

## 8. REGULATIONS AND ADVISORIES

No international regulations pertaining to fluorides were found. The national and state regulations and guidelines regarding fluorides, hydrogen fluoride, and fluorine in air, water, and other media are summarized in Table 8-1.

A chronic-duration oral MRL of 0.05 mg fluoride/kg/day has been derived for fluoride. This MRL is based on a NOAEL of 0.15 mg fluoride/kg/day and a LOAEL of 0.25 mg fluoride/kg/day for skeletal effects (increased fracture rate) (Li et al. 2001). The MRL was derived by dividing the NOAEL by an uncertainty factor of 3 to account for human variability.

An acute-duration inhalation MRL of 0.02 ppm fluoride has been derived for hydrogen fluoride. This MRL is based on a minimal LOAEL of 0.5 ppm for upper respiratory tract inflammation in humans exposed to hydrogen fluoride for 1 hour (Lund et al. 1997, 1999). The MRL was derived by dividing the unadjusted LOAEL by an uncertainty factor of 30 (3 for a use of a minimal LOAEL and 10 to account for human variability).

An acute-duration inhalation MRL of 0.01 ppm has been derived for fluorine. This MRL is based on a NOAEL of 10 ppm for respiratory irritation in humans exposed to fluorine for 15 minutes (Keplinger and Suissa 1968). The MRL was derived by dividing the 24-hour adjusted NOAEL of 0.1 ppm by an uncertainty factor of 10 to account for human variability.

EPA (IRIS 2003) derived an oral reference dose (RfD) of 0.06 mg/kg/day for fluorine (soluble fluoride). The RfD was based on a NOAEL of 0.06 mg/kg/day and a LOAEL of 0.12 mg/kg/day for the cosmetic effect of dental fluorosis in children (Hodge 1950). The NOAEL was divided by an uncertainty factor of 1 to derive the RfD.

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**Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine**

| Agency                      | Description  | Information   | Reference   |
|-----------------------------|--|---|---|
| <u>INTERNATIONAL</u>        |  |   |   |
| Guidelines:                 |  |   |   |
| IARC                        | Carcinogenicity classification<br>Fluoride and sodium fluoride   | Group 3 <sup>a</sup>  | IARC 1987   |
| WHO                         | Drinking water guideline<br>Fluoride   | 1.5 mg/L  | WHO 2001  |
| <u>NATIONAL</u>             |  |   |   |
| Regulations and Guidelines: |  |   |   |
| a. Air                      |  |   |   |
| ACGIH                       | TLV-TWA<br>Fluoride<br>Fluorine<br>STEL (ceiling)<br>Fluorine<br>Hydrogen fluoride   | 2.5 mg/m <sup>3</sup><br>1.0 ppm<br>2.0 ppm<br>3.0 ppm  | ACGIH 2000  |
| EPA                         | Accidental release prevention<br>Threshold quantity<br>Fluorine<br>Hydrogen fluoride<br>Accidental release prevention<br>Toxic end point<br>Fluorine<br>Hydrogen fluoride  | 1,000 pounds<br>1,000 pounds<br>0.0039 mg/L<br>0.0160 mg/L  | EPA 2001b<br>40CFR68.130<br>Table 1<br>EPA 2001a<br>40CFR68<br>Appendix A   |
| OSHA                        | PEL (8-hour TWA)<br>General industry<br>Fluoride<br>Fluorine<br>Hydrogen fluoride<br>PEL (8-hour TWA)<br>Construction industry<br>Fluoride<br>Fluorine<br>Hydrogen fluoride<br>PEL (8-hour TWA)<br>Shipyards<br>Fluoride<br>Fluorine<br>Hydrogen fluoride<br>Highly hazardous chemicals<br>Threshold quantity<br>Fluorine<br>Highly hazardous chemicals<br>Threshold quantity<br>Hydrogen fluoride | 2.5 mg/m <sup>3</sup><br>0.2 mg/m <sup>3</sup><br>2.0 mg/m <sup>3</sup><br>2.5 mg/m <sup>3</sup><br>0.2 mg/m <sup>3</sup><br>2.0 mg/m <sup>3</sup><br>2.5 mg/m <sup>3</sup><br>0.2 mg/m <sup>3</sup><br>2.0 mg/m <sup>3</sup><br>1,000 pounds<br>1,000 pounds | OSHA 2001c<br>29CFR1910.1000<br>Table Z-1<br>OSHA 2001f<br>29CFR1926.55<br>Appendix A<br>OSHA 2001a<br>29CFR1915.1000<br>Table Z<br>OSHA 2001d<br>29CFR1910.119<br>Appendix A<br>OSHA 2001e<br>29CFR1926.64<br>Appendix A |

