

<b>SAFETY DATA SHEET according to 2006/1907/EC</b>	
<b>Version:</b>	<b>01/20</b>
<b>Date:</b>	<b>21/07/2020</b>

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

<b>2 COMPOSITION/INFORMATION ABOUT THE COMPONENTS</b>
<b>2.1 Name:</b> Sugar Spheres _ All Sizes
<b>2.1.1 Granulometry:</b> 2.1.1 Granulometry:  All grades
<b>2.2 CAS number:</b> 92004-84-7
<b>2.3 EINCES:</b> 200-334-9

<b>3 HAZARD IDENTIFICATION</b>
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.

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

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

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

<b>7 HANDLING AND STORAGE</b>	
<b>7.1 HANDLING:</b>	Use normal measures for handling of food products: gloves and / or cleaned hands
<b>7.2 STORAGE:</b>	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.
<b>7.3 SPECIFIC USES:</b>	Pharmaceutical Excipients

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

<b>9 PHYSICAL AND CHEMICAL PROPERTIES</b>		
<b>9.1 PHYSICAL FORM</b>		
Appearance:	Solid granular	
Colour:	Dull white	
Odour:	Odourless	
<b>9.2 PROPERTIES</b>	<b>VALUE</b>	<b>UNIT</b>
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/m3
- Upper	n.a	g/m3
Density (20°C)	1,69	g/mL
Solubility (20°)	Sucrose soluble 100%	
pH (20°C, H2O)	5,6 (neutral)	

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

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

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

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

<b>13 DISPOSAL CONDITIONS</b>	
<b>13.1 PRODUCT:</b>	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.
<b>13.2 PACKAGING:</b>	Controlled disposal according to applicable local and state regulation.

<b>14 TRANSPORT INFORMATION</b>	
<b>14.1 ADR:</b>	n.a.
<b>14.2 IMCO:</b>	n.a.
<b>14.3 IATA:</b>	n.a.
<b>14.4 UN NUMBER:</b>	n.a.
<b>14.5 ADDITIONAL INFORMATION:</b>	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