CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance 1-naphthylacetic acid[1]

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SUMMARY

1-Naphthylacetic acid is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by France, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicants' decision, in accordance with Article 24e, to withdraw support for the inclusion of 1-naphthylacetic acid in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 8 December 2008 (2008/941/EC)[5] concerning the non-inclusion of 1-naphthylacetic acid in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants Amvac Chemical UK Limited and the 1-NAA Task Force made a resubmission application for the inclusion of 1-naphthylacetic acid in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, France, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 12 March 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicants for comments on 17 March 2010. The EFSA collated and forwarded all comments received to the Commission on 30 April 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on 1-naphthylacetic acid.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of 1-naphthylacetic acid as a plant growth regulator on apple as proposed by the applicants. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2010-00870, issued on 15 February 2011.
[2] Correspondence: praper@efsa.europa.eu
[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 335, 13.12.2008, p.91
[6] OJ L 15, 18.01.2008, p.5

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Data gaps were identified in the section on identity, physical and chemical properties and analytical methods. The technical specification for the Amvac source should be considered provisional at the time of the finalisation of the peer review (January 2011).

A data gap was identified in the mammalian toxicology section. The operator, worker and bystander risk assessment could be concluded.

Data gaps were identified in the section on residues. Sufficient European residue trials analysed with a validated analytical method and a new freezer storage stability study are required. The consumer risk assessment is not finalised since residue data are not available to address the use pattern that is expected to result in the most critical residue values. No critical area of concern was identified.

Data gaps were identified for further information on the route and rate of degradation in soil and for information on photolysis of 1-naphthylacetic acid in soil. The potential for groundwater contamination of 1-naphthylacetic acid above the parametric drinking water limit of 0.1 µg/L was assessed as low for the representative use of 'Amcotone', but high for the representative uses of 'Fruitone N' and 'Obsthormon 24A'.

Three data gaps were identified in the ecotoxicology section. A reproduction test is needed to address the long-term risk to birds. The risk to aquatic organisms needs to be addressed for the formulations 'Amcotone' and 'Fruitone N'. The analytical profile of the batches used in the ecotoxicology tests should be provided for the Amvac source. No critical area of concern was identified in the ecotoxicology section.

KEY WORDS

1-naphthylacetic acid, 1-naphthaleneacetic acid, 1-NAA, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 2229/2004[7], as amended by Commission Regulation (EC) No 1095/2007[8], lays down the detailed rules for the implementation of the fourth stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicants for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 2229/2004

1-Naphthylacetic acid is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State France, which was received by the EFSA on 30 October 2007 (France, 2007).

The peer review was initiated on 3 March 2008 by dispatching the DAR to Member States and the applicants Amvac Chemical UK Limited, the 1-NAA Task Force and Rhizopon for consultation and comments.

The peer review process was subsequently terminated following the applicants' decision, in accordance with Article 24e, to withdraw support for the inclusion of 1-naphthylacetic acid in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 8 December 2008 (2008/941/EC)[10] concerning the non-inclusion of 1-naphthylacetic acid in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants Amvac Chemical UK Limited and the 1-NAA Task Force made a resubmission application for the inclusion of 1-naphthylacetic acid in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18, France, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 12 March 2010 (France, 2010a).

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicants for comments on 17 March 2010. In addition, the EFSA conducted a public consultation on the Additional Report and the DAR. The EFSA collated and forwarded all comments received to the

[7] OJ L 379, 24.12.2004, p.13
[8] OJ L 246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 335, 13.12.2008, p.91

Commission on 30 April 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicants were invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicants' response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 28 May 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on 1-naphthylacetic acid within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information was required to be submitted by the applicants in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicants in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 2 June 2010; the applicants were also invited to give their view on the need for additional information. On the basis of the comments received, the applicants' response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology and that further information should be requested from the applicants in the areas of physical/chemical properties, mammalian toxicology, residues and fate and behaviour.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicants, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in December 2010 - January 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a plant growth regulator on apples, as proposed by the applicants. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report (EFSA, 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 22 June 2010),
- the Evaluation Table (24 January 2011),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of November 2010 containing all individually submitted addenda) (France, 2010b) and the

Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

1-naphthylacetic acid (IUPAC) is considered by the International Organization for Standardization not to require a common name. The sodium salt derivative of this substance is sodium 1-naphthylacetate (IUPAC).

The representative formulated products for the evaluation were 'Obsthormon 24A', a soluble concentrate (SL) containing 84 g/l 1-naphthylacetic acid, 'Amcotone', a wettable powder (WP) containing 0.45 % (w/w) of 1-naphthylacetic acid and 1.2% (w/w) of 2-(1-naphthyl)acetamide, and 'Fruitone N', a wettable powder (WP) containing 3.5 % (w/w) sodium 1-naphthylacetate, registered under different trade names in Europe.

The representative uses evaluated comprise high volume spraying on apples for pre-harvest fruit drop control. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev. 4 (European Commission, 2000), SANCO/10597/2003 rev. 8.1 (European Commission, 2009), and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of 1-naphthylacetic acid technical material is 980 g/kg for the Task Force and is open for the technical material of Amvac origin. No FAO specifications exist.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of 1-naphthylacetic acid or the representative formulations. However, the following data gaps were identified for the Amvac source: additional batch data and validated analytical methods for the determination of the active substance and impurities in the technical active substance as manufactured and an updated technical specification. As a consequence the technical specification for the Amvac source should be considered provisional. Data gaps were also identified for the melting, freezing or solidification point and solubility in organic solvents of 1-naphthylacetic acid for the Amvac source, the determination of long-term storage stability and physico-chemical characteristics for 'Amcotone' and 'Fruitone N' and a shelf-life study for 'Obsthormon 24A'. Data concerning flash point, auto-flammability temperature, surface tension and density were identified as data gaps for the Task Force for formal reasons because the final reports were not available during the peer review.

The main data regarding the identity of 1-naphthylacetic acid and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of 1-naphthylacetic acid and the impurities in the technical material and for the determination of the active substance in the representative formulations. 1-naphthylacetic acid residues in food of plant origin can be monitored by HPLC-UV; however a data gap was identified for an independent laboratory validation of the method. Monitoring methods for food of animal origin are not required as no MRL was proposed. Residues of 1-naphthylacetic acid in soil and water can be monitored by HPLC with fluorescence detection. A monitoring method for 1-naphthylacetic acid residues in air has been identified as a data gap. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance document was followed in the production of this conclusion: SANCO/222/2000 rev. 7 (European Commission, 2004b).

1-naphthylacetic acid was discussed during PRAPeR experts' meeting 83 in October 2010.

An issue that could not be finalised was identified for the Amvac source as it was not possible to establish whether the batches tested were in compliance with the proposed specification.

Although some toxicokinetic differences were observed, on the basis of the similarities among 1-naphthylacetic acid, 1-naphthylacetic acid-Na and 2-(1-naphthyl)acetamide it could be concluded that bridging of toxicity between the compounds was possible.

1-naphthylacetic acid was harmful in rats after oral administration, the oral LD_{50} was 1750 mg/kg bw ("harmful if swallowed" - Xn, R22 was proposed). 1-naphthylacetic acid was of low toxicity after dermal and inhalation acute exposure (LD_{50} above 2000 mg/kg bw and LC_{50} higher than 0.45 mg/l, respectively). 1-naphthylacetic acid did not show dermal irritation potential, whereas it is irritant to eyes, therefore Xi, R41 ("Risk of serious damage to eyes") was proposed. 1-naphthylacetic acid is not a skin sensitiser.

The toxicity of 1-naphthylacetic acid was evaluated in rats and dogs in repeated dose studies with doses ranging from 10 to 500 mg/kg bw/day. In rats the No Observed Adverse Effect Level (NOAEL) for 1-naphthylacetic acid was set at 10 mg/kg bw/day based on haematological alterations, hepatocellular vacuolisation and total bilirubin levels changes at 60 mg/kg/day. In dogs a NOAEL could not be set (the LOAEL was 50 mg/kg/day). However, daily administration of 1-naphthylacetic acid for 6 months caused very slight evidence of pericholangitis in the low group, a very slight to moderate degree of hepatic insult in the mid dose group, and a slight to severe degree of hepatic insult in the high dose group.

1-naphthylacetic acid gave negative results in the Ames assay. Equivocal results were obtained *in vitro* in the MLA/TK assay without and with metabolic activation. No indication of a clastogenic effect was observed in the mouse micronucleus test in bone marrow after a twice-oral administration. 1-naphthylacetic acid-Na is clastogenic *in vitro*, but the genotoxic potential *in vivo* was not demonstrated.

In the rats, repeated administration of 1-naphthylacetic acid-Na at doses up to 5000 ppm for up to two years caused increased relative liver and kidney weights, increased incidence of minimal to slight periportal hepatocellular vacuolar change and a slight increase in the incidence and severity of dilated mucosal glands of the stomach at terminal sacrifice. Changes were also observed in alkaline phosphatase and triglycerides at high doses. The NOAEL was established at 1000 ppm, equivalent to 43.8-55.8 mg/kg/day for males and females, respectively. Oral administration of 1-naphthylacetic acid-Na at dose levels up to 2500 ppm to male and female mice for at least 80 weeks resulted in an effect on bodyweight and treatment related microscopic findings to the liver, kidney and testis of animals given 2500 ppm of 1-naphthylacetic acid-Na. There was an increase in incidence of liver weight increase, hepatocyte vacuolation and inflammation of the liver in both sexes. In addition, there was an increase in kidney weight, intratubular microlithiasis and tubular basophilia in females and an increase in interstitial mononuclear cell infiltration in the kidneys of males. A slight increase in the severity of bilateral tubular degeneration of the testis with associated reduced spermatozoa in the epididymis and dilated rete testis was observed in males. The NOAEL in this study is 500 ppm, equivalent to 53.3 and 70.9 mg/kg/day in males and females, respectively.

