PROPOSED MODIFICATIONS TO IDENTIFIED ACUTE TOXICITY-BASED SOIL CLEANUP TARGET LEVELS (SCTLs)

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I. Introduction

The Methodology Focus Group of the Contaminated Soils Forum identified a number of issues that were of interest concerning the Florida Department of Environmental Protection (FDEP) Soil Cleanup Target Levels (SCTLs) most recently developed in the context of Chapter 62-777, FAC. One aspect of the SCTLs that the Methodology Focus Group elected to consider in greater depth was the development of certain SCTLs on the basis of potential acute toxic responses following a single soil exposure event in a child who may ingest as much as 10,000 mg (10 grams). This report summarizes the agency's rationale for selected SCTLs that are based on acute toxicity considerations, and discusses supplemental or alternative information that is useful in considering modifications to some of the acute toxicity-based SCTLs. This information can be considered by FDEP during rule revisions that are projected for early-2000.

For six substances (barium, copper, cyanide, fluoride, nickel and vanadium), a brief discussion is presented to summarize the basis for the acute toxicity-based SCTL, drawn from FDEP documentation. Next, a brief discussion and summary is presented of alternative information or approaches that are reasonable to consider in developing alternatives to the existing values. This information is provided as a point of discussion for the Methodology Focus Group and as the basis for proposing revisions to selected acute toxicity SCTLs. In each instance, the equation is used that was employed by the agency in the "Technical Report: Development of Soil Cleanup Target Levels (SCTLs) for Chapter 62-777, F.A.C." (FDEP, 1999), although alternative numerical values or assumptions are proposed in Tables 1 through 6 for each identified contaminant. The

development of the FDEP acute toxicity SCTL assumes a single soil ingestion event (10 grams, 1 day event). The equation for the acute toxicity SCTL based on this single exposure event is as follows:

$$SCTL_{acute} = \frac{BW}{\left[\frac{1}{\text{Acute Value}}\right] \times SI \times CF}$$

where:

BW = Body Weight (15 kg);

Acute Value = Safe Dose for Acute Exposure (chemical-specific, expressed as mg/kg);

SI = Amount of Soil Ingested (10 g); and,

CF = Conversion Factor (10^{-3} kg/g).

In addition, a bioavailability term was included in the derivation of proposed alternative acute toxicity-based SCTLs in this document. The FDEP calculation assumes 100% bioavailability, while the alternatives presented here propose other bioavailability terms in the calculation of alternative acute toxicity SCTLs.

The U.S. EPA and most state agencies support the use of bioavailability in risk assessment and risk-based decision making (ACS, 1998). Recent environmental guidance from the State of Michigan specified that a default soil bioavailability value of 50% is to be used in development of soil screening for inorganic analytes in the absence of analyte-specific values (MDEQ, 1998). This soil bioavailability value of 50% represents an estimate designed to account for matrix-specific considerations (e.g., soil bound contaminants). In the absence of analyte-specific bioavailability values and where applicable, a soil bioavailability value of 50% was employed in the development of the proposed revised acute toxicity SCTLs.

II. Summaries of Basis for Proposed Changes to Acute Toxicity-Based SCTLs

A. Barium

Summary of the FDEP Acute Toxicity SCTL Basis

As presented on the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS), the current chronic oral Reference Dose (RfD) for barium is 0.07 mg/kg·day (U.S. EPA, 1999a). That chronic oral RfD value was based on a No Observed Adverse Effects Level (NOAEL) of 0.21 mg/kg·day for humans resulting from the ingestion of barium chloride in drinking water. The soluble forms of barium salts (e.g., barium chloride) are regarded as more toxic compounds in comparison to the insoluble barium salts (e.g., barium sulfate). An additional reduction factor of three (3x) was applied to the 0.21 mg/kg·day value to derive the U.S. EPA oral RfD value. This additional adjustment was specifically included in order to account for database uncertainties and adult-to-child uncertainties (U.S. EPA, 1999a).

