



STAFF UPDATE REPORT

APP202098 – Submission review and proposal update

November 2015

Veterinary medicine substances for reassessment	HSNO Approval number
Liquid containing 1.4 - 2.6% 2-hydroxybenzoic acid, 0.7 - 1.3% carbaryl and 0.11 - 0.29% chlorocresol (trade name Fido's Ear Drops)	HSR001825
Flammable liquid containing 7 – 13 g/L chlorpyrifos and 100 – 120 g/L cypermethrin (trade name FLYPEL)	HSR001812
Flammable liquid containing 120 - 180 g/L chlorpyrifos (trade name Xterminate 10)	HSR001814
Flammable liquid containing 32 – 50% chlorpyrifos (no trade name products identified)	HSR001816
Collar containing 140 - 180 g/kg diazinon and 1.7 - 3.2 g/kg pyriproxyfen (trade names PetScience Flea Collar Plus for Cats & Kittens, PetScience Flea Collar Plus for Dogs & Puppies)	HSR001802
Collar containing 140 - 180 g/kg diazinon (trade names VitaPet 5 Month Flea Collar For Dogs, VitaPet 5 Month Flea Collar For Cats, Pet Team Flea Collar for Dogs, Pet Team Flea Collar for Cats)	HSR001807
Flammable liquid containing 360 - 440 g/litre diazinon (trade name TopClip 40)	HSR001953
Solid containing 20 – 50 g/kg diazinon (no registered trade name products identified)	HSR001808

Flammable liquid containing 0.26 – 5% **diazinon**
(no registered trade name products identified)

HSR002288

Non-plant protection substances for reassessment	HSNO Approval number
Dustable powder containing 50 g/kg carbaryl (trade name Kiwicare No Wasps Insecticidal Dust)	HSR000672
Wettable powder containing 800 g/kg carbaryl (trade name Kiwicare Carbaryl Insect Control; Wasp Nest Carbaryl 80)	HSR000819
Ready to use bait containing 5 g/kg chlorpyrifos (no registered trade name products identified)	HSR000164
Paste containing 5 g/kg chlorpyrifos (no registered trade name products identified)	HSR000166
Microencapsulated suspension concentrate containing 200 g/L chlorpyrifos (no registered trade name products identified)	HSR000168
Emulsifiable concentrate containing 240 g/litre chlorpyrifos (no registered trade name products identified)	HSR000169
Ready to use liquid containing 20 g/litre chlorpyrifos (no registered trade name products identified)	HSR000172
Flammable liquid containing 2.5 – 3% chlorpyrifos (no registered trade name products identified)	HSR001810
General purpose insect spray (contains diazinon) (no registered trade name products identified)	HSR001741
Aerosol containing 0.3 – 0.7% carbaryl and 0.4 – 0.8% piperonyl butoxide (no registered trade name products identified)	HSR001811

Executive Summary

1. This document is the Staff Update Report for the EPA's application to reassess substances containing carbaryl, chlorpyrifos and diazinon used in veterinary medicines and for other non-plant protection purposes (APP202098). This report provides an update to the proposals initially presented in the application that have been revised in light of information received from submitters. This report should be read in conjunction with the original application.
2. The purpose of the application (APP202098) is to review the use of these substances in New Zealand. The EPA's preliminary assessment determined that with the exception of one substance (carbaryl containing ear drops, approval no. HSR001825) the risks associated with all of the other substances outweigh the benefits. Therefore, staff propose that these approvals be revoked.
3. EPA staff proposed that the risk from carbaryl containing ear drops (HSR001825) be managed through additional labelling and packaging controls. As a result of submitters comments we have suggested proposed wording for these controls to clarify the requirements.
4. In the application we identified a number of areas where additional information would enable us to improve the accuracy of our risk assessment. For substances used as sheep ectoparasiticide solutions this included information such as the number of animals treated per day and information about the disposal of sheep dipping solution.
5. We received new information from a submitter which allowed us to refine our human health and environmental risk assessment of the diazinon based ectoparasiticide solution (HSR001953). Our revised human health risk assessment of this substance indicates that the predicted Risk Quotient (RQ) values for users of this substance and to workers exposed post-application are still significantly above the level of concern. The conclusions of the environmental risk assessment are largely unchanged from the previous application. Consequently our recommendation that this substance have its approval revoked remains the same.
6. We received no additional information about any other approvals, therefore, our recommendations that these substance approvals should be revoked remains the same.
7. We received some information about the proposed six month phase out period for the approvals to be revoked. The EPA staff noted these submissions but still believe that due to the high risks identified, this phase out period should not be extended.

Overview of the EPA-initiated Reassessment process for these substances

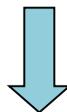
Grounds Application

Grounds must be established in order for an application for a reassessment to be lodged. An application for grounds is lodged with the EPA and is heard by an independent decision making committee established under HSNO.



Reassessment Application

Once grounds have been established, an application for a reassessment is lodged and notified for public consultation. The application contains the staff's initial assessment, including draft recommendations for the decision making committee



Staff Update Report

After receipt of submissions on the proposals in the application, EPA Staff prepare an update report taking into account information that has been submitted. This will be considered by the decision making committee.

This document is the Staff Update Report.



Consideration

Once the decision making committee is satisfied that they have sufficient information to make a decision, they will consider the application.



Decision

After consideration of the application, the decision making committee will issue its final decision.

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1. Background

1.1. Background to the reassessment

- 1.1.1. The Environmental Protection Authority (EPA) is reassessing substances containing carbaryl, chlorpyrifos and diazinon used in veterinary medicines and other non-plant protection products because of concerns about the safety and well-being of people and the environment arising from their use.
- 1.1.2. Chlorpyrifos and diazinon are organophosphates, and carbaryl is a carbamate compound. These organophosphates and carbamates (OPCs) are insecticides used against a broad range of insect pests for a variety of purposes including veterinary medicines and potentially for non-plant protection uses such as public health (e.g. for pest control in hospitals, restaurants etc.), and industrial uses (e.g. for building, warehouse or industrial structure pest control).
- 1.1.3. The acute health effects resulting from exposure to high levels of OPCs are well known from animal studies and numerous human poisoning incidents. Short term exposure can result in symptoms including increased sweating and salivation, dizziness, fatigue, runny nose or eyes, nausea, intestinal discomfort, confusion and changes in heart rate. At high levels of exposure more severe effects such as paralysis, seizures, loss of consciousness and death may occur.
- 1.1.4. As well as acute toxicity, there are concerns over the potential for OPCs to cause longer term adverse health effects in humans. These include the potential for chronic health effects following acute poisoning, and effects as a result of chronic exposure to lower levels that do not cause the clinical signs or symptoms of poisoning.
- 1.1.5. OPCs are also harmful to the environment. They are very toxic to the aquatic environment and to terrestrial invertebrates (e.g. bees).

