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Council briefing paper on OP dips

Background

A major effort to eradicate sheep scab was undertaken between 1976 and 1992. This included compulsory supervised national dipping during specified periods, movement controls, and segregating dipped and non-dipped sheep in markets. Fleece samples were checked for evidence of dipping. Where outbreaks occurred, there was full tracing of contact sheep by the State Veterinary Service. Eradication was not achieved despite this intensive effort. The reasons were attributed to a major increase in the size of the national flock, from 27 million in 1976 to 45 million in 1992, greater movement of sheep around the country, and a lack of commitment by some sheep farmers.

In 1992, dipping ceased to be compulsory and sheep scab was removed from the notifiable list of diseases. Farmers were still obliged however to deal promptly and satisfactorily with any outbreak of scab in their flocks.

The Sheep Scab Order was introduced in 1997. This was at the industry's request so that the industry could deal with those less responsible individuals who did not treat their sheep against scab. It became an offence for sheep farmers to have sheep with scab and not treat the whole flock.

The Sheep Scab Order 1997 gave powers to Local Authorities to investigate cases of scab and to require control measures under the supervision of a private veterinary surgeon.

OP sheep dips were removed from the market in December 1999 following Veterinary Products Committee (VPC) advice about possible health risks posed by the existing containers. However, the alternatives were limited, mainly synthetic pyrethroids (which are very damaging to water courses).

In July 2000 the VPC advised that in the short term OP sheep dips should be permitted to return to the market in their existing containers with the addition of a vented tap, whilst long-term improvements were developed that would minimise the risks of operator exposure to OP concentrate. This advice was based on a balanced risk assessment that took into account animal welfare concerns about the increasing incidence of sheep scab.

In June 2001 the VPC considered proposals from three manufacturers for closed transfer systems, i.e. improved container design. It advised Ministers that, subject to resolution of a number of issues, all of these were capable of meeting the objective of minimising operator exposure to OP concentrate.

In September 2001, the Government suspended the marketing authorisations for OP sheep dips, pending satisfactory completion of plans being developed by marketing authorisation holders for closed systems for transferring OP dip concentrate from the container to the dip bath. This action was taken in line with advice from the VPC.

November 2001 Defra announced that 2 OP sheep dip products had received approval to return to the market based on the incorporation of a closed transfer system

The two products incorporating the approved closed transfer systems were Osmonds Gold Fleece Sheep Dip, marketed by Cross Vetpharm Group Ltd. and Coopers Ectoforce Sheep Dip, marketed by Schering Plough. These products were available to farmers around the end of November 2001.

These products were then joined in the market place by Paracide Plus, marketed by Animax Ltd.

The situation today

There are 3 OP sheep dips currently licensed for use in the UK:

Paracide Plus, marketed by Animax Ltd;

Osmonds Gold Fleece™ Sheep Dip, marketed by Bimeda; and

Coopers Ectoforce™ Sheep Dip, marketed by Schering-Plough Animal Health.

The active ingredient of all three products is Diazinon, a broad-spectrum organophosphorus (OP) insecticide used for external parasite control on sheep, cattle and companion animals.

Appendix 1 summaries the products currently licensed for use in the UK for ectoparasite control in sheep. There are a range of dips, injectable products and pour-ons.

Synthetic pyrethroid dips (Novartis's Robust, Virbac's Auriplak and Bimeda's Ecofleece) have had their marketing authorisations suspended due to the toxicity of these products in water courses and the environment.

Organic status

The two main Organic certification bodies, the Soil Association and Organic Farmers and Growers, have different positions on the use of OP within an organic system.

The Soil Association (SA) have welcomed the temporary suspension of SP marketing authorisations and are considering prohibiting, permanently, the use of SP dips on environmental grounds. They also prohibit the use of all OP dips under SA certification UK5 symbol programme, meaning that animals treated with OPs cannot be marketed using the SA symbol (UK5).

The SA acknowledges that sheep scab will be the most problematic issue for sheep farmer members. They only allow however injectables containing moxidectin and doramectin (Cydectin 1% injectable solution for sheep and Dectomax injectable solution for cattle and sheep). There is a risk that statutory withdrawal periods of these two products will double in line with EU organic regulations – a 140 day withdrawal period would impact severely on the organic lamb sector.

