practice
GIDH	glutamic-acid dehydrogenase

GOT	glutamic-oxalacetic transaminase
GPT	glutamic-pyruvic transaminase
HDL	high density lipoproteins
HPRT	hypoxanthine- guanine phosphoribosyl transferase
i	increased, but not statistically significantly
ic	statistically significantly increased
MC	moisture content in soil (v/v)
Mc	mammalian cells
MWHC	maximum water holding capacity (soils)
n/a	not applicable
n.d.	not detected
n.r.	not reported
ns	not significant
o.m.	organic matter
PEC	Predicted Environmental Concentration
PEG	polyethylene glycol
pF	moisture tension (soil) in [log cm _{water column}]
PIEC	Predicted Initial Environmental Concentration
pointmut.	pointmutations
r	relative organ weight
r.a.	radioactivity
res.	result
Ri	Reliability Index, referring to the intrinsic reliability of a test with respect to the quality of the study
S. typh.	<i>Salmonella typhimurium</i>
SPE	Solid Phase Extraction
Sub.	Substance
T	temperature
TWA	time weighted average
TWAE	time weighted average environmental concentration

wat/sed	water/sediment systeem
w/w	weight per weight
-	negative
+	positive
-act.	without activation
+act.	with activation
%v/v	the percentage expressed by volume
%w/w	the percentage expressed by weight

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APPENDIX 3

PYRIDABEN

EXPOSURE MODEL CALCULATIONS

AND

RISK ASSESSMENT

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APPENDIX 3: Exposure model calculations and risk assessment

1. Basic application information

Product information

Product:	Nexter Pro (Pyridaben 75 WP in WSB)
Purpose:	Insecticide
Active substance (a.s.):	Pyridaben 750 g a.s./kg
Product type:	Wettable Powder (WP) in water-soluble bags
Package size:	0.2 kg cold water soluble bag (PVA)

1.1 OPERATOR EXPOSURE

Mechanical upward spraying on citrus

Application technique	:	Tractor-mounted air assisted broadcast Sprayer, high crop
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Input data:

Concentration a.s. in formulation	:	750 g a.s. /kg
Spray volume	:	1500 l/ha
Concentration in spray liquid	:	0.2 g a.s. /l
Application rate	:	0.3 kg a.s./ha (0.4 kg product/ha)

Manual up- and downward spraying on tomato

Application technique	:	Backpack and knapsack sprayer, manual application indoors
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Input data:

Concentration a.s. in formulation	:	750 g a.s. /kg
Spray volume	:	–1000-1250 l/ha
Concentration in spray liquid	:	0.2-0.25 g a.s. /l
Application rate	:	0.25 kg a.s./ha (0.33 kg product/ha)
PPE NL	:	overall reduction factor 0.1

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

1.2 BYSTANDER EXPOSURE

Mechanical upward spraying on citrus outdoors

Input data

Application rate	:	0.3 kg a.s. /ha
Spray volume	:	1500 l/ha
Dermal exposure	:	5% of the application rate (kg/ha) on an body surface of 2 m ² and dermal absorption of 1.2%
Inhalation exposure	:	0.06 mL spraying liquid per m ³ , a duration of 1 hour, a ventilation rate of 1.25 m ³ /hour, and inhalation absorption of 100%.

Manual up- and downward spraying on tomato indoors

The presence of bystanders should be prohibited.

1.3 WORKER EXPOSURE

Exposure calculations for re-entry activities in cultivation of citrus

Input data

Application rate	:	0.3 kg a.s./ha
Duration of activities	:	6 hours (3 h cutting, 3 h sorting/bundling)
Dermal exposure (transfer coefficient)	:	0.45 m ² /hour
PPE	:	reduction factor 0.1 (EUROPOEM model)

Exposure calculations for re-entry activities in cultivation of tomato

Input data

Application rate	:	0.25 kg a.s./ha
Duration of activities	:	6 hours (3 h cutting, 3 h sorting/bundling)
Dermal exposure (transfer coefficient)	:	0.25 m ² /hour
PPE	:	reduction factor 0.1 (EUROPOEM model)

1.4 RISK ASSESSMENT

Input data

Dermal absorption	:	0.4% for mixing and loading 1.2% for spraying
Inhalation absorption	:	100 %
(Semi-)chronic systemic AOEL	:	0.002 mg/kg bw/day

2. Operator Exposure

For the present purpose the original UK-POEM, DE (GM) and Dutch spreadsheets are used. The models differ from each other. The DE (GM) spreadsheet calculates with different reduction factors for PPE while the UK sheet only calculates with gloves as reduction factor. The NL sheet does not include PPE and default values are used. For NL it is assumed that the adequate use of personal protective equipment will reduce both dermal and inhalation exposure with a factor 10.

2.1 External exposure estimates with the UK model

The model is largely based on unpublished studies, carried out in the UK by industry and MAFF. 75th percentiles are calculated.

For wettable powders packaged in water soluble bags complete protection might be assumed during mixing and loading. Only an exposure estimate for application on citrus is made, since no data are available for manual up-and downward spraying indoors.

According to the notifier, the default volume of surface contamination of 400 ml/hour overestimates the potential surface contamination of operators of vehicles without cabs with a factor 10. Therefore, the notifier used a value of 40 ml/h for surface contamination. The notifier refers to an evaluation made by HSE on chlorpyrifos, for this refinement. However, no further data are available to support this assumption. Therefore, in the present calculation the default value of 400 ml/h is used.

Mechanical upward spraying on citrus, without PPE**THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)**

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	Nexter Pro	Active substance	pyridaben
Formulation type	WB (water-soluble bags)	a.s. concentration	750 mg/g
Dermal absorption from product	0.4 %	Dermal absorption from spray	1.2 %
PPE during mix/loading	None	PPE during application	None
Dose	0.4 kg product/ha	Work rate/day	15 ha
Application volume	1500 l/ha	Duration of spraying	6 h

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	0 mg/kg a.s.
Hand contamination/day	0 mg/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to a.s.	0 mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0 mg/kg a.s.
Inhalation exposure/day	0 mg/day
RPE	None
Transmission through RPE	100 %
Inhalation exposure to a.s.	0 mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Application volume	1500 spray/ha		
Volume of surface contamination	400 ml/h		
Distribution	Hands	Trunk	Legs
	10%	65%	25%
Clothing	None	Permeable	Permeable
Penetration	100%	2%	5%
Dermal exposure	10	5.2	5 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	121.2 ml/day		
Concentration of a.s. in spray solut	0.2 mg/ml		
Dermal exposure to a.s.	24.24 mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure to spray	0.05 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	0.2 mg/ml
Inhalation exposure to a.s.	0.06 mg/day
Percent absorbed	100 %
Absorbed dose	0.06 mg/day

ABSORBED DOSE

	Mix/load	Application
Dermal exposure to a.s.	0 mg/day	24.24 mg/day
Percent absorbed	0.4 %	1.2 %
Absorbed dose (dermal route)	0 mg/day	0.29088 mg/day
Inhalation exposure to a.s.	0 mg/day	0.06 mg/day
Absorbed dose	0 mg/day	0.35088 mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.35088 mg/day
Operator body weight	60 kg
Operator exposure	0.005848 mg/kg bw/day

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Mechanical upward spraying on citrus, with PPE**THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)**

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	Nexter Pro	Active substance	pyridaben
Formulation type	WB (water-soluble bags)	a.s. concentration	750 mg/g
Dermal absorption from product	0.4 %	Dermal absorption from spray	1.2 %
PPE during mix/loading	Gloves	PPE during application	Gloves
Dose	0.4 kg product/ha	Work rate/day	15 ha
Application volume	1500 l/ha	Duration of spraying	6 h

