

Safety Data Sheet

Conforms to Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II, as amended by Commission Regulation (EU) 2020/878

PRAGMA FLEX Bianco

Date of first edition: 5/26/2025

Safety Data Sheet dated 10/10/2025

version 2

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

1.1. Product identifier

Mixture identification:

Trade name: PRAGMA FLEX Bianco

Trade code: S100K0503 10

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

Recommended use: Cement-based adhesive mortar

Uses advised against: All uses other than recommended ones

1.3. Details of the supplier of the safety data sheet

Company: KERAKOLL S.p.A.

Via dell'Artigianato, 9

41049 Sassuolo (MODENA) - ITALY

Tel.+39 0536 816511 Fax. +39 0536816581

safety@kerakoll.com

1.4. Emergency telephone number

European emergency phone number 112

Ireland Emergency medical information: (seven days) contact National Poisons Information Centre, Beaumont Hospital, Dublin 9 DOV2NO, Ireland.

Members of the public Number (8 am-10 pm): +353 (0)1 809 2166

Healthcare professional telephone Number (24hrs): +353 (0)1 809 2566

Malta In case of emergency call: +356 2395 2000 (24h)

SECTION 2: Hazards identification



2.1. Classification of the substance or mixture

Regulation (EC) n. 1272/2008 (CLP)

Skin Irrit. 2 Causes skin irritation.

Eye Dam. 1 Causes serious eye damage.

Skin Sens. 1B May cause an allergic skin reaction.

STOT SE 3 May cause respiratory irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Regulation (EC) No 1272/2008 (CLP):

Hazard pictograms and Signal Word



Danger

Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

Precautionary statements

P102 Keep out of reach of children.

- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves and eye protection.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P501 Dispose of contents/container in accordance with applicable regulations.

Contains

Portland Cement (Cr VI < 0,0002%)
 Calcium diformate

Special provisions according to Annex XVII of REACH and subsequent amendments:

None.

2.3. Other hazards

When mixtures containing cement react with water, for instance when making concrete or mortar, or when the cement becomes wet, a strong alkaline solution is produced (high pH caused by the formation of calcium, sodium and potassium hydroxides).

Cement and mixtures containing cement may irritate the eyes, the mucous system, the throat and the respiratory system and cause coughing. Frequent inhalation of cement dust or mixtures containing cement over a long period of time increases the risk of developing lung diseases.

No PBT, vPvB or endocrine disruptor substances present in concentration >= 0.1%

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Mixture identification: PRAGMA FLEX Bianco

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Numb.	Classification	Registration Number
≥20-<50 %	Portland Cement (Cr VI < 0,0002%)	CAS:65997-15-1 EC:266-043-4	Skin Irrit. 2, H315; Eye Dam. 1, H318; Skin Sens. 1B, H317; STOT SE 3, H335	
≥1-<3 %	Calcium diformate	CAS:544-17-2 EC:208-863-7	Eye Dam. 1, H318	01-2119486476-24

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

- Immediately take off all contaminated clothing.
- OBTAIN IMMEDIATE MEDICAL ATTENTION.
- Remove contaminated clothing immediately and dispose off safely.
- After contact with skin, wash immediately with soap and plenty of water.

In case of eyes contact:

- After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.
- Protect uninjured eye.

In case of Ingestion:

- Do not induce vomiting, get medical attention showing the SDS and label hazardous.

In case of Inhalation:

- In case of inhalation, consult a doctor immediately and show him packing or label.

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

- Eye irritation
- Eye damages
- Skin Irritation
- Erythema

4.3. Indication of any immediate medical attention and special treatment needed

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

Use appropriate respiratory protection.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Suitable material for taking up: absorbing material, organic, sand

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Use localized ventilation system.

Don't use empty container before they have been cleaned.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.

Contaminated clothing should be changed before entering eating areas.

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

7.2. Conditions for safe storage, including any incompatibilities

The product must be stored in waterproof, dry, clean conditions and protected from contamination. Do not use aluminum containers due to incompatibility of the materials.

