Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.14 Application

Application Number: 2019-2698
Application: New Manufacturing Concentrate (Product Chemistry) – Guarantee, Identity of Formulants, Proportion of Formulants; New Product Label - Classifications
Product: Dry Fiesta MUP
Registration Number: 34623
Active ingredient (a.i.): Iron (present as ferric sodium EDTA trihydrate)
PMRA Document Number: 3383767

Purpose of Application

The purpose of this application was to register a manufacturing concentrate containing the active ingredient iron (present as ferric sodium EDTA trihydrate).

Chemistry Assessment

Dry Fiesta MUP is formulated as a granular product containing iron (present as ferric sodium EDTA trihydrate) at a concentration of 3.56%. This manufacturing concentrate has a density of 0.98-1.12 g/mL and pH of 4.82. The required chemistry data for Dry Fiesta MUP have been provided, reviewed and found to be acceptable.

Health Assessments

The toxicological profile of Dry Fiesta MUP was based on the toxicity testing with Dry Fiesta TGAI. Dry Fiesta MUP is expected to be of low toxicity by the oral, dermal and inhalation routes, and is minimally irritating to eyes, non-irritating to the skin and is expected to be a dermal sensitizer.

Waivers were accepted for short-term dermal toxicity, prenatal development toxicity and genotoxicity and mutagenicity testing based on toxicological information in publicly available scientific reports for FeNaEDTA and similar EDTA compounds.

Dietary and occupational exposure assessments were not required with this application.

Environmental and Value Assessments

Environmental and value assessments were not required with this application.

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Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Dry Fiesta MUP.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3002947	2019, Binder 1 Product Chemistry, DACO: 3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1, 3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15, 3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3002949	2019, Dry Fiesta MUP Preliminary Analysis, DACO: 3.3.1 CBI
3101406	2020, Dry Fiesta MUP: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10 CBI
3193821	2019, Dry Fiesta MUP Physical and Chemical Characteristics: Colour, Odour, Physical State, pH and Bulk Density, DACO: 3.5,3.5.1,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7 CBI
1753363	Kimmel, C.A., 1976, Effect of Route of Administration on the Toxicity and Teratogenicity of EDTA in the Rat, Kimmel, C.A., Effect of Route of Administration on the Toxicity and Teratogenicity of EDTA in the Rat, Toxicology and Applied Pharmacology 40, 299-306 (1977)., DACO: 4.8
1753368	Swenerton, H. and L.S. Hurley, 1971, Teratogenic Effects of a Chelating Agent and their Prevention by Zinc, DACO: 4.8
1753369	Munro, I.C., 2005, Sodium Iron EDTA (WHO Food Additives Series 32), Munro, I.C., Sodium Iron EDTA, WHO Food Additives Series 32), DACO: 4.8

B. Additional Information Considered

i) Published Information

PMRA Document Number	Reference
3367916	Whittaker, P., H. E. Seifried, R. H. C. San, J.J. Clarke and V.C. Dunkel. 2001, Genotoxicity of iron chelators in L5178Y Mouse Lymphoma Cells, Environ. Mol. Mutagen. 38: 347-356., doi: 10.1002/em.10033, DACO: 4.5.5
3367925	J McCann, E Choi, E Yamasaki, B N Ames, 1975, Detection of carcinogens as mutagens in Salmonella/microsome test: assay of 300 chemicals, Proc Natl Acad Sci USA. 72(12):5135-9., DACO: 4.5.5
3367927	European Chemicals Bureau, 2004, EU Risk Assessment Report edetic acid (EDTA). 1st Priority List,, DACO: 4.5.5
3367928	EFSA, 2010, EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of ferric sodium EDTA as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses, EFSA Journal 2010; 8(1):1414, doi: 10.2903/j.efsa.2010.1414, DACO: 4.3

3367940	Lanigan and Yamarik, 2002, Final report on the safety assessment of EDTA, calcium disodium EDTA, diammonium EDTA, dipotassium EDTA, disodium EDTA, TEA-EDTA, tetrasodium EDTA, tripotassium EDTA, trisodium EDTA, HEDTA, and trisodium HEDTA., J. Tox 21(2):95-142, doi: 10.1080/1091581029009652 2, DACO: 4.6.6
3367943	P. Sanchez-Pedreno, P, B. Garcia-Bravo and J. Frias-Iniesta., 2009, Contact allergy to tetrasodium EDTA in a sunscreen, Contact Dermatitis 2009: 61: 125-126, DACO: 4.6.6