Safety Data Sheet according to Regulation (EC) No. 1907/2006, Article 31

1. Identification of the Substance or Mixture and the Company/Undertaking

1.1. Product Identifier

Article Description: orthosis joint grease for joints with gear segments

Article Number: FT2000

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

No further relevant information available.

Application of the Substance/Mixture: grease

1.3. Details of the Supplier of the Safety Data Sheet

Manufacturer:

MOLYDAL SA 221 RUE PAUL LANGEVIN 60744 SAINT MAXIMIN CEDEX PHONE: + 33 (0)3 44 61 76 76 FAX: + 33 (0)3 44 25 17 78 www.molydal.com

Contact Support at:

Service technique molydal@molydale.com

Supplier:

Company FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH Dorette-von-Stern-Straße 5 21337 Lüneburg (Germany)

Phone: +49 4131 24445-0 Fax: +49 4131 24445-57 Email: info@fior-gentz.de

1.4. Emergency Number

ORFILA TEL: +33 (0) 1 45 42 59 59

2. Hazards Identification

2.1. Classification of the Substance or Mixture

The product is not classified according to CLP Regulation.

2.2. Label Elements

Labelling according to Regulation (EC) No. 1272/2008: none

Hazard Pictographs: none

Signal Word: none Hazard Warnings: none



2.3. Other Hazards

Results of PBT and vPvB Assessment

PBT: not applicable **vPvB:** not applicable

3. Composition/Information on Ingredients

3.2. Chemical Characterisation

mixtures

Description: mixture of ingredients with non-hazardous additions listed below.

Hazardous Ingredients: not available

Add. Information: take the wording of the hazard warnings from section 16.

4. First Aid Measures*

4.1. Description of First Aid Measures

General Information: no specific measures necessary.

After Inhalation: fresh air, rescue breathing if necessary, heat. Seek medical advice

if symptoms persist.

After Skin Contact: Clean with water and soap, if possible, also with polyethylene glycol

400.

Take off immediately all contaminated clothing.

After Eye Contact: rinse eyes holding eyelids open with running water for several minutes.

Seek medical advice if symptoms persist.

After Ingestion: do not induce vomiting, immediately get medical attention.

4.2. Most Important Symptoms and Effects, Both Immediate and Delayed

No further relevant information available.

After Inhalation: no further relevant information available

After Ingestion: gastrointestinal complaints

After Skin Contact: no further relevant information available

After Eye Contact: irritant effect

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

No further relevant information available.

5. Firefighting Measures*

5.1. Extinguishing Media

Suitable Extinguishing Media:

carbon dioxide, extinguishing powder or water spray. For large fires, use water spray. **Unsuitable Extinguishing media for Safety Reasons:** full water jet

5.2. Special Hazard Arising from the Substance or Mixture

The following products can be released in case of fire: carbon monoxide (CO); carbon dioxide (CO2).



5.3. Advice for Firefighters

Special Protective Equipment: Use self-contained breathing apparatus (SCBA).

Further Information: Use water spray to cool fire-exposed containers. Disposal of extinguishing water and firefighting residues according to official regulations.

6. Accidental Release Measures*

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Wear full protective equipment. Keep unprotected personnel away.

Ensure adequate ventilation.

Slip hazard through leaked/spilled product in particular.

Stop leak if without risk.

Keep away from heat, hot surfaces, sparks, open flame and any other ignition source. No smoking.

6.2. Environmental Precautions

If entering in waterways or sewer, inform responsible authorities.

Do not empty into drains/surface water/groundwater.

Prevent runoff into soil and underground.

6.3. Methods and Material for Containment and Cleaning

Soak up mechanically.

6.4. Reference to Other Sections

Information on safe handling, see section 7. Information on personal protective equipment, see section 8. Information on disposal, see section 13.

7. Handling and Storage*

7.1. Precautions for Safe Handling

No specific measures necessary.

Fire and Explosion Prevention: no specific measures necessary

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage:

Requirements on Storerooms and Containers: Store only in the original container.

Incompatible Products: Store separated from oxidizing agents.

Further Information on Storage Conditions: Store container tightly closed in a cool, dry place.

Recommended Storage Temperature: No further relevant information available.

Storage Class:

Classification according to German Ordinance on Industrial Safety and Health (BetrSichV): -

7.3. Specific End Uses

No further relevant information available.



8. Exposure Controls and Limitations/Personal Protection*

Additional Advice for Technical Equipment: not elsewhere specified, see section 7.

8.1. Control Parameters

Ingredients with Occupational Exposure Limits to be Controlled:

The product does not contain any relevant amounts of substances with occupational exposure limits to be controlled.

Additional Information: The lists valid at the time of creation served as basis.

8.2. Exposure Controls and Limitations

Personal Protection:

General Protective and Hygiene Measures:

Wash hands before breaks and at the end of each workday. Avoid contact with skin and eyes. Do not eat, drink, sniff or smoke when handling the product.