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**Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine**

| Agency                  | Description   | Information                          | Reference                           |
|-------------------------|---|--------------------------------------|-------------------------------------|
| <b>NATIONAL (cont.)</b> |   |                                      |                                     |
| OSHA                    | Brazing and gas welding fluxes shall have a cautionary wording to indicate that they contain fluorine compounds                                   |                                      | OSHA 2001b<br>29CFR1910.252(c)(1)   |
| NIOSH                   | REL (TWA)   |                                      | NIOSH 2001a                         |
|                         | Fluorine  | 0.2 mg/m <sup>3</sup>                | NIOSH 2001b                         |
|                         | Hydrogen fluoride   | 2.5 mg/m <sup>3</sup>                | NIOSH 2001c                         |
|                         | Sodium fluoride   | 2.5 mg/m <sup>3</sup>                |                                     |
| NIOSH                   | IDLH  |                                      | NIOSH 2001a                         |
|                         | Fluorine  | 25 ppm                               | NIOSH 2001b                         |
|                         | Hydrogen fluoride   | 30 ppm                               | NIOSH 2001c                         |
| USC                     | HAP   |                                      | USC 2001<br>42USC7412               |
| <b>b. Water</b>         |   |                                      |                                     |
| EPA                     | BPT effluent limitation—fluoride  |                                      | EPA 2001c                           |
|                         | Maximum for 1 day   | 6.1 kg/kkg                           | 40CFR415.82                         |
|                         | Average of daily values for 30 consecutive days   | 2.9 kg/kkg                           |                                     |
|                         | Effluent limitation—fluoride  |                                      | EPA 2001e                           |
|                         | Maximum for 1 day   | 75 mg/L                              | 40CFR422.42                         |
|                         | Average of daily values for 30 consecutive days   | 25 mg/L                              |                                     |
|                         | Groundwater protection standards at inactive uranium processing sites—listed constituents include fluorine and hydrogen fluoride                  |                                      | EPA 2001f<br>40CFR192<br>Appendix I |
|                         | MCLG—fluoride   | 4.0 mg/L                             | EPA 2001j<br>40CFR141.51(b)         |
|                         | MCL—fluoride  | 4.0 mg/L                             | EPA 2001k<br>40CFR141.62(b)         |
|                         | Secondary MCL—fluoride  | 2.0 mg/L                             | EPA 2001l<br>40CFR143.3             |
| EPA                     | Water pollution—hazardous substance designation   | Hydrogen fluoride<br>Sodium fluoride | EPA 2001r<br>40CFR116.4             |
|                         |   |                                      |                                     |
| <b>c. Food</b>          |   |                                      |                                     |
| EPA                     | Pesticides—fluorine compounds; residue tolerances   |                                      | EPA 2001n<br>40CFR180.145           |
|                         | Apricots, beets, blackberries, blueberries, boysenberries, broccoli, brussels sprouts, cabbage, cauliflower, citrus fruits, collards, cranberries | 7 ppm                                |                                     |

