

Stratosphere 2 predosed in capsules

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****Product identifier**

**Product name** : Stratosphere 2 predosed in capsules  
**Other means of identification** : None.  
**Product type** : Capsules, containing silver alloy and mercury (Hg)  
 I Spill: Alloy / Mercury 400/435 mg  
 II Spill: Alloy / Mercury 600/653 mg  
 III Spill: Alloy / Mercury 800/865 mg

**Relevant identified uses of the substance or mixture and uses advised against**

**Identified uses** : Dental filling material

**Details of the supplier of the safety data sheet****National contact**

Henry Schein Inc.  
 135 Duryea road  
 Melville NY 11747 USA

Authorized representative:  
 Henry Schein U.K. Holdings Ltd.  
 Medcare House, Centurion Close  
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 www.henryscheinbrand.com

UK : +44 (0)1634 87 87 50  
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**National advisory body/Poison Centre/Emergency telephone number**

**Telephone number** : +44 (0)1634 87 87 50

**SECTION 2: Hazards identification****Classification of the substance or mixture**

**Product definition** : Capsules, containing silver alloy and mercury (Hg).

**Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]**

H330 - Acute Toxicity (Inhalation) Category 1  
 H360 - Toxic to reproduction Category 1  
 H372 - Specific target organ toxicity (repeated exposure) Category 1  
 H410 - Hazardous to aquatic environment Chronic Hazard Category 1

**Classification according to Directive 67/548/EEC [DSD]****Europe**

The product is classified as dangerous according to Directive 67/548/EEC and its amendments.  
 T+; R26  
 N; R50/53

**Classification according to Directive 1999/45/EC [DPD]****Europe**

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.  
 See Section 16 for the full text of the R phrases or H statements declared above.  
 See Section 11 for more detailed information on health effects and symptoms.

**Label elements****Hazard pictograms**

**Signal word** : Danger

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**SECTION 2: Hazards identification**

**Hazard statements** : H330 - Fatal if inhaled.  
 H360D - May damage the unborn child.  
 H372 - Causes damage to organs through prolonged or repeated exposure.  
 H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements

**Prevention** : Wear protective gloves.

Europe



Very toxic, Dangerous for the environment

**Risk phrases** : R26- Very toxic by inhalation.  
 R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
 R61- May cause harm to the unborn child. R48- Danger of serious damage to health by prolonged exposure.

**Safety phrases** : S53- Avoid exposure - obtain special instructions before use.  
 S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).  
 S60- This material and its container must be disposed of as hazardous waste.  
 S61- Avoid release to the environment. Refer to special instructions/safety data sheet.

**Hazardous ingredients** : Mercury

**Supplemental label elements** : Not applicable.

**Other hazards**

**Other hazards which do not result in classification** : None.

**Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII** : Not applicable.

**Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII** : Not applicable.

**SECTION 3: Composition/information on ingredients**

**Substance/mixture** : Capsules, containing silver alloy and mercury (Hg).

Product/ingredient name	Identifiers	%	Classification		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
			See Section 16 for the full text of the R-phrases declared above.	See Section 16 for the full text of the H statements declared above.	

Type

1: Occupational exposure limits, if available, are listed in Section 8.

**SECTION 4: First aid measures**

**Description of first aid measures**

**Eye contact** : Check for and remove any contact lenses. Rinse with plenty of running water. Seek medical attention.

**Inhalation** : Allow the victim to rest in a well-ventilated area. Get medical attention immediately.

**Skin contact** : Wash contaminated skin with soap and water. Remove contaminated clothing and shoes.

**Ingestion** : Have conscious person drink several glasses of water or milk. Get medical attention immediately. Subsequently administer: activated charcoal (20 - 40 g in 10 % slurry).

**Protection of first-aiders** : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapours below their respective occupational exposure limits. Wear special protective clothing and positive pressure, self-contained breathing apparatus.

*Stratosphere 2 predosed in capsules***SECTION 4: First aid measures****Most important symptoms and effects, both acute and delayed****Potential acute health effects**

- Eye contact** : Not available.
- Inhalation** : R26- Very toxic by inhalation. R61- May cause harm to the unborn child.
- Skin contact** : May be harmful in contact with skin.
- Ingestion** : Possible risk of irreversible effects.

**Indication of any immediate medical attention and special treatment needed**

- Notes to physician** : Call local Poison Control Center for assistance.
- Specific treatments** : Not available.

**SECTION 5: Firefighting measures****Extinguishing media**

- Suitable extinguishing media** : Use extinguishing media suitable for surrounding materials.
- Unsuitable extinguishing media** : Not applicable.

**Special hazards arising from the substance or mixture**

- Hazards from the substance or mixture** : No specific fire or explosion hazard.
- Hazardous thermal decomposition products** : Mercury vapor.

**Advice for firefighters**

- Special protective actions for fire-fighters** : Avoid breathing dusts, vapours or fumes from burning materials.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
- Additional information** : None.

**SECTION 6: Accidental release measures****Personal precautions, protective equipment and emergency procedures**

- For non-emergency personnel** : Wear suitable gloves and eye/face protection.
- For emergency responders** : Wear suitable gloves and eye/face protection.
- Environmental precautions** : Do not allow to enter drains or watercourses.

