Public Release Summary
on

Evaluation of the new active

TEPRALOXYDIM

in the product

Aramo Herbicide

Australian Pesticides and Veterinary Medicines Authority

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Australia

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing (Therapeutic Goods Administration [TGA]), Environment Australia [EA] (Risk Assessment and Policy Section), the National Occupational Health and Safety Commission [NOHSC] and State departments of agriculture and environment.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of public release summaries for all products containing new active ingredients and for all proposed extensions of use for existing products.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the APVMA's publications *AgManual: The Requirements Manual for Agricultural Chemicals* and *Ag Requirements Series.*

This Public Release Summary is intended as a brief overview of the assessment that has been completed by the APVMA and its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience thereby encouraging public comment.

More detailed technical assessment reports on all aspects of the evaluation of this chemical can be obtained by completing the order form in the back of this publication and submitting with payment to the APVMA. Alternatively, the reports can be viewed at the APVMA Library, 1st Floor, 22 Brisbane Avenue, Barton, ACT.

The APVMA welcomes comment on the usefulness of this publication and suggestions for further improvement. Comments should be submitted to the Program Manager—Pesticides Division, Australian Pesticides and Veterinary Medicines Authority, PO Box E240, Kingston ACT 2604.

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LIST OF ABBREVIATIONS AND ACRONYMS

AC	active constituent
ACR	Acute to chronic ratio
ADI	Acceptable Daily Intake (for humans)
AHMAC	Australian Health Ministers Advisory Council
ai	active ingredient
ARfD	Acute Reference Dose (for humans)
BBA	Biologische Bundesanalstalt fur Land – und forstwirschaft
bw	bodyweight
CRP	Chemistry and Residues Program
d	day
DAT	Days After Treatment
DM	Dry Matter
DT_{50}	Time taken for 50% of the concentration to dissipate
DT_{90}	Time taken for 90% of the concentration to dissipate
EA	Environment Australia
E_bC_{50}	concentration at which the biomass of 50% of the test population is impacted
EC_{50}	concentration at which 50% of the test population are immobilised
EEC	Estimated Environmental Concentration
E_rC_{50}	concentration at which the rate of growth of 50% of the test population is impacted
EUP	End Use Product
Fo	original parent generation
FW	Fresh Weight
g	gram
GAP	Good Agricultural Practice
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GVP	Good Veterinary Practice
h	hour
ha	hectare
Hct	Heamatocrit
HDPE	High-density polyethylene
Hg	Haemoglobin
HPLC	High Pressure Liquid Chromatography *or* High Performance Liquid Chromatography
id	intradermal
im	intramuscular
ip	intraperitoneal
IPM	Integrated Pest Management
iv	intravenous
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
kg	kilogram
K_{oc}	Organic carbon partitioning coefficient
L	Litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
LC-MS/MS	liquid chromatography, mass spectroscopy
LOEC	Lowest Observable Effect Concentration
LOD	Limit of Detection – level at which residues can be detected
LOQ	Limit of Quantitation – level at which residues can be dquantified
mg	milligram
mL	millilitre
MRL	Maximum Residue Limit
MSDS	Material Safety Data Sheet

NDPSC	National Drugs and Poisons Schedule Committee
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short Term Intake
ng	nanogram
NHMRC	National Health and Medical Research Council
NOEC/NOEL	No Observable Effect Concentration Level
OC	Organic Carbon
OM	Organic Matter
PHI	Pre-harvest interval
po	oral
POEM	Predictive Operator Exposure Model (UK)
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
Q-value	Quotient-value
RBC	Red Blood Cell Count
s	second
sc	subcutaneous
SC	Suspension Concentrate
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
TRR	
T-Value	A value used to determine the First Aid Instructions for chemical products that contain two or more poisons
μg	microgram
vmd	volume median diameter
WG	Water Dispersible Granule
WHP	Withholding Period

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INTRODUCTION

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of *ARAMO HERBICIDE,* which contains the new active constituent tepraloxydim. The product is proposed to be used for the control of certain grass weeds in canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch.

Responses to this Public Release Summary will be considered prior to registration of the product. They will be taken into account by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

Copies of full technical evaluation reports on tepraloxydim, covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request (see order form on last page). They can also be viewed at the APVMA library located at the APVMA offices, First Floor, 22 Brisbane Avenue, Barton ACT 2604.

Written comments should be received by the APVMA by **3 June 2003**. They should be addressed to:

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Applicant
BASF Australia Limited

Product Details
It is proposed to register *ARAMO HERBICIDE,* containing 200g/L of tepraloxydim as an emulsifiable concentrate. The product will be formulated in Australia or overseas and packaged 1L and 10L packs.

ARAMO HERBICIDE is a member of the cyclohexanedione group of herbicides. The product has the inhibition of acetyl CoA carboxylase mode of action. With respect to weed resistance management, the product is a Group A herbicide.

The rate of product use is 175mL-300mL/ha. *ARAMO HERBICIDE* is proposed for registration in all states.

Formulations containing tepraloxydim are registered in the UK (provisionally), Japan, USA, Switzerland, several European countries and Thailand for a variety of vegetable crops, canola, flax, cotton, soybeans and potato.

CHEMISTRY AND MANUFACTURE

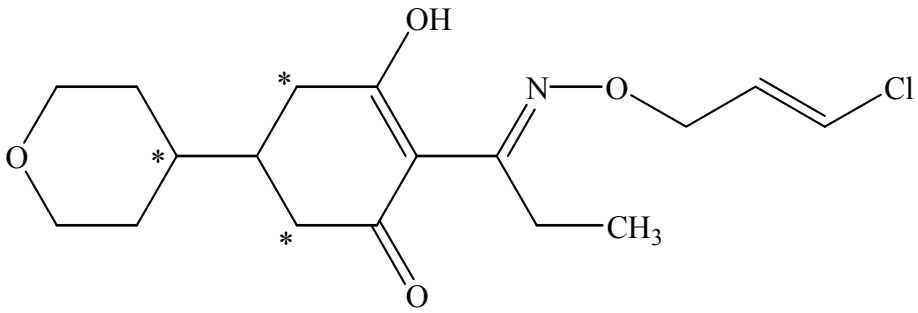
The APVMA has already approved a new active constituent (AC) tepraloxydim. Tepraloxydim is a new cyclohexanedione herbicide for early post emergence control of various grass weeds in canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch.
The APVMA is now considering registration of a formulated product *ARAMO HERBICIDE* containing the new active constituent, tepraloxydim.

Active Constituent

The chemical active constituent has the following properties:

Common name :	Tepraloxydim
Chemical name (IUPAC):	(EZ)-(RS)-2-{1-[(2E)-3-chloroallyloxyimino] propyl}-3-Hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one
CAS Registry Number:	149979-41-9
Empirical formula:	$C_{17}H_{24}ClNO_4$
Molecular weight:	341.83
Physical form:	Solid crystals
Colour:	white
Odour:	Odourless
Melting point	72.5-74.4^{0}C
Density:	1.284 g/cc at 20^{0}C
Vapour pressure at 25^{o}C:	2.7 X 10^{-5} Pa

Structural formula:



The Chemistry and Residues Program (CRP) of the APVMA has evaluated the chemistry aspect of the tepraloxydim active constituent (manufacturing process, quality control procedure, batch analysis results and analytical methods) and found them to be acceptable. The physical and chemical properties of tepraloxydim active constituent have been adequately demonstrated. Tepraloxydim will be sourced from Japan.

Formulated Product

Product name:	ARAMO HERBICIDE
Formulation type:	Emulsifiable concentrate
Active constituent concentration:	200 g/L tepraloxydim

Physical and Chemical Properties

Appearance:	Clear dark yellow liquid
Odour:	moderate aromatic
Density:	1.032 g/mL
pH:	3.9
Flash point	93^0C
Surface tension	31.2 mN/m

Storage stability
The CRP advises that the product might not remain within specifications after two years storage under normal conditions. Therefore CRP recommends that products containing tepraloxydim active constituent be regarded as date controlled products. Consequently, the CRP recommends that *ARAMO HERBICIDE* be assigned a two year shelf life when stored under normal conditions in the unopened container.

Packaging
The product will be packaged in 1L and 10L fluorinated HDPE packs and is satisfactory.

Labelling
The draft label is acceptable in respect of the chemistry aspects.

Recommendations
The Chemistry and Residues Program (CRP) has evaluated the chemistry and the manufacturing aspects of *ARAMO HERBICIDE* in data submitted by BASF Australia Ltd to support their application to register *ARAMO HERBICIDE*. The CRP is satisfied that the chemistry requirements of Section 14(5) Agricultural and Veterinary Chemicals Codes have been met.

TOXICOLOGICAL ASSESSMENT

Evaluation of Toxicology

The toxicological database for tepraloxydim, which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available. Where possible, considerations of the species specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher, which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

Toxicokinetics and Metabolism

In rats, absorption of ^{14}C-tepraloxydim from the gastro-intestinal (GI) tract was rapid and virtually complete, with peak blood concentrations of radiolabel occurring within 1 hour after oral dosing with 30 and 300 mg/kg bw. Low levels were present after 72 hours. Plasma concentrations were proportional to the dose. At 30 mg/kg, around 70% of the administered cyclohexene-radiolabel was excreted in the urine within 24 hours (oral, i.v., and repeat doses). Urinary excretion was approximately 70% and 60% after oral administration of 30 and 300 mg/kg, respectively. Around 35-55% of the administered radioactivity was recovered in the bile (30 or 300 mg/kg oral doses). The bioavailability of orally administered tepraloxydim is close to 100%, based on the combined radioactivity excreted in the urine and bile. Faecal excretion accounted for about 20% of the administered radioactivity. Highest tissue concentrations after oral dosing occurred in the stomach contents and stomach. Tissue concentrations, above those seen in plasma, were observed in thyroid and fat tissue in males, and ovaries, uterus and fat tissue in females. There were no significant differences between males and females, nor between cyclohexene-labelled and tetrahydropyrane-labelled tepraloxydim. Tepraloxydim is extensively metabolised, by oxidation at the pyran ring to the lactone via the hydroxy-metabolite, and cleavage of the oxime ether group with imine and oxazol as products. Plasma, kidney, liver and bile contained predominantly tepraloxydim, with about 30% and 2% unchanged in urine and faeces, respectively. Less than 5% was absorbed through rat skin at a dose of 0.005 mg/cm^2.

