

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Starburst 45
Product Code: 015, 018

Application: Dental filling material

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2. HAZARD 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/GHST]

H330 - Fatal if inhaled.

H360D - May damage unborn child.

H372 - Causes damage to organs through prolonged or repeated exposure.

H410 - Very toxic to aquatic life with long lasting effect.

Label elements**Hazard pictograms :**

Signal word : Danger

Hazard statements : H330 - Fatal if inhaled.
H360 - 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

General: P201 – Obtain special instructions before use.

P260 – Do not breathe dust/fume/gas/mist/vapours/spray.

P273 – Avoid release to the environment.

P284 – Wear respiratory protection.

P310 – Immediately call a POISON CENTRE or doctor/physician.

P501 – Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazardous ingredients: Mercury
Supplemental label elements: Not applicable

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 XII:
 Not applicable

3. COMPOSITION / INFORMATION ON INGREDIENTS

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

Product/ingredient name	Identifiers	%	Classification	Type
			Regulation (EC) No.	
Europe Mercury	CAS: 7439-97-6 EC: 231-106-7	50	H330; H360; H372; 410 Not classified	[1]
Silver	CAS: 7440-22-4 EC: 231-131-3	22.5-35	H228	[1]
Tin (Sn)	CAS: 7440-31-5 EC: 231-141-8	9-16	H400	[1]
Copper (Cu)	CAS: 7440-50-8 EC: 231-159-6	5-12.5	H410	-
Zinc	CAS: 7440-66-6 EC: 231-175-3	0-0.3		[1]

Type

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

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 (20-40g 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. In the event of a large spill wear special protective clothing and positive pressure, self-contained breathing apparatus.

Most important symptoms and effects both acute and delayed

Potential acute health effects

Eye contact: Not available.
 Inhalation: H330- very toxic by inhalation. H360- May cause harm to the unborn child.
 Skin contact: May be harmful in contact with skin.
 Ingestion: H372- Causes damage to organs through prolonged or repeated exposure.

Indication of any immediate medical and special treatment needed

Notes to physician: Call local Poison Control Centre for assistance.
 Specific treatments: Not available.

5. FIRE FIGHTING 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 vapour.

Advice for fire-fighters

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

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 '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 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

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 recover the capsule whilst mixing.
4. Small droplets of spilled mercury can be collected with the aid of 'mercury-collecting 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 into consideration. For details see for example JADA, August 2003, KEVIN R. MACMUNUS, 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 well-ventilated area.

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
Europe	
Mercury	EU OEL (Europe, 9/2006) TWA: 0,02 mg/m ³ 8 hour(s)
Silver	0.1 mg/m ³
Tin (Sn)	2 mg/m ³
Copper (Cu)	0.1 mg/1
Zinc	0.1 mg/m ³

Recommended monitoring procedures: Dräger Mercury vapour 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.

Body protection:	4-8 hours (breakthrough time): nitrile rubber
Other skin protection:	1-4 hours (breakthrough time): PVC butyl rubber
Respiratory protection:	Lab coat.
	Wash with soap and water.
	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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties.

Appearance:

Physical state:	Liquid
Colour:	Silver
Odour:	Odourless
pH:	Not applicable
Melting/freezing point:	-39°C 9 -38.2°F)
Initial boiling point & boiling range:	357°C (674.6°F)
Flash point:	No results available.
Vapour pressure:	0.0002 kPa (0.0002 mm Hg) (at 20°C)
Vapour density:	6.9 (Air = 1)
Relative density:	13,6
Solubility in water:	Non water soluble liquid
Partition coefficient:	
n-octanol/water:	The product is more soluble in octanol; log(octanol/water) = 4.5
Auto ignition temp:	No results available.
Decomposition temp:	No results available.
Viscosity:	No results available.
Oxidising properties:	Not applicable.
Other information:	No additional information.

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGY INFORMATION

Information on toxicological effects

Acute toxicity:	No results available.
Irritation/Corrosion:	No results available.
Sensitisation:	No results available.
Mutagenicity:	No results available.
Carcinogenicity:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.

SAFETY DATA SHEET

Reproductive toxicity: No results available.
Teratogenicity: No results available.
Potential acute health effects
Eye contact: No available.
Inhalation: H330 - Very toxic by inhalation. H360D - May damage unborn child.
Skin contact: May be harmful in contact with skin.
Ingestion: Possible risk of irreversible effects.
Potential chronic health effects: Chronic or excessive over-exposure may cause symptoms of mercury poisoning with muscle tremors, visual disturbance and kidney effects.
Other information: RTECS: OV4550000

12. ECOLOGICAL INFORMATION

Toxicity

Ingredient name	Species	Period	Result
Mercury	Daphnia (EC50)	48 hours	0.0052 mg/l
Mercury	Fish (LC50)	96 hours	0.35 mg/l

Persistence & degradability: Not applicable.
Bioaccumulative potential: Not applicable.
Mobility in soil: Not applicable.
Results of PBT & vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.
Other adverse effects: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Product

Methods of disposal: Dispose of via a licensed waste disposal contractor.
Hazardous waste: 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

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

14. TRANSPORT INFORMATION

	ADR/RID	ADN	IMDG	IATA
UN Number	2809	2809	2809	2809
UN proper shipping name	Mercury (metal) (Mercury)	Mercury (metal) (Mercury)	Mercury (metal) (Mercury)	Mercury (metal) (Mercury)
Transport hazard class(es)	8 	8 	8 	8 

SAFETY DATA SHEET

Packing group	III	III	III	III
Environmental hazards				
Additional information	Classification Code C9 Packaging instructions: P800		Packaging instructions: P800	Packaging instructions: 803

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

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.

16. FURTHER INFORMATION

Indicates information that has changed from previously issued version.
 Abbreviations & acronyms: ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling & 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
 PRN = 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

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

Justification

Europe

Full text of abbreviated H statements: H228-Flammable solid
 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]: H228-FLAMMABLE SOLIDS Category 1
 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

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use.