The majority of the Pour-ons listed in Appendix 1 are permitted by the SA but meat withdrawal periods are listed as at least double the statutory withdrawal periods.

Organic Farmers and Growers (OF&G) do allow farmers to use OP dips but only under derogation with approval from the Certification Office. They look to their organic farmers to be able to demonstrate that a suitable alternative is not available and that other management techniques and inputs cannot be expected to be effective. This demonstration must include a letter from a vet confirming the need to treat the sheep with an OP based treatment, and intelligence on how scab arrived on the farm and management measures taken to prevent its spread and recurrence.

Farmer / dipper training and competence

Under the Veterinary Medicines Regulations 2008, it is an offence to use sheep dip unless this is done by, or under the supervision and in the presence of, a person who holds a Certificate of Competence in

the Safe Use of Sheep Dip. In England and Wales, the Certificate of Competence is issued by the National Proficiency Tests Council, part of the City & Guilds Group.

As well as the requirements for dipping operations, any person who buys OP (or SP) sheep dip must have the NPTC Certificate of Competence in the Safe Use of Sheep Dips or satisfy the distributor selling the dip that they are acting on behalf of somebody who does have the Certificate.

Statutory safety precautions of the 3 OP dips

Marketing authorisations of all veterinary medicines and pharmaceutical products come with strict conditions. In the case of the three licensed OP dips, these include environmental and operator safety conditions and guidance for use. Appendix 2 shows the datasheet and conditions of license for Coopers Ectoforce™ Sheep Dip, marketed by Schering-Plough Animal Health. This has been provided as an example of the type and level of information available and which must be provided at the time of purchase to the dip purchaser.

All the OP dip product datasheets provide similar and explicit information about operator health and safety, protective clothing requirements, dispensing and disposal. There is specific medical advice, including toxicology and poisoning symptoms, for both the user and doctors.

Scientific advances and COT

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an independent scientific committee that provides advice to the Food Standards Agency, the Department of Health and other Government Departments and Agencies on matters concerning the toxicity of chemicals, including the effects of OP dips and pesticides.

COT is chaired by Professor David Coggon, Professor of Occupational and Environmental Medicine at the MRC Epidemiology Resource Centre, University of Southampton. The membership list of COT is given in Appendix 3. COT's website (<http://cot.food.gov.uk/>) provides details of previous meetings, reports and statements.

COT published a report in 1999 on organophosphates, which considered whether prolonged or repeated exposure to organophosphates, or acute exposures to organophosphates at levels insufficient to cause overt toxicity, can cause long-term adverse health effects. In the report, the Committee drew conclusions from the available data that the balance of evidence did not support an association between chronic low level organophosphate exposure and neuropsychological outcomes, peripheral neuropathy or psychiatric illness.

COT made recommendations for further research to address outstanding issues. The research had been funded jointly by a number of Government departments with the Veterinary Medicines Directorate taking a coordinating role. In 2007 COT considered a review of the Government-funded research available at the time.

In 2007 the Committee commented that other work had been published in the scientific literature and there would be a need to review all of the available research in order to advise on the current state of knowledge on organophosphates.

At a recent open meeting (September 2009), COT discussed three specific research papers on OPs, although one was discussed in a restricted business session as the report was not published. Since that September meeting, the third report has been published and the COT website updated to include the Committee's comments and conclusions on the findings of the said paper.

Paper 1: 'Disabling Neuropsychiatric Disease in Farmers Exposed to Organophosphates', Dr AC Povey and others; (http://randd.defra.gov.uk/Document.aspx?Document=VM02115_8183_FRP.pdf)

This report attempted to prove the theory that chronic low dose exposure to OP was associated with diseases such as Parkinsons, depression and dementia.

COT felt that there were major problems with the interpretation of the data from this study and the suggestion that further statistical analysis be carried out was made. There was no association with depression and a link with Parkinson's disease appeared unlikely. The evidence regarding peripheral neuropathy suggested an association with sheep dipping but the results were subject to recall bias and no definite conclusions could be reached.

