

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Printed Tin Text

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GOLD FLEECE SHEEP DIP
608 mg/ml Concentrate for Dip Emulsion
Dimpylate (Diazinon)

2. STATEMENT OF ACTIVE SUBSTANCES

Active Ingredient:
Dimpylate (Diazinon) 608 mg/ml
A clear yellow-coloured liquid.

3. PHARMACEUTICAL FORM

Concentrate for Dip Emulsion.

4. PACKAGE SIZE

5 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

INSTRUCTIONS FOR USE

- Please read all of this label and follow the instructions carefully – this is for your own safety, for the safety of others, and for the protection of the environment
- Handle with extreme caution - this product can be dangerous to people, animals, and all wildlife large and small, if the proper precautions are not taken
- Contains organophosphorus anticholinesterase products. Do not use if under medical advice not to work with such compounds
- Keep children well away from all dipping operations
- Store concentrate locked away in its original container, tightly closed, not above 25°C. Not to be mixed with any other dip product.
- Keep dipped sheep out of all water courses

- **Make sure all used sheep dip, including rinse water from washing protective clothing and equipment, drains back into the dip bath for safe disposal**
- **Report any environmental pollution immediately. For the UK ring 0800 80 70 60.**

BEFORE YOU PREPARE THE DIP BATH

1. Check that this product is an appropriate treatment for your sheep. **This product is effective against blowfly strike, ticks, keds, lice and scab infestations on sheep.** It must not be mixed with any other product.
2. Do not use if the expiry date on this product has passed (see side of can).
3. Consider the condition of the sheep. Sheep should never be dipped on a full stomach, or when suffering from wounds or open sores. You should not dip sheep when they are tired, thirsty or heat stressed and not within the 3 week period after shearing. Also do not dip sheep if their fleece is already wet, and consult your veterinary surgeon if your sheep are ill from any other disease. Also seek advice if dipping pregnant ewes. If dipping of pregnant sheep is essential they should be gently lowered into the bath and assisted out.
4. Ensure you have spare protective clothing available in case any items become damaged. (see below for "**PROTECTIVE CLOTHING**").
5. Dipping should only be carried out in a well ventilated area, preferably outdoors.
6. Only use a dip bath that is well designed and hazard free as shown in AS29 "Sheep Dipping", (free copy from HSE Books, telephone: 01787 881165). This is essential for the safety of operators and the environment.
7. Check that all those involved are adequately trained and competent. The National Proficiency Tests Council (NPTC) (tel: 024 7669 6553) has names of training providers.
8. It is vital to measure the concentrate and the water accurately: **DO NOT GUESS.** If you are not sure how to do so contact your supplier or seek other reliable help. You must know the exact capacity of your dip bath so that you can calculate the amount of dip concentrate that you must add to achieve the correct concentration in the dip wash. Essential information for filling, mixing and topping-up your dip bath is given below (see "**ON THE DAY OF DIPPING**").
9. Soft or rain water should be used whenever possible. If this is not possible, hard water should be softened. You need 1Kg (or 2lbs 3oz) of washing soda to 500 litres (or 110 gallons) of water and it needs to stand for 2-3 hours before dip concentrate is added.
10. Check that the draining pens drain into the dip bath. If they do not you must change the design **before** operations start. Draining pen floors should be impermeable e.g. concreted.
11. Check the bath for leaks and seal them **before** dipping operations begin.
12. Prepare a planned route for the sheep back to pasture or penning that avoids contact with water courses of any kind.
13. This product must be used externally on sheep only. It contains an organophosphate compound so an interval of at least 14 days should elapse between dipping and dosing with any drench etc. containing levamisole or an organophosphate.

PROTECTIVE CLOTHING

The recommended protective clothing is;-

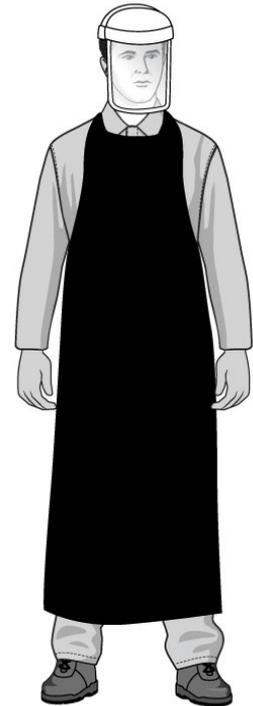
Face Shield (when handling dip concentrate)

**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



SAFETY PRECAUTIONS

- Make sure that everyone involved in dipping operations has the recommended protective clothing and **insist** that they wear it.
- Immediately wash off sheep dip, particularly dip concentrate, if it gets on your skin or in your eyes.
- 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.
- Immediately remove heavily contaminated clothes and wash contaminated areas of skin – see further instructions below under “**MEDICAL ADVICE TO USERS**” and “**DISPOSAL**”. Wash or destroy heavily contaminated clothes immediately.
- If you need to handle the sheep in the weeks following dipping wear protective clothing because dip residues remain on the fleece.

