CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance 2-(1-naphthyl)acetamide (notified as 1-naphthylacetamide)[1]

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SUMMARY

2-(1-naphthyl)acetamide is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3] (this substance was listed in this Regulation under the name 1-naphthylacetamide), 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 2-(1-naphthyl)acetamide 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 2-(1-naphthyl)acetamide 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-NAD Task Force made a resubmission application for the inclusion of 2-(1-naphthyl)acetamide 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 DAR was also distributed to the Member States for comments. 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 areas of mammalian toxicology and residues, and deliver its conclusions on 2-(1-naphthyl)acetamide.

[1] On request from the European Commission, Question No EFSA-Q-2010-00871, issued on 15 February 2011.

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[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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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of 2-(1-naphthyl)acetamide 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.

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

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

Data gaps were identified in the section on residues for sufficient European residue trials analysing for 2-(1-naphthyl)acetamide and 1-naphthylacetic acid residues and a new freezer storage stability study. No critical area of concern was identified.

Data gaps were identified for further information on the route and rate of degradation in soil. The potential for groundwater contamination by the parent 2-(1-naphthyl)acetamide above the parametric drinking water limit of 0.1 µg/L was assessed as low for all the representative uses. The potential for groundwater contamination by the metabolite 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 use of 'Amid-Thin W'.

Several data gaps were identified in the ecotoxicology section: 1) to address the long-term risk to birds, 2) to address the risk to non-target plants, 3) for the submission of toxicity studies on aquatic organisms with the formulations 'Amcotone' and 'Amid-Thin W' from Amvac, 4) to provide the analytical profile of the batches used in the ecotoxicology tests for the Amvac source. No critical area of concern was identified.

KEY WORDS

2-(1-naphthyl)acetamide, 1-naphthylacetamide, naphthaleneacetamide, 1-NAD, 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

2-(1-naphthyl)acetamide 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 7 April 2008 by dispatching the DAR to the applicants, Amvac Chemical UK Limited and the 1-NAD Task Force, 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 2-(1-napthyl)acetamide 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 2-(1-naphthyl)acetamide 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-NAD Task Force made a resubmission application for the inclusion of 2-(1-naphthyl)acetamide 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 DAR was also distributed to Member States for comments in view of the fact that the original peer review had been terminated following the applicants'

[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

notification of withdrawal of support. The EFSA collated and forwarded all comments received to the 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' responses 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 2-(1-naphthyl)acetamide within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were 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' responses 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 areas of mammalian toxicology and residues and that further information should be requested from the applicants in all areas.

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 apple, 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, 2011), 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; 23 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 December 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

2-(1-naphthyl)acetamide (IUPAC) is considered by the International Organization for Standardization not to require a common name. The name used in the Regulation[11] is 1-naphthylacetamide while in the DAR the name naphthaleneacetamide was used.

The representative formulated products for the evaluation were 'Amid-Thin W', a wettable powder (WP) containing 8.2% (w/w) 2-(1-naphthyl)acetamide and 'Amcotone', a wettable powder (WP) containing 1.2% (w/w) of 2-(1-naphthyl)acetamide and 0.45 % (w/w) of 1-naphthylacetic acid, 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 2-(1-naphthyl)acetamide 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 2-(1-naphthyl)acetamide or the representative formulations. However, the following data gaps were identified for the Amvac source: validation data for the 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 determination of long-term storage stability of the representative formulations 'Amid-Thin W' and 'Amcotone' and for accelerated storage stability at lower temperatures for 'Amcotone'.

The main data regarding the identity of 2-(1-naphthyl)acetamide and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of 2-(1-naphthyl)acetamide and the impurities in the technical material and for the determination of the active substance in the representative formulations. 2-(1-naphthyl)acetamide 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 plant method. Monitoring methods for food of animal origin are not required as no MRL was proposed. Residues of 2-(1-naphthyl)acetamide in soil can be monitored by HPLC/MS-MS while residues of 1-naphthylacetic acid can be monitored by HPLC with fluorescence detection. Residues of 2-(1-naphthyl)acetamide and 1-naphthylacetic acid in water can be monitored by HPLC with fluorescence detection. A monitoring method for 2-(1-naphthyl)acetamide residues in the 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 documents were followed in the production of this conclusion: SANCO/222/2000 rev. 7 (European Commission, 2004b) and SANCO/10597/2003 rev. 8. 1 (European Commission, 2009).

[11] OJ L 379, 24.12.2004, p.27

2-(1-naphthyl)acetamide was discussed during the PRAPeR experts' meeting 83 in October 2010.

A data gap and an issue that could not be finalised were 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.

2-(1-naphthyl)acetamide is "harmful if swallowed" (Xn; R22 proposed) based on a LD_{50} of 1655 mg/kg bw. It is not acutely toxic via dermal and inhalation routes. It is not a skin irritant or a skin sensitiser, but it is an eye irritant (R41 "risk of serious damage to eyes" was proposed).

After repeated exposure in subacute and subchronic studies, the rat showed the highest sensitivity (increased 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), with a relevant NOAEL of 5 mg/kg bw/day. 2-(1-naphthyl)acetamide did not show any genotoxic potential. No data were submitted on long-term toxicity and carcinogenicity of 2-(1-naphthyl)acetamide, however toxicological information was taken from studies performed with 1-naphthylacetic acid-Na, showing in rats 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 in males. The NOAEL was 43.8 mg/kg/day. No carcinogenic potential was shown. Similarly, no original studies were submitted for the reproductive toxicity of 2-(1-naphthyl)acetamide: the maternal and offspring (69 mg/kg bw/day) and reproductive toxicity (210 mg/kg bw/day) NOAELs were taken from studies performed with 1-naphthylacetic acid and its salt variant. The relevant maternal and developmental toxicity NOAELs in rats were both 10 mg/kg bw/day, based on increased incidence of small foetuses and skeletal foetal variants, as well as visceral malformations and omphalocele. The relevant maternal and developmental toxicity NOAELs in rabbits were 100 mg/kg bw/day and 20 mg/kg bw/day respectively. The experts agreed that a proposal for classification with R63 was appropriate in line with the proposal made for 1-naphthylacetic acid (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.

The operator exposure level is below the AOEL for the plant protection product (PPP) 'Amid-Thin W' (in the case of the Task Force PPP without the use of any Personal Protective Equipment, whereas for the Amvac PPP the use of gloves during M/L is needed (German model)). The same applies to re-entry exposure, where for the Amvac PPP gloves have to be worn to decrease the exposure level below the AOEL. Bystander exposure is below the AOEL for the representative products. With regard to the PPP 'Amcotone', the RMS provided an exposure assessment showing levels below the AOEL for operators and workers (without the use of PPE) and for bystanders (these calculations have not been 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).