COT considered that the study report had been drafted to a high standard and the investigators had been aware of the inevitable limitations in the study design. COT concluded that reassurance could not be drawn from the negative associations nor conclusions reached regarding causality from the positive associations reported from this study.

Paper 2: 'Neuropsychological and Psychiatric Functioning in Sheep farmers exposed to Organophosphate Pesticides', S Mackenzie Ross and others.

<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=14267>

This study aimed to determine whether low level exposure to OPs caused disabling neuropsychological and / or psychiatric disorder in a small subgroup of farm workers. It had three objectives:

Objective 1 : To establish whether farm workers with a history of low level exposure to OP's (insufficient to cause acute intoxication) showed evidence of physical disease, cognitive impairment and / or mood disorder.

Objective 2 : To determine the nature and severity of physical symptoms, neuropsychological abnormalities and psychiatric disorder in farm workers with a history of low level exposure to OP's.

Objective 3 : To investigate whether background factors (e.g. psychological profile, medical history or exposure history) render some individuals particularly vulnerable to the effects of OPs.

COT felt that this was a stronger study and commented that it had been well conducted. The interpretation of the results had been hampered by a number of aspects of the analyses undertaken however.

In considering possible conclusions, it was noted that there was some evidence of poorer mental performance in farmers, but that although a large number of tests had been performed, the analysis was not focused so it was not clear what was causing the poorer performance and additionally there was still a need to identify appropriate UK control data and adjust for age-dependent effects.

The summary was that no definite conclusions could be reached from this study report but that the data should be subject to further analysis.

The Committee discussed the extent to which these research projects addressed the research recommendations made by COT in 1999. The Committee concluded that the studies reviewed needed to be considered in the context of the review of Government funded research reviewed by COT in 2007 and the ongoing review of peer reviewed scientific literature on organophosphates.

No clear conclusions could be reached on the two reports reviewed above.

It was commented by a COT member that one particular difficulty with the epidemiological research of low level exposure to organophosphates in general related to distinguishing between organophosphate exposure and pesticide exposure in general, or the influence of farming as an occupation.

Paper 3: 'Clinical Evaluation of a Sample of Participants in the SHAPE Survey of Health and Pesticides Exposure' by Tony Fletcher and others;
(<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=1&ProjectID=9034>)

This project provided a clinical investigation of selected farmers who had reported symptoms of peripheral neuropathy in an earlier phase of the study with the objective of providing an overview of the reported ill health in relation to exposure to pesticides and veterinary medicines, and other potential risk factors.

(Peripheral neuropathy describes damage to the peripheral nervous system, which transmits information from the brain and spinal cord to every other part of the body.)

From a population of approximately 400 farmers who had had exposure to organophosphates (OPs) (including sheep dip) during the course of their work a sub sample of 47 farmers, were further sampled and invited to undergo detailed clinical assessment of peripheral neuropathy. The clinical examination included structured history, bedside neurological examination, electrodiagnostics (nerve conduction studies) and quantitative sensory tests (thermal, both cold and hot, and vibration thresholds).

The COT members discussed the methodology and research conclusions. They considered that a lack of adequate control data was a major weakness and that there was insufficient information on many aspects of neurophysiological investigations which would have been important for a full assessment of the data. However, Members also considered it important that the researchers should have an opportunity to respond. The COT Chairman summarised that in a selected sample, the researchers had found unusual patterns of neurophysiological responses, but that the tests undertaken were technique- and observer- dependent and the Committee could not conclude that genuine abnormalities had been identified.

The NFU position

The NFU reviewed its policy on OP use in May 2009. The position statement is given in Appendix 4.

I have carefully looked through all of the OP information again including our May 2009 position statement. Frankly, I am not sure there is more that we can do, other than continue to ask for on-going and updated assessments of the science and medical evidence. We should also continue to push for effective OP replacements, but as you will see, even the organic movement allows some use of OP's, which tells the story about alternatives.

I will pass on all this information to my successor, and the staff at the NFU are more than aware of the issues.