The FDEP acute oral value for barium (0.07 mg/kg) was set equivalent to the U.S. EPA chronic oral RfD value of 0.07 mg/kg•day. This chronic-based oral toxicity value is "approximately 40-fold less than the lower end of the frank toxicity level of soluble barium in humans" (FDEP, 1999). In addition, the bioavailability of barium in soil was set by FDEP equivalent to the maximum rate (i.e., 100%) (FDEP, 1999). Based on a single soil ingestion rate that is reflective of severe pica behavior (10 g/day) and a child assumed body weight of 15 kg, the FDEP acute toxicity SCTL for

barium is 105 mg/kg. Table 1 summarizes the derivation of the FDEP acute toxicity SCTL for barium. The documentation for development of the FDEP SCTLs (FDEP, 1999) states that background concentrations and chemical form considerations (e.g., soluble versus insoluble barium salts) should be taken into account when considering acute toxicity due to significant difference in toxicity responses. In the FDEP calculations, an assumption of a more toxic form (soluble barium chloride) was employed.

Rationale for Proposed Revision to the Acute Toxicity SCTL

The bioavailability of barium in solution (e.g., drinking water) is significantly elevated compared to barium in solid matrices containing available binding sites (e.g., soil organic carbon). As a result, FDEP's acute toxicity value should reflect this matrix-specific consideration. As mentioned previously, a default bioavailability value (50%) was identified for metals and inorganic analytes in soil (MDEQ, 1999). As presented in Table 1, a default soil bioavailability value of 50% is proposed for use in the calculation of a revised acute toxicity SCTL for barium in order to account for solid matrix effects, and to account for decreased bioavailability from soils on an acute basis.

As cited in the FDEP documentation (FDEP, 1999) and the Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile, evidence exists to indicate that children may exhibit varying sensitivities to barium compounds, dependent upon the form ingested (FDEP, 1999; ATSDR, 1992a). In at least one report, children were shown to have lower sensitivity to barium compounds (e.g., barium carbonate) present in foods

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Table 1

Derivation of the FDEP Acute Toxicity SCTL and a Proposed Revision to the Acute Toxicity SCTL for Barium

FDEP Acute Toxicity SCTL

U.S. EPA Acute Toxicity Baseline Value for Barium (mg/kg)	U.S. EPA Reduction Factor (unitless)	FDEP Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	FDEP Acute Toxicity SCTL (mg/kg)
0.21	3	0.07 [a]	15	100%	10	0.001	105

Proposed Revision to Acute Toxicity SCTL

Proposed Acute Toxicity Baseline Value for Barium (mg/kg)	Reduction Factor (unitless)	Proposed Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	Proposed Revision to Acute Toxicity SCTL (mg/kg)
3 [b]	10 [c]	0.30	15	50% [d]	10	0.001	900

[a] The basis for the FDEP acute oral value is the U.S. EPA chronic oral RfD value for barium. The barium chronic oral RfD value is based on a No Observed Adverse Effect Level (NOAEL) in humans resulting from the ingestion of barium chloride in drinking water (U.S. EPA, 1999a). It should be noted, however, that the bioavailability of analytes in solution (e.g., water) typically is much greater and more rapid than from solid matrices (e.g., soil).

[b] Based on the reported low end of the reported range for acute toxic effects for barium (3 mg/kg to 7 mg/kg; WHO, 1991).

[c] A reduction factor of ten (10) was included in order to account for potentially more sensitive individuals (e.g., children).

[d] Default bioavailability value for inorganic or metallic analytes in soil (MDEQ, 1999).

when compared to adults (Lewi and Bar-Khayim, 1964). As noted previously, an additional reduction factor of three (3x) was incorporated by U.S. EPA in the derivation of the oral RfD value, an adjustment made to account for database and adult-to-child uncertainties (U.S. EPA, 1999a). Therefore, the additional four-fold reduction factor (4x) that is indirectly employed in setting the FDEP acute SCTL, by using a 40-fold reduction rather than a 10-fold reduction is not necessary under standard practices for application of uncertainty factors.