Metabolism data are available in apples treated with either 2-(1-naphthyl)acetamide alone or with a sequential application of 2-(1-naphthyl)acetamide and of 1-naphthylacetic acid and its variant 1-naphthylacetic acid ethyl ester. 2-(1-naphthyl)acetamide was shown to be rapidly degraded into 1-naphthylacetic acid with a half-life of 5.5 days. Thus at harvest, 14 days after application of 2-(1-naphthyl)acetamide and 2 days after the last application of 1-naphthylacetic acid, the only identifiable residue was 1-naphthylacetic acid, 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 were thus assumed to be conjugates of 1-naphthylacetic acid. 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. 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 2-(1-naphthyl)acetamide is considered a precursor of 1-naphthylacetic acid, bridging evaluation was accepted, and the same toxicological reference values were allocated to both compounds. The residue definition relevant for risk assessment should therefore be the sum of 2-(1-naphthyl)acetamide and 1-naphthylacetic acid (and its salts), expressed as 2-(1-naphthyl)acetamide. As for the necessity to comply with the scope of the analytical method for monitoring, considering further the aspect of 1-naphthylacetic acid being a separate active substance, a split residue definition was proposed for the purpose of monitoring and MRL setting as a) 2-(1-naphthyl)acetamide expressed as 2-(1-naphthyl)acetamide and b) 1-naphthylacetic acid and its salts expressed as 1-naphthylacetic acid.

Four residue field trials with 2-(1-naphthyl)acetamide were submitted, of them only the two trials conducted in Southern Europe were suitable to support the critical GAP. Residues of 2-(1-naphthyl)acetamide and 1-naphthylacetic acid were below the LOQ of the analytical method used in these studies of 0.02 mg/kg and 0.04 mg/kg, respectively. To demonstrate that the results of the residue field trials are reliable, the trials will have to be supplemented by acceptable freezer storage stability data. Residue trials conducted in the USA were considered non-acceptable in terms of quality, and not compliant with European practices and conditions. Hence data gaps were identified for a freezer storage stability study, and for sufficient European residue trials analysed for 2-(1-naphthyl)acetamide and 1-naphthylacetic acid. A submitted processing study in apples with 1-naphthylacetic acid 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 2-(1-naphthyl)acetamide is applied to apple as defined by the GAP.

When using the available 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.

An MRL for 2-(1-naphthyl)acetamide in apples was proposed at the LOQ of 0.02 mg/kg. Independent of the data submitted with the 2-(1-naphthyl)acetamide dossier, an MRL for 1-naphthylacetic acid has previously been proposed at 0.05 mg/kg. Using the sum of 2-(1-naphthyl)acetamide and 1-naphthylacetic acid residues from the available South EU residue trial data in apple (0.06 mg/kg) in a chronic and acute dietary risk assessments 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 6% of the ARfD of 0.1 mg/kg bw.

4. Environmental fate and behaviour

No valid study investigating the route of degradation of 2-(1-naphthyl)acetamide in soil was available, therefore the mineralisation and the formation of unextractable residues could not be quantified. A data gap was identified for information on the route of degradation of 2-(1-naphthyl)acetamide in aerobic soil. In the available soil incubations under aerobic conditions in the dark, 2-(1-naphthyl)acetamide exhibited very low persistence forming the major (>10% applied radioactivity (AR)) metabolite 1-naphthylacetic acid. The metabolite 1-naphthylacetic acid exhibited low to moderate persistence[12]. The available data on rate of degradation for both the parent 2-(1-

[12] DT_{50} values for 1-naphthylacetic acid were derived from separate soil incubations that had low organic matter content.

naphthyl)acetamide and the metabolite 1-naphthylacetic acid were however derived from only 2 soil incubations. According to the current guideline, the rate of degradation should be investigated in a minimum of 4 soils for the parent molecule and 3 soils for the metabolites. A data gap was therefore identified during the peer review for determination of the aerobic rate of degradation in at least 2 additional soils for the parent and one additional soil for the metabolite. It is recommended that these additional studies are performed on soils with various properties (especially in terms of OM% and pH) that represent typical agricultural soils. No acceptable studies were available for the degradation under anaerobic conditions in soil or for the photodegradation in soil. Therefore a data gap was identified for information on the photolysis of 2-(1-naphthyl)acetamide in soil.

No valid data were available for the mobility of 2-(1-naphthyl)acetamide in soil. 1-Naphthylacetic acid exhibited high to very high mobility in soil.

PEC_{soil} (Predicted environmental concentrations (PEC)) values for 2-(1-naphthyl)acetamide and for 1-naphthylacetic acid were calculated using soil DT_{50} values that were considered as worst case based on the available data sets.

The degradation of 2-(1-naphthyl)acetamide was investigated in laboratory incubations in dark aerobic water systems without sediment. In these systems 2-(1-naphthyl)acetamide exhibited low persistence (SFO DT_{50} in water 2.9 - 4.4 days), forming the major metabolite 1-naphthylacetic acid that was formed up to about 100% in these natural waters. The degradation of 1-naphthylacetic acid was investigated in two separate laboratory incubations in dark aerobic natural sediment water systems. In this study, 1-naphthylacetic acid exhibited low persistence with significant (60 - 70% AR) mineralisation. In a laboratory sterile aqueous photolysis experiment, 2-(1-naphthyl)acetamide degraded to several degradation products, but none of them reached 10% AR at the study end. A separate aqueous photolysis experiment was available for 1-naphthylacetic acid, where four photodegradates were formed.

The necessary surface water and sediment exposure assessments (PEC) were carried out for 2-(1-naphthyl)acetamide and 1-naphthylacetic acid using the FOCUS (FOCUS, 2001) step 1 and step 2 approach. The results of these calculations can be found in Appendix A. The available groundwater exposure assessments were carried out using FOCUS (FOCUS, 2000) scenarios and the model PEARL 3.3.3[13] for 2-(1-naphthyl)acetamide and 1-naphthylacetic acid considering the available data sets.

The potential for groundwater exposure by 2-(1-naphthyl)acetamide from all representative uses 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. Likewise the potential for groundwater exposure by the metabolite 1-naphthylacetic acid 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 by 1-naphthylacetic acid as a metabolite of 2-(1-naphthyl)acetamide from the representative uses of the product 'Amid-Thin W' 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 of 1-naphthylacetic acid in the groundwater exceeded the parametric drinking water limit of 0.1 µg/L was 6 or 8 pending on the dose rate.

2-(1-naphthyl)acetamide has low potential for volatilization and the estimated atmospheric half-life is shorter than 2 days. Therefore, long-range transport through the atmosphere is not expected.

[13] Simulations correctly utilised the agreed Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7.

5. Ecotoxicology

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

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

The acute and short-term risk of 2-(1-naphthyl)acetamide to insectivorous birds via dietary exposure was assessed as low at tier I for the representative uses. The acute risk of the metabolite 1-naphthylacetic acid was assessed as low. No long-term toxicity study with birds was available either in the DAR or in the Additional Report. The long-term risk to birds needs to be addressed and a data gap was identified.

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 based on the use of a realistic deposition factor for the determination of the mean of the RUD value for grass in orchards. A risk assessment for earthworm-eating birds and mammals is not required since the $\log P_{ow} < 3$. Additionally, the risk to birds and mammals from consumption of contaminated water was assessed as low.

2-(1-naphthyl)acetamide is harmful to aquatic organisms. There were valid ecotoxicological studies on aquatic organisms with the formulation 'Amid-Thin W' from the Task Force. Valid acute toxicity studies on aquatic organisms with the formulations 'Amcotone' and 'Amid-Thin W' from Amvac were not available and a data gap was identified during the peer review process.

