

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

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

1.1 Product identifier

Trade name **FRAGOL GEAR P 220 FG**
Registration number (REACH) not relevant (mixture)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses Lubricant
Industrial use
Professional use
Uses advised against Do not use for private purposes (household)

1.3 Details of the supplier of the safety data sheet

FRAGOL AG
Solinger Straße 16
D-45481 Mülheim
Germany

Telephone: +49 (0)208-300 02-40
Telefax: +49 (0)208-300 02-77
e-mail: lubes@fragol.de
Website: www.fragol.de

e-mail (competent person) lubes@fragol.de

1.4 Emergency telephone number

Emergency information service +49 (0) 208-300 02-40
This number is only available during the following office hours: Mon-Fri 09:00 - 17:00

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

| Code | Supplemental hazard information |
|--------|--|
| EUH210 | safety data sheet available on request |

2.2 Label elements

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

- signal word Not required.
- pictograms Not required.
- supplemental hazard information
EUH210 Safety data sheet available on request.

2.3 Other hazards

Special danger of slipping by leaking/spilling product.

Results of PBT and vPvB assessment

Does not contain any substances that are assessed to be PBT or vPvB $\geq 0.1\%$.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.


SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

3.2 Mixtures

The product does not contain (other) ingredients which are classified according to present knowledge of the supplier and contribute to the classification of the product and hence require reporting in this section.

| Name of substance | Identifier | Wt% | Classification acc. to GHS | Pictograms | Notes |
|---|--|-----|---|---|-------|
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | CAS No 68411-46-1 EC No 270-128-1 REACH Reg. No 01-2119491299-23-xxxx | < 1 | Repr. 2 / H361f Aquatic Chronic 3 / H412 |  | |

All the percentages given are percentages by weight unless stated otherwise. For full text of H-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

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

Following inhalation

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

Following skin contact

Take off contaminated clothing. After contact with skin, wash immediately with plenty of water and soap. In all cases of doubt, or when symptoms persist, seek medical advice.

Following eye contact

Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

Treat symptomatically.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, Dry extinguishing powder, Carbon dioxide (CO₂),
Co-ordinate firefighting measures to the fire surroundings.

Unsuitable extinguishing media

Water jet.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

During fire hazardous fumes/smoke could be produced. 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.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133), Standard protective clothing for firefighters

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Wear suitable protective clothing and gloves.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomite, diatomaceous earth, acid binder, universal binder, sawdust).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

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.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Keep away from sources of ignition - No smoking. Use only in well-ventilated areas. Take precautionary measures against static discharge.

Advice on general occupational hygiene

Wash hands after use. Do not 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 feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- flammability hazards

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge.

- incompatible substances or mixtures

Keep away from oxidizing substances. Keep away from reducing substances.

Control of effects

Protect against external exposure, such as

Heat. High temperatures. UV-radiation/sunlight. Static discharges.

Consideration of other advice

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

7.3 Specific end use(s)

There is no additional information.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

No information available.

Relevant DNELs/DMELs/PNECs and other threshold levels

No data available.

| Relevant DNELs of components of the mixture | | | | | | |
|---|------------|-----------|-----------------------|------------------------------------|-------------------|----------------------------|
| Name of substance | CAS No | End-point | Threshold level | Protection goal, route of exposure | Used in | Exposure time |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | DNEL | 0,6 mg/m ³ | human, inhalatory | worker (industry) | chronic - systemic effects |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | DNEL | 0,08 mg/kg bw/day | human, dermal | worker (industry) | chronic - systemic effects |

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

| Relevant DNELs of components of the mixture | | | | | | |
|---|------------|-----------|------------------------|------------------------------------|-------------------------------|----------------------------|
| Name of substance | CAS No | End-point | Threshold level | Protection goal, route of exposure | Used in | Exposure time |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | DNEL | 0,14 mg/m ³ | human, inhalatory | consumer (private households) | chronic - systemic effects |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | DNEL | 0,04 mg/kg bw/day | human, dermal | consumer (private households) | chronic - systemic effects |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | DNEL | 0,04 mg/kg bw/day | human, oral | consumer (private households) | chronic - systemic effects |

| Relevant PNECs of components of the mixture | | | | | | |
|---|------------|-----------|-----------------|-----------------------|------------------------------|------------------------------|
| Name of substance | CAS No | End-point | Threshold level | Organism | Environmental compartment | Exposure time |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 0,51 mg/l | aquatic organisms | water | intermittent release |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 0,034 mg/l | aquatic organisms | freshwater | short-term (single instance) |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 0,003 mg/l | aquatic organisms | marine water | short-term (single instance) |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 10 mg/l | aquatic organisms | sewage treatment plant (STP) | short-term (single instance) |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 0,446 mg/kg | aquatic organisms | freshwater sediment | short-term (single instance) |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 0,045 mg/kg | aquatic organisms | marine sediment | short-term (single instance) |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | PNEC | 1,76 mg/kg | terrestrial organisms | soil | short-term (single instance) |

8.2 Exposure controls

Appropriate engineering controls

General ventilation. Provide eyewash stations and safety showers at the workplace.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection (EN 166).