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

Recommendation(s)

None in particular

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Community Occupational Exposure Limits (OEL)

OEL Type	Country	Occupational Exposure Limit
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Calcium carbonate
CAS: 471-34-1

NATIONAL	HUNGARY	Long Term: 10 mg/m3 inhalable aerosol Source: 5/2020. (II. 6.) ITM
NATIONAL	IRELAND	Long Term: 10 mg/m3 Inhalable fraction Source: 2021 Code of Practice
NATIONAL	IRELAND	Long Term: 4 mg/m3 Respirable fraction Source: 2021 Code of Practice
NATIONAL	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND	Long Term: 10 mg/m3 inhalable aerosol Source: EH40/2005 Workplace exposure limits
NATIONAL	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND	Long Term: 4 mg/m3 respirable aerosol Source: EH40/2005 Workplace exposure limits
NATIONAL	CROATIA	Long Term: 10 mg/m3 U Source: NN 1/2021
NATIONAL	CROATIA	Long Term: 4 mg/m3 R Source: NN 1/2021
NATIONAL	FRANCE	Long Term: 10 mg/m3 Source: INRS outil65
NATIONAL	LATVIA	Long Term: 6 mg/m3 Source: KN325P1
NATIONAL	POLAND	Long Term: 10 mg/m3 4) Source: Dz.U. 2018 poz. 1286
SUVA	SWITZERLAN D	Long Term: 3 mg/m3 TWA mg/m3: (a), Formel / Formal, NIOSH Source: suva.ch/valeurs-limites

Portland Cement (Cr VI <
0,0002%)
CAS: 65997-15-1

ACGIH		Long Term: 1 mg/m3 (8h) E,R, A4 - Pulm func, resp symptoms, asthma
NATIONAL	BELGIUM	Long Term: 1 mg/m3 Source: Code du bien-être au travail, Livre VI, Titre 1er, Annexe VI.1-1
NATIONAL	CROATIA	Long Term: 10 mg/m3 U Source: NN 1/2021
NATIONAL	CROATIA	Long Term: 4 mg/m3 R Source: NN 1/2021
NATIONAL	IRELAND	Long Term: 1 mg/m3 R Source: 2021 Code of Practice
NATIONAL	SPAIN	Long Term: 4 mg/m3 e, d Source: LEP 2022
NATIONAL	AUSTRIA	Long Term: 5 mg/m3 MAK, E Source: BGBl. II Nr. 156/2021
NATIONAL	FINLAND	Long Term: 5 mg/m3 hengittyvä pöly Source: HTP-ARVOT 2020
NATIONAL	FINLAND	Long Term: 1 mg/m3

