

Safety Data Sheet

According to Annex II to REACH -Regulation (EU) 2020/878 and to Annex II to UK REACH

IMPORTANT

Read this SDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	ImpressPLUS-5 Alginate Fast Set
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	(SU22) professional uses: Public domain (administration, education, entertainment, services, craftsmen); (SU20) Health services;
Restricted Use	None known
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number


Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Eye Irrit. 2: H319 STOT Re 2: H373
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2.2 Label Elements

Hazard Pictograms	
Signal Word	Warning
Hazard Statement	Eye Irrit. 2: H319 – Causes serious eye irritation. STOT RE 2: H373 – May cause damage to organs through prolonged or repeated exposure EUH – Contains: SPEARMINT EXTRACT. May produce and allergic reaction.
Precautionary Statement: Prevention	P260 - Do not breathe dust P270 – Do not eat, drink or smoke when using this product P280 - Wear eye protection/face protection
Precautionary Statement: Response	P280: Wear eye protection/face protection. P337+P313 – If eye irritation persists: Get medical advice/attention
Contains:	Diatomite

2.3 Other hazards

Other hazards	On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0.1% The product does not contain substances with endocrine disrupting properties in concentration $\geq 0.1\%$.
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Further information

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
Diatomite	01-211-9488518-22	68855-54-9	272-489-0		$70 \leq x < 85$	STOT RE 2:H373
Dipotassium Hexafluorotitanate	01-2119978268-20-0006	16919-27-0	240-969-9		$1.0 \leq x < 2.0$	Acute Tox. 4:H302 Eye Dam. 1:H318
Spearmint Extract		84696-51-5	283-656-2		$1.0 \leq x < 2.0$	Skin Sens. 1B: H317 Aquatic Chronic 2: H411
3,6-BIS(Diethylamino)-9-[2-(Ethoxycarbonyl)Phenyl]Xanthylum Chloride		2390-63-8	219-233-6	01-2120107345-66	$0.001 \leq x \leq 0.005$	Acute Tox.3: H301 Acute Tox 4: H332 Eye Dam 1: H318 Aquatic Acute 1: H400 M=100 Aquatic Chronic 1: H410 M=10

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove to open air. If the subject stops breathing administer artificial respiration. Get medical advice/attention immediately.
Eye Contact	Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
Skin contact	Remove contaminated clothing. Rinse skin with a shower immediately. Wash contaminated clothing before using again.
Ingestion	Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	Information not available
Eye Contact	Information not available
Skin contact	Information not available
Ingestion	Information not available

General information

	If you feel unwell, seek medical advice (show the label where possible).
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray
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5.2 Special hazards arising from the substance or mixture

	Do not breathe combustion products
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5.3 Advice for firefighters

	<p>Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining in to the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.</p> <p>Wear normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).</p>
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	If there are no contraindications, spray powder with water to prevent the formation of dust. Avoid breathing vapours/mists/gases. Wear suitable protective equipment (including personal protective equipment referred to under section 8 of this SDS) to prevent any contamination of skin, eyes and personal clothing. These indications apply to both processing staff and those involved in emergency procedures.
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6.2 Environmental precautions

	This product must not penetrate into the sewer system or come in to contact with surface water or ground water.
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6.3 Methods and material for containment and cleaning up

	<p>Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.</p> <p>Make sure the leakage site is well aired. Check compatibility for container material section 7. Contaminated material should be disposed of in compliance with the provisions set forth in section 13.</p>
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6.4 Reference to other sections

	Any information on personal protection and disposal is given in sections 8 and 13.
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	<p>Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.</p>
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7.2 Conditions for safe storage, including any incompatibilities

	Store only in the original container. Store the containers sealed, in a well-ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.
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7.3 Specific end use(S)

	Information not available.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Exposure Limit Values

Dipotassium hexfluorotitanate	
Predicted no-effect concentration - PNEC	
Normal value in fresh water	0.02 mg/l
Normal value in marine water	0.002 mg/l

Normal value for fresh water sediment	24.45 mg/kg/d
Normal value for marine water sediment	4.89 mg/kg/d
Normal value for marine water, intermittent release	0.11 mg/l
Normal value of STP microorganisms	1.5 mg/l
Normal value for the terrestrial compartment	19.1 mg/kg/d

Health – Derived no-effect level – DNEL/DMEL

Route of exposure	Effects in consumers. Acute local	Acute systemic	Chronic Local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Skin		37.5 mg/kg bw/d		37.5 mg/ kg bw/d		75 mg/kg bw/d		75 mg/kg bw/d
Inhalation						5.2 mg/m3	5.2 mg/kg	5.2 mg/kg

Diatomite

Predicted no-effect concentration - PNEC								
Normal value of STP microorganisms					100 mg/l			

Health – Derived no-effect level – DNEL/DMEL

Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic Local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				18.7 mg/kg/d				
Inhalation				0.05 mg/m3				0.05 mg/m3

VND - hazard identified but no DNEL/PNEC available. NEA - no exposure expected. NPI - no hazard identified; LOW = low hazard; MED = medium hazard; HIGH = high hazard.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m³; PNOC inhalable fraction: 10 mg/m³). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment. The above values are not TLVs, but guide values, to be used for particles that do not have their own TLV and that are insoluble or poorly soluble in water and have low toxicity.