Skin protection



Protective clothing (EN 340 & EN ISO 13688).

- hand protection



Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. 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. ATTENTION: Wearing moisture-proof gloves (occlusion) for longer than 4 hours is defined as a risk in Germany.

- breakthrough time of the glove material

Use gloves with a minimum breakthrough time of the glove material: >10 minutes (permeation: level 1).

- other protection measures

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

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Full face mask/half mask/quarter mask (EN 136/140). Breathing apparatus only in case of aerosol or mist formation.

Environmental exposure controls

Take appropriate precautions to avoid uncontrolled release into the environment. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|---|
| Physical state | liquid |
| Colour | light yellow |
| Odour | characteristic |
| Melting point/freezing point | not determined |
| Boiling point or initial boiling point and boiling range | not determined |
| Flammability | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit | LEL: UEL: not determined |
| Flash point | 249 °C (ASTM D92) |
| Auto-ignition temperature | not determined |
| Decomposition temperature | no data available |
| pH (value) | not determined |

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

| | |
|---------------------|--|
| Kinematic viscosity | 219,7 mm ² /s at 40 °C (ASTM D 445) |
|---------------------|--|

Solubility

| | |
|------------------|-----------|
| Water solubility | insoluble |
|------------------|-----------|

| | |
|---|-----------------------------------|
| Partition coefficient n-octanol/water (log value) | this information is not available |
|---|-----------------------------------|

| | |
|-----------------|----------------|
| Vapour pressure | not determined |
|-----------------|----------------|

Density and/or relative density

| | |
|---------|---------------------------------------|
| Density | 0,849 g/cm ³ (ASTM D 1298) |
|---------|---------------------------------------|

| | |
|-------------------------|---|
| Relative vapour density | information on this property is not available |
|-------------------------|---|

| | |
|--------------------------|-----------------------|
| Particle characteristics | not relevant (liquid) |
|--------------------------|-----------------------|

9.2 Other information

| | |
|--|---|
| Information with regard to physical hazard classes | hazard classes acc. to GHS (physical hazards): not relevant |
|--|---|

| | |
|------------------------------|------------------------------------|
| Other safety characteristics | there is no additional information |
|------------------------------|------------------------------------|

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials

Oxidisers.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Acute toxicity

Shall not be classified as acutely toxic.

- acute toxicity of components of the mixture

| Acute toxicity of components of the mixture | | | | | |
|---|------------|----------------|----------|--------------|---------|
| Name of substance | CAS No | Exposure route | Endpoint | Value | Species |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | oral | LD50 | >5.000 mg/kg | rat |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | 68411-46-1 | dermal | LD50 | >2.000 mg/kg | rat |

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Other information

May cause respiratory tract irritation when present in a form of oil mist or vapors at high temperatures.

11.2 Information on other hazards

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0.1\%$.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

Other information

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment.

| Aquatic toxicity (acute) of components of the mixture | | | | | |
|--|------------|----------|-----------|-----------------------|---------------|
| Name of substance | CAS No | Endpoint | Value | Species | Exposure time |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethyl-pentene | 68411-46-1 | LC50 | >100 mg/l | fish | 96 h |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethyl-pentene | 68411-46-1 | EC50 | 51 mg/l | aquatic invertebrates | 48 h |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethyl-pentene | 68411-46-1 | ErC50 | >100 mg/l | algae | 72 h |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethyl-pentene | 68411-46-1 | NOEC | 10 mg/l | aquatic invertebrates | 48 h |

| Aquatic toxicity (chronic) of components of the mixture | | | | | |
|--|------------|----------|-----------|-----------------------|---------------|
| Name of substance | CAS No | Endpoint | Value | Species | Exposure time |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethyl-pentene | 68411-46-1 | EC50 | >100 mg/l | aquatic invertebrates | 24 h |

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

The bioaccumulation potential is low.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Does not contain any substances that are assessed to be PBT or vPvB \geq 0.1%.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of \geq 0.1%.

12.7 Other adverse effects

Data are not available.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packagegings

Handle contaminated packages in the same way as the substance itself.

Relevant provisions relating to waste

Decision 2000/532/EC on the list of waste

Waste catalogue ordinance (Germany)

- product

13 02 06* synthetic engine, gear and lubricating oils

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- | | | |
|------|--|---|
| 14.1 | UN number or ID number | not subject to transport regulations |
| 14.2 | UN proper shipping name | not relevant |
| 14.3 | Transport hazard class(es) | none |
| 14.4 | Packing group | not assigned |
| 14.5 | Environmental hazards | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 | Special precautions for user | There is no additional information. |
| 14.7 | Maritime transport in bulk according to IMO instruments | No data available. |

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - additional information

Not subject to ICAO-IATA.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

| Name | Name acc. to inventory | Restriction | No |
|---|--|-------------|----|
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC | R3 | 3 |
| Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene | substances in tattoo inks and permanent make-up | R75 | 75 |

Legend

R3

- Shall not be used in:
 - ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ash-trays,
 - tricks and jokes,
 - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
- Articles not complying with paragraph 1 shall not be placed on the market.
- Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
 - can be used as fuel in decorative oil lamps for supply to the general public, and
 - present an aspiration hazard and are labelled with H304.
- Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
- Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
 - lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
 - grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
 - lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

Legend

R75

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;

(ii) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";

(ii) "Not to be used in products applied on mucous membranes";

(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;

(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:

(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);

(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

Legend

Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

None of the ingredients are listed.