		alveolijae Source: HTP-ARVOT 2020
NATIONAL	HUNGARY	Long Term: 10 mg/m3 N Source: 5/2020. (II. 6.) ITM rendelet
NATIONAL	LATVIA	Long Term: 6 mg/m3 Source: KN325P1
NATIONAL	POLAND	Long Term: 6 mg/m3 4) Source: Dz.U. 2018 poz. 1286
NATIONAL	POLAND	Long Term: 2 mg/m3 6), 7) Source: Dz.U. 2018 poz. 1286
SUVA	SWITZERLAN D	Long Term: 5 mg/m3 TWA mg/m3: (i), S, Poumons Asthme / Lunge Asthma Source: suva.ch/valeurs-limites
WEL-EH40	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND	Long Term: 10 mg/m3 Source: EH40/2005 Workplace exposure limits (Fourth Edition 2020)
WEL-EH40	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND	Long Term: 4 mg/m3 Source: EH40/2005 Workplace exposure limits (Fourth Edition 2020)
Limestone CAS: 1317-65-3	NATIONAL	BULGARIA Long Term: 10 mg/m3 Source: НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г.
	NATIONAL	ESTONIA Long Term: 10 mg/m3 Source: Vabariigi Valitsuse, 20. märtsi 2001. a määrus nr 105
	NATIONAL	ESTONIA Long Term: 5 mg/m3 Source: Vabariigi Valitsuse, 20. märtsi 2001. a määrus nr 105
	NATIONAL	GREECE Long Term: 10 mg/m3 εισπν. Source: ΦΕΚ 94/Α` 13.5.1999
	NATIONAL	GREECE Long Term: 5 mg/m3 αvapν. Source: ΦΕΚ 94/Α` 13.5.1999
	NATIONAL	SPAIN Long Term: 10 mg/m3 (1) inhalable aerosol Source: LEP 2022
	NATIONAL	HUNGARY Long Term: 10 mg/m3 N Source: 5/2020. (II. 6.) ITM rendelet
	WEL-EH40	UNITED Long Term: 10 mg/m3 KINGDOM OF Inhalable fraction GREAT Source: EH40/2005 Workplace exposure limits (Fourth Edition 2020) BRITAIN AND NORTHERN IRELAND
	WEL-EH40	UNITED Long Term: 4 mg/m3 KINGDOM OF Respirable fraction GREAT Source: EH40/2005 Workplace exposure limits (Fourth Edition 2020) BRITAIN AND NORTHERN IRELAND
	NATIONAL	BELGIUM Long Term: 10 mg/m3 Source: Code du bien-être au travail, Livre VI, Titre 1er, Annexe VI.1-1
	NATIONAL	IRELAND Long Term: 10 mg/m3 Source: 2021 Code of Practice

	NATIONAL	IRELAND	Long Term: 4 mg/m ³ Source: 2021 Code of Practice
	NATIONAL	SWITZERLAND	Long Term: 3 mg/m ³ (1) respirable aerosol Source: suva.ch/valeurs-limites
Kaolin CAS: 1332-58-7	ACGIH		Long Term: 2 mg/m ³ (8h) E,R, A4 - Pneumoconiosis
	NATIONAL	BELGIUM	Long Term: 2 mg/m ³ Source: Code du bien-être au travail, Livre VI, Titre 1er, Annexe VI.1-1
	NATIONAL	DENMARK	Long Term: 2 mg/m ³ Source: BEK nr 2203 af 29/11/2021
	NATIONAL	FINLAND	Long Term: 2 mg/m ³ alveolijae Source: HTP-ARVOT 2020
	NATIONAL	IRELAND	Long Term: 2 mg/m ³ Source: 2021 Code of Practice
	NATIONAL	POLAND	Long Term: 10 mg/m ³ 4), 7) Source: Dz.U. 2018 poz. 1286
	SUVA	SWITZERLAND	Long Term: 3 mg/m ³ TWA mg/m ³ : (a), Fib pulm / Lungenfibrose Source: suva.ch/valeurs-limites
	WEL-EH40	UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND	Long Term: 2 mg/m ³ Source: EH40/2005 Workplace exposure limits (Fourth Edition 2020)
	NATIONAL	CROATIA	Long Term: 2 mg/m ³ R Source: NN 1/2021
sodium chloride CAS: 7647-14-5	NATIONAL	LATVIA	Long Term: 5 mg/m ³ Source: KN325P1
	NATIONAL	LITHUANIA	Long Term: 5 mg/m ³ Source: 2011 m. rugsėjo 1 d. Nr. V-824/A1-389

Predicted No Effect Concentration (PNEC) values

Calcium diformate CAS: 544-17-2	Exposure Route: Fresh Water; PNEC Limit: 2 mg/l
	Exposure Route: Intermittent releases (fresh water); PNEC Limit: 10 mg/l
	Exposure Route: Marine water; PNEC Limit: 200 µg/l
	Exposure Route: Microorganisms in sewage treatments; PNEC Limit: 2.21 mg/l
	Exposure Route: Marine water sediments; PNEC Limit: 1.34 mg/kg
	Exposure Route: Freshwater sediments; PNEC Limit: 13.4 mg/kg
	Exposure Route: Soil; PNEC Limit: 1.5 mg/kg