Acute Studies

In acute studies in rats, tepraloxydim had an oral LD_{50} of approximately 5000 mg/kg in males and females, a dermal LD_{50} of >2000 mg/kg (no deaths), and an inhalation LC_{50} of >5100 mg/m^3 (no deaths). It was not a skin irritant but was a slight eye irritant in rabbits, and was non-sensitising in a guinea pig Maximisation test.

ARAMO HERBICIDE had an acute oral LD_{50} of between 2000 and 3000 mg/kg, a dermal LD_{50} of >4000 mg/kg (no deaths), and an inhalation LC_{50} of >5400 mg/m^3 (no deaths) in rats. *ARAMO HERBICIDE* was a moderate irritant to the skin and eyes of rabbits, but was non-sensitising to guinea pigs in a Buehler test.

Short-Term Studies

Mice were fed 0, 500, 2000, 5000 or 7500 ppm tepraloxydim in the diet for 28 days. Food consumption was slightly higher in 7500 ppm males, but body weight gain was reduced at ≥5000 ppm, leading to a slight body weight loss in 7500 ppm males. A slight anaemia (decreased red blood cells, haematocrit and haemoglobin) was seen in 7500 ppm males. Liver weights were increased in 2000 ppm males and both sexes at ≥5000 ppm, with microscopic evidence of centrilobular hepatocellular hypertrophy in ≥2000 ppm males. Kidney weights were also increased at ≥5000 ppm, with a slight fatty change of the proximal tubular cells of the kidneys at 7500 ppm. No effects were observed at 500 ppm (123 mg/kg/day).

Rats were fed tepraloxydim in the diet at 0, 500, 5000, 7500 or 10000 ppm for 4 weeks. Urine staining of the perineum was seen at ≥7500 ppm. Body weight gain and food consumption were reduced at ≥5000 ppm and ≥7500 ppm, respectively. Serum chemistry changes included slightly decreased chloride and glucose levels at ≥5000 ppm, decreases in triglyceride and alkaline phosphatase at ≥7500 ppm, and increased total protein, albumin, globulin, gamma glutamyltrans-peptidase and glutathione levels at ≥5000 ppm. IgG levels were slightly decreased at ≥7500 ppm. Histopathological changes included central hypertrophy in the liver and hyaline droplet degeneration in the kidney in males and decreased lipid deposition in the liver at ≥5000 ppm and lymphocyte depletion in the spleen and thymus at ≥7500 ppm. No treatment-related effects were seen at 500 ppm (equivalent to 46 mg/kg/day).

Tepraloxydim was dermally applied to rats at 0, 50, 200 or 1000 mg/kg/day, 6 hours/day for 28 days. A transient reduction in body weight gain occurred at 1000 mg/kg/day. In males, there were slight decreases in spleen weights at ≥200 mg/kg/day and in adrenal weights at 1000 mg/kg/day. There were no treatment-related abnormalities in macroscopic, microscopic or clinical pathology parameters.

Tepraloxydim was fed to Beagle dogs at 0, 1000, 4000, 8000 or 12000 ppm in the diet for 4 weeks. At 12000 ppm, vomiting, body weight loss and reduced food consumption occurred in one male dog and vomiting occurred in both females at the beginning of the study. Slight haematology and serum chemistry changes were noted at ≥4000 ppm but were within the normal reference range for Beagle dogs. Liver weights were increased in all treatment groups, with minimal to slight centrilobular hepatocellular hypertrophy at 12000 ppm.

Long-Term Studies

Mice were fed 0, 300, 1200 or 5000 ppm tepraloxydim in the diet for 3 months. Body weight gain was reduced at 5000 ppm. Haematological and serum chemistry changes included a slight increase in MCV and a decrease in platelets (females only) at ≥1200 ppm and decreases in potassium in males and triglycerides in females at 5000 ppm. Liver weights were increased at 5000 ppm, with centrilobular hepatocellular hypertrophy in all males and half the females at 5000 ppm and in 1/10 males at 1200 ppm. Moderate myocardial vacuolisation was observed in most animals at 5000 ppm and in a few animals at 1200 ppm. The NOEL was 300 ppm (equivalent to 95 mg/kg/day).

Rats were fed 0, 300, 3000 or 5000 ppm tepraloxydim in the diet for 13 weeks. Body weight gain was reduced at ≥3000 ppm and food consumption decreased in ≥3000 ppm males and 5000 ppm females. Increases in protein and albumin occurred at ≥3000 ppm. Serum cholesterol increased in ≥3000 ppm females at week 6, and triglycerides were reduced in 5000 ppm males. Serum glucose at ≥3000 ppm and sodium in 5000 ppm males decreased at week 6. Increased globulin levels and decreased chloride levels occurred from 300 ppm. Relative but not absolute liver weight was increased at 5000 ppm. Lipid deposition in the liver decreased at ≥3000 ppm, with increases in central hypertrophy and bile duct proliferation in 5000 ppm males. Hyaline droplet degeneration and tubular basophilia were seen in the kidneys of ≥3000 ppm males, while urothelial hyperplasia was seen in one male at 3000 ppm

and one female at 3000 and 5000 ppm. No NOEL could be established; the NOEL based on clinical chemistry changes was 300 ppm (equivalent to 22 mg/kg/day).

Beagle dogs were fed 0, 400, 2000 or 10000 ppm tepraloxydim in their diet for 3 months. There were no deaths or treatment-related clinical signs. At 10000 ppm, food consumption and food efficiency were slightly reduced in both sexes, leading to reduced body weight gain in the females. At 10000 ppm, tepraloxydim caused mild haemolytic anaemia (decreases in erythrocytes, haemoglobin, MCHC (males only) and haematocrit). In males, prothrombin time was decreased at 10000 ppm and partial thromboplastin time was decreased at ≥2000 ppm. Leucocyte counts were increased in ≥2000 ppm females. Serum chemistry effects at 10000 ppm included slight decreases in chloride and glucose and increases in AST, ALT, alkaline phosphatase, phosphate, globulins, triglycerides and cholesterol. Liver weights were increased at ≥2000 ppm, with microscopic evidence of liver hypertrophy and cholestasis at 10000 ppm. In the spleen, the incidence of haemosiderosis increased in 10000 ppm males and in ≥2000 ppm females and extramedullary haematopoiesis was evident in ≥2000 ppm females. Bone marrow hyperplasia (femur and sternum) was increased at ≥2000 ppm. Thyroid weights increased in 2000 ppm females and at 10000 ppm, and follicular distension in the thyroid was increased at 10000 ppm. Atrophy, giant cells and granular inflammation occurred in the testes and epididymides at 10000 ppm. The NOEL was 400 ppm (equivalent to 14 mg/kg/day).

Tepraloxydim at 0, 200, 1800 or 5000 ppm was administered to mice in the diet for 18 months. Body weight gain was reduced in 1800 ppm males and at 5000 ppm. Increased lymphocytes and decreased PMN differential counts occurred in 5000 ppm females. Lymphocyte counts were also slightly increased in 1800 ppm females at the end of the study. Liver weights were increased in 1800 ppm males and at 5000 ppm in both sexes, with microscopic evidence of minimal or slight hepatocellular hypertrophy in half of the males and a few females, and an increased incidence of eosinophilic and basophilic foci in the liver at 5000 ppm. Kidney weights were reduced in 1800 and 5000 ppm females but were not associated with any abnormal microscopic findings. The incidence of hepatocellular tumours (adenomas or carcinomas) was slightly increased in females at 5000 ppm. There were no effects at the lowest dose tested of 200 ppm (45 mg/kg/day).

In a carcinogenicity study, rats were fed (♂/♀) 0/0, 100/100, 600/600, or 3000/4000 ppm tepraloxydim in the diet for 24 months. Body weight gain and food consumption were reduced at 3000/4000 ppm. Ovary weights and the incidence of ovarian cysts increased at ≥600 ppm and granulosa cell tumours were slightly increased at 4000 ppm. At 3000 ppm, there were increases in testes weight and minor increases in the incidence of testicular masses, hyperplasia in Leydig cells and focal calcification. A slight increase in benign tumours in the adrenal medulla was seen in 3000 ppm males. Kidney cysts in females and retractions in males were increased at 3000/4000 ppm. Liver cell alterations were increased at 3000/4000 ppm, and cellular polymorphism increased in 4000 ppm females. Males treated with 3000 ppm showed an increase in hypertrophy and fatty infiltration in zone 3 liver cells. The NOEL was 100 ppm (equivalent to 5 mg/kg/day).

In a chronic toxicity study, tepraloxydim was fed to rats at (♂/♀) 0/0, 100/100, 600/600, or 3000/4000 ppm in the diet for 24 months. Body weight gain and food consumption were reduced and leucocyte counts increased at 3000/4000 ppm. Serum chemistry changes included decreased triglycerides at ≥600 ppm and increased cholesterol and total protein in ≥600 ppm females and 3000 ppm males, and increased albumin and magnesium at 3000/4000 ppm. Increased GGT levels were seen in males at 600 and 3000 ppm, and increased ALT levels were seen in females at 4000 ppm. Haematuria occurred in 3000 ppm males. Slight increases were seen in the incidence of eosinophilic foci in the liver at ≥600 ppm, in hepatocellular carcinoma and focal bile duct hyperplasia in ≥600 ppm males, in hepatocellular polymorphism in 4000 ppm females and in hyperplasia of the transitional cells of the urinary bladder in 4000 ppm females. Fatty infiltration in the liver decreased at 4000 ppm. A slight increase in granulosa cell tumours occurred in the ovaries and a slight

increase in the incidence of atrophy and spermatic granuloma were observed in the epididymides at 4000/3000 ppm. The NOEL was 100 ppm (equivalent to 5 mg/kg/day).