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	0 mg/kg a.s.
Hand contamination/day	0 mg/day
Protective clothing	Gloves
Transmission to skin	1 %
Dermal exposure to a.s.	0 mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0 mg/kg a.s.
Inhalation exposure/day	0 mg/day
RPE	None
Transmission through RPE	100 %
Inhalation exposure to a.s.	0 mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Application volume	1500 spray/ha		
Volume of surface contamination	400 ml/h		
Distribution	Hands	Trunk	Legs
	10%	63%	25%
Clothing	Gloves	Permeable	Permeable
Penetration	10%	2%	5%
Dermal exposure	4	5.2	5 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	85.2 ml/day		
Concentration of a.s. in spray solut	0.2 mg/ml		
Dermal exposure to a.s.	17.04 mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure to spray	0.05 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	0.2 mg/ml
Inhalation exposure to a.s.	0.06 mg/day
Percent absorbed	100 %
Absorbed dose	0.06 mg/day

ABSORBED DOSE

	Mix/load	Application
Dermal exposure to a.s.	0 mg/day	17.04 mg/day
Percent absorbed	0.4 %	1.2 %
Absorbed dose (dermal route)	0 mg/day	0.20448 mg/day
Inhalation exposure to a.s.	0 mg/day	0.06 mg/day
Absorbed dose	0 mg/day	0.26448 mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.26448 mg/day
Operator body weight	60 kg
Operator exposure	0.004408 mg/kg bw/day

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2.2 External exposure estimates with the German model

The German model is based on unpublished studies performed by industry and all carried out in Germany. For mixing/loading the nature of the formulation is an important variable. The format of exposure is mg/kg and the chosen statistic is the geometric mean (GM).

Within the German model no specific exposure values for mixing and loading are available for products packaged in water soluble bags. Taking the data for wettable powders would overestimate the exposure during mixing and loading. Therefore, exposure estimates for mixing and loading were based on exposure data for water dispersible granules, to represent a reasonable worst-case.

Only an exposure estimate for application on citrus is made, since no data are available for manual up-and downward spraying indoors.

Mechanical upward spraying on citrus, with and without PPE**= HIGH CROP TRACTOR MOUNTED =**

Treated area per day		A =	8	ha/d	at BBA = 8
Use rate		R =	0.3	kg a.i./ha	
Mixing/loading of the product [mg/person per kg a.i.]				Appl. of the spray [mg/pers. per kg a.i.]	
	liquid	solid: WP	solid: WG	I*a = 0,018	D*a/c = 1,2
I*m	0.0006	0.07	0.008	D*a/h = 0,7	D*a/b = 9,6
D*m/h	2.4	6	2		

Estimated inhalation exposure:

Im = I*m x R x A	0.008	0.3	8	0.0192 mg/pers. x d
Ia = I*a x R x A	0.018	0.3	8	0.0432 mg/pers. x d
I, in total =				0.0624 mg/pers. x d

Estimated dermal exposure:

Dm/h = D*m/h x R x A	2	0.3	8	4.8 mg/pers. x d
Da/h = D*a/h x R x A	0.7	0.3	8	1.68 mg/pers. x d
Da/c = D*a/c x R x A	1.2	0.3	8	2.88 mg/pers. x d
Da/b = D*a/b x R x A	9.6	0.3	8	23.04 mg/pers. x d
D, in total =				32.4 mg/pers. x d

Estimated inh. exp. PPE factor

Im =	0.0192	-	1	0.0192 mg/pers. x d
Ia =	0.0432	-	1	0.0432 mg/pers. x d
				0.0624 mg/pers. x d

Estimated derm. exp.

Dm/h =	4.8	SS 110	0.01	0.048 mg/pers. x d
Da/h =	1.68	SS 120	0.01	0.0168 mg/pers. x d
Da/c =	2.88	SS 420	0.5	1.44 mg/pers. x d
Da/b =	23.04	SS 220	0.05	1.152 mg/pers. x d
				2.6568 mg/pers. x d

	abs. rate	Estimated exposure		Systemic exposure	
		without PPE	with PPE	without PPE	with PPE
Inhalation: m/l	100%	0.0192	0.0192	0.0192	0.0192
Inhalation: appl.	100%	0.0432	0.0432	0.0432	0.0432
Dermal: m/l	0.4%	4.8	0.048	0.0192	0.000192
Dermal: appl.	1.2%	27.6	2.6088	0.3312	0.0313056
		mg/pers./d:		0.4128	0.0938976
kg bw:	70	mg/kg bw/d:		0.00589714	0.00134139
syst. AOEL:	0.002	% of AOEL:		294.857143	67.0697143

Possible PPE: specific instructions	Abbr.	Red.-factor	to lower:
Particle filtering half mask (m/l)	ST 110	0.08	Im
Half mask with comb. filter (m/l)	ST 210	0.02	
Particle filtering half mask (appl.)	ST 120	0.08	Ia
Half mask with comb. filter (appl.)	ST 220	0.02	
Protective gloves (m/l)	SS 110	0.01	Dm/h
Protective gloves (appl.)	SS 120	0.01	Da/h
Half mask (appl.)	ST 120 / 220	0.8	Da/c
Broad-brimmed headgear (appl.: high crops)	SS 420	0.5	Da/b
Hood and visor (appl.: high crops)	SS 520	0.05	
Protective garment + sturdy footwear (appl.)	SS 220	0.05	

2.3 Exposure estimates with the Dutch Glasshouse model

The Dutch model for manual up and downward spraying indoors is based on studies with ornamentals published in the scientific literature and on studies carried out in The Netherlands. Indicative 90th percentiles are deduced from the various exposure databases.

Nexter Pro is packaged in water soluble bags. In the Dutch model, reduction of exposure with a factor 100 is assumed for mixing and loading, when compared to exposure for a regular powder.

However, in the Dutch Glasshouse model, exposure values are presented as combined values for mixing, loading and application. As no data are available on the contribution of exposure during mixing and loading within the overall exposure figure, an assumption should be made for the reduction of the overall exposure value. Based on data from the German and UK model for hand-held applications, dermal exposure is distributed equally between mixing/loading and application. For inhalation exposure, most of exposure originates from mixing and loading. In the UK model complete protection is assumed for mixing and loading when products are packaged in water soluble bags

As a worst-case assumption, reduction of overall exposure during mixing/loading and application with a factor 10 is assumed for Nexter Pro.

Manual up- and downward spraying (indoor) on tomato

OPERATOR EXPOSURE		DUTCH GREENHOUSE MODEL		
Nexter Pro a.s. Pyridaben		Application including mixing and loading		
Parameter	Value	Unit	References, comments	
MANUAL SPRAYING on Roses in greenhouses				
AR Application rate	0.25	kg a.s./ha	summary of intended uses	
A Area treated	1	ha/ day	Dutch model	
Inhalation Exposure				
SV Surrogate Exposure Value	1	mg a.s./ kg a.s.	without PPE Dutch model	
RF Reduction factor	0.1		reduction factor for water soluble bagd	
Inhalation Exposure (without PPE)	0.025	mg a.s./ day	IE = SV x AR x A X RF	
Inhalation Exposure (with PPE)				
PPE-factor	0.1		with PPE reduction factor	
Inhalation Exposure (with PPE)	0.0025	mg a.s./ day	IE(PPE) = PPE factor x IE	
Dermal Exposure				
SV Surrogate Exposure Value	200	mg a.s./ kg a.s.	without PPE Dutch model	
RF Reduction factor	0.1		reduction factor for water soluble bagd	
Dermal Exposure	5	mg a.s./ day	DE = SV x AR x A	
Dermal Exposure (with PPE)				
PPE-factor	0.1		with PPE reduction factor	
Dermal Exposure (with PPE)	0.5	mg a.s./ day	DE(PPE) = PPE-factor x DE	
Internal exposure				
IF Inhalation Absorption Fraction	1			
DF Dermal Absorption Fraction	0.012			
AOEL	0.14	mg a.s./ day		
	Without PPE	With PPE		
Internal exposure	[mg a.s. / day]	[mg a.s. / day]		
Inhalation	0.0250	0.0025	IE(int) = IE x IF	
Dermal	0.060	0.006	DE(int) = DE x DF	
Total	0.085	0.009	sum	
% AOEL				
Inhalation	18	1.8	%AOEL = 100 x IE(int) / AOEL	
Dermal	43	4.3	%AOEL = 100 x DE(int) / AOEL	
Total	61	6.1	sum	

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2.4 Risk assessment for operator exposure

Risk assessment was performed using the 75th percentile from the UK-model (UK-75th), the geometric mean from the German model (DE-GM) and the 90th percentile from the Dutch model (NL-90th).

