

HIMACS JOINT ADHESIVE KIT

SAFETY DATA SHEET

- COMPONENT A

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE

COMPANY/UNDERTAKING

- 1.1 Product identifier: HI-MACS JOINT ADHESIVE KIT COMPONENT A
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:

Relevant identified uses: Adhesive.

Uses advised against: Do not use in medical applications involving permanent

implantation in the human body.

1.3 Details of the supplier of the safety data sheet:

LX Hausys CO., LTD.

98, Huam-ro, Jung-gu, Seoul, Republic of Korea, 04637 <u>miraclen@lxhausys.com</u> (Europe: timlie@lxhausys.com)

1.4 Emergency telephone number:

Should be followed each country's information.

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:
- 2.1.1 Classification according to Regulation (EC) No 1272/2008, GHS:

Physical hazard:

-Flammable liquid: Flam. Liq. Category 2, H225

Health hazard:

-Skin corrosion/irritation: Skin Irrit. Category 2, H315 -Serious eye damage/eye irritation: Eye Irrit. Category 2, H319 -Skin sensitization: Skin Sens. Category 1, H317

-Specific target organ toxicity – single exposure: STOT SE Category 3, H335 $\,$

- Target organ : Respiratory tract irritation

Environmental hazard:

-Aquatic Environment Acute 1, Chromic 1

2.1.2 Classification according to Directive 1999/45/EC:

Highly flammable: F; R11 Irritant:

Xi; R36/37/38

Sensitising: R43

2.1.3 Additional information: For full text of R-phrases and hazard statements: see SECTION 16.

2.2 Label elements:

Labelling according to Regulation (EC) No 1272/2008:

Hazard pictograms:



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Signal word: Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

Precautionary statements:

Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

- No smoking.

P233 Keep container tightly closed.

P240 Ground/bond container and receiving equipment.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P280 Wear protective gloves/protective clothing/eye protection/face protection.P261

Avoid breathing vapours.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing should not be allowed out of the workplace.

P264 Wash thoroughly after handling.

P273 Avoid release to the environment.

Responses:

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off Immediately all contaminated clothing.

Rinse SKIN with water/shower.

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

P362+P364 Take off contaminated clothing and wash before reuse.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P363 Wash contaminated clothing before reuse.

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

P304+P340 IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.

P312 IF exposed: call a POISON CENTER or doctor/physician.

P370+P378 Incase of fire: Use Dry chemical/carbon dioxide for extinction.

P391 Collect spillage. Hazardous to the aquatic environment

Storage:

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P235 Keep cool.

Disposal:

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazardous ingredients for labelling: Methyl methacrylate.

2.3 NFPA Rating:

Health: 2 flammability: 3 Reactivity: 0 Water reactivity: 0

2.4 Other hazards: There is no additional information.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substances: Not relevant.

Mixtures: Description of the mixture: Synthetic resin(s) and filler(s). The mixture

contains these substances:

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	EC/CAS No.	Classification				
Substance name			CLP			
		67/548/EEC	Hazard Class and Category Code(s)	Hazard statement	Pictogram/ Signal word	Conc.(%)
Methyl methacrylate 1,0	201-297-1/80-62-6	Highly flammabl e F; R11 Irritant Xi; R36²/37/38 Sensitisin g R43	Flam. Liq. 2 Skin Irrit. 2 Eye Irrit. 2 ² Skin Sens. 1 STOT SE 3	H225 H315 H319 ² H317 H335	GHS02 GHS07 Dgr	35~50
PMMA[Polymer]	618-466-4/ 9011-14-7					20~35
Aluminum Trihydrate	244-492-7/ 21645-51-2					10~20
Additives	-	-	-	-	-	3

¹Substance with workplace exposure limits.

Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

General advice

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Ingest activated charcoal. Do NOT induce vomiting. Call a physician immediately.

- **4.2 Most important symptoms and effects, both acute and delayed:** Symptoms and effects are not known to date.
- 4.3 Indication of any immediate medical attention and special treatment needed: None.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: water spray, alcohol resistant foam, dry chemical, carbon dioxide (CO_2) .

