



# SUBMISSION FORM

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<b>Submission on application number:</b>	APP202098
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I wish to keep my contact details confidential

The EPA will deal with any personal information you supply in your submission in accordance with the Privacy Act 1993. We will use your contact details for the purposes of processing the application that it relates to (or in exceptional situations for other reasons permitted under the Privacy Act 1993). Where your submission is made publicly available, your contact details will be removed only if you have indicated this as your preference in the tick box above. We may also use your contact details for the purpose of requesting your participation in customer surveys.

The EPA is likely to post your submission on its website at [www.epa.govt.nz](http://www.epa.govt.nz). We also may make your submission available in response to a request under the Official Information Act 1982.

- 
- I support the application
  - I oppose the application
  - I neither support or oppose the application

**The reasons for making my submission are<sup>1</sup>:**

I do not agree with the recommendations of EPA staff concerning HSR001953 (Topclip 40).

Further information is contained in the document appended to this submission form.

- 
- I wish to be heard in support of my submission (this means that you can speak at the hearing)
  - I do not wish to be heard in support of my submission (this means that you cannot speak at the hearing)

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**I wish for the EPA to make the following decision:**

Decline the recommendations of EPA staff in respect of HSR001953 (Topclip 40)

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<sup>1</sup> Further information can be appended to your submission, if you are sending this submission electronically and attaching a file we accept the following formats – Microsoft Word, Text, PDF, ZIP, JPEG and JPG. The file must be not more than 8Mb.

**EPA Reassessment:** APP202098

**Name:** Carbaryl, chlorpyrifos and diazinon used in veterinary medicines or for other non-plant protection uses

**Submitter:** John Hicking, Regulatory Affairs Executive  
Orion AgriScience Ltd, Unit 1, 15 Sir Gil Simpson Drive,  
Christchurch

**Submission Date:** 23 September 2015

## **Introduction**

This submission is on behalf of Orion AgriScience Ltd. Orion AgriScience is the manufacturer of 'Topclip 40' (HSR001953 – Flammable liquid containing 360 – 440 g/L diazinon). This submission solely relates to the changes proposed for this substance, and is silent on changes proposed for the other approvals covered by this reassessment application.

## **Background**

Topclip 40 (HSR001953) is used as a sheep parasiticide. It contains 400 g/L of diazinon, and is diluted in water and applied to sheep as an immersion dip, a shower dip, or via jetting.

As Topclip 40 contains diazinon, an organophosphorus compound ('OP'), it is a very effective insecticide, and gives immediate knockdown of blowfly and lice. Both conditions, especially blowfly, can be very distressing and painful to the animals, and effective treatment also has economic benefits in terms of the health of the sheep (associated with carcase weight gain and lambing efficiency), and the quality of the wool and fleece .

Topclip 40 has been registered and in widespread use in New Zealand since 1977. Diazinon products themselves have been in widespread use in New Zealand since 1964. Orion AgriScience has been the registrant and distributor of Topclip 40 since 1999, when the product was acquired from Novartis Animal Health. In the 16 years that Orion AgriScience has been responsible for this product, we are not aware of any incidents concerning ill health or adverse environmental effects arising from the use of Topclip 40.

Topclip 40 is an extremely cost effective treatment when compared to other blowfly and lice treatments. This is an important consideration for many sheep farmers where input costs have to be carefully managed to ensure their farming business is viable.

Removing Topclip 40 from the market will result in farmers either using alternative products which may be more toxic, more expensive or less effective. It also places pressure on existing products in terms of resistance management, as the burden of control falls on a smaller number of active ingredients. A further consequence may be that sheep are not treated for lice or blowfly to the same extent as currently, with serious animal welfare implications.

We believe that given the correct user precautions, the risks to health and the environment associated with use of Topclip 40 are minimised. Balanced against the long standing use of this product without known incident, and its effectiveness as an economical treatment for blowfly and lice, we believe its current approval should be retained.

### **Topclip 40 (HSR001953) Risk Analysis**

I note that the EPA application uses extensive exposure risk modelling, and comes to the conclusion that withdrawal of approval is necessary given the potential for adverse and significant risks for human health and the environment.

I note on in Section 3.52 (P.32) of the application that just 2 calls had been received by the National Poisons Centre about sheep dip (which would probably have been Topclip 40). The nature of these calls is not recorded, and there is no information to suggest that poisoning was involved.

I also note that the application does not appear to present any known incidents concerning adverse environmental effects arising from the use of Topclip 40.