The use of the chronic oral RfD value (already based on a reduction from a human NOAEL) to represent an acute, single dose is unnecessarily conservative. As reported in the literature (WHO, 1991; McNally, 1925; FDEP, 1999), an acute dose of 3 mg/kg of soluble barium compounds (e.g., salts) is at the lower end of the range for reported toxic effects for humans based on limited gastrointestinal effects (e.g., vomiting). As stated in FDEP (1999), "the symptoms at the lower end of the toxic range would be expected to be reversible within a few days, but may require medical attention". As a result, the proposed alternate acute toxicity value for barium in this document is based on the reported lower end value for the toxicity range based on limited effects (3 mg/kg) and a ten-fold (10x) reduction factor in order to account for potentially more sensitive individuals. As a result, the proposed acute oral benchmark value is 0.30 mg/kg. Based on this proposed acute oral benchmark value, a single soil ingestion value reflective of exceptional and severe pica behavior (10 g/day), a body weight of 15 kg and a default bioavailability value of 50%,

the proposed alternate acute toxicity SCTL for barium is 900 mg/kg (see Table 1).

B. Copper

Summary of the FDEP Acute Toxicity SCTL Basis

The FDEP acute oral value for copper is based on the upper end of the U.S. EPA National Center for Environmental Assessment (NCEA) range of values (0.04 to 0.07 mg/kg·day) for safe chronic exposures. No source documentation or details were provided by FDEP regarding the values cited from the NCEA. The rationale stated in FDEP (1999) for using the NCEA value of 0.07 mg/kg·day for acute toxicity SCTL considerations is that this level coincides with reported gastrointestinal effects for copper compounds in aqueous solution (e.g., tea). Based on a single soil ingestion value reflective of severe pica behavior (10 g/day), a bioavailability in soil of 100%, and a body weight of 15 kg, the FDEP acute toxicity SCTL for copper is 105 mg/kg. Table 2 summarizes the derivation of the FDEP acute toxicity SCTL for copper.

Rationale for Proposed Revision to the Acute Toxicity SCTL

As mentioned previously, the bioavailability of copper ions in solution (e.g., tea) is significantly elevated when compared to copper compounds in solid matrices containing available binding sites (e.g., soil organic carbon). Although this phenomenon of a matrix effect is well-described, it is worth noting that supporting documentation for this position regarding

Table 2

Derivation of the FDEP Acute Toxicity SCTL and a Proposed Revision to the Acute Toxicity SCTL for Copper

FDEP Acute Toxicity SCTL

U.S. EPA NCEA Acute Toxicity Baseline Value for Copper (mg/kg)	FDEP Reduction Factor (unitless)	FDEP Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	FDEP Acute Toxicity SCTL (mg/kg)
0.07[a]	1	0.07	15	100%	10	0.001	105

Proposed Revision to Acute Toxicity SCTL

Proposed Acute Toxicity Baseline Value for Copper (mg/kg)	Reduction Factor (unitless)	Proposed Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	Proposed Revision to Acute Toxicity SCTL (mg/kg)
0.5[b]	1 [c]	0.5	15	35% [d]	10	0.001	2,140[e]

a The copper level reported to cause gastrointestinal effects (0.07 mg/kg) resulting from the ingestion of copper chloride in solution (e.g., tea). However, as specifically stated in the ATSDR (1990) document "copper in soil is often bound to organic molecules, therefore, the bioavailability of copper from soil cannot be assessed based on bioavailability information from drinking water or food studies".

b Level which FAO/WHO Expert Committee concluded that no deleterious effects can be expected in humans on a chronic exposure basis (NRC, 1989).

c No additional reduction factor was included since acute toxicity value was based on no deleterious effects level.

d Bioavailability of copper in diet was reported to range from 30-40% (Wapnir, 1998; NRC, 1989). The value presented (35%) represents the midpoint of the reported range.

e Rounded from 2,143 mg/kg.

matrix-specific bioavailability may be found in the ATSDR toxicological profile document (ATSDR, 1990). As specifically stated in ATSDR (1990), "copper in soil is often bound to organic molecules, therefore, the bioavailability of copper from soil cannot be assessed based on bioavailability information from drinking water or food studies". Thus, food-based bioavailability values may still represent conservative estimates for soil bioavailability, since they are more representative of a soil exposure case than are solution-derived values. Based on a review of the literature, the reported range of bioavailability of copper in the diet is on the order of 30%-40% (Wapnir, 1998; NRC, 1989). The midpoint value (35%) of that reported range was selected as the representative soil bioavailability value for copper in this document.