Derived No Effect Level (DNEL) values

Calcium diformate CAS: 544-17-2	Exposure Route: Human Inhalation; Exposure Frequency: Long Term, systemic effects Worker Professional: 337 mg/m ³ ; Consumer: 83.2 mg/m ³
	Exposure Route: Human Inhalation; Exposure Frequency: Long Term, systemic effects Consumer: 83.2 mg/m ³
	Exposure Route: Human Dermal; Exposure Frequency: Long Term, systemic effects Worker Professional: 4.78 mg/kg; Consumer: 2390 mg/kg
	Exposure Route: Human Dermal; Exposure Frequency: Short Term, local effects Worker Professional: 16.7 mg/cm ² ; Consumer: 8.3 mg/cm ²
	Exposure Route: Human Dermal; Exposure Frequency: Long Term, local effects Consumer: 8.3 mg/cm ²
	Exposure Route: Human Oral; Exposure Frequency: Long Term, systemic effects Consumer: 23.9 mg/kg

8.2. Exposure controls

Eye protection:

Eye glasses with side protection.(EN166)

Protection for skin:

Chemical protection clothing. Safety shoes.

Protection for hands:

Protection for hands:

Suitable materials for safety gloves; EN 374:

Nitrile rubber - NBR: thickness $\geq 0,35\text{mm}$; breakthrough time $\geq 480\text{min}$.

Respiratory protection:

Particle filter P2 .

Thermal Hazards:

Not expected if used as intended

Environmental exposure controls:

Prevent the product from entering sewers or surface and underground water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Solid

Colour: White

Odour: N.A.

Odour threshold: N.A.

pH: Not Relevant

Kinematic viscosity: N.A.

Melting point/freezing point: N.A.

Boiling point or initial boiling point and boiling range: N.A.

Flash point: Not Applicable

Lower and upper explosion limit: N.A.

Relative vapour density: N.A.

Vapour pressure: N.A.

Density and/or relative density: N.A.

Solubility in water: N.A.

Solubility in oil: N.A.

Partition coefficient n-octanol/water (log value): N.A.

Auto-ignition temperature: N.A.

Decomposition temperature: N.A.

Flammability: N.A.

Volatile Organic compounds - VOCs = 0 % ; 0 g/l

Particle characteristics:

Particle size: N.A.

9.2. Other information

No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

The product is stable as long as it is properly stored (see Section 7).

Wet product is alkaline and incompatible with acids, with ammonium salts, with aluminium or other base metals. When in contact with hydrofluoric acid, mixtures containing cement dissolve to produce corrosive silicon tetrafluoride gas. Mixtures containing cement react with water to form silicates and calcium hydroxide. Silicates in cement react with powerful oxidizers such as fluorine, boron trifluoride, chlorine trifluoride, manganese trifluoride and oxygen difluoride.

Intact packaging and compliance with the appropriate storage conditions as indicated in Subsection 7.2 (adequate tightly closed and sealed containers, dry and cool place, no ventilation) are the essential conditions.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

Acids, ammonium salts, aluminium or other base metals. Uncontrolled use of aluminium dust in wet cement-containing products is to be avoided because it causes the production of hydrogen.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

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

Toxicological Information of the Preparation

a) acute toxicity	Not classified Based on available data, the classification criteria are not met
b) skin corrosion/irritation	The product is classified: Skin Irrit. 2(H315)
c) serious eye damage/irritation	The product is classified: Eye Dam. 1(H318)
d) respiratory or skin sensitisation	The product is classified: Skin Sens. 1B(H317)
e) germ cell mutagenicity	Not classified Based on available data, the classification criteria are not met
f) carcinogenicity	Not classified Based on available data, the classification criteria are not met
g) reproductive toxicity	Not classified Based on available data, the classification criteria are not met
h) STOT-single exposure	The product is classified: STOT SE 3(H335)
i) STOT-repeated exposure	Not classified Based on available data, the classification criteria are not met
j) aspiration hazard	Not classified Based on available data, the classification criteria are not met