ON THE DAY OF DIPPING

1. Choose a cool dry day for dipping and dip early in the day. Rams and fat sheep should be assisted through the dip bath and lambs should be dipped separately from the ewes.
2. 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 the capacity of the bath.
3. 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.
4. The dip concentrate container is fitted with a sealed closure incorporating a male inlet Quick Acting Shut-off coupling (QASC), a female outlet QASC and a draw tube that extends from beneath the outlet QASC to the marked corner of the

container. When the container is fitted correctly into the dispensing kit, the tilt mechanism allows withdrawal of the maximum amount of dip concentrate from the container. **The dip concentrate in the container must be dispensed directly into the dip tank only by using the Gold Fleece Sheep Dip Dispensing Kit.** Follow the instructions provided with the dispensing kit for fitting it onto the container of dip concentrate and for dispensing the dip concentrate safely.

- Initial fill.** To treat sheep scab, blowfly strike, ticks, keds and lice dilute the concentrated dip accurately 1 to 1500 in water. The following table is a useful guide.

Capacity of dip bath	Volume of dip to add	*Number of 60ml deliveries from dispensing gun
1000 litres (220 gallons)	660 ml	11
1365 litres (300 gallons)	900 ml	15
2000 litres (440 gallons)	1320 ml	22
3000 litres (660 gallons)	1980 ml	33
4500 litres (1000 gallons)	3000 ml	50

*The dispensing gun is fixed to deliver 60 ml only and is sealed for safety reasons. It must not be disassembled.

For intermediate volumes, you must add **60 ml** (1 x 60 ml delivery from the dispensing gun) of dip concentrate for every **100 litres** (22 gallons) of water.

Helpful conversion factors:-

1 gallon	= 4.55 litres	1 pint = 568 mL	1 fluid ounce = 28 mL
1 litre	= 0.22 gallons	= 1.75 pints	or 25 fluid ounces
1 cubic meter	= 1000 litres	= 220 gallons	1 cubic yard = 765 litres = 168 gallons

6. Replenishment.

Replenishment with one 60 ml delivery of concentrate treats 12 sheep. Baths less than 2250 litres (500 gallons) **must be** replenished after every 36 sheep dipped (3x60 ml deliveries from the dispensing gun) and the bath must be filled with water to its original level. Baths of 2250 litres (500 gallons) or more **must be** replenished after every 96 sheep dipped (8x60 ml deliveries from the dispensing gun) and the bath must be filled with water to its original level. Fouling the dip wash reduces dip effectiveness. Therefore, **do not dip more than 1 sheep per 2 litres of dip wash (see point 14 below)**

- Mix the dip concentrate into the water after the initial fill and after each replenishment by stirring thoroughly with a metal rod, preferably with a paddle attachment.
- 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. Care should be taken to ensure that the sheep do not swallow or inhale any wash.

10. 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. Care should be taken to ensure that the sheep do not swallow or inhale any wash.
11. 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.
12. After dipping, all sheep should stand in draining pens for not less than 10 minutes or until they have completely stopped dripping.
13. 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).
14. 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 (paragraph 6, above)**. You should then empty, clean and recharge the bath with fresh dip wash.
15. Post-dipping lameness may occur when sheep are dipped in dirty wash or in wash that has stood overnight.
16. Sheep should have at least three weeks growth of wool after shearing when they are dipped, to obtain good residual protection.

AFTER DIPPING

1. Dip wash must be used **only** on the day on which it is prepared.
2. Dispose of all dip wash remaining at the end of the days' dipping (see **DISPOSAL**).
3. Always cover the bath when not in use, and take action to prevent accidents to both humans and animals.
4. Do not house freshly dipped sheep in an enclosed building.
5. In the 3 month period after dipping you are advised not to shear sheep. If you sell the sheep you should tell the new owner when the animals were last dipped.
6. If you take sheep to market it is good practice to ask the auctioneer to record (and pass on to the new owner) the date your animals were last dipped particularly if they were dipped during the last 3 months. Also note instructions below under "**FOOD SAFETY**".
7. The Gold Fleece Sheep Dip dispensing kit may be re-used if the washing and storage instructions provided with the dispensing kit have been followed.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD: Treated sheep must not be slaughtered for human consumption within 49 days of treatment. Not to be used on animals producing milk for human consumption.

UK Authorised Veterinary Medicinal product

FOOD SAFETY

1. There are strict **withdrawal periods** that must be observed.
 - Meat:** After you have used this product it is unlawful to slaughter treated sheep for human consumption in less than **49 days** from the last treatment. Records must also be kept.
 - Milk:** It is unlawful to use Gold Fleece Sheep Dip on animals producing milk for human consumption.
2. Do not let livestock graze on land for 1 month following the spreading of used dip.

