

Safety Data Sheet

PulmoProDiff

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Reference number: D-CO-HE-O2-N2-002
Issue date: 11/4/2023 Version: 0.0

Warning



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

1.1. Product identifier

Trade name : PulmoProDiff 0,25 %/18 % Gas zur medizinischen Anwendung, druckverdichtet
SDS no : D-CO-HE-O2-N2-002

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

Relevant identified uses : Gas for medicinal use.
To be used and administered only by personnel specifically trained in the use and handling of this gas.
Note patient information leaflet.

Uses advised against : Consumer use.
Uses other than those listed above are not supported, contact your supplier for more information on other uses.
Attention: These products must not be applied to humans or animals unless they are expressly designated as medical or medicinal gases!.

1.3. Details of the supplier of the safety data sheet

Messer Industriegase GmbH
Messer- Platz 1
D - 65812 Bad Soden am Taunus
Germany
T +49 (0) 6196 7760-200 - F +49 (0) 6196 7760-280
SDB.de@messergroup.com - www.messer.de

1.4. Emergency telephone number

Emergency telephone number : Messer Produktionsgesellschaft mbH Salzgitter, +49 (0) 5341 21-9333, erreichbar Montags 0:00 bis Sonntags 24:00

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Physical hazards : Gases under pressure : Compressed gas H280

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS04

Signal word (CLP) : Warning
Hazard statements (CLP) : H280 - Contains gas under pressure; may explode if heated.
Precautionary statements (CLP)
- Storage : P403 - Store in a well-ventilated place.

Safety Data Sheet

PulmoProDiff

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Reference number: D-CO-HE-O2-N2-002

2.3. Other hazards

Not classified as PBT or vPvB.
The substance/mixture has no endocrine disrupting properties.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Nitrogen	CAS-No.: 7727-37-9 EC-No.: 231-783-9 EC Index-No.: --- REACH-no: *1	60.75	Press. Gas (Comp.), H280
oxygen	CAS-No.: 7782-44-7 EC-No.: 231-956-9 EC Index-No.: 008-001-00-8 REACH-no: *1	21	Ox. Gas 1, H270 Press. Gas (Comp.), H280
Helium	CAS-No.: 7440-59-7 EC-No.: 231-168-5 EC Index-No.: --- REACH-no: *1	18	Press. Gas (Comp.), H280
carbon monoxide	CAS-No.: 630-08-0 EC-No.: 211-128-3 EC Index-No.: 006-001-00-2 REACH-no: 01-2119480165-39	0.25	Flam. Gas 1B, H221 Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Repr. 1A, H360D STOT RE 1, H372

Full text of H- and EUH-statements: see section 16

Contains no other components or impurities which will influence the classification of the product.

*1: Listed in Annex IV / V REACH, exempted from registration.

*3: Registration not required: Substance manufactured or imported < 1t/y.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Inhalation : Adverse effects not expected from this product.
- Skin contact : Adverse effects not expected from this product.
- Eye contact : Adverse effects not expected from this product.
- Ingestion : Ingestion is not considered a potential route of exposure.

4.2. Most important symptoms and effects, both acute and delayed

See section 11.

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 or fog.
Product does not burn, use fire control measures appropriate for the surrounding fire.
- Unsuitable extinguishing media : Do not use water jet to extinguish.

5.2. Special hazards arising from the substance or mixture

- Specific hazards : Supports combustion.
Exposure to fire may cause containers to rupture/explode.
- Hazardous combustion products : carbon monoxide.

5.3. Advice for firefighters

- Specific methods : Use fire control measures appropriate for the surrounding fire. Exposure to fire and heat radiation may cause gas receptacles to rupture. Cool endangered receptacles with water spray jet from a protected position. Prevent water used in emergency cases from entering sewers and drainage systems.
If possible, stop flow of product.
Use water spray or fog to knock down fire fumes if possible.
Move containers away from the fire area if this can be done without risk.
- Special protective equipment for fire fighters : Standard protective clothing and equipment (Self Contained Breathing Apparatus) for fire fighters.
Standard EN 469 - Protective clothing for firefighters. Standard EN 659 - Protective gloves for firefighters.
Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel : Act in accordance with local emergency plan.
Stay upwind.
See section 8 of the SDS for more information on personal protective equipment.
- For emergency responders : See section 5.3 of the SDS for more information.