Appendix 1. Products currently licensed for use in the UK

Product Name	Active ingredient	Use	Statutory withdrawal periods	Comments
DIPS				
Coopers Ectoforce™ Sheep Dip	Diazinon	Prevention and treatment of blowfly strike, ticks, keds, lice and scab	Meat for 35 days. Not for use in sheep producing milk for human consumption.	Water soluble sachet delivery system.
Osmonds Gold Fleece™ Sheep Dip	Diazinon	Prevention and treatment of blowfly strike, ticks, keds, lice and scab	Meat for 35 days. Not for use in sheep producing milk for human consumption.	For use with re-usable sealed dispensing gun kit.
Paracide Plus	Diazinon	Control of scab, blowfly, ticks, keds and lice	Meat for 35 days. Not for use in sheep producing milk for human consumption.	Supplied with closed transfer pump system.
NB: Sheep must be dipped for at least 60 seconds with the head submerged twice for effective scab mite control. Protective clothing must be worn for operator safety.				

INJECTABLES

<ul style="list-style-type: none"> • Cydectin 1% injectable solution for sheep • Zermex 1% w/v Injectable solution for sheep 	Moxidectin	Prevention and treatment of psoroptic mange (Sheep scab). Treatment and control of endoparasites and nasal bots.	Meat for 70 days. Not for use in sheep producing milk for human consumption Can't be used in sheep vaccinated against footrot.	Inject subcutaneously Routine prevention of scab – 1 injection will protect against scab mite infestation for at least 28 days. Treatment of scab – 2 injections, 10 days apart. All sheep in the flock must be treated.
Dectomax injectable solution for cattle and sheep	Doramectin	Treatment and control of Psoroptes ovis (sheep scab mite) Treatment and control of gastrointestinal round worms, lungworms and nasal bots	Meat for 70 days. Not for use in sheep producing milk for human consumption	Inject subcutaneously Dose for scab control and Nematodirus battus: 1ml / 33kg LW. Dose for endoparasite control: 1ml / 50kg LW.
<ul style="list-style-type: none"> • Ivomec classic injection for cattle and sheep • Noromectin injectable • Panomec injectable for cattle, sheep and pigs • Qualimec 10mg/ml solution for injection • Ecomectin 10mg/ml Solution for Injection • Paramectin injection for sheep* • Paramectin Multi-injection 	Ivermectin	Treatment and control of sheep scab Treatment and control of gastrointestinal round worms, lungworms and nasal bots	Meat for 42 days. Not for use in sheep producing milk for human consumption *Paramectin meat withdrawal = 28 days	Inject subcutaneously 2 injections, 7 days apart, are required to treat clinical signs of sheep scab: all sheep in flock must be treated. A single injection is not adequate to eliminate all mites in clinical cases.

The voice of British farming

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1% solution for cattle, sheep and pigs <ul style="list-style-type: none"> • Virbamec Injectable Solution for cattle, swine and sheep • Bimectin 1% w/v Solution for Injection • Ecomec 1% Solution for Injection 				
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NB: The effect on mites by all the injectables listed is not instantaneous kill. A period of time is required to elapse between treatment and contact with any untreated sheep that may harbour mites. The time periods are as follows: Moxidectin – 12 days; Doramectin – 14 days; Ivermectin – 15 days.

POUR – ONS – none of these products are effective for Scab control

CLIK 5% pour on	Dicyclanil	Prevention of blowfly strike	Meat for 40 days. Not for use in sheep producing milk for human consumption	Insect growth inhibitor
Coopers Spot On insecticide	Deltamethrin	Control of ticks, lice, keds and established blowfly strike	Meat for 35 days. Not for use in sheep producing milk for human consumption	Synthetic pyrethroid
Crovect	Cypermethrin		Meat for 8 days. Not for use in sheep producing milk for human consumption	Synthetic pyrethroid
<ul style="list-style-type: none"> • Dysect sheep pour on • Zermasect Sheep Pour-On 	Alphacypermethrin		Meat for 28 days. Not for use in sheep producing milk for human consumption	Synthetic pyrethroid
Vetrazine pour on	Cyromazine		Meat for 3 days. Not for use in sheep producing milk for human consumption	Non-OP

Synthetic pyrethroid dips (Novartis's Robust, Virbac's Auriplak and Bimeda's Ecofleece) have had their marketing authorisations suspended due to the toxicity of these products in water courses and the environment.