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| Agency   | Description  | Information   | Reference                       |                           |
|--|--|---|---------------------------------|---------------------------|
| <u>NATIONAL</u> (cont.)  |  |   |                                 |                           |
| EPA  | Pesticides—fluorine compounds; residue tolerances  |   | EPA 2001n<br>40CFR180.145       |                           |
|  | Cucumbers, dewberries, eggplant, grapes, kale, kohlrabi, lettuce, loganberries, melons, nectarines, peaches, peppers, plums, pumpkins, radish, raspberries, rutabaga, squash, strawberries, tomatoes, turnip, youngberries | 7 ppm   |                                 |                           |
|  | Potatoes   | 2 ppm   |                                 |                           |
|  | Potatoes, processing waste<br>Kiwifruit  | 22 ppm<br>15 ppm  |                                 |                           |
| FDA  | Adhesive component, indirect food additive—for use only as bonding agent for aluminum foil, stabilizer, or preservative  | Total fluoride from all sources not to exceed 1% by weight of the finished adhesive | FDA 2000e<br>21CFR175.105(c)(5) |                           |
|  | Hydrogen fluoride<br>Sodium fluoride   |   |                                 |                           |
|  | Bottled water—no fluoride added  | <u>Temperature</u> <sup>b</sup>   | <u>mg/L</u>                     | FDA 2000g<br>21CFR165.110 |
|  |  | 53.7–below  | 2.4                             |                           |
|  |  | 53.8–58.3   | 2.2                             |                           |
|  |  | 58.4–63.8   | 2.0                             |                           |
|  |  | 63.9–70.6   | 1.8                             |                           |
|  |  | 70.7–79.2   | 1.6                             |                           |
|  |  | 79.3–90.5   | 1.4                             |                           |
|  | Bottled water—fluoride added   | <u>Temperature</u> <sup>b</sup>   | <u>mg/L</u>                     |                           |
|  |  | 53.7–below  | 1.7                             |                           |
|  |  | 53.8–58.3   | 1.5                             |                           |
|  |  | 58.4–63.8   | 1.3                             |                           |
| 63.9–70.6  |  | 1.2   |                                 |                           |
| 70.7–79.2  |  | 1.0   |                                 |                           |
| 79.3–90.5  |  | 0.8   |                                 |                           |
| Over-the-counter drug products                                     |  | FDA 2000b<br>21CFR355.50  |                                 |                           |
| Labeling—fluoride, fluorine, and sodium fluoride                   |  | FDA 2000c<br>21CFR355.60  |                                 |                           |
| Over-the-counter drug products                                     |  | FDA 2000d<br>21CFR355.70  |                                 |                           |
| Testing—fluoride   |  | FDA 2000a<br>21CFR355.10  |                                 |                           |
| Over-the-counter drug products                                     |  | FDA 2000f<br>21CFR310.545(a)(2)   |                                 |                           |
| Active ingredient—fluorine, hydrogen fluoride, and sodium fluoride |  |   |                                 |                           |

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| Agency                  | Description  | Information  | Reference   |
|-------------------------|--|--|---|
| <u>NATIONAL</u> (cont.) |  |  |   |
| FDA                     | Surface component, food contact—sodium fluoride for use as preservative only   |  | FDA 2000h<br>21CFR177.2800<br>(d)(5)  |
| d. Other                |  |  |   |
| ACGIH                   | Carcinogenicity classification<br>Fluoride<br>BEI<br>Fluorides in urine<br>Prior to shift<br>End of shift  | A4 <sup>c</sup><br><br><br>3 mg/g creatinine<br>10 mg/g creatinine   | ACGIH 2000  |
| CPSC                    | Requirements for child-resistant packaging for household products containing elemental fluoride  | More than 50 mg and more than 0.5%   | CPSC 2001<br>16CFR1700  |
| DOT                     | Hazardous materials<br>Reportable quantity<br>Fluorine<br>Hydrogen fluoride<br>Sodium fluoride   | <br><br>10 pounds<br>100 pounds<br>1,000 pounds  | DOT 2001<br>40CFR172.101<br>Appendix A  |
| EPA                     | RfD—fluorine<br>Toxic chemical release reporting;<br>Community Right-to-Know—effective date<br>Fluorine<br>Hydrogen fluoride<br>Contaminated soil—fluoride<br>Hazardous waste—health based limits for exclusion of waste-derived-residue<br>Fluorine residue concentration limit<br>Hazardous waste—identification and listing<br>Fluorine<br>Hydrogen fluoride<br>Pesticides—residue tolerances<br>Sodium fluoride<br>Superfund—reportable quantity<br>Fluorine<br>Hydrogen fluoride<br>Sodium fluoride | <br><br><br>01/01/95<br>01/01/87<br>Concentrations greater than 10 times UTS<br><br><br>4.0 mg/kg<br><br><br>P056<br>U134<br>Not more than 25% of pesticide formulation<br><br>1 pound<br>5,000 pounds<br>5,000 pounds | IRIS 2003<br>EPA 2001q<br>40CFR372.65<br><br>EPA 2001d<br>40CFR268.49(f)<br>EPA 2001g<br>40CFR266<br>Appendix VII<br><br>EPA 2001h<br>40CFR261.33(e)<br>EPA 2001i<br>40CFR261.33(f)<br>EPA 2001m<br>40CFR180.1001(d)<br>EPA 2001o<br>40CFR302.4<br>Appendix A |

