

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.1, 3.12 Application

Application Number: 2008-6101
Application: B.2.3 - New Formulants
B.2.4 - New Proportion of Formulants
B.3.1 - Changes to Product Labels-Application Rate Increase
B.3.12 - Changes to Product Labels-New Sites/Hosts
Product: AQUCAR 514 Water Treatment Microbiocide
Registration Number: 25606
Active ingredients (a.i.): Glutaraldehyde (GLT), N-Alkyl dimethyl benzyl ammonium chloride (QAC)
PMRA Document Number: 2076022

Purpose of Application

The purpose of this application was to amend the formulation of AQUCAR 514 Water Treatment Microbiocide (Registration number 25606), as well as adding new use sites (oil and gas field operations) amended to the label.

Chemistry Assessment

AQUCAR 514 Water Treatment Microbiocide is formulated as a solution containing glutaraldehyde at 14 % nominal and n-alkyl (40% C12, 50% C14, 10% C16) dimethyl benzyl ammonium chloride at 2.5% minimum. This end use product has a density of 1.035 g/mL and a pH between 3.1-4.5. All the chemistry requirements for AQUCAR 514 Water Treatment Microbiocide are complete.

Health Assessments

The change in formulations is not expected to alter the toxicological profile of the product.

A qualitative health assessment has been conducted to expand the currently registered AQUCAR 514 Water Treatment Microbiocide to include uses for the control of bacteria in oil and gas field operations. Exposure to mixer, loader, applicator and post-application workers was determined to be acceptable.

Environmental Assessment

An environmental assessment was not conducted as the use expansion is not expected to result in a potential increase in the environmental exposure and impact from that of the currently registered uses.

Value Assessment

Laboratory and field studies were conducted to evaluate the ability of AQUICAR 514 Water Treatment Microbiocide to reduce bacterial activity in oilfield waters. The laboratory studies were conducted using microbial samples taken in various oilfield contaminated waters to obtain representative challenge organisms. Aliquots of these contaminated samples were challenged with various concentrations of the biocides and incubated at a range of temperatures to represent the variety of conditions that can be found in oilfield applications. The field study was conducted in a water flood and the results were monitored at nine locations throughout the field. A scientific rationale was also provided to support the grouping of "Oil and gas production and transmission pipelines and systems" and of "Pipeline pigging and scraping operation". The data demonstrated that AQUICAR 514 Water Treatment Microbiocide is effective at reducing bacterial counts under representative use conditions.

Conclusion

The PMRA has completed an assessment of the available information for AQUICAR 514 Water Treatment Microbiocide and has found the information sufficient to approve the formulation amendment, as well as the addition of new use sites (oil and gas field operations) to the label of AQUICAR 514 Water Treatment Microbiocide.

References

PMRA#	Reference
1800468	Use Description/Scenario, DACO 5.2
1840831	Use Description/Scenario, DACO 5.2
1944377	Use Description/Scenario (Clarification Response), DACO 5.2
1944378	Post-application Exposure Description (Clarification Response), DACO 5.6
1944379	Dermal Absorption (<i>in vivo</i>) (Clarification Response), DACO 5.8
1744804	2006, Biocide Efficacy of UCARCIDE 14 in a Drilling Mud by the Time Kill Test, DACO: 10.2.3.2
1744803	2007, Biocide Efficacy Evaluation of Eight Dow Biocides for Potential Application in an Oilfield in Oman;, DACO: 10.2.3.2
1744810	2007, Efficacy of Various Biocides Against Anaerobic Sulfate Reducing Bacteria in Daqing Oilfield Water Samples by Traditional Method, DACO: 10.2.3.2
1744813	2006, Efficacy of Various Oilfield Biocides in Simulated Injection Water against Aerobic Iron Related Bacteria and Heterotrophic Bacteria Cultured from Daqing Oilfield Produced Water;, DACO: 10.2.3.2
1744815	2008, Biocide Evaluation of Fracture Water, DACO: 10.2.3.2
1744811	2008, Biocide Evaluation of Fracture Water II, DACO: 10.2.3.2
1744807	1989, UCARCIDE 142 Antimicrobial Field Trial in Water Flood in Ohio and Correction to UCARCIDE 142 Antimicrobial Field Trial, DACO: 10.2.3.2
1944337	2008-6100 DACO 10.2.3.2 Resonse, DACO: 10.2.3.2,10.2.3.3,10.2.3.4
1944339	2009, Evaluation of Biocide Efficacy against aerobic etc, DACO: 10.2.3.2 CBI
1944340	2010, Produced Water - Lab Efficacy, DACO: 10.2.3.2 CBI
1744858	2007, Glutaraldehyde Concentration by Potentiometric Hydroxylamine Hydrochloride Titration, DACO: 3.4.1
1744861	2007, n-Alkyl dimethyl benzyl ammonium chloride (ADBAC) in Glutaraldehyde-Based Products, DACO: 3.4.1
1744862	2008, AQUAR 514 Water Treatment Microbiocide Description of Formulation Process;, DACO: 3.2.2 CBI
1744889	2005, Materials Compatibility for UCARCIDE 142 Antimicrobial, DACO: 3.5.14
1800449	Data Code 3_3_1 Starting Materials Clarification, DACO: 3.2.1
1800450	Data Code 3_3_1 Establishing Limits Clarification, DACO: 3.3.1
1800451	Data Code 3_5_6 Specific Gravity Clarification, DACO: 3.5.6
1800452	Data Code 3_5_7 pH Clarification, DACO: 3.5.7
1800453	Data Code 3_5_8 Chemical Incompatibility Clarification, DACO: 3.5.8
1800454	Data Code 3_5_9 Viscosity Clarification, DACO: 3.5.9
1800455	Data Code 3_5_10 Storage Stability Clarification, DACO: 3.5.10
1800456	Data Code 3_5_11Flammability Clarification, DACO: 3.5.11
1800457	Data Code 3_5_12 Explodability Clarification, DACO: 3.5.12
1800458	Data Code 3_5_13 Miscibility Clarification, DACO: 3.5.13
1862405	3.4.1 Response to Agency Request, DACO: 3.4.1 CBI
1862406	3.5.5 Response to Agency Request, DACO: 3.5.5
1862407	3.5.9 Response to Agency Request, DACO: 3.5.9 CBI

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