Beagle dogs were fed 0, 100, 400 or 2000 ppm and in a subsequent supplementary study 0 or 8000 ppm tepraloxydim in the diet for 12 months. At 8000 ppm, tepraloxydim caused mild haemolytic anaemia (decreases in erythrocytes, haemoglobin, and haematocrit, and increases in platelets and reticulocytes), decreases in serum glucose and chloride, and increases in ALT, total protein, globulins, trigycerides, cholesterol and inorganic phosphate. Increased serum cholesterol and trigycerides occurred in 2000 ppm males. At ≥2000 ppm, liver weights increased in both sexes and epididymal weights were decreased. Kidney and thyroid weights were increased and testes weights were decreased at 8000 ppm. At 8000 ppm, histopathology revealed hepatocellular hypertrophy and cholestasis in the livers of all dogs, concretions in the gallbladder of 2/6 males, an increased incidence of distension of thyroid follicles in both sexes, degeneration and atrophy (loss of spermatids) of the germinal epithelium in the testes and epididymides of all males, a slightly increased incidence of haemosiderosis in the spleen and erythroid hyperplasia in the bone marrow. Diffuse hyperplasia of the transitional epithelium in the urinary bladder occurred at ≥2000 ppm, with focal haemorrhage in 8000 ppm males. The NOEL was 400 ppm (12 mg/kg/day).

Reproduction and Developmental Studies

In a two generation study, rats (F_0 and F_1) received 0, 100, 500, or 2500 ppm of tepraloxydim in their diet from 10 weeks prior to mating, through to the end of lactation. At 2500 ppm, there were reductions in body weight gain and food consumption during most of the study. Increased serum creatinine occurred in F_0 and F_1 males at ≥500 ppm and in 2500 ppm females and increases in serum albumin were seen in 2500 ppm males. There were no treatment-related changes seen at macroscopic or microscopic necropsy. There were no effects on male or female fertility indices, or female reproduction data attributable to treatment. Pup body weight gain was reduced during lactation at 2500 ppm and was associated, in 2500 ppm F_2 pups, with a delay in eye opening. The viability index decreased in 2500 ppm F_2 pups. There were no effects on clinical signs, reflex testing, and no abnormalities were seen at necropsy. A NOEL for adults was established at 100 ppm (at least 8 mg/kg/day), based on increases in serum creatinine in F_0 and F_1 males at 500 ppm and above. There were no effects on reproductive performance or fertility up to 2500 ppm (at least 204 mg/kg/day). The NOEL for neonates was 500 ppm, based on reductions in body weight gain at 2500 ppm.

Pregnant female rats received oral gavage doses of 0, 40, 120, or 360 mg/kg/day tepraloxydim between gestation days 6 and 15. There were no mortalities or clinical signs of toxicity. At 360 mg/kg/day, body weight gains and food consumption were reduced. Resorptions were increased and the percentage of live foetuses was decreased at 360 mg/kg/day. At 360 mg/kg/day, reduced foetal and placental weights were reflected in decreased gravid uterine weights. Two 360 mg/kg/day foetuses had filiformed tails, caused by the absence of caudal and sacral vertebrae. Other foetal skeletal changes included increased incidences of incomplete ossification/reduced size or non-ossification of sternebrae at ≥120 mg/kg/day and incomplete ossification of the skull and thoracic vertebral bodies and sternebrae with one ossification centre at 360 mg/kg/day. A maternal NOEL was established at 120 mg/kg/day, based on reductions in body weight gain and food consumption at 360 mg/kg/day. A NOEL for development was established at 40 mg/kg/day, based on reduced foetal weights and effects on foetal ossification at 120 mg/kg/day.

In a supplementary study, pregnant female rats received oral gavage doses of 0, 10, 20, or 40 mg/kg/day tepraloxydim between gestation days 6 and 15. Reductions in body weight gains during the treatment period were used to establish a maternal NOEL at 20 mg/kg/day. There was no evidence of embryo or foetal toxicity related to tepraloxydim treatment at 40 mg/kg/day.

Pregnant female rabbits received oral gavage doses of 0, 20, 60, or 180 mg/kg/day tepraloxydim between gestation days 7 and 19. There were no deaths or clinical signs of toxicity. During the treatment phase, there were reductions in food consumption at 180 mg/kg/day and in body weight gains at ≥60 mg/kg/day consequently a maternal NOEL was established at 20 mg/kg/day. There was no evidence of treatment-related embryo or foetal toxicity at 180 mg/kg/day.

Genotoxicity

Tepraloxydim was non-genotoxic in the following studies; a bacterial mutation assay with *S. typhimurium*, a mammalian cell mutation assay (CHO-HGPRT), an *in vitro* CHO chromosome aberration assay, a mouse micronucleus test, and an *in-vitro* UDS assay in primary rat hepatocytes.

Special Studies

Rats received single oral gavage doses of 0, 500, 1000, or 2000 mg/kg tepraloxydim. There were no deaths or signs of toxicity and body weight gains were similar in control and treated rats. Motor activity was reduced in all treated groups on the day of dosing, achieving statistical significance in treated females. Macroscopic and microscopic necropsies revealed no abnormalities related to treatment.

Tepraloxydim at 0, 400, 1500, or 6000 ppm was fed to rats in their diet for 3 months. There were no deaths and no overt signs of toxicity. Body weight gains were reduced in 1500 ppm females and at 6000 ppm. Food consumption and food efficiency were decreased at 6000 ppm. Motor activity at 6000 ppm was increased in females on day 50 and in males and females at day 85. There were no treatment-related changes to home cage observations or sensor/motor or reflex tests in FOBs, or at macroscopic or microscopic necropsy. There were no neurotoxic effects.

Tepraloxydim was fed to rats at 0 or 10000 ppm in the diet for 18 to 20 days to investigate the mechanism of elevation of serum bilirubin and creatinine levels. Body weight gain and food consumption were decreased in treated males, with an initial reduction in body weight gain occurring in treated females. Analysis of serum for bilirubin and creatinine showed elevated levels when routine tests were used, but no elevation following enzymatic analysis. Bilirubin levels were not increased when analysed by HPLC. These results suggest there may be some interference with the routine, colour-based analysis methods by either tepraloxydim or its metabolites.

5-OH-DP (Reg. No.: 275 522) is formed from the hydroxylation of tepraloxydim at the 5-position of the cyclohexene ring. 5-OH-DP is the main metabolite of tepraloxydim in oilseed rape/canola and soybeans, but accounted for only 0.2% of the administered radioactivity in rats.

In rats, 5-OH-DP was rapidly and completely absorbed (peak blood concentrations occurred at 1 hour after oral 30 and 300 mg/kg doses). Achieved plasma concentrations were greater than dose-proportional. Within 24 hours, 60-70% of the labelled metabolite was excreted in the urine, and around 20-30% in the faeces. Peak tissue concentrations occurred in the same tissues as tepraloxydim, but levels declined in all tissues thereafter. 5-OH-DP is metabolised to around 50% in rats, the main pathway being cleavage of the oxime ether bond followed by further oxidation steps.

5-OH-DP has an acute oral LD_{50} of >5000 mg/kg in rats. There was no evidence of treatment-related toxicity when 5-OH-DP was administered to rats in their diet for 3 months at 0, 300, 3000 or 5000 ppm, consequently the NOEL was 322 mg/kg/day.

In a rat developmental study, pregnant female rats received oral gavage doses of 0, 20, 40, 120, or 360 mg/kg/day 5-OH-DP between gestation days 6 and 15. A reduction in body

weight gain at 360 mg/kg/day set the maternal NOEL at 120 mg/kg/day. An increase in non-ossified sternebrae in foetuses at 360 mg/kg/day was used to establish a developmental NOEL of 120 mg/kg/day.

5-OH-DP was non-genotoxic in a bacterial mutation assay with *S. typhimurium* and a mouse micronucleus test. In unscheduled DNA synthesis (UDS) assays, 5-OH-DP caused slight increases in UDS when added at cytotoxic concentrations to primary rat hepatocyte cultures *in vitro*, but did not induce UDS when administered to rats *in vivo*.

Public Health Standards

Poisons Scheduling

The National Drugs and Poisons Schedule Committee (NDPSC) considered the toxicity of the product and its active ingredients and assessed the necessary controls to be implemented under States' poisons regulations to prevent the occurrence of poisoning.

On the basis of its toxicity, the NDPSC has included tepraloxydim in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate warning statements and first-aid directions on the product label.

NOEL/ADI

The Acceptable Daily Intake is that quantity of an agricultural compound which can safely be consumed on a daily basis for a lifetime and is based on the lowest NOEL obtained in the most sensitive species. This NOEL is then divided by a safety factor which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

The ADI for tepraloxydim was established at 0.05 mg/kg/day based on NOELs of 5 mg/kg/day in 2-year rat dietary studies and using a 100-fold safety factor in recognition of the extensive toxicological database available for tepraloxydim.

Acute Reference Dose (ARfD)

The acute reference dose is the maximum quantity of an agricultural or veterinary chemical that can safely be consumed as a single, isolated, event. The ARfD is derived from the lowest single or short term dose which causes no effect in the most sensitive species of experimental animal tested, together with a safety factor which reflects the quality of the toxicological database and takes into account the variability in responses between species and individuals.

In a developmental study in rats, the NOEL for foetotoxicity was 40 mg/kg/day and this is an appropriate endpoint to use in establishing an ARfD. Using a safety factor of 100, the ARfD is 0.4 mg/kg.

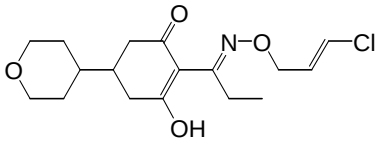
RESIDUES ASSESSMENT

Introduction

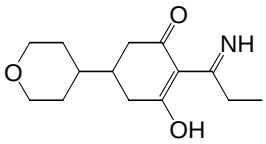
The application is for early post emergence use of tepraloxydim on grass weeds in chickpeas, field peas, lentils, faba beans, lupins, canola, subclover and vetch. The label advises to always apply with the non ionic surfactant at the label rate and not to apply more than once to any one crop.

Metabolism

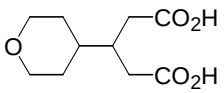
Sugarbeet were sprayed once with ^{14}C-tepraloxydim uniformly labelled in the 4(6) position of the cyclohexene ring. Only 8% of TRR in sugarbeet roots collected 45 days after treatment were identified, 4% each of the imine (DP-1) and the dicarboxylic acid (GP). In leaves, only trace amounts of the dicarboxylic acid were identified. Parent compound was not identified in sugarbeets. The majority of radioactive residues were incorporated into the carbohydrate pool.