1.2. Summary of application

- 1.2.1. The application, by the Chief Executive of the EPA, outlined our initial risk assessment of substances containing carbaryl, chlorpyrifos and diazinon used in veterinary medicines and for other non-plant protection purposes. Based on the results of the risks, cost and benefits assessment staff proposed that all but one approval should be revoked.
- 1.2.2. For one substance, carbaryl containing ear drops (HSR001825), staff considered that the benefits outweigh the risks, so we proposed that this approval should be retained. However, staff recommended that there should be a requirement for the substance to be supplied in

child resistant packaging as well as extra labelling controls warning users of the risks of the substance and how to mitigate these, for example, by wearing gloves.

2. Information taken into account

2.1. Submissions received on the application

2.1.1. The application was publicly notified on 25 August 2015 and submissions were sought on the application and preliminary proposals. The submission period closed on 6 October 2015.

2.1.2. The public submission period enabled members of the public, and in particular parties who may be affected by the outcomes of the application, to comment on the proposed controls and phase outs, and provide further information relevant to the reassessment of these substances.

Information sought through the submission process

2.1.3. The application highlighted a number of areas where key assumptions had been built into the risk assessment, or where significant data gaps had introduced uncertainty to the assessment. It was noted that additional information addressing those areas may allow for further refinement of the risk assessments.

2.1.4. Key areas where more information was requested included:

- Updated compositional information (including impurities and source of active ingredients) for the carbaryl ear drop product (HSR001825)
- Information on the dipping/showering/jetting of sheep/lambs, including the number of sheep/lambs treated per day for different application methods, equipment/facilities used, and methods for disposal of solution
- Submission of any available information on chlorpyrifos or diazinon that may allow refinement of the risk assessment modelling (i.e. dermal absorption studies, exposure monitoring studies, wool residue information), for substances used as flea collars or for control of blowfly strike, lice, and keds on sheep or lambs
- Information on whether any of the substances the EPA considers are no longer imported into or manufactured in New Zealand, are actually available
- Any additional information about the benefits of substances considered in this reassessment

Submissions received

2.1.5. Five submissions were received and detailed in the table. The submissions in full are available on the EPA website.¹ Two submissions supported the proposals outlined in the

¹ <http://www.epa.govt.nz/search-databases/Pages/applications-details.aspx?applID=APP202098>

application, two neither supported nor opposed the proposals and one opposed the proposals. No submitters requested to speak to their submissions at a hearing.

Submissions received

Submission Number	Submitter	Submitter Organisation (if relevant)
111533	Philippa Gibson	WorkSafe New Zealand - Auckland
111549	Oliver Sutherland	Te Rūnanga o Ngāi Tahu (Ngāi Tahu)
111551	John Hicking	Orion Crop Protection Ltd
111555	Ann Thompson	Federated Farmers of New Zealand (Incorporated)
111550	Chris Houston	Beef and Lamb New Zealand Ltd

2.1.6. Key points from the submissions are addressed throughout this report.

2.2. Matters addressed in this report

2.2.1. We have reviewed the information provided by Orion Crop Protection Ltd and consequently we have revisited some aspects of the risk assessment for the diazinon-containing sheep ectoparasiticide solution (HSR001953) as set out in the application including:

- a revised human health risk assessment (described in Appendix A)
- a revised environmental risk assessment (described in Appendix B)

2.2.2. We have also reviewed information which described the benefits of the diazinon-containing sheep ectoparasiticide solution (HSR001953), feedback about the proposed controls on the carbaryl containing ear drops (HSR001825) and some comments about the proposed phase out period.

2.2.3. In addition one submitter has raised some concerns about the environmental risk associated with the disposal of flea collars and about the possible human health legacy issues related to use of sheep ectoparasiticides.

3. Revised human health risk assessment for flammable liquid containing 360 - 440 g/litre diazinon (HSR001953)

3.1. Applicator risk assessment

3.1.1. Orion Crop Protection Ltd provided us with new information about the number of sheep that would be treated with diazinon based ectoparasiticide solution (HSR001953; Trade name TopClip 40) which allowed us to refine our risk assessment.

- 3.1.2. A full summary of the results of the human health risk assessment is included in Appendix A. The results indicate that even when full Personal Protective Equipment (PPE) is worn, the predicted exposures for the individual tasks involved in ectoparasiticide application (mixing and loading, application, clean up) are all significantly above the level of concern.
- 3.1.3. While there are still uncertainties in the risk assessment, which mean that EPA staff have adopted a conservative approach, we are still very concerned by the magnitude of the predicted exceedances.
- 3.1.4. EPA staff have not identified any controls which could manage the risks to users.
- 3.1.5. EPA staff note the comments of WorkSafe New Zealand who are not aware if PPE is regularly worn in this work environment or, if it is used, how well it is maintained.
- 3.1.6. The conclusions for applicator risks from this substance are therefore the same as in the application.

3.2. Post application shearer risk assessment

- 3.2.1. In the application the EPA requested information which could be used to refine the risk assessment to shearers.
- 3.2.2. Orion Crop Protection Ltd provided the EPA with a report from the United Kingdom (UK) which described the residues of diazinon in lambs' wool after dipping.
- 3.2.3. This report was reviewed by the EPA staff (see Appendix A). The results of the report indicate that the concentration of diazinon in the lambs' wool in the UK was significantly higher than that the levels found in Australian studies of wool residues, which were used in the risk assessment in the application (and also in a review of sheep ectoparasiticide products by the Australian Pesticide and Veterinary Medicines Authority (APVMA))².
- 3.2.4. Use of the new data would therefore lead to Risk Quotient (RQ) values significantly higher than those presented in the application.

