

SAFETY DATA SHEET according to 2006/1907/EC
Version: 01/16
Date: 21/06/2016

1 IDENTIFICATION OF THE PRODUCT AND COMPANY
1.1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION: Sugar Spheres
1.2 USE OF THE SUBSTANCE OR PREPARATION: Pharmaceutical Excipient
1.3 IDENTIFICATION OF THE COMPANY: Emilio Castelli sas Via S. Pellico, 46 20813 Bovisio Masciago (MB) Italy Tel. +39.0362.558350 Fax +39.0362.590836 E-mail ecastelli@ecastelli.it
1.4 EMERGENCY TELEPHONE: +39.0362.558350

2 COMPOSITION/INFORMATION ABOUT THE COMPONENTS
2.1 Name: Sugar Spheres 18-20
2.1.1 Granulometry: 2.1.1 Granulometry: 800-1000 micron
2.2 CAS number: 92004-84-7
2.3 EINCES: 200-344-9

3 HAZARD IDENTIFICATION
3.1 When used appropriately, no adverse effects are known to be caused by the product. The product is not toxic for the human or animal organism.

4 FIRST AID MEASURES
4.1 INHALATION: Not necessary.
4.2 CONTACT WITH SKIN: Wash with water.
4.3 CONTACT WITH EYES: Wash with water.
4.4 INGESTION: Allowed.

5 FIRE-FIGHTING MEASURES
5.1 SUITABLE EXTINGUISHING METHODS: Dry Foam, chemical powder, carbon anhydride, water.
5.2 METHODS NOT SUITABLE FOR SAFETY REASONS: None
5.3 SPECIAL EXPOSURE HAZARDS: None
5.4 SPECIAL PROTECTIVE EQUIPMENT : Not necessary

6 ACCIDENTAL RELEASE MEASURES	
6.1 PERSONAL PRECAUTIONS:	Not necessary
6.2 ENVIRONMENTAL PRECAUTION:	None
6.3 METHODS FOR CLEANING UP :	Hot water

7 HANDLING AND STORAGE	
7.1 HANDLING:	Use normal measures for handling of food products: gloves and / or cleaned hands
7.2 STORAGE:	In original container, at room temperature closed and protected from humidity and heat sources. To avoid aggregation store at temperatures between 10 and 25°C.
7.3 SPECIFIC USES:	Pharmaceutical Excipients

8 EXPOSURE CONTROLS / PERSONAL PROTECTION	
8.1 TLV – TWA: (mg/m³ MAK)	
8.2 PERSONAL PROTECTION EQUIPMENT:	
Respiratory protection:	Not necessary
Hand protection:	Gloves
Eye protection:	Not necessary
Skin protection:	Not necessary
8.3 SPECIFIC HYGIENE METHODS:	None
8.4 ADDITIONAL INFORMATION:	In case of burns due to hot product, irrigate with plenty cold water and seek medical assistance.

9 PHYSICAL AND CHEMICAL PROPERTIES		
9.1 PHYSICAL FORM		
Appearance:	Solid granular	
Colour:	Dull white	
Odour:	Odourless	
9.2 PROPERTIES	VALUE	UNIT
Melting point	187	°C
Freezing point	n.a.	°C
Ignition temperature	>300	°C
Autoignition	n.d	°C
Oxidising properties:	None	
Danger of explosion		
- Product:	No	
- Mixture powder/air	n.a	
Explosion limits		
- Lower:	n.a	g/m ³
- Upper	n.a	g/m ³
Density (20°C)	1,69	g/mL
Solubility (20°)	Sucrose soluble 100%	
pH (20°C, H ₂ O)	5,6 (neutral)	

SPECIFICATIONS	LIMITS
Sucrose	from 62,5% to 91,5%
Maize Starch	from 8,5% to 25%
Loss on Dry	≤ 4%
MICROBIAL LIMITS:	
TAMC	NMT 200 CFU/g
TYMC	NMT 200 CFU/g
Salmonella	absent
Escherichia Coli	absent
Staphilococcus aureus	absent
Pseudomonas Aeruginosa	absent

10 STABILITY AND REACTIVITY	
10.1 CONDITIONS TO AVOID:	Contact with flames
10.2 MATERIALS TO AVOID:	None
10.3 HAZARDOUS DECOMPOSITION PRODUCTS:	None. Stable at normal temperatures and with normal use.
10.4 ADDITIONAL INFORMATION:	Not potentially dangerous in normal conditions of use.

11 TOXICOLOGICAL INFORMATION	
11.1 ACUTE EFFECTS:	None
11.2 IRRITATION:	None
11.3 SENSITISATION:	None
11.4 CHRONIC TOXICITY:	None
11.5 ROUTE OF ENTRY:	Ingestion
11.6 ADDITIONAL INFORMATION:	Non-toxic through inhalation, contact or ingestion known to us.

12 ECOLOGICAL INFORMATION	
12.1 BIODEGRADABILITY: (28days)	This product is biodegradable in water and is substantially eliminated in Biological treatments. It is not toxic for aquatic life.

13 DISPOSAL CONDITIONS	
13.1 PRODUCT:	Dispose of product in accordance with local, state and federal regulations. Waste disposal by controlled incineration or designated landfill subject to applicable local and state regulation.
13.2 PACKAGING:	Controlled disposal according to applicable local and state regulation.

14 TRANSPORT INFORMATION	
14.1 ADR:	n.a.
14.2 IMCO:	n.a.
14.3 IATA:	n.a.
14.4 UN NUMBER:	n.a.
14.5 ADDITIONAL INFORMATION:	It is not classified as dangerous substance for transportation

15 REGULATORY INFORMATION

15.1 According to our data, this product is not dangerous in the sense of this directive.

16 OTHER INFORMATION

We are compliant to USP and EP current edition. Specifications are changeable according to the customer request.

n.a. – not applicable