Tepraloxydim (DP)

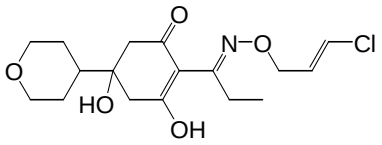


DP-1

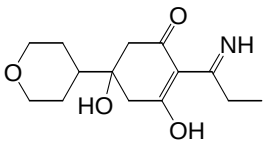


GP

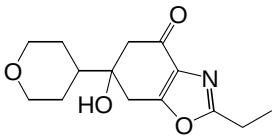
Canola plants were given a single foliar application of ^{14}C-tepraloxydim uniformly labelled in the 4(6) position of the cyclohexene ring. Parent compound was the major radioactive residue in canola plants immediately after application, comprising more than 80% of radioactive residues in the plant. At harvest 61 days after application, the major residue in seed was the 5-hydroxy tepraloxydim metabolite (5-OH-DP, 38% TRR), with lesser amounts of the diacid (GP, 12% TRR), the hydroxy-imine (5-OH-DP-1, 8% TRR) and the oxazole (6-OH-DP-2, 6% TRR). The diacid (GP, 10% TRR) was the major residue in straw. All other identified radioactive components comprised less than 5% of the TRR.



5-OH-DP



5-OH-DP-1



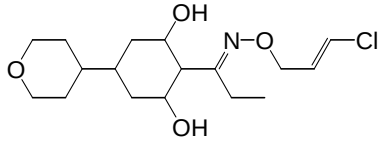
6-OH-DP-2

Soybean plants were given a single foliar application of ^{14}C-tepraloxydim uniformly labelled in the 4(6) position of the cyclohexene ring. Parent compound was a major residue in soybean plants and beans, comprising between 3.5 and 42% TRR in whole plant, leaf, bean, stalk and hulls. The dimethyl ester DMP of the acid GP comprised between 9 and 26% TRR and the hydroxy metabolite 5-hydroxytepraloxydim (5-OH-DP) comprised 16% TRR in beans, but was not identified in any other sample.

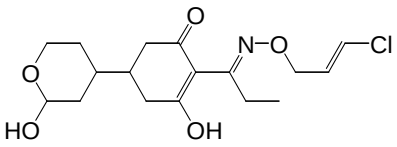
Overall, the metabolism of tepraloxydim in plants proceeds *via* three main pathways: cleavage of the oximino N-O bond, hydroxylation at the 5-position of the cyclohexenone ring and by ring opening of the cyclohexene ring.

Lactating goats were administered ^{14}C-tepraloxydim for 5-7 days. The majority of the administered dose was eliminated in urine (61-77%) and faeces (14-16%). Between 0.25 and 0.86% of the doses were recovered in tissues (liver, kidney, muscle and fat) with the remainder (*ca*. 5-14%) recovered in stomach and intestinal contents etc. Highest tissue residues were found in liver and kidney. Parent compound was the predominant residue in tissues and milk (31-72% TRR) with the exception of liver, where it comprised only 10% of the TRR. The major radioactive residue in liver was the diol 620M005 (17% TRR), formed from reduction of the α,β-unsaturated ketone.

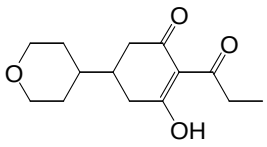
The metabolism of tepraloxydim in **hens** dosed for 28 consecutive days was similar to that in goats. The majority of the administered dose was recovered in excreta (82-94% of dose). Highest residues in tissues were present in liver. For a low dose group (10.5 ppm) 0.1% of the dose was present in liver, while radioactivity in other tissues and skin was ≤0.03% of the dose. A higher proportion of radioactivity was present in tissues of animals given a high dose (210 ppm). Radioactivity in liver, muscle and kidney amounted to 0.54, 0.36 and 0.20% of the dose, respectively, with ≤0.1% of the dose present in fat and skin. Egg whites and yolks contained approximately 0.5 and 0.1% of the dose, respectively. Parent compound was a major residue in all matrices, comprising 7-46% of TRR. The hemiacetal (2-OH-P-DP) comprised 1.3-12% TRR, the oxazole (DP-2) comprised 5-22% TRR and the diketone (DP-6) comprised 7-17% TRR.



620M005



2-OH-P-DP



DP-6

The metabolism of 5-hydroxytepraloxydim (5-OH-DP), a major metabolite of tepraloxydim in plants, was investigated in goats and hens. For goats given a low dose (9.4 ppm) 56% of the dose was eliminated in urine, 34% in faeces and cage wash, 0.09% in milk and 2.2% was recovered in tissues. Highest residues in tissues were in kidneys and liver. Results from the high dose animals (270 ppm) were qualitatively identical. Radioactivity in liver, kidney and milk from the low dose animal was characterised. Parent compound was the major residue in all cases, comprising 13-36% of TRR. For hens given the low lose (10 ppm) the predominant residue in eggs, liver, muscle, fat and skin was the parent compound (5-hydroxy tepraloxydim), comprising 13-74% TRR.

Analytical methods

Analytical methods to determine tepraloxydim and metabolites converted to 3-(tetrahydro-pyran-4-yl)-glutaric acid (GP) and 3-hydroxy-3-(tetrahydro-pyran-4-yl)-glutaric acid (OH-GP) in plant commodities and animal tissues and milk were provided.

Residues in plant matrices are extracted with methanol. Impurities in the crude extract are precipitated by addition of calcium hydroxide, then the remaining solution is treated with hydrogen peroxide/triethylamine to oxidise residues to the diacids GP and OH-GP. Following NH2-column cleanup residues are esterified with acidified methanol, then further cleaned up by solvent partitioning, silica gel and C-18 column chromatography. Residues are quantified by GC-MS as the methyl esters DMP and OH-DMP of the corresponding diacids, GP and OH-GP.

The method for animal commodities is similar to the plant method. Milk and cream samples are extracted with a mixture of acetonitrile and hexane, while other samples are extracted with aqueous methanol. Following the oxidation step residues are purified by C18 and then ion exchange chromatography, then esterified with acidified methanol. Extracts are purified by C18 column chromatography and ion exchange chromatography before quantification by GC-MS.

The methods have limits of quantitation of 0.05 mg/kg for each of the diacid methyl esters from plants and animal commodities except milk, where each compound has an LOQ of 0.01 mg/kg. The combined LOQ for the method is therefore 0.02 mg/kg for milk and 0.1 mg/kg for all other commodities.

Storage stability

Storage stability data for canola and soybean commodities were provided and indicated that residues do not degrade significantly when stored frozen for at least 24 months at <-18°C. Samples collected in the residues trials were stored frozen for less than 24 months prior to

analysis therefore it is concluded that the results obtained in the trials are a true reflection of the residues present at the time of sampling.
Storage stability tests for animal commodities were performed in the metabolism studies. No significant change in metabolite profile occurred in extracts of cow tissues and milk, poultry egg, liver and excreta after storage under frozen conditions for more than 18 months. It is concluded that residues in animal commodities are stable under frozen storage conditions for at least 18 months.

Residue definition
Tepraloxydim is metabolised to a number of metabolites present in varying quantities in plant and animal commodities. Analytical methods provided are capable of determining residues as two common moieties. It is appropriate to set the following residue definition for tepraloxydim in both plant and animal commodities:
Tepraloxydim: Sum of tepraloxydim and metabolites oxidised to 3-(tetrahydro-pyran-4-yl)-glutaric acid and 3-hydroxy-3-(tetrahydro-pyran-4-yl)-glutaric acid, expressed as tepraloxydim.

Residue trials
A total of 40 residue trials conducted throughout Australia were provided for chickpeas, field peas, lupins and canola. The trials involved a single application of a 100 g/L EC formulation at a rate of 60 g ai/ha (300 mL product/ha) (1× rate). Although a 100 g/L EC formulation was used in the trials it is noted that label directions state the product must be applied as a dilute spray in a minimum spray volume of 50 L/ha. The trials are considered to adequately reflect the proposed use of Aramo Herbicide containing 200 g/L tepraloxydim.
The residues data provided for lupins, chickpeas and field peas support a group MRL for VD 0070 Pulses of *0.1 mg/kg. Only a single result out of 40 trials at the proposed label rate of 60 g ai/ha exceeded 0.1 mg/kg, and in this sample one of the components of the residue was below the limit of quantitation of 0.05 mg/kg. Residues in pulse grains are therefore not expected to exceed 0.1 mg/kg when the product is used as proposed.
Residues in forage of lupins, chickpeas and field peas ranged from 0.508 to 2.008 mg/kg (dry weight) in 40 trials at the proposed maximum label rate of 60 g ai/ha (PHI *ca.* 4 weeks). Residues in straw were <0.1 mg/kg in all but one sample where residues were only slightly above the LOQ. The data support an MRL for AL 0157 Legume animal feeds of 3 mg/kg. This commodity description covers residues in lupin, chickpea and field pea forage, straw and fodder.
ARAMO HERBICIDE is also proposed for use on faba beans and lentils. No data were provided for these crops, however the use may be extrapolated from the data provided for chickpeas, lupins and field peas.[1] The use of *ARAMO HERBICIDE* on faba beans and lentils would be covered by the Pulse MRL (Table 1, *MRL Standard*) and the Legume animal feeds MRL (Table 4, *MRL Standard*).
Residues in canola grain were below the LOQ in all trials. The data support an MRL at the LOQ of *0.1 mg/kg for SO 0495 Rape seed (canola) with a withholding period of "Not required when used as directed" when applications are made before commencement of stem elongation. Residues in canola forage ranged from 0.500 to 1.920 mg/kg (dry weight) (PHI 4 weeks), while residues in straw were <0.1 mg/kg in all but 1 sample, which contained residues slightly above the LOQ. The data support an MRL of 3 mg/kg (dry weight) for canola forage and fodder (WHP 4 weeks).