3.3. Post application worker exposure

- 3.3.1. Orion Crop Protection Ltd also provided some information on the exposure of workers in the UK who handled animals after application of diazinon based ectoparasiticide solution to lambs. The tasks that the workers carried out included collecting wool samples from lambs (used for the analysis of wool residues described earlier), simulated drenching and examining the feet of the lambs. This exposure pathway was not considered in the EPA application as no information was available to assess it.

² APVMA, 2006 The reconsideration of approvals of selected sheep ectoparasiticide products and their associated labels Preliminary Review Findings Volume 1 of 2.

- 3.3.2. This information has been reviewed by EPA staff. The report outlines the workers' dermal exposure (through measuring exposure on their hands and clothing) and presents the results of biological monitoring of metabolites in the workers urine. The report does, however, suggest that post application handling of treated animals might potentially be a significant exposure route and that if use of this substance is to continue, there should be some thought given to how these risks could be managed.
- 3.3.3. We have not assessed this exposure route quantitatively due to the uncertainties in the data and the prior results indicating significant risks to workers.

3.4. Conservatism of the human health risk assessment and the apparent lack of poisoning incidents

- 3.4.1. Orion Crop Protection Ltd commented on the apparent discrepancy between the EPA's risk assessment which predicted very high RQ values and the lack of reported incidents involving diazinon based ectoparasiticide solution (HSR001953).
- 3.4.2. In the application it was pointed out that from the review of the National Poisons Centre (NPC) data there were only two incidents involving diazinon which could be attributed to the use of diazinon as an ectoparasiticide solution.
- 3.4.3. It should, however, be noted that of the 89 calls that the NPC received about diazinon since 2003, it was not possible to determine which diazinon substances were involved in the majority of calls since the substance involved was recorded only as diazinon (n=56 or 63 %). Therefore, it is possible that more calls to the NPC may have been related to sheep ectoparasiticide solution containing diazinon, but these details have not been recorded.
- 3.4.4. In addition, an absence of recorded incidents does not necessarily mean that incidents have not occurred, just that they have not been recorded. When an incident occurs in a workplace some staff may be reluctant to report this to enforcement agencies or health care providers because of concerns about losing their job. In addition if an employee does suffer adverse health effects following exposure it may not always be immediately clear what has caused the symptoms. For example, workers could be using multiple ectoparasiticide solutions within a short period of time, or the symptoms could be attributed to other sources.
- 3.4.5. In addition, the long-term effects of exposure are not readily attributable to specific chemicals. The quantification and verification of the impacts of long term exposure to diazinon cannot readily be addressed through provision of adverse effect reports, simply because it is extremely difficult to demonstrate cause and effect attributable to exposures occurring over a long timeframe.
- 3.4.6. EPA staff believe that the magnitude of the RQs, even for individual tasks, are a cause for concern irrespective of the level of conservatism in the risk assessment. Given the very high

toxicity of diazinon the risk assessment would need to be significantly refined in order for the conclusions to be changed. The conclusions of our risk assessment also appear to be consistent with those reached by the APVMA.

- 3.4.7. Ngāi Tahu suggested that given the results of the human health risk assessment it would be appropriate to direct the attention of the relevant industry bodies to the effects that past exposure may have had upon workers.
- 3.4.8. EPA staff note that both Beef and Lamb Ltd and Federated Farmers of New Zealand (Incorporated) have submitted on the reassessment application and are both aware of the results and conclusion of the human health risk assessment.

4. Updated environmental risk assessment for flammable liquid containing 360 - 440 g/litre diazinon (HSR001953)

4.1. Introduction

- 4.1.1. The EPA have received more information from Orion Crop Protection Ltd about the use pattern of diazinon as an ectoparasiticide solution (HSR001953, Trade name TopClip 40). This information regarded the volume of dipping solution used to treat animals, the time taken to treat one animal, stocking densities and some other information about animal treatment practices which could change the risks of the substance to the environment. The EPA have used this information to revise the risk assessment.
- 4.1.2. The revised risk assessment showed the same conclusions as the initial risk assessment. The risk assessments identified potential concerns for aquatic invertebrates from run off from the holding paddock (and possibly the treatment station) and from treated sheep on the paddock for multiple applications. In addition there are some concerns about disposal.
- 4.1.3. In the application staff requested information from submitters about the disposal of excess dipping solution. Orion Crop Protection Ltd identified that excess solution from plunge dipping is normally spread over land. While a quantitative environmental risk assessment has not been conducted for this practice there could be a potential risk to the soil and aquatic environments.
- 4.1.4. The submitter has stated that plunge dipping is not currently carried out very frequently (they estimated less than 1 % of applications occur via this method).
- 4.1.5. Shower dipping is the most common form of application (estimated by the submitter to be greater than 90 %). Since any dipping solution that runs off the sheep can be re-circulated there should be little or no waste solution to dispose of. This reduces the potential risks for

aquatic invertebrates from run off from holding paddocks or treatment stations identified in the previous risk assessment.

5. Benefits assessment

5.1. Flammable liquid containing 360 - 440 g/litre diazinon (HSR001953)

- 5.1.1. Orion Crop Protection Ltd provided a significant amount of information which illustrates how this substance is a very cost effective means of controlling ectoparasites in sheep.
- 5.1.2. This substance has 'knockdown' properties and kills insect larvae shortly after application, which gives immediate relief to the animal. This is in contrast to alternative Insect Growth Regulator (IGR) based products, which do not have knockdown properties, but tend to give longer term control of lice and blowfly maggots.
- 5.1.3. Orion Crop Protection Ltd pointed out that sheep farming profitability is volatile and suggested that removing a cheap ectoparasiticide option and requiring farmers to buy a more expensive option would have an impact on farmers' incomes.
- 5.1.4. EPA staff agree that this product is cost effective; however, this needs to be balanced against the risks of the substance. While in the short term there may be benefits for farmers from continued use of this substance, the human health risks from use may also have a financial implication for users, their families and the economy as a whole.
- 5.1.5. Orion Crop Protection Ltd also pointed out that removing this product from the market will increase the potential for resistance developing against other types of treatments.
- 5.1.6. In the AgResearch report commissioned by the EPA they state that it is difficult to predict whether this would translate into substantial problems in ectoparasite control and economic loss. Potentially, there may be some economic impacts felt in the sheep industry longer term depending on the development of pesticide resistance to newer actives and issues around pesticide residues and market access.
- 5.1.7. In their submissions both Federated Farmers and Beef and Lamb New Zealand stated that they believed that there were alternatives to diazinon as an ectoparasiticide solution and that although these were more expensive they could adequately manage ectoparasites.
- 5.1.8. In their report for the EPA, the New Zealand Institute of Economic Research (NZIER) state that the withdrawal of CCD organophosphates and carbamates is likely to have negligible costs given the wide range of substitutes available and the continued withdrawal of these products from the market by manufacturers without regulation requiring it.

