

16 Regulatory Status

Denatonium benzoate is used worldwide as a denaturant for alcohol. It is included in the FDA Inactive Ingredients Database (topical gel, solution and swab). Included in the Canadian Natural Health Products Ingredients Database.

As there is a lack of adequate data, any over the counter drug product containing ingredients offered for use as a nail-biting or thumb-sucking deterrent (including denatonium benzoate) cannot be generally recognized as safe and effective.⁽¹¹⁾

17 Related Substances

Sucrose octaacetate.

18 Comments

The EINECS number for denatonium benzoate is 223-095-2. The PubChem Compound ID (CID) for denatonium benzoate is 19518.

19 Specific References

- 1 Klein-Schwartz W. Denatonium benzoate: review of efficacy and safety. *Vet Hum Toxicol* 1991; 33: 545–547.
- 2 Sibert JR. Bittering agents in the prevention of accidental poisoning: children's reactions to denatonium benzoate (Bitrex). *Arch Emerg Med* 1991; 8 (1): 1–7.
- 3 Hansen SR. Denatonium benzoate as a deterrent to ingestion of toxic substances: toxicity and efficacy. *Vet Hum Toxicol* 1993; 35(3): 234–236.
- 4 Rodgers GC. Role of aversive bittering agents in the prevention of pediatric poisonings. *Pediatrics* 1994; 93 (Jan): 68–69.
- 5 White NC. The impact of bittering agents on suicidal ingestions of antifreeze. *Clin Toxicol* 2008; 46(6): 507–514.
- 6 White NC. The impact of bittering agents on pediatric ingestions of antifreeze. *Clin Pediatr* 2009; 49: 913–921.
- 7 Björkner B. Contact urticaria and asthma from denatonium benzoate (Bitrex). *Contact Dermatitis* 1980; 6(7): 466–471.
- 8 Health Canada Pest Management Regulatory Agency. Re-evaluation Decision: Denatonium benzoate, 27 April 2012.
- 9 Cosmetic Ingredient Review Expert Panel. Final report of the safety assessment of alcohol denat, including SD alcohol 3-A, SD alcohol 30, SD alcohol 39, SD alcohol 39-B, SD alcohol 39-C, SD alcohol 40, SD alcohol 40-B, and SD alcohol 40-C, and the denaturants, quassin, brucine sulfate/brucine, and denatonium benzoate. *Int J Toxicol* 2008; 27(Suppl.1): 1–43.
- 10 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 12th edn. New York: Wiley, 2012: 1328
- 11 US Food and Drug Administration. Code of Federal Regulations Title 21 (21CFR 310.536): Drug products containing active ingredients offered over-the-counter (OTC) for use as a nailbiting or thumbsucking deterrent. Revised 1 April 2014.

20 General References

- Anonymous. Relief for warts; none for nail biters. *FDA Consum* 1981; 15(Feb): 13.
- Aversion Technologies Inc. Material safety data sheet: Denatonium benzoate, November 2010. www.denatonium-benzoate.com (accessed 7 September 2014).
- Macfarlan Smith. Bitrex. <http://www.bitrex.com> (accessed 7 September 2014).
- Payne HAS. Bitrex – a bitter solution to safety. *Chem Ind* 1988; 22: 721–723.
- Payne HAS. Bitrex – a bitter solution to product safety. *Drug Cosmet Ind* 1989; 144(May): 30, 32, 34.

21 Author

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22 Date of Revision

4 May 2017.



Dextran

1 Nonproprietary Names

BP:	Dextran 1 for Injection Dextran 40 for Injection Dextran 60 for Injection Dextran 70 for Injection
JP:	Dextran 40 Dextran 70
PhEur:	Dextran 1 for Injection Dextran 40 for Injection Dextran 60 for Injection Dextran 70 for Injection
USP–NF:	Dextran 1 Dextran 40 Dextran 70

2 Synonyms

Glucose polymer; dextrans.

3 Chemical Name and CAS Registry Number

2,3,4,5-Tetrahydroxy-6-[3,4,5-trihydroxy-6-[[3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxymethyl]oxan-2-yl]oxyhexanal [9004-54-0]

4 Empirical Formula and Molecular Weight

Dextran is a branched high-molecular-weight polymer of α -D-glucose (dextrose). Dextran polymers are available in various average molecular weight fractions from 1000 Da (dextran 1) to 2 000 000 Da (dextran 2000), with the most common fractions being 1000 Da (dextran 1), 40 000 Da (dextran 40), and 70 000 Da (dextran 70).⁽¹⁾

The polymer main chain has $\alpha(1\rightarrow6)$ glycosidic linkages with branching occurring primarily at C3, $\alpha(1\rightarrow3)$ glycosidic linkages, and occasionally at C4, $\alpha(1\rightarrow4)$ glycosidic linkages or C2 $\alpha(1\rightarrow2)$ glycosidic linkages. Commercially available dextrans contain about 95% $\alpha(1\rightarrow6)$ glycosidic linkages of the main chain and about 5% side branching. About 80% of the side branches are single α -D-glucose subunits with the remaining branches a mixture of side-chains of various lengths.⁽²⁾