Toxicological information on main components of the mixture:

Calcium diformate	a) acute toxicity	LD50 Oral Rat = 3050 mg/kg LC50 Inhalation Dust Rat > 0.67 mg/l 4h LD50 Skin Rat > 2000 mg/kg 24h
	b) skin corrosion/irritation	Skin Irritant Rabbit Negative
	c) serious eye damage/irritation	Eye Irritant Rabbit Yes
	d) respiratory or skin sensitisation	Skin Sensitization Guinea pig Negative
	f) carcinogenicity	Carcinogenicity Oral Rat = 2000 mg/kg Genotoxicity Negative
	g) reproductive toxicity	No Observed Adverse Effect Level Rat = 956 mg/kg

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration $\geq 0.1\%$

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

Eco-Toxicological Information:

List of Eco-Toxicological properties of the product

Not classified for environmental hazards.

No data available for the product

List of Eco-Toxicological properties of the components

Component	Ident. Numb.	Ecotox Data
Calcium diformate	CAS: 544-17-2 - EINECS: 208- 863-7	a) Aquatic acute toxicity : LC50 Fish Danio zebra ≥ 1000 mg/L 96h German national guideline
		a) Aquatic acute toxicity : EC50 Daphnia Daphnia magna > 1000 mg/L 48h
		a) Aquatic acute toxicity : EC50 Algae Pseudokirchneriella subcapitata > 1000 mg/L 72h
		a) Aquatic acute toxicity : NOEC Algae Pseudokirchneriella subcapitata = 500 mg/L 72h

12.2. Persistence and degradability

Component	Persitence/Degradability:	Value	Notes:
Calcium diformate	Readily biodegradable	86.000	Guideline 306

12.3. Bioaccumulative potential

Component	Bioaccumulation	Test	Value
Calcium diformate	Bioaccumulative	LogPow	-2.300

12.4. Mobility in soil

Component	Test	Value
Calcium diformate	Koc	31.000

12.5. Results of PBT and vPvB assessment

No PBT or vPvB substances present in concentration >= 0.1%

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7. Other adverse effects

N.A.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force. Disposal through discharge into wastewater is not permitted

The product disposed of as such, pursuant to Regulation (EU) 1357/2014, must be classified as hazardous waste

A waste code according to the European List of Wastes (LoW) cannot be specified, due to dependence on the usage. Contact an authorized waste disposal service.

Properties of waste which render it hazardous (Annex III, Directive 2008/98/EC):

N.A.

SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

14.1. UN number or ID number

N/A

14.2. UN proper shipping name

ADR-Shipping Name: N/A

IATA-Shipping Name: N/A

IMDG-Shipping Name: N/A

14.3. Transport hazard class(es)

ADR-Class: N/A

IATA-Class: N/A

IMDG-Class: N/A

14.4. Packing group

ADR-Packing Group: N/A

IATA-Packing group: N/A

IMDG-Packing group: N/A

14.5. Environmental hazards

Marine pollutant: No

Environmental Pollutant: No

IMDG-EMS: N/A

14.6. Special precautions for user

Road and Rail (ADR-RID):

ADR-Label: N/A

ADR - Hazard identification number: N/A

ADR-Special Provisions: N/A

ADR-Transport category (Tunnel restriction code): N/A

ADR Limited Quantities: N/A

ADR Excepted Quantities: N/A

Air (IATA):

IATA-Passenger Aircraft: N/A

IATA-Cargo Aircraft: N/A

IATA-Label: N/A
IATA-Subsidiary hazards: N/A
IATA-Erg: N/A
IATA-Special Provisions: N/A

Sea (IMDG):

IMDG-Stowage and handling: N/A
IMDG-Segregation: N/A
IMDG-Subsidiary hazards: N/A
IMDG-Special Provisions: N/A

14.7. Maritime transport in bulk according to IMO instruments

N.A.