The product is also proposed for use on subclover and vetch. The use on these crops can be extrapolated from the data provided for chickpeas, field peas and lupins, and residues would

[1] See NRA Information Sheet, *Residues and minor* crops, January 2000, for crop extrapolations. Also located on APVMA website at http://www.apvma.gov.au/minor_use/permits_factsheets.shtml

be covered by the Legume animal feeds MRL of 3 mg/kg. The following grazing restraint is recommended in relation to the use on vetch and subclover crops:
DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

Animal commodity MRLs

Pulse and canola grains, forage and fodder may be consumed by livestock. The maximum anticipated livestock exposure is estimated at 3 ppm for mammalian animals and 0.1 ppm for poultry.

In an animal transfer study, cattle were dosed for 28 consecutive days at either 6.3, 19 or 63 ppm in the feed. At the 6.3 ppm level residues in all tissues and milk were below quantifiable levels (<0.02 mg/kg in milk and <0.1 mg/kg in tissues). At the 19 ppm feed level residues were below quantifiable levels in all tissues except muscle, which contained residues of 0.15 mg/kg. At the highest feeding level (63 ppm) quantifiable residues were detected in milk and all tissues of animals slaughtered at the end of the dosing period, except fat. Highest residues were present in kidney (0.39 mg/kg). After only 2 days depuration residues in all tissues and milk had fallen below quantifiable levels. Residues did not preferentially partition into cream. At the anticipated maximum exposure level of 3 ppm in the feed, residues of tepraloxydim in cattle tissues and milk are expected to be below the limit of quantitation, based on the results from the 6.3 ppm feed level in the cattle feeding study. MRLs set at the limit of quantitation are therefore appropriate for mammalian commodities.

Hens were dosed for 28 consecutive days at 5, 15 or 50 ppm in the feed in a poultry feeding study. Residues were detected in eggs, muscle, liver and fat at all dose levels, with highest residues occurring in liver. At the 5 ppm dose level residues in eggs, muscle, liver and fat were 0.14, 0.16, 0.81 and 0.17 mg/kg, respectively. Depuration animals were included for the 50 ppm dose group. Residues in eggs, muscle, liver and fat were 1.07, 0.91, 3.36 and 0.54 mg/kg after the dosing period. Residues in muscle and fat declined to <LOQ after 2 days depuration, while residues in eggs and liver had declined to 0.55 and 0.53 mg/kg respectively. Residues in all tissues and eggs were below quantifiable levels after 7 days depuration.

The estimated maximum dietary exposure of poultry to tepraloxydim residues is 0.1 ppm, 50 times lower than the lowest feeding level (5 ppm) in the hen feeding study. By scaling the 5 ppm results, it is estimated that residues in eggs, muscle (fat) and liver would be below quantifiable levels. It is therefore appropriate to set MRLs for poultry commodities at the limit of quantitation (*0.1 mg/kg) for each of these commodities.

The following animal MRLs are recommended:

Table 1

MO 0105	Edible offal (mammalian)	*0.1 mg/kg
MM 0095	Meat (mammalian)	*0.1 mg/kg
ML 0106	Milks	*0.02 mg/kg
PM 0110	Poultry meat	*0.1 mg/kg
PO 0111	Poultry, Edible offal of	*0.1 mg/kg
PE 0112	Eggs	*0.1 mg/kg

Spray drift

The product label states that the product may be applied only by ground rig equipment. Application by aircraft is not permitted. A conservative estimate of residues that could occur in pasture from spray drift, and the resultant residues that could occur in animal commodities consuming the contaminated pasture, is given below.

If 10% of the label rate (60 g ai/ha) to 1 ha drifts uniformly onto the adjacent 1 ha area the amount of chemical deposited would be 6 g ai/ha. The level of residues in pasture containing 1500 kg DM/ha would therefore be 4 mg/kg. Animals consuming contaminated pasture containing residues at 4 ppm would not be expected to develop finite residues in tissues or milk, based on results obtained in the cow transfer study provided. Even at much higher feeding levels, residues are not expected to occur in animal commodities.

The above calculation is considered to be very conservative because it overestimates the amount of chemical that would drift onto adjacent properties using ground rig equipment. However, it clearly demonstrates that animals exposed to residues in pasture resulting from spray drift are unlikely to develop finite residues in tissues or milk.

Estimated dietary intakes

The chronic dietary exposure to tepraloxydim is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and dietary intake data from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organisation, 1997].

The NEDI for tepraloxydim is equivalent to less than 1% of the ADI. It is concluded that the chronic dietary exposure is acceptably low.

The acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR using 97.5th percentile food consumption data from the 1995 National Nutrition Survey of Australia. NESTIs for relevant commodities were <1% of the acute reference dose (ARfD) for children aged 2-6 years and the general population aged 2 years and above. It is concluded that the acute dietary exposure is acceptably low.

Bioaccumulation potential

The log $P_{o/w}$ for tepraloxydim is 1.5 indicating the chemical is unlikely to accumulate in fat and tissues.

Animal transfer studies in cattle and poultry indicate that residues do not accumulate in fat or tissues. Even at exaggerated dose levels residues decline rapidly after cessation of feeding. For cows dosed at 63 ppm (20 times expected feeding level) residues in tissues and milk had declined to <LOQ after only 2 days depuration. Residues did not preferentially partition into cream.

It is concluded that tepraloxydim has low potential for bioaccumulation in animals.

Recommendations

MRL changes

The following changes will be made to the *MRL Standard*:

Table 1

Compound	Food		MRL (mg/kg)
ADD			
Tepraloxydim	MO 0105	Edible offal (mammalian)	*0.1
	PE 0112	Eggs	*0.1
	MM 0095	Meat (mammalian)	*0.1
	ML 0106	Milks	*0.02
	PM 0110	Poultry meat	*0.1
	PO 0111	Poultry, Edible offal of	*0.1
	VD 0070	Pulses	*0.1
	SO 0495	Rape seed (canola)	*0.1

The MRL recommendations indicated above will be conveyed to Food Standards Australia New Zealand (FSANZ) for consideration for incorporation into Standard 1.4.2 of the Food Standards Code and consequent adoption into the State/Territory food legislation.

Table 3

Compound		
ADD:	Tepraloxydim	Sum of tepraloxydim and metabolites oxidised to 3-(tetrahydro-pyran-4-yl)-glutaric acid and 3-hydroxy-3-(tetrahydro-pyran-4-yl)-glutaric acid, expressed as tepraloxydim

Table 4

Compound	Food		MRL (mg/kg)
ADD Tepraloxydim	AL 0157	Legume animal feeds	3
		Canola forage and fodder	3

Withholding periods
The following withholding periods are required in conjunction with the above MRLs:

Chickpeas, faba beans, field peas, lentils, lupins
Harvest: DO NOT HARVEST FOR 12 WEEKS AFTER APPLICATION
Grazing: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

Canola
Harvest: NOT REQUIRED WHEN USED AS DIRECTED
Grazing: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

Subclover, vetch
DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

ASSESSMENT OF OVERSEAS TRADE ASPECTS OF RESIDUES IN FOOD

Commodities exported and main destinations

Commodities relevant to this application that may be exported include faba beans, lentils, chickpeas, field peas, lupins, canola grain and animal commodities.

Export statistics for 2001/2002 (ABARE)

Commodity	Importing country	Total exported (kt)	% of total exports
Chickpeas	India	86.6	40.7%
	Pakistan	55.1	25.9%
	Bangladesh	44.4	20.9%
	Sri Lanka	6.3	2.9%
	United Kingdom	6.0	2.8%
	United Arab Emirates	5.7	2.7%
	ALL COUNTRIES	213.0	(value $167 m)
Field peas	India	265.7	57.9%
	Malaysia	24.2	5.3%
	Pakistan	22.7	4.9%
	Sri Lanka	22.2	4.8%
	Fiji	7.0	1.5%
	Belgium-Luxembourg	6.0	1.3%
	Tanzania	5.2	1.1%
	Mauritius	4.9	1.1%
	ALL COUNTRIES	459.1	(value $157 m)[1]
Faba beans	Egypt	159.7	67.1%
	Saudi Arabia	29.8	12.5%
	United Arab Emirates	18.0	7.5%
	Indonesia	7.9	3.3%
	Yemen	3.8	1.6%
	Italy	3.6	1.5%
	ALL COUNTRIES	237.9	
Lentils	ALL COUNTRIES (no breakdown available)	294.0	
Lupins	ALL COUNTRIES (no breakdown available)	660.2	(value $131 m)
Canola	Bangladesh	151.8	
	China	335.8	
	Japan	395.4	
	Pakistan	306.7	
	ALL COUNTRIES	1303	

1 Includes cowpeas

The value of Australian exports of total oilseeds in 2001-2002 was $740 m. Canola seed represents approximately 68% by weight of total oilseed exports.[2]. During the same period, Australia also exported *ca*. 31 kt of canola oil (total value of oilseed oil export was $53 m, canola oil represents *ca*. 63% of oil exports by weight). The major destinations for Australian canola oil are China, Japan and NZ. Canola seed meal was a very minor export commodity in 2001-2002.

Australia's livestock export market is valued at more than $4 b. Major destinations of Australian livestock are the USA and Japan, with each market worth approximately $1.7 b in 2001.

Overseas MRLs

The registrant has advised that the following MRLs are established for tepraloxydim in Japan and the UK. Tolerances are also established in the USA[3]:

Country	Commodity	MRL, mg/kg

[2] Source: ABARE Commodity Statistics 2002.

[3] Source: CFR website: http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html

Japan	Beans (dry) except soybean (kidney bean, adzuki bean)	0.2
United Kingdom	Dry peas, pulses	0.5
	Rape	1.0
USA	Cattle, goat, hog, horse, sheep and poultry fat	0.15
	Cattle, goat, hog, horse and sheep kidney	0.50
	Cattle, goat, hog, horse, sheep and poultry meat	0.20
	Cattle, goat, hog, horse, sheep and poultry meat by-products, except kidney	0.20
	Poultry liver	1.00
	Poultry meat by-products, except liver	0.20
	Egg	0.20
	Milk	0.10
	Canola seed	0.50

CODEX Alimentarius Commission MRL

Tepraloxydim has not been considered by Codex and no Codex MRLs (CXLs) have been established.