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**Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine**

| Agency                  | Description  | Information  | Reference               |                                     |                       |          |
|-------------------------|--|--|-------------------------|-------------------------------------|-----------------------|----------|
| <u>NATIONAL</u> (cont.) |  |  |                         |                                     |                       |          |
| EPA                     | Superfund—extremely hazardous<br>Reportable quantity               | Fluorine   | 10 pounds               | EPA 2001p<br>40CFR355<br>Appendix A |                       |          |
|                         |  | Hydrogen fluoride                                      | 100 pounds              |                                     |                       |          |
|                         | Threshold planning quantity  | Fluorine   | 500 pounds              |                                     |                       |          |
|                         |  | Hydrogen fluoride                                      | 100 pounds              |                                     |                       |          |
|                         | <u>STATE</u>   |  |                         |                                     |                       |          |
|                         | a. Air   |  |                         |                                     |                       |          |
| Connecticut             | HAP—fluoride, fluorine, and<br>hydrogen fluoride                   |  | BNA 2001                |                                     |                       |          |
| Hawaii                  | Air contaminant—hydrogen<br>fluoride                               |  | BNA 2001                |                                     |                       |          |
| Idaho                   | Toxic air pollutants<br>Fluoride                                   | OEL  | 2.5 mg/m <sup>3</sup>   | BNA 2001                            |                       |          |
|                         |  | EL   | 0.167 pounds/hour       |                                     |                       |          |
|                         |  | AAC  | 0.125 mg/m <sup>3</sup> |                                     |                       |          |
|                         | Fluorine   | OEL  | 2.0 mg/m <sup>3</sup>   |                                     |                       |          |
|                         |  | EL   | 0.133 pounds/hour       |                                     |                       |          |
|                         |  | AAC  | 0.1 mg/m <sup>3</sup>   |                                     |                       |          |
|                         | Michigan   | PEL (TWA)<br>Fluoride<br>Fluorine<br>Hydrogen fluoride | Fluoride                |                                     | 2.5 mg/m <sup>3</sup> | BNA 2001 |
|                         |  |  | Fluorine                |                                     | 0.2 mg/m <sup>3</sup> |          |
|                         |  |  | Hydrogen fluoride       |                                     | 3.0 ppm               |          |
| Montana                 | Air contaminant (TWA)<br>Fluoride<br>Fluorine<br>Hydrogen fluoride | Fluoride   | 2.5 mg/m <sup>3</sup>   | BNA 2001                            |                       |          |
|                         |  | Fluorine   | 0.2 mg/m <sup>3</sup>   |                                     |                       |          |
|                         |  | Hydrogen fluoride                                      | 2.0 mg/m <sup>3</sup>   |                                     |                       |          |
| New Mexico              | Toxic air pollutant<br>Fluorides                                   | OEL  | 2.5 mg/m <sup>3</sup>   | BNA 2001                            |                       |          |
|                         |  | Emissions  | 0.167 pounds/hour       |                                     |                       |          |
|                         | Fluorine   | OEL  | 2.0 mg/m <sup>3</sup>   |                                     |                       |          |
|                         |  | Emissions  | 0.133 pounds/hour       |                                     |                       |          |
| New York                | Air contaminant (TLV)<br>Fluoride<br>Fluorine<br>Hydrogen fluoride | Fluoride   | 2.5 mg/m <sup>3</sup>   | BNA 2001                            |                       |          |
|                         |  | Fluorine   | 0.2 mg/m <sup>3</sup>   |                                     |                       |          |
|                         |  | Hydrogen fluoride                                      | 2.0 mg/m <sup>3</sup>   |                                     |                       |          |