As reported by the National Research Council (NRC, 1989), a FAO/WHO Expert Committee concluded that no deleterious effects can be expected in humans whose copper intake from dietary sources is equal to or less than 0.5 mg/kg·day. As mentioned previously, this acceptable chronic copper intake value would be considered very conservative for single acute dose considerations. As a result, no additional reduction factor was used and the proposed revised acute oral toxicity value was assumed to be 0.5 mg/kg, per NRC (1989). Based on this acute oral value, a single soil ingestion value indicating severe pica behavior (10 g/day), a body weight of 15 kg, and an assumed soil bioavailability value of 35%, results in a revised acute toxicity SCTL for copper calculated to be 2,143 mg/kg. As presented in Table 2, the revised acute oral SCTL was rounded to 2,140 mg/kg.

C. Cyanide

Summary of the FDEP Acute Toxicity SCTL Basis

As presented on the U.S. EPA IRIS database, the current chronic oral RfD for cyanide is 0.02 mg/kg·day based on a NOAEL of 10.8 mg/kg·day in rats (U.S. EPA, 1999a). Assuming the chronic NOAEL as a starting point, a single soil ingestion value reflective of severe pica behavior (10 g/day), a bioavailability of 100%, reduction factor of five hundred (500x) in calculating the RfD, and a body weight of 15 kg, the FDEP acute toxicity SCTL for cyanide is 30 mg/kg (rounded from 32 mg/kg). The reduction factor (500x) was employed by U.S. EPA and by FDEP to account for uncertainties when deriving the chronic oral RfD value. This reduction factor includes a factor of ten (10x) for animal-to-human extrapolation, a factor of ten (10x) to account for more sensitive populations and a modifying factor of five (5x). Table 3 summarizes the derivation of the FDEP acute toxicity SCTL for cyanide in soil.

Rationale for Proposed Revision to the Acute Toxicity SCTL

As correctly stated in the FDEP (1999) technical document, no toxicity data of high quality for cyanide for humans (e.g., NOAEL or LOAEL) was located in the literature. Due to the lack of acceptable toxicity endpoints (e.g., nonlethal effects) for humans and the often exceptional toxicity of cyanide compounds, the chronic oral RfD value was also used in the present document as a foundation to calculate the proposed alternative acute toxicity SCTL. However, it is important to note that the U.S. EPA chronic oral RfD already includes a reduction factor (i.e., modifying

Table 3

Derivation of the FDEP Acute Toxicity SCTL and a Proposed Revision to the Acute Toxicity SCTL for Cyanide

FDEP Acute Toxicity SCTL

U.S. EPA Acute Toxicity Baseline Value for Cyanide (mg/kg)	U.S. EPA Reduction Factor (unitless)	FDEP Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	FDEP Acute Toxicity SCTL (mg/kg)
10.8	500[b]	0.02[a]	15	100%	10	0.001	30[c]

Proposed Revision to Acute Toxicity SCTL

Proposed Acute Toxicity Baseline Value for Cyanide (mg/kg)	Reduction Factor (unitless)	Proposed Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	Proposed Revision to Acute Toxicity SCTL (mg/kg)
10.8[a]	100[d]	0.11	15	100%	10	0.001	160[e]

[a] The FDEP acute oral toxicity value is the chronic oral RfD value for cyanide. The oral RfD value is based on animal (rat) ingestion studies (U.S. EPA, 1999a). No acceptable (e.g., NOAEL or LOAEL) toxicity data for cyanide for humans were located in the literature. Due to the lack of acceptable toxicity endpoints, the chronic oral RfD value for cyanide was also used to calculate the proposed revision to the acute toxicity SCTL.

[b] A reduction factor of five hundred (500) was used in the derivation of the chronic oral RfD value for cyanide (U.S. EPA, 1999a).

[c] Value was rounded to 30 mg/kg from 32 mg/kg.