- 5.1.9. The NZIER report also points out that there may be significant longer term trade and trade policy benefits by ensuring New Zealand does not become an outlier in organophosphate and carbamate use. Being an outlier (for example, allowing diazinon use on sheep while a major competitor Australia does not) increases the risks of New Zealand produce being excluded or sold at reduced prices in selected markets.
- 5.1.10. Orion Crop Protection Ltd point out that if this substance is withdrawn from the market, users may shift to another low cost alternative organophosphate product. If the chlorpyrifos based products (which are not currently being manufactured) also have their approval revoked, the only alternative organophosphate product would be one containing propetamphos which is used in an equivalent way.
- 5.1.11. The submitter has stated that propetamphos is more acutely toxic than diazinon. In the absence of a full review of all the available alternatives it is not possible to definitively comment whether or not propetamphos other alternatives are better or worse than diazinon.
- 5.1.12. EPA staff accept that there are some benefits associated with continued use of this substance. However these do not appear to be significant, particularly in light of the human health risks identified.

6. Comments on the proposed controls and phase out period

6.1. Controls for carbaryl containing ear drops (HSR001825)

- 6.1.1. WorkSafe New Zealand commented that they would like the EPA to change the wording of the Workplace Exposure Standards (WES) control description (code T2), to reflect the fact that WESs only relate to “airborne standards” and to list the full name of the Workplace Exposure Standards and Biological Exposure Indices document. EPA staff agree with these suggestions.
- 6.1.2. WorkSafe New Zealand correctly identified that although the EPA human health risk assessment concluded that there should be information on the product label informing users to wear gloves when using the product, this was not made explicitly clear in the proposed controls for this substance.
- 6.1.3. EPA staff agree that there should be an extra labelling control which makes it clear that manufacturers must state that users should wear gloves when handling the substance.
- 6.1.4. No submissions discussed the phase in time for the new controls for this substance, hence staff believe that the two years proposed in the application is still appropriate to allow time for product relabelling and packaging.

6.2. Proposed phase out periods

- 6.2.1. In the application the EPA proposed that given the high risks of these substances all uses should stop within six months of the decision.
- 6.2.2. Both WorkSafe New Zealand and Orion Crop Protection Ltd highlighted the fact that use of the diazinon based ectoparasiticide solution (HSR001953) is seasonal.
- 6.2.3. Orion Crop Protection Ltd informed the EPA that the main use periods of this substance for flystrike control are October to February, and for lice control from February to May, hence any phase out period would ideally finish at the end of the season, so that retailers or users do not end up with excess product that they must dispose of.
- 6.2.4. Staff consider that even given the seasonal nature of any of the substances proposed for phase out the six month phase out period should remain. This would ensure that the substances are available for use up until May 2016, at which point the substances will no longer be required until the next season.

7. Conclusions

- 7.1.1. We have reconsidered our position in light of the submissions. For all substances our general recommendations remain the same, namely that with the exception of the carbaryl containing ear drop (HSR001825), all approvals should be revoked.
- 7.1.2. We received extra information about the risks and benefits of diazinon based ectoparasiticide solution (HSR001953). Having reviewed this information our position still remains that the risks outweigh the benefits, hence the substance should be revoked.
- 7.1.3. We have changed our recommendations about some of the wording of the controls for the carbaryl containing ear drop to make the requirements clearer.

Appendix A: Revised health risk assessment for HSR001953 Flammable liquid containing 360 - 440 g/litre diazinon (Tradenname TopClip 40)

Operator exposures

Revised risk assessment

In the application the EPA determined the risks to those applying this product using exposure data gathered from an occupational exposure trial in Australia, which involved monitoring workers using a similar product containing diazinon (APVMA, 2006a). Exposure data were corrected to account for the number of sheep in the Australian study versus those assumed by the EPA to be treated in New Zealand. The results of the initial risk assessment indicated that there were significant risks to those who were involved in applying this product by either dipping, jetting, or using a shower dip.

In the application the EPA stated that the risk assessment could be refined with the following information.

- Dermal absorption studies for the product and the dipping solution.
- Exposure data for users of the dipping or jetting solution using practices similar to those carried out in New Zealand (for example a study similar to that carried out by Wood (2004) (in APVMA, 2006a) on diazinon sheep dipping).
- Information on the number of sheep treated per day.

EPA were not provided with any exposure monitoring data for workers engaged in tasks relating to applying diazinon to sheep or workers shearing treated sheep or any information on dermal absorption. However, information about the number of sheep that could be treated per day was provided by one submitter. This information has been used to carry out a revised human health risk assessment and is outlined below. The methodology and toxicological endpoints used are the same as that described in the original application and therefore these details have not been reproduced in the present document.

EPA staff acknowledge that the risk assessment is conservative. This conservatism is a consequence of a lack of data. The use of a default dermal absorption value of 75 % (due to an absence of other values) will lead to high Risk Quotient (RQ) values. EPA staff did not have any data about the possible exposures of New Zealand workers to sheep dipping solution; therefore it was necessary to use the results of an exposure monitoring study in Australia. The use of a range of data from average to maximum exposures, while reasonable for the individual tasks (e.g. mixing and loading, dipping, cleaning) will lead to a very conservative result if the maximum exposures are added together for all of the tasks.

Plunge dip (portable & fixed); of Sheep; for Biting louse, blowflies, ked; using Top Clip 40 [400 g active ingredient/L]; at use rate 200g/1000L; 1–2 or more application for blowflies

In the application the EPA assumed that this method of application would be used to treat 2000 sheep per day. The risk assessment indicated that the predicted exposures would be significantly higher than the level of concern. A submitter has provided information to the EPA that they believe that there would only be approximately 720 sheep treated per day. EPA have used this information to revise the risk assessment for the portable and fixed plunge dipping. Note that the exposure from clean up operations is not expect to change when a different number of sheep are treated and therefore these values have not been changed. Results of the original risk assessment are shown in Tables 1 and 3 and the results of the refined risk assessment are presented in Tables 2 and 4 below.