6.2. Environmental precautions

None.

6.3. Methods and material for containment and cleaning up

None.

6.4. Reference to other sections

See also sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Safe use of the product

- : The product must be handled in accordance with good industrial hygiene and safety procedures.
- Only experienced and properly instructed persons should handle gases under pressure.
- Consider pressure relief device(s) in gas installations.
- Ensure the complete gas system was (or is regularly) checked for leaks before use.
- Do not smoke while handling product.
- Use only properly specified equipment which is suitable for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.
- Use only oxygen approved lubricants and oxygen approved sealings.
- Avoid suck back of water, acid and alkalis.
- Do not breathe gas.
- Avoid release of product into work area.

Safe handling of the gas receptacle

- : Refer to supplier's container handling instructions.
- Do not allow backfeed into the container.
- Protect containers from physical damage; do not drag, roll, slide or drop.
- When moving cylinders, even for short distances, use a cart (trolley, hand truck, etc.) designed to transport cylinders.
- Leave valve protection caps in place until the container has been secured against either a wall or bench or placed in a container stand and is ready for use.
- If user experiences any difficulty operating valve discontinue use and contact supplier.
- Never attempt to repair or modify container valves or safety relief devices.
- Damaged valves should be reported immediately to the supplier.
- Keep container valve outlets clean and free from contaminants particularly oil and water.
- Replace valve outlet caps or plugs and container caps where supplied as soon as container is disconnected from equipment.
- Close container valve after each use and when empty, even if still connected to equipment.
- Never attempt to transfer gases from one cylinder/container to another.
- Never use direct flame or electrical heating devices to raise the pressure of a container.
- Do not remove or deface labels provided by the supplier for the identification of the content of the container.
- Suck back of water into the container must be prevented.
- Open valve slowly to avoid pressure shock.

7.2. Conditions for safe storage, including any incompatibilities

- Observe all regulations and local requirements regarding storage of containers.
- Containers should not be stored in conditions likely to encourage corrosion.
- Container valve guards or caps should be in place.
- Containers should be stored in the vertical position and properly secured to prevent them from falling over.
- Stored containers should be periodically checked for general condition and leakage.
- Keep container below 50°C in a well ventilated place.
- Store containers in location free from fire risk and away from sources of heat and ignition.
- Keep away from combustible materials.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

carbon monoxide (630-08-0)

Germany - Occupational Exposure Limits (TRGS 900)

Local name	Kohlenstoffmonoxid
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Safety Data Sheet

PulmoProDiff

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Reference number: D-CO-HE-02-N2-002

AGW (OEL TWA) [1]	35 mg/m ³
AGW (OEL TWA) [2]	30 ppm
Peak exposure limitation factor	2(II)
Remark	DFG - Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission); Z - Ein Risiko der Fruchtschädigung kann auch bei Einhaltung des AGW und des BGW nicht ausgeschlossen werden; EU - Europäische Union (Von der EU wurde ein Luftgrenzwert festgelegt: Abweichungen bei Wert und Spitzenbegrenzung sind möglich)
Regulatory reference	TRGS900
Germany - Biological limit values (TRGS 903)	
Local name	Kohlenstoffmonoxid (Kohlenmonoxid)
Biological limit value	5 % Parameter: CO-Hb - Untersuchungsmaterial: B = Vollblut - Probenahmezeitpunkt: b) Expositionsende, bzw. Schichtende - Festlegung/Begründung: 05/2013 DFG
Remark	Ableitung des BGW als Höchstwert wegen akut toxischer Effekte. Gesonderte Bewertung für Raucher
Regulatory reference	TRGS 903

carbon monoxide (630-08-0)	
DNEL: Derived no effect level (Workers)	
Acute - local effects, inhalation	117 ppm
Acute - systemic effects, inhalation	117 mg/m ³
Long-term - local effects, inhalation	23 ppm
Long-term - systemic effects, inhalation	23 mg/m ³