The risk to aquatic organisms from 2-(1-naphthyl)acetamide was assessed as low for the representative uses at $FOCUS_{sw}$ step 1. The risk from the metabolite 1-naphthylacetic acid was assessed as low for aquatic organisms for all representative uses.

No valid toxicity studies were available with non-target plants, therefore a data gap was identified to address the risk to non-target plants.

The risk to bees, non-target arthropods, earthworms, non-target soil micro-organisms 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 the effects data for the environmental compartments

6.1. Soil*)

Compound (name and/or code)	Persistence	Ecotoxicology
2-(1-naphthyl)acetamide	Very low persistence DT_{50}: 0.058 and 0.519 days (SFO, 20˚C, Soil water content 21 and 18%).	The risk of 2-(1-naphthyl)acetamide to earthworms was assessed as low
1-naphthylacetic acid	Low – moderate persistence DT_{50}: 4.4 and 77 days (SFO, 20-25˚C, 40-60% MWHC soil moisture).	The 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 (other than 1-NAA) 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

2-(1-naphthyl)acetamide	No data provided[(a)]	No	Yes	Yes	Harmful to aquatic organisms, end point driving the aquatic risk assessment: acute fish LC_{50} = 44 mg a.s./L (regulatory concentration including a safety factor of 100 = 0.44 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.
1-naphthylacetic acid	High – very high mobility K_{Foc} 45 - 87 mL/g	Yes The number of FOCUS scenarios exceeding the trigger values of 0.1 µg/L was 0, 6 and 8 for the representative uses of 'Amcotone' (Amvac), 'Amid-Thin W' (Amvac) and 'Amid-Thin W' (Task Force) respectively.	Yes	Yes	Toxic to aquatic organisms, end point driving the aquatic risk assessment: chronic daphnia NOEC or the aquatic plant EC_{50} = 10 mg a.s./L (regulatory concentration including a safety factor of 10 = 1 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.

(a): Data describing the mobility of 2-(1-naphthyl)acetamide were not provided in the dossier, consequently a conservative value of Koc of 0 mL/g was used in the exposure assessment

*) As the route of degradation in soils is not adequately described it is not possible to judge whether additional metabolites (other than 1-NAA) should be included in the residue definition.

6.3. Surface water and sediment*)

Compound (name and/or code)	Ecotoxicology
2-(1-naphthyl)acetamide	Harmful to aquatic organisms, end point driving the aquatic risk assessment: acute fish LC_{50} = 44 mg a.s./L (regulatory concentration including a safety factor of 100 = 0.44 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.
1-naphthylacetic acid	Toxic to aquatic organisms, end point driving the aquatic risk assessment: chronic daphnia NOEC = 22 mg a.s./L or the aquatic plant EC_{50} = 10 mg a.s./L (regulatory concentration including a safety factor of 10 = 2.2 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 (other than 1-NAA) should be included in the residue definition.

6.4. Air

Compound (name and/or code)	Toxicology
2-(1-naphthyl)acetamide	Not acutely toxic via inhalation

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

- Validation data for the analytical methods for the determination of active substance and impurities in the technical active substance as manufactured (relevant for the Amvac source; submission date proposed by the applicant: non-eligible interim report submitted, not peer reviewed, see section 1).
- An updated technical specification (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 1).
- Determination of long-term storage stability for 'Amid-Thin W' and 'Amcotone' (relevant for all representative uses; submission date proposed by the applicants: unknown (studies are in progress), see section 1).
- Determination of the accelerated storage stability at lower temperatures for 'Amcotone' (relevant for the 'Amcotone' uses; submission date proposed by the applicant: 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).
- Monitoring method for 2-(1-naphthyl)acetamide residues in the air (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown, see section 1).
- Compliance of batches tested in the mammalian toxicology studies with the proposed specification (relevant for the Amvac source; submission date proposed by the applicant: unknown, see section 2).
- Sufficient European residue trials analysing for 2-(1-naphthyl)acetamide and 1-naphthylacetic acid (relevant for all representative uses evaluated; submission date proposed by the applicants: Amvac: unknown; Task Force: 2011, 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 (at least in one soil) and the rate of degradation in at least two additional soils for the parent 2-(1-naphthyl)acetamide. The determination of the rate of degradation in at least one additional soil is also necessary for the metabolite 1-naphthylacetic acid. It is recommended that these additional studies are performed with radio-labelled molecule (preferable at the naphthalene moiety) especially for the route of degradation study. It is also recommended that these additional studies are performed on soils with various properties (especially in terms of OM% and pH) that represent typical properties of agricultural soils (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 2-(1-naphthyl)acetamide 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 ecotoxicology section (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).

- Information to address the risk to non-target plants (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 5).

- Toxicity study on aquatic organisms with the formulations 'Amcotone' and 'Amid-Thin W' (relevant for the Amvac uses evaluated; 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 gloves to decrease the operator and the worker exposure for the Amvac PPP 'Amid-Thin W'.

ISSUES THAT COULD NOT BE FINALISED

- The technical specification for the Amvac source should be considered provisional.

- Compliance of batches tested for the mammalian toxicology and ecotoxicology studies with the proposed Amvac specification is missing.

- 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 soil metabolites (other than 1-naphthylacetic acid) have not been performed.

- The long-term risk to birds could not be assessed with the available data.

- The risk to non-target plants could not be assessed with the available data.

- The aquatic risk assessment for the formulations 'Amcotone' and 'Amid-Thin W' from Amvac could not be finalized with the available data.

CRITICAL AREAS OF CONCERN

None

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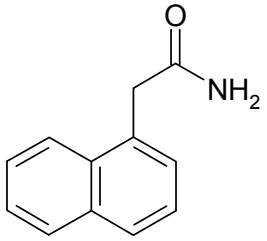
APPENDICES

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) ‡	2-(1-naphthyl)acetamide no ISO common name
Function (e.g. fungicide)	Plant growth regulator
Rapporteur Member State	France

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-(1-naphthyl)acetamide
Chemical name (CA) ‡	1-naphthaleneacetamide
CIPAC No ‡	282
CAS No ‡	86-86-2
EC No (EINECS or ELINCS) ‡	201-704-2
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	980 g/kg for Task Force Open for Amvac
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurity
Molecular formula ‡	$C_{12}H_{11}NO$
Molecular mass ‡	185.2 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	178 - 179ºC (99.1%) (Task Force) 184 - 185°C (98.8%) (Amvac)
Boiling point (state purity) ‡	Reaction or decomposition of active substance started just above the melting point.
Temperature of decomposition (state purity)	See above
Appearance (state purity) ‡	Off white odourless powder (99.1%) (Task Force) White odourless powder (98.8%) (Amvac)
Vapour pressure (state temperature, state purity) ‡	9.4×10^{-7} Pa at 20°C (98.9%)
Henry's law constant ‡	1.02×10^{-8} Pa.m^3.mol^{-1} at 20°C
Solubility in water (state temperature, state purity and pH) ‡	170 mg/l at 20°C (98.8%) Unbuffered ASTM type II water (Amvac) 152 mg/l at 20°C (99.6%, pH 4) (Task Force) 164 mg/l at 20°C (99.6%, pH 7) (Task Force) 154 mg/l at 20°C (99.6%, pH 9) (Task Force)
Solubility in organic solvents ‡ (state temperature, state purity)	At 20°C (99.6%): acetone : > 250 g/l methanol : >250 g/l xylene : < 1 g/l ethyl acetate : 1 < s < 2 g/l 1,2-dichloroethane : 1 < s < 2 g/l heptane : <1 g/l
Surface tension ‡ (state concentration and temperature, state purity)	71.4 mN/m (99.1%)
Partition co-efficient ‡ (state temperature, pH and purity)	At 25°C (98.8%) log $P_{O/W}$ = 1.58 at pH = 7
Dissociation constant (state purity) ‡	pKa = 0.41