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**Table 8-1. Regulations and Guidelines Applicable to Fluoride, Sodium Fluoride, Hydrogen Fluoride, and Fluorine**

| Agency               | Description                            | Information              | Reference             |          |        |
|----------------------|--|--------------------------|-----------------------|----------|--------|
| <i>STATE (cont.)</i> |  |                          |                       |          |        |
| Washington           | Toxic air pollutant—ASIL               | Fluoride                 | 8.3 µg/m <sup>3</sup> | BNA 2001 |        |
|                      |  | Fluorine                 | 5.3 µg/m <sup>3</sup> |          |        |
|                      |  | Hydrogen fluoride        | 8.7 µg/m <sup>3</sup> |          |        |
|                      | PEL                                    | Fluoride                 | 2.5 mg/m <sup>3</sup> | BNA 2001 |        |
|                      |  | Fluorine                 | 0.2 mg/m <sup>3</sup> |          |        |
|                      |  | Hydrogen fluoride (STEL) | 3.0 ppm               |          |        |
| Wisconsin            | Emission rate (pounds/hour)            | <25 feet                 | >25 feet              | BNA 2001 |        |
|                      |  | Fluoride                 | 0.2088                |          | 0.8640 |
|                      |  | Fluorine                 | 0.1656                |          | 0.6720 |
|                      |  | Hydrogen fluoride        | 0.1272                |          | 0.4800 |
| <b>b. Water</b>      |  |                          |                       |          |        |
| Alaska               | MCL—fluoride                           | 4.0 mg/L                 | BNA 2001              |          |        |
|                      | Secondary MCL—fluoride                 | 2.0 mg/L                 |                       |          |        |
| Arizona              | Drinking water guideline—fluoride      | 4.0 mg/L                 | HSDB 2003             |          |        |
|                      | Reporting limit—fluoride               | 2.0 mg/L                 | BNA 2001              |          |        |
| California           | Drinking water standards—fluoride      | 2.0 mg/L                 | HSDB 2003             |          |        |
| Connecticut          | MCL—fluoride                           | 4.0 mg/L                 | BNA 2001              |          |        |
| Delaware             | Drinking water standards—fluoride      | 1.8 mg/L                 | HSDB 2003             |          |        |
| Georgia              | MCL—fluoride                           | 4.0 mg/L                 | BNA 2001              |          |        |
| Hawaii               | Drinking water standards—fluoride      | 1.4–2.4 mg/L             | HSDB 2003             |          |        |
| Idaho                | Groundwater quality standards—fluoride | 4.0 mg/L                 | BNA 2001              |          |        |
| Kansas               | Agriculture—fluoride                   |                          | BNA 2001              |          |        |
|                      | Livestock                              | 2.0 mg/L                 |                       |          |        |
|                      | Irrigation                             | 1.0 mg/L                 |                       |          |        |
|                      | Public health food—fluoride            |                          |                       |          |        |
| Maine                | Domestic water supply                  | 2.0 mg/L                 | HSDB 2003             |          |        |
|                      | Drinking water guideline—fluoride      | 2.4 mg/L                 |                       |          |        |
|                      | Maximum exposure guideline             | 2.4 mg/L                 |                       |          |        |
| Mississippi          | Action level                           | 1.2 mg/L                 | BNA 2001              |          |        |
|                      | Groundwater standards—fluoride         | 4.0 ppm                  | BNA 2001              |          |        |
| Nebraska             | MCL—fluoride                           | 4.0 mg/L                 | BNA 2001              |          |        |

