



REGULATORY REVIEW DECISION FOR DIURON AND ITS ASSOCIATED END-USE PRODUCTS

Pest Control Products Board 2022©

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1.0. Introduction

Following initial authorization on use of pest control products, regulatory authorities all over the world may review the status of authorization routinely or when new information becomes available that a pest control product has safety concerns. The process of review must be based on the existing laws and regulations.

Pursuant to Regulation 11(2b) of the Pest Control Products (Registration) Regulations of 1984 of the Pest Control Products Act (PCPA), the Pest Control Products Board (PCPB) initiated a review of Diuron and Diuron based end use products based on new information that Diuron had specific target organ toxicity (may cause damage to organs through prolonged or repeated exposure) and is a suspected carcinogen. The Pest Control Products Board (PCPB) notified the registrants of the affected products to address the concerns raised.

2.0. Main objectives of the review

- I. Review existing scientific data in view of establishing the weight of evidence if any that supports the safety concerns.
- II. Make recommendations for consideration by the Board.

3.0 Uses of Diuron

3.1. Mode of Action of Diuron

Diuron is a pre-emergence and early post emergence contact herbicide belonging to the substituted urea herbicides. Diuron is a systemic substituted phenylurea, absorbed via roots and acts by strongly inhibiting photosynthesis. It is easily taken up from soil solution by the root system of plants and rapidly translocated into stems and leaves by the transpiration system, moving primarily via the xylem. Diuron primarily functions by inhibiting the Hill reaction in photosynthesis, limiting the production of high-energy compounds such as adenosine triphosphate (ATP) used for various metabolic processes.

3.2. Registered Uses of Diuron in Kenya

In Kenya, there are 11 products containing Diuron registered for control of weeds in sugarcane, pineapples, coffee, cotton, citrus or as biocides (algacides) for use in paint. These are presented in [Appendix III](#) (crop production) and [Appendix IV](#) (Biocides). The products are formulated as a wettable powder (WP), wettable granules (WG), Water Dispersible Granules (WDG), Flowable and suspension concentrate (SC).

3.3. Quantities of Diuron based products imported 2018-2021

A total of 407,768Kgs of Diuron based products were imported over the last 4 years (2018-2021).

Table 1: Quantities of Diuron based products imported 2018-2021

	2018	2019	2020	2021	Total
Quantities imported (Kgs)	87,140	95,740	90,740	134,148	407,768

4.0. Data considered in the review

To evaluate the identified aspects of concern, PCPB considered currently available relevant scientific information, data submitted by the applicants to support approval of the individual products in Kenya, initial information provided by stakeholders, various regulatory decisions made around the world including FAO/WHO Joint Meeting on Pesticide Residues, the European Union, the United States Environmental Protection Agency, Health Canada, Australia Pesticide and Veterinary Medicine Authority.

A summary of the regulatory decisions is presented in [Appendix I](#) while appendix II represents information collected from stakeholders.

5.0 Methodology of the Review

In compliance with the constitution of Kenya on the bill of rights and public participation, the Board wrote a circular to the local agents and the public notifying them of the intended review and called for any information that would assist the reviewers in arriving at the correct decision. The feedback was to be received within 90 days from the date of notification.

This was followed by a call for experts from Government institutions that included the Universities, Toxicological society of Kenya, KALRO, and KePHIS etc. After evaluation of the applications, four external experts were selected to team up with experts from PCPB.

Four active ingredients were reviewed and reports made and later submitted to the board of management. The board recommended that the outcome of the review be subjected to a second round of public participation.

6.0. Outcome of evaluation

6.1. Potential for carcinogenicity to humans:

Based on long term studies, effects were observed on the blood system and urothelial system (in rats hyperplasia and neoplasia in the urothelium was observed and in mice, hyperplasia in bladder epithelium and mammary carcinomas).

The 3,3',4,4'-Tetrachloroazobenzene (TCAB) which is one of the contaminants generated in production of several herbicides including Diuron was found to activate the Aryl Hydrocarbon Receptor (AHR) and causes a range of effects including tumours in experimental systems and therefore classified as probable carcinogenic to humans by IARC.

6.2. Hazard assessment

The Food and Agriculture Organisation (FAO) of the United Nations does not specify maximum levels for 3,3',4,4'-Tetrachloroazobenzene (TCAB) and 3,3',4,4'-tetrachloroazoxybenzene (TCAOB) in the active constituent Diuron.