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	UV spectra were performed up to 300 nm In methanol (neutral) λ max (nm) / ε (dm^3/mol/cm): 224 / 79000; 271 / 6140; 281 / 7280 In methanol/ 1M HCl (acidic) λ max (nm) / ε (dm^3/mol/cm): 224 / 78200; 271 / 6190; 281 / 7350 In methanol/ 1M NaOH (alkaline) λ max (nm) / ε (dm^3/mol/cm): - / -; 271 / 6160; 281 / 7290 98.9% (Amvac) Absorption was observed after 290 nm solution / λ max (nm) / ε (dm^3/mol/cm): neutral / 280.4 / 6747; 223 / 75840; acidic / 281 / 6758; 223 / 75910; alkaline / 281 / 6689; 223 / 72770
Flammability ‡ (state purity)	1-NAD is not auto-flammable, not highly flammable
Explosive properties ‡ (state purity)	Not explosive (purity 99.6% and 99.8%)
Oxidising properties ‡ (state purity)	Not oxidizing (purity 99.1%)

Summary of representative uses evaluated (name of active substance or the respective variant)

	Crop and/or situation (a)	Member State	Product name	FGI (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)	kg a.s./hl min max (g/hl)	water l/ha min max	kg a.s./ha min max (*) (g/ha)		
Amvac	Thinning in apples	Spain	Amid-Thin W	F	PGR	WP	82 g/kg	HV	Petal fall , approx. 10 days after full bloom	1	-	0.005 (5)	800-1000	0.04-0.05 (40-50)	Not applicable, as PHI is dictated by the moment of application (10 days after full bloom)	[1] [2][3] [4] [5]
	Apple (pre-harvest drop)	Spain	Amcotone	F	PGR	WP	4.5 g/kg 1-NAA acid 12 g/kg 1-NAD	HV	Petal fall , approx. 10 days after full bloom	1 to 2	6-10 day	0.00027 1-NAA acid 0.00072 1-NAD (0.27 1-NAA acid/, 0.72 1-NAD)	800-1000	0. 0027 1-NAA acid 0.0072 1-NAD (2.7 1-NAA acid/, 7.2 1-NAD)	30	[1] [2] [3] [4] [5]
Task Force	Apple	France	Amid-Thin W	F	Thinning	WP	82 g/kg	HV	BBCH 66-69 early spring	1	-	0.005 (5)	800-1600	0.08 max (80)	More than 56 days, depending on growth stage	[2] [3] [4]

a. For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
b. Outdoor or field use (F), glasshouse application (G) or indoor application (I)
c. E.g. biting and sucking insects, soil born insects, foliar fungi, weeds
d. E.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
e. GCPF codes - GIFAP Technical monograph No2, 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 plants – type of equipment used must be indicated
i. Concentration in g as/kg of g as/L
j. Growth stage at last treatment (BBCH monograph, Growth stages of plants, 1997, Blackwell, ISBN 3-8263-3152-4)
k. The minimum and maximum number of applications possible under practical conditions must be provided.
l. PHI – minimum pre-harvest interval
M. REMARKS MAY INCLUDE: EXTENT OF USE / ECONOMIC IMPORTANCE / RESTRICTIONS

[1] The compliance of the Amvac batches used in the mammalian toxicology and ecotoxicology with the proposed specification could not be demonstrated

[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 (other than 1-NAA).
[3] The long-term risk to birds should be addressed.
[4] The risk to non-target plants needs to be addressed.
[5] The risk from the formulation 'Amcotone' and 'Amid-Thin W' from Amvac to aquatic organisms could not be finalised.

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

Technical as (analytical technique)	Task Force	HPLC/UV
	Amvac	HPLC/UV, not validated
Impurities in technical as (analytical technique)	Task Force	HPLC/UV
	Amvac	HPLC/UV, not validated
Plant protection product (analytical technique)	Task Force	Amid – Thin W, HPLC/UV
	Amvac	Amid – Thin W, HPLC/UV Amcotone, HPLC-DAD

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		separately a) 1-NAD b) 1-NAA and its salts, expressed as 1-NAA
Food of animal origin		Not relevant
Soil		1-NAD and 1-NAA
Water	surface	1-NAD and 1-NAA
	drinking/ground	1-NAD and 1-NAA
Air		1-NAD

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC/UV (apples) :1-NAD: LOQ = 0.02 mg/kg 1-NAA: LOQ= 0.04 mg/kg Confirmed by HPLC-DAD ILV required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	1-NAA : HPLC/fluorescence : LOQ = 0.01 mg/kg 1-NAD : HPLC/MS-MS: LOQ = 0.05 mg/kg
Water (analytical technique and LOQ)	1-NAD : HPLC/Fluorescence : LOQ = 0.1 µg/l (surface water) Confirmatory method: HPLC-MS/MS not fully validated 1-NAA : HPLC/Fluorescence : LOQ = 0.1 µg/l (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/day (1-NAA), 933 mg/kg bw/day (1-NAA-Na)	1655 mg/kg bw/day (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).	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.

	Mice: ↓ platelets counts; ↑ liver and kidney organs weights without histopathology injuries (1-NAA-Na)	
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 extra rib 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)	Rats: 10 mg/kg bw/day Rabbit: 20 mg/kg bw/day

Rabbit: 30 mg/kg bw/day (LOAEL, 1-NAA-Na)	

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/</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/h</th></tr>
<tr><td>Tractor mounted equipment</td></tr>
<tr><td><u>With PPE:</u>
20% of AOEL (BBA, gloves, coverall, M/L & app
158% of AOEL (UK POEM, gloves, M/L & appli</td></tr>
</table>
<u>OBSTHORMON 24A</u>
BBA and UK POEM models
<table>
<tr><th>Apples, application rate 30 g 1-NAA acid/</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 & applic</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 han</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 (E</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 han</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 (</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	Not required.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not required
Plant residue definition for monitoring	separately a) 1-NAD b) 1-NAA and its salts, expressed as 1-NAA
Plant residue definition for risk assessment	1-NAD plus 1-NAA and its salts, expressed as 1-NAD
Conversion factor (monitoring to risk assessment)	None (there will be separate analyses in monitoring)

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

Animals covered	No study submitted
Time needed to reach a plateau concentration in milk and eggs	-
Animal residue definition for monitoring	Not necessary
Animal residue definition for risk assessment	Not necessary
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	-
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)	No	Not relevant	Not relevant