**Methods and materials for containment and cleaning up**

- Small spill** : Small droplets of spilled Mercury can be collected with the aid of a 'Mercury-collecting forceps' or a small amount of freshly mixed amalgam. That will easily absorb liquid Mercury. NEVER use a vacuum-cleaner!
- Large spill** : Evacuate surrounding areas. Do not clean up spills or dispose of, except under supervision of a specialist. Consult your local or regional authorities.

**Reference to other sections**

- : See Section 1 for emergency contact information.  
See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

**SECTION 7: Handling and storage**

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

**Precautions for safe handling**

- Protective measures** : Recommendations for safety precaution.  
Dental clinical personnel, when using silver amalgam, should exercise procedures to avoid personal contact with Mercury. Precaution should be taken to avoid exposure to Mercury vapour in the dental environment. Waste amalgam should be collected for disposal in a manner which will protect both those who handle the waste and the environment:  
1 Treat mercury and amalgam with care. Be MERCURY AWARE.  
2 Handling of mercury and mixing of amalgam should be done on a separate section of the working table (not close to a source of heat), with raised edges on all sides.  
This will prevent any spilled Mercury spreading and will facilitate its recovery. The surgery floor should be smooth, without cracks and the surgery well ventilated.  
3 Ideally a high-energy mixer should be equipped with a protective cap to

**SECTION 7: Handling and storage**

cover the capsule whilst mixing.  
 4 Small droplets of spilled Mercury can be collected with the aid of a 'Mercurycollecting forceps' or a small amount of freshly mixed amalgam. That will easily absorb liquid Mercury. NEVER use a vacuum-cleaner!  
 5 Removal of amalgam fillings must be done under water cooling and with effective suction. The use of eye protection and mouth mask is advisable.  
 6 The waste water drain of the spittoon should be equipped with an amalgam separator. Local regulations on the type and installation of such separator and handling/recycling of the amalgam waste should be taken in consideration. For details see for example JADA, august 2003, KEVIN R. MACMANUS, M.A., M.B.A.; P.L. FAN, Ph.D. "Purchasing, installing and operating dental amalgam separators, Practical issues".  
 7 Excess mixed amalgam should be kept in a special 'Mercontainer' or at least in a closed container filled with photographic fixer.  
 8 Empty capsules may retain product residues and can be hazardous.

**Advice on general occupational hygiene**

: Avoid breathing dust.

**Conditions for safe storage, including any incompatibilities**

: Store in a dry, cool and well-ventilated area.

**SECTION 8: Exposure controls/personal protection**

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

**Control parameters**

**Occupational exposure limits**

Product/ingredient name	Exposure limit values
<b>Europe</b>	
Mercury	<b>EU OEL (Europe, 9/2006).</b> TWA: 0,02 mg/m <sup>3</sup> 8 hour(s).
Silver	0.1 mg/m <sup>3</sup>
Tin (Sn)	2 mg/m <sup>3</sup>
Copper (Cu)	0.1 mg/l
Zinc	0.1 mg/m <sup>3</sup>

**Recommended monitoring procedures**

: Dräger Mercury vapor detection tube

**DNELs/DMELs**

: No DNELs/DMELs available.

**PNECs**

: No PNECs available

**Exposure controls**

**Appropriate engineering controls**

: Use only with adequate ventilation.

**Individual protection measures**

**Hygiene measures**

: Not applicable.

**Eye/face protection**

: safety glasses with side-shields

**Skin protection**

**Hand protection**

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.  
 4-8 hours (breakthrough time): nitrile rubber  
 1-4 hours (breakthrough time): PVC butyl rubber

**Body protection**

: Lab coat.

**Other skin protection**

: Wash with soap and water.

**Respiratory protection**

: Ventilation is normally required when handling or using this product.

**Environmental exposure controls**

: Avoid release to the environment. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. No special protection is required.

*Stratosphere 2 pre-dosed in capsules***SECTION 9: Physical and chemical properties****Information on basic physical and chemical properties****Appearance**

<b>Physical state</b>	: Liquid. (Silvery.)
<b>Colour</b>	: Silvery.
<b>Odour</b>	: Odourless.
<b>pH</b>	: Not applicable.
<b>Melting point/freezing point</b>	: -39°C (-38.2°F)
<b>Initial boiling point and boiling range</b>	: 357°C (674.6°F)
<b>Flash point</b>	: No results available.
<b>Relative density</b>	: 13,6
<b>Solubility in water</b>	: Non water-soluble liquid
<b>Auto-ignition temperature</b>	: No results available.
<b>Decomposition temperature</b>	: No results available.
<b>Viscosity</b>	: No results available.
<b>Oxidising properties</b>	: Not applicable
<b>Other information</b>	: No additional information.

**SECTION 10: Stability and reactivity**

<b>Reactivity</b>	: No additional information.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: The product is stable.
<b>Conditions to avoid</b>	: Keep away from heat and flame. Avoid release to the environment.
<b>Incompatible materials</b>	: Not applicable.
<b>Hazardous decomposition products</b>	: Mercury vapor.