I also note that that the AgResearch Report appended to the application 'The Use of Diazinon as a Veterinary Medicine in New Zealand – A report to ERMA New Zealand' states in the Executive Summary on P5 that 'no adverse events related to the use of any of the currently registered diazinon-containing products have been officially recorded in New Zealand.' It also states 'Environmental effects of the use of diazinon containing veterinary medicines appear to be negligible in New Zealand'.

It is difficult to reconcile the theoretical risks that the EPA modelling highlights with the safe record of use over nearly 40 years, where no incidents concerning harm to users or the environment are known.

### **Topclip 40 (HSR001953) Efficacy and Cost**

Topclip 40 is a cost effective product for treatment of lice and blowfly maggots on sheep.

It has 'knockdown' properties and kills insect larvae shortly after application. This is particularly important for blowfly maggots as it gives immediate relief from a painful and distressing condition. This knockdown activity is in contrast to IGR (Insect growth Regulator') based products, which do not have knockdown, but tend to give longer term control of lice and blowfly maggots.

In use, Topclip 40 is often mixed with an IGR product such as cyromazine to give a longer residual. This results in a very effective and economical knock down and long term insecticidal treatment.

Table 1 contains a summary of costs of knockdown blowfly maggot treatments. Further details of the calculations used to derive these costs are given in Appendix 1.

**Table 1. Cost (cents / lamb or sheep) of Knockdown Flystrike Treatments  
DIPS**

	Jetting Wand	Constant Replenishment Shower Dip	Standard Replenishment Shower Dip	Plunge Dipping	Jetting Race
Topclip 40 (HSR001953) (diazinon)	2.5 – 5.2	16.8	8.4	8.4	
Seraphos 1250 (proprymiphos)	5.6 – 11.2	28.8	28.8	28.8	33.7
Xterminate 10 (chlorpyrifos)	2.9 – 5.9	29.6	19.0	19.0	
Extinosad (spinosad)	17.9 – 44.9				

**POUR ONS**

Expo Extinosad (spinosad)	48 - 120
Wipe Out (deltamethrin)	7.9 – 126.6
Flypel (chlorpyrifos + cypermethrin)	22.6 – 54.3
Zapp Encore (trifluperon + imidacloprid)	19.5 – 81.3

The withdrawal of Topclip 40 from the New Zealand market would have the effect of either shifting use to other low cost organophosphorus compounds used for blowfly knockdown and lice control in sheep, and/or sheep may not be treated to the same extent as currently, with resulting animal welfare implications.

**The Effect of Withdrawal of Topclip 40 (HSR001953) from the New Zealand Market**

Should Topclip 40 be withdrawn from the New Zealand market, the possible effects will be as follows.

**Shift to a More Toxic Alternative**

It is likely that users shift from Topclip 40 to another low cost alternative OP product. Assuming chlorpyrifos containing products are also withdrawn from the market (in particular, Xterminate 10, HSR001814, containing 100 g/L chlorpyrifos); the alternative product would be Seraphos 1250 (HSR001803, containing 360 g/L proprymiphos). Seraphos 1250 is currently used in the same way and same situations as Topclip 40. However, proprymiphos is more acutely toxic than diazinon:

	LD50 (Oral) mg/kg	LD50 (Dermal) mg/kg	LC50 (Inhalation) mg/l
Diazinon	300	876	1.6
Propetamphos	59.5	486	0.69

(Source: <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>)

The removal of Topclip 40 will therefore probably result in greater hazards to those handling and using lice and flystrike knockdown products as a result of their choice being restricted.

**The Potential Development of Resistance Against Other Treatments**

Diazinon and other OP insecticides are effective broad spectrum insecticides. A low level of resistance to OP's is known, and this is not unexpected, e.g., there is resistance to the

Australian Green Blowfly. However, diazinon and other OP's remain effective against other blowfly species, and remain effective against lice.

Resistance to a number of products used for blowfly and lice control is known.

There is known resistance of blowfly to diflubenzuron based products. There is known widespread resistance in lice to a number of products, including synthetic pyrethroids (deltamethrin, cypermethrin, alpha-cypermethrin), and Insect Growth Regulators (IGR's) (diflubenzuron, triflumuron).

Removing any insecticide chemistry from the market, including OP's, places additional resistance pressure on remaining products.

By removing OP's, the only remaining products for blowfly knockdown would be propetamphos (another OP), spinosad, and imidacloprid (the latter being in combination with an IGR).