Appendix Table 5 Risk assessment of Nexter Pro for operators

Model	Route	Estimated internal exposure (mg a.s./day)		AOEL-systemic (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
Mechanical upward spraying on citrus						
UK- 75 th	Respiratory	0.06	0.06	0.12	50	50
	Dermal	0.29	0.20	0.12	242	167
	Total exposure	0.35	0.26	0.12	292	217
DE- GM	Respiratory	0.06	0.06	0.14	45	45
	Dermal	0.35	0.03	0.14	250	22
	Total exposure	0.41	0.09	0.14	295	67
Manual up- and downward spraying on tomato (indoor)						
NL-glasshouse	Respiratory	0.03	0.003	0.14	18	2
	Dermal	0.06	0.006	0.14	43	4
	Total exposure	0.09	0.009	0.14	61	6

For mechanical upward spraying on citrus, it is concluded that a safe use was identified for operators with PPE for mechanical upward spraying on citrus, using the German model.

For manual up- and downward spraying on tomato (indoor), it is concluded that a safe use was identified for operators without PPE for manual up- and downward spraying on tomato, using the Dutch Glasshouse model.

3. Bystander exposure

The presence of bystanders should be kept to a minimum. This can easily be achieved in a greenhouse, where no person should be allowed who is not involved in the spraying process. Therefore, no estimation of bystander exposure for manual up- and downward spraying in greenhouses will be made (tomato).

Outdoors such measures cannot be taken easily. Therefore, exposure estimates will be made for bystanders at mechanical upward spraying (citrus).

For bystander exposure, no formally approved models exist. As an estimate, the draft values proposed for the EUROPOEM II, 2002 model will be used. The values represent the 90th percentile exposure values. The

input data are presented in paragraph 1.2 of this appendix. Since bystanding should as much as possible be prevented and will usually occur incidentally, it cannot be assumed that bystanders will be using any kind of personal protective equipment. Therefore no correction for the use of this equipment should be made.

3.1 Exposure estimates

The values represent the 90th percentile exposure values for bystanders.

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3.1.1 Bystander exposure during mechanical upward spraying on citrus

BYSTANDER EXPOSURE		EUROPOEM MODEL		
Nexter Pro as Pyridaben		Outdoor application		
Parameter	Value	Unit	References, comments	
SPRAYING Process outdoor				
AR	Application rate	0.3	kg a.s. / ha	summary of intended uses
SV	Spray volume	1500	L / ha	summary of intended uses
Inhalation Exposure				
Default value				
SE	Surrogate Exposure Value	0.06	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation
RR	Respiratory rate	1.25	m3 / h	default
Inhalation Exposure		0.0150	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
Dermal Exposure				
Default value				
SE	Surrogate Exposure Value	0.05		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
Dermal Exposure		3	mg a.s./ day	DE = SE xSA X (AR x 100)
Internal exposure				
IF	Inhalation Absorption Fraction	1		
DF	Dermal Absorption Fraction	0.012		
AOEL		0.14	mg a.s./ day	
Without PPE				
Internal exposure		[mg a.s./ day]		
Inhalation		0.015	IE(int) = IE x IF	
Dermal		0.036	DE(int) = DE x DF	
Total		0.051	sum	
% AOEL				
Inhalation		10.7	%AOEL = 100 x IE(int) / AOEL	
Dermal		25.7	%AOEL = 100 x DE(int) / AOEL	
Total		36	sum	

3.1.2 Bystander exposure during manual spraying on tomatoes indoors

The presence of bystanders should be kept at a minimum. This can easily be achieved in greenhouses, where no person should be allowed who is not involved in the spraying process.

3.2 Risk assessment for bystanders

Appendix Table 7 Risk assessment of Nexter Pro for bystanders

Route	Estimated internal exposure (mg a.s./day)	AOEL systemic (mg a.s./day)	Risk-index
<i>Exposure during mechanical upward spraying on citrus</i>			
Respiratory	0.015	0.14	11
Dermal	0.036	0.14	26
Total exposure	0.051	0.14	36
<i>Exposure during manual up- and downward spraying on tomato</i>			
should be prohibited			

For bystander exposure during mechanical upward spraying on citrus, it is concluded that a safe use was identified for bystanders for mechanical upward spraying on citrus, using the EUROPOEM II model (90th percentile). No bystanders should be allowed in greenhouses during the application of Nexter Pro on tomatoes.

4. Worker exposure

For the use of Nexter Pro, re-entry activities should be considered for harvesting and sorting of citrus and tomatoes.

4.1 Exposure estimates

Four exposure studies delivered by the notifier were evaluated to estimate worker exposure. In addition exposure calculations based on models were performed.

4.1.1 Field studies

STUDY 1

Characteristics

reference	: Arts, 1996	GLP statement	: yes
type of study	: Dissipation of dislodgeable foliar residue on almonds	guideline	: EPA 132-1(a)
year of execution	: 1994-1995	acceptability	: Not acceptable
test substance	: BAS 300 11 I, 75% WP in water soluble bag, lot no. OAJ 030, 75.4% pyridaben	conclusion	: DT50 values (persistence) 19.4 and 6.97 days, DT50 values (modelling) 19.4 and 31.7 days.

Study design

The dissipation of dislodgable foliar residues (DFR) from leaves of almond trees treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated at two locations in California (USA).

The test sites A and B, located in Fresno County and Madera County in California (USA), each had one untreated and one treated plot. The treated plot consisted of 5 rows of 12-13 trees long. The first and the last tree in each row, and the outer rows, were treated but not sampled. In June and July 1994, the treated plots received two applications with BAS 300 11 I 30 days apart, at confirmed rate of 0.5 kg a.s./ha, in 120 L of water/ha. Crops were irrigated throughout the study by microspray under tree irrigation, which prevented the residue from being washed off. Meteorological data for A and B were recorded at 32 and 19 km from the test site and results are shown in Appendix Table 8.

From each of the three central rows in each plot, 160 leaf discs were collected and analysed before and after each application and after 1, 3, 5, 7, 9, 11, 13, 15, 17, 20, 24, 28, 34 and 40 days. Pyridaben residues were dislodged from the leaf discs of each sample by addition of 0.01% Aerosol OT 75 (soap) solution followed by shaking at 200 rpm for 10 minutes. After decantation of the liquid this procedure was repeated. Field fortification samples were made by spiking 0.01% Aerosol OT 75 (soap) extracts of 160 leaves from the untreated plot with BAS 300 11 I after each application event and at days 7, 17, 34 and 70. Tank mix samples were collected for analysis before and after each application. Samples were stored frozen prior to analysis (tank mix: 5 months; field fortification solutions: 4 months; dislodgable solutions: 4 months). It was claimed that BAS 300 11 I was stable in water under refrigeration and in AOT solution under freezing conditions, but the three stability studies concerned (studies 94082, 94098 and 94107) were still underway and the reports have not been submitted. In study 3 of this section however, interim results were presented demonstrating that pyridaben was stable in frozen 0.01% AOT solution for 360 days (14%, 18% and 17% loss after 3, 6 and 12 months).