8.2 Exposure controls



8.2.1 Appropriate engineering controls

	<p>As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.</p> <p>When choosing personal protective equipment, ask your chemical substance supplier for advice.</p> <p>Personal protective equipment must be CE marked, showing that it complies with applicable standards.</p> <p>Provide an emergency shower with face and eye wash station.</p> <p>Exposure levels must be kept as low as possible to avoid significant build-up in the organism.</p> <p>Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).</p>
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8.2.2 Individual protection measures

Skin protection	Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.
Eye/face protection	Wear airtight protective goggles (see standard EN 16321).
Hand protection	In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.
Respiratory protection	Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

8.2.3 Environmental Exposure controls

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Powder	Vapour pressure	Not available
Colour	Orange	Relative vapour density	Not applicable
Odour	Spearmint	Density and/or relative density	2.3g/cm ³
pH	Not applicable	Partition coefficient: n-octanol/water	Not applicable
Melting point	Not available	Autoignition temperature	Not applicable
Freezing point	Not available	Solubility	Insoluble in water
Initial boiling point	Not available	Decomposition temperature	Not available
Flash point	Not applicable.	Kinematic viscosity	Not applicable
Flammability (solid, gas)	Not flammable	Particle characteristics	Not available
Lower explosive limit	Not applicable	Auto-ignition temperature	Not applicable
Upper explosive limit	Not applicable		

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Information not available

9.2.2 Other safety characteristics

Information not available

10. STABILITY AND REACTIVITY

10.1 Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2 Chemical stability

The product is stable under normal conditions of use and storage

10.3 Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

10.4 Conditions to avoid

Avoid environmental dust build-up.

10.5 Incompatible materials

Information not available.

10.6 Hazardous decomposition products

Information not available

11. TOXICOLOGICAL INFORMATION

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information	Information not available
Information on likely routes of exposure	Information not available
Delayed and immediate effects as well as chronic effects from short and long-term exposure	Information not available

Interactive effects	Information not available
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Acute toxicity	
ATE (inhalation) of the mixture:	Not classified (no significant component)
ATE (oral) of the mixture	≥2000 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)
DIPOSTASSIUM HEXAFLUOROTITANTE	
LD50 (Oral):	324 mg/kg OECD 401

3,6-BIS(DIETHYLAMINO)-9-[2-(ETHOXYCARBONYL)PHENYL]XANTHYLIUM CHLORIDE	
LD50 (Oral):	>50 mg/kg OECD 423

DIATOMITE	
LD50 (Oral):	>2000 mg/kg OECD 401

Skin corrosion/irritation	Does not meet the classification criteria for this hazard class
Serious eye damage/irritation	Causes serious eye irritation
Respiratory of skin sensitisation	May produce an allergic reaction. Contains SPEARMINT EXTRACT
Germ cell mutagenicity	Does not meet the classification criteria for this hazard class
Carcinogenicity	Does not meet the classification criteria for this hazard class
Reproductive toxicity	Does not meet the classification criteria for this hazard class
STOT-single exposure	Does not meet the classification criteria for this hazard class
STOT-repeated exposure	May cause damage to organs
Aspiration hazard	Does not meet the classification criteria for this hazard class

11.2 Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

12. ECOLOGICAL INFORMATION

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1 Toxicity

Dipotassium Hexafluorotitante	LC50-for Fish	172 mg/l/96h OECD 203
	EC50 - for Crustacea.	48.2 mg/l/48h OECD 203
	EC50 - for Algae / Aquatic Plants	11 mg/l/72h OECD 211
	EC10 - for Algae / Aquatic Plants	1.4 mg/l/72h OECD 201
	Chronic NOEC for Crustacea	10 mg/l OECD 211
3,6-BIS(DIETHYLAMINO)-9-[2-(ETHOXYCARBONYL)PHENYL]XANTHYLIUM CHLORIDE	EC50 - for Crustacea.	0.12 mg/l/48h OECD 202
	EC50 - for Algae / Aquatic Plants	0.0033 mg/l/72h OECD 201
	LC50-for Fish	>100mg/l/96h OECD 203
Diatomite	EC50 - for Crustacea.	>100mg/l/48h OECD 202
	EC50 - for Algae / Aquatic Plants	>100mg/l/72h OECD 201

12.2 Persistence and degradability

3,6-BIS(DIETHYLAMINO)-9-[2-(ETHOXYCARBONYL)PHENYL]XANTHYLIUM CHLORIDE	NOT rapidly degradable. 5%/28d, OECD 301B
Dipotassium hexfluorotitanate	Degradability : Information not available
Diatomite	Degradability : Information not available

12.3 Bio accumulative potential

	Information not available
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12.4 Mobility in soil

	Information not available
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12.5 Results of PBT and vPvB assessment

	On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0.1%.
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12.6 Other adverse effects

	Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.
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12.7 Other adverse affects

	No data is available on this product.
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13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

	Dispose of in compliance with all local and national regulations.
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General information

	Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
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Disposal Methods

	Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
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Disposal of packaging

	Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.
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14. TRANSPORT INFORMATION

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1 UN number

	Not applicable.
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14.2 UN proper shipping name

	Not applicable.
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14.3 Transport hazard class(es)

ADR/RID	Not applicable.
Subsidiary risk IMDG	Not applicable.
Subsidiary risk IATA Subsidiary risk	Not applicable.

14.4 Packing group

Packing Group	Not applicable.
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14.5 Environmental hazards

Environmental hazards	Not applicable.
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14.6 Special precautions for user

	Not applicable.
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14.7 Maritime transport in bulk according to IMO instruments n bulk according to Annex II of MARPOL73/78 and the IBC Code.

	Information not relevant.
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15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Contained substance

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Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors
not applicable

Substances in Candidate List (Art. 59 REACH) : On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH): None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012: None

Substances subject to the Rotterdam Convention: None

Substances subject to the Stockholm Convention: None

Healthcare controls: Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2 Chemical Safety Assessment

	A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.
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16. OTHER INFORMATION
Other information

Text of Hazard Statements in Section 2 and 3

Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Sens. 1B	Skin sensitization, category 1B
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile

Further information

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.