

HIMACS JOINT ADSHESIVE KIT

SAFETY DATA SHEET

- COMPONENT B

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

COMPANY/UNDERTAKING

- 1.1 Product identifier: HI-MACS JOINT ADHESIVE KIT COMPONENT B
- 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:

Skin sensitization: A. Skin Sens. Category 1, H317
Eye Irritation: B. Eye Irrit. Category 2, H319

Aquatic Environment: - Chronic 2

2.1.2 Classification according to Directive 1999/45/EC:

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:



Signal word: Warning **Hazard statements:**

H317 May cause an allergic skin reaction.H319

Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P261 Avoid breathing vapours.

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

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

P264 Wash thoroughly after handling.

P273 Avoid release to the environment. P302+P352 IF ON

SKIN: wash with plenty of water.

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.

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

P391 Collect spillage. Hazardous to the aquatic environment

P363 Wash contaminated clothing before reuse.

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

Hazardous ingredients for labelling: Dibenzoyl peroxide.

2.3 NFPA Rating

Health: 2 Flammability: 1 Reactivity: 0 Water reactivity: 0

2.4 Other hazards: There is no additional information.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances: Not relevant.

3.2 Mixtures: Description of the mixture: Plasticizer. The mixture contains these substances:

Substance name	EC/CAS No.	Classification				
		67/548/EEC		Conc.		
			Hazard Class and	Hazard	Pictogram/	(%)
			Category Code(s)	statement	Signal word	
Dipropylene	248-258-5/	-	-	-	-	94
Glycol dibenzoate	27138-31-4					
Dibenzoyl peroxide1	202-327-6 / 94-36-0	Explosive E; R3 Oxidising O; R7 Irritant Xi; R36 Sensitising R43	Org. Perox. B Eye Irrit. 2 Skin Sens. 1	H241 H319 H317	GHS01 GHS02 GHS07 Dgr	3
Fumed silica, crystfree1	601-216-3/ 112945-52- 5	-	-	-	-	3

¹Substance with workplace exposure limits.

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 unconsciousn ess 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. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

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Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Ingest activated charcoal. DoNOT 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:

Hazardous combustion products: nitrogen oxides (NOx), carbon monoxide (CO), carbon dioxide (CO_2).

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). Pla ce in appropriate containers for disposal. Ventilate affected area.
- **6.4 Reference to other sections:** Hazardous combustion products: see section 5. Personal prot ective equipment: see section 8. Incompatible materials: see section 10. Disposal considerat ions: 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. Use only in well-ventilated areas. 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 at temperatures below 30°C. Water mist may be used to cool closed containers. Incompatible products: Polymerization accelerators and easily oxidized materials. Reacts violently in contact with acids, amines, driers.
- **7.3** Specific end use(s): No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

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

8.2 Exposure controls:

Substance	CAS Number	Workplace exposure limit				Comments
		Long-term exposure limit		Short-term exposure limit		
		(8-hr TWA re	ferenceperiod) mg/m³	(15-minute ro	eferenceperiod) mg/m³	
Dibenzoyl peroxide	94-36-0	-	5	-	-	-
Fumed silica, Crystalline-free	-	-	0.1	-	-	-

- **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 thesegloves.

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				
Арреагансе.	colour: light yellow				
Odour:	slight				
Odour threshold:	no data available				
pH:	6.5 ~ 7.5 at 20 °C				
Melting point/freezing point:	no data available				
Initial boiling point and boiling range:	>100 ℃				
Flash point:	230 °C (Cleveland open cup)				
Evaporation rate:	no data available				
Flammability (solid, gas):	not applicable				
Upper/lower flammability or explosive limits:	no data available				
Vapour pressure (147°C):	1.3 hps				
Vapour density:	no data available				
Relative density:	1.1 at 20 ℃				
Solubility(ies):	immiscible in water				
Partition coefficient: n-octanol/water:	no data available				
Auto-ignition temperature:	No spontaneous combustion under 200 ℃				
Decomposition temperature:	103°C				
Viscosity:	> 1,000 mPa . s (cP) at 20 ℃				
Explosive properties:	no data available				
Oxidising properties:	no data available				

9.2 Other information: No data available.

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SECTION 10: STABILITY AND REACTIVITY

- **10.1 Reactiveity:** Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials"
- **10.2** Chemical stability: Decomposition starting from 103°C: Dibenzoyl peroxide 100%.
- **10.3** Possibility of hazardous reactions: No data available.
- **10.4** Conditions to avoid: Keep away from heat and ignition sources.
- **10.5 Incompatible materials:** Reacts violently in contact with acids, amines, driers, polymerization accelerators and easily oxidized materials.
- **10.6** Hazardous decomposition products: Benzoic acid, biphenyls, benzene

SECTION 11: TOXICOLOGICAL INFORMATION

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

Substances:

Oxydipropyl dibenzoate

Acute toxicity: LD50, oral: 8000 mg/kg (RTECS, 59814)

<u>Dibenzoyl peroxide</u>

Acute toxicity: LD50, oral: 7710 mg/kg (RTECS, 19455)

Mixtures:

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

Oral rat LD50: > 2,000 mg/kg % from US NLM / ECHA

Skin rabbit LD50: No data available

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

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

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.

<u>Specific target organ toxicity (STOT) - single exposure:</u> Based on available data, the classification criteria are not met.

<u>Specific target organ roxicity (STOT) - repeated exposure:</u> Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

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

SECTION 12: ECOLOGICAL INFORMATION

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

Fish $LC50: > 2.0 \text{ mg/L}, 96 \text{ h} \times \text{from US NLM / ECHA}$

Crustacean LC50 : > 2.0 mg/L, 48 h Algae EC50 : > 1.0 mg/L, 72 h

- **12.2** Persistence and degradability: No data available.
- **12.3** Bioaccumulative potential: No data available.
- **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.

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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

14.1UN number: No data available.

14.2UN proper shipping name: No data available. **14.3Transport hazard class(es):** No data available.

14.4 Packing group: No data available.

14.5Environmental hazards: No data available.

14.6Marine pollution: No

14.7Special precautions for user: No data available.

14.8 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: No dataavailable.

SECTION 15: REGULATORY INFORMATION

- **15.1** Safety, 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 n or restrictions under Title VIII of Regulation (EC) No. 1907/2006.
- **15.2 Chemical safety assessment:** Chemical safety assessment for substances in this mixture is not available.

SECTION 16: OTHER INFORMATION

List of relevant hazard statements:

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.R7

May cause fire.

R36 Irritating to eyes.

R43 May cause sensitisation by skin contact.

Instructions for the training: Product handling instruction shall be included into the education al 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): Mixt ure should not be used for any other purpose than for which is appointed (point 1.2). Becaus e 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 andregulations. 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 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.

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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

E explosive Eye Irrit. irritation

"Globally Harmonized System of Classification and Labelling of Chemicals"

developed by the United Nations

O oxidising

Org. Perox. organic peroxide

PBT Persistent, Bioaccumulative and Toxic

ppm parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

Skin Sens. skin sensitisation

vPvB very Persistent and very Bioaccumulative

Xi irritant

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