CARBON DIOXIDE-RELEASING LAXATIVES

Date: December 7, 2006

Note: The mechanism of action for carbon dioxide-releasing laxatives is the release of carbon dioxide from several ingredients, inducing gentle pressure in the rectum which promotes bowel movement.

Table 1: Medicinal ingredients

Proper name(s)	Common name(s)	Source material(s)
Monobasic sodium phosphate/Sodium phosphate monobasic (USP 29; O'Neil *et al.* 2001)	**Sodium biphosphate** (O'Neil *et al.* 2001) **Sodium dihydrogen phosphate** (O'Neil *et al.* 2001) **Monosodium orthophosphate** (O'Neil *et al.* 2001) **Primary sodium phosphate** (O'Neil *et al.* 2001)	**Sodium phosphate monobasic*** (USP 29; O'Neil *et al.* 2001) CAS No. 007558-80-7[+] **Sodium phosphate monohydrate monobasic*** (USP 29; O'Neil *et al.* 2001) CAS No. 010049-21-5[+] **Sodium phosphate dihydrate monobasic*** (USP 29; O'Neil *et al.* 2001) CAS No. 013472-35-0[+]
Sodium acid pyrophosphate (O'Neil *et al.* 2001)	**Disodium pyrophosphate** (Gottschalck and McEwen 2006) **Sodium acid pyrophosphate** (O'Neil *et al.* 2001) **Disodium dihydrogen pyrophosphate** (O'Neil *et al.* 2001) **Diphosphoric acid disodium salt** (Gottschalck and McEwen 2006)	**Disodium pyrophosphate** (O'Neil *et al.* 2001) (No USP or BP pharmacopoeial grade) CAS No. 007758-16-9[+] **Sodium acid pyrophosphate** (O'Neil *et al.* 2001) **Disodium dihydrogen pyrophosphate** (O'Neil *et al.* 2001) **Diphosphoric acid disodium salt** (Gottschalck and McEwen 2006)
Sodium bicarbonate (Gottschalck & McEwen	**Sodium bicarbonate** (Gottschalck and McEwen	**Sodium bicarbonate*** (Gottschalck and McEwen

Proper name(s)	Common name(s)	Source material(s)
2006; USP 29; Sweetman 2002; O'Neil *et al.* 2001)	2006; USP 29; Sweetman 2002; O'Neil *et al.* 2001) **Baking soda** (Gottschalck and McEwen 2006; Sweetman 2002; O'Neil *et al.* 2001) **Carbonic acid monosodium salt** (Gottschalck and McEwen 2006; USP 29) **Sodium hydrogen carbonate** (Gottschalck and McEwen 2006; Sweetman 2002; O'Neil *et al.* 2001)	2006; USP 29; Sweetman 2002; O'Neil *et al.* 2001) CAS No. 000144-55-8[+]
Potassium bitartrate (USP 29; O'Neil *et al.* 2001) **Butanedioic acid 2,3-dihydroxy-, [R-(R*,R*)]-, monopotassium salt** (USP 29)	**Potassium bitartrate** (USP 29; O'Neil *et al.* 2001) **Potassium acid tartrate** (O'Neil *et al.* 2001) **Potassium hydrogen tartrate** (O'Neil *et al.* 2001) **Cream of tartar** (O'Neil *et al.* 2001)-	**Potassium bitartrate*** (USP 29; O'Neil *et al*. 2001) CAS No. 000868-14-4[+] **Potassium acid tartrate** (O'Neil *et al.* 2001) **Potassium hydrogen tartrate** (O'Neil *et al.* 2001) **Cream of tartar** (O'Neil *et al.* 2001)

*Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Compendium of Monographs Guidance Document) or requires citation of an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File's registered owner.
[+]The CAS number may be provided as additional information.

Route(s) of administration: Rectal (FDA 1985)

Dosage form(s): Suppository (FDA 1985)

Use(s) or Purpose(s): Statement(s) to the effect of:

- For relief of occasional constipation (irregularity of the bowel; lack of regular bowel movement) (FDA 1985)
- Laxative (FDA 1985)

- Promotes evacuation of the lower bowel (Sweetman 2002).

Dose(s):

Subpopulation: Adults and children 12 years and older (FDA 1985)

Quantity:

One suppository per day containing:
1.2-1.5 g Monobasic sodium phosphate + 0.04-0.05 g Sodium acid pyrophosphate + 1-1.5 g Sodium bicarbonate (FDA 1985)

One suppository per day containing:
0.6 g Sodium bicarbonate + 0.9 g Potassium bitartrate (FDA 1985)

Permitted combinations:

Medicinal ingredients are not allowed singly; they are permitted only in the above combinations (FDA 1985).

Directions for use: Statements to the effect of:

- Do not take within 2 hours of another medicine as the desired effect of the other medicine may be reduced (Berardi *et al.* 2002).
- Remove suppository from wrapper (for suppositories packaged in a wrapper) (FDA 1990).
- Place under running water for 30 seconds, or in a cup of water for at least 10 seconds before insertion (FDA 1985).
- Do not lubricate with mineral oil or petrolatum prior to rectal insertion (FDA 1985).
- Gently insert in the rectum.
- Allow 5-30 minutes to produce bowel movement (FDA 1985).

Duration of use: Do not use for more than 7 days (FDA 1985).

Risk information: Statements to the effect of:

Cautions and warnings:

- Consult a health care practitioner before using if you are on a sodium-restricted diet (FDA 2004).
- Consult a health care practitioner if condition persists or worsens (FDA 1990).
- Consult a health care practitioner promptly in case of bleeding (FDA 1990).

Contraindications:

- Do not use in the presence of abdominal pain, nausea, fever or vomiting (FDA 1985).

Non-medicinal ingredients: Must be chosen from the current List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications: Must comply with the minimum specifications outlined in the current Compendium of Monographs.

References:

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-care. 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

FDA 2004: USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 201. Drug Labeling for Over-the-Counter Drugs; 2004. [Accessed 2006-02-28]. Available at: http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26269.pdf

FDA 1990: USA Department of Health and Human Services: Food and Drug Administration. 55 CFR Part 346. Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph; 1990. [Accessed 2006-01-26]. Available at: http://www.fda.gov/cder/otcmonographs/Anorectal/anorectal_FR_19900803.pdf

FDA 1985: USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 334. Laxative Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; 1985. [Accessed 2005-08-30]. Available at: http://www.fda.gov/cder/otcmonographs/Laxative/laxative_TF_19850115.pdf.

Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook. 10th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2006.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th edition. Whitehouse Station (NJ): Merck and Co., Inc; 2001.

Sweetman SC, editor. Martindale: The Complete Drug Reference. 33rd edition. Grayslake (IL): Pharmaceutical Press; 2002.

USP 29: United States Pharmacopeia and the National Formulary (USP 29/NF 24). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2006.