Dislodgable solution samples were analysed by method D9401 (extraction with dichloromethane, florisil column clean-up, GC-ECD, LOQ 0.005 µg/cm²). Field fortification solutions and tank mixes were diluted with acetonitrile and analysed by HPLC/UV.

Appendix Table 8 Meteorological conditions at Fresno and Madera

site	parameter	June	July	August	September	October
Fresno	avg min air temp (°C)	14	17	16	14	9
	avg max air temp (°C)	33	36	36	31	25
	precipitation (mm)	0	0	0	2.5	25.4
Madera	avg min air temp (°C)	14	17	16	14	9
	avg max air temp (°C)	33	36	36	31	25
	precipitation (mm)	0	0	0	2.5	17.8

Results

The mean concentrations of pyridaben in the tank mixes ranged between 92% and 99% of the nominal concentrations. The mean recoveries of laboratory fortified AOT solution ranged between 93% and 101% at fortification levels equivalent to 0.005-1.0 µg/cm², showing that the analytical procedure was valid. The mean concentrations of pyridaben in the field fortification solutions ranged between 89% and 96% of the nominal concentrations. The mean recoveries of field fortified AOT solution for site A/B was 44%/44% (0.005 µg/cm²), 64%/66% (0.025 µg/cm²) and 65%/66% (0.05 µg/cm²), with corresponding coefficients of variation of 41%/37%, 16%/21% and 18%/16%. Since the measured DFRs were >0.05 µg/cm², the study results are considered to be acceptable.

The DFRs (not corrected for field spike recoveries) at site A and B are shown in Appendix Table 9. Maximum DFRs were 0.91-0.94 µg/cm² just after the second treatment, declining to 0.20 µg/cm² after 40 days.

Appendix Table 9 Dislodgable foliar residues (µg/cm²)^(A) on leaves from almond trees at various times after treatment T1 and T2 with BAS 300 11 I performed at 30 days interval at 0.56 kg a.s./ha

event	foliar dislodgable residue (µg/cm ²) ^(A)	
	Fresno	Madera
-T1	0.000	0.000
T1	0.606	0.822
-T2	0.208	0.185
T2	0.914	0.907
day 1	0.940	0.676
day 3	0.821	0.678
day 5	0.760	0.456
day 7	0.585	0.428
day 9	0.622	0.402
day 11	0.664	0.363
day 13	0.581	0.352
day 15	0.512	0.302
day 17	0.424	0.264
day 20	0.488	0.299
day 24	0.470	0.270
day 28	0.419	0.224
day 34	0.181	0.182
day 40	0.204	0.195

(A) Note: the area used for calculation of the DFR was the sum of the area of the upper side and underside of the leaves.

DT50 estimations

DT50 values for dissipation of pyridaben DFRs were calculated following the recommendations and procedures of the "Guidance document on estimating persistence and degradation kinetics from Environmental Fate studies on pesticides in EU registration" (SANCO/10058/2005). The procedures described in this document for estimation of persistence DT50 values in soil were followed (SFO = single first-order, FOMC = first-order multi-compartment, DFOP = double first-order parallel model, HS = hockey stick). All calculations were performed with ModelMaker v 4.0 software. SFO, FOMC, and where required DFOP and HS models were evaluated by the RMS. The results for the best fit model are presented in Appendix

Table 10. DT50 values (persistence) at A and B were 19.4 and 6.97 days, respectively, and DT90 values 64.5 and 171 days. DT50 values (modelling) at A and B were 19.4 and 31.7 days, respectively.

Appendix Table 10 Half-lives for dissipation of dislodgable foliar residues of pyridaben on leaves from almond trees after treatment T1 and T2 with BAS 300 11 I performed at 30 days interval at 0.56 kg a.s./ha

location	parameters for:	best fit kinetics	Chi ² (error)	r ²	DT50 (d)	DT90 (d)
Fresno	persistence	SFO	8.49	0.926	19.4	64.5
	modelling	SFO	8.49	0.926	19.4	64.5
Madera	persistence	FOMC	7.46	0.969	6.97	171
	modelling	DFOP	7.89	0.967	31.7	105

Conclusions

The dissipation of dislodgable foliar residues (DFR) from leaves of almond trees treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated at two locations in California (USA). Maximum DFRs were 0.91-0.94 $\mu\text{g}/\text{cm}^2$ just after the second treatment, declining to 0.20 $\mu\text{g}/\text{cm}^2$ after 40 days. DT50 values (persistence) were 19.4 and 6.97 days, and DT50 values (modelling) 19.4 and 31.7 days, respectively.

Acceptability

1. The DT50 values are reliable, but the residue may have been underestimated since field recoveries were below 100%. During risk assessment this may be accounted for by correcting the maximum measured residues from this study by a factor of 100%/66%, 66% being the recovery of pyridaben from field fortified AOT solution at the highest fortification level. **With this annotation the results are acceptable.**
2. The results are not useful to evaluate the dissipation of DFR from leaves of citrus trees, due to possible differences in adsorptive and absorptive capacity of the different leaves. In addition, the proposed GAP for citrus involves one application per season, whereas the almond trees were sprayed twice, and the dissipation rate of DFRs may be time dependent (e.g., older residues dissipate slower). Furthermore, almonds received a low volume treatment (100 L/ha), whereas citrus should receive a high volume treatment (750-6000 L/ha).
3. **Considering the annotation in the above point, the study cannot be used for worker risk assessment of Nexter Pro.**
4. Appendix V of the report presented a statistical analysis with DT50 estimations. The authors corrected the residues for the average recovery of field spikes at 0.025 and 0.05 $\mu\text{g}/\text{cm}^2$. This procedure (multiplication by a constant factor) does not affect the DT50 estimations. The authors concluded that the data from the two sites could be combined and for the combined data set a half-life of 13 days was reported (assuming non-linear dissipation). The above estimations by the RMS however showed that dissipation at Fresno could be best predicted by SFO, but at Madera non-linear models gave a much better fit than SFO. Combination of the data sets from the two sites is therefore not preferred.

5. Together with the above study report an exposure and margin of safety assessment for re-entry into almonds treated with Nexter Pro was submitted. This report has not been evaluated as it is not relevant for the proposed uses.

STUDY 2

Characteristics

reference	: Arts, 1995a	GLP statement	: yes
type of study	: Dissipation of dislodgable foliar residue on citrus	guideline	: EPA 132-1(a)
year of execution	: 1994-1995	acceptability	: Acceptable
test substance	: BAS 300 11 I, 75% WP in water soluble bag, lot no. OAJ 030, 75.4% pyridaben	conclusion	: DT50 values (persistence) 4.3, 0.44 and 1.1 days, DT90 values (persistence) 34, 1.5 and 3.7 days, DT50 values (modelling) 10.3, 0.44 and 1.1 days.

Study design

The dissipation of dislodgable foliar residues (DFR) from leaves of citrus trees treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated at three locations in the USA.