SECTION 15: Regulatory information

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

EN 196-10 – "Methods of Testing Cement - Part 10: Determination of the water-soluble chromium (VI) content of cement"

According to Annex XVII, Point 47, under Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as amended by Regulation No. 552/2009, cement and mixtures containing cement shall not be placed on the market or used if they contain, after mixing with water, more than 0.0002% (2 ppm) of soluble chromium (VI) of the total dry weight of the cement. Considering that once mixed with water, white cement does not contain more than 0.0002% (2 ppm) of water-soluble Cr (VI) on the total dry weight, the same mixture can be marketed without the addition of reducing agents. Cement is a mixture and, as such, is not subject to REACH registration, which is mandatory for substances. Cement clinker is a substance, but it is exempt from registration pursuant to article 2.7 (b) and Annex V.10 of REACH.

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)

Regulation (EU) n. 2020/1182 (ATP 15 CLP)

Regulation (EU) n. 2021/643 (ATP 16 CLP)

Regulation (EU) n. 2021/849 (ATP 17 CLP)

Regulation (EU) n. 2022/692 (ATP 18 CLP)

Regulation (EU) n. 2023/707

Regulation (EU) n. 2023/1434 (ATP 19 CLP)

Regulation (EU) n. 2023/1435 (ATP 20 CLP)

Regulation (EU) n. 2024/197 (ATP 21 CLP)

Regulation (EU) n. 2020/878

Regulation (EC) nr 648/2004 (Detergents).

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product: None.

Restrictions related to the substances contained: 75

Provisions related to directive EU 2012/18 (Seveso III):

None

Explosives precursors – Regulation 2019/1148

No substances listed

Regulation (EU) No 649/2012 (PIC regulation)

No substances listed

German Water Hazard Class.

1: Low hazard to waters

German Lagerklasse according to TRGS 510:

LGK 11

SVHC Substances:

No SVHC substances present in concentration $\geq 0.1\%$

15.2. Chemical safety assessment

A Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

Calcium diformate

SECTION 16: Other information

Code	Description
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

Code	Hazard class and hazard category	Description
3.2/2	Skin Irrit. 2	Skin irritation, Category 2
3.3/1	Eye Dam. 1	Serious eye damage, Category 1
3.4.2/1B	Skin Sens. 1B	Skin Sensitisation, Category 1B
3.8/3	STOT SE 3	Specific target organ toxicity — single exposure, Category 3

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Skin Irrit. 2, H315	Calculation method
Eye Dam. 1, H318	Calculation method
Skin Sens. 1B, H317	Calculation method
STOT SE 3, H335	Calculation method

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

Legend to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

BCF: Biological Concentration Factor

BEI: Biological Exposure Index

BOD: Biochemical Oxygen Demand

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

CAV: Poison Center

CE: European Community

CLP: Classification, Labeling, Packaging.

CMR: Carcinogenic, Mutagenic and Reprotoxic

COD: Chemical Oxygen Demand

COV: Volatile Organic Compound

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DMEL: Derived Minimal Effect Level

DNEL: Derived No Effect Level.

DPD: Dangerous Preparations Directive

DSD: Dangerous Substances Directive
EC50: Half Maximal Effective Concentration
ECHA: European Chemicals Agency
EINECS: European Inventory of Existing Commercial Chemical Substances.
ES: Exposure Scenario
GefStoffVO: Ordinance on Hazardous Substances, Germany.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
IC50: half maximal inhibitory concentration
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG: International Maritime Code for Dangerous Goods.
INCI: International Nomenclature of Cosmetic Ingredients.
IRCCS: Scientific Institute for Research, Hospitalization and Health Care
KAFH: Keep Away From Heat
KSt: Explosion coefficient.
LC50: Lethal concentration, for 50 percent of test population.
LD50: Lethal dose, for 50 percent of test population.
LDLo: Leathal Dose Low
N.A.: Not Applicable
N/A: Not Applicable
N/D: Not defined/ Not available
NA: Not available
NIOSH: National Institute for Occupational Safety and Health
NOAEL: No Observed Adverse Effect Level
OSHA: Occupational Safety and Health Administration
PBT: Persistent, Bioaccumulative and Toxic
PGK: Packaging Instruction
PNEC: Predicted No Effect Concentration.
PSG: Passengers
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TWATLV: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
vPvB: Very Persistent, Very Bioaccumulative.
WGK: German Water Hazard Class.

