

ORIGINAL

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 U.S. Environmental Protection Agency
 1201 Constitution Avenue, NW
 Washington, DC 20004-3302

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Re: TSCA 8(e) Submission for Vanadium Compounds (multiple CASRNs)

Dear Sir or Madam:

The Vanadium Producers & Reclaimers Association (VPRA) hereby provides information to the United States Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) section 8(e), 15 U.S.C. § 2607(e). The enclosed information consists of slides that were part of a power point presentation given at an industry meeting on December 13, 2010, in London, England. The slides convey test results on bioavailability, irritation and sensitization, mutagenicity, and acute toxicity from studies initiated in Europe for vanadium and certain vanadium compounds which are manufactured by VPRA members, as follows:

- Vanadium (V) (CASRN 7440-62-2);
- Vanadium trioxide (V₂O₃) (CASRN 1314-34-7);
- Vanadium pentoxide (V₂O₅) (CASRN 1314-62-1);
- Ammonium polyvanadate (NH₄V₃O₈) (CASRN 12207-63-5); and
- Sodium metavanadate (NaVO₃) (CASRN 13718-26-8).

Due to the inclusion of the information on the bioavailability of these compounds and the possible interaction of bioavailability and the physical-chemical properties of the species tested, this information is also being included. Finally, the ability to begin to compare results across the tested vanadium compounds is considered significant for purposes of all of these results. However, the information being reported is limited in that no additional details

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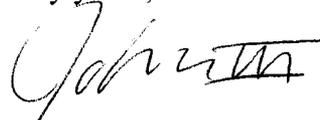
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beyond the slides presented are available at this time. Thus, for example, potency and mutagenicity test endpoints associated with the data are not known.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Hilbert", written in a cursive style.

John Hilbert, President

Vanadium Producers & Reclaimers Association

Enclosure



Data submission for REACH

Vanitec HSE Meeting

London, 2010-12-13



Physico-chemical (new) data

Physico-chemical data	V	V ₂ O ₅	NH ₄ V ₃ O ₈	V ₂ O ₃
Relative density	6.6	3.6	3.2	5.2
Water solubility (mg/L)	0.15	920	176	333 after 264 h
Oxidising properties	derogation	Not oxidising oxygen content: 44%	derogation	derogation
Flammability	non-flammable particles > 5 µm	derogation	derogation	derogation
Granulometry (D50 in µm)	32.3	262.5	29.1	266.5
Dustiness (mg/kg)	633	Granules: 48 Powders: 458 - 682	667	196
Transformation/D., incl. speciation	Testing ongoing	Testing ongoing	Testing ongoing	Testing ongoing
Bioaccessibility, incl. speciation	see next slide	see next slide	see next slide	see next slide



Bioaccessibility – after 2 h

	PBS, pH 7.4	GMB, pH 7.4	ALF, pH 4.5	GST, pH 1.5	ASW, pH 6.5
V metal	≤ DL	≤ DL	≤ 1.2 % IV	≤ 1.2 % IV	≤ DL
V₂O₃	≤ 5 % V	≤ 6 % V	≤ 14 % IV	≤ 9 % IV ≤ 4 % V	≤ 3 % IV ≤ 5 % V
VO₂	≤ 29 % IV ≤ 68 % V	≤ 100 % V	≤ 94 % IV ≤ 15 % V	≤ 74 % IV ≤ 32 % V	≤ 54 % IV ≤ 51 % V
NaVO₃	≤ 100 % V	≤ 93 % V	≤ 65 % IV ≤ 40 % V	≤ 4 % IV ≤ 90 % V	≤ 5 % IV ≤ 89 % V
V₂O₅	≤ 99 % V	≤ 100 % V	≤ 99 % IV	100 % V	≤ 95 % V

- Loading of 100 mg/L
- Solubility & speciation after 2 & 24 h

- Phosphate-buffered saline (PBS, pH 7.4)
- Artificial lysosomal fluid (ALF, pH 4.5)
- Artificial sweat solution (ASW, pH 6.5)
- Gamble's solution (GMB, pH 7.4)
- Artificial gastric fluid (GST, pH 1.5)