By removing OP's, the only remaining products for lice knockdown would be synthetic pyrethroids (which, as discussed above, have known resistance issues), propetamphos (another OP), spinosad, and imidacloprid (the latter being in combination with an IGR).

Whilst not resistance, a shift away from broad spectrum insecticides such as OP's could result in a change in the prevalence of ectoparasites. As the AgResearch Report 'The Use of Diazinon as a Veterinary medicine in New Zealand – A report to ERMA New Zealand' appended to the application states on P8, sucking lice and mange mites may become more prevalent if OP's are removed.

### **Animal Welfare**

By removing Topclip 40, an effective and economical treatment from the market, the result could be that more expensive alternatives are not used, or are used but to a lesser extent. The result of this is that animals could suffer to a greater extent from the distressing effects of flystrike, or carry a large and debilitating lice population.

### **Potential Benefits on the Continued Use of OP's**

Sheep farming profitability is volatile, and some years farms can struggle even to achieve profitability. The average farm net cash income (sheep and beef) income for 2011/12 was \$81800\*. There is therefore pressure to reduce farm input costs. Removal of economical products, leaving only higher cost alternatives, will have a detrimental effect on farming profitability.

Topclip 40 is a cost effective product. Table 1 above shows the cost advantages of Topclip 40 over alternative products. Spinosad is approximately 8 times the cost of diazinon. Removing diazinon will have a major effect on the cost of farm inputs for the treatment of flystrike, and will contribute towards the erosion of profitability in the sheep farming sector.

\*Farm Monitoring 2012, MPI. Figure quoted is from the National Sheep and Beef Farm Model

**In respect of the further specific information sought by the agency:**

A number of questions have been raised by the EPA in their application. Some of the specific points which have been raised are answered below.

**Information on the dipping/showering/jetting of sheep/lambs, including the number of sheep/lambs treated per day for different application methods:**

Plunge Dipping: Assuming one sheep takes approximately 40 seconds to dip, and assuming an 8 hour working day, one treatment station would process approximately 720 animals per day.

Shower Dipping: Assuming 40 animals are processed per batch, total dipping time per batch is approximately 10 minutes, and assuming an 8 hour working day, one treatment station would process approximately 1920 animals per day.

Jetting: Assuming it takes approximately 40 seconds to jet each animal, and assuming an 8 hour working day, one treatment station would process approximately 720 animals per day.

**Information on the dipping/showering/jetting of sheep/lambs, including equipment/facilities used:**

Plunge Dipping: Sheep are forced to swim through the dip, with the length of the dipping tank being a minimum of 9 metres. Sheep should remain in the dip for approximately 60 seconds, and should be dunked at least twice. This is done manually by using a long implement. Plunge Dipping has become less popular in recent years, and is now quite rare (We estimate less than 1% of sheep would be treated by this method).

Shower Dipping: Sheep are confined in batches in an enclosed area, and the dip wash is showered onto them via an overhead rotating arm with nozzles. The spray is a coarse droplet, as best practice is to deliver coarse droplets to the back of the sheep to allow saturation of the wool. The area used has a bunded concrete base with drainage into a sump, from where the solution is recirculated. The animals would be showered for approximately 5 minutes (the actual time being largely dependent on the length of the wool). This would be followed by a standing time of approximately 5 minutes to allow for excess dip to drip from the sheep. This is by far the most common method of application. We estimate over 90% of sheep would be treated via this method. This method does not involve the production of small respirable aerosols, and does not involve workers having to touch the sheep during the dipping process.

Jetting: This is a method of application where sheep are individually treated with a jetting wand which is a multiple nozzle device which is combed from the poll to the tail and on from the forequarters to the neck. Jetting may also be undertaken where the sheep pass through a race where strategically placed jets wet the sheep with the dip as they pass.

**Information on the dipping/showering/jetting of sheep/lambs, including methods for disposal of solution:**

For plunge dipping, the usual practice for any used dip that is left over at the end of dipping operations to be disposed of 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, the spray solution is recirculated (which involves replenishment and reinforcement), and is carried out in such a way that there should be no unused dip left over at the end of the treatment.

For jetting, the spray solution is used entirely in the treatment operation, and there is no disposal of unused dip.

**How many sheep can be treated with 1000L of dip solution?**

For plunge and shower dipping, I believe the figure used in the EPA application of 4.8 – 8 L solution/animal is too high. The average would be around 4 L/animal. Therefore 1000 L of dip solution would treat around 250 animals.