Appendix 2: the datasheet and conditions of license for Coopers Ectoforce™ Sheep Dip, marketed by Schering-Plough Animal Health

Coopers Ectoforce Sheep Dip

Introduction



Company name: Intervet / Schering-Plough Animal Health
 Address: Walton Manor
 Walton
 Milton Keynes
 MK7 7AJ
 Telephone: 01908 685685 (Customer Support Centre)
 Telephone: 01908 665050 (Switchboard)
 Fax: 01908 685555
 Email: support.uk@intervet.com
 Website: www.intervet.co.uk

Presentation

An emulsifiable dip concentrate with a yellow colour and distinct odour, containing diazinon 60% w/w.

Uses

For the prevention and treatment of blowfly strike, ticks, keds, lice, and scab infestations on sheep.

Dosage and administration

To prepare the bath

Check that the bath is clean and only use clean water. Prepare the bath and mix in the dip concentrate on the day of dipping. Use a container of known volume to calibrate an appropriate volume in the bath. The calibrated volume should be an exact multiple of 150 litres.

Fill the dip bath with water to the accurately calibrated level. To prevent overspill **do not fill the bath to capacity** and make sure you allow for water displacement by the sheep. Surge baffles can help prevent spillage.

Follow the instructions for dispensing the dip safely.

Initial fill.

To treat sheep scab, blowfly strike, ticks, keds and lice the product must be used at a concentration of 0.04 % w/w diazinon. This concentration of diazinon is achieved by adding the required number of 100 ml packs to the dip bath. The required number of packs can be calculated as follows or by using the dip calculator provided with the product:

Number of packs to add to the dip bath

Bath Size	Number of 100 ml packs
450 litres (100 gallons)	3
900 litres (200 gallons)	6

1800 litres (400 gallons)	12
2250 litres (500 gallons)	15

Once you have calculated the number of 100 ml packs you require then follow these directions:

Remove the aluminium foil bags from the pack. Open the bags by way of the tear strip at the top of each bag. **Do not** use scissors, a knife or any sharp implement to open the bag. Remove the inner pouch from each bag and place it carefully on a dry, flat, surface near the dip.

Before opening the pouch visually examine it for leakage of product from the inner water soluble sachet. Should there be leakage into the pouch then under **NO circumstances should the pouch be opened but instead take the entire pack back to where you bought it.**

Open each pouch using the tear strip. **Do not use scissors, a knife or any sharp implement to open the pouch.** Keeping the pouch with the open end uppermost go immediately to the dip bath, invert the pouch and drop the inner water soluble sachet into the dip bath at a distance from the water surface of no more than 6 inches. This is to prevent splashing. Hold the handle of the pouch while you drop the sachet into the dip bath. It is important that you do not touch the water soluble sachet and that it does not come into contact with water before it goes into the dip bath as this could cause it to dissolve prematurely.

Continue to add all the required number of sachets to the dip bath in the same manner. The water soluble sachets will float on the surface of the dip bath and the speed at which they release the product will depend on water temperature. **Do not** attempt to hasten the process by touching the sachets. After at least 5 minutes has elapsed and the sachets have released the product, mix the dip by stirring thoroughly with a metal rod, preferably with a paddle attachment. Dipping should not proceed until the sachets have fully dissolved and the dip has been thoroughly mixed.

Always remember to mix both after the initial fill and after each replenishment.

To replenish the bath

Baths less than 2250 litres (500 gallons)

Add 200 ml (2 x 100 ml packs) of dip after every 40 sheep dipped and fill the bath with water to its original level.

Baths of 2250 litres (500 gallons) or more

Add 500 ml (5 x 100 ml packs) of dip after every 100 sheep dipped and fill the bath with water to its original level.

When adding the required number of packs to the dip bath follow the same directions as for the Initial Fill.

For sheep scab all parts of the animal, except the head and ears, should remain under the dip wash mixture for at least a minute.

Plunge the head under at least twice, allowing time for the animal to breathe between plunges. For blowfly strike, ticks, keds and lice infestations, animals should remain in the dip bath for at least half a minute and the head should be plunged once.

