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Japan

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Designation of Fludioxonil as a new Food Additive

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:
On August 10, 2010, the Japanese Government announced it would designate a new food additives Fludioxonil. The domestic comment period will closed on August 24, 2010 however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

General Information:
On August 10, 2010, the Japanese Government announced plans to designate a new food additives, Fludioxonil. The domestic comment period will close on August 24, 2010 however MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Also, please note that the proposal of new MRLs of Fludioxonil as a pesticide is in progress (GAIN report JA0020).

The actual WTO-SPS notifications can be found at the site below.
http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm

After the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

The comments to GOJ can be either Japanese or English.
If you have comments, please send them directly to the Japanese Government at:

Dr. M. ISOZAKI (isozaki-makiko@mhlw.go.jp)
Mr. T. GOTOU (gotou-takashi@mhlw.go.jp)
Mr. Y. NAKAO (nakao-yuusuke@mhlw.go.jp)
(tel. ex. 2453)

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Food Additive Regulations:

Designation of Fludioxonil as Food Additive

The Ministry of Health, Labour and Welfare is going to newly designate Fludioxonil as an authorized food additive.

Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. When use standards or compositional specifications are established for food additives based on Article 11 of the law, those additives are not permitted to be used or marketed unless they meet these standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of Fludioxonil. The conclusion of the committee outlined below.

ɔf conclusion

The Minister should designate Fludioxonil, based on Article 10 of the Food Sanitation Law, as a food additive unlikely to harm human health and establish compositional specifications and other necessary standards for this substance, based on Article 11 of the law (see Attachment 2-1).

Additional Information

Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 2-2)

Attachment 2-1

Fludioxonil

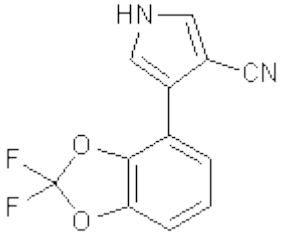
Standard for use

The following is the maximum use amount of the fludioxonil for each target commodity.
Kiwifruit: 0.020 g /kg
Citrus fruits excluding *unshu* orange: 0.010 g/kg
Apricot, Apple, Cherry, Japanese plum, Nectarine, Loquat,Peach, Pear, Pomegranate, Quince: 0.0050 g/kg (for apricot, cherry, Japanese plum, nectarine, and peach, the limit is applied to one kilogram of each fruit from which the stone is removed)

Compositional specifications

Substance name Fludioxonil

Structural formula



Molecular formula $C_{12}H_6F_2N_2O_2$
Mol. Weight 248.19
Chemical name [CAS number]
4-(2,2-difluorobenzo[*d*][1,3]dioxol-4-yl)-1*H*-pyrrole-3-carbonitrile [131341-86-1]
Content Fludioxonil contains not less than 97.0% of fludioxonil ($C_{12}H_6F_2N_2O_2$).
Description Fludioxonil occurs as a white to soft yellow powder. It is odorless.
Identification Determine the infrared absorption spectrum of Fludioxonil, as directed in the Paste Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.
Purity
(1) Melting point 199–201°C.
(2) Lead Not more than 2.0 mg/g as Pb.
Test Solution Place 1.0 g of Fludioxonil into a 300-ml Kjeldahl flask, add 10 ml of nitric acid and 5 ml of sulfuric acid, and heat until red-brown fumes are almost no longer evolved. After cooling, heat with an additional 2 ml of nitric acid until strong white fumes appear. After cooling, add 10 ml of diluted hydrochloric acid (1 in 4), boil for 15 minutes, and cool. Use the resulting solution as the sample solution. To the sample solution, add 10 ml of a solution of diammonium hydrogen citrate (1 in 2), and make weakly alkaline with ammonia solution using thymol blue as indicator. After cooling, transfer the content of the Kjeldahl flask into a 200-ml separating funnel, wash the flask with water, and add the washings to the funnel to about 100 ml. Add 5 ml of a solution of ammonium pyrrolidine dithiocarbamate (3 in 100), and allow to stand for 5 minutes. Add 10 ml of butyl acetate, shake for 5 minutes, and allow to stand. Using the butyl acetate phase as the test solution.
Control Solution Measure exactly 1 ml of the Lead Standard Stock Solution, and add water to make exactly 100 ml. Using exactly measured 2 ml of the resulting solution, proceed in the same manner as for the sample solution, starting from "add10 ml of a solution of diammonium hydrogen citrate."
Procedure Proceed as directed under the Method 1 of the Lead Limit Test.
Water Content Not more than 0.50% (1.0 g, Direct Titration).
Assay
Test Solution and Standard Solution Weigh accurately about 0.06 g each of the test sample and fludioxonil for assay, and dissolve each in methanol to make exactly 100 ml.
Procedure Analyze 10 ml each of the test solution and the standard solution by liquid chromatography according to the operating conditions given below. Measure the peak areas (A_T and A_S) of fludioxonil for the test solution and the standard solution, and determine the content by the formula:

$$\text{Content (\%) of fuldioxonil } (C_{12}H_6F_2N_2O_2) = \frac{\text{Weight (g) of fuldioxonil for assay}}{\text{Weight (g) the sample}} \times \frac{A_T}{A_S} \times 100$$

Operating Conditions
etector: Ultraviolet absorption spectrophotometer (determination wavelength: 270 nm).
olumn: Stainless steel tube of 4.0 mm internal diameter and 25 cm length.
olumn packing material: 5 μm octadecylsilanized silica gel for liquid chromatography.
olumn temperature: A constant temperature at 25–40°C.
obile phase: Use a solution prepared as follows—Dissolve 3.8 g of monopotassium phosphate and 5.8 g of anhydrous disodium phosphate in water to make 1L. To 100 ml of the resulting solution, add 500 ml of water, 300 ml of acetonitrile, and 100 ml of methanol.

Flow rate: 1 ml/minute.

Reagent

Fludioxonil for Assay $C_{12}H_6F_2N_2O_2$ White crystals or crystalline powder.

Content Not less than 99% of fludioxonil ($C_{12}H_6F_2N_2O_2$), calculated on the anhydrous basis.

Identification Measure the absorption spectrum of Fludioxonil for Assay as directed in the Potassium Bromide Disk Method or Paste Method under Infrared Spectrophotometry. It exhibits absorption bands at about 3289 cm^{-1}, 2223 cm^{-1}, 1652 cm^{-1}, 1530 cm^{-1}, and 1236 cm^{-1}.

Melting point 200–201°C.

Reference Spectrum

Fludioxonil