Glycerin may also be used orally in doses of 1.0–1.5 g/kg body-weight to reduce intraocular pressure.

When used as an excipient or food additive, glycerin is not usually associated with any adverse effects and is generally regarded as a nontoxic and nonirritant material.

LD<sub>50</sub> (guinea pig, oral): 7.75 g/kg<sup>(8)</sup> LD<sub>50</sub> (mouse, IP): 8.98 g/kg LD<sub>50</sub> (mouse, IV): 4.25 g/kg LD<sub>50</sub> (mouse, oral): 4.1 g/kg LD<sub>50</sub> (mouse, SC): 0.09 g/kg LD<sub>50</sub> (rabbit, IV): 0.05 g/kg LD<sub>50</sub> (rat, IP): 4.42 g/kg LD<sub>50</sub> (rat, oral): 12.6 g/kg LD<sub>50</sub> (rat, SC): 0.1 g/kg

# **15 Handling Precautions**

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. In the UK, the recommended long-term (8hour TWA) exposure limit for glycerin mist is 10 mg/m<sup>3.(9)</sup> Glycerin is combustible and may react explosively with strong oxidizing agents; *see* Section 12.

## 16 Regulatory Status

GRAS listed. Accepted as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (inhalations; injections; nasal and ophthalmic preparations; oral capsules, solutions, suspensions and tablets; otic, rectal, topical, transdermal, and vaginal preparations). Included in nonparenteral and parenteral medicines licensed in the UK.

## 17 Related Substances

#### **18 Comments**

The EINECS number for glycerin is 200-289-5.

Some pharmacopeias also contain specifications for diluted glycerin solutions. The JP 2001 contains a monograph for 'glycerin' that contains 84-87% of propane-1,2,3-triol (C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>). The PhEur 2002 contains a monograph for 'glycerol 85 per cent' that contains 83.5-88.5% of propane-1,2,3-triol (C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>).

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## 21 Author

JC Price.

## 22 Date of Revision

8 October 2002.

Applications in Phormoceutical For

or recensiogy

Givenyi behemage is used in connectes, toods, and smil pharmachanical formulations. In communic, it is mainly used as a viscobity-increasing agent in combines are I able L. in pharmaceutical formulations, giviered behevate is mainly used as a tablet and capsule labreau.<sup>10</sup> and as a heithe county escipient, it has been increasanted for the encondation of various drugs tuch as artimoids.<sup>11</sup> It has been investigated for use in the preparation at sustained release tables.<sup>10</sup> and as a matus forthing agent for the controlled