Potential for accumulation (yes/no):	No	Not relevant	Not relevant
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	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)
Apples Amid-Thin W Amcotone	S-EU	<0.02; <0.02 (mg/kg) (1-NAD) <0.04; <0.04 (mg/kg) (1-NAA) <0.06; <0.06 (mg/kg) (sum of 1-NAD and 1-NAA expressed as 1-NAD)	Note: Samples were stored 287 days before being analyzed which is not yet covered by storage stability data.	0.02*mg/kg (1-NAD) 0.04* mg/kg (1-NAA)**	0.02 mg/kg 0.04 mg/kg 0.06	0.02 mg/kg 0.04 mg/kg 0.06
Apples Amid-Thin W	N-EU (N-France)	No data available (data gap)				

** As 1-NAA is an active substance, MRL for 1-NAA has to be set also in accordance with 1-NAA uses.

(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

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

ADI	0.1 mg/kg bw/day
TMDI (% ADI) according to **EFSA PRIMo model rev. 2_0**	DE child: 0.7 % (based on residue data from Task Force study – to be confirmed when new trials and/or stability data will be available)
ARfD	0.1 mg/kg bw
IESTI (% ARfD) according to **EFSA PRIMo model rev. 2_0**	UK infant: 5.9% (based on residue data from Task Force study – to be confirmed when new trials and/or stability data will be available)

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	
No study submitted	-	-	-	-

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

Apples	0.02*mg/kg for 1-NAD As 1-NAA is an active substance, MRL for 1-NAA has to be set also in accordance with 1-NAA uses. 0.05 mg/kg for 1-NAA (based on residue data from Task Force study – to be confirmed when new trials and/or stability data will be available)

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

Mineralization after 100 days ‡	No valid route of degradation study was available – data gap.
Non-extractable residues after 100 days ‡	No valid route of degradation study was available – data gap.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	1-NAA Although the study on route of degradation was not considered valid, it was clearly demonstrated that 1-NAA is the major degradation product. A data gap has been set for a proper route of degradation study.

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 ‡

Parent 1-NAD	Aerobic conditions						
Soil type		pH	t. °C /moisture content %	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	χ^2 (%)	Method of calculation
Sandy loam		7.6	20°C / 21.1	0.058 / 0.19	0.058	15.2	SFO
Humic sand soil		5.2	20°C / 17.8	0.519 / 1.7	0.519	3.4	SFO

Metabolite 1-NAA	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 normalised only for temperature

Field studies ‡

No data, not required

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	No data, not required

Laboratory studies ‡

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

1-NAD (parent)
No valid data available. No study required because of all PEC_{GW} < 0.1 µg/L for the representative uses with a conservative set of values for mobility of the parent (K_{OC} = 0 L/kg; 1/n = 1).

1-NAA (metabolite)							
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 validated data – No data required
Aged residues leaching ‡ 1-NAA metabolite	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, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent (1-NAD) Method of calculation	DT_{50} (d): 3 days (considered as worst case based on the available data set) Kinetics: SFO

Application data	Crop: apples Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 65 % Number of applications: 1 for Amid-Thin W and 2 for Amcotone Interval (d): - Application rate(s): 80 g a.s./ha for Amid-Thin W - Task Force, 50 g a.s./ha for Amid-Thin W - Amvac, 9.9[1] g a.s./ha for Amcotone

[1] no degradation between applications was considered and it includes the sum of 1-NAA and 1-NAD, as a worst case

1-NAD Initial PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average
Amid-Thin W (Task Force)	0.037	-
Amid-thin W (Amvac)	0.023	-
Amcotone (Amvac)	0.009	-
Plateau concentration	Not provided	

Metabolites Method of calculation	1-NAA Molecular mass: 186.2 DT$_{50}$ (d): 77 d Kinetics: 1st order
Application data	Calculations for 1-NAA are done assuming that 1-NAD degrades rapidly to 1-NAA, and then 1-NAA is considered as parent with the same GAP as 1-NAD.

1-NAA Initial PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average
Amid-Thin W (Task Force)	0.037	-
Amid-Thin W (Amvac)	0.023	-
Amcotone (Amvac)	0.009	-
Plateau concentration	Not provided	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	1-NAD is hydrolytically stable at 50°C and pH 4, 7 and 9
Photolytic degradation of active substance and metabolites above 10 % ‡	1-NAD: DT_{50} and DT_{90} in irradiated samples (Xenon light source) were 4.7 and 15.7 d, respectively. No major metabolite was formed 1-NAA: DT_{50} values of 1.6 – 2.9 d (equivalent to US solar days at 40°N, year-round average) were determined. Major metabolites comprised: 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 another study indicated maximum observed formation of 14.4%), PD-1 (max. 15.6% in natural water, consists of two components) and PD-3 (max. 13.3% in natural water).
Quantum yield of direct phototransformation in water at Σ > 290 nm	9.9×10^{-4} reacted molecules/absorbed photons
Readily biodegradable ‡ (no)	No valid data submitted; substance considered not ready biodegradable.

Degradation in water / sediment

Parent										
Water system*)	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
TNO (surface water system)	9.1	-	20	-	-	2.9 d – 9.6 d	0.899	-	-	SFO
Kromme Rijn (surface water system)	7.8	-	20	-	-	4.4 d – 14.4 d	0.974	-	-	SFO

*)The degradation of 2-(1-naphthyl)acetamide was investigated under laboratory incubations in dark aerobic water systems without sediment

The mineralization to CO_2 was minimal (<2%) by the end of the study (day 28)

Metabolite 1 (1-NAA)*)	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	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				
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				

*) the degradation of the metabolite 1-NAA in water sediment systems was investigated in two separate studies

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): 185.23 Water solubility (mg/L): 170 K_{OC} (L/kg): 20 (considered as realistic worst case for PEC_{water}) DT_{50} soil (d): 3 (considered as worst case based on the available data set) DT_{50} water/sediment system (d): 4.4 DT_{50} water (d): 4.4 DT_{50} sediment (d): 1000 (default value) Crop interception (%): full canopy
Metabolite 1-NAA Parameters used in FOCUSsw step 1 and 2	**Amid-Thin W – Task force** (metabolite modelled with the parent)**:** Molecular weight (g/mol): 186.2 % in water-sed: 21.3% (max. observed in sediment in a study where 1-NAA was applied as parent) % in soil: 78.10% **Amcotone and Amid-Thin W – Amvac** (metabolite modelled as a parent)**:** K_{fOC} (L/kg): 61.5 mL/g (the correct value is 61.2 mL/g) DT_{50} soil (d): 18.4 (the worse case DT_{50} of 77 days should have been used) DT_{50} water/sediment system (d): 9.5 DT_{50} water (d): 7 DT_{50} sediment (d): 1000 (default value)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	**Amid-Thin W – Task force:** Crop: pome / stone fruit (late application) Crop interception: full canopy Application rate(s): 80 g a.s./ha Number of applications: 1 Interval (d): - Application window: North Europe / March-May South Europe / March-May **Amcotone – Amvac :** Crop: pome / stone fruit (early application) Crop interception: full canopy Application Rate: 9.9 g a.s./ha (sum of 1-NAA and 1-

NAD, as a worst case) Number of applications: 2 Interval (d): 6 Application window: March-May (worst case, actual application likely in May- June) **Amid-Thin W – Amvac:** Crop: pome / stone fruit (early application) Crop interception: full canopy Application Rate: 50 g a.s./ha Number of applications: 1 Interval (d): - Application window: March-May (worst case, actual application likely in May- June)