PNEC (Predicted No-Effect Concentration) : None established.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Provide adequate general and local exhaust ventilation.
Systems under pressure should be regularly checked for leakages.
Ensure exposure is below occupational exposure limits (where available).
Consider the use of a work permit system e.g. for maintenance activities.

8.2.2. Individual protection measures, e.g. personal protective equipment

A risk assessment should be conducted and documented in each work area to assess the risks related to the use of the product and to select the PPE that matches the relevant risk.

The following recommendations should be considered:

PPE compliant to the recommended EN/ISO standards should be selected.

• Eye/face protection

: Wear safety glasses with side shields.

Standard EN 166 - Personal eye-protection - specifications.

• Skin protection

- Hand protection

: Wear working gloves when handling gas containers.

Standard EN 388 - Protective gloves against mechanical risks, performance level 1 or higher.

- Other

: Wear safety shoes while handling containers.

Standard EN ISO 20345 - Personal protective equipment - Safety footwear.

- Respiratory protection : Self contained breathing apparatus is recommended, where unknown exposure may be expected, e.g. during maintenance activities on installation systems.
Standard EN 137 - Self-contained open-circuit compressed air breathing apparatus with full face mask.
When indicated by a risk assessment, Respiratory Protective Equipment must be used. The selection of the Respiratory Protective Device (RPD) must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected RPD.
- Thermal hazards : None in addition to the above sections.

8.2.3. Environmental exposure controls

None necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
- Physical state at 20°C / 101.3kPa	: Gas.
- Colour	: Colourless.
Odour	: Odourless.
Melting point / Freezing point	: Not applicable for gases and gas mixtures.
Boiling point	: Not applicable for gas mixtures. It is technically not possible to determine the boiling point or range of this mixture. Component with lowest boiling point: Helium -269 °C
Flammability	: Non flammable.
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not applicable for gases and gas mixtures.
Auto-ignition temperature	: Non flammable.
Decomposition temperature	: Not applicable.
pH	: Not applicable for gases and gas mixtures.
Viscosity, kinematic	: Not applicable for gases and gas mixtures.
Water solubility [20°C]	: Mixture is partially soluble in water
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure [20°C]	: Not applicable.
Vapour pressure [50°C]	: Not applicable.
Density and/or relative density	: Not applicable.
Relative vapour density (air=1)	: Lighter or similar to air.
Particle characteristics	: Not applicable for gases and gas mixtures.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosion limits	: Non flammable.
Oxidising properties	: No oxidising properties.

9.2.2. Other safety characteristics

Other data	: None.
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SECTION 10: Stability and reactivity

10.1. Reactivity

Data for mixtures are not available.
This mixture contains components with the following reactivity : Can form explosive mixture with air. May react violently with oxidants. Violently oxidises organic material.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Avoid moisture in installation systems.

10.5. Incompatible materials

For additional information on compatibility refer to ISO 11114.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity : Classification criteria are not met.

carbon monoxide (630-08-0)

LC50 Inhalation - Rat [ppm]	3760 ppm/1h (ADR) 1300 ppm/4h (CLP)
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Skin corrosion/irritation : No known effects from this product.

Serious eye damage/irritation : No known effects from this product.

Respiratory or skin sensitisation : No known effects from this product.

Germ cell mutagenicity : No known effects from this product.

Carcinogenicity : No known effects from this product.

Toxic for reproduction : Fertility : No known effects from this product.

Toxic for reproduction : unborn child : Classification criteria are not met.

