

Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

Application Number: 2011-2576
Application: Changes TGAI Chemistry - New source (site), same registrant
Product: NEU1173H TGAI
Registration Number: 29523
Active ingredients (a.i.): Iron (present as FeHEDTA)
PMRA Document Number : 2198977

Purpose of Application

The purpose of this application was to add an alternate source for the technical NEU1173H TGAI (Registration number 29523).

Chemistry Assessment

Accepted Name: FeHEDTA
Chemical Name: Hydroxyethylethylenediaminetriacetic acid, ferric complex

NEU1173H TGAI has the following properties:

Property	Result
Colour and physical state	Deep red liquid
Nominal concentration	4.51 %
Odour	Odourless
Density	1.38 – 1.40 g/mL
Vapour pressure	Not applicable
pH	5.47
Solubility in water	Miscible in all proportions
n-Octanol/water partition coefficient	Not applicable

The chemistry requirements for NEU1173H TGAI are complete.

Health Assessments

The new source of NEU1173H TGAI was considered toxicologically equivalent to the currently

registered source. Subsequently, no toxicological data were submitted or are required.

Dietary and occupational assessments were not required for this application.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of available information for NEU1173H TGAI and has found the information sufficient to support the registration of the new source for NEU1173H TGAI.

References

PMRA No	Title
2068837	2011, NEU1173H TGAI Binder 2 Addendum 22June11, DACO: 2.0,2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, CBI
2212630	2012, Clarification response explanations for NEU1173H TGAI, DACO: 2.12.1,2.13.1,2.2 CBI
2113390	2011, NEU1173H TGAI Batch Data Study with methodology, DACO: 2.13,2.13.1,2.13.3 CBI
2109768	2011, NEU1173H TGAI 5-Batch Analysis, DACO: 2.13,2.13.1,2.13.3 CBI
2180625	2012, LOQ rationale for ammonium and EDTA, DACO: 2.13.1 CBI
2180627	2012, Confirmation of identity- Loss on Drying study, DACO: 2.13.2,2.13.3
2180626	2008, Nitrate analysis method, DACO: 2.13.1 CBI
2218065	2012, NEU1173H Akzo Noble letter in response to DACO: 2.13.1 clarification request, DACO: 2.13.1 CBI
2180628	2012, Submission 2011-2576 deficiency response CL, DACO: 0.8

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