[d] As stated in IRIS (U.S. EPA, 1999a), "a modifying factor of 5 is used to account for the apparent tolerance to cyanide when it is ingested in food rather than administered by gavage or by drinking water". Thus, the five hundred (500) reduction factor for cyanide (used in the FDEP derivation) includes a drinking water/gavage component that is not applicable for acute soil ingestion considerations. As a result, the reduction factor of one hundred (100) should be used in order to account for animal-to-human extrapolation and more sensitive individuals (e.g., children).

[e] Rounded from 162 mg/kg.

factor) of five (5x), a value which is specifically included in order to account for differences between toxicity following food intake and that following nonfood exposures (e.g., drinking water). As stated in the IRIS database profile, "a modifying factor of 5 is used to account for the apparent tolerance to cyanide when it is ingested with food rather than when it is administered by gavage [direct gastric intubatia] or by drinking water" (U.S. EPA, 1999a). This observation reasonably may be extended to the soil matrix as well. This "drinking water" modifying factor would then not be applicable for soil ingestion considerations in acute circumstances. Removing the drinking water modifying factor of five (5x), an aggregate reduction factor of one hundred (100x) was used to derive the proposed revision to the acute toxicity SCTL. The initial reduction factor of one hundred (100x) applied in calculation of the U.S. EPA RfD was based on a factor of ten (10x) for animal-to-human species extrapolation and a factor of ten (10x) for sensitive populations (e.g., children). As a result, the proposed acute oral value is calculated as 0.11 mg/kg.

Bioavailability considerations for solid matrices (e.g., food) have been taken into account by removing the drinking water modifying factor (see above). In order to avoid the potential for "double counting" regarding the modifying factor, it was conservatively assumed that 100% of the cyanide in soil was bioavailable in this term of the equation.

Based on a single soil ingestion value reflective of severe pica behavior (10 g/day), a soil bioavailability of 100%, a reduction factor of one hundred

(100x) and a body weight of 15 kg, the proposed alternate acute toxicity SCTL for cyanide is 160 mg/kg (rounded from 162 mg/kg). Table 3 summarizes both the derivation of the FDEP acute toxicity SCTL for cyanide and the proposed revision to the acute toxicity SCTL for cyanide.

D. Fluoride

Summary of the FDEP Acute Toxicity SCTL Basis

The FDEP acute toxicity SCTL for fluoride in soil is based on a single dose of less than or equal to 5 mg after which no gastrointestinal symptoms were reported. Based on a single soil ingestion value reflective of severe pica behavior (10 g/day) and a bioavailability in soil of 100%, the FDEP acute toxicity SCTL is 500 mg/kg (5 mg ingested dose per 10 g of soil). Table 4 presents the derivation of the FDEP acute toxicity value for fluoride in soil.

Rationale for Proposed Revision to the Acute Toxicity SCTL

The Hazardous Substances Data Bank (HSDB, 1999), includes an entry which states that "accidental ingestion of sodium fluoride by children usually does not present serious risk if the amount of fluoride ingested is less than 5 mg/kg". Using the low end (3 mg/kg) of the reported range that may cause limited gastrointestinal symptoms (3 mg/kg to 5 mg/kg), the proposed acute toxicity is 3 mg/kg for fluoride. No reduction factor was included since the proposed toxicity value was based on a study of children and as stated in the ATSDR, "the faster uptake of fluoride to the

Table 4

Derivation of the FDEP Acute Toxicity SCTL and a Proposed Revision to the Acute Toxicity SCTL for Fluoride

FDEP Acute Toxicity SCTL

FDEP Acute Toxicity Baseline Value for Fluoride (mg/kg)	FDEP Reduction Factor (unitless)	FDEP Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	FDEP Acute Toxicity SCTL (mg/kg)
NR[a]	NR	NR	NA	100%	10	0.001	500[e]

Proposed Revision to Acute Toxicity SCTL

Proposed Acute Toxicity Baseline Value for Fluoride (mg/kg)	Reduction Factor (unitless)	Revised Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	Proposed Revision to Acute Toxicity SCTL (mg/kg)
3[b]	1[c]	3	15	90%[d]	10	0.001	5,000