STOT-single exposure : No known effects from this product.

STOT-repeated exposure : Classification criteria are not met.

Aspiration hazard : Not applicable for gases and gas mixtures.

11.2. Information on other hazards

Other information : The substance/mixture has no endocrine disrupting properties.

SECTION 12: Ecological information

12.1. Toxicity

Assessment : No ecological damage caused by this product.

EC50 48h - Daphnia magna [mg/l] : No data available.

EC50 72h - Algae [mg/l] : No data available.

LC50 96 h - Fish [mg/l] : No data available.

carbon monoxide (630-08-0)

EC50 48h - Daphnia magna [mg/l]	No data available.
EC50 72h - Algae [mg/l]	No data available.
LC50 96 h - Fish [mg/l]	No data available.

Safety Data Sheet

PulmoProDiff

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Reference number: D-CO-HE-O2-N2-002

Helium (7440-59-7)	
EC50 48h - Daphnia magna [mg/l]	No data available.
EC50 72h - Algae [mg/l]	No data available.
LC50 96 h - Fish [mg/l]	No data available.

oxygen (7782-44-7)	
EC50 48h - Daphnia magna [mg/l]	No data available.
EC50 72h - Algae [mg/l]	No data available.
LC50 96 h - Fish [mg/l]	No data available.

Nitrogen (7727-37-9)	
EC50 48h - Daphnia magna [mg/l]	No data available.
EC50 72h - Algae [mg/l]	No data available.
LC50 96 h - Fish [mg/l]	No data available.

12.2. Persistence and degradability

Assessment : No data available.

12.3. Bioaccumulative potential

Assessment : No data available.

12.4. Mobility in soil

Assessment : Because of its high volatility, the product is unlikely to cause ground or water pollution.
Partition into soil is unlikely.

12.5. Results of PBT and vPvB assessment

Assessment : Not classified as PBT or vPvB.

12.6. Endocrine disrupting properties

Assessment : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects : No known effects from this product.
Effect on the ozone layer : No effect on the ozone layer.
Effect on global warming : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not discharge into any place where its accumulation could be dangerous.
May be vented to atmosphere in a well ventilated place.
Return unused product in original container to supplier.

List of hazardous waste codes (from Commission Decision 2000/532/EC as amended) : 16 05 05 : Gases in pressure containers other than those mentioned in 16 05 04.

13.2. Additional information

External treatment and disposal of waste should comply with applicable local and/or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number

In accordance with ADR / RID / IMDG / IATA / ADN

UN-No. : 1956

14.2. UN proper shipping name

Transport by road/rail (ADR/RID) : COMPRESSED GAS, N.O.S. (Nitrogen, carbon monoxide)

Transport by air (ICAO-TI / IATA-DGR) : Compressed gas, n.o.s. (Nitrogen, carbon monoxide)

Transport by sea (IMDG) : COMPRESSED GAS, N.O.S. (Nitrogen, carbon monoxide)

14.3. Transport hazard class(es)

Labelling



2.2 : Non flammable, non-toxic gases.

Transport by road/rail (ADR/RID)

Class : 2

Classification code : 1A

Hazard identification number : 20

Tunnel Restriction : E - Passage forbidden through tunnels of category E

Transport by air (ICAO-TI / IATA-DGR)

Class / Div. (Sub. risk(s)) : 2.2

Transport by sea (IMDG)

Class / Div. (Sub. risk(s)) : 2.2

Emergency Schedule (EmS) - Fire : F-C

Emergency Schedule (EmS) - Spillage : S-V

14.4. Packing group

Transport by road/rail (ADR/RID) : Not applicable.

Transport by air (ICAO-TI / IATA-DGR) : Not applicable.

Transport by sea (IMDG) : Not applicable.

14.5. Environmental hazards

Transport by road/rail (ADR/RID) : None.

Transport by air (ICAO-TI / IATA-DGR) : None.

Transport by sea (IMDG) : None.