Table 1 Range of RQs for portable plunge dipping of 2000 sheep/day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 200g/1000L; 1–2 or more application for blowflies (numbers have been rounded).

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	11272	43960	14	19
Applicator/Handler	14584	53504	872	3864
Clean up crew	516	1801	23	118
Total	26372	99265	909	4001

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Table 2 Range of RQs for portable plunge dipping of 720 sheep/day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 200g/1000L; 1–2 or more application for blowflies (numbers have been rounded).

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	4057	15826	5	7

Applicator/Handler	5249	19261	314	1390
Clean up crew	516	1801	23	118
Total	9822	36888	342	1515

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Table 3 Range of RQs for fixed plunge dipping of 2000 sheep/day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 200g/1000L; 1–2 or more application for blowflies (numbers have been)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	11272	43960	14	19
Applicator/Handler	13632	74568	320	848
Clean up crew	516	1801	23	118
Total	25420	120329	357	985

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Table 4 Range of RQs for fixed plunge dipping of 720 sheep/day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 200g/1000L; 1–2 or more application for blowflies (numbers have been)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	4057	15826	5	7
Applicator/Handler	4908	26845	114	306
Clean up crew	516	1801	23	118

Total	9481	44472	142	430
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A External patch exposure data from APVMA (2006a)

B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Shower dip of Sheep; for Biting louse, blowflies, ked; using Top clip 40 [400 g active ingredient/L]; at use rate, 400g/1000L; 1–2 or more application for blowflies

In the application EPA staff assumed that up to 2000 sheep per day would be treated per day. A submitter has indicated that there would be approximately 1920 sheep treated per day. EPA staff consider that these differences are so small that the risk assessment does not need to be revised from the original application. The RQ values as shown in Table 5 are significantly above the level of concern.

Table 5 Range of RQs for shower dip of 2000 sheep per day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 400g/1000L; 1–2 or more application for blowflies (numbers have been rounded so the totals may not exactly add up)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	11268	43960	14	19
Applicator/Handler	7624	52452	756	2776
Clean up crew	516	1801	23	118
Total	19408	98213	793	2913

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Jetting (Automatic & Hand); of Sheep; for Biting louse, blowflies, ked; using Top clip 40 [400 g active ingredient/L]; at use rate, 500g/1000L; 1–2 or more application for blowflies

In the application EPA staff assumed that up to 500 sheep per day would be treated per day. A submitter has indicated that approximately 720 sheep would be treated per day by jetting. Consequently the EPA have revised the risk assessment to take this into account. The result of the original risk assessment are shown in tables 6 and 8 and results from the revised risk assessment are shown in tables 7 and 9.

Table 6 Range of RQs for automatic jetting of 500 sheep per day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 500g/1000L; 1–2 or more application for blowflies (numbers have been rounded)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	2817	10990	3.4	4.8
Applicator/Handler	5781	18952	1026	11062
Clean up crew	516	1801	23	118
Total	9114	31743	1052	11184

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Table 7 Range of RQs for automatic jetting of 720 sheep per day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 500g/1000L; 1–2 or more application for blowflies (numbers have been rounded)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	4057	15826	5	7
Applicator/Handler	8324	27291	1477	15929

Clean up crew	516	1801	23	118
Total	12897	44918	1504	16054

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Table 8 Range of RQs for hand jetting of 500 sheep per day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 500g/1000L; 1–2 or more application for blowflies (numbers have been rounded)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	2817	10990	3.4	4.8
Applicator/Handler	73385	174960	51420	142985
Clean up crew	516	1801	23	118
Total	76718	187751	51446	143108

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Table 9 Range of RQs for hand jetting of 720 sheep per day for biting louse, blowflies and ked using Top clip 40 [400 g active ingredient/L]; at use rate, 500g/1000L; 1–2 or more application for blowflies (numbers have been rounded)

	No PPE ^A		PPE ^B	
	Mean	Maximum	Mean	Maximum
Mixer/loader	4057	15826	5	7
Applicator/Handler	105676	251944	74042	205895
Clean up crew	516	1801	23	118
Total	110249	269571	74070	206020

^A External patch exposure data from APVMA (2006a)

^B Internal patch exposure data from APVMA (2006a) Washable cotton hat; Half face respirator; Elbow-length PVC gloves, cuff folded outwards; Cotton overalls done up to neck/wrists; Water resistant footwear/boots; Waterproof full-length bib apron

Conclusions of operator risk assessment

The results indicate that all of the use scenarios considered with the revised numbers of sheep had predicted exposure to users significantly greater than the AOEL. The magnitude of the exceedances (even if PPE is worn) are still of concern.

Post-application worker exposure

Shearers

Shearers are considered the occupational group most at risk from exposure to diazinon after application to sheep by dipping or jetting mixes. Shearers are exposed to the wool grease while handling the sheep. In the application form the EPA assessed the risks to a shearer from being exposed to wool grease contaminated with diazinon residues. This was the same approach as the APVMA used (APVMA, 2006b). To determine the residues on the wool, the EPA used data published by the APVMA in their review of sheep ectoparasiticide products (APVMA, 2006b). These data came from a number of studies in Australia supplied to the APVMA by a variety of application methods.

In the application EPA requested the following information which could be used to refine the risk assessment for shearers.

- Dermal absorption studies for the active ingredient in wool grease.
- Information on residue levels in wool following application.
- An occupational exposure study of shearers to pesticide residues in wool grease.

A submitter has provided the EPA with information about the residues of diazinon in lamb's wool after dipping. The study was carried out in the UK in the early 1990s. The lambs were dipped in a solution containing between 122 - 575 mg diazinon/l. The study indicated that there was significant variation in the diazinon concentration over time and at different depths in the sheep dip, however the average concentration was 428 mg/l and the range of concentrations that the lambs were treated with was similar to that which sheep might be expected to be treated with in New Zealand e.g. 200 mg/l for plunge dipping, 400 mg/l for shower dipping and 500 mg/l for jetting. Two separate groups of sheep were studied, one group who were kept outdoors on pasture and one group who were kept indoors.

