

has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the indirect ingredient, one or more of these limited conditions of use, which may include the category of food-contact surface(s), technical effect(s) or functional use(s) of the indirect ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, such use of a substance may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that the use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with §170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food-contact surfaces only within such limitation(s), including the category of food-contact surface(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, prior to general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this part does not authorize the use of such substance for the purpose of adding the ingredient to the food through extraction from the food-contact surface.

(d) The listing of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception to the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient

under part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

[42 FR 14658, Mar. 15, 1977, as amended at 48 FR 48457, 48459, Oct. 19, 1983]

### Subpart B—Listing of Specific Substances Affirmed as GRAS

#### § 186.1093 Sulfamic acid.

(a) Sulfamic acid ( $\text{H}_3\text{NO}_3\text{S}$ , CAS Reg. No. 5329-14-6) is a white crystalline solid manufactured from urea, sulfur trioxide, and sulfuric acid. It is soluble and highly ionized in water.

(b) In accordance with §186.1(b)(1), the ingredient is used as an indirect food ingredient with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the current good manufacturing practice of using this ingredient in the manufacture of paper and paperboard that contact food.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29954, July 9, 1982]

#### § 186.1256 Clay (kaolin).

(a) Clay (kaolin)  $\text{Al}_2\text{O}_3 \cdot 2\text{SiO}_2 \cdot n\text{H}_2\text{O}$ , CAS Reg. No. 1332-58-7) consists of hydrated aluminum silicate. The commercial

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products of clay (kaolin) contain varying quantities of alkalis and alkaline earths. Clay (kaolin) is a white to yellowish or grayish fine powder. There are at least three different minerals, kaolinite, dickite, and nacrite, classified as kaolin. Kaolinite or china clay is whiter, less contaminated with extraneous minerals, and less plastic in water.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in the manufacture of paper and paperboard that contact food.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[47 FR 43367, Oct. 1, 1982]

## § 186.1275 Dextrans.

(a) Dextrans (CAS Reg. No. 9004-54-0) are high molecular weight polysaccharides produced by bacterial fermentation of sucrose. Commercially available dextrans are synthesized from sucrose by *Leuconostoc mesenteroides* strain NRRL B-512(F). Partial depolymerization and purification of the fermented mixture shall produce a product that is free of viable microorganisms.

(b) The ingredient is used or intended for use as a constituent of food-contact surfaces.

(c) The ingredient is used at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 29288, July 7, 1978, as amended at 48 FR 48457, Oct. 19, 1983]

## 21 CFR Ch. I (4-1-09 Edition)

## § 186.1300 Ferric oxide.

(a) Ferric oxide (iron (III) oxide,  $\text{Fe}_2\text{O}_3$ , CAS Reg. No. 1309-37-1) occurs naturally as the mineral hematite. It may be prepared synthetically by heating brown iron hydroxide oxide. The product is red-brown to black trigonal crystals.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect human food ingredient with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a constituent of paper and paperboard used for food packaging.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16867, May 12, 1988; 53 FR 20939, June 7, 1988]

## § 186.1316 Formic acid.

(a) Formic acid ( $\text{CH}_2\text{O}_2$ , CAS Reg. No. 64-18-6) is also referred to as methanoic acid or hydrogen carboxylic acid. It occurs naturally in some insects and is contained in the free acid state in a number of plants. Formic acid is prepared by the reaction of sodium formate with sulfuric acid and is isolated by distillation.

(b) Formic acid is used as a constituent of paper and paperboard used for food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for formic acid different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980]

## § 186.1374 Iron oxides.

(a) Iron oxides (oxides of iron, CAS Reg. No. 1332-37-2) are undefined mixtures of iron (II) oxide (CAS Reg. No. 1345-25-1, black cubic crystals) and iron