14.6. Special precautions for user

Packing Instruction(s)

Transport by road/rail (ADR/RID) : P200.

Transport by air (ICAO-TI / IATA-DGR)

Passenger and Cargo Aircraft : 200.

Cargo Aircraft only : 200.

Transport by sea (IMDG) : P200.

Special transport precautions

: Avoid transport on vehicles where the load space is not separated from the driver's compartment.

Ensure vehicle driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.

Before transporting product containers:

- Ensure there is adequate ventilation.

- Ensure that containers are firmly secured.

- Ensure valve is closed and not leaking.

- Ensure valve outlet cap nut or plug (where provided) is correctly fitted.

- Ensure valve protection device (where provided) is correctly fitted.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

EU-Regulations

Restrictions on use	: Contains no substance(s) listed on the REACH Candidate List.
Other information, restriction and prohibition regulations	: None. Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals). Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants).
Seveso Directive : 2012/18/EU (Seveso III)	: Not covered.

National regulations

Water hazard class (WGK)	: nwg - Non-hazardous to water.
Regulatory reference	: National / local legislations : Gesetz zum Schutz der arbeitenden Jugend (Jugendarbeitsschutzgesetz-JArbSchG) Betriebssicherheitsverordnung-BetrSichV TRBS 3145/TRGS 745 - Ortsbewegliche Druckgasbehälter – Füllen, Bereithalten, innerbetriebliche Beförderung, Entleeren TRGS 510 - Lagerung von Gefahrstoffen in ortsbeweglichen Behältern TRGS 407 - Tätigkeiten mit Gasen – Gefährdungsbeurteilung TRBS 2141 - Gefährdungen durch Dampf und Druck - Allgemeine Anforderungen. Classification for storage according to TRGS 510: 2A Gase (ohne Aerosolpackungen und Feuerzeuge).

15.2. Chemical safety assessment

A CSA does not need to be carried out for this product.

SECTION 16: Other information

Indication of changes	: Revised safety data sheet in accordance with commission regulation (EU) No 2020/878.
Abbreviations and acronyms	: ATE - Acute Toxicity Estimate. CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008. REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006. EINECS - European Inventory of Existing Commercial Chemical Substances. CAS# - Chemical Abstract Service number. PPE - Personal Protection Equipment. LC50 - Lethal Concentration to 50 % of a test population. RMM - Risk Management Measures. PBT - Persistent, Bioaccumulative and Toxic. vPvB - Very Persistent and Very Bioaccumulative. STOT- SE : Specific Target Organ Toxicity - Single Exposure. CSA - Chemical Safety Assessment. EN - European Standard. UN - United Nations. ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road. IATA - International Air Transport Association. IMDG code - International Maritime Dangerous Goods. RID - Regulations concerning the International Carriage of Dangerous Goods by Rail. WGK - Water Hazard Class. STOT - RE : Specific Target Organ Toxicity - Repeated Exposure. UFI : Unique Formula Identifier.

Safety Data Sheet

PulmoProDiff

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Reference number: D-CO-HE-O2-N2-002

Training advice : None.
Further information : Classification in accordance with the procedures and calculation methods of Regulation (EC) 1272/2008 (CLP).
Classification using data from databases maintained by the European Industrial Gases Association (EIGA). Data is maintained in EIGA doc 169 : 'Classification and Labelling Guide', downloadable at : <http://www.eiga.eu>.

Full text of H- and EUH-statements	
Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Flam. Gas 1B	Flammable gases, Category 1B
H221	Flammable gas.
H270	May cause or intensify fire; oxidiser.
H280	Contains gas under pressure; may explode if heated.
H331	Toxic if inhaled.
H360D	May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
Ox. Gas 1	Oxidising Gases, Category 1
Press. Gas (Comp.)	Gases under pressure : Compressed gas
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

DISCLAIMER OF LIABILITY : Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out.
Details given in this document are believed to be correct at the time of going to press.
Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.

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