

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

Application Number:	2019-1044
Application:	New End-Use Product (Product Chemistry) - Guarantee, Identity of
	Formulants, Proportion of Formulants
Product:	Klercide Cleanroom Quat
Registration Number:	33736
Active ingredient (a.i.):	Didecyldimethylammonium chloride
PMRA Document Number	: 3021214

Purpose of Application

The purpose of this application was to register the end-use product Klercide Cleanroom Quat, a hard-surface sanitizer.

Chemistry Assessment

Klercide Cleanroom Quat is formulated as a solution containing dodecyl dimethyl ammonium chloride at a concentration of 0.037%. This end-use product has a specific gravity of 0.998 and a pH between 5.5 and 7. The required chemistry data for Klercide Cleanroom Quat have been provided, reviewed and found to be acceptable.

Health Assessments

Klercide Cleanroom Quat is of low acute toxicity via the inhalation route, and is considered to be of low acute toxicity via the oral and dermal routes of exposure. It is considered minimally irritating to the eyes and slightly irritating to the skin, and is not expected to cause an allergic skin reaction.

A quantitative risk assessment for loaders and applicators handling Klercide Cleanroom Quat for use on listed sites to control bacterial contaminants was conducted. No risks of concern were identified provided that workers follow the label directions and wear the personal protective equipment identified on the label.

A dietary exposure assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.



Value Assessment

Two scientifically valid laboratory studies were provided to support the value of the product as a hard surface sanitizer. Both studies were conducted using representative bacterial species. These studies demonstrated that the product was able to reduce the microbes by greater than 99.9%. Therefore, this product has been shown to have acceptable value.

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 Klercide Cleanroom Quat.

References

PMRA Document	Reference
Number	
2972166	2017, XLS-FRTU Non-Food Contact Sanitizing Efficacy (EPA Reg. No.
	1677-[pending]), DACO: 10.2.3.2
2972167	2017, XLS-FRTU Supplemental Non-Food Contact Sanitizing Efficacy
	(EPA Reg. No. 1677-[pending]), DACO: 10.2.3.2
2972156	2017, XLS-FRTU Chemical Characterization, DACO: 3.2.1, 3.2.2, 3.2.3,
	3.3.1, 3.4.1, 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,
	3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2972157	2017, XLS-FRTU Accelerated Storage Stability, DACO: 3.5.10, 3.5.14 CBI
2972158	2017, XLS-FRTU Accelerated Storage Stability, DACO: 3.5.10, 3.5.14 CBI
2972159	2019, Formulation Type and Container Description, DACO: 3.5.4, 3.5.5 CBI
3073234	2019, Supplement to Primary Validation of QATM 278 For Determination of
	Quat Content in Klercide Low Residue Quat (912875), DACO: 3.4.1 CBI
2972160	2017, Citation of Existing Studies to Satisfy Data Requirements for XLS-
	FRTU, DACO: 4.1,4.6.1,4.6.2,4.6.3,4.6.5,4.6.6
2972161	2017, Citation of Existing Studies to Satisfy Data Requirements for XLS-
	FRTU, DACO: 4.6.4
2972162	2017, An Acute Toxicity Study of XLS-FRTU by the Nose Only Inhalation
	Route in Rats, DACO: 4.6.3
2987285	2016, An Acute Toxicity Study of FSC 35K, Applied as a Concentrate, by
	Oral Gavage in Rats, DACO: 4.6.1
2987286	2016, An Acute Toxicity Study of FSC 35K, Applied as a Concentrate, by
	Dermal Administration in Rats, DACO: 4.6.2
2987287	2016, An Acute Skin Irritation Study of FSC 35K Use-Solution by Dermal
	Administration in Rabbits, DACO: 4.6.5
2987288	2016, An Acute Irritation Study of FSC 35K Use-Solution by Ocular
	Administration in Rabbits, DACO: 4.6.4
2987289	2016, A Sensitization Study of FSC 35K Use-Solution by Dermal
	Administration in Guinea Pigs-Modified Buehler Design, DACO: 4.6.6
2987290	2019, Bridging to Studies from a Similar Product to Satisfy Data
	Requirements for XLS-FRTU, DACO: 4.1

ISSN: 1911-8082

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