Potential risk to Australian export trade

The residues data provided in support of this application suggest that residues of tepraloxydim above quantifiable levels are unlikely to occur in treated pulse or canola grains when the product is used as proposed. Animals may consume treated crop waste however based on available residues trial and animal transfer data it is unlikely that quantifiable residues would occur in animal tissues, milk or eggs as a result of the proposed uses.

On the basis that residues are unlikely to occur in crop or animal commodities the risk to trade is considered to be negligible.

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

NOHSC has conducted a risk assessment on *ARAMO HERBICIDE* containing tepraloxydim at 200g/L as an emulsifiable concentrate to be used for the control of grass weeds in canola, chickpeas, field peas, lupins, faba beans, lentils, subclover and vetch. *ARAMO HERBICIDE* can be safely used by workers when handled in accordance with the control measures indicated in this assessment.

Tepraloxydim is not on the NOHSC *List of Designated Hazardous Substances*, and cannot be classified as hazardous based on the data provided. *ARAMO HERBICIDE* is classified as hazardous based on the non-active ingredients in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

The following risk phrases apply for *ARAMO HERBICIDE*:

R36 Irritating to eyes
R38 Irritating to skin
R65 Harmful: may cause lung damage if swallowed

Tepraloxydim is a white odourless powder and is manufactured overseas. It has low oral dermal and inhalation toxicity in rats. Tepraloxydim is not a skin irritant but is a slight eye irritant in rabbits. It is not a skin sensitiser in guinea pigs.

ARAMO HERBICIDE has low oral, dermal and inhalation toxicity, is a moderate skin and eye irritant, and is not a skin sensitiser in guinea pigs.

Formulation, packaging, transport, storage and retailing
ARAMO HERBICIDE will be formulated in Australia from the imported tepraloxydim and will be packed in 1 and 10 L fluorinated packs.

Formulators, and packers will handle the active constituent and the product. Transport workers, storemen and retail workers will handle the packaged product and may be contaminated if packaging was breached.

Use and exposure
ARAMO HERBICIDE will be applied by ground application equipment only. The maximum application rate is 300 mL/ha in 100 L of water/ha. When spraying dense populations, a rate of 150 L/ha is used.

The main routes of exposure are dermal, and ocular. Mixer/loaders, ground applicators, clean-up personnel and re-entry workers may be exposed to product during end use.

There are no available worker exposure data on *ARAMO HERBICIDE*. NOHSC used the UK Predictive Operator Exposure Model (POEM) and the Pesticide Handlers Exposure Database (PHED) to estimate worker exposure to *ARAMO HERBICIDE*.

Based on the toxicological assessment and the above estimates from POEM and PHED, the use of protective clothing, gloves, and face shield or goggles are required while preparing the spray, and clothing and gloves during spraying. The PPE are necessary to protect workers from acute and repeated exposure.

Entry into treated areas
Workers may be exposed to the product during re-entry activities such as irrigation, crop checking, thinning, weeding or harvesting.

Based on generic foliar residue data, NOHSC recommends a restricted entry period until the spray has dried. When prior entry is necessary, cotton overalls buttoned to the neck and wrist and chemical resistant gloves should be worn to reduce exposure.

Recommendations for safe use
Workers handling the product should follow the instructions and Safety Directions on the product label. Safety Directions include the use of cotton overalls buttoned to the neck and wrist, elbow-length nitrile gloves and face shield or goggles when preparing the spray and use of cotton overalls buttoned to the neck and wrist, and elbow-length PVC or nitrile gloves when using the prepared spray.

The PPE recommended should meet the relevant *Standards-Australia*.

Re-entry statement
"Do not allow entry into treated areas until the spray has dried. If prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and chemical resistant gloves. Clothing must be laundered after each day's use."

Conclusion
NOHSC supports the registration of tepraloxydim at 200 g/L in *ARAMO HERBICIDE*, as an emulsifiable concentrate, for the control of grass weeds in canola, chickpeas, field peas, lupins, faba beans, lentils, subclover and vetch.

ARAMO HERBICIDE can be safely used if handled in accordance with the instructions on the product label or MSDS.

ENVIRONMENTAL ASSESSMENT

Introduction

BASF Australia Ltd has applied for registration of the new end use product *ARAMO HERBICIDE* which contains the new active constituent tepraloxydim at 200g//L. Tepraloxydim is a systemic cyclohexonedione herbicide that inhibits acetyl coA carboxylase and is classified as a Group A herbicide for resistance management purposes.

Environmental Exposure

ARAMO HERBICIDE is a Group A herbicide (acetyl coA carboxylase inhibitor) for weed resistance management and is to be applied as a foliar spray at an application rate of 175-300 mL of EUP per ha, equivalent to 35-60 g a.i./ha. The lower doses will provide effective control if applied under ideal conditions to susceptible grass weeds that are smaller, actively growing and free from temperature or water stress. The weeds to be controlled (early post-emergent) are annual ryegrass, barley grass, brome grass, paradoxa grass, wild oats, volunteer barley, volunteer oats, volunteer triticale and volunteer wheat in canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch.

The label advises to always apply with the non-ionic surfactant Hasten (at 1%) or similar adjuvant at the label rate and not to apply more than once to any one crop. *ARAMO HERBICIDE* is to be applied by ground application only with a volume mean diameter (VMD) of spray droplets of 200-300 µm (fine to medium droplets) in a minimum of 50 L water per ha. A spray volume of 150 L/ha should be used for dense populations.

Environmental Chemistry and Fate

Abiotic transformation

Tepraloxydim was stable to hydrolysis at pH 7-8.8, but degraded at acidic pH 4 with a half-life of 6.6 d at 22°C with the oxazole DP-2 and DP-8 as the major degradates. The compound is also expected to be stable at pH > 8.8. Photodegradation in water was relatively rapid with half-lives of 0.72, 1.5 and 1.6 d at pH 5, 7 and 9, respectively. Major degradates were the imine DP-1, the oxazole DP-2, DP-6 and the glutaric acid GP. Computer modelling estimated an aqueous photodegradation half-life of 11 d in June in the northern hemisphere at pH 7 for parent tepraloxydim, and DT50 values of 13 and 6.5 for the degradates DP-1 and DP-2, respectively. In soil, photolysis was also relatively rapid with a half-life of 1.1 d for parent and 31, 12 and 54 d for the major degradates DP-1, GP and FP, respectively. In a natural water of pH 8.0, the major degradates DP-1, DP-2 and DP-6 photolysed with DT50 values of 14, 6 and 7 d, respectively, under continuous light.

Biotic transformation

The aerobic soil biodegradation of tepraloxydim was rapid with half-lives of 4.6-10.1 d and a maximum of 64% of the originally applied radioactivity mineralised to $^{14}CO_2$ after 61 d in six soils. The major metabolites of DP-1, DP-2 and DP-4 were similar to those found in abiotic degradation pathways. In a sterile aerobic soil, the half-life was estimated at 167 d. When incubated in an anaerobic soil, the DT50 and DT90 values for both isomers of tepraloxydim were 41 and 135 d, respectively, with 43% $^{14}CO_2$ at 120 DAT and DP-2 as the major metabolite.

In two natural pond water/sediment systems, tepraloxydim biodegraded with DT50 and DT90 values of 49-171 and ≥162 d, respectively, in the whole system and 41-129 and ≥136 d in the aerobic surface water only. Parent compound and most of the metabolites (DP-1 was the only major one) were found mainly in the water phase with only 18-31% found in the sediment at 100 DAT. Tepraloxydim was poorly biodegradable in a standard OECD ready biodegradability test.

Mobility
The adsorption/desorption studies on nine soils indicated high to very high mobility in soil for parent tepraloxydim and generally high mobility for the metabolites DP-1 and DP-2 in six soils, with some exceptions. Before ageing, 70% of the originally applied tepraloxydim leached through 25 cm of a loamy sand soil whereas after aerobic ageing for 30 d, only 4-5%was found in the leachate and 42-44% in the top 5 cm of soil.

While a lysimeter study found that the majority of applied radioactivity was retained in the soil after the collection of 343-398 L of leachate in 17 months, parent compound was still detectable (but not quantifiable) 335 DAT in both the leachate and top 10 cm of soil, despite the relatively short laboratory aerobic soil metabolism half-life of 4.6-10.1 d. The mean amount of residues in the leachates during the whole study was 0.35-1.1% of the originally applied radioactivity while a maximum of 0.18% was concentrated in canola (straw) grown in the lysimeters.
In other lysimeters containing the same loamy sand soil, a maximum of 0.99% of the originally applied radioactivity (containing detectable but not quantifiable amounts of parent tepraloxydim and various metabolites) was in the leachates. At 403 DAT, parent and metabolites DP-1 and DP-2 were found only in the top 10 cm of soil but by 747-759 DAT, only unidentifiable (most likely bound) residues were found in the top 30 cm. Residues in crops were <1.2%.
Tepraloxydim volatilised from a bean plant (about 8%) and from a loamy sand soil (about 4%) when applied at 100 g a.i./ha and subjected to a light wind for 24 h.

Field dissipation
Bare soils treated twice at 128-171 g a.i./ha at three US sites showed dissipation of tepraloxydim with DT50 values of <1-9 d. The DT90 values were reliable only for one site (8 d) but 30 d after the last treatment at another site parent compound was nondetectable. The metabolites DP-1 and DP-2 dissipated with DT50 values of 17-75 and 20-210 d, respectively. The metabolite GP was only found at one site with DT50 and DT90 values of <1 and <4 d, respectively, with no detections of any residues below the 5 cm soil layer.
Dissipation was somewhat slower from three bare soils in Canada treated once at 169-170 g a.i./ha with DT50 and DT90 values of 3-12 and 20-76 d, although the longer values must be treated with caution. No residues of parent or metabolites were detected below 5 cm soil depth at any sampling time and no parent was found after 30 DAT in the top 5 cm. DT50 times for DP-1 and DP-2 were quite variable at <1 to <60 d and 198-235 d, respectively.