Seveso Directive

| 2012/18/EU (Seveso III) | | | |
|-------------------------|---------------------------------------|---|-------|
| No | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the application of lower and upper-tier requirements | Notes |
| | not assigned | | |

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

None of the ingredients are listed.

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

None of the ingredients are listed.

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

National regulations (Germany)

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK 1 slightly hazardous to water
(water hazard class)

Technical instructions on air quality control (Germany)

| Number | Group of substances | Class | Conc. | Mass flow | Mass concentration | Notation |
|--------|---------------------|-------|----------|-----------|----------------------|----------|
| 5.2.5 | organic substances | | ≥ 25 wt% | 0,5 kg/h | 50 mg/m ³ | 3) |

Notation

3) a total mass flow of 0.50 kg/h or a total mass concentration of 50 mg/m³, each of which to be indicated as total carbon, shall not be exceeded (except organic particulate matter)

Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK) 10 (combustible liquids)

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

SECTION 16: Other information

Indication of changes (revised safety data sheet)

| Section | Former entry (text/value) | Actual entry (text/value) |
|---------|--|---|
| 2.2 | Labelling according to Regulation (EC) No 1272/2008 (CLP): Not required. | Labelling according to Regulation (EC) No 1272/2008 (CLP) |
| 2.2 | | - signal word: Not required. |
| 2.2 | | - pictograms: Not required. |
| 2.2 | | - supplemental hazard information: change in the listing (table) |
| 2.3 | Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB. | Results of PBT and vPvB assessment: Does not contain any substances that are assessed to be PBT or vPvB \geq 0.1%. |
| 3.2 | | Mixtures: change in the listing (table) |
| 8.2 | Appropriate engineering controls: General ventilation. | Appropriate engineering controls: General ventilation. Provide eyewash stations and safety showers at the workplace. |
| 11.1 | | Acute toxicity of components of the mixture |
| 11.1 | | Acute toxicity of components of the mixture: change in the listing (table) |
| 12.1 | | Aquatic toxicity (acute) of components of the mixture: change in the listing (table) |
| 12.1 | | Aquatic toxicity (chronic) of components of the mixture: change in the listing (table) |
| 12.5 | Results of PBT and vPvB assessment: Does not contain any substances that are assessed to be a PBT or a vPvB \geq 0.1%. | Results of PBT and vPvB assessment: Does not contain any substances that are assessed to be PBT or vPvB \geq 0.1%. |
| 15.1 | | Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR): None of the ingredients are listed. |
| 15.1 | | Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013: None of the ingredients are listed. |
| 15.1 | | Technical instructions on air quality control (Germany) |
| 15.1 | | Technical instructions on air quality control (Germany): change in the listing (table) |
| 16 | | Abbreviations and acronyms: change in the listing (table) |

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|-----------------|---|
| ADN | Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways) |
| ADR | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| Aquatic Chronic | Hazardous to the aquatic environment - chronic hazard |
| CAS | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances) |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| DMEL | Derived Minimal Effect Level |
| DNEL | Derived No-Effect Level |
| EC50 | Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval |
| EC No | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| ErC50 | ≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control |
| GHS | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations |
| IATA | International Air Transport Association |
| IATA/DGR | Dangerous Goods Regulations (DGR) for the air transport (IATA) |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods Code |
| index No | The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 |
| LC50 | Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval |
| LD50 | Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval |
| LEL | Lower explosion limit (LEL) |
| LGK | Lagerklasse (storage class according to TRGS 510, Germany) |
| NLP | No-Longer Polymer |
| NOEC | No Observed Effect Concentration |
| PBT | Persistent, Bioaccumulative and Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| Repr. | Reproductive toxicity |
| RID | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail) |

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

amended by 2020/878/EU

FRAGOL

FRAGOL GEAR P 220 FG

Version number: 12.0
Replaces version of: 2022-09-06 (11)

Revision: 2023-08-17

| Abbr. | Descriptions of used abbreviations |
|-------|--|
| SVHC | Substance of Very High Concern |
| TRGS | Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany) |
| UEL | Upper explosion limit (UEL) |
| vPvB | Very Persistent and very Bioaccumulative |

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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).

List of relevant phrases (code and full text as stated in section 2 and 3)

| Code | Text |
|-------|--|
| H361f | Suspected of damaging fertility. |
| H412 | Harmful to aquatic life with long lasting effects. |

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product. FRAGOL cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.