Unsuitable extinguishing media: water jet.

5.2 Special hazards arising from the substance or mixture: In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent

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²Classification according to manufacturer.

vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products: nitrogen oxides (NOx), carbon monoxide (CO), carbon dioxide (CO₂).

5.3 Advice for firefighters: In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- **6.1** Personal precautions, protective equipment and emergency procedures:
 - **For non-emergency personnel:** Ensure adequate ventilation. Use personal protective equipment. Remove all sources of ignition. Remove persons to safety.
 - For emergency responders: Wear breathing apparatus if exposed to vapours.
- **6.2 Environmental precautions:** Keep away from drains, surface and ground water. Retain contaminated washing water and dispose it.
- **6.3** Methods and material for containment and cleaning up: Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage (sawdust, diatomite, sand, universal binder). Place in appropriate containers for disposal. Ventilate affected area.
- **6.4 Reference to other sections:** Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: HANDLING AND STORAGE

- 7.1 Precautions for safe handling: Use local and general ventilation. Keep away from sources of ignition No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air. Wash hands after use. Do not to eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feeding stuffs.
- **7.2**Conditions for safe storage, including any incompatibilities: Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight. Keep away from sources of ignition No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Take precautionary measures against static discharge. Ground/bond container and receiving equipment.
- **7.3**Specific end use(s): No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Occupational exposure limit values listed in EH40/2005 Workplace exposure limits:

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		Workplace ex		
Substance	CAS Number	Long-term exposure limit (8-hr TWA reference period) ppm mg/m³	Short-term exposurelimit(15-minute reference period) ppm mg/m ³	Comments
Methyl methacrylate	80-62-6	50 208	100 416	-
Titanium dioxide total inhalable respirable	13463-67-7	- 10 - 4		-
Carbon black	1333-86-4	- 3.5	- 7	-

- **8.2** Exposure controls:
- **8.2.1** Appropriate engineering controls: General ventilation.
- 8.2.2 Individual protection measures, such as personal protective equipment:
- **8.2.2.1 Eye/face protection:** Wear eye/face protection.
- **8.2.2.2** Skin protection:

Hand protection: Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Other: Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

- **8.2.2.3 Respiratory protection:** In case of inadequate ventilation wear respiratory protection.
- **8.2.2.4** Thermal hazards: No data available.
- **8.2.3 Environmental exposure controls:** Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Appearance:	liquid colour: various		
Odour:	acrylic		
Odour threshold:	no data available		
pH:	6.5 ~ 7.5 at 20°C *Sample : H2O=1:5(V/V)		
SS	no data available		
Initial boiling point and boiling range:	>98°C		
Flash point:	< 20°C (Rapid equilibrium method)		
Evaporation rate:	no data available		
Flammability (solid, gas):	not applicable		
Upper/lower flammability or explosive	2.1 vol. % (lower)		
limits:	12.5 vol. % (upper)		
Vapour pressure (20°C):	39 hps		
Vapour density:	no data available		
Relative density:	1.20 - 1.24 kg/l		
Solubility(ies):	partially miscible in water		
Partition coefficient: n-octanol/water:	no data available		
Auto-ignition temperature:	430°C		
Decomposition temperature:	no data available		

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Viscosity:	> 1,000mPa s(cP) at 20°C	
Explosive properties:	no data available	
Oxidising properties:	no data available	

9.2 Other information: No data available.

SECTION 10: STABILITY AND REACTIVITY

- **10.1 Reactivity:** Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". The mixture contains reactive substance(s): risk of ignition.
- **10.2** Chemical stability: No decomposition if stored and applied as directed.
- **10.3** Possibility of hazardous reactions: No data available.
- **10.4 Conditions to avoid:** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. UV radiation/ sunlight.

Incompatible materials: Oxidisers - reducing agents.

10.5 Hazardous decomposition products: Methyl methacrylate monomer.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects: Test data are not available for the complete mixture.

