

SAFETY DATA SHEETS

This SDS packet was issued with item:

077108301

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

077085251 077085269 077085277 077085525 077086754 077086762 077086770 077086788 077086853 077086861
077086879 077087109 077087117 077087125 077087133 077087141 077087158 077087166 077087174 077087604
077087661 077087679 077090707 077090715 077090723 077090731 077090749 077090756 077090764 077090772
077090780 077090798 077090806 077092968 077092976 077092984 077092992 077093008 077093016 077093024
077093032 077108012 077108020 077108038 077108046 077108053 077108061 077108079 077108087 077108095
077108103 077108111 077108129 077108277 077108285 077108293 077108319 077108327 077108335 077108343
077108350 077108368 077108376 077108384 079878983 079878986 079878989 079878992 079878995 079878998
079879001 079879453 079879456 079879459 079879462 079879465 079879468 079879471 079879474 079879477
079879480 079879483 079879503 079879506 079879512 079879515 079879518 079879521 079879524 079879527
079879530 079879533 079879553 079879556 079879559 079879562 079879565 079879568 079879571 079879574
079879577 079879580 079879583 079879721 079879724 079879727 079879730 079879733 079879736 079879739
079879742 079879760 079879763 079879766

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

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

- **Product identifier**
- **Trade name:** ***Heliomolar / Heliomolar HB***
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Light-curing resin-based dental restorative material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
2785 Skyview Avenue, Unit 1, Mississauga, Ontario L4W4Y3
CANADA
Tel. +1 800 263 8182
Fax +1 905 238 5711
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General MSDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182


2 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

1565-94-2	Bis-GMA	⚠ H315; H319	10-25%
72869-86-4	urethane dimethacrylate	⚠ H319; H317; H402; H412	2.5-10%
6701-13-9	decamethylene dimethacrylate	⚠ H319; H317	2.5-10%

3 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 Irritant
Irritating to eyes. May cause sensitisation by skin contact.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

- **Labelling according to EU guidelines:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

(Contd. on page 2)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 1)

· **Code letter and hazard designation of product:**



Irritant

· **Hazard-determining components of labelling:**

urethane dimethacrylate
decamethylene dimethacrylate

· **Risk phrases:**

Irritating to eyes.
May cause sensitisation by skin contact.

· **Safety phrases:**

Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.
· **vPvB:** Not applicable.

4 First aid measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Rinse with water.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards arising from the substance or mixture** No further relevant information available.

(Contd. on page 3)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 2)

- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

(Contd. on page 4)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 3)

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Pasty
Color:	According to product specification
Odor:	Characteristic
Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapor pressure:** Not determined.

- **Density at 20°C (68°F):** 1.81-1.90 g/cm³ (35-15.856 lbs/gal)

- **Relative density** Not determined.

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

Water:	Nearly insoluble.
--------	-------------------

- **Segregation coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.

(Contd. on page 5)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 4)

- **Chemical stability**
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

USA

(Contd. on page 6)

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 5)

14 Transport information

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **IARC (International Agency for Research on Cancer)**

7631-86-9 silicon dioxide, chemically prepared

3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

13760-80-0 ytterbium trifluoride

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

(Contd. on page 7)

USA

Material Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 6

Reviewed on 07/07/2011

Trade name: *Heliomolar / Heliomolar HB*

(Contd. of page 6)

· Product related hazard informations:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· Hazard symbols:*Irritant***· Hazard-determining components of labelling:**

urethane dimethacrylate
decamethylene dimethacrylate

· Risk phrases:

Irritating to eyes.
May cause sensitisation by skin contact.

· Safety phrases:

Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.

· National regulations:**· Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the EC-directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019


1 Identification

- **Product identifier**
- **Trade name:** ***Heliomolar / Heliomolar HB***
- **Application of the substance / the mixture** Light-curing resin-based dental restorative material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
Bis-GMA
urethane dimethacrylate
1,10-decandiol dimethacrylate
- **Hazard statements**
Causes skin irritation.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 1)

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

· **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

CAS: 36425-15-7	Bis-GMA	10-25%
CAS: 13760-80-0	ytterbium trifluoride	≥10-<20%
CAS: 72869-86-4	urethane dimethacrylate	≥2.5-<10%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	≥2.5-<10%

4 First-aid measures

· **Description of first aid measures**· **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Rinse with water.· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist consult doctor.· **Information for doctor:**· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 3)

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Not suitable are gloves made of the following materials:**
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
 - Form:** Pasty
 - Color:** According to product specification
 - Odor:** Characteristic
 - Odor threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
 - Melting point/Melting range:** Undetermined.
 - Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower:** Not determined.
 - Upper:** Not determined.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 4)

· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	1.81-1.90 g/cm ³ (15.104-15.856 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Nearly insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 5)

- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void | |
| · UN proper shipping name | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void | |
| · Transport hazard class(es) | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR/RID/ADN, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. | |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· Section 355 (extremely hazardous substances):
None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 6)

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

CAS: 13760-80-0 ytterbium trifluoride

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS07

· **Signal word** Warning· **Hazard-determining components of labeling:**

Bis-GMA

urethane dimethacrylate

1,10-decandiol dimethacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

· **National regulations:**· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

US

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/25/2019

Version number 8

Reviewed on 03/21/2019

Trade name: **Heliomolar / Heliomolar HB**

(Contd. of page 7)

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 03/25/2019 / 7

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

· *** Data compared to the previous version altered.**

US