In reproductive toxicity studies the lowest relevant maternal and offspring NOAELs were 69 mg/kg bw/day, whereas the reproductive NOAEL was 210 mg/kg bw/day. For the developmental toxicity studies the experts agreed on the maternal and developmental NOAEL: in rabbit at 100 mg/kg bw/day and 30 mg/kg bw/day (LOAEL), respectively (study performed with 1-naphthylacetic acid-Na); in rats at 150 mg/kg bw/day and 15 mg/kg bw/day (study performed with 1-naphthylacetic acid-Na). In addition, the experts agreed that a proposal for classification with R63 was appropriate (based mainly on rabbit, where major defects affecting the head - oral cavity palatin ridge irregularity - were seen in the low dose of 30 mg/kg bw/day, not dose-related, other major defects were sporadically observed, and also supported by other studies in rats and rabbits).

All the reference values were based on the developmental toxicity NOAEL of 15 mg/kg bw/day in rat (study performed with 1-naphthylacetic acid-Na), supported by the 90-day rat and the 1-year dog studies. The **Acceptable Daily Intake** (ADI) is 0.1 mg/kg bw/day (a Safety Factor (SF) of 150 was applied). The **Acceptable Operator Exposure Level** (AOEL) is 0.07 mg/kg bw/day (SF of 150 and correcting for 70% oral absorption). The **Acute Reference Dose** (ARfD) is 0.1 mg/kg bw (SF of 150). The malformations of the oral cavity were considered together as relevant to increase the SF to 150, in order to get a 300 margin of safety between the reference values and the critical effect at 30 mg/kg bw/day.

Operator exposure to 1-naphthylaectic acid is below the AOEL for 'Amcotone' (no need for Personal Protective Equipment - PPE), 'Fruitone N' (PPE is used, coverall and gloves during all phases) and 'Obsthormon 24A' (even without the use of PPE). For the three plant protection products (PPP) bystander exposure is below the AOEL. Worker exposure to 1-NAA for 'Fruitone N' and 'Obsthormon 24A' will be below the AOEL with the use of gloves (during the written procedure the RMS proposed a tier II approach to refine the assessment which is not peer reviewed), whereas it is below the AOEL without the use of PPE for 'Amcotone' (calculations not peer reviewed).

3. Residues

The assessment in the residue section is based on the guidance documents listed in the document SANCO 1607/VI/97 rev.2 (European Commission, 1999).

A metabolism study is available in apples treated with sequential application of 1-naphthylacetic acid, its variant 1-naphthylacetic acid ethyl ester, and 2-(1-naphthyl)acetamide. 1-naphthylacetic acid was the only identifiable residue accounting for approx 22% of the total radioactive residue (TRR) in apple, though the absolute level was very low (0.002 mg/kg). Two unknown compounds, present together at approx 37% of the TRR (0.004 mg/kg), released 1-naphthylacetic acid upon hydrolysis, and are thus supposed to be conjugates of 1-naphthylacetic acid. A metabolism study in olives confirmed the findings in the apple study. 1-naphthylacetic acid was the only identified residue accounting for a total of approx 36% TRR, around 8% present as free 1-naphthylacetic acid (0.002 mg/kg) and 28% as conjugates (0.009 mg/kg) in olives. The exact total application rates in the metabolism studies could not be determined but it was assumed that the studies would reflect the usual GAP in apples and were therefore conducted at approx normal rate (1N). Since they were present below the trigger value for significant residues as set out in current guidance, it was proposed to disregard the conjugated residues and to define the residue by default as free 1-naphthylacetic acid alone. It is noted this conclusion is only applicable to the evaluated representative uses in apple and may have to be reviewed for other uses. As for the necessity to comply with the scope of the analytical method for monitoring the residue definition should be specified as 1-naphthylacetic acid and its salts expressed as 1-naphthylacetic acid. The analytical method is unable to distinguish whether 1-naphthylacetic acid or the variant 1-naphthylacetic acid sodium was applied in accordance with the representative use pattern.

Four residue trials with 1-naphthylacetic acid conducted in Northern Europe in one growing season were submitted. Residues of 1-naphthylacetic acid were below the LOQ of the analytical method. However, it could not be demonstrated that the results of the residue field trials are reliable, since acceptable freezer storage stability data to confirm the validity of these results are not available. Apart from this deficiency, the use pattern for Northern Europe does not reflect the critical conditions for the representative uses in Southern Europe. Acceptable and eligible residue trials in apple according to critical GAP criteria are not available for either of the two applicants. Residue trials conducted in the USA and in Japan were considered not compliant with European practices and conditions. Hence data gaps were set for a freezer storage stability study, and for sufficient European residue trials analysed with a fully validated analytical method and covered by acceptable storage stability data. A submitted processing study in apples was not considered valid; however processing data are unlikely to be triggered following current guidance. Also residues in succeeding crops are not considered an issue in the orchard when 1-naphthylacetic acid is applied to apple as defined by the GAP.

When using the available but insufficient residue trial data in the assessment of livestock exposure and of residue levels in animal matrices, there is indication that significant residues are not expected to occur in food of animal origin; however this will need to be reassessed when sufficient acceptable residue trial data are available.

An MRL in apples was proposed at the LOQ of the analytical method used in the North-European residue trials of 0.05 mg/kg. When using the proposed MRL in a chronic and acute dietary risk assessment for consumers (EFSA PRIMo rev.2) the TMDI was below 1% of the ADI of 0.1 mg/kg bw/day and the IESTI was below 5% of the ARfD of 0.1 mg/kg bw. The MRL proposal and the consumer risk assessment will have to be revisited upon submission of residue trials conforming to critical GAP criteria (South-European use pattern).

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, 1-naphthylacetic acid exhibited low to moderate persistence. The available data on rate of degradation in soil however were derived from only 2 soils, of which both had a low organic matter content (0.4 – 1.43%). According to the current guideline, rate of degradation should be addressed in a minimum of 4 soils with organic matter content of 2 – 5%. No reliable information was available on the route of degradation of 1-NAA in soil. Therefore a data gap was identified during the peer review for information on the aerobic route of degradation (at least in one soil) and rate of degradation in at least 2 additional soils. Due to the data gap on the route of degradation in soil, no valid data on mineralisation or on the formation of unextractable residues were available. Ensuring that the route and rate of degradation are studied in a wide range of soil types, it is recommended that the additional studies are performed on soils with organic matter content higher than 2% and on pH different from the range of 6.2 – 6.4 that was used in the available soil incubations. Moreover, it is recommended that these additional studies are performed with radio-labelled molecule (preferable at the naphthalene moiety).

No acceptable studies were available for the degradation under anaerobic conditions in soil or for the photodegradation in soil. A data gap was therefore identified for information on the photolysis of 1-napthylacetic acid in soil.

1-naphthylacetic acid exhibited high to very high mobility in soil.

PEC_{soil} (Predicted environmental concentrations (PEC)) values for 1-naphthylacetic acid were calculated using the worst-case laboratory soil DT_{50}.

In laboratory incubations in dark aerobic natural sediment water systems, 1-naphthylacetic acid exhibited low persistence (SFO whole system DT_{50} 6.2-9.5 days). In these studies the mineralisation was the major sink accounting for 60 - 70% AR at the end of the study, while the unextractable fraction from the sediment accounted for a maximum of 24 - 27% AR. In a laboratory aqueous photolysis experiment, where four photodegradates were formed (1-naphthaldehyde, phthalic acid, PD-1[11], PD-3), the rate of decline of 1-naphthylacetic acid was faster than that which occurred in the aerobic sediment water studies.

The necessary surface water and sediment exposure assessments were carried out for 1-naphthylacetic acid using the FOCUS (FOCUS, 2001) step 1 and step 2 approaches. The results of these calculations can be found in Appendix A. The groundwater exposure assessments were carried out using FOCUS (FOCUS, 2000) scenarios and PEARL 3.3.3[12] model for 1-naphthylacetic acid considering the available data set. The potential for groundwater exposure from the representative use of the product 'Amcotone' above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all the 9 FOCUS groundwater scenarios. The potential for groundwater exposure from the representative uses of the products 'Fruitone N' and 'Obsthormon

[11] PD-1 consists of two different compounds as detailed in Appendix B.
[12] Simulations correctly utilised the agreed Q_{10} of 2.58 (EFSA, 2007), Walker equation coefficient of 0.7

24A' above the parametric drinking water limit of 0.1 µg/L was concluded to be high in a wide range of geoclimatic situations represented by the FOCUS groundwater scenarios. The number of FOCUS scenarios where the predicted concentration in the groundwater exceeded the parametric drinking water limit of 0.1 µg/L was 3 and 8 for the representative uses of 'Obsthormon 24A' and 'Fruitone N', respectively.

1-naphthylacetic acid has the potential for volatilization with an estimated atmospheric half-life shorter than 2 days. Therefore, long-range transport through the atmosphere is not expected. Volatilisation from plant surface and soil may be expected.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001).

The analytical profile of the batches used in the ecotoxicological studies was not available and a data gap was identified for the Amvac source.