6.3. Dietary risk assessment

The residue data from supervised residue trials for NISAN 800 WG and DIUREX 80 WP on Pineapples and HEXARON 600 WG on Sugarcane were evaluated. The consumer risk assessment reports for DEACON 600 WDG, KARMEX 80 DF and DORIAN 80 SC were not submitted by the registrants.

Data gaps were identified on metabolites of toxicological concerns, especially due to uncertainties in fate of groundwater contaminants which may pose consumer safety risk. Consumer risk assessment was therefore not conclusive.

6.4. Effects on non-target organisms

Diuron was practically non-toxic or slightly toxic to birds, moderately toxic to most aquatic animals (fish and aquatic invertebrates) but highly toxic to one species of scud. Algae were very sensitive to Diuron. It is slightly toxic to bees.

6.5. Fate and behaviour in soil and water

Diuron is persistent in terrestrial environments. The half-life of Diuron in soil ranges from 30 to 365 days with a typical time of 90 days. The major route of dissipation for Diuron in the environment is microbial degradation in water. Diuron also degrades through photolysis in both water and soil, but at a slower rate.

In contrast to its persistence in laboratory studies of hydrolysis, aqueous and soil photolysis, and aerobic and anaerobic soil metabolism, Diuron degraded relatively quickly in aquatic metabolism laboratory studies, with a half-life of 33 days under aerobic conditions and of 5 days under anaerobic conditions. The major metabolism degradation under aerobic conditions was N'-(3-chlorophenyl)-N, N-dimethylurea (MCPDMU) which reached 25% of the applied dose by the end of the study and was evenly distributed between the soil and aqueous phase. The minor degradates identified were DCPMU and CPMU and were primarily associated with the soil phase. The major degradation under anaerobic conditions was MCPDMU, which was mainly associated with the aqueous phase. The two minor degradates were PDMU and MCPMU.

Diuron has low to moderate potential for mobility in soil; minor residues have been found in groundwater following land applications.

7.0. Incident reports

As of 30th October 2022, there were no incidents relating to the human health or environmental aspects of concern reported.

8.0. Proposed review decision for Diuron

Information related to the aspects of concern indicates that the potential human health and environmental risks are unacceptable under current conditions of use.

Hazard and risk assessment reports were submitted for Diurex 80 WP (Pineapples), Nisan 800 WG (Pineapples), and Hexaron 600 WG (Sugarcane). Registrants of the other Diuron based pest control products did not defend their respective products.

The sources of Diuron technical material used to formulate the three products Diurex 80WP, Hexaron 600 WG and Nisan 800 WG were similar. The products did not have detailed five-batch reports and assessments for purity profiles were based on the information obtained from summary dossiers. The relevant impurities of the Diuron technical materials used to formulate the three products were within the FAO Specification (1980) while Australia (2002) specification for impurities which are fairly current were not provided in products under review. There were data gaps in the latest and detailed five-batch reports for the three products.

The toxicological database submitted and assessed had data gaps for the Technical grade active ingredient and DIUREX 80WP. However taking note of the global regulatory review that established concerns for the Diuron and its associated metabolites and impurities, namely specific target organ toxicity (may cause damage to organs through prolonged or repeated exposure) and suspected carcinogen due to increased incidence of bladder, kidney, uterine and mammary tumours in mice; leading to their withdrawal or approval with restrictions. The risk to the outdoor worker and operator was found to be unacceptable for the representative

products using the Kenya good agricultural practices. Based on this; conclusion on the acceptable use cannot be finalized for representative uses in Kenya.

Residue data for Diurex 80 WP (Pineapples), Nisan 800 WG (Pineapples), and Hexaron 600 WG (Sugarcane) could not support Kenyan GAP. Consumer risk assessment was not conclusive due to a possible risk for groundwater due to uncertainties as regards the fate of certain metabolites.

The data provided for Diurex 80 WP, Nisan 800 WG and Hexaron 600 WG did not demonstrate safety of the products to the environment. However, Diuron is moderately toxic to most aquatic organisms (fish, aquatic invertebrates and algae). Due to its limited mobility (persistence) in soil and its stability in water, Diuron may contaminate surface waters through runoff for a long time after application and consequently, the actual Diuron levels in the runoff could be more concentrated especially in drier areas. Of particular interest is runoff from farms and although there are studies on the fate of Diuron in Kenyan soils, there are no reports providing monitoring data on levels of Diuron and its metabolites/degradates in Kenyan water systems that can be attributed to runoff. Bioavailability of Diuron in aquatic systems is therefore imminent and may pose a risk to aquatic systems in Kenya.