NA Not applicable.
NR Not reported.

a An absolute dose of 5 mg was used as the basis to derive the proposed FDEP acute toxicity SCTL for fluoride.
b The value reflects the low end of reported range causing gastrointestinal symptoms (3 mg/kg to 5 mg/kg). As stated in HSDB, "accidental ingestion of sodium fluoride by children usually does not present serious risk if the amount of fluoride ingested is less than 5 mg/kg" (HSDB, 1999).
c No reduction factor was included since the acute toxicity endpoint was based on a sensitive potential receptor group (e.g., children).
d Based on the reported bioavailbility from food sources (Cerklewski, 1997).
e The proposed FDEP value was based on 5 mg (single dose) per 10 grams of soil (FDEP, 1999).

bone in children helps clear fluoride from the bloodstream" (ATSDR, 1993). Table 4 summarizes the derivation of the proposed revision to the acute toxicity value for fluoride.

A review of the literature indicates that approximately 90% of fluoride in food is bioavailable (Cerklewski, 1997). As a result, the bioavailability of fluoride from soil was assumed to be 90%.

Based on a single soil ingestion value reflective of severe pica behavior (10 g/day), a soil bioavailability of 90% and a body weight of 15 kg, the revised acute toxicity SCTL for fluoride is 5,000 mg/kg. The U.S. EPA Region III Risk-Based Concentration Table (RBC) for the child residential exposure scenario presents a soil target of 4,700 mg/kg for fluorine, based on chronic soil ingestion (U.S. EPA, 1999b). A comparison of the revised acute toxicity SCTL and the applicable chronic risk-based value (RBC) indicates that acute toxicity considerations for fluoride in soil is limited and chronic-based SCTLs would be more applicable. Table 4 summarizes the derivation of the revised acute toxicity SCTL for fluoride.

E. Nickel

Summary of the FDEP Acute Toxicity SCTL Basis

The FDEP acute toxicity SCTL for nickel is based on the low end (7 mg/kg) of the predicted ingested dose range (7 mg/kg to 36 mg/kg) for workers who ingested nickel sulfate and nickel chloride in solution

(Sunderman et al., 1988). An additional reduction factor of one hundred (100x) was used to derive an acute oral value of 0.07 mg/kg. The scientific rationale for the reduction factor of one hundred (100x) was not presented, though presumably it was designed to represent a 10-fold reduction for LOAEL to NOAEL extrapolation and as additional 10-fold reduction for potential sensitive populations.

Based on a single soil ingestion value reflective of severe pica behavior (10 g/day), a reduction factor of one hundred (100x), a soil bioavailability of 100% and a body weight of 15 kg, the FDEP acute toxicity SCTL for nickel is 105 mg/kg. Table 5 summarizes the derivation of the FDEP acute toxicity SCTL for nickel.

Rationale for Proposed Revision to the Acute Toxicity SCTL

The proposed revision to the acute toxicity SCTL for nickel in the present document is based also on the low end (7 mg/kg) of the predicted ingested dose range (7 mg/kg to 36 mg/kg) for workers who ingested nickel sulfate and nickel chloride in water (Sunderman et al., 1988). It is reasonable to assume that those individuals in the group receiving the lowest doses were those whose symptoms were "predominantly gastrointestinal and resolved within a day or two". A reduction factor of ten (10x) was applied to account for potentially more sensitive groups, resulting in a revised acute oral value of 0.7 mg/kg. However, according to the current ATSDR (1997) Toxicological Profile, nickel in solids (e.g., food) is on the order of forty (40x) times less bioavailable than nickel in solution (e.g., water). As a result, the bioavailability of nickel in soil

Table 5

Derivation of the FDEP Acute Toxicity SCTL and a Proposed Revision to the Acute Toxicity SCTL for Nickel

FDEP Acute Toxicity SCTL

FDEP Acute Toxicity Baseline Value for Nickel (mg/kg)	FDEP Reduction Factor (unitless)	FDEP Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	FDEP Acute Toxicity SCTL (mg/kg)
7 [a]	100 [b]	0.07	15	100%	10	0.001	105