Substances:

Methyl methacrylate

Acute toxicity: LD50, oral: 7872 mg/kg (RTECS, 47796)

Mixtures:

Acute toxicity:

bbit LD50 : > 2,000 mg/kg

Inhalation rat LC50 (mist, 4h): No data available

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation. Respiratory

or skin sensitisation: May cause an allergic skin reaction.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

<u>Carcinogenicity:</u> Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

Specific target organ toxicity (STOT) - single exposure: May cause respiratory irritation.

Specific target organ roxicity (STOT) - repeated exposure: Based on available data, the

classification criteria are not met.

<u>Aspiration hazard:</u> Based on available data, the classification criteria are not met.

<u>Other information:</u> Repeated and prolonged exposure to solvents may cause brain and nervous system damage.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity: Mixture is not classified as hazardous to the aquatic environment.

Fish LC50 : $> 100 \, \text{mg/L}$, 96 h \times from US NLM /ECHA

Crustacean LC50 : > 20 mg/L, 48 h Algae $= \frac{1}{1000} = \frac{1}{10$

12.2 Persistence and degradability

12.3 Bioaccumulative potential: No data available.

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- **12.4** Mobility in soil: No data available.
- 12.5 Results of PBT and vPvB assessment: No data available.
- **12.6** Other adverse effects: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods: Dispose off in accordance with local and national regulations. Do not empty into drains. Avoid release to the environment. Handle contaminated packages in the same way as the substance itself.

SECTION 14: TRANSPORT INFORMATION

- **14.1 UN number:** 1133
- **14.2 UN proper shipping name:** ADHESIVES containing flammable liquid
- **14.3** Transport hazard class(es): 3.
- **14.4** Packing group: Π
- **14.5** Environmental hazards: No data available.
- **14.6 Marine pollution:** No
- **14.7 Special precautions for user:** Fire EmS Guide : F-E. Spillage EmS Guide : S-D
- 14.8 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: No dataavailable.

SECTION 15: REGULATORY INFORMATION

- **15.1Safety, health and environmental regulations/legislation specific for the substance or mixture:** The substances in the mixture are not subject to the authorisation under Title VII nor restrictions under Title VIII of Regulation (EC) No. 1907/2006.
- 15.2Chemical safety assessment: Chemical safety assessment for substances in this mixture is not available.

SECTION 16: OTHER INFORMATION

List of relevant hazard statements:

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- R11 Highly flammable.
- R36/37/38 Irritating to eyes, respiratory system and skin.
- R43 May cause sensitisation by skin contact.
- **Instructions for the training:** Product handling instruction shall be included into the educational system about the safety work (initial training, training at the workplace, repeated training) according to specific conditions at the workplace.

Recommended restrictions on use (i.e. non-statutory recommendations by supplier):

Mixture should not be used for any other purpose than for which is appointed (point1.2). Because of the fact that specific conditions of use of substance are out of supplier's control, it is responsibility of the user to adjust the prescribed warnings to local laws and regulations. Safety information describes the product in terms of safety and it cannot be considered as technical information about product.

Sources of key data used to compile the Safety Data Sheet: SDS was elaborated According to requirements set in Annex II of Regulation (EC) No 1907/2006 of the European

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Parliament and of the Council. SDS was prepared using data from the producer. This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Classification procedure:

Physical and chemical properties: The classification is based on tested mixture.

Health hazards/environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Purpose of SDS: Purpose of this SDS is to provide relevant information for users of product to ensure proper handling and control of risks/hazards.

Abbreviations and acronyms

CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of

substances and mixtures

EH40/2005 EH40/2005 Workplace exposure limits, Table 1: List of approved workplace

exposure limits

Eye Irrit. Eye irritation

F highly flammable

Flam. Liq. flammable liquid

GHS "Globally Harmonized System of Classification and Labelling of Chemicals"

developed by the United Nations

PBT Persistent, Bioaccumulative and Toxic

ppm parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

Skin Irrit. skin irritation
Skin Sens. skin sensitisation

STOT SE specific target organ toxicity - single exposure vPvB very Persistent and very Bioaccumulative

Xi irritant

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