Accumulation
The octanol-water partition coefficient (log K_{OW}) for tepraloxydim at pH 6.9 and 8.9 were low at 0.20 and -1.15, indicating bioaccumulation in aquatic organisms is not likely to be significant (no study provided). This is also true for the metabolites DP-1, DP-2, DP-6 and GP with log K_{OW} values of <1.8 for environmentally relevant pHs.

Environmental Toxicology
Birds
Tepraloxydim was practically nontoxic to adult bobwhite quail in a single oral dose test with the LD50 > 2,000 mg a.i./kg bw, and to quail chicks and mallard ducklings in 5-d dietary tests with LC50 values of >5,869 and >5,914 mg a.i./kg food, respectively. Young adult mallards fed tepraloxydim-contaminated food for 22 weeks experienced significant adverse effects on reproductive parameters giving NOEC and LOEC values of 90 and 350 mg a.i./kg food, respectively, with a MATC of 177 mg a.i./kg food. A summary indicated a NOEC of 1,000 mg a.i./kg food was found in a bobwhite quail reproduction study, but this was not submitted and therefore not assessed.

Fish
Technical grade tepraloxydim was practically nontoxic to rainbow trout fingerlings and carp with a 96-h LC50 > 97 mg a.i./L, while formulated material (with no adjuvant) was toxic to trout with a 96-h LC50 between 2.97 and 6.53 mg a.i./L. The technical grade was harmful to bluegill sunfish with a 96-h LC50 of 77.9 (67.2, 90.4) mg a.i./L but the imine metabolite DP-1 was practically nontoxic to trout with a 96-h LC50 of >96.2 mg/L. In a chronic 28-d study of juvenile trout, technical tepraloxydim was very slightly toxic giving NOEC and LOEC values of 9.9 and 48.8 mg a.i./L, respectively, with a MATC of 22.0 mg a.i./L.

Aquatic invertebrates
Similar to fish, technical grade tepraloxydim and the imine metabolite DP-1 were practically nontoxic to daphnids with 48-h EC50s of >100 mg a.i./L, while EC formulated material was toxic to daphnids with a 48-h EC50 of 5.6 (5.1, 6.2) mg a.i./L. When daphnids were chronically exposed to technical tepraloxydim, the 21-d NOEC and LOEC values were 49.8 and 98.2 mg a.i./L, respectively, with a MATC of 69.9 mg a.i./L, which is considered very slightly toxic.

Aquatic plants
Formulated tepraloxydim was more toxic to the green alga *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) with a 72-h E_bC50 of 5.1 (4.6, 5.6) mg a.i./L compared to technical grade's 72-h E_bC50 of 76 (66, 89) mg a.i./L. Technical grade also had little effect on the blue-green alga *Anabaena flos-aqua* with a 120-h E_bC50 of 110 (72, 143) mg a.i./L while the imine metabolite DP-1 was similarly nontoxic to green algae (72-h E_rC50 and E_bC50 > 100 mg/L).
As *Lemna* spp. are monocotyledonous and tepraloxydim is targetted at these types of plants, the toxicity to *L. gibba* of both the TGAC (14-d NOEC and LOEC of 1.1 and 2.2 mg a.i./L, respectively) and formulated material (7-d NOEC and LOEC of 0.29 and 0.57 mg a.i./L, respectively) is suprisingly low. This also contrasts with the lower toxicity of the TGAC compared to the formulated material, as evident in the fish, aquatic invertebrate and algal studies. Nevertheless, duckweed was the most sensitive aquatic plant to tepraloxydim.

Terrestrial invertebrates
Technical grade tepraloxydim was not toxic to earthworms with a 14-d LC50 of >1,000 mg a.i./kg soil dw but the EC-formulated material caused 42% mortality at 267 mg a.i./kg soil dw. Despite a variable dose response, honeybees were relatively insensitive to oral and contact routes of exposure to technical material with 48-h LC/LD50s of >200 µg a.i./bee. According to IOBC criteria, the 65% total adverse effect on parasitic wasps exposed to 98.1 g a.i./ha plus adjuvant on glass plates was slightly harmful while the 15% effect when this species was exposed to treated wheat seedlings was harmless. Treatment with 100 g a.i./ha of formulated material with adjuvant was harmless to rove beetles after 80 d and slightly harmful to green lacewings after 91 d. However, 100% overall adverse effect was observed when predatory mites were exposed to bean leaves treated with formulated tepraloxydim at 98.1 g a.i./ha with adjuvant.

Soil microorganism processes
Formulated tepraloxydim at 0.667 mg a.i./kg soil dw (equivalent to 435 g a.i./ha mixed in the top 5 cm of soil) had a negligible effect on soil respiration, ammonification and nitrification processes after 28 d. Neither parent tepraloxydim nor the DP-1 metabolite caused any inhibitory effects on growth of the bacterium *Pseudomonas putida* over 16-17 h at 1,000 mg/L.

Terrestrial Plants
A tier 1 seedling emergence study found the monocots ryegrass, corn and oats were severely affected by formulated tepraloxydim at 140 g a.i./ha plus adjuvant. Onion seedlings were

initially affected but recovered by 21 DAT to be equivalent to controls and only tomatoes out of six dicots tested showed any adverse effect (reduced dry weight). When the ryegrass, corn and oat were further tested (tier 2), ryegrass was the most sensitive species with NOEC and LOEC values of 0.56 and 1.1 g a.i./ha, respectively, based on phytotoxicity ratings of slight stunting to plant death.
The tier 1 vegetative vigour test found ryegrass, corn and oat seedlings suffered 100% mortality by 7 DAT with 140 g a.i./ha plus adjuvant. Onion (a monocot) was not adversely affected but cabbages had a 23% reduced dry weight compared to controls. Further testing showed corn seedlings were the most sensitive with NOEC and LOEC values of 1.1 and 2.2 g a.i./ha, respectively, based on phytotoxicity, plant height and dry weight.

Environmental Hazard

Estimated Environmental Concentrations

The maximum single application rate of *ARAMO HERBICIDE* is 60 g a.i./ha. Given a direct application to bare soil at the maximum rate, incorporation into the top 10 cm (although tepraloxydim is highly mobile in soils, its relatively rapid aerobic soil half-life and aged residue leaching study indicated most residues would be found in the top 10 cm of treated soil) and a soil bulk density of 1,300 kg/m^3, the estimated environmental concentration (EEC) of tepraloxydim in soil would be 0.046 mg a.i./kg soil. Given that *ARAMO HERBICIDE* should only be applied once to any crop and the aerobic soil metabolism half-life is relatively fast (4.6-10.1 d), no accumulation is expected provided the same plot of land is not cropped more than once per year with a crop to be treated.
In a worst-case scenario of a direct overspray of a 15 cm deep body of water with the maximum single application rate of 60 g a.i./ha, the EEC would be 0.04 mg a.i./L.

Hazard to Terrestrial Organisms

The proposed use pattern of *ARAMO HERBICIDE* on canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch will result in exposure of nontarget organisms. Due to the low maximum application rate of 60 g a.i./ha and the relatively low toxicity of tepraloxydim and its major metabolites to these organisms, the acute and chronic hazards from a single application to birds, earthworms, honeybees, parasitic wasps, rove beetles, green lacewings and soil microorganism processes are expected to be low.

However, the proposed use of *ARAMO HERBICIDE* is expected to adversely affect predatory mites and most terrestrial monocotyledonous plants. Provided recruitment from neighbouring untreated areas is possible, effects on mites are expected to be temporary as tepraloxydim residues are not expected to be persistent. A statement on the label may be relevant indicating that *ARAMO HERBICIDE* is harmful to mites and is not suitable for use in IPM programs where predatory mites are present, although the company indicates that IPM is not practiced in the crops for which *ARAMO HERBICIDE* is proposed. Given that tepraloxydim is not persistent in soil, a 5 m buffer zone upwind of sensitive native grasslands will reduce the hazard to terrestrial monocotyledons to an acceptable level.

Hazard to Aquatic Organisms

A worst case direct overspray of a 15 cm deep body of water with *ARAMO HERBICIDE* at the maximum application rate of 60 g a.i./ha is not expected to be an acute or chronic hazard to fish, aquatic invertebrates, algae or duckweed.

EFFICACY AND SAFETY ASSESSMENT

Justification and Use Pattern

ARAMO HERBICIDE is a post emergence grass herbicide with plant systemic activity. Tepraloxydim is a member of the cyclohexanedione or 'dim' group of herbicides. *ARAMO HERBICIDE* controls some of the 'fop' resistant grass weed population and as such will be useful in managing resistance.
The label claims are for the control of certain grass weeds including Annual rye grass in canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch in all States.

Evaluation of Efficacy and Crop Safety

1 Adequacy of efficacy data

Trial design *(controls, treatments, replicates*)
Extensive trial work has been conducted, all of it using standard experimental designs. The treatments were applied at typical growth stages of the weeds and crops.

Analysis of trial data, interpretation
Data presentation was excellent. Data analysis and interpretation were appropriate. Conclusions drawn were consistent with the data, particularly as they relate to recommended rates and adjuvant requirements.

Trial validation, location, date
Reputable independent research teams conducted the trials. The trials were located at typical locations for the particular crops right through the cropping belt and established at the standard sowing times for the crop. Site location took into account soil texture, pH, and rainfall.

2 Claims

Efficacy
The efficacy data presented was extensive. The label claims were well supported by the data.

Phytotoxicity
Some transient phytotoxicity was noted on chickpeas and canola. There did not seem to be a strong relationship between phytotoxicity and yield effects, although phytotoxicity tended to be related to slightly lower, although not significantly different yields. All other crops showed no ill effects for the herbicide. Phytotoxicity was also observed with certain mixers which have been excluded from the recommendations.

3 Directions for use

Extensive data was presented in support of the label rates and the inclusion of surfactants. Trial data was presented in support of mixing partner recommendations. The data show that the claimed mixing partners are compatible in terms of efficacy and crop safety.

4 Recommendations

Registration of the product was recommended with respect to efficacy and crop safety. The APVMA has considered the above findings of its advisor and has accepted the recommendations.