There are other alternative products registered for similar uses on pineapples in Kenya, however there are few post-emergence herbicides registered for similar uses on sugarcane i.e. ; Glyphosate, Glyphosate Isopropyl amine, Paraquat Dichloride and 2,4-D Dimethyl amine. Some of the alternative products such as glyphosate, Paraquat dichloride and glufosinate ammonium are currently subject of discussion in the global arena due to some safety concerns. There is a need to look for other viable options for use by farmers.

9.0. Proposed risk reduction measures

1. Immediate revocation and stoppage of importation of all non-supported Diuron based products for use in Kenya namely, DORIAN 80 SC, KARMEX 80 DF, and DEACON 600 WDG.
2. Immediate termination of any ongoing registration of any Diuron based products for agricultural use in Kenya.
3. Phased withdrawal of Diuron based products for agricultural use by (December, 31st 2024).
4. Immediate restriction on use of Diuron based products to commercial grower users only to mitigate against workers and operators.
5. Environmental monitoring of Diuron in surface water bodies in close proximity to commercial farms.
6. Paints and other industrial products containing Diuron are subjected to labelling to mitigate against occupational exposure to painters and paint handlers.
7. Advise registration of low risk products for use in control of weeds in sugarcane and pineapple plantations/fields.
8. Importers to submit importation and sale data during the phase out period.

10. 0. References

The list of pest control products <https://www.pcpb.go.ke/on-crops/>

https://www.pcpb.go.ke/wpcontent/uploads/2020/10/guidance_on_dossier_evaluation_for_the_registration.pdf

<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4873> (accessed 12th May 2022)

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-special-review-decision/2022/chlorothalonil/document.html> (Accessed 12th May 2022)

https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/fs_PC-081901_1-Apr-99.pdf

<https://www.fao.org/3/cb8313en/cb8313en.pdf> (Accessed 12th May 2022)

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2005.25r> (accessed 10th May 2022)

https://www.iarc.who.int/wp-content/uploads/2018/07/Volume-117_news-item.pdf (accessed 10th May 2022)

11.0. APPENDIXES

Appendix I: Summary of international regulatory decisions

Country/Region	Regulatory decision	Classification	Mitigation measures
European Union	Withdrawn in European market	Acute Toxicity Category 4-H302, Carcinogenicity Category 2 - H351(Suspected of causing cancer), Specific Target Organ Toxicity Repeated Exposure Category 2 (STOT RE)- H373, Chronic Aquatic toxicity Category 1 - H400 and Chronic Aquatic toxicity Category 1 - H410 (Harmful to aquatic life with long lasting effect).	Withdrawn (decision on non-inclusion to Annex I) taken
United States of America	Proposed termination/revocation of registration except for use as preservative in paint	Likely human carcinogen	Terminate all herbicide uses on food and feed crops to address dietary and aggregate risks of concern to the general public and ecological risks of concern Occupational painters: -Reduced application rates -require PPE language to be included on the paint can labels to protect occupational painters using airless spray equipment -require registrant-sponsored applicator stewardship plans aimed training on proper PPE use.
Canada	Continued usage following the review in 2011. Product containing Diuron approved for use ¹ .	Causes eye irritation, harmful if swallowed, may irritate nose, throat and eyes ²	³ Wear long pants, a long-sleeved shirt, shoes plus socks, goggles or face shield, chemical resistant gloves and a dust/mist respirator during mixing, loading, application, clean-up and repair activities. In addition, wear a chemical-resistant apron during mixing,

¹ https://pr-rp.hc-sc.gc.ca/lr-re/result-eng.php?p_search_label=diuron&searchfield1=NONE&operator1=CONTAIN&criteria1=&logicfield1=AND&searchfield2=NONE&operator2=CONTAIN&criteria2=&logicfield2=AND&searchfield3=NONE&operator3=CONTAIN&criteria3=&logicfield3=AND&searchfield4=NONE&operator4=CONTAIN&criteria4=&logic