The study determined the concentration in wool at 1, 2, 4, 6, 8 and 10 weeks after dipping (the results were presented in terms of mg/kg wool). These values in wool for the UK can be directly compared with those used in the Australian assessment of diazinon residues in wool by the APVMA. It should be

noted that in the risk assessment in the reassessment application the EPA (as per the APVMA assessment) assumed that all of the diazinon in the sheep wool was contained in the wool grease and that the wool grease composed 13 % of the total wool. Comparison of the UK study values to the Australian values indicates that the concentrations of diazinon in wool found in the UK study were significantly higher than those found in the Australian review. While it was noted that the degradation of diazinon on wool was significantly slower on lambs kept indoors than those outdoors, even the mean residue on lambs kept outdoors after 10 weeks (523 mg diazinon/kg wool) was significantly higher than those observed in the Australian studies at 8 weeks (148 mg/kg).

It is not known why the residues in this study appear to be so much higher than those observed in studies in Australia. This could be due to differences in a range of possible ectoparasiticide products factors such as the application methods, wool type or, environmental conditions, sampling method or analytical test. The EPA have not used these values to revise the risk assessment since the risks with the lower residues in wool were already significantly above the level of concern. Use of the new data would therefore lead to risk quotient values significantly higher than those presented in the application. These data do, however, show the fact that there can be significant variation in the residues levels in wool that can occur in different conditions and that ideally the EPA risk assessment would use residue levels obtained in New Zealand from a representative set of use conditions.

Animal handler exposure

A submitter provided the EPA with a study which provides information about the exposure of workers in the UK who handled animals after application. The tasks that the workers carried out included collecting wool samples from lambs (used for the analysis of wool residues described earlier), simulated drenching and examining the feet of the lambs. These exposure pathways were not considered in the EPA application.

There were two sets of 50 lambs, one group that was kept outdoors and one group that was kept indoors. In total the exposure of four workers were examined (2 for the group of lambs who were kept indoors and 2 for the group who were kept outdoors). The sheep were dipped in a solution containing between 122 - 575 mg diazinon/l (average 438 g/l). The sheep were handled at 1, 2, 4, 6, 8 and 10 weeks after application. From the information provided it is not completely clear how many lambs were handled but it appears that all the lambs had their feet examined and had drenching simulated on them while 25 lambs from each group had their wool sampled. Handlers wore wellington boots and a boiler suit when handling the lambs. In addition the group handling the lambs who were outdoors wore waterproof trousers. After handling, the handler's hands were swabbed using cotton wool pads. In addition the handlers boiler suits were sampled by cutting section from the legs, arms and torsos.

The study also examined the effectiveness of hand washing on the removal of diazinon from the handlers hands. This was done at 6 weeks after the application. One operator handled 12 lambs and then got their hands swabbed. The same operator then handled 12 more lambs but then washed their hands before getting them swabbed.

The results of this analysis are presented in the forms of tables which show the exposures of the handlers hands, legs arms and torsos at different times after dipping. Given the small number of samples and some of the uncertainties about the handling procedures used and their applicability for New Zealand, the EPA have not summed these data and compared them to the Acceptable Operator Exposure Level (AOEL) to estimate Risk Quotient values. Instead the main conclusions of this report are presented below.

In addition to the residue sampling on hands and arms and torsos outlined above urine samples were also taken from each operator the day before the handling session (to provide a baseline metabolite value) and during the 24 hour period immediately after handling the lambs at 1, 2, 4, 6, 8 and 10 weeks. The urine samples taken from the handler on the day prior to the first handling were used as negative controls for the urinary metabolites for each handler. The samples were then sent for analysis of the diazinon metabolite diethylphosphate and diethylthiophosphate.

Diazinon concentrations on the hands

The results showed significant variation in exposure between handlers. In general there was substantially less exposure on the hands of the handlers who handled the sheep who were outdoors than those who handled sheep indoors. In addition the breakdown of the diazinon appeared to be quicker on sheep outdoors than those who were indoors. While there was a significant reduction in the diazinon values over time, residues were still observed at 10 weeks after the application

Staff note that if the exposures reported in this report from hand exposure alone were compared to the AOEL value for a 70 kg operator assuming 75 % dermal absorption, even using the lowest values at 10 weeks for sheep kept outdoors, the risk quotient values would still be above the level of concern.

Diazinon concentrations on the hands after washing

The study showed that that hand washing after handling treated animals significantly reduced the exposure by up to an order of magnitude.

Exposure on a boiler suit

The results showed significant variation in exposure between handlers. In one operator the highest exposure was found on the upper front torso, while on other operators the highest exposure was found on the legs. In general exposure of handlers handling sheep who were kept outdoors was less than those who handled sheep kept indoors. Significant degradation was observed over time, with approximately half of the samples taken from the handlers handling sheep who were kept outdoors not showing any traces of diazinon by week 10. The limit of detection while not stated appears to be 0.001 mg. The data provided do not provide sufficient information to calculate an estimate of the extent of diazinon absorption.

Metabolites in urine

The results indicated significant variation in the amount of metabolites excreted in the 24 hour period post handling. In general the results did not indicate significant reduction in the concentration of both DEP and DETP over time (from 1 to 10 weeks). In addition, the handlers of sheep who were kept outside appeared to have higher concentrations of DEP and DETP in their urine which is the opposite from the other findings of the report.

Conclusions on post-application exposure

It is difficult to determine how valid the data contained in this report are for use in a New Zealand context. The report does suggest that there is the potential for worker exposure for workers handling treated sheep for a period of time of up to 10 weeks, which is consistent with the information on wool residues over time available in the Australian studies that were previously considered. The information provided does not alter the previous conclusions that there may be significant risks to workers shearing treated sheep, and suggests that there may be similar concerns for other workers handling treated sheep.

References

APVMA, 2006a the reconsideration of approvals of the active constituent diazinon, registrations of products containing diazinon and approval of their associated labels Part 2. Available online at <http://apvma.gov.au/sites/default/files/diazinon-phase-6-prf-vol2.pdf> Accessed 06/01/2015

APVMA, 2006b The reconsideration of approvals of selected sheep ectoparasiticide products and their associated labels Preliminary Review Findings Volume 1 of 2. Available online at <http://apvma.gov.au/sites/default/files/sheep-ectoparasiticide-phase-6-preliminary-review-findings-vol1.pdf> Accessed 06/01/2015

Appendix B Revised environmental risk assessment for HSR001953 Flammable liquid containing 360 - 440 g/litre diazinon (Tradename TopClip 40)

Introduction

The EPA has received additional information from a submitter about the use patterns of this substance. This information related to the volume of dipping solution used to treat animals, the time taken to treat one animal, stocking densities and some other information about animal treatment practices which could change the risks of the substance to the environment. The EPA have used this information to revise the risk assessment.

