

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2009-3475
Application: New / Changes TGAI or ISP Prod Chemistry-Specifications
Product: Amvac Naled Technical
Registration Number: 23202
Active ingredients (a.i.): Naled (NAL)
PMRA Document Number : 1941800

Purpose of Application

The purpose of this Category B.1.3-S-A-TGAI submission is to amend the guarantee from minimal to nominal and to update impurities. This follows an earlier attempt to update the specifications via a Cat C (2008-4469), which was rejected by CES.

Chemistry Assessment

Common Name: Amvac Naled Technical
Chemical Name: 1,2-dibromo-2,2-dichloroethyl dimethyl phosphate

Amvac Naled Technical has the following properties:

Property	Result
Colour and physical state	Slightly yellow
Nominal concentration	94.5%
Odour	Pungent
Density	1.960-1.977 g/mL at 25°C
Vapour pressure	266 mPa at 20°C
pH	1.8-2.0
Solubility in water	Practically insoluble
n-Octanol/water partition coefficient	Rapidly hydrolyzes in aqueous media.

The chemistry requirements for Amvac Naled Technical have been completed.

Health Assessments

The amendments requested in this application are not expected to alter the toxicology profile or the residues in food and feed crops treated with end-use products containing naled. Therefore, no change in the toxicology profile or increase in dietary exposure to naled is anticipated.

An occupational exposure assessment was not required for this application.

Environmental and Value Assessments

Neither an environmental or value assessment was required for this application.

Conclusion

The PMRA has completed the assessment of all available information and is able to support the addition of a new manufacturing site and the .changes to the specifications of the TGAI.

References

PMRA No.	Title
1799463	1999, Description of Materials Used to Produce Naled Technical, DACO: 2.11.2 CBI
1799464	1999, Description of the Production Process for Naled, DACO: 2.11.3 CBI
1799465	1999, Discussion of Formation of Impurities for Naled Technical, DACO: 2.11.4 CBI
1799467	1999, Naled Technical: Enforcement Analytical Method, DACO: 3.4.1 CBI
1799469	1999, Naled Technical: Preliminary Analysis, DACO: 2.13 CBI
1930178	1980, n-Octanol-Water Partition Coefficients of Naled and Dichlorvos, DACO: 2.14.11 CBI

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