The test sites A, B and C, located in Fresno County (California), Seminole County (Florida) and Willacy County (Texas), each had one untreated and one treated plot. The treated plot consisted of 5 rows of 12-13 trees long. The first and the last tree in each row, and the outer rows, were treated but not sampled. In May and June 1994, the treated plots received two applications with BAS 300 11 I 30 days apart, at confirmed rate of 0.5 kg a.s./ha, in 192 L of water/ha. Crops were irrigated throughout the study by in-furrow or microspray under tree irrigation, which prevented the residue from being washed off. Meteorological data for A/B/C were recorded at 18/13/5 km from the test site and results are shown in Appendix Table 11.

From each of the three central rows in each plot, 40 leaf discs were collected and analysed before and after each application and after 1, 2, 3, 4, 5, 7, 9, 11, 13, 15, 17, 20, 24, 28, 34, 50, 70 and 90 days. Pyridaben residues were dislodged from the leaf discs of each sample by addition of 0.01% Aerosol OT 75 (soap) solution followed by shaking at 200 rpm for 10 minutes. After decantation of the liquid this procedure was repeated. Field fortification samples were made by spiking 0.01% Aerosol OT 75 (soap) extracts of 40 leaves from the untreated plot with BAS 300 11 I after each application event and at days 7, 17, 34/35 and 70. Tank mix samples were collected for analysis before and after each application. Samples were stored frozen prior to analysis (tank mix: 5 months; citrus leaf disc field fortification solutions: 20 days; fortification solutions: 2 months; dislodgable solutions: 1 month, 20 days). It was claimed that BAS 300 11 I was stable in water under refrigeration and in AOT solution under freezing conditions, but the three stability studies concerned (studies 94082, 94098 and 94107) were still underway and the reports have not been submitted. In study 3 of this section however, interim results were presented demonstrating that pyridaben was stable in frozen 0.01% AOT solution for 360 days (14%, 18% and 17% loss after 3, 6 and 12 months).

Dislodgeable solution samples were analysed by method D9401 (extraction with dichloromethane, florisil column clean-up, GC-ECD, LOQ 0.005 µg/cm²). Field fortification solutions and tank mixes were diluted with acetonitrile and analysed by HPLC/UV.

Appendix Table 11 Meteorological conditions at Fresno, Seminole and Willacy

site	parameter	May	June	July	August	Sept.
Fresno	avg min air temp (°C)	14	13	17	15	13
	avg max air temp (°C)	29	33	36	36	31
	precipitation (mm)	0	0	0	0	6
Semi-nola	avg min air temp (°C)	20	23	23	22	21
	avg max air temp (°C)	33	33	37	35	35
	precipitation (mm) ^(A)	37	48	3	79	36
Willacy	avg min air temp (°C)	18	22	22	22	22
	avg max air temp (°C)	31	33	33	32	31
	precipitation (mm) ^(B)	22	250	258	162	83

(A) The first rainfall after treatment 1 was recorded at 2DAT (5.1 mm) and after treatment 2 at 12 hours post application (25.4 mm).

(B) The first rainfall after treatment 1 was recorded at 2DAT (5.1 mm) and after treatment 2 at 1DAT (7.6 mm).

Results

The mean concentrations of pyridaben in the tank mixes ranged between 80% and 96% of the nominal concentrations (mean method validation recoveries and mean concurrent lab fortification recoveries were in range 86-99%). The mean recoveries of laboratory fortified field fortification solution concurrently analysed during sample analysis were 95-96% at fortification levels equivalent to 0.005-0.05 µg/cm². The mean concentrations of pyridaben in the field fortification solutions determined pre-shipment were around 100%, but for the returned solutions after use in the field they ranged between 58% and 72% of the nominal concentrations. The mean recoveries of laboratory fortified AOT solution during method validation ranged between 94% and 103% at fortification levels equivalent to 0.005-0.05 µg/cm², showing that the analytical procedure was valid. This was supported by the mean recoveries of laboratory fortified AOT solution concurrently analysed during sample analysis which were 94-98% at fortification levels equivalent to 0.005-0.05 µg/cm². The mean recoveries of field fortified AOT solution for site A/B/C was 59%/55%/48% (0.005 µg/cm²), 55%/63%/72% (0.025 µg/cm²) and 48%/66%/72% (0.05 µg/cm²), with corresponding coefficients of variation of 23%/41%/44%, 10%/18%/18% and 12%/24%/25%. The measured DFRs were generally >0.025 µg/cm², and in case lower values were recorded, these residues represented only a low fraction of the initial residue, so that the decline curve was always adequately described by residue values ≥0.025 µg/cm². The study results are considered to be acceptable.

The DFRs (not corrected for field spike recoveries) are shown in Appendix Table 12. Maximum DFRs were 0.81-1.23 µg/cm² just after the second treatment, declining after 70 days to 0.039 µg/cm² at Fresno and to <0.005 µg/cm² at Seminole and Willacy.

Appendix Table 12 Dislodgeable foliar residues ($\mu\text{g}/\text{cm}^2$)^(A) on leaves from citrus trees at various times after two treatments with BAS 300 11 I performed at 30 days interval at 0.56 kg a.s./ha

event	foliar dislodgeable residue ($\mu\text{g}/\text{cm}^2$) ^(A)		
	Fresno	Seminole	Willacy
-T1	0.000	0.000	0.000
T1	1.190	1.060	1.000
-T2	0.066	0.029	0.016
T2	1.233	0.841	0.806
day 1	1.170	0.123	0.554
day 2	0.943	0.114	0.137
day 3	0.749	0.074	0.078
day 4	0.638	0.102	0.086
day 5	0.523	0.079	0.052
day 7	0.599	0.032	0.075
day 9	0.337	0.021	0.057
day 11	0.333	0.028	0.060
day 13	0.323	0.025	0.054
day 15	0.274	0.015	0.047
day 17	0.246	0.005	0.040
day 20	0.347	0.008	0.024
day 24	0.225	0.006	0.025
day 28	0.165	0.006	0.022
day 34	0.102	0.003	0.026
day 40	0.071	0.001	0.022
day 50	0.044	0.0006	0.008
day 70	0.039	0.0000	0.006

(A) Note: the area used for calculation of the DFR was the sum of the area of the upper side and underside of the leaves.

DT50 estimations

DT50 values for dissipation of pyridaben DFRs were calculated following the recommendations and procedures of the "Guidance document on estimating persistence and degradation kinetics from Environmental Fate studies on pesticides in EU registration" (SANCO/10058/2005). The procedures described in this document for estimation of persistence DT50 values in soil were followed (SFO = single first-order, FOMC = first-order multi-compartment, DFOP = double first-order parallel model, HS = hockey stick). All calculations were performed with ModelMaker v 4.0 software. SFO, FOMC, and where required DFOP and HS models were evaluated by the RMS. The results for the best fit model are presented in Appendix Table 13. At A, B and C, respectively, DT50 values (persistence) were 4.3, 0.44 and 1.1 days, DT90 values (persistence) 34, 1.5 and 3.7 days, and DT50 values (modelling) 10.3, 0.44 and 1.1 days.

Appendix Table 13 Half-lives for dissipation of dislodgable foliar residues of pyridaben on leaves from citrus trees after two treatments with BAS 300 11 I performed at 30 days interval at 0.56 kg a.s./ha

location	parameters for:	best fit kinetics	Chi ² (error)	r ²	DT50 (d)	DT90 (d)
Fresno	persistence	DFOP	11.01	0.975	4.3	34
	modelling	FOMC	11.58	0.971	10.3	34
Seminole	persistence	SFO	44.03 ^(A)	0.949	0.44	1.5
	modelling	SFO	44.03 ^(A)	0.949	0.44	1.5
Willacy	persistence	SFO	35.61 ^(A)	0.940	1.1	3.7
	modelling	SFO	35.61 ^(A)	0.940	1.1	3.7

(A) Error high due to high residuals for numerous data points with very low residues. The fit was acceptable for the data points through day 5 after T2 (90% degradation or more).