Respiratory Protection: With appropriate ventilation not necessary.

Hand Protection: Protective gloves. Selection of the glove material considering breakthrough times, permeation rates and degradation.

Glove Material: The selection of a suitable glove depends not only on the material but also on other quality characteristics and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the durability of glove materials is unpredictable and must therefore be checked before using them.

- nitrile rubber
- natural rubber (latex)
- gloves made of neoprene

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: When transferring content, protective goggles are recommended.

Skin and Body Protection: oil-resistant protective clothing

9. Physical and Chemical Properties*

9.1. Information on Basic Physical and Chemical Properties

General Information

Appearance:

Physical State: solid Colour: white

Odour: characteristic not determined

pH Value: not applicable

Change in State

Melting Point/Melting Range:not determinedBoiling Point/Boiling Range:not determined

Flash Point: not applicable Ignitability (Solid, Gas): not determined Ignition Temperature: > 400°C not determined

Self-Ignitability: The product is not self-igniting. **Risk of Explosion:** The product is not explosive.



Explosive Limits: not available

Lower:

Upper: not determined

Vapour Pressure:

Density:

Vapour Density:

Evaporation Rate:

Solubility in/Miscibility with Water:

Partition Coefficient (n-Octanol/Water):

0.1hPa
unknown
not applicable
insoluble
not determined

Viscosity

Dynamic: not applicable **Kinematic:** not applicable

Solvent Concentration

Organic Solvents: 0.0%

9.2. Other Information

not worked penetration at 25°C:

220 - 250 1/10mm

10. Stability and Reactivity

10.1. Reactivity

No further relevant information available.

10.2. Chemical Stability

Thermal Decomposition/Conditions to Avoid:

No decomposition if used appropriately as intended.

10.3. Possibility of Hazardous Reactions

No hazardous reactions known.

10.4. Conditions to Avoid

No further relevant information available.

10.5. Incompatible Materials

No further relevant information available.

10.6. Hazardous Decomposition Products

No hazardous decomposition products known.

11. Toxicological Information*

11.1. Information on Toxicological Effects

Acute Toxicity:

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

Primary Irritant Effect:

Skin Corrosion/Irritation:

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



Serious Eye Damage/Eye Irritation:

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

CMR Effects (Carcinogenic, Mutagenic and Reprotoxic Effect):

Germ Cell Mutagenicity:

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

Carciogenicity:

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 - Single Exposure:

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

Specific Target Organ Toxicity - Repeated Exposure:

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

Aspiration Hazard:

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

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. Bioaccumulation Potential

No further relevant information available.

12.4. Mobility in Soil

No further relevant information available.

Ecotoxicological Information:

Note:

The product should not be toxic for aquatic organisms at maximum solubility in water.

Probably has no long term harmful effect for aquatic organisms.

Additional Ecological Information:

General Information: In general not hazardous to water.

12.5. Results of PBT and vPvB Assessment

PBT: not applicable **vPvB:** not applicable

12.6. Other Harmful Effects

No further relevant information available.

13. Disposal Considerations*

13.1. Waste Treatment Methods

Recommendation:

Must be subjected to special treatment in accordance with local, state and federal regulations.



European Waste Catalogue:

12 01 12* spent waxes and fats

Uncleaned Packaging:

Recommendation: disposal in accordance with local, state and federal regulations

14. Transport Information*

14.1. UN Number

ADR, ADN, IMDG, IATA: not available

14.2. UN Proper Shipping Name

ADR, ADN, IMDG, IATA: not available

14.3. Transport Hazard Class

ADN, IMDG, IATA: not available Class: not applicable

ADN/R Class: not available

14.4. Packaging Group

ADR, IMDG, IATA: not available

14.5. Environmental Hazards

Marine Pollutant: no

14.6. Special Precautions for Users

not applicable

14.7. Transport in Bulk According to Annex II of MARPOL and the IBC Code

not applicable

UN "Model Regulation": not available

15. Legal Regulations*

15.1. Safety, Health and Environmental Protection Regulations and Specific Legal **Regulations for the Substance or Mixture**

Directive 2012/18/EU

Listed Hazardous Substances – ANNEX I: contains none of the ingredients.

Water Hazard Class: in general not hazardous to water.

15.2. Chemical Safety Assessment

A chemical safety assessment has not been performed.

16. Other Information

The information does not constitute any guarantee with regard to product properties and do not create a contractual legal relationship.

Abbreviations and Acronyms:

Accord européen sur le transport des marchandises dangereuses par Route (European ADR:

Agreement concerning the International Carriage of Dangerous Goods by Road)

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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

Globally Harmonised System of Classification and Labelling of Chemicals GHS:

IATA: International Air Transport Association

International Maritime Code for Dangerous Goods IMDG:

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

^{*} Data has changed compared to the previous version