



## **ADVICE SUMMARY**

### **APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT**

**Product name:** COBALT ADVANCED INSECTICIDE

**Applicant:** DOW AGROSCIENCES AUSTRALIA LIMITED

**Product number:** 68678

**Application number:** 58890

**Purpose of Application and Description of Use:** Registration of 300 g/L chlorpyrifos and 15.4 g/L lambda-cyhalothrin oil in water emulsion product for control of certain pests in broadacre crops.

**Active Constituent(s):** CHLORPYRIFOS  
LAMBDA-CYHALOTHRIN

#### **Regulatory Decision:**

To grant the application subject to the following conditions:

#### **Standard Conditions of Registration/Approval**

1. Containers must meet AgVet Code Regulation 18
2. Agricultural products must meet Active Constituents Quality Assurance Requirements
3. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

## **Non-Standard Conditions of Registration/Approval**

Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 37 of the NRA / APVMA Gazette dated October 2000 (Chlorpyrifos Final Stage).\*

*\*Explanatory Note: you should be aware that the APVMA will take steps to apply the outcomes of that reconsideration to this registration/approval as it thinks fit.*

## **ADVICE**

### **Australian Government Department of Health And Ageing, Office of Chemical Safety**

Dow Agrosiences Australia Limited has applied to register a new product Cobalt Advanced Insecticide, containing chlorpyrifos at 300.0 g/L and lambda-cyhalothrin at 15.4 g/L. The product is an emulsion oil in water (EW) formulation for control of certain pests in wheat, barley, canola, pulses, lucerne and pastures. The product is intended for professional use by ground boom or aerial application methods.

The data package provided comprised six acute toxicology studies on a product similar to that for which Australian registration is sought.

The acute toxicology studies were conducted in accordance with contemporary test guidelines. The acute toxicology data submitted were considered to be adequate for the assessment of the toxicology profile of, and the establishment of Safety Directions for, the product.

Based on the findings of the toxicological studies evaluated, the product has moderate acute oral toxicity in female rats, low acute dermal and low acute inhalation toxicity in male and female rats. The product is a moderate skin irritant in male rabbits, moderate eye irritant in male and female rabbits and is not a skin sensitiser in female CBA/J mice (local lymph node assay).

Based on the recommendations in this human health risk assessment and on the toxicology profile of Cobalt Insecticide, this consideration was referred by the delegate of the Secretary to the Department of Health for Chemical Scheduling. The Chemical Scheduling Delegate sought advice from the Advisory Committee on Chemical Scheduling (ACCS). It was considered at the ACCS meeting in March 2014. The lambda-cyhalothrin entry in Schedule 6 has been amended to extend exemption clause (b) from 1 to 1.6 per cent. Based on the new entry in the SUSMP, the product Cobalt Advanced Insecticide containing chlorpyrifos at 300.0 g/L and lambda-cyhalothrin at 15.4 g/L is considered a Schedule 6 poison.

The toxicology data and other information on the product provided and considered during this assessment justify the recommendations made and the Safety Directions established.

The APVMA has considered the advice from the Department of Environment and is satisfied that the risk posed by the proposed product is similar to that already accepted for the registered reference products and has been previously considered the risk associated with the nominated reference products acceptable.

## Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
74782	S	Dalal, V	Acute dermal toxicity study of GF-2595 in rats	2011	Toxicology	Acute dermal studies, product	Applicant	
74785	S	Dalal, V	Acute eye irritation study of GF-2595 in rabbits	2011	Toxicology	Acute eye irritation studies, product	Applicant	
74783	S	Krieger, SM & Garlinghouse, CR	GF-2595: Acute liquid aerosol inhalation toxicity study in F344/DuCrI rats	2011	Toxicology	acute inhalation studies, product	Applicant	
74781	S	Dalal, V	Acute oral toxicity study of GF-2595 in rats	2011	Toxicology	Acute oral studies, product	Applicant	
74784	S	Dalal, V	Acute dermal irritation study of GF-2595 in rabbits	2011	Toxicology	Acute skin irritation studies, product	Applicant	
74786	S	Dalal, V	Skin sensitisation study of GF-2595 by local lymph node assay in mice	2011	Toxicology	Acute skin sensitisation studies, product	Applicant	

## Australian Government Department of Environment

The Department of Environment assessed data submitted by Dow Agrosciences in support of the proposed registration.

The APVMA currently has a number of products registered with the single active constituent lambda-cyhalothrin. The application rate of the active and situations on the approved product labels are consistent with those proposed on the product label.

The APVMA currently has a number of products registered with the single active constituent chlorpyrifos. The application rate of the active and situations on the approved product labels are consistent with those proposed on the product label. It

The APVMA has considered the advice from the Department of Environment and is satisfied that the risk posed by the proposed product is similar to that already accepted for the registered reference products and has been previously considered the risk associated with the nominated reference products acceptable.

## Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
74796	S	Rebstock, M.	GF-2595: Acute Toxicity to the Cladoceran, Daphnia magna, Determined Under Static-Renewal Test	2012	Environment toxicology	Aquatic organisms acute	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
			Conditions					
74795	S	Verge, E.	GF-2595-Acute Oral and Contact Toxicity to the Honeybee <i>Apis mellifera</i> L. (Hymenoptera, Apidae) in the Laboratory (Dose Response Test).	2012	Environment toxicology	Non-target invertebrates (terrestrial) bees	Applicant	
74794	S	Anon	Section 6 - Environmental Assessment.	2000	Environment toxicology	Other information	Public	
74797	S	Anon	Review Report for the active substance lambda-cyhalothrin.	2001	Environment toxicology	Other information	Public	

### State/External Efficacy Reviewer

The applicant seeks to register a new product "Cobalt Advanced Insecticide" (300 g/L chlorpyrifos and 15.4 g/L lambda-cyhalothrin) for the control of a range of mite species, aphids and the larvae (grubs) of other common insect pests in a range of crop and pasture situations. Both of these insecticide active ingredients are registered in a wide range of crop/insect pest situations and have been used extensively over many years as standalone products under various trade names.

