7. REGULATIONS AND ADVISORIES

Because of its potential to cause adverse health effects in exposed persons, a number of regulations and advisories have been established for ethylene oxide by various international, national, and state agencies. These regulations and advisories are summarized in Table 7-1.
### TABLE 7-1. Regulations and Guidelines Applicable to Ethylene Oxide

<table>
<thead>
<tr>
<th>Agency</th>
<th>Description</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>IARC</td>
<td>Carcinogenic classification</td>
<td>Group 2A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>IARC 1987</td>
</tr>
</tbody>
</table>

#### National

**Regulations:**

*a. Air:

EPA OAQPS*  
Hazardous air pollutant notice of intent to list  
No data  
EPA 1985b

*OSHA*  
PEL  
TWA  
Excursion limit (15 min)  
1 ppm  
5 ppm  
OSHA 1988b  
29 CFR 1910.1047

*b. Nonspecific media:

EPA OERR*  
Reportable quantity  
1 lb  
EPA 1985c  
(40 CFR 302.4)

Reportable quantity (proposed)  
10 lb  
EPA 1987a

Extremely hazardous substance threshold planning quantity  
1000 lb  
EPA 1987b  
(40 CFR 355)

EPA OPP*  
Tolerances for residues on raw agricultural commodities  
50 ppm  
40 CFR 180.151

EPA OSW*  
Hazardous waste constituent (Appendix VIII)  
Land disposal restrictions  
No data  
EPA 1980  
(40 CFR 261)

EPA OTS*  
Health and safety data reporting rule  
Preliminary assessment information rule  
Toxic chemical release reporting  
No data  
EPA 1988a (40 CFR 716.120)

No data  
EPA 1982b (40 CFR 712.30)

No data  
EPA 1988b  
(40 CFR 372)

FDA*  
Pungiant for spices permitted  
Tolerance for residue in ground spices  
50 ppm  
21 CFR 193.200

Maximum residue limits in medical devices (proposed)  
5-250 ppm  
FDA 1978

Maximum residue limits in drug products (proposed)  
5-35 ppm  
FDA 1978

Maximum daily exposure level to residues in drug products (proposed)  
30 µg/kg/day  
30 days  
FDA 1978

#### Guidelines:

*a. Air:

ACGIH*  
TLV TWA  
Suspected human carcinogen  
1 ppm (2 mg/m<sup>3</sup>)  
ACGIH 1986

NIOSH*  
IDLH  
Recommended exposure limits  
TWA  
Ceiling (10 min/day)  
<0.1 ppm  
5 ppm  
NIOSH 1988  
NIOSH 1985b

*b. Other:

EPA*  
Carcinogenic classification group B1<sup>b</sup>  
EPA 1985a
7. REGULATIONS AND ADVISORIES

**TABLE 7-1 (Continued)**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Description</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulations:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Air:</td>
<td>Acceptable ambient air concentration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connecticut</td>
<td></td>
<td>20 µg/m³ (8 hr)</td>
<td>NATICH 1988</td>
</tr>
<tr>
<td>Indiana</td>
<td></td>
<td>450 µg/m³ (8 hr)</td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td></td>
<td>0.048 mg/m³ (8 hr)</td>
<td></td>
</tr>
<tr>
<td>New York</td>
<td></td>
<td>6.67 µg/m³ (1 yr)</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td></td>
<td>0.10 µg/m³ (annual)</td>
<td></td>
</tr>
<tr>
<td>North Dakota</td>
<td></td>
<td>0.0 (bact)</td>
<td></td>
</tr>
<tr>
<td>Pennsylvania (Philadelphia)</td>
<td></td>
<td>4.87 µg/m³ (1 yr)</td>
<td></td>
</tr>
<tr>
<td>Rhode Island</td>
<td></td>
<td>0.01 µg/m³ (annual)</td>
<td></td>
</tr>
<tr>
<td>South Carolina</td>
<td></td>
<td>10 µg/m³ (24 hr)</td>
<td></td>
</tr>
<tr>
<td>South Dakota</td>
<td></td>
<td>20 µg/m³ (8 hr)</td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td></td>
<td>20 µg/m³ (24 hr)</td>
<td></td>
</tr>
</tbody>
</table>

\[a\] Group 2A: Probably carcinogenic to humans.


IARC = International Agency for Research on Cancer; EPA = Environmental Protection Agency; OAQPS = Office of Air Quality, Planning and Standards; OSHA = Occupational Safety and Health Administration; PEL = Permissible Exposure Limit; TWA = Time-Weighted Average; OAQPS = Office of Air Quality Planning and Standards; OERR = Office of Emergency and Remedial Response; OPP = Office of Pesticide Programs; OSW = Office of Solid Wastes; OTS = Office of Toxic Substances; FDA = Food and Drug Administration; ACGIH = American Conference of Governmental Industrial Hygienists; TLV = Threshold Limit Value; NIOSH = National Institute for Occupational Safety and Health; IDLH = Immediately Dangerous to Life or Health Level.