Printing date 25.03.2019

vivader

Version number 7

Revision: 21.03.2019

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

· 1.1 Product identifier

• Trade name: MultiCore HB / Flow (Base)

• 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 Two-component core build-up material
- 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 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, 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* triethylene glycol dimethacrylate • Hazard statements H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. · Precautionary statements P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves / eye protection / face protection. P302+P352 IF ON SKIN: Wash with plenty of water. P321 Specific treatment (see on this label).

(Contd. on page 2)

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Base)

(Contd. of page 1) P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501

Dispose of contents/container in accordance with local/regional/national/international regulations.

#### • 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: 13760-80-0	ytterbium trifluoride	≥10-<20%
EINECS: 237-354-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 36425-15-7	Bis-GMA	10-25%
NLP: 500-089-0	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 72869-86-4	urethane dimethacrylate	≥2.5-<10%
EINECS: 276-957-5	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	
CAS: 109-16-0	triethylene glycol dimethacrylate	≥2.5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3,	
	H335	
· Additional information	ion. For the wording of the listed hazard phrases refer to section 16	

**Additional information:** For the wording of the listed hazard 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 eve 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.

(Contd. on page 3) GR

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Base)

(Contd. of page 2)

• 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.
- 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.

 $\cdot$  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:
- General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories. Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

• **Respiratory protection:** Not required.

• Protection of hands:



Protective gloves

(Contd. on page 4)

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Base)

(Contd. of page 3) 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

# **SECTION 9: Physical and chemical properties**

#### •9.1 Information on basic physical and chemical properties

• General Information

Series an Ingermation		
Appearance:		
Form:	Pasty	
Colour:	According to product specification	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	: Undetermined.	
Flash point:	Not applicable.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Nearly insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
	Not determined.	
Dynamic:	Not delet mined.	

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

(Contd. of page 4)

# Trade name: MultiCore HB / Flow (Base)

• 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.
- · 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 Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation
- Causes skin irritation.
- Serious eye damage/irritation
- Causes serious eye irritation.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- · Additional toxicological information: No further relevant information available.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- $\cdot$  **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

#### **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 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

(Contd. on page 6)

GB

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Base)

· 12.6 Other adverse effects No further relevant information available.

(Contd. of page 5)

# **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.

SECTION 14: Transport information	on
· 14.1 UN-Number · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR/RID/ADN, 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 Annex Marpol and the IBC Code	<b>x II of</b> Not applicable.
• Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

# **SECTION 15: Regulatory information**

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· 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.

(Contd. on page 7)

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Base)

(Contd. of page 6) 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) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 \* Data compared to the previous version altered.

Printing date 25.03.2019

vivader

Version number 7

Revision: 21.03.2019

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

· 1.1 Product identifier

• Trade name: MultiCore HB / Flow (Catalyst)

• 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 Two-component core build-up material
- · 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 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, 9494 Schaan, Liechtenstein)

# **SECTION 2: Hazards identification**

#### · 2.1 Classification of the substance or mixture

 $\cdot$  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* triethylene glycol dimethacrylate dibenzovl peroxide • Hazard statements H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. · Precautionary statements P261 Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves / eye protection / face protection. P280 *P302+P352* IF ON SKIN: Wash with plenty of water.

(Contd. on page 2)

GB

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Catalyst)

(Contd. of page 1)

# P321 Specific treatment (see on this label). P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P501 Dispose of contents/container in accordance with local/regional/national/international

Dispose of contents/container in accordance with local/regional/national/international regulations.

• 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 components:		
CAS: 13760-80-0	ytterbium trifluoride	≥10-<20%
EINECS: 237-354-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 36425-15-7	Bis-GMA	10-25%
NLP: 500-089-0	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 72869-86-4	urethane dimethacrylate	<i>≥</i> 2.5-<10%
EINECS: 276-957-5	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	
CAS: 109-16-0	triethylene glycol dimethacrylate	<i>≥</i> 2.5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 94-36-0	dibenzoyl peroxide	<b>≥</b> 0.1-<1%
EINECS: 202-327-6	Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	
Additional information	an. For the wording of the listed hazard physics refer to section 16	

· Additional information: For the wording of the listed hazard 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.

(Contd. on page 3)

GB

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Catalyst)

(Contd. of page 2) • 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.

- 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: Store in a cool place.

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:
- General protective and hygienic measures: Usual hygienic measures for dental practice and dental laboratories. Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

• Respiratory protection: Not required.

(Contd. on page 4)

GB

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Catalyst)

(Contd. of page 3)

#### · 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

9.1 Information on basic physical and ch	nemical properties	
General Information		
Appearance:		
Form:	Pasty	
Colour:	According to product specification	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range:	Undetermined.	
Flash point:	Not applicable.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Nearly insoluble.	

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Catalyst)

(Contd. of page 4)

• Partition coefficient: n-octanol/water: Not determined.

Viscosity:

Dynamic:

*Kinematic:* 9.2 *Other information* 

Not determined. Not determined. 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.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 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 Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation
- Causes skin irritation.
- · Serious eye damage/irritation
- Causes serious eye irritation.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- Additional toxicological information: No further relevant information available.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

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

(Contd. on page 6)

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Catalyst)

· 12.6 Other adverse effects No further relevant information available.

(Contd. of page 5)

# **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.

SECTION 14: Transport information	on
· 14.1 UN-Number · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR/RID/ADN, 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 Annex Marpol and the IBC Code	x <b>II of</b> Not applicable.
• Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

# **SECTION 15: Regulatory information**

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· 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

H241 Heating may cause a fire or explosion.

(Contd. on page 7)

Printing date 25.03.2019

Version number 7

Revision: 21.03.2019

# Trade name: MultiCore HB / Flow (Catalyst)

(Contd. of page 6) 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) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Org. Perox. B: Organic peroxides - Type B Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 • \* Data compared to the previous version altered.