Risk assessment

The methodology, physical-chemical properties, environmental fate endpoints and ecotoxicology endpoint used in the environmental risk assessment are the same as that described in the original application and therefore these details have not been reproduced in the present document.

Under this description and approval number just one product (Topclip 40) is on the market. Topclip 40 is used to control lice, keds and blowfly strike in sheep. The recommended dose rate is for plunge and standard shower dip 500 ml product/1000 L water (200 g a.i./1000 L) and for constant replenishment shower dip 1 L product/1000 L water (400 g active ingredient (a.i.)/ 1000 L). For jetting of lambs the rate is 250 ml product/ 200 L water (500 g a.i./ 1000 L) and maximal 1 L solution per animal.

The new use information provided by a submitter was used to refine the risk assessment. The amount of dip solution used has been revised from 4.8 – 8 L per animal to an average of 4 Litres (L) dip solution per animal with a plunge dip/ shower dip, therefore 250 animals can be treated with 1000 L of dip solution. For the jetting of lambs, 1 L solution per animal is the worst case situation, as was previously assumed.

Consistent with the human health assessment one application per year per sheep is assessed and in addition a worst case situation of three applications was assessed in the original risk assessment. Based on information provided by the submitter, this has been revised to a maximum of two applications per season.

For the revised risk assessment the EPA will also use the following figures:

- Plunge dip/ standard shower dip: 200 g a.i./ 1000 L results in 0.8 g a.i./ sheep,
- Constant replenishment shower dip: 400 g a.i./ 1000 L results in 1.6 g a.i./sheep,
- Jetting of lambs: 500 g a.i./ 1000 L and 1 L solution per animal results in 0.5 g a.i./lamb.

Risks of diazinon from treated sheep on the pasture

The revised risk assessment results are provided in tables 1 and 2.

Table 1 Predicted environmental concentrations and risk quotients of diazinon using one application

Compartment	Species	Effect	Assessment factor	PEC	PNEC	Risk Quotient
soil	earthworm	LC ₅₀ = 65 mg a.i. /kg	10	plunge dip 0.0267 mg/kg soil	6.5 mg a.i./kg	0.004
				constant shower dip 0.0533 mg/kg soil		0.008
				Jetting lamb 0.0235 mg/kg soil		0.004
Ground water	Fish	LC ₅₀ = 0.27 mg a.i./L	100	Plunge dip 0.58 µg/L	2.7 µg a.i./L	0.21
				constant shower dip 1.16 µg/L		0.43
				0.51 µg/L jetting		0.19
	Daphnia	EC ₅₀ = 0.001 mg a.i./L	100	Plunge dip 0.58 µg/L	0.01 µg a.i./L	58
				constant shower dip 1.16 µg/L		116
				0.51 µg/L jetting		51
Surface water	Fish	LC ₅₀ = 0.27 mg a.i./L	100	Plunge dip 0.19 µg/L	2.7 µg a.i./L	0.07
				constant shower dip 0.39 µg/L		0.14

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				Jetting 0.17 µg/L		0.06
	Daphnia	EC ₅₀ = 0.001 mg a.i./L	100	Plunge dip 0.19 µg/L	0.01 µg a.i./L	19
constant shower dip 0.39 µg/L				39		
Jetting 0.17 µg/L				17		

L(E) C₅₀ is the concentration of a substance that will be lethal (L) or induce an effect (E) to 50% of the tested population

Table 2 Predicted environmental concentrations and risk quotients of diazinon using two applications

Compartment	Species	Effect	Assessment factor	PEC	PNEC	Risk Quotient
soil	earthworm	LC ₅₀ = 65 mg a.i. /kg	10	plunge dip 0.0533 mg/kg soil	6.5 mg a.i./kg	0.008
				constant shower dip 0.107 mg/kg soil		0.016
				Jetting lamb 0.047 mg/kg soil		0.007
Ground water	Fish	LC ₅₀ = 0.27 mg a.i./L	100	Plunge dip 1.16 µg/L	2.7 µg a.i./L	0.43
				constant shower dip 2.33 µg/L		0.86
				Jetting 1.03 µg/L		0.38
	Daphnia		100	Plunge dip 1.16 µg/L	0.01 µg a.i./L	116

		EC ₅₀ = 0.001 mg a.i./L		constant shower dip 2.33 µg/L		233
				Jetting 1.03 µg/L		103
Surface water	Fish	LC ₅₀ = 0.27 mg a.i./L	100	Plunge dip 0.39 µg/L	2.7 µg a.i./L	0.14
				constant shower dip 0.78 µg/L		0.29
				Jetting 0.34 µg/L		0.13
	Daphnia	EC ₅₀ = 0.001 mg a.i./L	100	Plunge dip 0.39 µg/L	0.01 µg a.i./L	39
				constant shower dip 0.78 µg/L		78
				Jetting 0.34 µg/L		34

L(E) C₅₀ is the concentration of a substance that will be lethal (L) or induce an effect (E) to 50% of the tested population

The use of Topclip 40 does not pose a risk to soil organisms, based on RQ values being < 1. This is consistent with the original risk assessment.

The RQ values for aquatic organisms are similar to those calculated in the original evaluation and are > 1 so further assessment is needed. This Tier A assessment is a worst case calculation where it is assumed that 100% of the applied dose is excreted on the pasture. The assessment can be refined by taking metabolism into consideration and to refine the initial predicted environmental concentration in soil (PEC soil initial) by taking into account the potential for metabolism by the animal (PEC soil refined = PEC soil initial x Fraction of dose considered to be active).

Although no data on metabolism in sheep are available, it is known that diazinon is extensively metabolised and is excreted via urine in rat (>90% after 24 hours). Two major metabolites are determined in urine, G27550 and GS31144 38.2% and 17.3% respectively. The amount of diazinon in urine was 0.06 -0.17% of the radioactive dose administered. The same pattern was found in goat, an average of 75% is excreted via urine and G27550 and GS31144 were detected as major

metabolites. In chickens the same pattern was determined (EFSA 2006). As the metabolic pathways of the rat, ruminants (goat) and chickens do not differ significantly, it is likely that the metabolism in sheep will follow the same pathway.