For jetting, the maximum application rate assumed in the EPA application is 1 L/animal. The use rate for jetting is 0.5 – 1 L/animal. I therefore agree with the EPA figure. Therefore 1000 L of dip solution would treat a minimum of 100 animals.

**How many treatments are required per season?**

1 – 2 treatments per season. The EPA application assumes 1 – 3. Topclip 40 itself does have residual properties of up to 4 weeks, so a degree of extended protection would be provided, negating repeated treatments. In addition, Topclip 40 is often mixed with an IGR product for extended residual control. Therefore 3 treatments would be extremely unlikely.

**What is the stock density per ha for adult sheep and lambs?**

The maximum stocking density would be around 25 animals/ha.

**Is the assumption of stock density in a holding paddock (3 sheep/m<sup>2</sup>) valid?**

No, it is too high. A figure of 1 animals/m<sup>2</sup> is more valid.

**Would you expect 2000 sheep to be in a holding paddock, and is there likely to be run-off from the holding paddock into local waterways?**

Yes – it would be possible for 2000 sheep to be kept in one holding paddock. Run off of dip from a holding paddock is unlikely. For the most popular method of treatment, shower dipping, it is usual practice for sheep to be held in the treatment pan for approximately 5 minutes after showering has finished. This collects dip for reuse, and minimises the amount of drip once the animals are released into the holding paddock. Small amounts of drip that fall after this time period would fall as discrete drops onto the soil, and would not be expected to contaminate waterways. It must be noted that diazinon is widely used as an agricultural insecticide, including on paddocks which house sheep. Any drip from treated animals would be significantly less than permitted broad acre spraying of diazinon.

**Proposed Phase Out**

I note in the application that a phase out of 6 months is recommended by EPA staff.

Please note that I do not believe that an arbitrary phase out period based on a specific time period of 6 months from the date of the final decision is appropriate.



In manufacturing and distributing a product such as Topclip 40, the timeframe from forecasting and production planning with overseas and local suppliers of ingredients, labels, packaging, etc., and placing forward orders, through the steps of ordering, awaiting delivery of ingredients from overseas (which can have lengthy lead times), manufacturing an inventory for the forthcoming season, transport into the distribution channels for sale to the final user, and then use by the final user until the end of the use season, will exceed 6 months.

It must also be noted that approximately 80% of our agricultural products are sold in a seasonal pattern. Most of our formulations, including Topclip 40, are manufactured locally, so manufacturing occurs all year round (even though they are seasonal), so as to be able to build up enough inventory for when the season begins.

The lead time for a product such as Topclip 40 is effectively around 9 – 10 months.

Use of most products in agriculture is very seasonal. The main use periods of Topclip 40 for flystrike control are October to February, and for lice control from February to May.

By late this year (when a final decision on the review may be made), we will already be well advanced with production planning, forecasting and forward ordering of ingredients, labels, packaging, etc. from our suppliers for the season beginning October 2016.

It is therefore more appropriate for any phase out period to finish at the end of the use season, rather than an arbitrary 6 months from the date of the final decision. Given that, as discussed above, the lead times are around 9 – 10 months, if a decision is made to withdraw approvals, I would ask that the phase out period finishes at the end of the season for which preparations will have already begun.

## **Discussion**

Orion AgriScience has been the registrant and distributor of Topclip 40 since 1999, when the product was acquired from Novartis Animal Health. In the 16 years that Orion AgriScience has been responsible for this product, we are not aware of any incidents concerning ill health or adverse environmental effects arising from the use of Topclip 40.

There are no other known incidents arising from use of Topclip 40 in nearly 40 years of use.

I do not believe the benefits of retaining use of Topclip 40 have not been properly considered in the EPA application. The benefits receive cursory reference in Section 3.74 on P36.

I believe that the risks, in terms of both occupational exposure and environmental damage, to have been overstated in the EPA application, and the benefits have been understated.

Whilst OP's are very toxic, when used responsibly, as with other hazardous materials, the risks can be effectively managed.

I do not believe it appropriate to withdraw approval for an effective, economic and useful product that has been safely used for many years without definitive evidence of the significant risks that are claimed.

## **Conclusion**

Despite common usage in New Zealand for many years, no adverse issues or events concerning the use of Topclip 40 (HSR001953) are known. By revoking approval, an effective and economical product widely used in sheep farming will be lost.