Conclusions

The dissipation of dislodgable foliar residues (DFR) from leaves of citrus trees treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated at three locations in California, Florida and Texas (USA). Maximum DFRs were 0.81-1.23 µg/cm² just after the second treatment, declining after 70 days to 0.039 µg/cm² at Fresno (California) and to <0.005 µg/cm² at the other two locations.

In California, Florida and Texas, respectively, DT50 values (persistence) were 4.3, 0.44 and 1.1 days, DT90 values (persistence) 34, 1.5 and 3.7 days, and DT50 values (modelling) 10.3, 0.44 and 1.1 days.

Acceptability

1. The DT50s are reliable, but the residue may have been underestimated since field recoveries were below 100%. During risk assessment this may be accounted for by correcting the maximum measured residues from this study by a factor of 100%/72%, 72% being the recovery of pyridaben from field fortified AOT solution at the highest fortification level.
2. The study trees received 2 applications of 0.56 kg a.s./ha, versus a single application of 0.3 kg a.s./ha according to the proposed GAP. The proposed GAP for citrus involves one application per season, whereas the trees in this study were sprayed twice, and the dissipation rate of DFRs may be time dependent (older residues are likely to dissipate slower). The results are worst case in this respect. The study trees received a low volume treatment (100 L/ha), whereas the proposed GAP states a high volume treatment (750-6000 L/ha). The different water volumes may result in different distributions, but sufficient leaves were sampled per sampling time, and the number of samplings was high. Hence the difference in spray volume is considered not to hamper extrapolation. The study trees received 2 application of 0.56 kg/ha, versus a single application of 0.3 kg/ha according to the proposed GAP. No information has been submitted which demonstrates that the magnitude and dissipation rate of DFRs is independent of the dose, and this represents an uncertainty in the extrapolation.
3. The results are **acceptable with the annotations in the above two points**.
4. Appendix 5 of the report presented a risk assessment of dermal exposure of citrus harvesters to pyridaben. This report has not been evaluated in detail but where relevant its assumptions are taken into consideration during the risk assessment of dermal exposure of citrus harvesters performed by the RMS.

STUDY 3

Characteristics

reference	: Arts, 1996	GLP statement	: yes
type of study	: Dissipation of dislodgable foliar residue on greenhouse ornamentals	guideline	: EPA 132-1(a)
year of execution	: 1994-1995	acceptability	: Not acceptable
test substance	: BAS 300 11 I, 75% WP in water soluble bag, lot no. OAJ 030, 75.4% pyridaben	conclusion	: DT50 for roses 24.5 days. For chrysanthemums DT50 99.8 days, only 33% dissipation by study end (60 days after T2) .

Study design

The dissipation of dislodgable foliar residues (DFR) from leaves of chrysanthemum and rose leaves treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated under greenhouse conditions in Granville County, North Carolina (USA).

Treated and untreated plots were located in different greenhouses. The untreated plot consisted of one replicate, and the treated plot of 3 replicates of 2 rows each of 27-28 potted chrysanthemum or rose plants. Only the middlemost 25 plants of each row were sampled. The treated plots received two applications with BAS 300 11 I 7 days apart, at confirmed rate of 0.5 kg a.s./ha, in 210 L of water/ha (application dates 26 August and 2 September, 1994). Crops stages at 1st application: chrysanthemums canopy mostly full sized, 1-2 weeks pre-bloom, roses mature plants with flowers and buds present, with new shoots, leaf and bud growth continuing. Crops stages at 2nd application: chrysanthemums canopy mostly full, 1 week pre-bloom, roses mature plants with new shoots, buds and growth still pushing. Crops were irrigated by drip irrigation with an individual drip emitter placed in each pot, such that no foliage was wetted. Meteorological data are shown in Appendix Table 14.

From each replicate, 50 leaf discs were collected and analysed before and after each application and after 1, 3, 5, 7, 14, 33 and 60 days. Pyridaben residues were dislodged from the leaf discs of each sample by addition of 0.01% Aerosol OT 75 (soap) solution followed by shaking at 200 rpm for 10 minutes. After decantation of the liquid this procedure was repeated. Field fortification samples were made by spiking 0.01% Aerosol OT 75 (soap) extracts of 50 leaves from the untreated plot with BAS 300 11 I after each application event and at days 3, 7 and 31 after application 2. Tank mix samples were collected for analysis before and after each application. Samples were stored frozen prior to analysis (tank mix: 6 months; leaf disc field fortification solutions: 7 months; dislodgable solutions: 6 months). It was claimed that BAS 300 11 I was stable in water under refrigeration and in AOT solution under freezing conditions, but the three stability studies concerned (studies 94082, 94098 and 94107) were still underway and the final reports have not been submitted. Interim results however were presented demonstrating that pyridaben was stable in frozen 0.01% AOT solution for 360 days (14%, 18% and 17% loss after 3, 6 and 12 months).

Dislodgeable solution samples were analysed by method D9401 (extraction with dichloromethane, florisil column clean-up, GC-ECD, LOQ 0.005 µg/cm²). Field fortification solutions and tank mixes were diluted with acetonitrile and analysed by HPLC/UV.

Appendix Table 14 Meteorological conditions in the treated greenhouse

parameter	August	September	October	November
avg min air temp (°C)	21	18	12	12
avg max air temp (°C)	31	29	28	29
avg min rel hum. (%)	64	56	53	43
avg min rel hum. (%)	99	99	97	98

Results

The mean concentration of pyridaben in the tank mixes was 100% (SD 2%) of the nominal concentrations (mean concurrent lab fortification recovery was 105%). The mean concentrations of pyridaben in the field fortification solutions determined pre-shipment and post-shipment was 99% and 102%, respectively. The mean recoveries of laboratory fortified field fortification solution samples analysed concurrently with the field fortification samples were 88/93% with SD 7%/4% for roses/chrysanthemums at fortification levels 0.005-1.0 µg/cm². The mean recovery of field fortified AOT solution for roses/chrysanthemums was 77%/70% (SD 7%/8%) at fortification levels 0.016-0.16 µg/cm². The mean recoveries of laboratory fortified AOT solution concurrently analysed during sample analysis were 89% (roses, SD 7%) and 92% (chrysanthemums, SD 4%) at fortification levels equivalent to 0.005-0.5 µg/cm². The submitted validation data demonstrate the reliability of the study results.

The DFRs (not corrected for recoveries) are shown in Appendix Table 15. Maximum DFRs in roses and chrysanthemums, respectively, were 0.77 and 0.54 µg/cm² just after the second treatment, declining after 60 days to 0.15 and 0.30 µg/cm².

Appendix Table 15 Dislodgeable foliar residues (µg/cm²)^(A) on leaves from greenhouse roses and chrysanthemums at various times after two treatments with BAS 300 11 I performed at 7 days interval at 0.56 kg a.s./ha

event	foliar dislodgeable residue (µg/cm ²) ^(A)	
	roses	chrysanthemums
-T1	0.000	0.000
T1	0.343	0.312
-T2	0.161	0.179
T2	0.765	0.451
day 1	0.688	0.538
day 3	0.584	0.404
day 5	0.618	0.442
day 7	0.673	0.437
day 14	0.491	0.491
day 30	0.277	0.381
day 60	0.148	0.302

(A) Note: the area used for calculation of the DFR was the sum of the area of the upper side and underside of the leaves.

