



## Phospho-soda® Serious Adverse Experience Rate (USA only)

YEAR	Total Bowel Prep dosage Sales*	Serious Adverse Experiences**	SAE/Million Bowel Prep Doses Sold
1991	988,920	3	3.03
1992	1,220,172	1	0.82
1993	1,176,326	6	5.10
1994	1,409,172	2	1.42
1995	1,687,752	2	1.19
1996	2,097,792	8	3.81
1997	2,425,464	3	1.24
1998	3,036,996	3	0.99
1999	3,902,820	4	1.02
2000	4,489,848	7	1.56
2001	5,382,168	1	0.19
2002	5,674,956	9	1.59
2003	5,084,556	12	2.36
<b>Total</b>	<b>38,576,942</b>	<b>61</b>	<b>Average = 1.58</b>

\*Dosage is expressed in terms of the number of 3 Fl. Oz. (90 mL) equivalents sold; this is the usual bowel cleansing dose (2 x 45 mL). This does not include the individual 1.5 Fl. Oz. units which are sold as part of Fleet Prep Kits. Inclusion of these would artificially lower the SAE rate.

\*\*Serious Adverse Experiences were obtained from the literature, from reports made directly to C. B. Fleet and from FDA's spontaneous reporting system database. The 2003 data does not include any possible SAE's from the FDA Spontaneous Reporting System after May 2003. An update will be performed once all FDA 2003 data is available.