## Appendix 1

PRODUCT	ACTIVE INGREDIENT	APP METHOD	DILUTION	APP RATE	COST (JULY 11)	COST / SHEEP
<b>DIPS</b>						
EXTINOSAD	SPINOSAD	JETTING WAND	1/1000	2 - 5 L / SHEEP	\$899 / 10 L	17.9 - 44.9
TOPCLIP	DIAZINON	JETTING WAND	1 / 800	0.5 - 1 L / SHEEP	\$840 / 20 L	2.5 - 5.2
TOPCLIP		CR SHOWER DIPPING	1 / 1000	4 L / SHEEP (AV)	\$840 / 20 L	16.8
TOPCLIP		SR SHOWER DIPPING	1 / 2000	4 L / SHEEP (AV)	\$840 / 20 L	8.4
TOPCLIP		PLUNGE DIPPING	1 / 2000	4 L / SHEEP (AV)	\$840 / 20 L	8.4
TOPCLIP		AUTOMATIC JETTING RACE	1 / 500	3 L / SHEEP (AV)	\$840 / 20 L	25.2
SERAPHOS 1250	PROPETAMPHOS	JETTING WAND	1 / 800	0.5 - 1 L / SHEEP	\$450 / 5 L	5.6 - 11.2
SERAPHOS 1250		CR SHOWER DIPPING	1 / 1250	4 L / SHEEP (AV)	\$450 / 5 L	28.8
SERAPHOS 1250		SR SHOWER DIPPING	1 / 1250	4 L / SHEEP (AV)	\$450 / 5 L	28.8
SERAPHOS 1250		PLUNGE DIPPING	1 / 1250	4 L / SHEEP (AV)	\$450 / 5 L	28.8
SERAPHOS 1250		AUTOMATIC JETTING RACE	1 / 800	3 L / SHEEP (AV)	\$450 / 5 L	33.7
ERASE	IVERMECTIN	AUTOMATIC JETTING RACE	1 / 500		NO LONGER ON MARKET	
ERASE		JETTING WAND	1 / 500		NO LONGER ON MARKET	
XTERMINATE 10	CHLORPYRIFOS	JETTING WAND	1 / 400	0.5 - 1 L / SHEEP	\$475 / 20 L	2.9 - 5.9
XTERMINATE 10		CR SHOWER DIPPING	1 / 320	4 L / SHEEP (AV)	\$475 / 20 L	29.6
XTERMINATE 10		SR SHOWER DIPPING	1 / 500	4 L / SHEEP (AV)	\$475 / 20 L	19.0
XTERMINATE 10		PLUNGE DIPPING	1 / 500	4 L / SHEEP (AV)	\$475 / 20 L	19.0
XTERMINATE 10		AUTOMATIC JETTING RACE	1 / 400	3 L / SHEEP (AV)	\$475 / 20 L	17.8
CYREX LIQUID	SPINOSAD + CYROMAZINE	CR SHOWER DIPPING	1 / 500	4 L / SHEEP (AV)	\$1120 / 10 L	89.6
CYREX LIQUID		AUTOMATIC JETTING RACE	1 / 500	2 - 5 L / SHEEP	\$1120 / 10 L	44.8 - 112.0
<b>POUR ONS</b>						
EXPO EXTINOSAD POUR ON	SPINOSAD	POUR ON	N/A	10 - 25 ML / SHEEP	\$480 / 10 L	48 - 120
DURACIDE	ALPHA CYPERMETHRIN	POUR ON	N/A	5 - 32 ML / SHEEP	NO LONGER ON MARKET	
WIPE OUT	DELTAMETHRIN	POUR ON	N/A	2 - 32 ML / SHEEP	\$395 / 10 L	7.9 - 126.6
MAGGO	PROPETAMPHOS	DRESSING AFFECTED AREA	1 / 40		\$79 / 1 L	
FLYPEL	CHLORPYRIFOS + CYPERMETHRIN	POUR ON	N/A	5 - 12 ML / SHEEP	\$226 / 5 L	22.6 - 54.3
ZAPP ENCORE	TRIFLUMERON + IMIDACLOPRID	POUR ON	N/A	6 - 25 ML / SHEEP	\$650 / 20 L	19.5 - 81.3
VANQUISH	ALPHA CYPERMETHRIN	POUR ON	N/A	15 - 20 ML / SHEEP	NO LONGER ON MARKET	

CR = CONSTANT REPLENISHMENT  
SR = STANDARD REPLENISHMENT