To control ticks, dip ewes in spring before lambing. If the infestation is severe, dip again 6 weeks later (excluding young lambs). Hogs and other sheep should be dipped as soon as possible after ticks appear.

After dipping, all sheep should stand in draining pens for not less than 10 minutes or until they have completely stopped dripping.

If large amounts of scum form on the surface of the bath skim it off and place in a secure container. This must be clearly marked and disposed of safely (see "DISPOSAL" below).

Fouling of the dip wash reduces dip effectiveness. Therefore, do not dip more than 1 sheep per 2 litres of dip wash that was in the bath at the start of dipping. For example, if the total volume of wash in your dip bath was 1000 litres (220 gallons) you should not dip more than 500 sheep no matter how many times you have replenished and topped-up the bath (see above). You should then empty, clean and recharge the bath with fresh dip wash.

Post-dipping lameness may occur when sheep are dipped in dirty wash or in wash that has stood overnight.

Sheep should have at least three weeks growth of wool after shearing when they are dipped, to obtain good residual protection.

Contra-indications, warnings, etc

General precautions

Sheep should never be dipped on a full stomach, when the wool is wet, or when they are heated, tired, thirsty, or suffering from wounds or open sores.

Choose a cool dry day and dip early in the morning.

Rams and fat sheep should be assisted through the bath and lambs dipped separately from the ewes.

Care should be taken to ensure that the sheep do not swallow or inhale any wash.

As this is an organophosphorus sheep dip, an interval of at least 14 days should elapse between dipping and dosing with any drench, etc. containing levamisole or an organophosphorus compound.

To avoid Post Dipping Lameness

Post dipping lameness may occur when the sheep are dipped in dirty wash, or wash which has been allowed to stand in the bath overnight or longer. It is important that the dip bath should be emptied and thoroughly cleaned at the end of each days dipping or earlier if it becomes very dirty during the day's dipping.

Care should be taken not to overdose.

Overdosing may invalidate the stated meat withholding times as indicated below.

Protection of consumers

Sheep may be slaughtered for human consumption only after 35 days from the last treatment. Not suitable for use on sheep that are being milked for human consumption.

Protection of operators

Use Tear Strip to open the foil bag. DO NOT use scissors, a knife or any sharp implement.

Do not use product if liquid has leaked from the water soluble sachet into the clear protective pouch. Instead take it back in its original packaging to where you bought it.

Product should be used immediately after opening the clear protective pouch.

Protective clothing must be worn when handling the product packaging and when opening the pack.

Prior to use store in original container.

Diazinon is an organophosphorus compound. Do not use if under medical advice not to work with such compounds. If you have previously felt unwell after using a product containing an organophosphorus compound, consult your doctor before working with this product and show the doctor the product label.

When handling concentrate including dip replenishment

Use only in a dip bath that is well designed and hazard free.

Check that all those involved in dipping operations are adequately trained and competent.

Keep children well away from all dipping operations.

Make sure that everyone has the recommended protective clothing and insist that they wear it. Ensure you have spare protective clothing available in case any items become damaged.

The recommended protective clothing is:-

- **Face Shield (when handling dip concentrate).**
- **Bib apron (over boiler suit) or waterproof coat (PVC or nitrile).**
- **Gloves (Non-lined or flock-lined, PVC or nitrile, heavy duty gauntlet style - 0.5 mm thick and at least 300 mm long).**
- **Waterproof leggings/trousers (PVC or nitrile to be worn outside your boots).**
- **Wellington boots.**

When working with diluted dips and freshly dipped sheep

Dipping should be carried out in a well-ventilated area, preferably outdoors.

Before leaving the work area wash and remove protective clothing and do not smoke, drink, eat or use the toilet during dipping operations.

Always wash hands, face and exposed skin immediately after leaving the work area.

Protective clothing should be washed each day after dipping operations to prevent build-up of chemicals in the material. Wash dipping equipment after use. Check and replace any worn or damaged items of protective clothing.

Immediately wash off sheep dip particularly dip concentrate, if it gets on your skin or in your eyes.

Immediately remove heavily contaminated clothes and wash contaminated areas of skin – see further instructions below under "MEDICAL ADVICE TO USERS". Wash or destroy heavily contaminated clothes immediately.