DT50 estimations

DT50 values for dissipation of pyridaben DFRs were calculated following the recommendations and procedures of the “Guidance document on estimating persistence and degradation kinetics from Environmental Fate studies on pesticides in EU registration” (SANCO/10058/2005). The procedures described in this document for estimation of persistence DT50 values in soil were followed (SFO = single first-order, FOMC = first-order multi-compartment, DFOP = double first-order parallel model, HS = hockey stick). All calculations were performed with ModelMaker v 4.0 software. SFO, FOMC, and where required DFOP and HS models were evaluated by the RMS. The results for the best fit model are presented in Appendix Table 16. For roses and chrysanthemums, respectively, DT50 values (persistence and modelling) were 24.5 and 99.8 days and DT90 values 81.5 and 332 days. In the case of chrysanthemum however, only 33% dissipation had occurred by study end (60 days after T2), and the coefficient of correlation for first order regression analysis was low ($r^2 = 0.635$). For this reason, it is appropriate to characterise the rate of dissipation in chrysanthemums, not only by stating a DT50 value, by also by the extent of dissipation at study end (33% 60 days after T2).

Appendix Table 16 Half-lives for dissipation of dislodgable foliar residues of pyridaben on leaves from greenhouse roses and chrysanthemums at various times after two treatments with BAS 300 11 I performed at 7 days interval at 0.56 kg a.s./ha

crop	parameters for:	best fit kinetics	Chi ² (error)	r ²	DT50 (d)	DT90 (d)
roses	persistence	SFO	6.75	0.950	24.5	81.5
	modelling	SFO	6.75	0.950	24.5	81.5
chrysanthemums	persistence	SFO	7.43	0.635	99.8	332
	modelling	SFO	7.43	0.635	99.8	332

Conclusions

The dissipation of dislodgable foliar residues (DFR) from leaves of roses and chrysanthemums treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated under greenhouse conditions in North Carolina (USA). Maximum DFRs in roses and chrysanthemums, respectively, were 0.77 and 0.54 $\mu\text{g}/\text{cm}^2$ just after the second treatment, declining after 60 days to 0.15 and 0.30 $\mu\text{g}/\text{cm}^2$. For roses, the DT50 value (persistence and modelling) was 24.5 days. For chrysanthemums, only 33% dissipation had occurred by study end (60 days after T2), and during this period the rate of dissipation was characterised by a DT50 value (persistence and modelling) of 99.8 days.

Acceptability

1. The DT50s are reliable, but the residue may have been underestimated since field recoveries were below 100%. During risk assessment this may be accounted for by correcting the maximum measured residues from this study by a factor of 100%/77% (roses) or 100%/70% (chrysanthemums), 77% and 70% being the mean recovery of pyridaben from field fortified AOT solution. **With this annotation the results are acceptable.**

2. The results are not useful to evaluate the dissipation of DFR from leaves of tomato (and citrus), due to possible differences in adsorptive and absorptive capacity of the different leaves. In addition the proposed GAP for tomato involves one application per season, whereas the ornamentals were sprayed twice, and the dissipation rate of DFR's may be time dependent (e.g. older residues dissipate slower). Furthermore, ornamentals received a low volume treatment (120 L/ha), whereas tomatoes should receive a high volume treatment (625-5000 L/ha).
3. **Considering the annotation in the above point, the study cannot be used for worker risk assessment of Nexter Pro.**

STUDY 4

Characteristics

reference	: Arts, 1995b	GLP statement	: yes
type of study	: Dissipation of dislodgable soil residues (almonds)	guideline	: EPA 132-1(b)
year of execution	: 1994-1995	acceptability	: Not acceptable
test substance	: BAS 300 11 I, 75% WP in water soluble bag, lot no. OAJ 030, 75.4% pyridaben	conclusion	: DT50 11.5 days

Study design

The dissipation of dislodgable soil residues (DSR) from soil under almond trees treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated at one location in California (USA).

The test site, located in Fresno County (California, USA), had one untreated and one treated plot. The treated plot consisted of 5 rows of 21 trees long. The first and last tree in each row, and the outer rows, were treated but not sampled. In June and July 1994, the trees of the treated plots received two applications with BAS 300 11 I 30 days apart, at confirmed rate of 0.5 kg a.s./ha, in 480 L of water/ha. Crops were irrigated throughout the study by microspray under tree irrigation, which prevented the residue from being washed off. Meteorological data were recorded at 32 km from the test site and results are shown in Appendix Table 17.

From the soil underneath each of the three central rows in each plot, a soil dust sample ($\leq 147 \mu\text{m}$, $\geq 50 \text{ g}$) was collected and analysed before and after each application and after 1, 3, 5, 7, 9, 11, 13, 15, 17, 20, 24 and 28 days. The soil dust sample was collected by firmly positioning a wooden frame with a 100 mesh brass screen on the ground around the tree drip line, and drawing the dust through the screen using a portable vacuum cleaner. Field fortification samples were made by spiking soil dust collected from the untreated plot with BAS 300 11 I after each application event and at days 7, 17 and 34 after treatment 2. Tank mix samples were collected for analysis before and after each application. Samples were stored frozen prior to analysis for 7-9 months. It was claimed that BAS 300 11 I was stable in soil under freezing conditions, but the stability study concerned (study A99448) has not been submitted. This does not invalidate the study since field fortification samples gave acceptable recoveries (see below).

Pyridaben residues were extracted from the soil dust with methanol, followed by florisil column clean-up and GC-ECD analysis, LOQ 0.01 mg/kg). Field fortification solutions and tank mixes were diluted with acetonitrile and analysed by HPLC/UV.

Appendix Table 17 Meteorological conditions

site	parameter	June	July	August	September	October
Fresno	avg min air temp (°C)	14	17	16	14	9
	avg max air temp (°C)	33	36	36	31	25
	precipitation (mm)	0	0	0	2.5	25.4

Results

The mean recovery of laboratory fortified untreated soil dust samples during method validation was 93% (SD 4%) at fortification levels 0.01-0.1 mg/kg. The mean recovery of laboratory fortified untreated soil dust samples analysed concurrently with the study samples was 89% (SD 7%) at fortification levels 0.01-20 mg/kg. The concentration of pyridaben in the tank mixes was in the range 94-108% of the nominal concentrations (mean concurrent lab fortification recovery was 101%). The concentrations of pyridaben in the field fortification solutions determined pre-shipment and post-shipment was in the range 90-105% (mean concurrent lab fortification recovery was 88%, SD 3%). The mean recovery of field fortified untreated soil dust samples was 89% (SD 3%) at fortification levels 0.1-10 mg/kg. The submitted validation data demonstrate the reliability of the study results.

The DSRs (not corrected for field spike recoveries) are shown in Appendix Table 18. The maximum DSR was 13.7 mg/kg just after the second treatment, declining to 2.54 mg/kg after 28 days.

Appendix Table 18 Dislodgable residues (mg/kg) on soil underneath almond trees at various times after treatment T1 and T2 with BAS 300 11 I performed at 30 days interval at 0.56 kg a.s./ha

event	dislodgable soil residue (mg/kg)
-T1	0.00
T1	10.37
-T2	1.557
T2	13.66
day 1	12.17
day 3	8.823
day 5	9.727
day 7	9.597
day 9	6.370
day 11	4.663
day 13	7.170
day 15	6.347
day 17	3.393
day 20	4.150
day 24	3.367
day 28	2.540

DT50 estimations

DT50 values for dissipation of pyridaben DSRs were calculated following the recommendations and procedures of the "Guidance document on estimating persistence and degradation kinetics from

Environmental Fate studies on pesticides in EU registration” (SANCO/10058/2005). The procedures described in this document for estimation of persistence DT50 values in soil were followed (SFO = single first-order, FOMC = first-order multi-compartment, DFOP = double first-order parallel model, HS = hockey stick). All calculations were performed with ModelMaker v 4.0 software. SFO, FOMC, and where required DFOP and HS models were evaluated by the RMS. The results for the best fit model are presented in Appendix Table 19. The DT50 value (persistence and modelling) was 11.5 days.