Country/Region	Regulatory decision	Classification	Mitigation measures
			<p>loading, clean-up and repair activities.</p> <p>Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours or until sprays have dried.</p> <p>B APPLY BY AIR.</p> <p>SOIL LIMITATIONS: Do not use on sand, loamy sand, or gravelly soils with less than 1% organic matter as crop injury may result.</p> <p>Do not replant treated areas to any crop within two years after last application as injury to subsequent crops may result.</p> <p>Requires authorization by Provincial Permit. Provincial permits must include specifications of measures: prevent treated water from endangering fish, release of treated water & notify downstream users of irrigation & drinking water</p>
Australia	Continued usage as per 2012 regulatory instruction		<p>DO NOT apply by air</p> <p>DO NOT use in water-logged areas DO NOT apply if greater than 50 mm rainfall is expected within 3 days of application</p> <p>DO NOT irrigate within 3 days of application DO NOT apply to fields where the slope exceeds 3% Apply as a COARSE spray only DO NOT spot spray greater than 5% of total farm area⁴</p>
JMPR Evaluation	No evaluation available		
WHO-International Agency for Research on		Classified TCAB as <i>probably carcinogenic to humans</i> (Group 2A)	Governments to take action to protect human health

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((accessed 10th May 2022)

² https://pr-rp.hc-sc.gc.ca/1_1/view_label?p_ukid=234095829 (accessed 10th May 2022)

³ https://pr-rp.hc-sc.gc.ca/1_1/view_label?p_ukid=234095829 (accessed 10th May 2022)

⁴ https://apvma.gov.au/sites/default/files/publication/18696-final_diuron_report.pdf (accessed 12th May 2022)

Country/Region	Regulatory decision	Classification	Mitigation measures
Cancer			

Appendix II: Public comments on Diuron and end use products

No	Comments	Respondent
1.	We have adopted Crop protection management strategies, which ensure responsible use of pesticides and guarantee minimal negative impact to people and environment.	Africalla Kenya LTD
2.	Essential for pea Ascochyta control and rust in beans.	Kenya Flower Council
3.	Not required at Finlay Flowers	Finlays Flowers
4.	We have a phase out plan for product Diuron for June 2023.	Shalimar Flowers
5.	<p>Diuron is essential for the control of pulse disease including Ascochyta in Peas, Chocolate Spot in Faba Beans, Septoria tritici in wheat and Ramularia in Barley. As a multi-site inhibitor Diuron plays a crucial role in reducing resistance development amongst new SDHI and triazole fungicides including bixafen and prothioconazole respectively.</p> <p>Whilst the product has been lost in Europe, this was a result of the active ingredient no longer being supported through registration because of a change in regulatory requirements rather than a specific concern over the safety of the product.</p>	Agriventure Kenya
6.	Active ingredient that must be withdrawn immediately. Proposed withdrawal in Kenya should be based on: 1) Carcinogenicity 2) Reproductive toxicity	-K, KOAN, RODI, RTFI
7.	<p>Diuron is a highly effective multi-site inhibitor and like that a cornerstone in resistance management. This is essential for growers and helps to ensure that a range of tools remain effective in the prevention and control of fungal diseases in plants.</p> <p>Withdrawal of Diuron would leave farmers vulnerable to alternative active substances which would not only be less effective or less desirable from a resistance management or crop tolerance perspective, but they also cost more than chlorothalonil. This means that in addition to potential yield losses, the gross margin of crops (e.g., potatoes) would</p>	Syngenta Kenya

No	Comments	Respondent
	<p>decrease.</p> <p>The risk assessments for Diuron demonstrated that there is no risk using this fungicide according to the label recommendations stated for the targeted uses: operators, consumers and the environment remain safe when the product is used properly. Diuron based products remain key in allowing for a certain level of productivity for such economically important crops as wheat and barley, peas, beans, coffee, and potato.</p> <p>Regulatory decisions should be accounting for both the safety and the socio-economic importance of crop protection products linking it to the food security challenge in Kenya.</p>	
8.	Based on its possibility to cause cancer, it should be removed from the Kenyan market under the precautionary principle. This is also supported by the fact that it is highly toxic to fish & amphibians	Greenpeace Africa
9.	Okay to discontinue	Agricultural Employers' Association (AEA)
10.	<p>Active ingredient that must be withdrawn immediately.</p> <p>Proposed withdrawal in Kenya should be based on:</p> <ul style="list-style-type: none"> • Genotoxicity which results in carcinogenicity (now category 1B) • Contamination of groundwater by the metabolites • Risk to aquatic species like amphibians and fish 	BIBA-K, KOAN, RODI, RTFI
11.	<p>a) Increase public capacity building on safe use of pesticide application, create public awareness, PPEs, do more research and allow industry self-regulation.</p> <p>b) Identify and publicize crops in which the selected active ingredients have been proved to be harmful to humans, animals</p>	Fresh Produce Consortium of Kenya (FPC Kenya)