Use during pregnancy and lactation

There have been no reported complications in pregnancy or lactation. If dipping of pregnant sheep is essential, they should be gently lowered into the bath and assisted out.

Handling sheep in the weeks following dipping

It is good practice not to shear sheep in the 3 months after dipping. Handle sheep as little as possible after dipping as dip residues remain on the sheep for some weeks. If you need to handle sheep, wear coveralls and wellington boots. If the sheep are wet also wear waterproof trousers and coat. Always wash hands with soap and water after handling sheep or fleece, and before eating, drinking or smoking.

Medical advice to users

If you feel unwell after using this product consult your doctor and show your doctor this label. Treat any cases of heavy contamination as an emergency. You should go straight to hospital after removing contaminated clothing, and rinse with plenty of water areas of skin which came into contact with sheep dip. If sheep dip has been swallowed go straight to hospital and take this label with you.

Medical Advice to Doctors

Poisoning from organophosphorus compounds in sheep dips results from blockage of acetylcholinesterase, with a resultant over-activity of acetylcholine.

Symptoms include headache, exhaustion and weakness, mental confusion together with blurred vision, excessive salivation and sweating, cramp-like abdominal pain, chest tightness, diarrhoea, constricted pupils, and bronchorrhoea. These may develop for up to 24 hours after exposure.

Severe poisoning can include general muscle twitching, loss of co-ordination, extreme difficulty with breathing and convulsions which may lead to unconsciousness in the absence of medical treatment. Treat symptomatically and seek urgent hospital transfer if poisoning is suspected.

Advice is available from the National Poisons Information Service. (Either access TOXBASE on the Internet/NHS web at <http://www.spib.acl.co.uk> or telephone: 0870 600 6266). Further information for health professionals is contained in MS17 entitled "Medical aspects of work related exposure to organophosphates" and is available from HSE books on tel: 01787 881165 or fax 01787 313995.

Environmental warnings

Dangerous to fish and other aquatic life. Do not contaminate surface waters. Harmful to game, wild and domestic birds and mammals. Do not allow access to dilute dip.

It is an offence to permit any poisonous, noxious or polluting matter to enter any river, stream or watercourse.

Any unwanted product should be disposed of by a licensed waste disposal contractor.

To dispose of used sheep dip an authorisation under the Groundwater Regulations 1998 is required. To apply for an authorisation contact the Environment Agency (EA) or the Scottish Environment Protection Agency (SEPA) or the Environment and Heritage Service of the Department of the Environment for Northern Ireland (EHS/DENI). Alternatively spent dip wash should be disposed of by a licensed waste disposal contractor.

Hazard warnings

Toxic if swallowed. Harmful in contact with skin. Irritating to eyes and skin. For animal treatment only. For external use only. Keep out of the reach of children. As this is an organophosphorus sheep dip, an interval of at least 14 days should elapse between dipping and dosing with any drench, etc. containing levamisole or an organophosphorus compound.

Pharmaceutical precautions

Store below 25°C.

Prior to use store in original container.

Do not open the aluminium foil bags until you are ready to prepare the dip bath.

Not to be mixed with any other dip.

Keep away from food, drink and animal feeding stuffs.

Incompatible with copper sulphate and its solutions.

Legal category

POM-VPS

Packaging Quantities

Primary pack: Polyvinyl alcohol Water Soluble Sachet –1 x 100 ml

Secondary pack: Polyamide/Polyethylene Laminated Film pouch to hold a single sachet: 1 x 100 ml

Tertiary pack: Aluminium barrier foil bag to hold single pouch.

Display carton: Printed, corrugated carton with self-closing lid to hold 5 x 100 ml bags.

Further information

Nil.

Marketing authorisation number.

Vm 0201/4168

Appendix 3: Membership of COT (with hyperlinks to the COT website and CVs)**Chairman of COT: [Professor David Coggon OBE MA PhD DM FRCP FFOM FFPH FMedSci](#)**

Professor of Occupational and Environmental Medicine at the MRC Epidemiology Resource Centre, University of Southampton.

Dr David Bell BSc (Hons) PhD

Reader of Molecular Toxicology at the University of Nottingham.