The acute risk to insectivorous birds via dietary exposure was assessed as low at tier I for the representative uses. Short-term dietary and long-term toxicity studies with birds were not available in either the DAR or in the Additional Report. A weight-of-evidence approach is used to demonstrate that low short-term risks are expected with the uses of 1-naphthylacetic acid: the LD_{50} of 2051 mg/kg bw/day resulting from the dietary study with 1-naphthylacetic acid is far above 28.4 mg a.s./kg bw/day, which is the minimal LD_{50} value resulting in low short-term risks for insectivorous birds. The weight-of-evidence approach was enough to conclude on a low short-term risk to insectivorous birds. A data gap was identified for the submission of information to address the long-term risk to birds. The acute risk to mammals via dietary exposure was assessed as low at tier I. The long-term risk to mammals was assessed as low at tier II with refinement of RUD based on a realistic deposition factor and dissipation value. A risk assessment for earthworm-eating birds and mammals is not required since the $logP_{ow} < 3$. Additionally, the risk to birds and mammals from consumption of contaminated water was assessed as low.

1-naphthylacetic acid is toxic to aquatic organisms. The risk assessment was driven by the end points for the aquatic plant *Lemna gibba*. Toxicity tests were conducted on *Daphnia magna* and algae with the formulated product 'Obsthormon 24A'. Toxicity studies were submitted with the formulation 'Spollonante G' that is comparable with 'Obsthormon 24A'. There were no valid ecotoxicological studies on aquatic organisms with the formulations 'Amcotone' and 'Fruitone N'. Therefore, a data gap was identified for the submission of ecotoxicological studies to address the toxicity from the 'Amcotone' and 'Fruitone N' formulation to aquatic organisms. The risk to aquatic organisms from 1-naphthylacetic acid was assessed as low for the representative uses at $FOCUS_{sw}$ step 1. The risk from metabolites (1-naphthaldehyde, phthalic acid, PD-1 and PD-3) was assessed as low for aquatic organisms for the representative uses.

The risk to bees, non-target arthropods, earthworms, non-target soil micro-organisms, non-target plants and the function of waste water treatment plants was assessed as low for all representative uses.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil*)

Compound (name and/or code)	Persistence	Ecotoxicology
1-naphthylacetic acid (1-NAA)	Low – moderate persistence DT_{50}: 4.4 and 77 days (SFO, 20-25˚C, 40-60% MWHC soil moisture).	The acute risk of 1-naphthylacetic acid to earthworms was assessed as low

*) As the route of degradation in soils is not adequately described it is not possible to judge whether additional metabolites should be included in the residue definition.

6.2. Ground water*)

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
1-naphthylacetic acid (1-NAA)	High – very high mobility K_{Foc} 45 - 87 mL/g	The number of FOCUS scenarios exceeding the trigger values of 0.1 µg/L was 0, 3 and 8 for the representative uses of 'Amcotone', 'Obsthormon 24A' and 'Fruitone N' respectively.	Yes	Yes	Toxic to aquatic organisms, end point driving the aquatic risk assessment: aquatic plant EC_{50} fronds = 5.09 mg a.s./L (regulatory concentration including a safety factor of 10 = 0.509 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.

*) As the route of degradation in soils is not adequately described it is not possible to judge whether additional metabolites should be included in the residue definition.

6.3. Surface water and sediment*)

Compound (name and/or code)	Ecotoxicology
1-naphthylacetic acid (1-NAA)	Toxic to aquatic organisms, end point driving the aquatic risk assessment: aquatic plant EC_{50} fronds = 5.09 mg a.s./L (regulatory concentration including a safety factor of 10 = 0.509 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.
1–naphthaldehyde	No data available and no data required. A low risk to the aquatic environment was indicated in the surface water risk assessment, on the basis of the assumption of a 10-fold higher toxicity than the active substance.
phthalic acid	No data available and no data required. A low risk to the aquatic environment was indicated in the surface water risk assessment, on the basis of the assumption of a 10-fold higher toxicity than the active substance.
PD-1	No data available and no data required. A low risk to the aquatic environment was indicated in the surface water risk assessment, on the basis of the assumption of a 10-fold higher toxicity than the active substance.
PD-3	No data available and no data required. A low risk to the aquatic environment was indicated in the surface water risk assessment, on the basis of the assumption of a 10-fold higher toxicity than the active substance.

*) As the route of degradation in soils is not adequately described it is not possible to judge whether additional metabolites should be included in the residue definition.

6.4. Air

Compound (name and/or code)	Toxicology
1-naphthylacetic acid (1-NAA)	Not acutely toxic via inhalation

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Additional batch data and validated analytical methods for the determination of the active substance and impurities in the technical material (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 1).
- An updated technical specification (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 1).
- Melting, freezing or solidification point and solubility in organic solvents of 1-naphthylacetic acid (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 1).
- Determination of long-term storage stability for 'Amcotone' and 'Fruitone N' (relevant for the Amvac source; submission date proposed by the applicant: unknown (studies are in progress), see section 1).
- Shelf-life study for 'Obsthormon 24A' (relevant for the Task Force source; submission date proposed by the applicant: unknown, see section 1).
- Determination of the flash point, auto-flammability temperature, surface tension and density (relevant for the Task Force source; submission date proposed by the applicant: draft reports submitted and evaluated by the RMS, see section 1).
- Monitoring method for 1-naphthylacetic acid residues in the air (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown, see section 1).
- ILV of the residue method in plants (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown but study is ongoing, see section 1).
- The impurity content of 1-naphthylacetic acid ethyl ester batches used in the toxicological data package (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 2).
- Sufficient European residue trials analysed with a validated analytical method (relevant for all representative uses evaluated; submission date proposed by the applicants: Amvac: unknown; Task Force: non-eligible data submitted, not peer reviewed, see section 3).
- A freezer storage stability study (relevant for all representative uses evaluated; submission date proposed by the applicants: Amvac: unknown; Task Force: non-eligible interim report submitted, not peer reviewed, see section 3).
- Information on the aerobic route of degradation in at least one soil and rate of degradation in at least two additional soils. It is recommended that the additional studies are performed on soils with organic matter content higher than 2% and on pH different from the range of 6.2 – 6.4. It is also recommended that these additional studies are performed with radio-labelled molecule (preferable at the naphthalene moiety) (relevant for all representative uses evaluated; submission date proposed by the applicants: draft reports submitted and evaluated by the RMS, but not peer reviewed, see section 4).
- Information on photolysis of 1-naphthylacetic acid in soil (relevant for all representative uses evaluated; submission date proposed by the applicants: draft reports submitted and evaluated by the RMS, but not peer reviewed, see section 4).

- The analytical profile of the batches used in the ecotoxicological studies (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 5).
- Information to address the long-term risk to birds (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown, see section 5).
- Toxicity studies on aquatic organisms with the formulations 'Amcotone' and 'Fruitone N' (relevant for the 'Amcotone' and 'Fruitone N' use; submission date proposed by the applicants: unknown, see section 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Use of PPE (Coverall and gloves during all phases) for operators exposed to 'Fruitone N' and use of gloves for re-entry workers exposed to 'Fruitone N' and 'Obsthormon 24A' (see section 2).

ISSUES THAT COULD NOT BE FINALISED

- The technical specification for the Amvac source should be considered provisional.
- It was not possible to establish whether the batches tested from the Amvac source were in compliance with the proposed specification because the impurity content of the 1-naphthylacetic acid ethyl ester batches used in the toxicological and ecotoxicological data package needs to be clarified.
- The consumer risk assessment is not finalised since residue data are not available to address the use pattern that is expected to result in the most critical residue values.
- The route and rate of degradation in soil including the assessment of the potential for photolysis could not be finalised. Consequently, risk assessments for potentially formed metabolites have not been performed.
- The long-term risk to birds could not be assessed based on the available data.
- The risk to aquatic organisms from the exposure to the formulations 'Amcotone' and 'Fruitone N' could not be finalized based on the available data.

CRITICAL AREAS OF CONCERN

None

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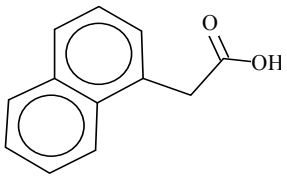
APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	1-naphthylacetic acid
Function (*e.g.* fungicide)	Plant growth regulator
Rapporteur Member State	France
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	1-naphthylacetic acid
Chemical name (CA) ‡	1-naphthaleneacetic acid
CIPAC No ‡	1-NAA: 313 1-NAA-Na: 313.011
CAS No ‡	1-NAA: 86-87-3 1-NAA-Na: 15165-79-4
EC No (EINECS or ELINCS) ‡	201-705-8
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	980 g/kg (Task Force) Open (Amvac)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	$C_{12}H_{10}O_2$
Molecular mass ‡	1-NAA: 186.2 g/mol 1-NAA-Na: 208.2 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	128-132°C (pure 1-NAA, 97.8%) 280.1-281.7°C (pure 1-NAA-Na, 99.1 %) 279.7°C (technical 1-NAA-Na, 97.7%)
Boiling point (state purity) ‡	322.3°C (pure 1-NAA, 97.8%)
Temperature of decomposition (state purity)	Starts to decompose at 360°C (pure 1-NAA-Na), at 340°C (Technical 1-NAA-Na)
Appearance (state purity) ‡	White powder with small lumps free from visible impurities (pure 1-NAA, 99.5%) White powder (pure 1-NAA-Na, 99.1%) Free flowing off white powder (technical 1-NAA-Na, 97.7%)
Vapour pressure (state temperature, state purity) ‡	Vp = $1.27.10^{-3}$ Pa at 20°C (pure 1-NAA, 99.5%) Vp = $6.12.10^{-4}$ Pa at 25°C (pure 1-NAA, 99.5%) Vp<2.10^{-4} Pa at 25°C (pure 1-NAA-Na, 99.1%)
Henry's law constant ‡	H= $3.03.10^{-4}$ Pa m^3 mol^{-1} (pure 1-NAA, 99.5%) at 20°C and pH 7 H = $1.26.10^{-7}$ Pa m^3 mol^{-1} at 20°C and pH 10.80 (Pure and technical 1-NAA-Na)
Solubility in water (state temperature, state purity and pH) ‡	For pure 1-NAA (99.5%): At pH 4, Ws= 584.2 ± 70.6 mg/L at 20°C At pH 7, Ws= 375.7 ± 16.8 mg/L at 20°C At pH 9, Ws= 525.8 ± 24.2 mg/L at 20°C For pure 1-NAA-Na (99.1%) At pH 10.8, Ws= 295.5 g/L at 20°C