No	Comments	Respondent
	<p>and the environment.</p> <p>c) Follow Plant Protection (General) Regulations, 2021 where such incidences of perceived harmful effects of a pesticide are suspected.</p>	

Appendix III: Registered pest control products containing Diuron for use in agriculture

	Product particulars	Active ingredient	Registered uses	Status: Hazard & Risk assessment submitted for review
1.	DEACON 600 WDG	Diuron 468g/kg + Hexazinone 132g/kg	Early post-emergence herbicide for control of Broadleaf weeds, Annual & Perennial grasses in Sugarcane. REI: 12hours; PHI- 150 days	Not submitted
2.	DIUREX 80 WP	Diuron 80% w/w	Pre-emergence herbicide for control of Broadleaf weeds & Grass weeds in Pineapples, Sugarcane, Coffee, Cotton & Citrus. REI: 12hours; Pineapples: PHI- 60 days; Sugarcane: PHI- 150 days; Coffee: PHI- 60 days; Cotton Seed: PHI- 60 days	Submitted
3.	KARMEX 80 DF	Diuron 80g/Kg	Pre-emergence and Early post-emergence herbicide for the control of Grass & Broadleaf weeds in Sugarcane. REI: 24hours Sugarcane: PHI- 150day	Not submitted
4.	NISAN 800 WG	Diuron 400 g/kg + Bromacil 400 g/kg	Pre-emergence herbicide for control of Broadleaf weeds and Grass in Pineapples. REI: 12hours Pineapple: PHI- 150 days	Submitted
5.	HEXARON 600 WG	Diuron 468g/kg + Hexazinone 132g/kg	Early post-emergence herbicide for control of annual and perennial grasses and broad-leaved weeds in sugarcane. REI: 12hours Sugarcane: PHI- 150 days	Submitted
6.	DORIAN 80 SC	Diuron 800 g/L	Pre-emergence herbicide for control of Broadleaf Weeds and grasses in Pineapples. REI: 12hours Pineapples: PHI-510 days	Not submitted

Appendix IV: Registered Diuron based products for use as biocides

	Trade name & Reg. No.	Active ingredient	Local agent	Use
1.	ACTICIDE EPW PCPB(TCR)0423	3-(3,4-Dichlorophenyl)-1,1-dimethylurea (Diuron) 20% + Methyl 1H-benzimidazol-2-ylcarbamate (Carbendazim) 9% + 2-Octyl-2H-isothiazol-3-one 3%	Brenntag Kenya Limited	Biocide for the complete protection of paints & coatings from fungal & algal growth
2.	ROCIMA 363 BIOCIDES PCPB(TCR)0418	Diuron 20% + Carbendazim 7.5% + 2-n-octyl-4-isothiazolin-3-one 2.7%	Dow Chemicals E.A. Ltd.	A film preservative to prevent surface growth of fungi and algae to be used in paints and coatings.
3.	MERGAL S89 PASTE PCPB(TCR)0416	Diuron 19% + 2-Benzimidazole Carbamic acid, methyl ester 10% + Kaolin 7-10% + 2-Octyl-2isothiazole-3-one 2.2%	Basco Products (Kenya) Ltd.	Dry film fungicide preservative for control of growth of fungi and algae on paints, masonry coatings, plasters, EIFS, adhesives and caulks on architectural designs.
4.	PARMETOL DF 19 FORTE PCPB(TCR)0404	Carbendazim 100g/kg + Diuron 200g/kg	Craftsman Enterprise (K) Ltd	As a dry film preservative of microbiological damage on coated surfaces
5.	MERGAL S89 PCPB(TCR)0399	Carbendazim 9.9% + Diuron 19%	Crown Paints Kenya Ltd	Dry film Preservative