LABELLING REQUIREMENTS

Pack Label

CAUTION

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

ARAMO® HERBICIDE

ACTIVE CONSTITUENT: 200 g/L TEPRALOXYDIM

SOLVENT: 719 g/L LIQUID HYDROCARBONS

GROUP	A	HERBICIDE

For the control of certain grass weeds in canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch, as per the DIRECTIONS FOR USE table in the ATTACHED LEAFLET.

IMPORTANT: READ THE ATTACHED LEAFLET BEFORE USE.

BASF
BASF Australia Ltd
ABN 62 008 437 867
Norwest Business Park, 7 Maitland Place
Baulkham Hills NSW 2153

CONTENTS: 1, 10 L

® = Registered trademark of BASF

STORAGE AND DISPOSAL

Store in the closed, original container in a dry, cool, well-ventilated area out of direct sunlight.

Triple or preferably pressure rinse containers before disposal. Add rinsings to spray tank. Do NOT dispose of undiluted chemicals on-site. If recycling, replace cap and return clean containers to recycler or designated collection point.

If not recycling, break, crush, or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should NOT be burnt.

SAFETY DIRECTIONS

Will irritate the eyes and skin. Avoid contact with eyes and skin. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length nitrile gloves and face shield or goggles. When using the prepared spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length PVC or nitrile gloves. After each day's use, wash gloves, face shield or goggles and contaminated clothing.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Telephone 131126 Australia-wide.

MSDS

Additional information is listed in the Material Safety Data Sheet.

CONDITIONS OF SALE

All conditions and warranties rights and remedies implied by law or arising in contract or tort whether due to the negligence of BASF Australia Ltd or otherwise are hereby expressly excluded so far as the same may legally be done provided however that any rights of the Buyer pursuant to non excludable conditions or warranties of the Trade Practices Act 1974 or any relevant legislation of any State are expressly preserved but the liability of BASF Australia Ltd or any intermediate Seller pursuant thereto shall be limited if so permitted by the said legislation to the replacement of the goods sold or the supply of equivalent goods and all liability for indirect or consequential loss or damage of whatsoever nature is expressly excluded. This product must be used or applied strictly in accordance with the instructions appearing hereon. This product is solely sold for use in Australia and must not be exported without the prior written consent of BASF Australia Ltd.

THIS PRODUCT IS NOT CONSIDERED TO BE A DANGEROUS GOOD UNDER THE AUSTRALIAN CODE FOR THE TRANSPORT OF DANGEROUS GOODS BY ROAD AND RAIL.
FOR SPECIALIST ADVICE IN AN **EMERGENCY ONLY** **PHONE 1 800 033 111** TOLL FREE - ALL HOURS - AUSTRALIA WIDE

Batch No:

Date of Manufacture:

Expiry Date:

NRA Approval No: 55220/0603

CAUTION

KEEP OUT OF REACH OF CHILDREN

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ARAMO® HERBICIDE

ACTIVE CONSTITUENT: 200 g/L TEPRALOXYDIM

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GROUP	A	HERBICIDE

For the control of certain grass weeds in canola, chickpeas, faba beans, field peas, lentils, lupins, subclover and vetch, as per the DIRECTIONS FOR USE table.

THIS LEAFLET IS PART OF THE LABEL

BASF
BASF Australia Ltd
ABN 62 008 437 867
Norwest Business Park, 7 Maitland Place
Baulkham Hills NSW 2153

DIRECTIONS FOR USE

RESTRAINTS: Do NOT apply without the addition of an adjuvant.
Do NOT apply to crops or weeds stressed by factors such as root or foliar diseases, water-logging, nutrient deficiencies, or extremes of temperature and moisture.
Do NOT apply if rain is expected within one hour of application.
Do NOT apply ARAMO Herbicide more than once to any one crop.

CROP	WEEDS CONTROLLED	STAGE OF WEED GROWTH	RATE (mL/ha)	*CRITICAL COMMENTS*
Canola, chickpeas, faba beans, field peas, lentils, lupins, subclover, vetch	Annual ryegrass (*Lolium rigidum*)	2 leaf to fully tillered	175 to 300	Always apply with Hasten^{+} or Kwickin^{+} at 1L/100L spray volume, or similar adjuvant at the label rate (See COMPATIBILITY section). The lower doses will provide effective control if applied under ideal conditions to susceptible weeds that are smaller, actively growing and free from temperature or water stress. Do NOT apply after the commencement of stem elongation in canola. Use only in clover and vetch crops grown for seed production. Do NOT graze or cut green forage or hay for stockfeed.
	Barley grass *(Hordeum leporinum)*, brome grass (*Bromus* spp.), paradoxa grass *(Phalaris paradoxa),* wild oats (*Avena* spp.), volunteer barley (*Hordeum vulgare*), volunteer oats (*Avena sativa*), volunteer triticale (*Triticale* sp.), volunteer wheat (*Triticum aestivum*).	2 leaf to fully tillered	175 to 250	

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

WITHHOLDING PERIODS

HARVEST

CANOLA: **NOT REQUIRED WHEN USED AS DIRECTED.**

CHICKPEAS, FABA BEANS, FIELD PEAS, LENTILS, LUPINS: **DO NOT HARVEST FOR 12 WEEKS AFTER APPLICATION.**

GRAZING

CANOLA, CHICKPEAS, FABA BEANS, FIELD PEAS, LENTILS, LUPINS, SUBCLOVER, VETCH: **DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION**

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GENERAL INSTRUCTIONS

RESISTANT WEEDS WARNING

GROUP	A	HERBICIDE

ARAMO Herbicide is a member of the cyclohexanedione group of herbicides. The product has the inhibition of acetyl coA carboxylase mode of action. For weed resistance management, the product is a Group A herbicide. Some naturally-occurring weed biotypes resistant to the product and other Group A herbicides may exist through normal genetic variability in any weed population. The resistant individuals can eventually dominate the weed population if these herbicides are used repeatedly. These resistant weeds will not be controlled by this product or other Group A herbicides.

Since the occurrence of resistant weeds is difficult to detect prior to use, BASF Australia Ltd accepts no liability for any losses that may result from the failure of this product to control resistant weeds.

MIXING

To ensure even mixing, half-fill the spray tank with clean water and add the required amount of product. Add spray additive and agitate thoroughly, then add the remainder of the water. Agitate again before spraying commences.

APPLICATION

Apply ARAMO by ground application only. ARAMO should be applied with calibrated spray equipment producing a median droplet range of 200 to 300 microns VMD. Apply in a minimum of 50 litres of water per hectare. Use 150 L/ha when spraying dense populations.

COMPATIBILITY

ARAMO is compatible with the following grass herbicides: Verdict^{+}, Shogun^{+}, Targa^{+} and Fusion^{+}. ARAMO is also compatible with Lontrel^{+}. ARAMO may also be applied in tank mixtures with any one of the following products: Fastac® Duo, omethoate, Talstar^{+}, deltamethrin, chlorpyrifos. ARAMO may also be mixed with dimethoate but only at the higher rates of ARAMO. The following adjuvants are compatible with ARAMO: Hasten, D-C Trate^{+}, Kwickin, Uptake^{+} and Enhance^{+}. No NOT mix ARAMO with Basagran®.

CROP SAFETY

Do NOT apply after the commencement of stem elongation in canola.

RE-ENTRY PERIOD

Do NOT allow entry into treated areas until the spray has dried. If prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and chemical resistant gloves. Clothing must be laundered after each day's use.

PROTECTION OF CROPS, NATIVE AND OTHER NON-TARGET PLANTS

Do NOT apply under weather conditions or from spraying equipment that may cause spray to drift onto nearby susceptible plants/crops, cropping lands, pastures or non-target plants. Do NOT apply within 5 m upwind of sensitive native grasslands.

PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

Do NOT contaminate streams, rivers or waterways with the chemical or used containers.

STORAGE AND DISPOSAL

Store in the closed, original container in a dry, cool, well-ventilated area out of direct sunlight.

Triple or preferably pressure rinse containers before disposal. Add rinsings to spray tank. Do NOT dispose of undiluted chemicals on-site. If recycling, replace cap and return clean containers to recycler or designated collection point.

If not recycling, break, crush, or puncture and bury empty containers in a local authority landfill. If no landfill is available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should NOT be burnt.

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PHONE 1 800 033 111
TOLL FREE - ALL HOURS - AUSTRALIA WIDE

NRA Approval No.: 55220/0603

GLOSSARY

Active constituent	The substance that is primarily responsible for the effect produced by a chemical product.
Acute	Having rapid onset and of short duration.
Carcinogenicity	The ability to cause cancer.
Chronic	Of long duration.
Codex MRL	Internationally published standard maximum residue limit.
Desorption	Removal of an absorbed material from a surface.
Efficacy	Production of the desired effect.
Formulation	A combination of both active and inactive constituents to form the end use product.
Genotoxicity	The ability to damage genetic material
Hydrophobic	Water repelling
Leaching	Removal of a compound by use of a solvent.
Log P_{ow}	Log to base 10 of octonol water partioning co-efficient.
Metabolism	The conversion of food into energy
Photodegradation	Breakdown of chemicals due to the action of light.
Photolysis	Breakdown of chemicals due to the action of light.
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body.
Toxicology	The study of the nature and effects of poisons.

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Australian Pesticides and Veterinary Medicines Authority 2001, *Ag Labelling Code—Code of Practice for Labelling Agricultural Chemical Products*, APVMA, Canberra. (See footnote below)

Footnote:
Updated versions of these documents are available on the APVMA website http://www.APVMA.gov.au.

APVMA PUBLICATIONS ORDER FORM

To receive a copy of the full technical report for the evaluation of tepraloxydim in the product *ARAMO HERBICIDE*, please fill in this form and send it, along with payment of $30 to:

David Hutchison
Pesticides Division
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
Kingston ACT 2604

Alternatively, fax this form, along with your credit card details, to:
David Hutchison, Pesticides Division at (02) 6272 3218.

Name (Mr, Mrs, Ms, Dr)_____

Position _____

Company/organisation _____

Address _____

Contact phone number (___) _____

I enclose payment by cheque, money order or credit card for $_____

Make cheques payable to 'Australian Pesticides and Veterinary Medicines Authority'.

___ Bankcard ___ Visa ___ Mastercard

Card number _____/_____/_____/_____ Expiry date ...../...../.....

Signature_____ Date _____