1-NAD as Amid-Thin W (Task Force 80 g a.s./ha)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	30.16	-	5.19	-
	24 h	25.67	27.92	5.13	5.16
	2 d	21.93	25.83	4.38	4.95
	4 d	16.00	22.32	3.20	4.36
	7 d	9.97	18.22	1.99	3.58
	14 d	3.31	12.13	0.66	2.39
	21 d	1.09	8.75	0.21	1.73
	28 d	0.36	6.73	0.07	1.33
	42 d	0.04	4.53	0.00	0.89

1-NAD as Amid-Thin W (Task Force 80 g a.s./ha)

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	4.19	-	0.56	-
	24 h	3.52	3.85	0.48	0.52
	2 d	3.01	3.56	0.41	0.48
	4 d	2.83	3.15	0.30	0.42
	7 d	1.77	2.77	0.19	0.34
	14 d	0.60	1.93	0.06	0.23
	21 d	0.20	1.41	0.02	0.16
	28 d	0.07	1.09	0.00	0.12
	42 d	0.00	0.73	0..00	0.08
Southern EU	0 h	4.19	-	0.68	-
	24 h	3.52	3.85	0.58	0.63

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	2 d	3.01	3.56	0.50	0.59
	4 d	3.45	3.23	0.37	0.51
	7 d	2.16	3.02	0.23	0.42
	14 d	0.74	2.17	0.08	0.28
	21 d	0.25	1.60	0.02	0.20
	28 d	0.08	1.24	0.00	0.15
	42 d	0.01	0.84	0.00	0.10

1-NAA as Amid-Thin W (Task Force 80 g a.s./ha)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	21.29	-	4.07	-
	24 h	18.16	19.73	3.63	3.85
	2 d	15.52	18.27	3.10	3.60
	4 d	11.32	15.79	2.26	3.13
	7 d	7.06	12.89	1.41	2.56
	14 d	2.34	8.58	0.46	1.71
	21 d	0.77	6.19	0.15	1.23
	28 d	0.25	4.76	0.05	0.94
	42 d	0.02	3.21	0.00	0.64

1-NAA as Amid-Thin W (Task Force 80 g a.s./ha)

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.95	-	0.19	-
	24 h	0.81	0.88	0.16	0.17
	2 d	0.70	0.82	0.14	0.16
	4 d	0.51	0.71	0.10	0.14
	7 d	0.32	0.58	0.06	0.11
	14 d	0.11	0.39	0.02	0.07
	21 d	0.03	0.28	0.00	0.05
	28 d	0.11	0.21	0.00	0.04
	42 d	0.03	0.14	0.00	0.02
Southern EU	0 h	1.44	-	0.28	-

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	24 h	1.23	1.33	0.24	0.26
	2 d	1.05	1.24	0.21	0.24
	4 d	0.77	1.07	0.15	0.21
	7 d	0.49	0.88	0.09	0.17
	14 d	0.16	0.59	0.03	0.11
	21 d	0.05	0.42	0.01	0.08
	28 d	0.01	0.33	0.00	0.06
	42 d	0.00	0.22	0.00	0.04

1-NAA as Amid-Thin W (Amvac 50 g a.s./ha) according to Step 2 (Northern EU)

	PEC_{SW} (µg/L)		**PEC_{sed} (µg/kg dry sediment)**	
Time (days)	**Actual**	**TWA**	**Actual**	**TWA**
0	4.8662	---	2.3885	---
1	4.1847	4.5254	2.1803	2.2844
2	3.8044	4.2600	1.9902	2.1848
4	3.9493	3.9652	1.6583	2.0027
7	2.9331	3.7193	1.2613	1.7666
14	1.5488	2.9443	0.6660	1.3497
21	0.8179	2.3447	0.3517	1.0640
28	0.4319	1.9098	0.1857	0.8630
42	0.1204	1.3545	0.0518	0.6103
50	0.0580	1.1515	0.0250	0.5186
100	0.0006	0.5820	0.0003	0.2620

1-NAA as Amid-Thin W (Amvac 50 g a.s./ha) according to Step 2 (Southern EU)

	PEC_{SW} (µg/L)		**PEC_{sed} (µg/kg dry sediment)**	
Time (days)	**Actual**	**TWA**	**Actual**	**TWA**
0	4.8662	---	2.8771	---
1	4.1847	4.5254	2.6263	2.7517
2	3.8044	4.2600	2.3973	2.6317
4	4.7442	4.0646	1.9975	2.4123
7	3.5330	4.0725	1.5193	2.1279
14	1.8656	3.3427	0.8023	1.6258
21	0.9852	2.6884	0.4236	1.2816
28	0.5202	2.1985	0.2237	1.0396
42	0.1451	1.5636	0.0624	0.7352
50	0.0699	1.3299	0.0301	0.6246
100	0.0007	0.6726	0.0003	0.3156

1-NAA as Amcotone (Amvac 2x9.9 g a.s./ha) according to Step 2 (Northern EU)

	PEC_{SW} (µg/L)		**PEC_{sed} (µg/kg dry sediment)**	
Time (days)	**Actual**	**TWA**	**Actual**	**TWA**
0	1.2954	---	0.6904	---
1	1.1369	1.2161	0.6302	0.6603
2	1.0342	1.1508	0.5753	0.6315
4	1.1404	1.0827	0.4793	0.5789
7	0.8478	1.0387	0.3646	0.5106

14	0.4477	0.8329	0.1925	0.3901
21	0.2364	0.6656	0.1017	0.3075
28	0.1248	0.5429	0.0537	0.2495
42	0.0348	0.3855	0.0150	0.1764
50	0.0168	0.3277	0.0072	0.1499
100	0.0002	0.1657	0.0001	0.0757

1-NAA as Amcotone (Amvac 2x9.9 g a.s./ha) according to Step 2 (Southern EU)

	PEC_{SW} (µg/L)		**PEC_{sed} (µg/kg dry sediment)**	
Time (days)	**Actual**	**TWA**	**Actual**	**TWA**
0	1.4234	---	0.8643	---
1	1.2737	1.3486	0.7889	0.8266
2	1.1627	1.2834	0.7202	0.7906
4	0.9688	1.1735	0.6001	0.7247
7	0.7368	1.0340	0.4564	0.6392
14	0.3891	0.7895	0.2410	0.4884
21	0.2055	0.6223	0.1273	0.3850
28	0.1085	0.5047	0.0672	0.3123
42	0.0303	0.3569	0.0187	0.2208
50	0.0146	0.3032	0.0090	0.1876
100	0.0002	0.1532	0.0001	0.0948

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Task Force: PECgw were calculated with FOCUS PEARL 3.3.3.
Parent 1-NAD	Molecular weight (g/mol): 185.23 Water solubility (mg/L): 170 K_{OC}: 0 L/kg 1/n: 0.9 DT_{50} soil (d): 0.519 days
Metabolite 1-NAA	Molecular weight (g/mol): 186.2 Water solubility (mg/L): 376 K_{FOC} (L/kg): 61.18 1/n: 0.84 DT_{50} soil (d): 77 days Formation fraction: 1

Agronomic parameters used for simulations of the representative uses

	Amcotone (Amvac)	**Amid-Thin W (Amvac)**	**Amid-Thin W (Task Force)**
Crop	Apples	Apples	Apples
Application Rate	2 x 9.9 g/ha*)	1 x 50 g/ha	1 x 80 g/ha
Interception	65% (BBCH 65-70)	65% (BBCH 65-70)	65% (BBCH 66-69)
Application dates	15 May, 1 June	15 May	15 May
Dose rate applied to soil in PEARL modelling	0.003465 kg/ha (9.9x0.35/1000)	0.0175kg/ha (50x0.35/1000)	0.028kg/ha 80x0.35/1000

*) sum of 1-NAA and 1-NAD as a worst case

Focus modelling results the 80th percentile annual average concentration of 1-NAD and 1-NAA using FOCUS Pearl v3.3.3.