Professor Alan Boobis OBE BSc PhD CBiol FIBiol

Professor of Biochemical Pharmacology, Imperial College, London.

Dr Rebecca Dearman BSc (Hons) PhD

Head of Immunology at the Syngenta Central Toxicology Laboratory, Macclesfield, Cheshire.

Professor Corinne de Vries MSc PhD

Professor of Pharmacoepidemiology at the Department of Pharmacy and Pharmacology, University of Bath.

Dr Clifford R Elcombe BSc PhD FBTS

Co-founder and Research Director of CXR Biosciences, currently a Senior Lecturer in the Biomedical Research Centre, University of Dundee Medical School.

Dr John Foster BSc PhD FRCPath

Senior principal pathologist, Department of Safety Assessment at AstraZeneca Pharmaceuticals.

Dr Anna Hansell MSc MB BCh MRCP MFPHM PhD

Senior Lecturer and Wellcome Intermediate Clinical Fellow, Imperial College London.

Professor David Harrison BSc ME ChB MD FRCPath FFtCPEd FRCSEd

Professor of Pathology, University of Edinburgh. Honorary Consultant in Histopathology, Royal Infirmary of Edinburgh. Director of the Edinburgh Cancer Research Centre and Cancer Research UK Clinical Cancer Centre.

Professor Justin Konje MBBS MD MRCOG Dip Ultrasound

Professor of Obstetrics and Gynaecology and Head of Clinical Division of Obstetrics and Gynaecology, Reproductive Sciences Section at University of Leicester and University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary.

Professor Brian G. Lake BSc PhD DSc FBTS

Head of Leatherhead Food Research, Molecular Sciences Department, Leatherhead, Surrey

Dr Geraldine McNeill MB ChB, MSc, PhD, RPH Nutr

Senior Lecturer in Nutrition Epidemiology, Department of Environmental and Occupational Medicine, University of Aberdeen and head of the Public Health Nutrition research group, the Rowett Research Institute.

Professor Ian Morris BPharm PhD DSc

Professor of Pharmacology and Physiology, Associate Dean for Research, Hull York Medical School.

Dr Nicholas Plant BSc (Hons) PhD

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Dr David Ray BSc PhD

Associate Professor of Neurotoxicology at the University of Nottingham.

Dr David Tuthill MB BCH MRCP FRCPCH

Consultant Paediatrician at the Children's Hospital for Wales and Chair of the multidisciplinary Cardiff Nutrition Care Team.

Ms Alison Ward BA (Hons)

Public Interest Representative

Ms Alma Williams OBE BA

Free-Lance Author, writer and consultant on consumer affairs.

Appendix 4 NFU position statement as of May 2009

“The NFU is a membership organisation and the health and safety of our members and consumers is of paramount importance.

“Improving and protecting the health and welfare of the national sheep flock is also a priority and as members of SCOPS (Sustainable Control of Parasites in Sheep) and RUMA (Responsible Use of Medicines in Agriculture Alliance), NFU view the appropriate and responsible use of veterinary medicines by our farmer members as a major commitment to this.

“Ectoparasitic diseases of sheep such as blowfly strike, ticks and scab infestation, can be truly horrific and organophosphate dips are currently the best veterinary medicinal product available in the fight to control and prevent infestation.

“Organophosphates dips can be dangerous chemicals if not used correctly or safely.

“Under the Veterinary Medicines Regulations 2008, it is an offence to use sheep dip unless this is done by, or under the supervision and in the presence of, a person who holds a Certificate of Competence in the Safe Use of Sheep Dip. This ensures that the dip user understands the safety precautions and licence conditions of the OP product.

“The NFU is guided by the scientific and regulatory advice given in relation to OP products. If the conditions of the product licence and the manufacturers’ guidelines are adhered to during sheep dipping, the NFU is satisfied that the inherent risk of these chemicals can be minimised. However, if scientific evidence comes to light evidencing that there is a remaining risk with OP products, even when the product licence and manufacturers’ guidelines are adhered to, we would need to revisit the use of OPs in controlling ectoparasitic diseases.

“The NFU would welcome any research into alternatives to OP products.”