Solubility in organic solvents ‡
(state temperature, state purity)

Pure 1-NAA (99.5%)

Solvent	**Solubility (g/L)**
heptane	0.588 ± 0.062
p-xylene	24.34 ± 0.85
1,2-dichloro-ethane	133.0 ± 10.4
methanol	> 250
acetone	> 250
ethyl acetate	181.3 ± 2.3

Pure 1-NAA-Na (99.1%):

Solvent	**Solubility (10^{-3}g/L)**
heptane	0.15 ± 0.04
p-xylene	0.36 ± 0.04
1,2-dichloromethane	7.03 ± 1.16
methanol	274.1± 10.3 **(g/L)**
acetone	31.57± 4.24
ethyl acetate	133.7 ± 5.07

Technical 1-NAA-Na (97.7%):

Solvent	**Solubility (g/L)**
heptane	<10
p-xylene	<10
1,2-dichloroethane	<10
methanol	409-511
acetone	<10
ethyl acetate	<10

Surface tension ‡
(state concentration and temperature, state purity)

35.9 mN/m at 25°C

39.5 mN/m at 40°C (90 % saturated solution)

Partition co-efficient ‡
(state temperature, pH and purity)

Pure 1-NAA (97.8%), shake flasks method:

Log $P_{O/W}$ = 2.24 at pH 3

Log $P_{O/W}$ = -0.02 ± 0.02 at pH 7

Log $P_{O/W}$ = 0.32 ± 0.03 at pH 9

Pure 1-NAA-Na (99.1%), HPLC method:

Log $P_{O/W}$ = 4.11 at pH 3

Dissociation constant (state purity) ‡

pKa = 4.23 at 20°C (calculation)

pKa= 4.02 at 25°C (titration method on pure 1-NAA-Na [99.1%])

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Pure 1-NAA (97.8%): λ_{max} = 223 nm; ε = 72500 L.mol^{-1}.cm^{-1} (acid pH) λ_{max} = 223 nm; ε = 79600 L.mol^{-1}.cm^{-1} (neutral pH) λ_{max} = 282 nm; ε = 7020 L.mol^{-1}.cm^{-1} (basic pH) Pure 1-NAA-Na (99.1%): λ_{max} = 222 nm; ε = 183135 L.mol^{-1}.cm^{-1} (pH 1.71) λ_{max} = 223 nm; ε = 76956 L.mol^{-1}.cm^{-1} (pH 5.30) λ_{max} = 223 nm; ε = 70495 L.mol^{-1}.cm^{-1} (pH 11.97)
Flammability ‡ (state purity)	Not highly flammable (pure 1-NAA, 97.8%)
Explosive properties ‡ (state purity)	Not explosive
Oxidising properties ‡ (state purity)	No oxidising properties

Summary of representative uses evaluated (1-NAA)*

	Crop and/or situation (a)	Member State	Product name	F G I (b)	Use (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
						Type (d-f)	Conc of a.s. g/kg (i)	method kind (f-h)	growth stage and season (j)	number min max (k)	interval between applications (min)	g a.s./hl min max	water l/ha min max	g a.s./ha min max (*)		
Amvac	Apple	Spain	Amcotone	F	PGR Preharvest fruit drop control	WP	4.5 g/kg 1-NAA acid 12 g/kg 1-NAD	High volume sprayer	Petal fall , approx. 10 days after full bloom	1 to 2	6-10 days	0.27 1-NAA acid/, 0.72 1-NAD	800-1000	2.7 1-NAA acid/, 7.2 1-NAD	30	[1] [2] [3] [4] [5]
	Apple	Spain	Fruitone N	F	PGR Preharvest fruit drop control	WP	35 g/kg 1-NAA-Na (equiv. 31.3 g/kg 1-NAA acid)	High volume sprayer	Up to 2 weeks prior to harvest	1 to 2	5 days	2.0-4.2 1-NAA acid (2.3-4.7 1-NAA-Na)	400-2000	8.2-84 1-NAA acid (9.2-94 1-NAA-Na)	2	[1] [2] [3] [4] [5]
Task Force	Apple	North EU	Obsthormon 24A	F	PGR Preharvest fruit drop control	SL	84 g/l 1-NAA acid	High volume sprayer	BBCH 81-87 summer fall	2	1-2 weeks	1.5	1000	1-NAA acid 15	7	[2] [3] [4]
	Apple	South EU	Obsthormon 24A	F	PGR Preharvest fruit drop control	SL	84 g/l 1-NAA acid	High volume sprayer	BBCH 81-87 summer fall	2	1-2 weeks	3	1000	1-NAA acid 30	7	[2] [3] [4]

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

[1] It was not possible to establish whether the batches tested in the mammalian toxicology and ecotoxicology studies from the Amvac source were in compliance with the proposed specification

[2] The route and rate of degradation in soil including the assessment of the potential for photolysis could not be finalised. Consequently, risk assessments have not been performed for potentially formed soil metabolites.

[3] The consumer risk assessment is not finalised since residue data are not available to address the use pattern that is expected to result in the most critical residue values.

[4] The long-term risk for birds could not be assessed with the available data.

[5] The risk of the formulations 'Amcotone' and 'Fruitone N' to aquatic organisms could not be addressed with the available data.

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Task Force: HPLC-UV Amvac: data gap	
Impurities in technical as (analytical technique)	Task Force	Gobbi: HPLC-UV Nufarm: HPLC-UV
	Amvac	data gap
Plant protection product (analytical technique)	Task Force	Obsthormon 24A: HPLC-DAD
	Amvac	Amcotone: HPLC-DAD Fruitone N: HPLC-DAD

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		1-NAA and its salts expressed as 1-NAA
Food of animal origin		-
Soil		1-NAA
Water	surface	1-NAA
	drinking/ground	1-NAA
Air		1-NAA

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-UV, LOQ = 0.04 mg/kg (1-NAA in apples) ILV required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	HPLC-fluorescence detection, LOQ = 0.011 mg/kg
Water (analytical technique and LOQ)	HPLC-fluorescence detection, LOQ = 0.1 µg/L in drinking water, groundwater and surface water
Air (analytical technique and LOQ)	Data gap
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

	1-NAA	1-NAD
Rate and extent of oral absorption ‡	Oral absorption: 70% Rats At 1 mg/kg: > 80% based on urinary excretion (24h) At 100 mg/kg: 74% based on urinary excretion (24h) At 250 mg/kg: 77% based on urinary excretion (24h) Man At 5 mg/man: 90% based on urinary excretion (48 h).	Oral absorption: 70% Rats At 1 mg/kg: 70% based on urinary excretion (24 h) At 100 mg/kg: 65% based on urinary excretion (24h) T_{max} = 1 hour, AUC 350 µg/ml/h (males) and 305 µg/ml/h (females)
Distribution ‡	Rats Highest residues levels found in liver and kidney (following oral treatment with 1-NAA-Ethyl ester)	Rats Highest residues levels found in liver, kidney, renal fat and carcass but remained low
Potential for accumulation ‡	Rats: no bioaccumulation potential	Rats: no bioaccumulation potential
Rate and extent of excretion ‡	Rats: At 100 mg/kg: 90% at 48 h mainly via urine (≅ 70%)	Rats: At 100 mg/kg: 90% at 48 h mainly via urine (≅ 70%) At 500 mg/kg bw/day: 3 to 14 % of the parent compound found in faeces
Metabolism in animals ‡	Rats: Conjugation with glycine after a low dose administration and to glucuronic acid at high dose (1-NAA). Ester cleavage followed by glycine and glucuronide conjugation at the low and repeated doses and glucuronide conjugation at the high dose (1-NAA-Et). Formation of hydroxy-NAA isomers (1-NAA and 1-NAA-Et)	Rats: Amide cleavage followed mainly by glycine conjugation at low dose and glucuronide conjugation at high dose. Hydroxylation of the naphthalene ring is an additional route of metabolism and several hydroxy-NAA isomers and dihydrodiol metabolite were formed.
Toxicologically relevant compounds ‡ (animals and plants)	Parent	Parent
Toxicologically relevant compounds ‡ (environment)	Parent	Parent

Acute toxicity (Annex IIA, point 5.2)

	1-NAA	1-NAD
Rat LD_{50} oral ‡	1750 mg/kg bw (1-NAA), 933 mg/kg bw/day (1-NAA-Na)	1655 mg/kg bw (males)
Rat LD_{50} dermal ‡	> 2000 mg/kg bw/day (1-NAA and 1-NAA-Na)	> 2000 mg/kg bw/day
Rat LC_{50} inhalation ‡	> 0.45 mg/l (1-NAA, whole body), > 5.0 mg/l (1-NAA-Na, nose-only)	> 2.17 mg/l (whole body)
Skin irritation ‡	Not irritant (1-NAA and 1-NAA-Na)	Not irritant
Eye irritation ‡	Irritant (1-NAA and 1-NAA-Na)	Irritant
Skin sensitisation ‡	1-NAA: not sensitizer (LLNA) 1-NAA-Na: not sensitizer (M&K)	Not sensitizer (M&K)