**SECTION 11: Toxicological information****Information on toxicological effects**

<b>Acute toxicity</b>	: No results available.
<b>Irritation/Corrosion</b>	: No results available.
<b>Sensitisation</b>	: No results available.
<b>Mutagenicity</b>	: No results available.
<b>Carcinogenicity</b>	: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.
<b>Reproductive toxicity</b>	: No results available.
<b>Teratogenicity</b>	: No results available.
<b>Potential acute health effects</b>	
<b>Eye contact</b>	: Not available.
<b>Inhalation</b>	: R26- Very toxic by inhalation. R61- May cause harm to the unborn child.
<b>Skin contact</b>	: May be harmful in contact with skin.
<b>Ingestion</b>	: Possible risk of irreversible effects.
<b>Potential chronic health effects</b>	: Chronic or excessive over-exposure may cause symptoms of Mercury poisoning with muscle tremors, visual disturbance and kidney effects.
<b>Other information</b>	: RTECS: OV4550000

**Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II**

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**SECTION 12: Ecological information**

<b>Toxicity</b>	:	Ingredient name	Species	Period	Result
		Mercury	Daphnia (EC50)	48 hours	0.0052 mg/l
		Mercury	Fish (LC50)	96 hours	0.35 mg/l
<b>Persistence and degradability</b>	:	Not applicable.			
<b>Bioaccumulative potential</b>	:	Not applicable.			
<b>Mobility in soil</b>	:	Not available.			
<b>Results of PBT and vPvB assessment</b>					
<b>PBT</b>	:	Not applicable.			
<b>vPvB</b>	:	Not applicable.			
<b>Other adverse effects</b>	:	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.			

**SECTION 13: Disposal considerations****Waste treatment methods****Product**

<b>Methods of disposal</b>	:	Dispose of via a licensed waste disposal contractor.
<b>Hazardous waste</b>	:	The classification of the product may meet the criteria for a hazardous waste.





**European waste catalogue (EWC)**

Waste code	Waste designation
18 01 10*	amalgam waste from dental care

**Packaging**

<b>Methods of disposal</b>	:	Dispose of via a licensed waste disposal contractor.
<b>Special precautions</b>	:	Avoid breathing dust.

**SECTION 14: Transport information**

	ADR/RID	ADN	IMDG	IATA
<b>UN number</b>	3506	3506	3506	3506
<b>UN proper shipping name</b>	Mercury contained in manufactured articles	Mercury contained in manufactured articles	Mercury contained in manufactured articles	Mercury contained in manufactured articles
<b>Transport hazard class (es)</b>	8 	8 	8 	8 
<b>Packing group</b>	III	III	III	III
<b>Environmental hazards</b>				
<b>Additional information</b>	Classification CodeC9Packaging instructions:P800		Packaging instructions:P800	Packaging instructions:869

<b>Special precautions for user</b>	:	No additional information.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	:	Not available.

*Stratosphere 2 predosed in capsules***SECTION 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****EU Regulation (EC) No. 1907/2006 (REACH)****Annex XIV - List of substances subject to authorisation****Substances of very high concern**

None of the components are listed.

**National regulations**

Not applicable.

**Chemical Safety Assessment** : No Chemical Safety Assessment has been carried out.**SECTION 16: Other information**

✔ Indicates information that has changed from previously issued version.

**Abbreviations and acronyms**

: ATE = Acute Toxicity Estimate  
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]  
 DMEL = Derived Minimal Effect Level  
 DNEL = Derived No Effect Level  
 EUH statement = CLP-specific Hazard statement  
 PBT = Persistent, Bioaccumulative and Toxic  
 PNEC = Predicted No Effect Concentration  
 RRN = REACH Registration Number  
 vPvB = Very Persistent and Very Bioaccumulative

**Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]**

Classification	Justification
H330 - Acute Toxicity (Inhalation) Category 1 H360 - Toxic to reproduction Category 1 H372 - Specific target organ toxicity (repeated exposure) Category 1 H410 - Hazardous to aquatic environment Chronic Hazard Category 1	

**Europe****Full text of abbreviated H statements**

: H330 - Fatal if inhaled.  
 H360D - May damage the unborn child.  
 H372 - Causes damage to organs through prolonged or repeated exposure.  
 H400 - Very toxic to aquatic life.  
 H410 - Very toxic to aquatic life with long lasting effects.

**Full text of classifications [CLP/GHS]**

: H330 - ACUTE TOXICITY: INHALATION Category 1  
 H360D - REPRODUCTION TOXICITY Category 1B  
 H372 - SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) Category 1  
 H400 - Hazardous to aquatic environment Acute effects Category 1  
 H410 - Hazardous to aquatic environment Chronic effects Category 1

**Full text of abbreviated R phrases**

: R26- Very toxic by inhalation.  
 R50- Very toxic to aquatic organisms.  
 R50/53- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Full text of classifications [DSD/DPD]**

: T+; Toxic  
 N; Harmful

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**Date of previous issue**

: No previous validation.

**Version**

: 1

**Notice to reader**

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