

# **Evaluation Report for Category B, Subcategory B.1.2 Application**

Application Number:	2013-2700
Application:	New Source of Technical Grade Active Ingredient by a New
	Registrant
Product:	Sulphur Mills Technical Sulphur
<b>Registration Number:</b>	31868
Active ingredients (a.i.):	sulphur
<b>PMRA Document Number</b>	r : 2535007

# Background

The source of sulphur used to determine chemical equivalence was Registration Number 18569.

## **Purpose of Application**

The purpose of this application was to register a new source of the active ingredient, sulphur, by a different Registrant.

#### **Chemistry Assessment**

Common Name:	Sulfur
	This substance is considered by the International Organization for
	Standardization not to require a common name.
IUPAC Chemical Name:	Sulfur
CAS Chemical Name:	Sulfur

Property	Result
Colour and physical state	Light yellow granular solid
Nominal guarantee	Sulphur at 99.8%Available chlorine present as
	1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins at
	28.6% (limits 27.7-29.5%)
Odour	Odourless
Specific gravity	0.90 g/mL at 24°C
Vapour pressure	0.21 mPa at 25°C (extrapolated)
pH	6.5-7
Solubility in water	0.063 g/m <sup>3</sup> (pH 7, 20°C)
n-Octanol/water partition	Log K <sub>ow</sub> 5.68 (pH 7)
coefficient	

Sulphur Mill Technical Sulphur has the following properties:



The chemistry requirements for Sulphur Mill Technical Sulphur have been fulfilled.

# Health and Environmental Assessments

As the new source of sulphur is acceptable, the health and environmental risk profiles are expected to be similar to that of the product used to determine equivalence. No additional assessments were required.

# Value Assessment

A value assessment is not required for technical grade active ingredient products.

## Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Sulphur Mills Technical Sulphur.

## References

PMRA	Reference
Document	
Number	
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	2.11.4, 2.14.10, 2.14.11 ,2.14.12,2.14.13 CBI
2305339	2005, Technical Sulphur and Sulphur Dust- Validation of the Analytical Method for the
	Determination of the Active Ingredient Content, DACO: 2.13.1 CBI
2305341	2005, Technical Sulphur and Sulphur Dust- Validation of the Analytical Method for the
	Determination of the Heavy Metal Content, DACO: 2.13.1 CBI
2305343	2005, Technical Sulphur - Analysis of 5-Batch Samples, DACO: 2.13.1, 2.13.2, 2.13.3
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2305345	2005, Technical Sulphur- Determination of the Colour, Odour and Physical State,
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2305348	2011, Bulk Density of Sulphur Technical, DACO: 2.14.6
2305350	2005, Technical Sulphur- Determination of the Water Solubility, DACO: 2.14.7
2305351	2005, Technical Sulphur- Determination of the Solubility in Organic Solvents, DACO:
	2.14.8
2305352	2005, Technical Sulphur- Determination of the Vapour Pressure, DACO: 2.14.9
2429046	2014, 2.11.2-SM-Sulphur TGAI - addresses, DACO: 2.11.2 CBI
2429047	2014, Description of Raw Material -05.05.2014, DACO: 2.11.2 CBI
2429048	2014, Method of Manufacture of Sulphur Technical, DACO: 2.11.3 CBI

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	Active Ingredient to Determine the % Sulphur and to Quantify its Associated Impurities,
	DACO: 2.13.4 CBI
2429050	2012, Analysis of 5 Representative Production Batches of Sulphur Technical Grade
	Active Ingredient to Determine the % Sulphur and to Quantify its Associated Impurities,
	DACO: 2.13.4 CBI
2429051	2012, Analysis of 5 Representative Production Batches of Sulphur Technical Grade
	Active Ingredient to Determine the % Sulphur and to Quantify its Associated Impurities,
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	DACO: 2.13.4 CBI
2429053	2011, pH of Sulphur Technical, DACO: 2.14.15,830.7000

ISSN: 1911-8082

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