Short term toxicity (Annex IIA, point 5.3)

	1-NAA	1-NAD
Target / critical effect ‡	Rats: - ↓ RBC counts, haemoglobulin and hematocrit, ↑ alaninoaminotransferase and alkaline phosphatase; ↑ liver and kidney organ weights, hepatocellular hypertrophy (1-NAA) - ↓ erythrocytes counts, hematocrit, hemoglobin, and platelet counts, ↑ liver and kidney organs weights, hepatocellular hypertrophy and vacuolation of periportal hepatocytes (1-NAA-Na) Dog: -Congestive pericholangitis, toxic degeneration of hepatocytes, centrilobular necrosis, periportal fibrosis, hepatocellular hypertrophy and development of a hyperplastic nodule in one dog (1-NAA) - ↑ transaminases, ↑ liver weights, lesions in the gastrointestinal tract (ulcerative duodenitis and erosive gastritis), hypocellularity of the bone marrow, sinusoidal histiocytosis in the liver (1-NAA-Na). Mice: ↓ platelets counts; ↑ liver and kidney organs weights without histopathology injuries (1-NAA-Na)	Rats: ↑ liver and kidney weight, centrilobular hepatocellular hypertrophy, foci of mineralization of Peyers' patches and/or mucosa of the small and large intestine and large intestine dilatation Dog: ↓ erythrocytes, haemoglobin and haematocrit ; Haemolysis; ↑ haematopoiesis; ↑ liver weight (F); pigment accumulation in liver and spleen
Relevant oral NOAEL ‡	90-day, rat: 10 mg/kg bw/day (1-NAA)	90-day, rat: 5 mg/kg bw/day
Relevant dermal NOAEL ‡	21-day, Rat: 1000 mg/kg bw/day	21-day, Rat: 300 mg/kg bw/day
Relevant inhalation NOAEL ‡	No data. Not required.	No data. Not required.

Genotoxicity ‡ (Annex IIA, point 5.4)

1-NAA	1-NAD
Devoid of genotoxic potential	Devoid of genotoxic potential

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

	1-NAA	1-NAD
Target/critical effect ‡	1-NAA-Na Rats : - ↑ relative liver and kidney weights, ↑ incidence of minimal to slight periportal hepatocellular vacuolar change and a slight increase in the incidence and severity of dilated mucosal glands of the stomach. - Focal alveolar macrophage accumulations (female) Mice: - ↑ liver and kidney weight; hepatocytes vacuolation and inflammation; minor kidney inflammation; - Bilateral tubular degeneration in testis and ↓ spermatozoa in epididymis.	No data available with 1-NAD. Bridging from studies performed with 1-NAA-Na.
Relevant NOAEL ‡	2-year, rat, 43.8 mg/kg bw/day of 1-NAA-Na, equivalent to 39.17 mg/kg bw/day of 1-NAA (males)	
Carcinogenicity ‡	No carcinogenic potential (1-NAA-Na)	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

	1-NAA	1-NAD
Reproduction target / critical effect ‡	Rats: - Parental toxicity: decreased body weight and food consumption (1-NAA and 1-NAA-Na) - Decreased pup survival and mean pup weight at parental toxic dose (1-NAA-Na)	No data available with 1-NAD. Bridging from studies performed with 1-NAA and 1-NAA-Na.
Relevant parental NOAEL ‡	- 69 mg/kg bw/day in males and 81 mg/kg in females bw/day of 1-NAA-Na, equivalent to 62 and 72 mg/kg bw/day of 1-NAA, respectively	
Relevant reproductive NOAEL ‡	-210 mg/kg/day for males and 239 mg/kg/day for females, equivalent to 188 and 205 mg/kg bw/day of 1-NAA, respectively	

Relevant offspring NOAEL ‡	-69 mg/kg bw/day in males and 81 mg/kg bw/day of 1-NAA-Na, equivalent to 62 and 72 mg/kg bw/day of 1-NAA, respectively,	

Developmental toxicity

	1-NAA	1-NAD
Developmental target / critical effect ‡	Rats: - Malformation on sternum ; - Minor skeletal defects (cervical ribs; cervical arch 7 cartilage fused to arch 6 cartilage) and interparietal incomplete ossification (1-NAA-Na). Rabbits: - Slight reduction in mean total implantations; slight reduction in mean viable fetuses (1-NAA) - Majors defects (cleft palate and stiffened jaw); minor skeletal defects and variants (supernumerary thoracolumbar ribs and vertebra), 1-NAA-Na.	Rats - Increased incidence of small foetuses and skeletal foetal variants (cervical ribs) - Visceral malformation, omphalocele Rabbits - Minor skeletal anomalies (13th extraribs and extra lumbar vertebrae)
Relevant maternal NOAEL ‡	Rats: 150 mg/kg bw/day (1-NAA-Na) Rabbit: 100 mg/kg bw/day (1-NAA-Na)	Rats: 10 mg/kg bw/day Rabbit: 100 mg/kg bw/day
Relevant developmental NOAEL ‡	Rats: 15 mg/kg bw/day (1-NAA-Na) Rabbit: 30 mg/kg bw/day (LOAEL, 1-NAA-Na)	NOAEL: Rats: 10 mg/kg bw/day Rabbit: 20 mg/kg bw/day

Acute neurotoxicity ‡	Not required
Repeated neurotoxicity ‡	Not required
Delayed neurotoxicity ‡	Not required

Other toxicological studies (Annex IIA, point 5.8)

1-NAA and 1-NAD

Mechanism studies ‡	Not required
Studies performed on metabolites or impurities ‡	No available data

Medical data ‡ (Annex IIA, point 5.9)

1-NAA and 1-NAD

No evidence of toxicological concern from medical surveillance of manufacturing plant personnel

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
1-NAA and 1-NAD			
ADI ‡	0.10 mg/kg bw/day	Developmental study in rat, supported by 90-day study in rat and 1-year study in dog	150
AOEL ‡	0.07 mg/kg bw/day	Developmental study in rat, supported by 90-day study in rat and 1-year study in dog	150 70% oral absorption correction
ARfD ‡	0.10 mg/kg bw	Developmental study in rat, supported by 90-day study in rat and 1-year study in dog	150

Dermal absorption ‡ (Annex IIIA, point 7.3)

1-NAA	
FRUITONE N OBSTHORMON 24A AMCOTONE	70% (default value)
1-NAD	
AMID THIN W (8.2% 1-NAD WP (from Task Force))	1% (non diluted product) 21% (diluted product)
AMCOTONE (1.2% 1-NAD WP) AMID-THIN W (8.2% 1-NAD WP (from Amvac))	70% (default value)

Exposure scenarios (Annex IIIA, point 7.2)

<table>
<tr><th></th><th>1-NAA</th><th>1-NAD</th></tr>
<tr><td>Operator</td><td>
<u>AMCOTONE (0.45% 1-NAA + 1.2% 1-NAD) (calculations not peer reviewed)</u>
BBA and UK POEM models
<table>
<tr><th>Apples, application rate 2.7 g 1-NAA acid/ha</th></tr>
<tr><td>Tractor mounted equipment</td></tr>
<tr><td><u>Without PPE:</u>
6.3% of AOEL (German BBA)
9.2% of AOEL (UK POEM)</td></tr>
</table>
<u>FRUITONE N</u>
BBA model
<table>
<tr><th>Apples, application rate 94 g 1-NAA-Na/ha</th></tr>
<tr><td>Tractor mounted equipment</td></tr>
<tr><td><u>With PPE:</u>
20% of AOEL (BBA, gloves, coverall, M/L & application)
158% of AOEL (UK POEM, gloves, M/L & application)</td></tr>
</table>
<u>OBSTHORMON 24A</u>
BBA and UK POEM models
<table>
<tr><th>Apples, application rate 30 g 1-NAA acid/ha (South EU, worst case)</th></tr>
<tr><td>Tractor mounted equipment</td></tr>
<tr><td><u>Without PPE :</u>
48% of AOEL (German BBA),
<u>With PPE:</u>
47% of AOEL (UK POEM, Gloves M/L & application)</td></tr>
</table>
</td><td>
<u>AMCOTONE (0.45% 1-NAA + 1.2% 1-NAD) (calculations not peer reviewed)</u>
BBA and UK POEM models
<table>
<tr><th>Apples, application rate 7.2 g a.s./ha</th></tr>
<tr><td>Tractor mounted equipment</td></tr>
<tr><td><u>Without PPE:</u>
17% of AOEL (German BBA)
41% of AOEL (UK POEM)</td></tr>
</table>
<u>AMID THIN W (Task Force)</u>
BBA and UK POEM models
<table>
<tr><th colspan="2">Apples, application rate 80 g a.s./ha</th></tr>
<tr><td>Tractor mounted equipment</td><td>High crop hand held</td></tr>
<tr><td><u>Without PPE :</u>
33% AOEL (German BBA),
84% AOEL (UK POEM)</td><td><u>Without PPE:</u>
16.5% AOEL (BBA)</td></tr>
</table>
<u>AMID THIN W (AMVAC):</u>
BBA and UK POEM models
<table>
<tr><th colspan="2">Apples, application rate 50 g a.s./ha</th></tr>
<tr><td>Tractor mounted equipment</td><td>High crop hand held</td></tr>
<tr><td><u>With PPE :</u>
67% AOEL (BBA, Gloves M/L)
85% AOEL (UK POEM, Gloves M/L & application)</td><td><u>Without PPE:</u>
66% of AOEL (BBA)</td></tr>
</table>
</td></tr>
<tr><td>Workers</td><td>
<u>AMCOTONE</u>
11 % of AOEL (without PPE; calculations not peer reviewed)

