## **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

077108053

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 077108061 077108079 077108087 077108095 077108103 077108111 077108129 077108277 077108285 077108293 077108301 077108319 077108327 077108335 077108343 077108350 077108368 077108376 077108384 079878983 079878986 079878989 079878992 079878995 079878998 079879453 079879456 079879459 079879462 079879465 079879468 079879471 079879474 079879477 079879480 079879483 079879553 079879556 079879512 079879515 079879518 079879521 079879524 079879574 079879530 079879533 079879553 079879556 079879559 079879562 079879565 079879568 079879571 079879574 079879577 079879580 079879583 079879721 079879724 079879727 079879730 079879733 079879736 079879739 079879742 079879760 079879763 079879766



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 Skymark 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	<b>♦</b> H315; H319	10-25%
72869-86-4 urethane dimethacrylate	<b>♦</b> <i>H319; H317; H402; H412</i>	2.5-10%
6701-13-9 decamethylene dimethacrylate	<b>♦</b> 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/EWG usually if they are in the finished state and intended for the final user.

(Contd. on page 2)

-USA

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 = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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

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

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: CharacteristicOdour 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  $20^{\circ}C$  (68°F): 1.81-1.90 g/cm<sup>3</sup> (35-15.856 lbs/gal)

Relative density
 Vapour density
 Evaporation rate
 Not determined.
 Not determined.

· Solubility in / Miscibility with

Water: Nearly insoluble.

 $\cdot \textit{Segregation coefficient (n-octonol/water):} \ \textit{Not determined}.$ 

· 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

(Contd. of page 4)

# 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

· 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)

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)

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# 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/EWG usually if they are in the finished state and intended for the final user.

#### · Hazard symbols:



rritani

# · 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.

– US



Printing date 20.04.2015 Version number 7 Revision: 30.03.2015

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- · Trade name: Heliomolar / Heliomolar HB
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Light-curing resin-based dental restorative material
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent AG
Bendererstrasse 2

FL-9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

*Tel:* +423 235 35 35 *Fax:* +423 235 33 60

· Further information obtainable from:

Regulatory Affairs sds@ivoclarvivadent.com

· 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

## SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

Bis-GMA

urethane dimethacrylate

1,10-decandiol dimethacrylate

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

*P363* Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

(Contd. on page 2)

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# Trade name: Heliomolar / Heliomolar HB

(Contd. of page 1)

#### · Additional information:

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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

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

# SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous compone	ents:	
CAS: 1565-94-2	Bis-GMA	10-<25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	ytterbium trifluoride	10-<25%
EINECS: 237-354-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
	urethane dimethacrylate	3-<10%
EINECS: 276-957-5	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	
	1,10-decandiol dimethacrylate	3-<10%
EINECS: 229-745-1	Eye Irrit. 2, H319; Skin Sens. 1, H317	

<sup>·</sup> Additional information: For the wording of the listed risk phrases refer to section 16.

# **SECTION 4: First aid measures**

- · 4.1 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.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

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

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Not required.

(Contd. on page 3)

-GB

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# Trade name: Heliomolar / Heliomolar HB

(Contd. of page 2)

- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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.

### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 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 container tightly sealed.* 

· 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients 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 valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- $\cdot \textit{General protective and hygienic measures:} \\$

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.

- $\cdot \textit{Respiratory protection:} \ \textit{Not required}.$
- · 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 (Contd. on page 4)

- GE

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# Trade name: Heliomolar / Heliomolar HB

(Contd. of page 3)

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

DECELOTIVE TO SECURE WITH CITCUIT PROPERTIES	SECTION 9: Ph	iysical and	l chemical	properties
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<ul> <li>9.1 Information on</li> </ul>	basic physical	l and chemical	l properties
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· General Information

· Appearance:

Form: Pasty

Colour: According to product specification

Odour: CharacteristicOdour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

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

· Flash point: Not applicable.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:Not determined.Upper:Not determined.

· Vapour pressure: Not determined.

Density at 20 °C:
 Relative density
 Vapour density
 Evaporation rate
 1.81-1.90 g/cm³
 Not determined.
 Not determined.
 Not determined.

· Solubility in / Miscibility with

water: Nearly insoluble.

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

**Dynamic:** Not determined. **Kinematic:** Not determined.

• 9.2 Other information No further relevant information available.

### SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 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.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.

(Contd. on page 5)

GB

Printing date 20.04.2015 Version number 7 Revision: 30.03.2015

# Trade name: Heliomolar / Heliomolar HB

(Contd. of page 4)

· 10.4 Conditions to avoid

Protect from exposure to the light.

Keep away from heat and direct sunlight.

- · 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

### SECTION 11: Toxicological information

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

## SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (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.

- · 12.5 Results of PBT and vPvB assessment
- $\cdot$  **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

### **SECTION 13: Disposal considerations**

- · 13.1 Waste treatment methods
- · Recommendation

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

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	Transport		arma	TOW
				44U.H

- · 14.1 UN-Number
- · ADR, ADN, IMDG, IATA Void
- · 14.2 UN proper shipping name
- · ADR, ADN, IMDG, IATA Void

(Contd. on page 6)

GB

Printing date 20.04.2015 Version number 7 Revision: 30.03.2015

# Trade name: Heliomolar / Heliomolar HB

		(Contd. of page 5
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
Class	Void	
· 14.4 Packing group		
· ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards:		
· Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Transport in bulk according to Ani	nex II of	
MARPOL73/78 and the IBC Code	Not applicable.	
· UN ''Model Regulation'':	-	

## SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

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

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

# SECTION 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.

### · Relevant phrases

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

#### · 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

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eve Irrit. 2: Serious eve damage/eve irritation, Hazard Ca

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

· \* Data compared to the previous version altered.

GF