Label claims for Cobalt Insecticide have been adopted from currently registered labels for Lorsban 500 EC Insecticide (500 g/L chlorpyrifos) and Karate Zeon Insecticide (250 g/L lambda-cyhalothrin). For each insect pest/crop situation claimed, the use rate of Cobalt Advanced Insecticide closely mirrors the use rate of either reference product for that specific pest and situation.

All of the trials submitted in support of the application were undertaken in the field using small plots and with treatments applied by hand held, backpack gas propelled spraying equipment using a range of nozzle types and application volumes in the range of 80 – 100 L/ha. Treatments were replicated four times in all trials and laid out in a Randomised Complete Block design. The host crops ranged from cereals (seven trials), mixed pasture (seven trials) and canola. Not all pests or pest/host combinations included on the proposed label were represented in the trials; however extrapolation between crops/situations was considered reasonable as an indication that the proposed product would be effective in specific situations as claimed on the proposed label.

Most trials had a wide range of Cobalt Advanced Insecticide rates applied, varying depending on the target pest, from 50ml/ha of product to 600 ml/ha. All trials included an untreated control and most had industry standards which included standalone rates of each of the actives in the proposed product (chlorpyrifos and lambda-cyhalothrin).

All trials were appropriately designed, replicated and analyzed.

From the data provided, the APVMA is satisfied that if used according to label directions, the product should be both efficacious and safe to use for the control of redlegged earth mite, lucerne flea, blackheaded cockchafer, pasture webworm, cutworm, aphids and brown pasture loopers in broad acre crops and also these insects together with native budworm, Lucerne leaf roller, sitona weevil, spotted alfalfa aphid and blue green and pea aphid in Lucerne and pastures.

## Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
74813	S	Downard, P	GF-2595 FOR control of pests in broadacre crops - Aerial application Report No.: ARM 102021PD	2010	Efficacy and safety	Efficacy	Applicant	
74812	S	Downard, P	GF-2595 as a post-em treatment for Bryobia and Balaustium mite and other crop establishment pest control Report No.: ARM 102026PD	2010	Efficacy and safety	Efficacy	Applicant	
74811	S	Downard, P	GF-2595 for blackheaded pasture cockchafer ( <i>Aphodius tasmaniae</i> ) control Report No.: ARM 102023PD	2010	Efficacy and safety	Efficacy	Applicant	
74810	S	Downard, P	GF-2595 for pasture webworm ( <i>Hednota</i> sp.) control Report No.: ARM 102011PD	2010	Efficacy and safety	Efficacy	Applicant	
74809	S	Downard, P	GF-2595 AS a post-emergence treatment for <i>Halotydeus destructor</i> , <i>Penthaleus</i> spp. and crop establishment pests Report No.: ARM 102008PD	2010	Efficacy and safety	Efficacy	Applicant	
74798	S	Downard, P	GF-2595 as bare earth treatment for <i>Halotydeus destructor</i> , <i>Penthaleus</i> spp. and other crop establishment pests Report No.: ARM 102003PD	2010	Efficacy and safety	Efficacy	Applicant	
74799	S	Downard, P	GF-2595 as bare earth treatment for <i>Halotydeus destructor</i> , <i>Penthaleus</i> spp. and other crop establishment pests Report No.: ARM 102004PD	2010	Efficacy and safety	Efficacy	Applicant	
74800	S	Downard, P	GF-2595 as bare earth treatment for <i>Halotydeus destructor</i> , <i>Penthaleus</i> spp. and other crop establishment pests Report No.: ARM 102004PD	2010	Efficacy and safety	Efficacy	Applicant	
74801	S	Downard, P	GF-2595 as a post-emergence treatment for <i>Halotydeus destructor</i> , <i>Penthaleus</i> spp. and crop establishment pests Report No.: ARM 102007PD	2010	Efficacy and safety	Efficacy	Applicant	
74802	S	Downard, P	GF-2595 as a post-em treatment for <i>Bryobia</i> and <i>Balaustium</i> mite & other crop establishment pest control Report No.: ARM 102009PD	2010	Efficacy and safety	Efficacy	Applicant	
74803	S	Downard, P	GF-2595 for cutworm ( <i>Agrotis</i> spp.) control in establishing crops Report No.: ARM 102012PD	2010	Efficacy and safety	Efficacy	Applicant	
74804	S	Downard, P	GF-2595 for brown pasture looper ( <i>Ciampa arietaria</i> ) control in establishing crops Report No.: ARM 102013PD	2010	Efficacy and safety	Efficacy	Applicant	
74805	S	Downard, P	GF-2595 for repellency of and/or knockdown of aphids in broadacre crops Report No.: ARM 102015PD	2010	Efficacy and safety	Efficacy	Applicant	
74806	S	Downard, P	GF-2595 for repellency of and/or knockdown of aphids in broadacre crops Report No.: ARM 102014PD	2010	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
74807	S	Downard, P	GF-2595 for control of pests in broadacre crops - Aerial application Report No.: ARM 102020PD	2010	Efficacy and safety	Efficacy	Applicant	
74808	S	Downard, P	GF-2595 as bare earth treatment for Halotydeus destructor, Penthaleus spp. and other crop establishment pests Report No.: ARM 102005PD	2010	Efficacy and safety	Efficacy	Applicant	

\* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application