Scenario	Amcotone (Amvac) µg/L		Amid-Thin W (Amvac) µg/L		Amid Thin W (Task Force) µg/L	
	1-NAD	1-NAA	1-NAD	1-NAA	1-NAD	1-NAA
Châteaudun	<0.001	0.034	<0.001	0.133	<0.001	0.266
Hamburg	<0.001	0.042	<0.001	0.162	<0.001	0.326
Jokioinen	<0.001	0.042	<0.001	0.293	<0.001	0.545
Kremsmünster	<0.001	0.030	<0.001	0.108	<0.001	0.222
Okehampton	<0.001	0.033	<0.001	0.129	<0.001	0.245
Piacenza	<0.001	0.067	<0.001	0.202	<0.001	0.397
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Sevilla	<0.001	0.018	<0.001	0.075	<0.001	0.154
Thiva	<0.001	0.024	<0.001	0.089	<0.001	0.175

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 0.19 days for reaction with OH radicals ($1.5x10^6$ OH/cm^3) assuming 12 hours of sunlight (calculated by AOPWIN v1.92a, June 2008)
Volatilisation ‡	No data available
Metabolites	No data available

PEC (air)

Method of calculation	Expert judgement based on: $V_P = 9.4 \times 10^{-7}$ Pa at 20°C and Henry's law constant = 1.02×10^{-8} $Pa.m^3.mol^{-1}$

$PEC_{(a)}$

Maximum concentration	Negligible

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-NAD and 1-NAA Surface Water*: 1-NAD and 1-NAA Sediment*: 1-NAD and 1-NAA Ground water*: 1-NAD and 1-NAA Air: 1-NAD *) As the route of degradation in soils is not adequately described it is not possible to judge whether additional metabolites (other than 1-NAA) should be included in the residue definition.

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

R 53

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 ‡				
Japanese quail *(Coturnix coturnix japonica)*	1-NAD	Acute	* > 2000	-
Japanese quail	1-NAD	Dietary	4371	5620
Bobwhite quail	Metabolite 1-NAA	Dietary	* > 1606	
Bobwhite quail	Metabolite 1-NAA	Acute	> 2510	-
	a.s.	Long-term		
Mammals ‡				
rat	1-NAD	Acute	* 1655 (male)	-
rat	1-NAD	Acute	> 5050	-
mouse	1-NAD	Acute	1933 (female)	-
rat	Luxan Vruchtdunner	Acute	> 2000	-
rat	Amid-Thin W (Amvac)	Acute	> 10000	-
rat	Metabolite 1-NAA	Acute	> 2000	-
rat	1-NAD	Long-term (90-day oral)	5	
rat	1-NAD	Long-term (90-day oral)	73.8	
rat	1-NAD	Long-term (teratology)	* 10 mg/kg bw/day (maternal) 100 mg/kg bw/day (developmental)	
mouse	1-NAD	Long-term 18 months carcinogenicity	195 mg/kg bw/day	
Additional higher tier studies ‡				

* Endpoints used in the risk assessment

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

Worst-case scenario of one application of 80 g a.s./ha as Amid-Thin W (Task Force) on pome fruits

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds) 1-NAD				
Insectivorous bird	Acute	4.33	> 462	10
Insectivorous bird	Short-term	2.41	> 666	10
Insectivorous bird	Long-term	-	- [1]	5
Tier 1 (Birds) 1-NAA				
Insectivorous bird	Acute	4.33[2]	> 580	10
Tier 1 (Mammals) 1-NAD				

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Small herbivorous mammal	Acute	9.45	175	10
Small herbivorous mammal	Long-term	2.69	**3.71**	5
Tier 1 (Mammals) 1-NAA				
	Acute	9.45[2]	> 212	10
Higher tier refinement (Mammals) 1-NAD				
Small herbivorous mammal	Long-term	1.58	6.42	5
	Refinement of RUD_{LT} based on realistic foliage interception of 65 %			

[1] No long-term TER was calculated as no avian reproduction study is available
[2] it was assumed that 100 % of parent compound (1-NAD) is transformed to its metabolite (1-NAA).

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[1] (mg/L)
Laboratory tests ‡				
Fish				
Rainbow trout	1-NAD	96 hr (static)	Mortality, LC_{50}	44
Rainbow trout	Amid-Thin W (Task Force)	96 hr (static)	Mortality, EC_{50}	> 100 (8.2 a.s.)
Rainbow trout	Metabolite 1-NAA	96 hr (static)	Mortality, LC_{50}	> 56 < 100
Cyprinus carpio	Metabolite 1-NAA-Na	96 hr (static)	Mortality, LC_{50}	> 100
Rainbow trout	Metabolite 1-NAA	28 d (semi-static)	Growth NOEC	10
Aquatic invertebrate				
Daphnia magna	1-NAD	48 h (static)	Mortality, EC_{50}	> 56 < 100 (nom)
	Amid-Thin W (Task Force)	48 h (static)	Mortality, EC_{50}	> 100 (mm) (8.2 a.s.)
	Metabolite 1-NAA	48 h (static)	Mortality, EC_{50}	> 56 < 100 (nom)
	1-NAA-Na	48 h (static)	Mortality, EC_{50}	> 100 (nom)
	Metabolite 1-NAA	21 days (semi static)	Reproduction, NOEC	22 (nom)
Sediment dwelling organisms				
Indicate species.	a.s.	28 d (static)	NOEC	Not required
Algae				
Desmodesmus subspicatus	1-NAD	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 > 100

