

Evaluation Report for Category B Subcategory 2.1, 2.3 Application

Application Number: 2011-1825
Application: B.2.1 New / Changes EP or MA Product Chemistry-Guarantee
 B.2.3 New / Changes EP or MA Product Chemistry-Identity of Formulants
Product: GF-2668 Manufacturing Concentrate
Registration Number: 30956
Active ingredients (a.i.): 2,4-D, present as choline salt (DXJ) / Herbicide
PMRA Document Number : 2403806

Purpose of Application

The purpose of this submission is to register a manufacturing concentrate for a new choline salt form of 2,4-D.

Chemistry Assessment

GF-2668 Manufacturing Concentrate is formulated as a solution containing 2,4-D, present as choline salt, at a nominal concentration of 44.5%. This manufacturing concentrate has a density of 1.2125 g/mL and pH of 4.8. The chemistry requirements for GF-2668 Manufacturing Concentrate are complete.

Health Assessments

GF-2668 Manufacturing Concentrate was of slight acute toxicity via the oral route ($LD_{50} = 1100$ mg/kg bw) and low acute toxicity by the dermal ($LD_{50} = 1100$ mg/kg bw) and inhalation ($LC_{50} > 5.22$ mg/L) routes in the rat. It was moderately irritating to the eye and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in mice.

Summary of acute toxicity studies with GF-2668 Manufacturing Concentrate and label recommendations

Parameter	Species	Result	Primary Display Panel Labelling
Acute Oral LD_{50} Up and Down (425)	rat 2 at 550 mg/kg 3 at 1100 mg/kg 1 at 2190 mg/kg	$LD_{50} \text{ } \text{♀} = 1100$ mg/kg	CAUTION - POISON
Acute Dermal LD_{50}	5 rats/sex/dose Dosed at 5000 mg/kg	$LD_{50} \text{ } \text{♂♀} > 5000$ mg/kg	No hazard signal words required.

Acute Inhalation LC ₅₀	5 rats/sex/dose Dosed at 5.22 mg/L	LC ₅₀ ♂♀ > 5.22 mg/L	No hazard signal words required.
Primary Eye Irritation	3 ♂ rabbits dose Dosed with 0.1 mL	MAS ^a = 29/110 MIS ^b = 33.3/110	WARNING - EYE IRRITANT
Primary Skin Irritation	3 ♂ rats/dose Dosed with 0.5 g or mL for 4 hours	MAS= 2.6/8	CAUTION - SKIN IRRITANT
Skin Sensitization LLNA	6 ♀ mice /dose Dosed with 5, 25 or 50 %	Stimulation Index 5% - 1.3 25% - 1.2 50% - 1.1	No hazard signal words required.

^a MAS = Maximum Average Score for 24, 48 and 72 hrs

^b MIS = Maximum Irritation Score

Environmental and Value Assessments

Environmental and value assessments were not conducted for this type of application.

Conclusion

The Pest Management Regulatory Agency (PMRA) has carried out an evaluation of available information and has concluded that the registration of a manufacturing concentrate for a new choline salt form of 2,4-D (present as choline salt) can be supported.

References

Chemistry

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- 2046316 2010, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production and Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for GF-2668
- 2046317 2010, Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2668, DACO: 3.5,3.5.1,3.5.11,3.5.12,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
- 2055369 2011, GF-2668 Manufacturing Concentrate, Storage Stability Data, DACO: 3.5.10
- 2055370 2011, GF-2668 Manufacturing Concentrate, Miscibility, DACO: 3.5.13 CBI
- 2055371 2011, GF-2668 Manufacturing Concentrate, Corrosion Characteristics, DACO: 3.5.14
- 2055372 2011, GF-2668 Manufacturing Concentrate, Dielectric Breakdown Voltage, DACO: 3.5.15 CBI
- 2258954 2012, 1 Yr Summary - GLP storage stability for GF-2668 in HDPE and Stainless Steel bottles, DACO: 3.5.10,3.5.14 CBI

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2263897 2012, Storage Stability and Package Corrosion Characteristics of GF-2668 in
HDPE and Stainless Steel; One-Year Ambient Study, DACO: 3.5.10,3.5.14 CBI

Health

2046319 2010, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1
2046320 2010, Acute Dermal Toxicity Study in Rats, DACO: 4.6.2
2046321 2010, Acute Liquid Aerosol Inhalation Toxicity Study in Rats, DACO: 4.6.3
2046322 2010, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
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