Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1, 1.3, 7.0 Application

Application Number: 2009-3605
Application: B.1.1 (Product chemistry – new source same registrant)
B.1.3 (Product chemistry – specifications)
B.7.0 (Reinstatement of registered product)
Product: 1-Naphthaleneacetic Acid Technical, Sodium Salt
Registration Number: 30739
Active ingredients (a.i.): 1-Naphthaleneacetic acid, present as sodium salt (NAA)
PMRA Document Number: 2244100

Purpose of Application

The purpose of this application was to register 1-Naphthaleneacetic Acid Technical, Sodium Salt. This is a grandfathered active ingredient therefore it has never been registered.

Chemistry Assessment

Common Name:	1-naphthaleneacetic acid, present as sodium salt or Sodium α-naphthaleneacetate
IUPAC* Chemical Name:	Sodium 1-naphthylacetate
CAS† Chemical Name:	Sodium 1-naphthaleneacetate

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Canada

1-Naphthaleneacetic Acid Technical, Sodium Salt has the following properties:

Property	Result
Colour and physical state	White powder
Nominal concentration	86.05% as the acid
Odour	Odourless
Density	0.40 – 0.54 g/cm^3
Vapour pressure	$<2.0 \times 10^{-4}$ Pa at 25˚C
pH	9.1 for a 1% aqueous dilution
Solubility in water	295.5 g/L
n-Octanol/water partition coefficient	Log P = 2.6 for the acid

The chemistry requirements for 1-Naphthaleneacetic Acid Technical, Sodium Salt have been fulfilled.

Health Assessments

1-Naphthaleneacetic acid is of low toxicity to rats via the oral route (LD_{50} > 2880 mg/kg) and to rabbits via the dermal route (LD_{50} > 2000 mg/kg). It is moderately toxic via inhalation route (LC_{50} > 0.45 mg/L [maximum attainable concentration]). It is severely but reversibly irritating to the eye and it is minimally irritating to skin of rabbits. It is not a dermal sensitizer in guinea pigs.

No new residue data were submitted to support registering the grandfathered source of 1-naphthaleneacetic acid (present as sodium salt) for 1-Naphthaleneacetic Acid Technical, Sodium Salt. Since registering the grandfathered active will not have any impact on the related registered end-use products, no change in the magnitude of the residues is anticipated. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of 1-Naphthaleneacetic Acid Technical, Sodium Salt.

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