

## Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

**Application Number:** 2014-1899  
**Application:** B.1.1 – New Source Same Registrant  
 B.1.3 – Changes in Specifications  
**Product:** NEU1173H TGAI  
**Registration Number:** 29523  
**Active ingredients (a.i.):** Iron present as FEHEDTA  
**PMRA Document Number :** 2505991

### Purpose of Application

The purpose of this application was to add a new source with a slightly different method of manufacture for NEU1173H TGAI.

### Chemistry Assessment

**Common Name:** NEU1173H TGAI  
**IUPAC Chemical Name:** Hydroxyethylethylenediaminetriacetic acid, ferric complex  
**CAS Chemical Name:** Iron, [N-(2-[bis[(carboxy-.kappa.O)methyl]amino-kappa.N]ethyl)-N-[2-(hydroxy-.kappa.O)ethyl]glycinato(3-)--.kappa.N,.kappa.O)-

NEU1173H TGAI has the following properties:

Property	Result
Colour and physical state	Deep red liquid
Nominal concentration	27.24%
Odour	Odorless
Density at 20°C	1.38 – 1.40 g/mL
Vapor pressure at 25°C	Same as water since it is a salt soluble in water.
pH	5.47 ± 1.14 (1% dilution)
Solubility in water	Miscible in all proportions
n-Octanol/water partition coefficient	log K <sub>ow</sub> < 0

The chemistry requirements for NEU1173H TGAI have been fulfilled.

### Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

### Conclusion

The PMRA has reviewed the information provided in support of the new source of the technical product NEU1173H TGAI. Based on this review, the new source of NEU1173H TGAI is acceptable.

## References

- 2428740 2014, 29523 NEU1173H TGAI Chemistry Volume 28May14, DACO: 2.0,2.1, 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2, 2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15, 2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.16,2.2,2.3,2.3.1,2.4, 2.5,2.6,2.7,2.8,2.9,830.7000 CBI
- 2428742 2014, NEU010-120069 NEU1173H TGAI Akzo Lima 5-batch Signed 27 May14, DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
- 2481286 2014, 29523 NEU1173H TGAI Chemistry Volume revised 9Dec14, DACO: 2.0, 2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3, 2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3, 2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9, 830.7000 CBI

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