Proposed Revision to Acute Toxicity SCTL

Proposed Acute Toxicity Baseline Value Nickel (mg/kg)	Reduction Factor (unitless)	Revised Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	Proposed Revision to Acute Toxicity SCTL (mg/kg)
7	10 [c]	0.7	15	5.0% [c]	10	0.001	21,000

[a] The FDEP acute toxicity value is based on the low end of the reported toxicity range (7 mg/kg to 36 mg/kg). The value is based on the ingestion of nickel sulfate, nickel chloride and boric acid in drinking water (Sunderman et al., 1988). As mentioned previously, the bioavailability of analytes in solution (e.g., water) is significantly greater than solid matrices (e.g., soil).

[b] No scientific basis was presented for the derivation of this factor.

[c] A reduction factor of ten (10) was included in order to account for more sensitive individuals (e.g., children).

[d] As stated in the ATSDR (1997), the bioavailability of nickel in food is 40 times less than the bioavailability of nickel in solution (e.g., water). As a result, if the bioavailability of nickel in solution is conservatively assumed to be complete (100%), then the corresponding soil bioavailability would be 2.5% (100%/40). It was conservatively assumed that 5% represents the bioavailability of nickel in soil.

would be approximately 2.5%, if the bioavailability of nickel in aqueous solution is conservatively assumed to be at the maximum (100%). Therefore, the revised acute toxicity SCTL for nickel in soil is based on a conservative bioavailability value of 5%.

Based on a single soil ingestion value reflective of severe pica behavior (10 g/day), a reduction factor of ten (10x), a soil bioavailability of 5%, and a body weight of 15 kg, the proposed revision to the acute toxicity SCTL for nickel is 21,000 mg/kg. The RBC for nickel for the child residential exposure scenario is 1,600 mg/kg based on chronic soil ingestion (U.S. EPA, 1999b). A comparison of the revised acute toxicity SCTL and the applicable chronic risk-based value (RBC) indicates that acute toxicity considerations for nickel in soil is limited and chronic-based SCTLs would be more applicable. Table 5 summarizes the derivation of the proposed revision to the acute toxicity SCTL for nickel.

F. Vanadium

Summary of the FDEP Acute Toxicity SCTL Basis

The FDEP acute toxicity SCTL for vanadium is based on an acute oral toxicity value of 0.01 mg/kg. The FDEP acute oral value was based on the low end the range reported to cause gastrointestinal and other symptoms (0.47 mg/kg to 1.3 mg/kg; Dimond et al., 1963) and a reduction factor of fifty (50x). The technical rationale for the reduction factor of fifty (50x) is not provided. It should be noted that the FDEP acute oral value of (0.01

mg/kg) is essentially equal to the U.S. EPA chronic oral value for vanadium pentoxide (0.009 mg/kg; U.S. EPA, 1999a). It was assumed that vanadium was 100% bioavailable from soil. Table 6 summarizes the derivation of the FDEP acute toxicity SCTL for vanadium in soil.

Rationale for Proposed Revision to the Acute Toxicity SCTL

As discussed for other compounds in this document, the use of extended duration studies to represent a single acute dose is unnecessarily conservative. The FDEP acute oral value of 0.01 mg/kg was based on a human study where volunteers ingested ammonium vanadyl tartrate in capsules over a 45 day to 68 day period (1.5 to 3.2 months; Dimond et al., 1963). From a review of the cited study, the FDEP evaluation concluded that 0.47 mg/kg•day represented LOAEL citing gastrointestinal effects based on the lower end of the dosage range (0.47 to 1.3 mg/kg•day) (Dimond et al., 1963). However, based the same study, the ATSDR derived a NOAEL of 1.3 mg/kg•day for systemic effects in humans citing the Dimond et al. (1963) study, and based on a lack of systemic toxicity in any organ system at the highest dose tested (1.3 mg/kg•day). As noted in the ATSDR (1992b) document regarding the Dimond et al. study, since vehicle and compound controls were not used, it is difficult to determine whether this effect (gastrointestinal) was caused by the vanadium. There is no way to determine whether the ammonium moiety of the vanadium compound used in the Dimond et al. study, or the vanadium itself may have been the sole source of the gastrointestinal irritation. More recent dietary supplementation studies of vanadyl compounds in humans without the ammonium ion indicate that doses even above 1.3