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| Agency               | Description  | Information                       | Reference |
|----------------------|--|-----------------------------------|-----------|
| <i>STATE (cont.)</i> |  |                                   |           |
| New Jersey           | Groundwater quality criteria—<br>fluoride                                  | 2.0 mg/L                          | BNA 2001  |
|                      | PQL—fluoride   | 0.5 mg/L                          |           |
| New York             | Groundwater effluent limitations—<br>fluoride                              | 3.0 mg/L                          | BNA 2001  |
|                      | MCL—fluoride   | 2.2 mg/L                          | BNA 2001  |
| North Carolina       | Drinking water standards—<br>fluoride                                      | 4.0 mg/L                          | HSDB 2003 |
| North Dakota         | MCL—fluoride   | 4.0 mg/L                          | BNA 2001  |
| Oklahoma             | MCL—fluoride   | 4.0 mg/L                          | BNA 2001  |
| Pennsylvania         | Drinking water standards—<br>fluoride                                      | 2.0 mg/L                          | HSDB 2003 |
| Rhode Island         | MCLG—fluoride  | 4.0 ppm                           | BNA 2001  |
|                      | MCL—fluoride   | 4.0 ppm                           |           |
| South Dakota         | Groundwater quality standards—<br>fluoride                                 | 2.4 mg/L                          | BNA 2001  |
| Tennessee            | MCL—fluoride   | 4.0 ppm                           | BNA 2001  |
| Texas                | MCL—fluoride   | 4.0 mg/L                          | BNA 2001  |
| Utah                 | Groundwater standards  | 4.0 mg/L                          | BNA 2001  |
|                      | MCL—fluoride   | 4.0 mg/L                          | BNA 2001  |
| Vermont              | Groundwater quality standards—<br>fluoride                                 |                                   | BNA 2001  |
|                      | Enforcement standard   | 4.0 mg/L                          |           |
|                      | Preventive action level  | 2.0 mg/L                          |           |
|                      | MCL—fluoride   | 4.0 mg/L                          | BNA 2001  |
| Washington           | MCL—fluoride   | 4.0 mg/L                          | BNA 2001  |
| West Virginia        | Groundwater standards  | Not to exceed 4.0 mg/L            | BNA 2001  |
| Wisconsin            | MCLG—fluoride  | 4.0 mg/L                          | BNA 2001  |
|                      | MCL—fluoride   | 4.0 mg/L                          |           |
|                      | Groundwater standards—fluoride   |                                   | BNA 2001  |
|                      | Enforcement standard   | 4.0 mg/L                          |           |
|                      | Preventive action limit  | 0.8 mg/L                          |           |
| c. Food              |  | No data                           |           |
| d. Other             |  |                                   |           |
| Connecticut          | Use of pesticides; control of<br>registrations and uses—sodium<br>fluoride | For use as a wood<br>preservative | BNA 2001  |



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| Agency               | Description  | Information | Reference |
|----------------------|--|-------------|-----------|
| <i>STATE (cont.)</i> |  |             |           |
| Minnesota            | Hazardous substance—fluoride (as F, as dust), fluorides (inorganic), fluorine, and hydrogen fluoride |             | BNA 2001  |
| New Jersey           | Hazardous substance—fluorine and hydrogen fluoride   |             | BNA 2001  |

<sup>a</sup>Group 3: not classifiable as to its carcinogenicity to humans

<sup>b</sup>Temperature: annual average of maximum daily air temperatures (EF)

<sup>c</sup>A4: not classifiable as a human carcinogen

AAC = acceptable ambient concentrations; ACGIH = American Conference of Governmental Industrial Hygienists; ASIL = acceptable source impact levels; BEI = biological exposure indices; BNA = Bureau of National Affairs; BPT = best practicable control technology; CFR = Code of Federal Regulations; CPSC = Consumer Product Safety Commission; DOT = Department of Transportation; EL = emissions levels; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HAP = hazardous air pollutant; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life and health; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; OEL = occupational exposure limit; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation level; REL = recommended exposure limit; RfD = reference dose; STEL = short term exposure limit; TLV = threshold limit values; TWA = time-weighted average; USC = United States Code; UTS = universal treatment standards; WHO = World Health Organization