Based on the metabolic pathway the amount of diazinon is not considered to be significant and the fraction of dose considered to be active will be very small (almost 0) but the two major metabolites are considered to be relevant. The toxicity of G27550 and GS31144 is tested for fish, Daphnia and alga. The L(E) C₅₀ is > 100 mg/L for these organisms for both metabolites, which is significant lower than the toxicity of diazinon. Therefore, as with the previous evaluation, EPA staff consider the overall risk of one application to aquatic organisms from treated sheep in the pasture not significant. However multiple applications may cause adverse effects to aquatic organisms.

Holding paddock

After treatment, animals are turned out into holding paddocks or yards where any drippings will contaminate the soil. In the application the EPA assumed that approximately half the applied active ingredient runs off and that the stock density in the holding paddock was 3 sheep / m² (APVMA, 2006).

Information obtained from a submitter has stated that the stock density in the holding paddock is 1 sheep/ m². This new information was used to revise the risk assessment from the previous assumption of 3 sheep/m².

The PEC soil was calculated to be 5.3 mg diazinon/kg soil, compared with a value of 32 mg diazinon/kg soil in the original assessment. This is significantly less than the LC₅₀ for earthworms which is 65 mg ai/kg soil. Therefore it is unlikely that diazinon will cause adverse effects on soil invertebrates in the holding paddock. Furthermore diazinon is considered to be non persistent (DT₅₀ = 23 days) so residues will degrade within a reasonable period. The dose rates for plunge dip and jetting are lower so the possible effects of these methods will be even smaller.

There is also a potential for run off from the holding paddock into water ways. Based on the methodology used in the application, the calculated PEC of diazinon in a pond from run off following treatment by dipping is 5.3 µg/L, compared with 10.7 µg/L in the original assessment. As calculated previously, the PEC following jetting was calculated to be 1.6667 µg diazinon/L.

The EC₅₀ for Daphnia is 1 µg/L. As the PECs are > 1 µg/L there is a potential hazard to aquatic invertebrates. This calculation does not take fate and behaviour of the substance into account.

Further information provided by a submitter revealed that shower dip is considerably more widely used than plunge dip (it was estimated that less than 1% of sheep would be treated by plunge dipping). The sheep are held in the treatment area for approximately 5 minutes after the shower dip has finished before the sheep are allowed in the holding paddock. The collected drip will be re-used and the drip after shower dip in the holding paddock is minimal.

Diazinon is known to be slightly mobile and can leach in soil. The EPA expect the overall risk from run off from the holding paddocks after shower dipping to be low based on the information provided about how this procedure is conducted. Even so, run off from the holding paddock should not be allowed to contaminate natural waterways.

Conclusion

Based on the $RQ < 1$ the use of Topclip 40 does not pose a risk to soil organisms from treated sheep on the pasture or from sheep in a holding paddock.

Based on the Tier A assessment the use of Topclip 40 poses a risk to aquatic organisms from treated sheep in the pasture. In the further assessment the metabolism of diazinon is taken into account.

Based on the metabolic pathway the amount of diazinon is not considered to be significant but two major metabolites (G27550 and GS31144) are relevant. However the toxicity of both metabolites is > 100 mg/L, which is significant lower than the toxicity of diazinon. EPA staff therefore consider the overall risk of one application to aquatic organisms from treated sheep in the pasture not significant. However multiple applications may cause adverse effects to aquatic organisms.

Further run off from the holding paddock might pose a risk to aquatic organisms, this risk is expected to be low after shower dipping. However, run off should not be allowed to contaminate natural waterways.

EPA staff note that these conclusions are based on an assumption that the treated animals do not leave the holding paddock until the product has dried and adsorbed onto the fleece and they do not enter a waterway within 1 hour after treatment.

Treatment station and equipment

There is potential for significant environmental exposure from a treatment station. This depends on the construction of the station and whether the direct drip is collected and recycled or not. Due to a lack of data the EPA is not able to perform a quantitative risk assessment. Further information revealed that shower dip is more used than plunge dip. The sheep are held in the treatment area for approximately 5 minutes after the shower dip has finished before being allowed in the holding paddock. The collected drip will be re-used and the drip in the holding paddock after shower dip is minimal.

However based on the potential risks from run-off from the holding paddock especially after plunge dip the EPA consider that run-off from treatment station might pose a risk to the aquatic environment.

Disposal of used dip

There is potential for significant environmental exposure from incorrect disposal of used dip. Normal practice could be stripping the dip out and cover the reduced dip until cleaning out the dip for the next

dip treatment. The dip is disposed onto ground. During the resting period the amount of active ingredient is reduced by degradation which reduces the environmental impact.

It is also possible that the used dip is stripped out and disposed on a paddock shortly after finishing the treatment. This might result in significant environmental risks.

Further information revealed that for plunge dipping common practice is to dispose the left over solution by spreading onto an area of land which is not used for cropping or grazing. The dip then soaks into the soil where it is biologically and chemically degraded. For shower dipping and jetting there will be no unused solution left.

Disposal of used dip solution to land is not considered to be a sustainable option, however, EPA staff note that a submitter has stated that plunge dipping is currently rarely used (their estimation is less than 1%).

References

APVMA (2006). The reconsideration of approvals of the active constituent diazinon, registrations of products containing diazinon and approval of their associated labels, Part 2, Volume2 Technical reports June 2006

<http://apvma.gov.au/sites/default/files/diazinon-phase-6-prf-vol2.pdf>

ATSDR (Agency for Toxic Substances and Disease Registry, 1997) Toxicological profile for chlorfenvinphos. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, Atlanta, Georgia.

CVMP (2008) Revised Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in Support of the VICH Guidelines GL6 and GL38. EMEA/CVMP/ERA/418282/2005-Rev 1. London, 23 June 2008.

EC (2003). Technical guidance document on risk assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market – Part II.

EFSA (2006a) Conclusion on pesticide peer review: peer review of the pesticide risk assessment of the active substance diazinon, EFSA Scientific Report 85, 1-73

EPA Substance Database

VICH guidelines: GL 6: Guideline on environmental impact assessment for veterinary medicinal products phase I, VICH GL 38: Guideline on environmental impact assessment for veterinary medicinal products phase II <http://www.vichsec.org/guidelines/biologicals/bio-quality/impurities.html>