<u>FRUITONE N</u>
Without PPE: 376 % of AOEL
With PPE: 37% of AOEL (gloves)

<u>OBSTHORMON 24A</u>
Without PPE: 120 % of AOEL
With PPE: 12% of AOEL (gloves)
</td><td>
<u>AMCOTONE</u>
29 % of AOEL (without PPE; calculations not peer reviewed)

<u>AMID THIN W (Task Force):</u>
Without PPE: 4.6% of AOEL

<u>AMID THIN W (AMVAC):</u>
Without PPE: 202% of AOEL
With PPE: 20% of AOEL (gloves)
</td></tr>
</table>

Bystanders	**AMCOTONE** 0.38% AOEL (**calculations not peer reviewed**) **FRUITONE N** 13 % of AOEL **OBSTHORMON 24A** 4.2 % of AOEL	**AMCOTONE** 1% AOEL (**calculations not peer reviewed**) **AMID THIN W (Task Force)** 3% of AOEL **AMID THIN W (AMVAC)** 7% of AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal	
Substance classified (name)	Active substance: 1-NAA **Xn** "Harmful" **R22** "Harmful if swallowed" **R41** "Risk of serious damage to eyes" **Repr. Cat 3. R63** "Possible risk of harm to the unborn child"	Active substance: 1-NAD **Xn** "Harmful" **R22** "Harmful if swallowed" **R41** "Risk of serious damage to eyes" **Repr. Cat 3. R63** "Possible risk of harm to the unborn child"

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruits (apple)
Rotational crops	Not applicable
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No study submitted
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No study submitted
Plant residue definition for monitoring	1-NAA and its salts expressed as 1-NAA
Plant residue definition for risk assessment	1-NAA and its salts expressed as 1-NAA
Conversion factor (monitoring to risk assessment)	None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Ruminants
Time needed to reach a plateau concentration in milk and eggs	No plateau observed
Animal residue definition for monitoring	None set
Animal residue definition for risk assessment	None set
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not relevant

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

On going study on apples (data gap)

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Open[13]	Not relevant	Not relevant

[13] to be reassessed when sufficient acceptable residue trial data are available

Potential for accumulation (yes/no):	No data provided to address this point	Not relevant	Not relevant
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Unlikely to occur	Not relevant	Not relevant
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	No study	Not relevant	Not relevant
Liver	No study	Not relevant	Not relevant
Kidney	No study	Not relevant	Not relevant
Fat	No study	Not relevant	Not relevant
Milk	No study		
Eggs		Not relevant	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Apple (Amcotone)	S	Acceptable data not available (data gap)				
Apple (Fruitone N)	S	Acceptable data not available (data gap)	cGAP			
Apple (Obsthormon 24A)	N	4 x <0.05	Residue trials results not supported by valid and eligible freezer storage stability data (data gap)	0.05*	0.05	0.05
	S	Data non-eligible for peer review (data gap)				

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

* MRL set at the limit of quantification of the analytical method used in the residue trials.

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.1 mg/kg bw/day
TMDI (% ADI) according to the EFSA PRIMo model rev. 2_0	DE child: <1% (provisional estimate)
ARfD	0.1 mg/kg bw
IESTI (% ARfD) according to the EFSA PRIMo model rev. 2_0	UK infant: <5% (provisional estimate)

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Apple/ apple juice	No acceptable study provided	-	Not relevant	No study
Apple/ apple pomace	No acceptable study provided	-	Not relevant	No study

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Apple	0.05 mg/kg [14]

[14] to be reassessed when sufficient acceptable residue trial data are available

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	No valid study on the route of degradation is available – data gap
Non-extractable residues after 100 days ‡	No valid study on the route of degradation is available – data gap
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No valid study on the route of degradation is available – data gap

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	No data provided – not required
Soil photolysis ‡	No data provided – data gap

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	OM %	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	1.43	6.4	25°C / 40-60%	4.4 / 14.7	6.4*	0.97	SFO
Loamy sand	0.4	6.2	20°C / 44%	77 / 257	77	0.99	SFO

* Value normalized only for temperature

Field studies ‡

No data provided

pH dependence ‡ (yes / no) (if yes type of dependence)	Not assessed
Soil accumulation and plateau concentration ‡	No data provided

Laboratory studies ‡

Parent / Metabolite	Anaerobic conditions
No data provided – Not required for the representative uses	

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent (1-NAA) ‡							
Soil Type	OC %	Soil pH (H_2O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.1 (Sand)	0.59	6.9	0.43	72.12	0.31	52.38	0.841
Speyer 2.2 (Loamy sand)	2.27	6.8	1.05	46.12	1.01	44.65	0.864
Cranfield 164 (Silt loam)	2.0	7.2	2.72	138.03	1.731	86.53	0.822
Arithmetic mean/median						61.2	0.842
pH dependence, Yes or No			no				

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data provided - Not required
Aged residues leaching ‡	An indicative study indicates that aged residues of 1-NAA do not leach in significant amount (0.35 % of AR in the leachate A and 0.21 % of AR in the leachate B).
Lysimeter/ field leaching studies ‡	No data provided

PEC (soil) (Annex IIIA, point 9.1.3)

Parent (1-NAA)	PEC calculations have been derived using the worst case soil DT_{50} from lab.: 77 days (SFO kinetics)
Method of calculation	
Application data	Crop: apples Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 80 % for Obsthormon 24A and for Fruitone N and 65 % for Amcotone Number of applications: 2* Interval (d): 0 (worst case*) Application rates: 30 g 1-NAA acid/ha for Obsthormon 24A; 9.9** g as/ha for Amcotone and 94 g 1-NAA-Na/ha for Fruitone N

* Calculation was carried out using a unique load of product instead of two applications to derive worst case initial concentration
** sum of 1-NAA and 1-NAD as a worst case

Initial $PEC_{(s)}$ (mg/kg)	Multiple application (modelled as a single application) Actual
Obsthormon 24A	0.016
Amcotone	0.009
Fruitone N	0.05*
Plateau concentration	Not provided

* PECsoil is calculated for the application of sodium salt of 1-NAA. To express PEC as 1-NAA the reported PEC should be multiplied by 0.89

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	1-NAA is hydrolytically stable at 50°C and pH 4, 7 and 9
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} of 1-NAA: 1.6-2.9 d (equivalent to US solar days at 40°N, year-round average) A number of metabolites were identified under different incubation conditions: 1-naphthaldehyde (max. 17.5% at pH 7), phthalic acid (max. 12.7% at pH 9, 10.4% in natural water; note: preliminary results of an other study indicated maximum observed formation of 14.4%) PD-1 (max. 15.6% in natural water, consists of two components) PD-3 (max. 13.3% in natural water)
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.00131
Readily biodegradable ‡ (yes/no)	Substance not ready biodegradable

Degradation in water / sediment

Parent	Distribution: max. in water 98% after 0 d.; max. sed 21.3 % after 6 d									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water (dissipation)	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Lake (water / sediment system)	7.53	8.1	20	6.2 d-20.7 d	0.978	4.7 d-15.5 d	0.988	-	-	SFO
Pool (water / sediment system)	8.41	8.0	20	9.5 d-31.6 d	0.936	7.0 d-23.4 d	0.968	-	-	SFO

Mineralization and non extractable residues				
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d (end of the study)
Lake	7.53	8.1	60 % of AR at the end of the study (at day 104)	24.1 % of AR after 30 days
Pool	8.41	8.0	70 % of AR at the end of the study (at day 104)	27.2 % of AR after 30 days

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent Parameters used in FOCUSsw step 1 and 2	FOCUS calculator : FOCUS Step 1-2 version 1.1 Molecular weight (g/mol) : 186.2 Water solubility (mg/L): 376 K_{fOC} (L/kg): 61.18 DT_{50} soil (d)*: 3 days (step 1) and 18.4 days (Step 2) DT_{50} water/sediment system (d): 9.5 days DT_{50} water (d): 7 days

	DT_{50} sediment (d): 1000 days (default value)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop : pome / stone fruit Obsthormon 24A: Crop interception: full canopy (crop interception as defined in FOCUS STEPS 1/2 tool; corresponding to 70% based on FOCUS (2001)) Number of applications: 2 Interval (d): 7 Application rate(s): 30 g 1-NAA acid/ha in South 15 g 1-NAA acid/ha in North Application window: June to September. Fruitone N, worst case compared to Amcotone: Crop interception: full canopy (70%) Number of applications: 2 Interval (d): 14 Application rate(s): 94 g 1-NAA-Na/ha Application window: June to September (season application as defined in FOCUS STEPS 1/2 tool)

*The DT_{50} soil used in the PECsw calculations differ from the final endpoint. Additional calculations were performed with worst case soil DT_{50} value of 77 days (being the final endpoint for PEC calculation); it has rationally no impact on initial PECsw in FOCUS step 1 and step 2 calculations.

1-NAA as Obsthormon 24A:

Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
FOCUS step 1 Southern Europe (worst case)	0 h	24.33	-	11.31	-
FOCUS step 2 Southern Europe (worst case)	0 h	3.80	-	2.28	

1-NAA as Fruitone N, worst case compared to Amcotone:

Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
FOCUS step 1	0 h	76.23*		35.44*	-
FOCUS step 2	0 h	6.69*		4.07*	

*: PEC_{sw} and PEC_{SED} are calculated for the application of sodium salt of 1-NAA. To express PEC as 1-NAA acid the reported PEC should be multiplied by 0.89.