Bioaccessibility – after 24 h

	PBS, pH 7.4	GMB, pH 7.4	ALF, pH 4.5	GST, pH 1.5	ASW, pH 6.5
V metal	≤ 1.4 % V	≤ 1.2 % V	≤ 1.5 % IV	≤ 1.6 % IV	≤ 0.7 % IV ≤ 1.3 % V
V₂O₃	≤ 9 % V	≤ 7 % V	≤ 18 % IV	≤ 11 % IV ≤ 5 % V	≤ 13 % IV ≤ 13% V
VO₂	100 % V	100 % V	≤ 90 % IV ≤ 11 % V	≤ 74 % IV ≤ 50 % V	≤ 32 % IV ≤ 72% V
NaVO₃	100 % V	100 % V	100 % IV	≤ 6 % IV ≤ 90 % V	≤ 5 % IV ≤ 99 % V
V₂O₅	≤ 98 % V	100 % V	100 % IV	100 % V	≤ 94 % V



Bioaccessibility – Read-across conclusions

Solubility:

- VOSO_4 , NaVO_3 , and V_2O_5 : ~ 100% dissolution in all physiological media
- V_2O_3 : 7 - 20%
dissolution in all physiological media
- V metal: 0.5 - 1.6% dissolution in all physiological media

Speciation:

- V substances transform to the pentavalent form in all media except in ALF
- in ALF, even pentavalent forms are converted to tetravalent species



Irritation/sensitisation

Toxicol. Data	V metal	V ₂ O ₅	NH ₄ V ₃ O ₈	V ₂ O ₃	VOSO ₄	NaVO ₃
Skin irritation	Negative	Negative	Negative	Negative		
Skin corrosion	Not needed	Not needed	Not needed	Not needed		
Eye irritation	Negative	Danger Cat.1	Danger Cat.1	Warning Cat 2		
Skin sensitisation	Read-across	Read-across	Read-across	Negative *	Negative*	Negative*

- *Skin sensitisation acc. to Magnusson & Kligman
- V₂O₃: No classification according to 67/548 EEC
Classification according to EC 1272/2008



Mutagenicity

Toxicological Data	V metal	V ₂ O ₅	NH ₄ V ₃ O ₈	V ₂ O ₃	VOSO ₄
<i>in vitro</i> micronucleus assay (OECD 487, draft)	Read-across	Positive	Read-across	Positive	Positive
<i>in vitro</i> mammalian cell gene mutation assay (OECD 476)	Read-across	Negative	Read-across	Negative	Negative

→ All V substances: no gene mutations

→ All V substances: clastogenic effects at high concentrations (common for metals)

→ No overinterpretation of *in vitro* results at unphysiologically high concentrations

→ All V substances: Classification is not supported (Argumentation based on HERAG)

→ Ongoing *in vivo* study with V₂O₅ acc. to OECD 474 in bone marrow of rats, incl. tissue analysis



Acute toxicity

Toxicol. Data - LD50 [mg/kg]	V metal	V ₂ O ₅	NH ₄ V ₃ O ₈	V ₂ O ₃	VO ₂
		*Techn. grade, pulverised		Techn. grade, pulverised	
Oral route	> 2000	221 (f) 314 (m)	> 50-200	5639 (f) 8713 (m)	448
Dermal route	Read-across	> 2500	> 2000	> 2500	
Inhalation route	* Submission of expert statement	2.21 (f) 4.4 (m)	0.84	> 6.65	

* FeV80: Stable atmosphere could not be established.

- Data of the most toxic grade → C&L of V₂O₅: Acute Tox. 3; H301 Toxic if swallowed
- Current C&L (EC 1272/2008): Acute Tox. 4; H302 Harmful if swallowed
- Submitted C&L proposal for analytical grade: Acute Tox. 4; H302 Harmful if swallowed