Paragraphs modified from the previous revision:

- SECTION 1: Identification of the substance/mixture and of the company/undertaking
- SECTION 2: Hazards identification
- SECTION 9: Physical and chemical properties



Exposure Scenario

Calcium Diformate

Exposure Scenario, 13/07/2021

Substance identity	
	Calcium Diformate
CAS No.	544-17-2
EINECS No.	208-863-7
Registration number	01-2119486476-24

Table of contents

1. **ES 1** Widespread use by professional workers; Fillers, putties, plasters, modelling clay (PC9b)

1. ES 1

Widespread use by professional workers; Fillers, putties, plasters, modelling clay (PC9b)

1.1 TITLE SECTION

Exposure Scenario name	Professional application of coatings and inks - Use in rigid foams, coatings, adhesives and sealants - Barrier (Sealant)
Date - Version	13/07/2021 - 1.0
Life Cycle Stage	Widespread use by professional workers
Main user group	Professional uses
Sector(s) of use	Professional uses (SU22)
Product Categories	Fillers, putties, plasters, modelling clay (PC9b)

Environment Contributing Scenario

CS1	ERC8c - ERC8f
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Worker Contributing Scenario

CS2 Rolling, Brushing - Material transfers	PROC9 - PROC10
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1.2 Conditions of use affecting exposure

1.2. CS1: Environment Contributing Scenario (ERC8c, ERC8f)

Environmental release categories	Widespread use leading to inclusion into/onto article (indoor) - Widespread use leading to inclusion into/onto article (outdoor) (ERC8c, ERC8f)
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*Product (article) characteristics***Physical form of product:**

Solid, medium dustiness

Vapour pressure:

= 0.00022 Pa

Concentration of substance in product:

Covers percentage substance in the product up to 100 %.

1.2. CS2: Worker Contributing Scenario: Rolling, Brushing - Material transfers (PROC9, PROC10)

Process Categories	Transfer of substance or mixture into small containers (dedicated filling line, including weighing) - Roller application or brushing (PROC9, PROC10)
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*Product (article) characteristics***Physical form of product:**

Solid, medium dustiness

Vapour pressure:

= 0.00022 Pa

Concentration of substance in product:

Covers percentage substance in the product up to 100 %.

*Amount used, frequency and duration of use/exposure***Duration:**

Covers daily exposures up to 8 hours

Frequency:

Use frequency = 230 days per year

*Technical and organisational conditions and measures***Technical and organisational measures**

Ensure that direction of application is only horizontal or downward.

Avoid direct eye contact with product, also via contamination on hands.

Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Supervision in place to check that the risk management measures in place are being used correctly and operation conditions followed.

Conditions and measures related to personal protection, hygiene and health evaluation

Personal protection

Use suitable eye protection.

For further specification, refer to section 8 of the SDS.

Other conditions affecting worker exposure

Indoor use

Professional use

Temperature: Assumes use at not more than 20 °C above ambient temperature.

1.3 Exposure estimation and reference to its source

1.3. CS1: Environment Contributing Scenario (ERC8c, ERC8f)

Additional information on exposure estimation:

As no environmental hazard was identified no environmental-related exposure assessment and risk characterization was performed.

1.3. CS2: Worker Contributing Scenario: Rolling, Brushing - Material transfers (PROC9, PROC10)

Exposure route, Health effect, Exposure indicator	Exposure level	Calculation method	Risk Characterization Ratio (RCR)
combined routes, systemic, long-term	N/A	ECETOC TRA worker v3	< 1

1.4 Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Guidance to check compliance with the exposure scenario:

Where other risk management measures/operational conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.