Appendix Table 19 Half-lives for dissipation of dislodgable residues of pyridaben on soil underneath almond trees after treatment T1 and T2 with BAS 300 11 I performed at 30 days interval at 0.56 kg a.s./ha

location	parameters for:	best fit kinetics	Chi ² (error)	r ²	DT50 (d)	DT90 (d)
Fresno	persistence	SFO	12.50	0.900	11.5	38.2
	modelling	SFO	12.50	0.900	11.5	38.2

Conclusions

The dissipation of dislodgable residues (DSR) from soil underneath almond trees treated twice with BAS 300 11 I at rate 0.56 kg pyridaben/ha was investigated at one location in California (USA). The maximum DSR was 13.7 mg/kg just after the second treatment, declining to 2.54 mg/kg after 28 days. The DT50 value (persistence and modelling) was 11.5 days.

Acceptability

1. The results are not useful to evaluate the dissipation of DSR from soil under citrus trees, due to possible differences in DSR formation rates in different crops. In addition, the proposed GAP for citrus involves one application per season, whereas the almond trees were sprayed twice, and the dissipation rate of DSRs may be time dependent (e.g., older residues dissipate slower).
2. **Considering the annotation in the above point, the study cannot be used for worker risk assessment of Nexter Pro.**

4.1.2 Exposure estimates with EUROPOEM II

4.1.2.1 Re-entry activities in citrus outdoors, based on EUROPOEM II

Based on the DRF study (Arts, 1995a), foliar residue decline should be taken into consideration. A preharvest interval of 14 days (GAP) is given. For the calculation the mean DFR at day 13 is taken from the three sites, resulting in a DRF of 0.13 µg/cm² (1.3 mg/m²). A mean DFR is considered justified since sufficient leaves were sampled per sampling time.

WORKER EXPOSURE		EUROPOEM MODEL		
Nexter Pro as pyridaben		Re-entry in the field, DFR model		
Parameter	Value	Unit	References, comments	
SPRAYING Process outdoor				
AR Application rate	0.3	kg a.s./ha	summary of intended uses	
Worker				
Duration				
Tc Cutting	3	hour	Dutch model	
Tsb Sorting/ bundling	3	hour	Dutch model	
Inhalation Exposure			without PPE	
no model available			-	
Dermal Exposure				
LAI Leaf area index (surrogate value)	2	m2/ m2	Europoem II	
DFR Dislodgeable foliar residue	1.3	mg a.s./m2	DFR = AR X 100 / LAI	
TC Transfer coefficient	0.45	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)	
Dermal Exposure	3.51	mg a.s./ day	DE = DFR x TC x (Tc+Tsb)	
Internal exposure				
DF Dermal Absorption Fraction	0.012	mg a.s./ day	reduction factor	
PPE-factor dermal	0.1			
AOEL	0.14			
		Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]		
Inhalation	-	-	no model available	
Dermal	0.042	0.004	DE(int) = DE x DF	
Total	0.042	0.004	sum	
% AOEL				
Inhalation	-	-	no model available	
Dermal	30	3	%AOEL = 100 x DE(int) / AOEL	
Total	30	3	sum	

It must be emphasized that the knowledge on the various factors that are relevant for the actual exposure under practical conditions are still far from complete, so these data have to be considered as preliminary estimates.

The inhalation exposure cannot be estimated in a similar way due to lack of data. On the basis of expert judgment it is however considered unlikely that the level of inhalation exposure is higher than the estimates

for operators. Moreover, based on the vapour pressure of pyridaben ($< 1 \cdot 10^{-5}$ Pa), inhalation exposure during re-entry activities in citrus is considered negligible.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

4.1.2.2 Re-entry activities in tomato indoors, based on EUROPOEM II

WORKER EXPOSURE		EUROPOEM MODEL		
Nexter Pro as pyridaben		Re-entry in greenhouses		
Parameter	Value	Unit	References, comments	
SPRAYING Process indoor				
AR	Application rate	0.25	kg a.s./ha	summary of intended uses
Worker				
Duration				
Tc	Cutting	3	hour	Dutch model
Tsb	Sorting/ bundling	3	hour	Dutch model
Inhalation Exposure				
without PPE				
Task Specific Factor				
Surrogate value (indicative)				
TF	Cutting	0.1	(mg a.s./hr)/ (kg/ha)	Europoem II
TF	Sorting/ bundling	0.01	(mg a.s./hr)/ (kg/ha)	Europoem II
Inhalation Exposure				
	Cutting	0.075	mg a.s./ day	IE = AR x Tc x TF
	Sorting/ bundling	0.0075	mg a.s./ day	IE = AR x Tsb x TF
	Total	0.0825	mg a.s./ day	sum
Dermal Exposure				
LAI	Leaf area index (surrogate value)	2	m2/ m2	Europoem II
DFR	Dislodgeable foliar residue	12.5	mg a.s./m2	DFR = AR X 100 / LAI
TC	Transfer coefficient	0.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
	Dermal Exposure	18.75	mg a.s./ day	DE = DFR x TC x (Tc+Tsb)
Internal exposure				
IF	Inhalation Absorption Fraction	1		
DF	Dermal Absorption Fraction	0.012		
	PPE-factor inhalation	1		reduction factor
	PPE-factor dermal	0.1		reduction factor
	AOEL	0.14	mg a.s./ day	
Without PPE				
With PPE				
Internal exposure		[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	0.0825	0.0083	IE(int) = IE x IF
	Dermal	0.225	0.023	DE(int) = DE x DF
	Total	0.308	0.031	sum
% AOEL				
	Inhalation	59	6	%AOEL = 100 x IE(int) / AOEL
	Dermal	161	16	%AOEL = 100 x DE(int) / AOEL
	Total	220	22	sum

A generic assessment of protective clothing might be used to estimate the actual exposure of protected workers. In view of the fact that the potential exposure is assessed by taking the 75-90th percentile from the relevant exposure data, it is considered appropriate to use values of about a factor 10 for the protection afforded by adequate protective gloves and protective clothing; this presumes that a reasonable degree of personal hygiene is taken care of by the workers. The value of a factor 10 is appropriate for generic use at the level of placement on Annex I of the compound under consideration, i.e. for consideration (of pyridaben) at the community level. For the registration of plant protection products in Member States, a more elaborate consideration of crops, techniques and work methods may lead to (some) adjustment of these values. In the generic approach, the dermal exposure estimates will decrease 10-fold.

4.1 Risk assessment for workers

Appendix Table 22 Risk assessment of Nexter Pro for workers

Route	Estimated internal exposure		AOEL	% AOEL	
	(mg a.s./day)		Systemic		
	without PPE	with PPE	(mg a.s./day)	without PPE	with PPE
Mechanical upward spraying on citrus					
Respiratory	-	-	0.14	-	-
Dermal	0.042	0.004	0.14	30	3
Total exposure	0.042	0.004	0.14	30	3
Manual up- and downward spraying on tomato (indoor)					
Respiratory	0.0825	0.0083	0.14	59	6
Dermal	0.225	0.023	0.14	161	16
Total exposure	0.308	0.031	0.14	220	22

For worker exposure during re-entry activities in citrus, it is concluded that a safe use was identified for workers without PPE during re-entry activities in citrus, using the EUROPOEM II.

For worker exposure during re-entry activities in tomato, it is concluded that a safe use was identified for workers with PPE during re-entry activities in tomato, using the EUROPOEM II.