MATERIAL SAFETY DATA SHEET

According to European Regulation 1907/2006 (REACH), European Regulation 1272/2008 (CLP) and European Regulation 453/2010

ACID SACCHARIN E-954

Issued: February 2003 Version: 09 (06/06/12)

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1. Identification of the substance/mixture and of the company/undertaking.

1.1. Product identifier:

Acid Saccharin.

1.2. Relevant identified uses of the substance or mixture and uses advised against:

Food additive sweetener E-954, used in food and as an excipient in pharmaceutical products.

1.3. Details of the supplier of the safety data sheet:

Productos Aditivos, S.A.

Planta: Av. Ferreria, 40. Pol. Ind. La Ferreria

E – 08110 Montcada i Reixac

(España)

Tel.: +34 93 564 48 97

Fax: +34 93 564 15 30

E-mail: info@productosaditivos.com Web: www.productosaditivos.com

1.4. Emergency telephone number:

National Toxicological Information Service of Spain: +34 91 562 04 20

Catalonia Emergency: +34 93 586 77 00 Productos Aditivos SA: +34 673 653 345

2. Hazards identification.

2.1. Classification of the substance or mixture.

Not classified as hazardous according to Regulation 1272/2008.

2.2. Label elements.

No Hazard label required.

2.3. Other hazards.

Not classified as PBT or vPvB.

3. Composition / Information on components.

Name: 1,2-benzisothiazol-3-(2H)-one-1,1-dioxide. *Synonymous:* Insoluble saccharin, saccharin imide.

Formula: C₇H₅NO₃S

Relative molecular mass: 183.2 N° CAS: 81-07-2; EINECS: 201-321-0

4. First aid measures.

- 4.1. Description of first aid measures.
 - ✓ *Inhalation exposure*: An excessive exposure by inhalation is very difficult. In this case, get the person to fresh air.
 - ✓ Skin contact: No hazard by skin contact. Wash with a solution of 3 % sodium bicarbonate, followed with more tap water.
 - ✓ Eyes contact: Wash briefly with a solution of 0.5 % of sodium bicarbonate in water. Flush with plenty of water. Apply topic eyewash if required. Get medical advice if necessary.
 - ✓ *Ingestion:* Due to its taste, an excessive exposure is very difficult. If it occurs, give a plenty of water, induce vomiting and get medical advice if necessary.
- 4.2. Most important symptoms and effects, both acute and delayed.

None reported.

4.3 Indication of any immediate medical attention and special treatment needed.

Described above.

5. Fire fighting measures.

5.1. Extinguishing media:

Water. Foam. Powder. CO₂.

5.2. Special hazards arising from the substance or mixture:

When burning, the product gives off sulphurous and nitrous gases, CO and CO2.

5.3. Advice for fire-fighters:

Wear self-containing breathing apparels and fireproof clothes.

6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency y procedures:

Wear glasses, gloves and mask for dust.

6.2. Environmental precautions:

Collect and send to plant for reprocessing or incineration according to Point 13.

6.3. Methods and material for containment and cleaning up:

Sweep or vacuum, avoiding dust formation, and wash with water. Send solid wastes to treatment.

7. Handling and storage.

7.1. Precautions for safe handling:

Wear glasses, gloves and masks to avoid dust inhalation.

7.2. Conditions for safe storage, including any incompatibilities:

Store at room temperature and dry conditions in a well-closed packaging.

Indications for plants or warehouses: under certain conditions the dust suspended in air can be ignited by static electricity.

7.3. Specific end use(s):

Due its food use, the product must be protected from humidity and possible external vectors or pests during storage. Packages must be kept separate from walls and floor.

8. Exposure controls/personal protection.

8.1. Control parameters:

Food additive, not applicable.

8.2. Exposure controls:

No risk of excessive exposure during a normal product handling.

9. Physical and Chemicals properties.

Appearance: Crystals or crystalline powder

Relative density: 0.83 kg/L

Odour: Odourles

Flavour: Intensely sweet

Solubility: Solubility in water: Very slightly soluble in water: 2 g/l at 20°C, 13 g/l at 75°C.

Soluble in basic solutions.

pH (saturated solution, 20°C): 1,0 to 1,5

Melting point: 228 °C - 229 °C Flammability: No flamable

Oxidising properties: No oxidising properties

10. Stability and reactivity.

10.1. Reactivity:

The product is not particularly reactive.

10.2. Chemical stability:

The product is chemically stable.

10.3. Possibility of hazardous reactions:

No hazardous reactions in normal conditions.

10.4. Conditions to avoid:

Avoid suspension of dust in the air.

10.5. Incompatible materials.

Avoid contact with strong oxidising agents, strong acids and nitrites.

10.6. Hazardous decomposition products:

See section 5.2 of this document.

11. Toxicological information:

- 11.1 Information on toxicological effects:
- ✓ Toxicological effects if the user comes into contact with the substance: No allergic reactions are known.
- ✓ Toxicity to animals: Acute oral toxicity (LD50): 14.200 mg/kg (rat)
- √ ADI (Acceptable Daily Intake) as acid saccharin: 5 mg/Kg body weight/day (EC, JECFA).
- ✓ Other information: None relevant.

12. Ecological Information

12.1. Toxicity:

No data available.

12.2. Persistence and degradability:

Can be processed in a standard sewage treatment plant, producing ${\rm CO_2}$, sulphate and nitrogen derived substances.

Other information:

COD: 1,8 g O₂/g acid saccharin. BOD: 4,33 mg O₂/g acid saccharin.

12.3. Bio-accumulative potential:

No bio-accumulative.

12.4. Mobility in soil:

No data available.

12.5. Results of PBT and vPvB assessment:

No PBT or vPvB.

12.6 Other adverse effects.

No data available.

13. Disposal considerations.

13.1 Waste treatment methods:

Disposal of the substance: Any applicable regulation must be observed. The product can be incinerated in an incineration plant, using a post burning and a collector of sulphurous and nitrous gases.

Disposal of the packaging: Any applicable regulation must be observed. Cardboard and plastic packages can be incinerated. Metallic parts of drums must be removed before incinerating.

14. Transport information.

The product is not considered hazardous for transport.

14.1. UN number: N/A

14.2. UN proper shipping name: N/A

14.3. Transport hazard class(es): N/A

14.4. Packing group: N/A

14.5. Environmental hazards:

No special hazards to the environment.

14.6. Especial precautions for user:

No special precautions required by the user.

15. Regulatory information.

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

The substance is approved as a food additive (sweetener E-954) by Directive 94/35/EC, and is included in the European Pharmacopoeia 7th edition, and 34th USP / NP.

15.2. Chemical safety assessment:

No Applicable: food additive (sweetener E-954).

16. Other information.

Changes in this version: Adaptation of the safety data sheet to the requirements of Regulation 453/2010

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of this publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release, and is not to be considered as warranty or Quality Specification. The information relates only to the specific material designated and is not valid for such material used in combination with any other materials or in any process.