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Anabaena flos-aquae	1-NAD	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	Ongoing
Desmodesmus subspicatus	Amid-Thin W (Task Force)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 (8.2 a.s.) > 100 (8.2 a.s.)
Pseudokirchneriella subcapitata (formerly *Selenastrum capricornutum)*	Metabolite 1-NAA	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	47 (nom) > 100 (nom)
Pseudokirchneriella subcapitata (formerly *Selenastrum capricornutum)*	(1-NAA-Na)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	22.1 > 32.6
Anabaena flos-aquae	Metabolite 1-NAA	120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	35 78
Pseudokirchneriella subcapitata (formerly *Selenastrum capricornutum)*	Metabolite 1-NAA as contained in the product K-Salt Fruit Fix 800	72 h (static)	Biomass: E_bC_{50}	9.1 (nom)
Pseudokirchneriella subcapitata (formerly *Selenastrum capricornutum)*	Metabolite 1-NAA as contained in the product Fruit Fix Super Concentrate 800	72 h (static)	Biomass: E_bC_{50}	14.9 (mm)
Higher plant				
Lemna minor	1-NAD	14 d (static)	Fronds, NOEC	7.4
Myriophillum	1-NAD	14 d (static)	Fronds, NOEC	Ongoing
Lemna minor	Amid-Thin W (Task Force)	7 d (static)	Fronds, NOEC	8.6 (nom)
Myriophillum	Metabolite 1-NAA	14 d (static)	Fronds, EC_{50}	> 10 mg/L
Lemna gibba G3	Metabolite 1-NAA as contained in the product K-Salt Fruit Fix 800	14 d (static)	EC_{50} (mean frond count)	5.09 (nom)
Lemna gibba G3	Metabolite 1-NAA as contained in the product Fruit Fix Super Concentrate 800	14 d (static)	EC_{50} (mean frond count)	5.61 (mm)
Microcosm or mesocosm tests: not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Worst-case scenario of one application of 80 g a.s./ha as Amid-Thin W (Task Force) on pome fruits

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC_i	TER	Annex VI Trigger
1-NAD	Fish	44000	Acute	30.16	1459	100
	Aquatic invertebrates	> 56000	Acute	30.16	1857	100
	Algae	> 100000	Chronic	30.16	3316	10
	Higher plants	> 8600*	Chronic	30.16	285	10
Metabolite 1-NAA	Fish	> 56000	Acute	21.29	2630	100
	Fish	10000	Chronic	21.29	470	10
	Aquatic invertebrates	> 56000	Acute	21.29	1033	100
	Aquatic invertebrates	22000	chronic	21.29	2630	10
	Algae*	9100	Acute	21.29	427	10
	Higher plants*	5090	Chronic	21.29	239	10
Product Amid-Thin W (Task Force)	Fish	> 8200 (a.s.)	Acute	30.16	271	100
	Aquatic invertebrates	> 8200 (a.s.)	Acute	30.16	271	100
	Aquatic invertebrates	> 8200 (a.s.)	Chronic	30.16	271	10
	Aquatic plant	860 (a.s.)	Chronic	30.16	28	10

*: toxicity endpoint obtained with a formulated product

Bioconcentration				
	Active substance	Metabolite 1-NAA	Metabolite2	Metabolite3
$logP_{O/W}$	1.6	-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-NAD	> 138.7	> 100
Preparation		
Metabolite 1-NAA	> 100	> 100
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)

Test substance	Route	Hazard quotient	Annex VI Trigger
1-NAA	Contact	< 1	50
1-NAA	oral	< 0.98	50

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
Typhlodromus pyri ‡	Product Luxan Vruchtdunner[1]	Mortality (LR_{50})	> 40 g a.s./ha
Aphidius rhopalosiphi ‡	Product Luxan Vruchtdunner[1]	Mortality (LR_{50})	> 40 g a.s./ha

[1] preparation similar to the preparation Amid-Thin W (Task Force), on the basis of the composition

Worst-case scenario of one application of 80 g a.s./ha as Amid-Thin W (Task Force) on pome fruits

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Product Luxan Vruchtdunner	*Typhlodromus pyri*	> 40 a.s.	< 2	0.58	2
Product Luxan Vruchtdunner	*Aphidius rhopalosiphi*	> 40 a.s.	< 2	0.58	2

[1] A drift factor of 29.20 % was used for a distance of 3 m from the treated field

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 based on laboratory testing results Literature data on formulated product with 500 g/kg 1-NAD (application rate 100 g as/ha) indicated effects below 50 % of mortality.

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
Earthworms			
Eisenia foetida foetida	1-NAA	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil
Other soil macro-organisms: not required			
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		< 16 % effect at day 28 at 0.107 and 0.53 mg a.s./kg d.w.soil (80 g a.s/ha and 400 g a.s./ha)
Carbon mineralisation	a.s. ‡		< 7 % effect at day 28 at 0.107 and 0.53 mg a.s./kg d.w.soil (80 g a.s/ha and 400 g a.s./ha)
Field studies not required			

Toxicity/exposure ratios for soil organisms

Worst case scenario of one application of 80 g a.s./ha as Amid-Thin W (Task Force) on pome fruits

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia foetida foetida	1-NAA	Acute	0.037	>27027	10
	1-NAA	Chronic		Not required	5

[1] PEC soil, max without foliage interception and assuming that 100 % of 1-NAD is transformed in 1-NAA in soil

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

Laboratory dose response tests

Most sensitive species	Test substance1	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)	TER	Trigger
Daucus carota	K-salt Fruit Fix 800					5
Daucus carota	Fruit Fix super concentrate					5

[1] toxicity studies provided with these formulations are not representative for the formulation that Amvac and the Task Force included in the GAP. Therefore results could not be used in the risk assessment.

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

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-NAD, 1-NAA
water	1-NAD, 1-NAA
sediment	1-NAD, 1-NAA
groundwater	1-NAD, 1-NAA

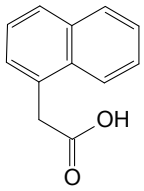
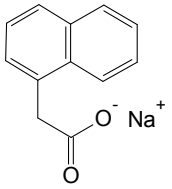
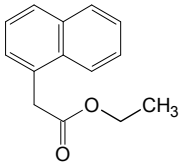
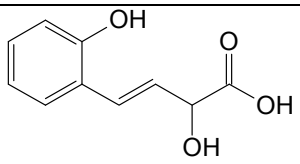
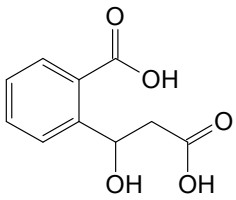
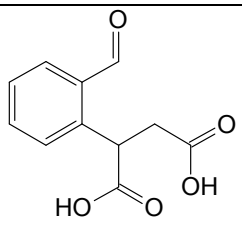
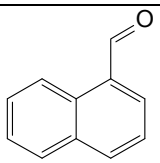
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

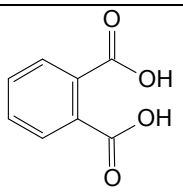
	RMS proposal
Active substance	R52: Harmful to aquatic organisms (pending for new studies to be submitted) R53: May cause long-term adverse effects in the aquatic environment

	RMS proposal
Preparation Amid-Thin W (Task Force)	Based on study results, the product should not be classified

Preparation Amid-Thin W (Amvac)	Not classified (pending for new studies on the a.s. to be submitted)
Preparation Amcotone	Not classified (pending for new studies on the a.s. to be submitted)

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
1-naphthylacetic acid 1-NAA	1-naphthylacetic acid	
1-NAA-Na	sodium 1-naphthylacetate	
1-naphthylacetic acid ethyl ester 1-NAA-Et	ethyl 1-naphthylacetate	
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	

phthalic acid M4	phthalic acid	

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

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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)
ASTM	American Society for Testing and Materials, ASTM International
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)
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-MS-MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
HPLC-DAD	high performance liquid chromatography with diode array detector
HQ	hazard quotient
HV	high volume sprayer
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
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
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
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
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
RAC	raw agricultural commodity
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