9. SPECIAL WARNING(S), IF NECESSARY
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Keep away from food, drink and animal foodstuffs.
Wash out container and dispose of safely.

MEDICAL ADVICE TO USERS

- If you have previously felt unwell after using a product containing an organophosphorus compound consult your doctor before working with this product and show your doctor this label.
- 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 rinsing 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.
- Your copy of "Sheep Dipping" (AS29) includes further medical advice

INFORMATION FOR 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 bronchorrhea. 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 to medical practitioners:** Advice on clinical management is available from the National Poisons Information Service. Further information for health professionals is contained in MS17 entitled "Medical aspects of work related exposure to organophosphates" and is available from HSE books - tel: 01787 881165 or fax: 01787 313995

FURTHER INFORMATION

- If, after you have read the label, you need further information speak to your supplier. At your merchants speak to the AMTRA Qualified Person.
- If your supplier is unable to help, telephone the Health and Safety Executive tel: 0845 3450055 or the Veterinary Medicines Directorate tel: 01932 336911.

INCOMPATIBILITIES

Incompatible with copper sulphate and its solutions.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

DO NOT STORE ABOVE 25°C

Store in original container, tightly closed in a safe place.

Not to be mixed with any other dip.

In freezing conditions, the container must be shaken vigorously before use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

DISPOSAL

- **It is an offence** to permit any poisonous, noxious or polluting matter to enter any river, stream, watercourse, land drain or soakaway.
- To dispose of used sheep dip you must have an authorisation under the Groundwater Regulations 1998. To apply for an authorisation contact the Environment Agency (EA). In Scotland you should contact your local office of the Scottish Environment Protection Agency (SEPA). In Northern Ireland you should contact the Environment and Heritage Service of the Department of the Environment for Northern Ireland (EHS/DENI).
- Used sheep dip may be disposed of by using a licensed waste disposal contractor. If you wish to do so contact the EA, SEPA or EHS.
- To dispose of **unused** dip concentrate and contaminated items e.g. clothing, use a licensed disposal contractor. You may be able to make arrangements for the return of unused dip concentrate to your supplier.
- Rinse the empty container three times, as directed in the washing instructions provided with the Dispensing Kit and dispose of rinsings in the dip tank. Because the container is a closed, sealed system, it **must** be punctured before crushing. Dispose of rinsed containers in accordance with guidance from your local waste regulation authority.
- Do not apply dip to areas where wild fowl are likely to graze. Geese are particularly vulnerable. In any case use wild bird scarers on land where used dip has been spread.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

EACH CONTAINER OF GOLD FLEECE SHEEP DIP **MUST NOT** BE SOLD WITHOUT 1x PAIR OF GLOVES, 1x LAMINATED DISPENSING KIT INSTRUCTION CARD AND 1x LAMINATED SHEEP DIPPING SAFETY CARD. ENSURE THAT ALL THOSE WHO ARE INVOLVED IN THE DIPPING PROCESS READ THE SAFETY CARD AND HAVE IT AVAILABLE NEAR TO THE DIP FOR REFERENCE.

THIS PRODUCT **MUST ONLY BE USED** IN CONJUNCTION WITH A GOLD FLEECE DISPENSING KIT (AVAILABLE FROM YOUR GOLD FLEECE SUPPLIER). THE PURPOSE OF THE DISPENSING KIT IS TO INCREASE YOUR SAFETY WHEN HANDLING THIS ORGANOPHOSPHATE PRODUCT.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND SITE OF BATCH RELEASE

Marketing authorisation holder:
Bimeda Animal Health Limited
2 / 3 / 4 Airtón Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4031

17. MANUFACTURER’S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Container Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GOLD FLEECE SHEEP DIP, 608 mg/ml Concentrate for Dip Emulsion
Dimpylate (Diazinon)

2. STATEMENT OF ACTIVE SUBSTANCES

Active Ingredient:
Dimpylate (Diazinon) 608 mg/ml,

3. PHARMACEUTICAL FORM

Concentrate for Dip Emulsion.

4. PACKAGE SIZE

5 litre x 2

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD: Treated sheep must not be slaughtered for human consumption within 49 days of treatment. Not suitable for sheep that are being milked for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only.
Keep away from food, drink and animal foodstuffs.
Wash out container and dispose of safely.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C
Store in original container, tightly closed in a safe place.
Not to be mixed with any other dip.
Keep container in outer carton.
In freezing conditions, the container must be shaken vigorously before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4031

UK Authorised Veterinary Medicinal Product

17. MANUFACTURER'S BATCH NUMBER

Batch No:

Approved 02 July 2021

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date. The signature is stylized and includes a large, looped initial.