As four major metabolites were characterized in the photolysis study, initial PEC_{SW} values were calculated by the RMS, multiplying initial PEC (FOCUS step 1) of the parent compound with the max. weight proportion observed in the study:

	Max. formation (% AR)	PEC_{SW} (µg/l) Obsthormon 24A	PEC_{SW} (µg/l) Fruitone N, Amcotone
1–naphthaldehyde	17.5	4.26	11.87
Phthalic acid	14.4	3.50	9.77
PD1	15.6	3.80	10.58
PD3	13.3	3.24	9.02

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Model: FOCUS Pearl v3.3.3 Active substance: 1-NAA Molecular mass: 186.2 g/mol Vapour pressure: 6.12 x 10^{-4} Pa Solubility: 376 mg/L $K_{fOC:}$ 61.5 mL/g (the correct value is 61.2 mL/g) Freundlich constant: 0.842 DT_{50} in soil: 77 days Q_{10} / Moisture exponent: 2.58 / 0.7 Plant uptake: 0

Agronomic parameters used for simulations of the three representative uses

	Amcotone (Amvac)	**Fruitone N (Amvac)**	**Obsthormon 24A (Task Force)**
Crop	Apples	Apples	Apples
Application Rate	2 x 9.9 g a.s./ha [1)]	2 x 94 g a.s. in salt form/ha	2 x 30 g a.s./ha
Interception	65% (BBCH 65-70)	80% (BBCH 81-87)	80% (BBCH 81 - 87)
Application dates	15 May, 1 June	15 Aug, 1 Sept	15 Aug, 1 Sept
Dose rate applied to soil in PEARL modelling	0.003465 kg/ha (9.9x0.35/1000)	0.0167 kg/ha (94x186.2/209.2*x0.2/1000)	0.006 kg/ha 30x0.2/1000

[1)] sum of 1-NAA and 1-NAD as a worst case,
* Correction factor as the application rate of 94 g a.s. /ha refers to sodium salt of 1-NAA.

80th percentile annual average concentration of 1-naphthylacetic acid (1-NAA) using FOCUS Pearl v3.3.3

Scenario	**1-NAA as Amcotone (Amvac)** µg/L	**1-NAA as Fruitone N (Amvac)** µg/L	**1-NAA as Obsthormon 24A (Task Force)** µg/L
Châteaudun	0.0316	0.3507	0.0788
Hamburg	0.0392	0.5360	0.1215
Jokioinen	0.0081	0.1773	0.0324
Kremsmünster	0.0248	0.3154	0.0687
Okehampton	0.0293	0.3940	0.0887
Piacenza	0.0623	0.6740	0.1795
Porto	0.0000	0.0047	0.0003
Sevilla	0.0166	0.1557	0.0340
Thiva	0.0227	0.2510	0.662

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	No data available, not required
Quantum yield of direct phototransformation	No data available, not required
Photochemical oxidative degradation in air ‡	Atkinson half-life of 0.289 days for reaction with

	OH radicals ($1.5x10^6$ OH/cm^3) assuming 12 hours of sunlight
Volatilisation ‡	From soil: No data available, not required
	From plants: 30% loss of applied radioactivity in 24 hours
Metabolites	No data available, not required

PEC (air)

Method of calculation	Vp = 6.12 x 10^{-4} Pa at 25°C Henry's law constant = 3.03*10^{-4} Pa.m^3 mol^{-1} at 20°C Volatilisation from plant surface and soil may be expected. However the potential for long-term transport is low due to the short half-life in air (estimated DT_{50}: 0.289 d).

PEC(a)

Maximum concentration	Not calculated.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Soil*: 1-NAA Surface Water*: 1-NAA, 1-naphthaldehyde, phthalic acid, PD-1 and PD-3 Sediment*: 1-NAA Ground water*: 1-NAA Air: 1-NAA * As the route of degradation in soils is not adequately described it is not possible to judge whether additional metabolites should be included in the residue definition.

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

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Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail.	a.s.	Acute	> 2510	-
	a.s.	Short-term	-	-
	a.s.	Long-term	-	-
Mammals ‡				
rat	1-NAA-Na	Acute	933 mg/kg bw/day (females)[1]	-
rat	Fruitone N	Acute	> 10000	-
rat	Obsthormon 24A	Acute	> 2000	-
rat	Late Val	Acute	> 2000	-
rat	1-NAA-Na	Long-term	15 mg/kg bw/day[1] (maternal[2] and developmental)	-
Additional higher tier studies ‡				
Study ongoing: Determination of residue levels of 1-NAA on/in non-target arthropods in the laboratory after one application with 1-NAA formulation				

[1] corresponding to NOAEL = 13.4 mg/kg bw/day in terms of 1-NAA (acid form)
[2] this end point comes from a teratology study with rats (1-NAA NA).

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Worst-case exposure scenario of 2 applications of Fruitone N at 94 g 1-NAA-Na/ha with 5 days interval

Indicator species/Category	Time scale	ETE[2]	TER	Annex VI Trigger
Tier 1 (Birds)				
	Acute	5.08	> 494	10
	Short-term	2.84	-[1]	10
	Long-term	2.84	-	5
Tier 1 (Mammals)				
	Acute	15.55	49	10
	Long-term	5.4	**2.48**	5
Tier 2 (Mammals)				
	Long-term	1.20 - 4.30	**3.08 -** 11.2	5
	Refinement of RUD based on realistic deposition factor and dissipation value. Calculations of TER for DT_{50} of 10 days (default value) and 1.4 days (measured value not fully reliable).			

[1] A weight-of-evidence approach is used to demonstrate that low short-term risks are expected with the uses of 1-NAA: the LD_{50} of 2051 mg a.s./kg bw resulting from the dietary study with 1-NAA (bobwhite quail Fink, 1976a) is far above 28.4 mg a.s./kg bw/day, which is the minimal LD_{50} value resulting in low short-term risks for insectivorous birds.
[2] ETE is calculated for the application of sodium salt of 1-NAA. To express ETE as 1-NAA acid the reported ETE should be multiplied by 0.89.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡				
Fish				
Cyprinus carpio	1-NAA	96 hr (static)	Mortality, EC_{50}	> 56 < 100 (nom)
	1-NAA-Na	96 hr (static)	Mortality, EC_{50}	> 82[1] (nom)
Onchorhynchus mykiss	1-NAA	96 hr (static)	Mortality, EC_{50}	75 (nom)
	Spollonante G	96 hr (static)	Mortality, EC_{50}	37 (nom) ²
	1-NAA	28 d (semi-static)	Growth, NOEC	10 (nom)
Aquatic invertebrate				
Daphnia magna	1-NAA	48 h (static)	Mortality, EC_{50}	> 56 < 100 (nom)
	1-NAA-Na	48 h (static)	Mortality, EC_{50}	> 82[1] (nom)
	1-NAA	21 d (semi-static)	Reproduction, NOEC	22 (nom)
	Spollonante G	48 h (static)	Mortality, EC_{50}	> 100 (mm)²
Sediment-dwelling organisms				
Indicate species.	a.s.	28 d (static)	NOEC	Not required
Algae				
Pseudokirchneriella subcapitata (formerly *Selenastrum capricornutum*)	1-NAA	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	47 (nom) > 100 (nom)
Anabaena flos-aquae	1-NAA	120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	35 78
Pseudokirchneriella subcapitata (formerly *Selenastrum capricornutum*)	1-NAA-Na	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	18.05[1] (nom) 26.62[1] (nom)
	Spollonante G	72 h (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	43 (mm)² > 100 (mm)²
	K-Salt Fruit Fix 800[3]	72 h (static)	Biomass: E_bC_{50}	9.1 (nom)
	Fruit Fix Super Concentrate 800[3]	72 h (static)	Biomass: E_bC_{50}	14.9 (mm)
Higher plant				
Myriophillum	a.s.	14 d (static)	Fronds, EC_{50}	Ongoing study
Lemna gibba G3	K-Salt Fruit Fix 800[3]	14 d (static)	Fronds, EC_{50}	5.09 (nom)
	Fruit Fix Super Concentrate 800[3]	14 d (static)	Fronds, EC_{50}	5.61 (mm)
Microcosm or mesocosm tests not required				
Note: - The formulation Spollonante G has a similar composition as Obsthormon 24A				

[1] Expressed in terms of 1-NAA-acid form

² End points are presented as units of a.s.