Table 6

Derivation of the FDEP Acute Toxicity SCTL and a Proposed Revision to the Acute Toxicity SCTL for Vanadium

FDEP Acute Toxicity SCTL

FDEP Acute Toxicity Baseline Value for Vanadium (mg/kg)	FDEP Reduction Factor (unitless)	FDEP Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	FDEP Acute Toxicity SCTL (mg/kg)
0.47[a]	50[b]	0.01	15	100%	10	0.001	15

Proposed Revision to Acute Toxicity SCTL

Proposed Acute Toxicity Baseline Value Vanadium (mg/kg)	Reduction Factor (unitless)	Revised Acute Oral Value (mg/kg)	Body Weight (kg)	Bioavailability from Soil (unitless)	Acute Soil Ingestion Rate (g)	Conversion Factor (kg/g)	Proposed Revision to Acute Toxicity SCTL (mg/kg)
1.43[e]	10[d]	0.143	15	50%[c]	10	0.001	430[f]

a The ATSDR (1992b) states that "since the vehicle and compound controls were not used, it is difficult to determine whether this effect was caused by vanadium. No systemic effects were observed in volunteers consuming ammonium vanadyl tartrate in capsules...". The FDEP acute toxicity value is not based on the ATSDR-derived NOAEL from the cited study (Dimond et al., 1963).
b No scientific basis was presented for the derivation of this factor aside from a text comment.
c Default bioavailability value for inorganic or metallic analytes in soil (MDEQ, 1999).
d A reduction factor of ten (10) was included in the revised acute toxicity calculation in order to account for potentially more sensitive individuals (e.g., children).
e Value based on a recent dietary supplementation study with vanadyl sulfate (Boden et al., 1996).
f Value rounded from 429 mg/kg.

mg/kg·day from the Dimond et al. study are well-tolerated. For example, a dietary supplementation study with sodium metavanadate at a dosage of 125 mg/day (approximately 1.79 mg/kg·day over a 14 day period) was well-tolerated with limited mild gastrointestinal symptoms (Goldfine et al., 1995). In another study, vanadyl sulfate administered to non-insulin dependent diabetic patients at a level of 1.43 mg/kg·day for 28 days was also well-tolerated with limited mild gastrointestinal symptoms (Boden et al., 1996). Based on the more recent dietary supplement studies of shorter duration (e.g., 28 days), a 1.43 mg/kg acute oral value and a ten-fold (10x) reduction factor were used to derive a proposed revised acute oral value of 0.143 mg/kg. The ten-fold (10x) reduction factor was included in the proposed acute oral value in order to account for potentially more sensitive individuals (e.g., children).

No bioavailability values for vanadium in soil were identified in the literature. As a result, a default bioavailability value (50%) for metals and other inorganic analytes in soil was used (MDEQ, 1999).

Based on the proposed revision to the acute oral value, a single soil ingestion value reflective of severe pica behavior (10 g/day), a body weight of 15 kg, and a default bioavailability value of 50%, the revised acute toxicity SCTL for vanadium is calculated to be 430 mg/kg (rounded from 429 mg/kg). Table 6 presents the derivation of the revised acute toxicity SCTL for vanadium in soil.

III. Conclusion

The development of acute toxicity-based SCTLs by the FDEP for six substances (barium, copper, cyanide, fluoride, nickel and vanadium) based on a single severe soil ingestion event by a child, was investigated in detail. A review of the available literature indicates that revisions to the FDEP acute toxicity SCTLs may be appropriate in some cases. As a result, proposed revised acute toxicity SCTLs were developed in this report based on soil bioavailability, revised acute toxicity data and other applicable chemical-specific considerations. In some cases (e.g., nickel and fluoride), acute toxicity considerations may not be warranted; rather these substances may be adequately addressed by SCTL values that reflect chronic exposure circumstances which are the basis for the majority of the FDEP SCTLs under Chapter 62-777, F.A.C.

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