[3] Formulated product containing 1-NAA. Endpoint was used in risk assessment as Annex II data as the a.s. concentration was followed in the medium through the test.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)
FOCUS Step1
Worst-case scenario of two applications of 94 g 1-NAA-Na/ha (5-day interval) as Fruitone N on pome fruits

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)[1]	TER	Annex VI Trigger
1-NAA	Fish (acute)	> 56 000	Acute	76.23	735	100
	Invertebrate (acute)	> 56 000		76.23	735	100
	Algae *	9100	Chronic	76.23	119	10
	Aquatic plant *	5090		76.23	67	10
	Fish (chronic)	10 000		76.23	131	10
	Invertebrate (chronic)	22 000		76.23	289	10
	Sediment-dwelling organisms	-		Not required	10	
1-naphthaldehyde **	Fish (acute)	> 5600	Acute	11.87	471	100
	Invertebrate (acute)	> 5600		11.87	471	100
	Algae	910	Chronic	11.87	77	10
	Aquatic plant	509		11.87	42	10
	Fish (chronic)	1000		11.87	84	10
	Invertebrate (chronic)	2200		11.87	185.3	10
phthalic acid **	Fish (acute)	> 5600	Acute	9.77	579	100
	Invertebrate (acute)	> 5600		9.77	579	100
	Algae	910	Chronic	9.77	94	10
	Aquatic plant	509		9.77	53	10
	Fish (chronic)	1000		9.77	103	10
	Invertebrate (chronic)	2200		9.77	227	10
PD-1 **	Fish (acute)	> 5600	Acute	10.6	528	100
	Invertebrate (acute)	> 5600		10.6	528	100
	Algae	910	Chronic	10.6	85	10
	Aquatic plant	509		10.6	48	10
	Fish (chronic)	1000		10.6	94.3	10
	Invertebrate (chronic)	2200		10.6	207.5	10
PD-3 **	Fish (acute)	> 5600	Acute	9.02	620	100
	Invertebrate (acute)	> 5600		9.02	620	100
	Algae	910	Chronic	9.02	100	10

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i (µg/L)[1]	TER	Annex VI Trigger
	Aquatic plant	509		9.02	56	10
	Fish (chronic)	1000		9.02	110	10
	Invertebrate (chronic)	2200		9.02	243	10

*: toxicity endpoint obtained with a formulated product.
**: as no toxicity values were available for metabolites, a factor 10 was applied on the toxicity value of parent compound.
[1] The endpoints that drive the aquatic risk assessment were expressed in terms of 1-NAA acid. To express PEC as 1-NAA acid the reported PEC should be multiplied by 0.89 resulting in a lower PECsw than 76.23 µg /L. The TERs values will be higher than the current ones but the outcome of the risk assessment will not change.

Bioconcentration				
	Active substance	Metabolite 1	Metabolite 2	Metabolite 3
$logP_{O/W}$	- 0.02			
Bioconcentration factor (BCF)[1] ‡				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

[1] only required if log $P_{O/W}$ >3.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
1-NAA	> 120	> 120
1-NAA-Na	> 82[1]	> 82[1]
Field or semi-field tests		
Not required		

[1] Expressed in terms of 1-NAA-acid form

Hazard quotients for honey bees (Annex IIIA, point 10.4)
Crop and application rate

Test substance	Route	Hazard quotient[1]	Annex VI Trigger
1-NAA	Contact	< 1.15	50
1-NAA	oral	< 1.15	50

[1] HQ are calculated for the application of sodium salt of 1-NAA. To express HQ as 1-NAA the reported HQ should be multiplied by 0.89.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)
Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri	Late Val (100 g/L 1-NAA)	Mortality	> 188 (a.s.)

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri	Laboratory test, dried residues, 7 d, Spollonante G	Mortality Reproduction	LR_{50} > 42.0 g a.s./ha No effect on reproduction up to 42.0 g a.s./ha
Aphidius rhopalosiphi	Late Val (100 g/L 1-NAA)	Mortality	25.6 (a.s.)
Aphidius rhopalosiphi	Laboratory test, dried residues, 48 h, Spollonante G	Mortality Reproduction	LR_{50} > 42.0 g a.s./ha No effect on reproduction up to 42.0 g a.s./ha

Apple Fruitone N 94 g 1-NAA-Na /ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field[2]	HQ off-field (3 m)	Trigger
Late Val	*Typhlodromus pyri*	> 188 (a.s.)	< 0.27 (leaves) < 0.3 (ground)[1]	< 0.69 < 0.77	2
Spollonante G		> 42 (a.s.)	< 1.21 (leaves) < 1.36 (ground)[1]	< 0.30 < 0.35	
Late Val	*Aphidius rhopalosiphi*	25.6 (a.s.)	1.99 (leaves) 2.22 (ground)[1]	0.51 0.57	2
Spollonante G		> 42 (a.s.)	< 1.21 (leaves) < 1.36 (ground)[1]	< 0.30 < 0.35	

[1] HQ in-field taking into account 70% of interception by the crop

[2] HQ are calculated for the application of sodium salt of 1-NAA. To express HQ as 1-NAA acid the reported HQ should be multiplied by 0.89.

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Coccinella septempunctata	Larvae	1-NAA solution of 440 mg/L (larvae dipped)	-	Mortality, pupation	No effect	50 %
Orius strigicollis poppius	Adults	1-NAA solution of 440 mg/L (painted on surface of body)	-	Mortality	No effect	50 %
Amblyseius (Neoseiulus) californicus	Adults	1-NAA solution of 440 mg/L (dipped with host leaves)	-	Mortality, egg production	No effect	50 %

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point

Test organism	Test substance	Time scale	End point
Earthworms			
	1-NAA	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil (mg a.s/ha)
	a.s. ‡	Chronic 8 weeks	Not required
Other soil macro-organisms			
Soil mite	a.s. ‡		Not required
Collembola			
	a.s. ‡	Chronic	Not required
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		Effects < 25% at 0.53 mg 1-NAD/kg (corresponding to 0.4 mg 1-NAA/kg)
Carbon mineralisation	a.s. ‡		Effects < 25% at 0.53 mg 1-NAD/kg (corresponding to 0.4 mg 1-NAA/kg)
Field studies			
Not required			

Toxicity/exposure ratios for soil organisms
Apple Fruitone N 94 g 1-NAA-Na/ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia foetida foetida	1-NAA	Acute	0.05 (PECsoil,ini)	>20000	10
	a.s. ‡	Chronic		Not required	5
Other soil macro-organisms					
Soil mite	a.s. ‡			Not required	
Collembola	a.s. ‡			Not required	

[1] PEC is calculated for the application of sodium salt of 1-NAA. To express PEC as 1-NAA the reported PEC should be multiplied by 0.89.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)
Preliminary screening data

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g a.s./ha)[1] vegetative vigour	ER_{50} (g a.s./ha)[1] emergence	Exposure (g a.s./ha)[1]	TER	Trigger
Daucus carota	Obsthormon 24A	> 60 g NAA/ha	> 60 g NAA/ha	14	> 4.28*	5

[1] based on a MAF value of 1.7, and the drift value of 29.2% at 1 m
* the observed effects at the maximum application rate of 60 g a.s./ha are below 50% (17% in one test and 15 % in the other). The risk is considered as low.

Additional studies (e.g. semi-field or field studies)

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	*Not required
Pseudomonas sp	*Not required

*no study was available. However, according to the GAP for apple trees, it was assumed that contamination of water waste treatment plant was unlikely. Therefore, the risk of contamination of biological methods for sewage treatment is considered to be low.

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

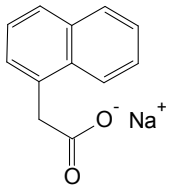
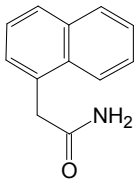
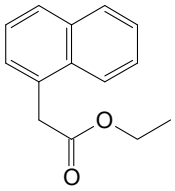
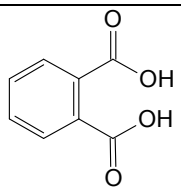
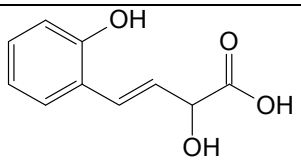
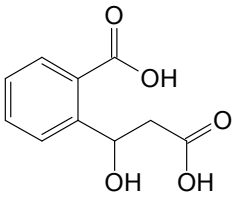
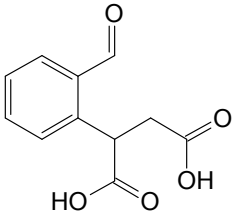
Compartment	
soil	1-NAA
water	1-NAA
sediment	1-NAA
groundwater	1-NAA

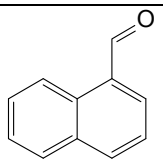
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS proposal
Active substance	R51/R53 (based on the toxicity of 1-NAA on *Lemna gibba* G3; the test was conducted with the formulation K-Salt Fruit Fix 800 but 1-NAA concentrations were analysed and this endpoint is used as Annex II data)

	RMS/peer review proposal
Preparation Obsthormon 24A	R52/53
Preparation Fruitone N	Not classified (pending for new studies to be submitted)
Preparation Amcotone	Not classified (pending for new studies to be submitted)

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula*
1-NAA-Na	sodium 1-naphthylacetate	
1-NAD	2-(1-naphthyl)acetamide	
1-naphthylacetic acid ethyl ester 1-NAA-Et	ethyl 1-naphthylacetate	
phthalic acid M4	phthalic acid	
PD-1	(3*E*)-2-hydroxy-4-(2-hydroxyphenyl)-3-butenoic acid 2-(2-carboxy-1-hydroxyethyl)benzoic acid	 
PD-3	2-(2-formylphenyl)succinic acid	

1 –naphthaldehyde M III	1-naphthaldehyde	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
λ	wavelength
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AUC	area under curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETE	estimated theoretical exposure
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use

g	gram
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-UV	high performance liquid chromatography with ultra violet detector
HPLC-DAD	high performance liquid chromatography with diode array detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on 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)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LLNA	local lymph node assay
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
MLA	mouse lymphoma assay
MLA/TK	mouse lymphoma thymidine kinase assay
mm	millimetre
mN	milli-newton
MOS	margin of safety
MRL	maximum residue limit or level
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram

nm	nanometre
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PGR	plant growth regulator
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RBC	red blood cell
RPE	respiratory protective equipment
RUD	residue per unit dose
SL	soluble concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WP	wettable powder
WHO	World Health Organisation

wk	week
yr	year